

Celsion CORP  
Form 10-Q  
May 08, 2014

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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 March 31, 2014

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**

(State or other jurisdiction of incorporation or organization)

**52-1256615**

(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

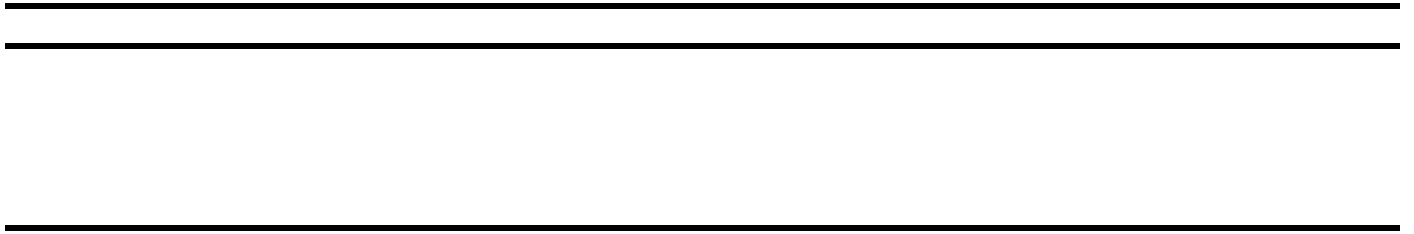
Accelerated filer

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 May 7, 2014, the Registrant had 17,217,066 shares of Common Stock, \$.01 par value per share, outstanding.



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

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## 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 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. 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>March 31, 2014</b>	<b>December 31, 2013</b>
	<b>(unaudited)</b>	
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$4,606,267	\$5,718,504
Investment securities – available for sale, at fair value	47,255,487	37,156,381
Accrued interest receivable on investment securities	339,791	212,048
Advances, deposits and other current assets	620,979	675,186
Total current assets	52,822,524	43,762,119
<b>Property and equipment</b> (at cost, less accumulated depreciation of \$1,349,690 and \$1,264,190, respectively)	747,386	832,886
<b>Other assets:</b>		
Deposits, deferred fees and other assets	1,120,931	1,054,942
Patent licensing fees, net	18,750	20,625
Total other assets	1,139,681	1,075,567
<b>Total assets</b>	<b>\$54,709,591</b>	<b>\$45,670,572</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$2,102,013	\$1,452,436
Accrued liabilities	2,205,838	2,707,653
Notes payable - current portion	439,218	10,891
Deferred revenue - current portion	500,000	500,000
Total current liabilities	5,247,069	4,670,980
Common stock warrant liability	–	3,026
Notes payable – non-current portion	4,560,782	5,000,000
Deferred revenue - non-current portion	3,875,000	4,000,000
Other non-current liabilities	467,545	472,731
<b>Total liabilities</b>	<b>14,150,396</b>	<b>14,146,737</b>
<b>Stockholders' equity:</b>	-	-

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Preferred stock, \$0.01 par value: 100,000 shares authorized; no shares issued or outstanding at March 31, 2014 and December 31, 2013, respectively		
Common stock, \$0.01 par value; 75,000,000 shares authorized; 17,347,665 and 13,737,970 shares issued at March 31, 2014 and December 31, 2013, and 17,217,066 and 13,604,975 shares outstanding at March 31, 2014 and December 31, 2013, respectively	173,477	137,380
Additional paid-in capital	217,535,506	203,139,142
Accumulated other comprehensive loss	(27,897 )	(44,166 )
Accumulated deficit	(174,744,150)	(169,287,157)
Subtotal	42,936,936	33,945,199
Treasury stock, at cost (130,599 and 132,995 shares at March 31, 2014 and December 31, 2013, respectively)	(2,377,741 )	(2,421,364 )
<b>Total stockholders' equity</b>	<b>40,559,195</b>	<b>31,523,835</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$54,709,591</b>	<b>\$45,670,572</b>

See accompanying notes to the financial statements.



**CELSION CORPORATION****STATEMENTS OF OPERATIONS****(Unaudited)**

	<b>Three Months</b>	
	<b>Ended March 31</b>	
	<b>2014</b>	<b>2013</b>
<b>Licensing revenue</b>	\$125,000	\$125,000
<b>Operating expenses:</b>		
Research and development	2,893,168	3,203,177
General and administrative	2,433,857	1,688,729
<b>Total operating expenses</b>	5,327,025	4,891,906
<b>Loss from operations</b>	(5,202,025 )	(4,766,906)
<b>Other income (expense):</b>		
Gain from change in valuation of common stock warrant liability	3,026	4,280,297
Investment income, net	7,019	16,563
Interest expense	(230,713 )	(180,928 )
<b>Total other (expense) income, net</b>	(220,668 )	4,115,932
<b>Net loss</b>	(5,422,693 )	(650,974 )
Non-cash deemed dividend from beneficial conversion feature on convertible preferred stock	—	(4,601,410)
<b>Net loss attributable to common shareholders</b>	\$(5,422,693 )	\$(5,252,384)
<b>Net loss attributable to common shareholders per common share – basic and diluted</b>	\$(0.33 )	\$(0.55 )
<b>Weighted average shares outstanding – basic and diluted</b>	16,371,097	9,554,668

See accompanying notes to the financial statements.



**CELSION CORPORATION**

**STATEMENTS OF COMPREHENSIVE LOSS**

**(Unaudited)**

	<b>Three Months</b>	
	<b>Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
<b>Net loss</b>	\$(5,422,693)	\$(650,974)
Changes in:		
Realized loss on investment securities recognized in investment income, net	20,610	53,740
Unrealized loss on investment securities	(4,341 )	(85,689 )
Other comprehensive gain (loss)	16,269	(31,949 )
<b>Total comprehensive loss</b>	<b>\$(5,406,424)</b>	<b>\$(682,923)</b>

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

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

	<b>Three Months</b>	
	<b>Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$(5,422,693 )	\$(650,974 )
Non-cash items included in net loss:		
Depreciation and amortization	87,375	76,875
Change in fair value of common stock warrant liability	(3,026 )	(4,280,297 )
Deferred revenue	(125,000 )	(125,000 )
Stock-based compensation	607,230	263,192
Treasury shares issued for services and 401(k) matching contribution	9,323	20,835
Change in deferred rent liability	(5,186 )	(3,829 )
Deferred finance charges	89,675	31,560
Net changes in:		
Deposits, advances, other current assets and other assets	(229,200 )	(225,660 )
Accounts payable	649,577	1,841,037
Accrued liabilities	(501,815 )	(157,534 )
Cash received for non-refundable research and development fee	–	5,000,000
<b>Net cash (used in) provided by operating activities:</b>	<b>(4,843,740 )</b>	<b>1,790,205</b>
<b>Cash flows from investing activities:</b>		
Purchases of investment securities	(17,862,837)	(20,245,204)
Proceeds from sale and maturity of investment securities	7,780,000	3,048,000
<b>Net cash used in investing activities</b>	<b>(10,082,837)</b>	<b>(17,197,204)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from sale of common stock equity, net of issuance costs	13,825,231	6,711,173
Proceeds from sale of preferred stock, net of issuance costs	–	13,648,663
Proceeds from exercise of common stock warrants	–	261,944
Proceeds from exercise of options to purchase common stock	–	174,871
Principal payments on notes payable	(10,891 )	(14,461 )
<b>Net cash provided by financing activities</b>	<b>13,814,340</b>	<b>20,782,190</b>
<b>Decrease in cash and cash equivalents</b>	<b>(1,112,237 )</b>	<b>(5,375,191 )</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>5,718,504</b>	<b>14,991,488</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$4,606,267</b>	<b>\$20,366,679</b>
<b>Supplemental disclosures of cash flow information:</b>		
Interest paid	\$141,038	\$180,928

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

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**CELSION CORPORATION**

**NOTES TO FINANCIAL STATEMENTS (UNAUDITED)**

**FOR THE THREE MONTHS ENDED MARCH 31, 2014 AND 2013**

**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 and recurrent chest wall breast cancer.

**Note 2. Basis of Presentation**

The accompanying unaudited financial statements of Celsion have been prepared in accordance with generally accepted accounting principles in the United States (GAAP) 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 month period ended March 31, 2014 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, 2013 filed on March 13, 2014 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.

### **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.

### **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.

On October 28, 2013, the Company effected a 4.5-to-1 reverse stock split of its common stock which was made effective for trading purposes as of the commencement of trading on October 29, 2013. Immediately prior to the reverse stock split, the Company had 61,226,873 shares of common stock outstanding were combined and converted into 13,604,975 shares of the Company's common stock as a result of the reverse stock split. All share, and per share amounts related to common stock, preferred stock, stock options, warrants and restricted stock included in these financial statements have been restated to reflect the reverse stock split. In addition, in accordance with *Accounting Standards Update (ASU) No. 2010-01, Equity (Topic 505): Accounting for Distributions to Shareholders with Components of Stock and Cash*, the changes in the Company's common stock as a result of the reverse stock split require the per share components of the current and prior period financial statements presented be based on the new number of shares. Therefore, net loss per common share for the three months ended March 31, 2013 has been adjusted to reflect post reverse stock split shares.

For the three months ended March 31, 2014 and 2013, 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 three month periods ended March 31, 2014 and 2013 were 6,244,886 and 4,685,862, respectively.

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

Investment securities available for sale of \$47,255,487 and \$37,156,381 as of March 31, 2014 and December 31, 2013, 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>March 31, 2014</b>		<b>December 31, 2013</b>	
	<b>Cost</b>	<b>Fair Value</b>	<b>Cost</b>	<b>Fair Value</b>
<b>Corporate bond maturities</b>				
Within 3 months	\$11,798,892	\$11,750,665	\$7,799,033	\$7,797,689
Between 3-12 months	35,484,492	35,504,822	29,401,514	29,358,692
<b>Total</b>	<b>\$47,283,384</b>	<b>\$47,255,487</b>	<b>\$37,200,547</b>	<b>\$37,156,381</b>

The following table shows the Company's investment securities with unrealized holding gains and losses and their fair value by investment category and length of time that individual securities have been in a continuous unrealized loss position at March 31, 2014 and December 31, 2013. 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	March 31, 2014		December 31, 2013	
	Fair Value	Unrealized	Fair Value	Unrealized
		Holding		Holding
		Gains		Gains
	(Losses)		(Losses)	
Available for Sale (all unrealized holding gains and losses are less than 12 months at date of measurement)				
Bonds – corporate issuances with unrealized gains	\$4,366,735	\$ 97	\$6,650,095	\$ 1,907
Bonds – corporate issuances with unrealized losses	42,888,752	(27,994 )	30,506,286	(46,073 )
<b>Total</b>	<b>\$47,255,487</b>	<b>\$ (27,897 )</b>	<b>\$37,156,381</b>	<b>\$ (44,166 )</b>

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 March 31,	
	2014	2013
Interest and dividend income	\$27,629	\$70,303
Realized losses	(20,610)	(53,740)
	\$7,019	\$16,563

The following table presents the change, by component, in accumulated other comprehensive loss for the first three months of 2014.

	Accumulated Other Comprehensive Loss
Balance at January 1, 2014	\$ (44,166 )
Unrealized losses on investment securities	(4,341 )
Realized loss reclassified from other accumulated comprehensive loss	20,610
Net other comprehensive loss, net	16,269
Balance at March 31, 2014	\$ (27,897 )

#### 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 March 31, 2014 and December 31, 2013 on the Company's Balance Sheets:

	<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 March 31, 2014				
Short-term investments available for sale Bonds – corporate issuances	\$ 47,255,487	\$ 47,255,487	\$	\$
As of December 31, 2013				
Short-term investments available for sale Bonds – corporate issuances	\$ 37,156,381	\$ 37,156,381	\$	\$
<b>Liabilities:</b>				
As of March 31, 2014				
Common stock warrant liability	\$	\$	\$	\$
As of December 31, 2013				
Common stock warrant liability	\$ 3,026	\$	\$	\$ 3,026

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 three months ended March 31, 2014.

#### Note 7. Accrued Liabilities

Accrued liabilities at March 31, 2014 and December 31, 2013 include the following:

	<b>March 31,</b>	<b>December</b>
	<b>2014</b>	<b>31,</b>
		<b>2013</b>
Amounts due to contract research organizations and other contractual agreements	\$ 1,411,249	\$ 1,711,934
Accrued payroll and related benefits	661,151	900,434
Accrued professional fees	65,000	63,500
Accrued interest on notes payable	48,438	
Other	20,000	31,785
Total accrued liabilities	\$ 2,205,838	\$ 2,707,653

**Note 8. Note Payable*****Hercules Credit Agreement***

In November 2013, the Company entered into a loan agreement with Hercules Technology Growth Capital, Inc. (“Hercules”) which permits up to \$20 million in capital to be distributed in multiple tranches (the “Hercules Credit Agreement”). The Company drew the first tranche of \$5 million upon closing of the Hercules Credit Agreement in November 2013 and used approximately \$4 million of the proceeds to repay the outstanding obligations under its loan agreement with Oxford Finance LLC and Horizon Technology Finance Corporation as discussed further below. The Company anticipates that it will use any additional funding up to \$15 million as provided under the agreement for working capital or in support of its previously announced strategic acquisition initiative, which is designed to identify new technologies and clinical stage products for its development pipeline.

The obligations under the Hercules Credit Agreement are in the form of secured indebtedness bearing interest at a calculated prime-based variable rate (11.25% per annum since inception). Payments under the loan agreement are interest only for the first twelve months after loan closing, followed by a 30-month amortization period of principal and interest through the scheduled maturity date.

As a fee in connection with the Hercules Credit Agreement, the Company issued Hercules a warrant exercisable for a total of 194,986 shares of the Company's common stock (the "Hercules Warrant") at a per share exercise price of \$3.59, with 50% immediately exercisable for cash or by net exercise from November 25, 2013 and the remaining 50% to be exercisable upon Hercules funding any subsequent tranches. The Hercules Warrant will expire November 25, 2018. Hercules has certain rights to register the common stock underlying the Hercules Warrant pursuant to a Registration Rights Agreement with the Company dated November 25, 2013. The registration rights expire on the date when such stock may be sold under Rule 144 without restriction or upon the first year anniversary of the registration statement for such stock, whichever is earlier.

The Company valued the Hercules Warrant using the Black-Scholes option pricing model and recorded \$521,763 in 2013 as deferred financing fees. In calculating the value of the warrants, the Company assumed a volatility rate of 102%, risk free interest rate of 1.37%, an expected life of 5 years, a stock price of \$3.55 (closing price on date of the Hercules Warrant) and no expected forfeitures nor dividends. In connection with the Hercules Credit Agreement, the Company incurred cash expenses of \$352,378 which were also recorded as deferred financing fees. These deferred financing fees are being amortized as interest expense using the effective interest method over the life of the loan. For the first three months of 2014, the Company incurred \$140,625 in interest expense and amortized \$89,676 in deferred financing fees as interest expense in connection with the Hercules Credit Agreement.

The Hercules Credit Agreement contains customary covenants, including covenants that limit or restrict the Company's ability to grant 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 Hercules Credit Agreement, the lenders may cease making loans, terminate the Hercules 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 Hercules 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 effect on the Company or its assets, cross-defaults to other material indebtedness, bankruptcy and insolvency defaults and material judgment defaults. The Company has maintained compliance with these covenants.

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

For the year ending March 31: **Hercules**

**Credit**

**Agreement**

2015	\$439,218
2016	1,878,096
2017	2,104,767
2018	577,919
Total	\$5,000,000

***Oxford & Horizon Credit Agreement***

In June 2012, the Company entered into a Loan and Security Agreement (the “Oxford & Horizon Credit Agreement”) with Oxford Finance LLC (“Oxford”) and Horizon Technology Finance Corporation (“Horizon”). The Oxford & Horizon Credit Agreement provided 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 could have been 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 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.

The Term A Loan was originally scheduled to mature on October 15, 2015. As a result of the Hercules Credit Agreement discussed above, the Company terminated the Oxford & Horizon Credit Agreement and repaid the outstanding principle, accrued interest and termination fees totaling approximately \$4.1 million.

The proceeds of the Oxford & Horizon Credit Agreement were used to fund the Company's working capital and general corporate purposes. The obligations under the Oxford & Horizon Credit Agreement were secured by substantially all assets of the Company other than its intellectual property and certain other agreed-upon exclusions.

As a fee in connection with the Oxford & Horizon Credit Agreement, the Company issued warrants to Horizon and Oxford (the "Oxford & Horizon 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 of \$13.14 per share, 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. This resulted in 11,415 warrant shares issued in connection with the Term A Loan. The Oxford & Horizon Warrants issued in connection with the Term A Loan are exercisable for cash or by net exercise and will expire seven years after their issuance, which is June 27, 2019.

The Company valued the Oxford & Horizon 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 \$12.60 (which was the closing price on date of issuing the Oxford & Horizon Warrant) and no expected forfeitures nor dividends. In connection with the Oxford & Horizon Credit Agreement, the Company incurred cash expenses of \$217,715 which were recorded as deferred financing fees in 2012. These deferred financing fees were amortized as interest expense over the life of the loan. During the first three months of 2013, the Company paid \$146,874 in interest expense and amortized \$31,560 of deferred financing fees as interest expense. The Term A Loan bore interest at a fixed rate of 11.75%.

### ***Capital Lease***

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 quarter of 2014, the Company made principal and interest payments totaling \$11,303 to satisfy the remaining obligation under this capital lease.

### **Note 9. Stockholders' Equity**

#### ***January 2014 Common Stock Offering***



On January 15, 2014, 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 3,603,604 shares of its common stock, par value \$0.01 per share, and warrants to purchase up to 1,801,802 shares of Common Stock, for an aggregate purchase price of approximately \$15 million (the “*January 2014 Common Stock Offering*”). The shares of common stock and warrants were sold in units, with each unit consisting of one share of common stock, a Series A warrant to purchase 0.25 share of common stock and a Series B warrant to purchase 0.25 share of common stock. Each unit was sold at a purchase price of \$4.1625. Each Series A warrant will be exercisable at any time on or after its issuance date and until the five-year anniversary of the issuance date. Each Series B warrant will be exercisable at any time on or after its issuance date and until the one-year anniversary of the issuance date. Each warrant has an exercise price of \$4.10 per share. Under the purchase agreement, the Company is prohibited, for a period of nine months after the closing, from effecting or entering into an agreement to issue common stock or any other securities that are at any time convertible into, or exercisable or exchangeable for, or otherwise entitle the holder thereof to receive, common stock to the extent such issuance or sale involves certain variable conversion, exercise or exchange prices or such agreement provides for sale of securities at a price to be determined in the future.

### ***Controlled Equity Offering***

On February 1, 2013, the Company entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement (the “*ATM Agreement*”) with Cantor Fitzgerald & Co., as sales agent (“Cantor”), pursuant to which the Company may offer and sell, from time to time, through Cantor, shares of its 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 1,195,927 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 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 January 2014 Common Stock Offering, the Company agreed to not sell any ATM Shares until July 22, 2014.

### ***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 2,682,764 shares of common stock, and the warrants are exercisable to purchase an aggregate of up to 1,341,382 shares of common stock. Each warrant has an exercise price of \$5.31 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 the date of 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 a one-time, non-cash deemed dividend related to the beneficial conversion feature connected to the preferred stock in the Preferred Stock Offering of approximately \$4.6 million in the first three months of 2013.

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 %

During 2013, 2,682,764 shares of common stock in the aggregate were issued upon conversion of all of the 15,000.00422 shares of the Series A 0% convertible preferred stock.

### *May 2013 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 1,392,109 shares of its common stock for an aggregate purchase price of approximately \$9.8 million.

### ***Reverse Stock Split***

On October 28, 2013, the Company effected a 4.5-to-1 reverse stock split of its common stock which was made effective for trading purposes as of the commencement of trading on October 29, 2013. As of October 28, 2013, each nine shares of issued and outstanding common stock and equivalents were combined and converted into two shares of common stock outstanding at the time of the reverse stock split. Weighted average shares outstanding and loss attributable to common stockholders of the Company for the three months ended March 31, 2013 have been adjusted to reflect the reverse stock split.

## **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 222,222 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 222,222 to a total of 444,444 shares in 2010 and by 500,000 to a total of 944,444 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 148,148 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>Three Months</b>		<b>Ended March</b>	
	<b>31,</b>			
	<b>2014</b>		<b>2013</b>	
Risk-free interest rate	2.75	%	0.85	%
Expected volatility	100.72	%	83.41	%
Expected life (in years)	10.00		5.25	
Expected forfeiture rate	5	%	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 2014 and 2013 grants was generated using the simplified method.

A summary of the Company's stock option and restricted stock awards for the three months ended March 31, 2014 is as follows:

Equity Awards	Stock Options		Restricted Stock Awards		Weighted
	Options Outstanding	Weighted Average Exercise Price	Non-vested Restricted Stock Outstanding	Weighted Average Grant Date Fair Value	Average Contractual Terms of Equity Awards (in years)
Equity awards outstanding at December 31, 2013	861,905	\$ 12.30	2,112	\$ 16.29	
Equity awards granted	323,200	\$ 3.66	4,500	\$ 3.72	
Equity awards exercised	—	—	(6,091)	\$ 8.00	
Equity awards forfeited, cancelled or expired	(10,555 )	\$ 34.14	—	—	
Equity awards outstanding at March 31, 2014	1,174,550	\$ 9.72	521	\$ 4.63	6.95
Aggregate intrinsic value of outstanding awards at March 31, 2014	\$ —		\$ 1,756		
Equity awards exercisable at March 31, 2014	779,446	\$ 12.07			5.74
Aggregate intrinsic value of awards exercisable at March 31, 2014	\$ —				

Total compensation cost related to employee stock options and restricted stock awards amounted to \$607,230 and \$263,192 for the three months ended March 31, 2014 and 2013, respectively. No compensation cost related to share-based payments arrangements was capitalized as part of the cost of any asset as of March 31, 2014 and 2013.

As of March 31, 2014, there was \$1.2 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 2.1 years. The weighted average grant-date fair value was \$3.31 and \$3.92 per share for the options granted during the three months ended March 31, 2014 and 2013, respectively. The weighted average grant-date fair value was \$3.72 for the restricted stock awards granted during the three months ended March 31, 2014. The Company granted 4,500 restricted stock awards during the first three months of 2014. No restricted stock grants were issued in the first three months of 2013.

Collectively, for all the stock option plans as of March 31, 2014, there were a total of 1,189,528 shares reserved, which were comprised of 1,175,071 equity awards granted and 14,457 equity awards available for future issuance.

**Note 11. Warrants*****Common Stock Warrants***

Following is a summary of all warrant activity for the first three months of 2014:

<b>Warrants</b>	<b>Number of Warrants Issued</b>	<b>Weighted Average Exercise Price</b>
Warrants outstanding at December 31, 2013	3,268,013	\$ 10.43
Warrants granted in connection with the January 2014 Common Stock Offering, as more fully described in Note 9	1,801,802	\$ 4.10
Warrants exercised for common stock	—	—
Warrants outstanding at March 31, 2014	5,069,815	\$ 8.18
Aggregate intrinsic value of outstanding warrants at March 31, 2014	\$-	
Weighted average remaining contractual terms (in years)	3.13	

***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 448,478 shares of its common stock and warrants to purchase 224,239 shares of common stock. The warrants have an exercise price of \$23.58 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.

The fair value of the warrants at March 31, 2014 and December 31, 2013 was \$-0- and \$3,026, respectively, calculated using the Black-Scholes option-pricing model with the following ranges of assumptions:

	<b>March 31, 2014</b>		<b>December 31, 2013</b>	
Risk-free interest rate	0.13	%	0.13	%
Expected volatility	64.74	%	64.74	%
Expected life (in years)	1.25		1.25	
Expected forfeiture rate	0.0	%	0.0	%
Expected dividend yield	0.00	%	0.00	%

The following is a summary of the changes in the common stock warrant liability for the three months ended March 31, 2014:

Beginning balance as of January 1, 2014	\$ 3,026
Gain from the adjustment for the change in fair value included in net income	(3,026)
Ending balance as of March 31, 2014	\$ –

## **Note 12. Contingent Liabilities and Commitments**

In July 2011, the Company, as a tenant, and a landlord executed a lease (the “Lease”) 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**

### *Technology Development Contract and Commercial Supply Agreement with Zhejiang Hisun Pharmaceutical Co. Ltd.*

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 mainland China, Hong Kong and Macau (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 (CHINA FDA). As of March 31, 2014, 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 the China territory. 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 includes development of the next generation liposomal formulation 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 FDA; 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.

*Development, Product Supply and Commercialization Agreement with Yakult Honsha*

In the fourth quarter of 2008, the Company entered into a Development, Product Supply and Commercialization Agreement with Yakult Honsha 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 we have the potential to 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. We will receive double digit escalating royalties on the sale ThermoDox® in Japan, when and if any such sales occur. We also will be the exclusive supplier of ThermoDox® to Yakult.

In January 2011, the Company amended its Development, Product Supply and Commercialization Agreement with Yakult to provide for up to \$4.0 million in an accelerated partial payment to the Company of a future drug approval milestone, which included \$2.0 million paid to the Company upon the closing of the preferred equity financing the Company conducted in January 2011 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, the Company agreed to reduce future drug approval milestone payments by approximately forty percent (40%).

**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, 2013 filed on March 13, 2014 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 and 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 OPTIMA study) and a Phase II clinical trial for recurrent chest wall breast cancer (the DIGNITY Study). 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 (RFA) did not meet the primary endpoint of Progression Free Survival (PFS) for the 701 patient clinical trial (the “HEAT Study”) in patients with hepatocellular carcinoma (HCC), also known as primary liver cancer. Specifically, we determined, after conferring with the HEAT Study independent Data Monitoring Committee (DMC), 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 trial, ThermoDox® was well-tolerated with no unexpected serious adverse events. Following the announcement of the HEAT Study results, we continue to follow patients for overall survival, the secondary endpoint of the HEAT Study, on a quarterly basis. We have conducted a comprehensive analysis of the data from the HEAT Study to assess the future strategic value of ThermoDox®. As part of this analysis, we are also re-evaluating 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.

The data from the HEAT Study post-hoc analysis suggests that ThermoDox® may substantially improve overall survival, when compared to the control group, in patients if their tumors undergo optimal RFA treatment. Data from five overall survival sweeps have been conducted since the top line PFS data from the HEAT Study was announced in January 2013. In April 2014, we announced that the latest overall survival data from the post-hoc analysis of results from the HEAT Study supports continued clinical development through a prospective pivotal Phase III Study. As reported on April 24, 2014, data from the latest HEAT Study post-hoc analysis as of March 31, 2014 suggest that ThermoDox® may markedly improve overall survival, compared to RFA control, in patients whose lesions undergo RFA treatment for 45 minutes or more. These findings apply to patients with single HCC lesions (64.4% of the HEAT Study population) from both size cohorts of the HEAT Study (3-5 cm and 5-7 cm) and represent a subgroup of 285 patients (41% of the patients in the HEAT Study). For this large subgroup, clinical results indicate a 50% improvement in overall survival, a Hazard Ratio of 0.666 (95% CI 0.434 - 1.022), and a p-Value of 0.06. Median overall survival for this subgroup has not yet been reached. We may choose to end this analysis of overall survival once the median is reached for either or both arms of the study.

Emerging data from the HEAT Study post-hoc analysis has been presented at various scientific and medical conferences in 2013 and 2014 by key HEAT Study investigators and leading liver cancer experts. The presentations include:

- World Conference on Interventional Oncology in May 2013
- International Liver Cancer Association Annual Conference in September 2013
- European Conference on Interventional Oncology in June 2013 and April 2014

The Company also completed computational modeling with supplementary preclinical animal studies supporting the relationship between heating duration and clinical outcomes.

On February 24, 2014, we announced that the United States Food and Drug Administration (FDA), after its customary 30 day review period, has provided and allowed, subject to compliance with regulatory standards, clearance for the Company's planned pivotal, double-blind, placebo-controlled Phase III trial (the "OPTIMA Study") of ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin in combination with RFA in primary liver cancer, also known as hepatocellular carcinoma (HCC). The OPTIMA Study trial design is based on the comprehensive analysis of data from the HEAT Study, which, as described above, demonstrated that treatment with ThermoDox® resulted in a 50 percent improvement in overall survival in a substantial number of HCC patients that received an optimized RFA treatment. The Company expects to launch the study in the first half of 2014. The OPTIMA Study is designed with extensive input from globally recognized HCC researchers and clinicians and after receiving formal written consultation from the FDA. The OPTIMA Study is expected to enroll approximately 550 patients globally, with up to 100 sites in the United States, Europe, China and Asia Pacific, and will evaluate ThermoDox® in combination with RFA, which will be standardized to a minimum of 45 minutes across all investigators and sites for treating lesions 3 to 7 centimeters, versus standardized RFA alone. The primary endpoint for the trial is overall survival, and the secondary endpoint for the trial is PFS and Safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee.

In addition, the Company recently met with the China State Food and Drug Administration (CHINA FDA) to discuss the OPTIMA Phase III trial including minimum patient enrollment requirements supporting ThermoDox®'s registration in China. Based on those discussions, we are submitting an application for accelerated approval of the study in China. The Company plans to expand its clinical site footprint in Europe and will meet with the European Medicines Agency (EMA) during 2014.

In April 2013, we 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, 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 in January 2013, 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, results of operations, financial condition and market value.



In 2007, the Company sold its medical device franchise to Boston Scientific Corporation for net aggregate payments of \$43 million, receiving \$13 million in 2007 and \$15 million in each of 2008 and 2009. Since this divestiture, we have dedicated our efforts and resources to the development and commercialization of cancer drugs including tumor-targeting treatments using focused heat energy in combination with heat-activated drug delivery systems. To support our research and development, we have raised gross proceeds of approximately \$95 million in equity financings and warrant and option exercises in the years 2009 through 2013. In January 2014, the Company raised net proceeds of \$14 million through an equity financing and, including its cash, investments and interest receivable totaling \$43.1 million at the end 2013, has \$57 million to fund its operations in 2014 and beyond. During 2012 and 2013, the Company secured two credit facilities totaling \$20 million collectively and currently has up to \$15 million remaining under the surviving facility.

On December 5, 2008, we entered into a development, product supply and commercialization agreement with Yakult Honsha Co., Ltd. (the Yakult Agreement) under which we granted Yakult an exclusive right to commercialize and market ThermoDox® for the Japanese market. We received a \$2.5 million upfront 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. 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 registrational batches of ThermoDox®. On January 18, 2013, we broadened our relationship with Hisun by entering into a technology development contract, 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 China for approval of ThermoDox®. Following our announcement of the HEAT Study results on January 31, 2013, we 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 the next steps in relation to ThermoDox®, which include the continued subgroup analysis of the Chinese cohort of patients in the HEAT Study for primary liver cancer 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 China territory. This expanded collaboration includes development of the next generation liposomal formulation with the goal of creating safer, more efficacious versions of

marketed cancer chemotherapeutics.

As a result of the risks and uncertainties discussed in this Annual Report on Form 10-K, 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 any of our research and development activities, preclinical studies or clinical trials 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 activities, preclinical studies and clinical trials, or if we are in a position to pursue manufacturing or commercialization activities, we will need significant additional capital to develop our product candidates through development and clinical trials, obtain regulatory approvals and manufacture and commercialize approved products, if any. 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 MONTHS ENDED MARCH 31, 2014 AND 2013

### Results of Operations

For the three months ended March 31, 2014, our net loss was \$5.4 million compared to \$0.7 million for the same period of 2013. As of March 31, 2014, we had \$52.2 million in cash and short-term investments including accrued interest from short term investments.

	Three Months Ended March 31,				
	(In thousands)		Change		
	2014	2013	Increase (Decrease)		%
<b>Licensing Revenue:</b>	\$ 125	\$ 125	\$ –	–	%
<b>Operating Expenses:</b>					
Clinical Research	1,804	2,033	(229)	(12.7)	%
Chemistry, Manufacturing and Controls	1,089	1,170	(81)	(6.9)	%
Research and development	2,893	3,203	(310)	(9.7)	%
General and administrative	2,434	1,689	745	44.1	%
Total operating expenses	5,327	4,892	435	8.9	%
<b>Loss from operations</b>	<b>\$(5,202)</b>	<b>\$(4,767)</b>	<b>\$ 435</b>	<b>9.1</b>	<b>%</b>

### *Comparison of the three months ended March 31, 2014 and 2013*

#### Licensing Revenue

In January 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 be amortized over the 10 year term of the agreement; therefore we recorded deferred revenue of \$125,000 in each of the first quarters of 2014 and 2013.

Research and Development Expenses

Research and development (R&D) expenses decreased by \$0.3 million from \$3.2 million in the first quarter of 2013 to \$2.9 million in the same period of 2014. Costs associated with the HEAT Study decreased to \$0.3 million in the first quarter of 2014 from \$1.3 million in the same period of 2013 primarily due to the reduced costs associated with the HEAT Study as we follow patients for overall survival. We incurred costs of \$0.7 million related to the initiation of the OPTIMA Study in the first quarter of 2014. Costs associated with our recurrent chest wall breast cancer clinical trial remained relatively unchanged at \$0.1 million in the first quarter of 2014 and 2013. Other R&D costs related to preclinical operations and regulatory operations remained unchanged at \$0.1 million in the first quarter of 2014 compared to the same period of 2013. Costs associated with the production of ThermoDox® decreased slightly to \$1.1 million in the first quarter of 2014 compared to \$1.2 million incurred during the first quarter of 2013.

General and Administrative Expenses

General and administrative (G&A) expenses increased by \$0.7 million to \$2.4 million in the first quarter of 2014 compared to \$1.7 million in the same period of 2013. This increase is primarily the result of increases in insurance costs (\$0.2 million) coupled with increases in personnel costs (\$0.5 million). Higher personnel costs reflect \$0.2 million increase in non-cash stock option expense.

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 and 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. At March 31, 2014, the fair value of this liability was \$0 and the resulting benefit was insignificant in the first quarter of 2014. At March 31, 2013, the decrease in the fair value of this liability resulted in the Company recording a non-cash benefit of \$4.3 million based on the change in the fair value of the warrants during the first quarter of 2013.

The Company incurred \$0.2 million in interest expense in each of the first quarters of 2014 and 2013 in connection with its debt facilities.

**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 development 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 revenue, and we had an accumulated deficit of \$175 million at March 31, 2014.

At March 31, 2014, we had total current assets of \$52.8 million (including cash, cash equivalents and short term investments and related interest receivable on short term investments of \$52.2 million) and current liabilities of \$5.2 million, resulting in net working capital of \$47.6 million. At December 31, 2013 we had total current assets of \$43.8 million (including cash, cash equivalents and short term investments and related interest receivable on short term investments of \$43.1 million) and current liabilities of \$4.7 million, resulting in net working capital of \$39.1 million.

Net cash used in operating activities for the first quarter of 2014 was \$4.8 million. The net loss for the first quarter of 2014 included \$0.6 million in non-cash stock-based compensation expense.

The \$4.8 million net cash used in operating activities was mostly funded from cash and short term investments. At March 31, 2014, we had cash, cash equivalents and short term investments and related interest receivable on short term investments of \$52.2 million.

Net cash provided by financing activities was \$13.8 million during the first quarter of 2014 which resulted from the net proceeds from sale of 3,603,604 shares of its common stock in a registered direct offering the Company completed in January 2014.

In January 2014, the Company sold in a registered direct offering, an aggregate of 3,603,604 shares of common stock and warrants to purchase up to 1,801,802 shares of Common Stock, for an aggregate purchase price of approximately \$15 million.

On November 25, 2013, the Company entered into the Hercules Credit Agreement, pursuant to which the Company may borrow a secured term loan of up to \$20 million in multiple tranches. The Company drew the first tranche of \$5 million at the closing on November 25, 2013 and used approximately \$4 million of the proceeds to repay the outstanding obligations under a loan agreement with Oxford Finance LLC and Horizon Technology Finance Corporation. The Company may request an additional \$15 million in up to three advances with each advance in a minimum amount of \$5 million, unless otherwise agreed upon by the Company and Hercules, before June 30, 2014 unless extended upon Hercules' consent. The loan bears an interest at a floating per annum rate equal to the greater of (i) 11.25 percent and (ii) the sum of 11.25 percent plus the prime rate minus 3.25 percent. Payments under the loan agreement are interest only for the first twelve months after loan closing, followed by a 30-month amortization period of principal and interest through the scheduled maturity date.

We believe that our cash and investment resources of \$52.2 million on hand at March 31, 2014 are sufficient to fund operations through 2016. However, our future capital requirements will depend upon numerous unpredictable factors, including, without limitation, the cost, timing, progress and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates, our efforts to implement new collaborations, licenses and strategic transactions, general and administrative expenses, capital expenditures and other unforeseen uses of cash.

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 financing alternatives. If we raise additional funds through the issuance of equity securities, the percentage ownership of our stockholders could be significantly diluted and the newly issued 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 may 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 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. We also will continue to look for government sponsored research collaborations and grants to help offset future anticipated losses from operations and, to a lesser extent, interest income.

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 terminate 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.

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 pays Cantor a commission of 3% of the aggregate gross proceeds from each sale of ATM Shares. From February 1, 2013 through February 25, 2013, the Company has sold and issued an aggregate of 1,195,927 shares under the ATM Agreement, receiving approximately \$6.8 million in net proceeds. In connection with the registered direct offering in January 2014, the Company agreed not to sell any ATM Shares until July 22, 2014.

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 three months ended March 31, 2014 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, 2013 filed on March 13, 2014 with the Securities and Exchange Commission.

### **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 March 31, 2014, 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 three months ended March 31, 2014 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, 2013 filed on March 13, 2014 with the Securities and Exchange Commission (SEC). 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 Form 10-K for the fiscal year ended December 31, 2013 filed on March 13, 2014 with the SEC including our consolidated financial statements and related notes, and our other filings made from time to time with the SEC.

### **RISKS RELATED TO OUR BUSINESS**

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

Since our inception, our expenses have substantially exceeded our revenue, resulting in continuing losses and an accumulated deficit of \$175 million at March 31, 2014. For the years ended December 31, 2011, 2012, 2013 and the three months ended March 31, 2014, we incurred a net loss of \$23.2 million, \$26.6 million, \$8.3 million and \$5.4 million, respectively. We currently have no product revenue and do not expect to generate any product revenue for the foreseeable future. Because we are committed to continuing our product research, development, clinical trial and

commercialization programs, we will continue to incur 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. The amount of future losses is uncertain. Our ability to achieve profitability, if ever, will depend on, among other things, us or our collaborators successfully developing product candidates, obtaining regulatory approvals to market and commercialize product candidates, manufacturing any approved products on commercially reasonable terms, establishing a sales and marketing organization or suitable third party alternatives for any approved product and raising sufficient funds to finance business activities. If we or our collaborators are unable to develop and commercialize one or more of our product candidates or if sales revenue from any product candidate that receives approval is insufficient, we will not achieve profitability, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

**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.**

On January 31, 2013, we announced that our lead product ThermoDox® in combination with radiofrequency ablation (RFA) failed to meet the primary endpoint of the Phase III clinical trial for primary liver cancer, known as 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®. We expect to launch a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox® in combination with RFA in primary liver cancer, known as the OPTIMA study, in the first half of 2014. The trial design of the OPTIMA study is based on the overall survival data from the post-hoc analysis of results from the HEAT Study. ThermoDox® is also being evaluated in a Phase II clinical trial for recurrent chest wall breast cancer and other preclinical studies.

Preclinical testing and clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development, as evidenced by the failure of ThermoDox® to meet its primary endpoint in the HEAT Study. 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. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects. We may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates. 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 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 continue to follow the patients enrolled in the Heat study to the secondary endpoint, overall survival. Based on the overall survival data from the post-hoc analysis of results from the HEAT Study, launched a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox® in combination with RFA in primary liver cancer, known as the OPTIMA Study, in the first quarter of 2014. ThermoDox® is currently also being evaluated in Phase II clinical trials and other preclinical studies. We do not expect to realize any revenue 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 March 31, 2014, we had approximately \$52.2 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 recurrent chest wall breast cancer and other preclinical studies, and we launched the OPTIMA study in the first quarter of 2014. We will continue to 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. Our future capital requirements will depend upon numerous unpredictable factors, including, without limitation, the cost, timing, progress and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates, our efforts to implement new collaborations, licenses and strategic transactions, general and administrative expenses, capital expenditures and other unforeseen uses of cash. 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 are unable to obtain additional capital on a timely basis or on acceptable terms, we may be required to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, if any, limit strategic opportunities or undergo corporate restructuring activities. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates 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 may not successfully engage in strategic transactions, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expense and present significant distractions to our management.**

We may consider strategic alternatives intended to further the development of our business, which may include acquiring businesses, technologies or products, out- or in-licensing product candidates or technologies or entering into a business combination with another company. Any strategic transaction may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and have a material adverse effect on our business, results of operations, financial condition and prospects. Conversely, any failure to enter any strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.

**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 investigators, clinical research organizations (CROs), clinical data management organizations and consultants to design, conduct, supervise and monitor our clinical trials. Because we do not have the ability to conduct our own clinical trials, we must rely on the efforts of others and have limited control over, and cannot 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 we cannot contract with acceptable third parties on commercially reasonable terms or at all, 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 more 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.

In all events, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. The FDA requires clinical trials to be conducted in accordance with good clinical practices, including for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Any such event could have a material adverse effect on our business, financial condition, results of operations and prospects.

**Because we rely on third party manufacturing and supply partners, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.**

We rely on third party supply and manufacturing partners to supply the materials and components for, and manufacture, our research and development, preclinical and clinical trial drug supplies. We do not own manufacturing facilities or supply sources for such components and materials. There can be no assurance that our supply of research and development, preclinical and clinical development drugs and other materials will not be limited, interrupted, restricted in certain geographic regions or of satisfactory quality or continue to be available at acceptable prices. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by FDA and foreign regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices. In the event that any of our suppliers or manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all.

**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 revenue 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.

**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.

**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.

**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.

**Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.**

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruptions of our operations. For instance, the loss of preclinical data or data from any clinical trial involving our product candidates could result in delays in our development and regulatory filing efforts and significantly increase our costs. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could



be delayed.

## **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 as reported on The NASDAQ Capital Market had a high price of \$42.12 and a low price of \$3.47 in the 52-week period ended December 31, 2013, as adjusted to reflect the 4.5-to-1 reverse split of our common stock effected as of October 28, 2013, and a high price of \$4.57 and a low price of \$3.03 from January 2, 2014 through May 7, 2014. 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:

results of preclinical and clinical studies of our product candidates or those of our competitors;

regulatory or legal developments in the U.S. and other countries, especially changes in laws and regulations applicable to our product candidates;

actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;

introductions and announcements of new products by us or our competitors, and the timing of these introductions or announcements;

announcements by us or our competitors of significant acquisitions or other strategic transactions or capital commitments;

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;

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 anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

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 May 7, 2014, we had 17,217,066 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 May 7, 2014, we have a significant number of securities convertible into, or allowing the purchase of, our common stock, including 5,069,815 shares of common stock issuable upon exercise of warrants outstanding, 1,175,071 options to purchase shares of our common stock and restricted stock awards outstanding, and 14,475 shares of common stock reserved for future issuance under our stock incentive plans. Under the Controlled Equity Offering<sup>SM</sup> 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 and we only sold \$6.8 million under the agreement as of May 7, 2014.

**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 May 7, 2014, the closing sale price of our common stock was \$3.19, 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 \$54 million and the total market value of our listed securities was approximately \$55 million. There is no assurance that we will continue to meet the minimum closing price requirement and other listing requirements. As of March 31, 2014, we had stockholders' equity of \$40.6 million.

On October 28, 2013, we effected a 4.5-to-1 reverse stock split of our common stock primarily for purposes of increasing the market price of our common stock, among others, and our common stock started to trade on the post-split basis on October 29, 2013. Other companies have found that the increased stock prices resulting from reverse splits tend to diminish over time unless supported by positive developments in the business. The closing price of our common stock as reported on The NASDAQ Capital Market has declined from \$5.14 on October 29, 2013 to \$3.19 on May 7, 2014.

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.

**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 2013, 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 carry forwards. The Company determined that it experienced an ownership change, as defined by Section 382, in connection with certain common stock offerings on July 25, 2011, February 5, 2013 and on June 3, 2013. As a result, the utilization of the Company's federal tax net operating loss carry forwards generated prior to the ownership changes 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 cash 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.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

Form of  
Series A  
Common  
Stock  
Purchase  
Warrant  
incorporated  
herein by  
reference to  
4.1 Exhibit 4.1  
to the  
Current  
Report on  
Form 8-K of  
the Company  
filed with the  
SEC on  
January 21,  
2014.

Form of  
Series B  
Common  
Stock  
Purchase  
Warrant  
incorporated  
herein by  
reference to  
4.2 Exhibit 4.2  
to the  
Current  
Report on  
Form 8-K of  
the Company  
filed with the  
SEC on  
January 21,  
2014.

10.1 Securities  
Purchase  
Agreement



dated as of  
January 15,  
2014, 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  
January 21,  
2014.

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.

The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, formatted in XBRL (Extensible Business Reporting Language):

(i) the unaudited Balance Sheets, (ii) the unaudited

101\*\* 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.



**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.

May 8, 2014

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

**EXHIBIT INDEX**

**Exhibit Description of**

**Number Documents**

- 4.1 Form of Series A Common Stock Purchase Warrant incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed with the SEC on January 21, 2014.
- 4.2 Form of Series B Common Stock Purchase Warrant incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K of the Company filed with the SEC on January 21, 2014.
- 10.1 Securities Purchase Agreement dated as of January 15, 2014, 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 January 21, 2014.
- 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 March 31, 2014, 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.