

Celsion CORP  
Form 10-Q  
November 09, 2012

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 September 30, 2012

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-15911

CELSION CORPORATION  
(Exact name of Registrant as specified in its charter)

Delaware 52-1256615  
(State or other jurisdiction of incorporation (I.R.S. Employer Identification Number)  
or organization)

997 Lenox Drive, Suite 100  
Lawrenceville, NJ 08648  
(Address of principal executive offices)

(609) 896-9100  
(Registrant's telephone number, including area code)

(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):

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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 November 9, 2012, the Registrant had 35,012,924 shares of Common Stock, \$.01 par value per share, outstanding.

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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 (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical fact are “forward-looking statements” for purposes of this Quarterly Report on Form 10-Q, including 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 unforeseen 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, and other financial items, any changes in approaches to medical treatment, any introduction of new products by others, any possible acquisitions of other technologies, assets or businesses, any possible actions by customers, suppliers, competitors and regulatory authorities, 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 thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, such expectations or any of the forward-looking statements may prove to be incorrect and actual results could differ materially from those projected or assumed in the forward-looking statements. 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. 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, and, where appropriate, its subsidiaries.

## 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.

## PART I: FINANCIAL INFORMATION

## Item 1. FINANCIAL STATEMENTS

CELSION CORPORATION  
BALANCE SHEETS

	September 30, 2012 (unaudited)	December 31, 2011
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 8,318,336	\$ 20,145,854
Investment securities – available for sale, at fair value	14,229,181	10,157,160
Accrued interest receivable on investment securities	133,552	243,745
Advances and deposits for investigator grants	807,795	758,297
Vendor reimbursements receivable	173,598	–
Other current assets	103,728	203,429
Total current assets	23,766,190	31,508,485
Property and equipment (at cost, less accumulated depreciation of \$799,712 and \$643,472, respectively)	1,007,590	782,720
Other assets:		
Deposits, deferred fees and other assets	605,372	322,629
Patent licensing fees, net	30,000	35,625
Total other assets	635,372	358,254
Total assets	\$ 25,409,152	\$ 32,649,459
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,944,956	\$ 4,010,203
Accrued liabilities	2,715,509	2,031,934
Notes payable - current portion	945,433	110,287
Total current liabilities	6,605,898	6,152,424
Common stock warrant liability	1,417,248	166,398
Notes payable – non-current portion	4,140,186	71,602
Other non-current liabilities	221,832	65,467
Total liabilities	12,385,164	6,455,891
Stockholders' equity:		
Common stock, \$0.01 par value; 75,000,000 shares authorized and 35,459,494 and 33,899,057 shares issued at September 30, 2012 and December 31, 2011 and 34,792,207 and 33,186,325 shares outstanding at September 30, 2012 and December 31, 2011, respectively	354,595	338,991
Additional paid-in capital	158,121,079	153,237,225
Accumulated other comprehensive loss	(131,306 )	(276,700 )
Accumulated deficit	(142,620,295 )	(124,221,823 )
Subtotal	15,724,073	29,077,693

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Treasury stock, at cost (667,287 and 712,732 shares at September 30, 2012 and December 31, 2011, respectively)	(2,700,085 )	(2,884,125 )
Total stockholders' equity	13,023,988	26,193,568
Total liabilities and stockholders' equity	\$ 25,409,152	\$ 32,649,459

See accompanying notes to the financial statements.

CELSION CORPORATION  
STATEMENTS OF OPERATIONS  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Licensing revenue	\$	\$	\$	\$ 2,000,000
Operating expenses:				
Research and development	3,539,309	5,414,284	12,344,559	14,726,942
General and administrative	1,420,258	1,408,828	4,586,005	3,906,095
Total operating expenses	4,959,567	6,823,112	16,930,564	18,633,037
Loss from operations	(4,959,567)	(6,823,112)	(16,930,564)	(16,633,037)
Other (expense) income:				
(Loss) gain from valuation of common stock warrant liability	(881,127)	375,378	(1,250,850)	(42,482)
Investment (loss) income, net	(5,581)	26,347	61,828	26,911
Interest and dividend expense	(171,720)	(13,710)	(187,995)	(494,797)
Other income (expense)	-	42,145	(1,040)	42,145
Total other (expense) income, net	(1,058,428)	430,160	(1,378,057)	(468,223)
Net Loss	\$ (6,017,995)	\$ (6,392,952)	\$ (18,308,621)	\$ (17,101,260)
Net loss per common share – basic and diluted	\$ (0.18)	\$ (0.25)	\$ (0.55)	\$ (0.93)
Weighted average shares outstanding – basic and diluted	33,641,810	25,150,084	33,412,822	18,360,149

See accompanying notes to the financial statements.

CELSION CORPORATION  
 STATEMENTS OF COMPREHENSIVE LOSS  
 (Unaudited)

	Three Months Ended September		Nine Months Ended September	
	30,	2011	30,	2011
	2012	2011	2012	2011
Net Loss	\$ (6,017,995)	\$ (6,392,952)	\$ (18,308,621)	\$ (17,101,260)
Other comprehensive gain (loss)				
Unrealized gain (loss) on investment securities	184,294	(178,681)	145,394	(138,763)
Comprehensive loss	\$ (5,833,701)	\$ (6,571,633)	\$ (18,163,227)	\$ (17,240,023)

See accompanying notes to the financial statements.



CELSION CORPORATION  
STATEMENTS OF CASH FLOWS  
(Unaudited)

	Nine Months Ended September 30,	
	2012	2011
<b>Cash flows from operating activities:</b>		
Net loss	\$ (18,308,621)	\$ (17,101,260)
<b>Non-cash items included in net loss:</b>		
Depreciation and amortization	161,865	129,735
Change in fair value of common stock warrant liability	1,250,850	42,482
Stock-based compensation	850,990	892,894
Treasury shares issued for services and 401(k) matching contribution	94,189	116,188
Change in deferred rent liability	59,085	-
<b>Net changes in:</b>		
Accrued interest on short term investments and other current assets	9,897	(259,666)
Accounts payable	(967,967)	(1,775,932)
Other accrued liabilities	683,575	(347,422)
<b>Net cash used in operating activities:</b>	<b>(16,166,137)</b>	<b>(18,302,981)</b>
<b>Cash flows from investing activities:</b>		
Purchases of investment securities	(16,213,657)	(10,415,493)
Proceeds from sale and maturity of investment securities	12,287,030	395,556
Security deposit on letter of credit	-	(250,000)
Purchases of property and equipment	(381,110)	(328,866)
<b>Net cash used in investing activities</b>	<b>(4,307,737)</b>	<b>(10,598,803)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from sale of 8% Series A Redeemable, Convertible Preferred Stock, net of issuance costs	-	4,324,080
Proceeds from sale of common stock equity, net of issuance costs	-	34,268,411
Proceeds from notes payable	4,814,398	-
Proceeds from exercise of common stock warrants	3,823,690	394,336
Proceeds from exercise of options to purchase common stock	104,538	-
Principal payments on notes payable	(96,270)	(91,069)
<b>Net cash provided by financing activities</b>	<b>8,646,356</b>	<b>38,895,758</b>
<b>(Decrease) increase in cash and cash equivalents</b>	<b>(11,827,518)</b>	<b>9,993,974</b>
Cash and cash equivalents at beginning of period	20,145,854	1,138,916
<b>Cash and cash equivalents at end of period</b>	<b>\$ 8,318,336</b>	<b>\$ 11,132,890</b>
<b>Supplemental disclosures of cash flow information:</b>		
Interest and preferred stock dividends paid	\$ 187,995	\$ 481,087

See accompanying notes to the financial statements.



CELSION CORPORATION  
NOTES TO FINANCIAL STATEMENTS (UNAUDITED)  
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2012 AND 2011

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 innovative oncology drug development company focused on improving treatment for those suffering with difficult-to-treat forms of cancer. We are working to develop and commercialize more efficient, effective, targeted chemotherapeutic oncology drugs based on our proprietary heat-activated liposomal technology. Our lead product ThermoDox® is being tested in human clinical trials for the treatment of primary liver cancer, recurrent chest wall breast cancer and colorectal liver metastases.

Note 2. Basis of Presentation

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

In the opinion of management, all adjustments, consisting only of normal recurring accruals considered necessary for a fair presentation, have been included in the accompanying unaudited financial statements. Operating results for the three and nine month periods ended September 30, 2012 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/A for the fiscal year ended December 31, 2011 filed with the Securities and Exchange Commission on March 15, 2012.

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

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

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

Note 3. New Accounting Pronouncements

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

In June 2011, the Financial Accounting Standards Board (FASB) amended its guidance on the presentation of comprehensive income in financial statements to improve the comparability, consistency and transparency of financial

reporting and to increase the prominence of items that are recorded in other comprehensive income. The new accounting guidance requires entities to report components of comprehensive income in either (1) a continuous statement of comprehensive income or (2) two separate but consecutive statements. The provisions of this new guidance are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We have incorporated this guidance into these financial statements and they did not have a material impact on the Company's financial statements.

There were no new accounting pronouncements issued or effective during the first nine months of 2012 that have had or are expected to have a material impact on the Company's financial statements.

## Note 4. Net Loss per Common Share

Basic earnings per share is calculated based upon the net 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 options, warrants and their equivalents are computed using the treasury stock method.

For the three and nine months ended September 30, 2012 and 2011, 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 outstanding warrants and equity awards for the three and nine month periods ended September 30, 2012 and 2011 were 13,643,404 and 11,492,716 common stock equivalent shares, respectively.

## Note 5. Investment Securities - Available For Sale

Investment securities available for sale of \$14,229,181 and \$10,157,160 as of September 30, 2012 and December 31, 2011, respectively, consist of commercial paper, corporate debt securities and equity 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.

Investment securities - available for sale - at fair value	September 30, 2012	December 31, 2011
Bonds - corporate issuances	\$ 14,091,590	\$ 10,157,160
Equity securities	137,591	-
Total short-term investments, available for sale	\$ 14,229,181	\$ 10,157,160

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

	September 30, 2012		December 31, 2011	
	Cost	Fair Value	Cost	Fair Value
<b>Short-term investments</b>				
Bonds- corporate issuances	\$ 14,252,114	\$ 14,091,590	\$ 10,325,487	\$ 10,157,160
Equity securities	108,373	137,591	108,373	-
Total	\$ 14,360,487	\$ 14,229,181	\$ 10,433,860	\$ 10,157,160
<b>Bond maturities</b>				
Within 3 months	\$ 6,084,600	\$ 6,010,500	\$ 5,128,560	\$ 5,036,920
Between 3-12 months	8,167,514	8,081,090	5,196,927	5,120,240
Total	\$ 14,252,114	\$ 14,091,590	\$ 10,325,487	\$ 10,157,160



The following table shows the Company's investment securities gross unrealized losses and fair value by investment category and length of time that individual securities have been in a continuous unrealized loss position at September 30, 2012 and December 31, 2011. 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	Less than 12 months		September 30, 2012 12 months or Longer		Total	
	Fair Value	Gross Unrealized Holding Losses	Fair Value	Gross Unrealized Holding Gains	Fair Value	Gross Unrealized Holding (Losses) Gains
<b>Available for Sale</b>						
Bonds – corporate issuances	\$ 14,091,590	\$ (160,524)	\$ –	\$ –	\$ 14,091,590	\$ (160,524)
Equity securities	–	–	137,591	29,218	137,591	29,218
	\$ 14,091,590	\$ (160,524)	\$ 137,591	\$ 29,218	\$ 14,229,181	\$ (131,306)

Description of Securities	Less than 12 months		December 31, 2011 12 months or Longer		Total	
	Fair Value	Gross Unrealized Holding Losses	Fair Value	Gross Unrealized Holding Losses	Fair Value	Gross Unrealized Holding Losses
<b>Available for Sale</b>						
Bonds – corporate issuances	\$ 10,157,160	\$ (168,327)	\$ –	\$ –	\$ 10,157,160	\$ (168,327)
Equity securities	–	(93,924)	–	(14,449)	–	(108,373)
	\$ 10,157,160	\$ (262,251)	\$ –	\$ (14,449)	\$ 10,157,160	\$ (276,700)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Interest and dividend income	\$ 115,449	\$ 26,347	\$ 380,034	\$ 26,911
Realized losses	(121,030)	–	(318,206)	–
	\$ (5,581)	\$ 26,347	\$ 61,828	\$ 26,911

#### 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 September 30, 2012 and December 31, 2011 on the Company's Balance Sheet:

	Total Fair Value on the Balance Sheet	Quoted Prices In Active Markets For Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
As of September 30, 2012				
Short-term investments available for sale				
Bonds – corporate issuances	\$ 14,091,590	\$ 14,091,590	\$ –	\$ –
Equity Securities	137,591	–	–	137,591
As of December 31, 2011				
Short-term investments available for sale				
Bonds – corporate issuances	\$ 10,157,160	\$ 10,157,160	\$ –	\$ –
Equity Securities	–	–	–	–
<b>Liabilities:</b>				
As of September 30, 2012				
Common stock warrant liability	\$ 1,417,248	\$ –	\$ –	\$ 1,417,248
As of December 31, 2011				
Common stock warrant liability	\$ 166,398	\$ –	\$ –	\$ 166,398

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 nine month period ended September 30, 2012.

## Note 7. Other Accrued Liabilities

Accrued liabilities at September 30, 2012 and December 31, 2011 include the following:

	September 30, 2012	December 31, 2011
Amounts due to Contract Research Organizations and other contractual agreements	\$ 2,256,514	\$ 1,234,875
Accrued payroll and related benefits	322,713	632,425
Accrued professional fees	108,653	137,400
Other	27,629	27,234
<b>Total</b>	<b>\$ 2,715,509</b>	<b>\$ 2,031,934</b>

## Note 8. Note Payable

On June 27, 2012, the Company entered into a Loan and Security Agreement (the "Credit Agreement") with Oxford Finance LLC ("Oxford") and Horizon Technology Finance Corporation ("Horizon"). The Credit Agreement provides for a secured term loan of up to \$10 million, with 50% of any loans to be funded by Oxford and 50% to be funded by Horizon. The aggregate loan amount may be advanced in two tranches of \$5 million each. The first tranche (the "Term A Loan") was made available to the Company on June 27, 2012 and the second tranche (the "Term B Loan") may be made available, if at all, during the period beginning on the date that the Company achieves positive data in its Phase III clinical trial of RFA and ThermoDox® (the HEAT Study) and ending on March 31, 2013. The Term A Loan is scheduled to mature on October 15, 2015 (or, if the Term B Loan is made available, January 1, 2016) and the Term B Loan is scheduled to mature on January 1, 2016. The proceeds of the Credit Agreement will be used to fund the Company's working capital and general corporate purposes. The obligations under the Credit Agreement are secured by substantially all assets of the Company other than its intellectual property and certain other agreed-upon exclusions.

The Term A Loan bears interest at a fixed rate of 11.75%. If it is made available, the Term B Loan will bear interest at a fixed rate equal to the greater of (i) 11.75% or (ii) the sum of (a) the three month U.S. LIBOR rate (but not less than 0.47%) three days prior to the funding of the loan plus (b) 11.28%. Generally, the Company is required to pay principal and interest in equal monthly installments. However for an initial period extending for the Term A Loan through May 1, 2013 (or, if the Term B Loan is made available, January 1, 2016) and for the Term B Loan through August 1, 2013, the Company is only required to make interest payments. The Company is also obligated to pay other customary facility fees for a credit facility of this size and type.

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

As a fee in connection with the Credit Agreement, the Company issued warrants to Horizon and Oxford (the "Warrants") to purchase the number of shares of the Company's common stock equal to 3% of each loan amount divided by the exercise price, which was calculated as the average NASDAQ closing price of The Company common stock

for the three days prior to the funding of the loan amount (\$2.92 per share for the Term A Loan). This resulted in 51,370 warrant shares issued in connection with the Term A Loan and additional warrant shares issuable in connection with the Term B Loan, if that is made available. The Warrants issued in connection with the Term A Loan are immediately exercisable for cash or by net exercise and will expire seven years after their issuance, which is June 27, 2019.

The Company valued the Warrants using the Black-Scholes option pricing model and recorded \$73,654 as deferred financing fees. In calculating the value of the warrants, the Company assumed a volatility rate of 74.3%, risk free interest rate of 1.10%, an expected life of 3.5 years, a stock price of \$2.80 (closing price on date of the Warrant) and no expected forfeitures nor dividends. In connection with the Credit Agreement, the Company incurred cash expenses of \$207,207 which were recorded as deferred financing fees. These deferred financing fees will be amortized as interest expense over the life of the loan.

For the period since the Credit Agreement's inception through September 30, 2012, \$21,605 in deferred financing fees were amortized as interest expense. Also, the Company paid \$146,875 in interest expense on the Credit facility during this same period.

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

	Credit Agreement
For the year ending September 30:	
2013	\$ 886,616
2014	1,936,586
2015	2,176,798
	\$ 5,000,000

In October 2009, the Company financed \$288,200 of lab equipment through a capital lease. This lease obligation had thirty monthly payments of \$11,654 through April 2012. During the first half of 2012, the Company has made principal and interest payments totaling \$58,270. The lease obligation was paid in full during the second quarter of 2012.

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 nine months of 2012, the Company made principal and interest payments totaling \$50,863. The outstanding lease obligation is \$85,618 as of September 30, 2012.

#### Note 9. Stock Based Compensation

##### Stock Options Plans

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

In 2007, the Company adopted the Celsion Corporation 2007 Stock Incentive Plan (the "2007 Plan") under which 1,000,000 shares were authorized for issuance. The purpose of the 2007 Plan is to promote the long-term growth and profitability of the Company by providing incentives to improve stockholder value and enable the Company to attract, retain and reward the best available persons for positions of substantial responsibility. The 2007 Plan permits the granting of equity awards in the form of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights, phantom stock, and performance awards, or in any combination of the foregoing. At the Annual Meetings of Stockholders of Celsion held on June 25, 2010 and June 7, 2012, the stockholders approved amendments to the Plan. The only material difference between the existing Plan and the amended Plan was the number of shares of common stock available for issuance under the amended Plan which was increased by 1,000,000 to a total of 2,000,000 shares in 2010 and by 2,250,000 to a total of 4,250,000 shares in 2012.

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

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

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

	Nine Months ended September 30,			
	2012		2011	
Risk-free interest rate	1.60 -	2.97%	2.29 -	2.97%
Expected volatility	80.2 -	82.3%	72.2 -	81.1%
Expected life (in years)	5.0 -	6.25	6.25	
Expected forfeiture rate	0.0% -	7.5%	0.0%	
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 2012 and 2011 grants was generated using the simplified method.

A summary of the Company's stock option and restricted stock awards for nine month period ended September 30, 2012 is as follows:

Equity Awards	Stock Options		Restricted Stock Awards		Weighted Average Contractual Terms of Equity Awards (in years)
	Options Outstanding	Weighted Average Exercise Price	Non-vested Restricted Stock Outstanding	Weighted Average Grant Date Fair Value	
Equity awards outstanding at December 31, 2011	3,113,144	\$ 3.75	54,867	\$ 3.16	
Equity awards granted	623,251	\$ 2.11	5,544	\$ 2.10	
Equity awards exercised	(38,750)	\$ 2.70	(9,557)	\$ 2.86	
Equity awards forfeited, cancelled or expired	(264,669)	\$ 6.80	(6,667)	2.86	
Equity awards outstanding at September 30, 2012	3,432,976	\$ 3.24	44,167	\$ 3.13	6.81
Aggregate intrinsic value of outstanding awards at September 30, 2012	\$ 7,723,556		\$ 239,385		
Equity awards exercisable at September 30, 2012	2,062,954	\$ 3.74			5.57
	\$ 3,574,674				

Aggregate intrinsic value of awards  
exercisable at September 30, 2012

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Total compensation cost related to employee stock options and restricted stock awards amounted to \$276,107 and \$332,918 for the three months ended September 30, 2012 and 2011, respectively. Total compensation cost related to employee stock options and restricted stock awards amounted to \$850,990 and \$892,894 for the nine months ended September 30, 2012 and 2011, respectively. No compensation cost related to share-based payments arrangements was capitalized as part of the cost of any asset as of September 30, 2012 or 2011.

As of September 30, 2012, there was \$1.8 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 1.9 years. The weighted average grant-date fair value was \$1.48 and \$2.62 per share for the options granted during the nine months ended September 30, 2012 and 2011, respectively. The weighted average grant-date fair value was \$2.10 and \$2.68 for the restricted stock awards granted during the nine months ended September 30, 2012 and 2011, respectively.

Collectively, for all the stock option plans as of September 30, 2012, there were a total of 6,013,334 shares reserved, which were comprised of 3,477,143 equity awards granted and 2,536,191 equity awards available for future issuance.

#### Note 10. Warrants

##### Common Stock Warrants

Following is a summary of all warrant activity for 2012:

Warrants	Number of Warrants Issued	Weighted Average Exercise Price
Warrants outstanding at December 31, 2011	11,627,001	\$ 3.15
Warrants granted in connection with the Credit Agreement as more fully described in Note 9	51,370	\$ 2.92
Warrants exercised for common stock	(1,512,110 )	2.58
Warrants outstanding at September 30, 2012	10,166,261	\$ 3.23
Aggregate intrinsic value of outstanding warrants at September 30, 2012	\$ 22,232,473	
Weighted average remaining contractual terms (years)	4.20	

During the third quarter of 2012, the Company received gross proceeds of approximately \$3.9 million from the exercise of warrants to purchase 1,512,110 shares of common stock. During the 4th quarter of 2012 and as of the date of this Form 10Q filing, the Company received additional proceeds of approximately \$681,000 from the exercise of warrants and options to purchase common stock.



## Common Stock Warrant Liability

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

The fair value of the warrants at September 30, 2012 and December 31, 2011 was \$1,417,248 and \$166,398, respectively, calculated using the Black-Scholes option-pricing model with the following assumptions:

	September 30, 2012	December 31,2011
Risk-free interest rate	0.62%	0.83%
Expected volatility	55.14%	75.17%
Expected life (in years)	1.25	1.6
Expected forfeiture rate	0.0%	0.0%
Expected dividend yield	0.00%	0.00%

As a result of this change in the warrant liability, the Company recorded a non-cash loss of \$1.3 million in the nine months ended September 30, 2012. The following is a summary of the changes in the common stock warrant liability for the nine months ended September 30, 2012:

Beginning balance, January 1, 2012	\$ 166,398
Issuances	-
Loss from the adjustment for the change in fair value included in net loss	1,250,850
Ending balance, September 30, 2012	\$ 1,417,248

## Note 11. Contingent Liabilities and Commitments

In July 2011, the Company executed a lease (the "Lease") with Brandywine Operating Partnership, L.P. (Brandywine), a Delaware limited partnership for a 10,870 square foot premises located in Lawrenceville, New Jersey. In October 2011, the Company relocated its offices to Lawrenceville, New Jersey from Columbia, Maryland. The lease has a term of 66 months and provides for 6 months rent free, with the first monthly rent payment of approximately \$23,000 due 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.



Note 12. Technology Development and Licensing Agreements

On May 7, 2012 the Company announced the signing of a long term commercial supply agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. (Hisun) for the production of ThermoDox® in the China territory. In accordance with the terms of the agreement, Hisun will be responsible for providing all of the technical and regulatory support services, including the costs of all technical transfer, registrational 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 registrational batches of ThermoDox®. Hisun is also obligated to certain performance requirements under the agreement. The agreement will initially be limited to a percentage of the production requirements of ThermoDox® in the China territory with Hisun retaining an option for additional global supply after local regulatory approval in the China territory. In addition, Hisun will collaborate with Celsion around the regulatory approval activities for ThermoDox® with the China State Food and Drug Administration (SFDA). As of September 30, 2012, the Company has incurred approximately \$95,000 in costs to be reimbursed to Hisun.

On December 5, 2008, we entered into a development, product supply and commercialization agreement with Yakult Honsha Co. (the Yakult Agreement) under which Yakult was granted the exclusive right to commercialize and market ThermoDox® for the Japanese market. We were paid a \$2.5 million up-front licensing fee and may receive additional payments from Yakult upon receipt of marketing approval by the Japanese Ministry of Health, Labor and Welfare as well as upon the achievement of certain levels of sales and approval for new indications. Under the Yakult Agreement, we will receive double digit escalating royalties on the sale of ThermoDox® in Japan, when and if any such sales occur and we also will be the exclusive supplier of ThermoDox® to Yakult. Concurrent with a convertible preferred stock equity financing in January 2011, we amended the Yakult Agreement to provide for up to \$4.0 million in accelerated partial payments to us on a drug approval milestone. The terms of the Yakult Agreement provided for the payment to us of \$2.0 million upon the closing of the preferred equity financing. The second \$2.0 million was conditioned upon the resumption of enrollment of Japanese patients in the Japan cohort of the HEAT study, which has not been resumed. In consideration of the \$2.0 million accelerated milestone payment from Yakult, we have agreed to reduce future drug approval milestone payments by approximately twenty percent (20%). All other milestone payments are unaffected.

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

Forward-Looking Statements

Statements and terms such as “expect”, “anticipate”, “estimate”, “plan”, “believe” and words of similar import regarding our expectations as to the development and effectiveness of our technologies, the potential demand for our products, and other aspects of our present and future business operations, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our industry, business and operations, we cannot guarantee that actual results will not differ materially from our expectations. In evaluating such forward-looking statements, readers should specifically consider the various factors contained in our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2011, which factors include, without limitation, unforeseen changes in the course of research and development activities and in clinical trials; possible changes in cost and timing of development and testing, capital structure, and other financial items; changes in approaches to medical treatment; introduction of new products by others; possible acquisitions of other technologies, assets or businesses; and possible actions by customers, suppliers, 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/A, 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 Corporation is an innovative 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 and effective, targeted chemotherapeutic oncology drugs based on our proprietary heat-activated liposomal technology. The promise of this drug technology is to maximize efficacy while minimizing side effects common to cancer treatments.

Our lead product ThermoDox® is being evaluated in a Phase III clinical trial for primary liver cancer (the HEAT study), Phase II clinical trial for colorectal liver metastasis (CRLM) and a Phase II clinical trial for recurrent chest wall breast cancer. The Company expects to report top line data from the HEAT Study in January 2013. 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.

The U.S. Food and Drug Administration (FDA) has granted our Phase III HEAT study for ThermoDox®, in combination with radiofrequency ablation, a Special Protocol Assessment and has designated it as a Fast Track Development Program. We have received written guidance from the FDA stating that, assuming the results of our ongoing studies are adequate, we may submit our New Drug Application (NDA) for ThermoDox® pursuant to

Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act. A 505(b) (2) NDA provides that some of the information from the reports required for marketing approval may come from studies that the applicant does not own or for which the applicant does not have a legal right of reference and permits a manufacturer to obtain marketing approval for a drug without needing to conduct or obtain a right of reference for all of the required studies. The availability of Section 505(b) (2) and the designation of ThermoDox® as a Fast Track Development Program may provide us with an expedited pathway to approval. There can be no assurance, however, that the results of our ongoing studies will be adequate to obtain approval of ThermoDox® under Section 505(b)(2). Drug research and development is an inherently uncertain process and there is a high risk of failure at every stage prior to approval and the timing and the outcome of clinical results is extremely difficult to predict. Clinical development successes and failures can have a disproportionate positive or negative impact on our scientific and medical prospects, financial prospects, financial condition, and market value.

In December 2011, the European Medicines Agency (EMA) provided written, scientific advice confirming that the HEAT study is acceptable as a basis for submission of a marketing authorization application (MAA). Based on feedback and guidance received from the EMA, we expect that future results demonstrating a convincing magnitude of improvement in progression-free survival, the study's primary endpoint, along with a favorable benefit-risk ratio in the HEAT study, would be sufficient as the primary basis for registration of ThermoDox® in Europe. The EMA also supported our manufacturing strategy and technology transfer protocols, which will allow us to establish multiple manufacturing sites to support commercialization of ThermoDox® outside the United States.

In March of 2011, we announced that the European Commission granted orphan drug designation for ThermoDox® in primary liver cancer, which provides assistance and incentives, including ten years of marketing exclusivity subsequent to product approval, in support of product candidates intended for the treatment of a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union. ThermoDox® also holds orphan drug designation in the U.S.

We have also demonstrated the feasibility for a product pipeline of cancer drugs that employ our heat activated liposomal technology in combination with known chemotherapeutics, including docetaxel and carboplatin. We believe that our technology can improve efficacy and safety of anticancer agents whose mechanism of action and safety profile are well understood by the medical and regulatory communities. Our approach provides a comparatively cost effective, low risk approval pathway. An element of our business strategy is to pursue, as resources permit, the research and development of a range of product candidates for a variety of indications. This is intended to allow us to diversify the risks associated with our research and development expenditures. 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.

Additionally, in 2009, we formed 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. Philips & Celsion are currently negotiating a new agreement reflecting our progress to clinical development status. In August 2012, we announced FDA Clearance to commence a Phase II Study of ThermoDox® and Philip's Sonalleve® MR-Guided HIFU technology for the palliation of painful metastases to the bone caused by prostate cancer. In June 2012, we announced a collaboration with the University of Oxford, in the UK, to begin a clinical study of ThermoDox plus HIFU in the treatment of metastatic liver cancer. The trial, which is supported by the National Institute for Health Research Oxford Biomedical Research Centre, will be carried out as a multi-disciplinary collaboration between Celsion, the Oxford University Institute of Biomedical Engineering, and the Oxford University Hospitals NHS Trust. This early phase clinical study is being finalized and will require approval from a local Ethics Committee. Treatment of the first patient is targeted for the first half of 2013. In addition, we are working with the Focused Ultrasound Foundation in preclinical studies designed to explore the use of ThermoDox in combination with MR-guided HIFU for the treatment of pancreatic cancer. The studies are being conducted at the University of Washington (UW) School of Medicine. The UW research is expected to include animal models to confirm the ability of HIFU to target high concentrations of doxorubicin in proprietary pancreatic cancer cell lines, and in vivo studies to assess the response to these tumors treated using ThermoDox with and without HIFU-induced hyperthermia. We believe that these collaborations are just the beginning for combining important device technologies such as HIFU with our low heat activated liposomal technology. For certain markets, we may seek licensing partners to share in the development and commercialization costs. We will also evaluate licensing cancer products from third parties for cancer treatments to expand our product pipeline.

On May 30, 2012, we announced that we had reached our enrollment objective of 700 patients in the HEAT Study. On November 9, 2012, we announced 380 progression free survival (PFS) events have been realized in the HEAT Study. According to the study's protocol, 380 events of progression trigger the data collection process, unblinding and final analysis of the results by the study's independent Data Monitoring Committee (DMC). PFS is the HEAT Study's primary end point which has been granted Special Protocol Assessment by the FDA. Following review by the DMC, the Company plans to disclose top line results from the pivotal Phase III HEAT Study in January of 2013.

On November 28, 2011, we announced that the independent Date Monitoring Committee (DMC) for the HEAT study completed a pre-planned interim analysis for safety, efficacy and futility and unanimously recommended that the study continue to its final analysis as planned. The DMC evaluated data from 613 patients in its review, which was conducted following realization of 219 PFS events within the study population.

Consistent with our global regulatory strategy, we announced on April 23, 2012, that randomization of at least 200 patients in the People's Republic of China (PRC), a requirement for registrational filing in the PRC, had been completed. The HEAT study had already enrolled a sufficient number to support registrational filings in South Korea and Taiwan, two important markets for ThermoDox®.

In January 2012, we announced the enrollment of our first patient in the randomized Phase II study of ThermoDox® in combination with radiofrequency ablation for the treatment of colorectal liver metastases (the ABLATE Study). The ABLATE Study is expected to enroll up to 88 patients with colorectal cancer metastasized to the liver. Patients will be randomized to receive either RFA plus ThermoDox® or RFA alone for the treatment of their liver tumors. The primary study endpoint is based on one year local tumor recurrence, with secondary endpoints of time to progression and overall survival.

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 the mainland China, Hong Kong and Macau (the China territory). Per 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, registrational 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®. We will repay Hisun for the aggregate amount of these development costs and fees commencing on the successful completion of three registrational batches of ThermoDox®. The batches are expected to be successfully delivered in mid 2013, and repayment of the development costs will occur at any time on or prior to the fourth year anniversary of the signing of the agreement, which in total is expected to be approximately \$2.0 million. 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 us in relation to the regulatory approval activities for ThermoDox® with the China State Food and Drug Administration (SFDA).

On June 27, 2012, we entered into a Loan and Security Agreement (the Credit Agreement) with Oxford Finance LLC (Oxford) and Horizon Technology Finance Corporation (Horizon). The Credit Agreement provides for a secured term loan of up to \$10 million, with 50% of any loans to be funded by Oxford and 50% to be funded by Horizon. The aggregate loan amount may be advanced in two tranches of \$5 million each. The first tranche (the Term A Loan) was made available to us on June 27, 2012 and the second tranche (the Term B Loan) may be made available, if at all, during the period beginning on the date that we achieve positive data in our hepatocellular carcinoma Phase III clinical trial of RFA and ThermoDox® and ending on March 31, 2013. The Term A Loan is scheduled to mature on October 15, 2015 (or, if the Term B Loan is made available, January 1, 2016) and the Term B Loan is scheduled to mature on January 1, 2016. As a fee in connection with the Credit Agreement, we issued warrants to Horizon and Oxford (the Warrants) to purchase the number of shares of Celsion's common stock equal to 3% of each loan amount divided by the exercise price, which is calculated as the average NASDAQ closing price of our common stock for the three days prior to the funding of the loan amount (\$2.92 per share for the Term A Loan). This results in 51,370 warrant shares issuable in connection with the Term A Loan and additional warrant shares issuable in connection with the Term B Loan, if that is made available. The Warrants are immediately exercisable for cash or by net exercise and will expire seven years after their issuance, which is June 27, 2019 for the Warrants issued connection with the Term A Loan.

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

As a result of the uncertainties discussed above, among others, we are unable to estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from



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

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

## FINANCIAL REVIEW FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2012 AND 2011

### Results of Operations

For the three months ended September 30, 2012, our net loss was \$6.0 million, or \$0.18 per basic and diluted share, compared to \$6.4 million, or \$0.25 per basic and diluted share, for the same period of 2011. For the nine months ended September 30, 2012, our net loss was \$18.3 million, or \$0.55 per basic and diluted share, compared to \$17.1 million, or \$0.93 per basic and diluted share, for the same period of 2011. As of September 30, 2012, we had \$22.7 million in cash and short-term investments (including accrued interest from short term investments).

	Three Months Ended September 30,			
	(\$ amounts in 000's)		Change Increase (Decrease)	
	2012	2011	\$	%
<b>Operating Expenses:</b>				
Clinical Research	\$ 2,813	\$ 4,195	\$ (1,382)	(32.9)%
Chemistry, Manufacturing and Controls	727	1,219	(492)	(40.4)%
Research and development	3,540	5,414	(1,874)	(34.6)%
General and administrative	1,420	1,409	11	0.1%
Total operating expenses	\$ 4,960	\$ 6,823	\$ (1,863)	(27.3)%
Loss from operations	\$ (4,960)	\$ (6,823)	\$ (1,863)	(27.3)%

	Nine Months Ended September 30,			
	(\$ amounts in 000's)		Change Increase (Decrease)	
	2012	2011	\$	%
Licensing Revenue:	\$ —	\$ 2,000	\$ (2,000)	(100)%
<b>Operating Expenses:</b>				
Clinical Research	\$ 9,162	\$ 11,759	\$ (2,597)	(22.1)%
Chemistry, Manufacturing and Controls	3,183	2,968	215	7.2%
Research and development	12,345	14,727	(2,382)	(16.2)%
General and administrative	4,586	3,906	680	17.4%
Total operating expenses	\$ 16,931	\$ 18,633	\$ (1,702)	(9.1)%
Loss from operations	\$ (16,931)	\$ (16,633)	\$ (298)	(1.8)%

Comparison of the three months ended September 30, 2012 and 2011

Research and Development Expenses

Research and development (R&D) expenses decreased by \$1.9 million from \$5.4 million in the third quarter of 2011 to \$3.5 million in the same period of 2012. Costs associated with the HEAT Study decreased to \$1.6 million in the third quarter of 2012 compared to \$3.1 million in the same period of 2011 primarily due to reaching the enrollment targets for this pivotal study in the second quarter of 2012. Costs associated with our recurrent chest wall breast cancer clinical trial remained relatively unchanged at \$0.1 million in the third quarter of 2012 compared to the same period of 2011. Costs associated with our colorectal liver metastases trial were insignificant in the third quarter of 2012 compared to \$0.2 million in the same period of 2011. Other costs associated with the clinical department remained relatively unchanged at \$0.4 million in the third quarter of 2012 compared to the same period of 2011. Preclinical costs remained relatively unchanged at \$0.2 million in the third quarter of 2012 compared to the same period of 2011. Costs associated with regulatory activities increased to \$0.4 million in the third quarter of 2012 compared to \$0.1 million the same period of 2011 as the Company is preparing for submission of its New Drug Application (NDA). Costs associated with the production of ThermoDox® decreased to \$0.7 million in the third quarter of 2012 compared to \$1.2 million in the same period of 2011 primarily due to the timing of the production of registration batches and ongoing progress towards developing our commercial manufacturing capabilities for ThermoDox®.

General and Administrative Expenses

General and administrative (G&A) expenses were relatively unchanged at \$1.4 million in the third quarter of 2012 compared the same period of 2011. We continue to carefully monitor operating costs and focus our financial resources on patient follow-up in the HEAT Study.

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. This liability is calculated at its fair market value using the Black-Scholes option-pricing model and is adjusted at the end of each quarter. For the third quarter of 2012, we recorded a non cash loss of \$881,000 based on the change in the fair value of the warrants from the end of the prior quarter compared to recording a non cash gain of \$375,000 in the same period of 2011.

In connection with the Credit Facility entered into during the second quarter of 2012, the Company incurred \$0.2 million in interest expense in the third quarter of 2012.

Comparison of the nine months ended September 30, 2012 and 2011

Licensing Revenue

In the first nine months of 2011, we recognized \$2.0 million in licensing revenue in relation to the amendment of our development, product supply and commercialization agreement for ThermoDox® with Yakult Honsha Co. Concurrent with a convertible preferred stock equity financing in January 2011, we amended the Yakult Agreement to provide for up to \$4.0 million in accelerated partial payments to us on a drug approval milestone. The terms of the Yakult Agreement provided for the payment to us of \$2.0 million upon the closing of the preferred equity financing. The second \$2.0 million was conditioned upon the resumption of enrollment of Japanese patients in the Japan cohort of the HEAT study, which has not been resumed. In consideration of the \$2.0 million accelerated milestone payment from Yakult, we have agreed to reduce future drug approval milestone payments by approximately

twenty percent (20%). All other milestone payments are unaffected. We had no licensing revenue in the first nine months of 2012.

#### Research and Development Expenses

Research and development (R&D) expenses decreased by \$2.4 million from \$14.7 million in the first nine months of 2011 to \$12.3 million in the same period of 2012. Costs associated with the HEAT Study decreased to \$6.0 million in the first nine months of 2012 compared to \$9.2 million in the same period of 2011 primarily due to reaching enrollment targets for this pivotal study in the second quarter of 2012. Costs associated with our recurrent chest wall breast cancer clinical trial remained relatively unchanged at \$0.3 million in the first nine months of 2012 compared to the same period of 2011. Costs associated with our colorectal liver metastases trial remained relatively unchanged at \$0.2 million in the first nine months of 2012 compared to the same period of 2011. Preclinical costs increased to \$0.7 million in the first nine months of 2012 compared to \$0.5 million in the same period of 2011. Costs associated with regulatory activities increased to \$0.7 million in the first nine months of 2012 compared to \$0.3 million the same period of 2011 as the Company is preparing for submission of its New Drug Application (NDA). Costs associated with the production of ThermoDox® increased to \$3.2 million in the first nine months of 2012 compared to \$3.0 million in the same period of 2011 primarily due to the production of registration batches and ongoing progress towards developing our commercial manufacturing capabilities for ThermoDox®.

### General and Administrative Expenses

General and administrative (G&A) expenses increased to \$4.6 million in the first nine months of 2012 compared to \$3.9 million in the same period of 2011. This increase is largely the result of an increase in professional fees related to product pre-commercialization market analysis, business development activities, and personnel costs in the first nine months of 2012 compared to the same period of 2011. We continue to carefully monitor operating costs and focus our financial resources on patient follow-up in the Phase III HEAT Study.

### Other Expense and Income

A warrant liability was incurred as a result of warrants we issued in a public offering in September 2009. This liability is calculated at its fair market value using the Black-Scholes option-pricing model and is adjusted at the end of each quarter. For the first nine months of 2012, we recorded a non cash loss of \$1.3 million based on the change in the fair value of the warrants from the end of the prior quarter compared to recording a non cash loss of \$42,000 in the same period of 2011.

We incurred \$0.2 million in interest expense in the first nine months of 2012, in connection with the credit facility we entered into during the second quarter of 2012. In connection with the shares of preferred stock we issued in a January 2011 preferred stock offering, we incurred dividend expense of approximately \$0.5 million in the first nine months of 2011. All of the outstanding shares of preferred stock mandatorily converted into common stock in August 2011. We did not incur any dividend expense in the first nine months of 2012.

### 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. The process of developing and commercializing ThermoDox® requires significant research and development work and clinical trial studies, as well as significant manufacturing and process development efforts. We expect these activities, together with our general and administrative expenses to result in significant operating losses for the foreseeable future. Our expenses have significantly and regularly exceeded our revenues, and we had an accumulated deficit of \$143 million at September 30, 2012.

As of September 30, 2012, we had total current assets of \$23.8 million (including cash, short term investments and related accrued interest on the short term investments of \$22.7 million) and current liabilities of \$6.6 million, resulting in working capital of \$17.2 million. At December 31, 2011, we had total current assets of \$31.5 million (including cash and short term investments and related accrued interest on the short term investments of \$30.5 million) and current liabilities of \$6.2 million, resulting in working capital of \$25.3 million.

On June 27, 2012, we entered into a Loan and Security Agreement (the Credit Agreement) with Oxford Finance LLC (Oxford) and Horizon Technology Finance Corporation (Horizon). The Credit Agreement provides for a secured term loan of up to \$10 million, with 50% of any loans to be funded by Oxford and 50% to be funded by Horizon. The aggregate loan amount may be advanced in two tranches of \$5 million each. The first tranche (the Term A Loan) was made available to us on June 27, 2012 and the second tranche (the Term B Loan) may be made available, if at all, during the period beginning on the date that we achieve positive data in its hepatocellular carcinoma Phase III clinical trial of RFA and ThermoDox® and ending on March 31, 2013. The Term A Loan is scheduled to mature on October 15, 2015 (or, if the Term B Loan is made available, January 1, 2016) and the Term B Loan is scheduled to mature on

January 1, 2016. We may use the proceeds of the Credit Agreement to fund our working capital and general corporate purposes. The obligations under the Credit Agreement are secured by substantially all of our assets other than our intellectual property and certain other agreed-upon exclusions.

The Term A Loan bears interest at a fixed rate of 11.75%. If it is made available, the Term B Loan will bear interest at a fixed rate equal to the greater of (i) 11.75% or (ii) the sum of (a) the three month U.S. LIBOR rate (but not less than 0.47%) three days prior to the funding of the loan plus (b) 11.28%. Generally, we are required to pay principal and interest in equal monthly installments. However for an initial period extending for the Term A Loan through May 1, 2013 (or, if the Term B Loan is made available, January 1, 2016) and for the Term B Loan through August 1, 2013, we are only required to make interest payments. We are also obligated to pay other customary facility fees for a credit facility of this size and type.

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

During the third quarter of 2012, the Company received gross proceeds of approximately \$4.0 million from the exercise of warrants and options to purchase 1,550,860 shares of common stock. Also summarize warrant and option exercises subsequent to Q3.

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

If adequate funds are not available through either the capital markets, strategic alliances, or collaborators, we may be required to delay, reduce the scope of or eliminate our research, development or clinical programs or our manufacturing or commercialization efforts, 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. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, may have a negative effect on our business, results of operations and financial condition.

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

We have no off-balance sheet financing arrangements other than in connection with our operating leases, which are disclosed in the contractual commitments table in our Form 10-K/A for the year ended December 31, 2011.

#### 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 September 30, 2012, 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 nine months ended September 30, 2012 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/A for the year ended December 31, 2011 and Item 1A of our Quarterly Reports on Forms 10-Q for the quarters ended June 30, 2012 and March 31, 2012. 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/A for the year ended December 31, 2011 and our Quarterly Reports on Forms 10-Q for the quarters ended June 30, 2012 and March 31, 2012, including our consolidated financial statements and related notes, and our other filings made from time to time with the Securities and Exchange Commission.

### RISKS RELATING TO OUR BUSINESS

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

Since Celsion's inception, our expenses have substantially exceeded our revenues, resulting in continuing losses and an accumulated deficit of \$143 million at September 30, 2012. For the nine months ended September 30, 2012, we incurred a net loss of \$18.3 million. Because we presently have no product revenues and we are committed to continuing our product research, development and commercialization programs, we will continue to experience significant operating losses unless and until we complete the development of ThermoDox® and other new products and these products have been clinically tested, approved by the FDA and successfully marketed.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development.

We have a number of drug candidates in research and development ranging from the early discovery research phase through preclinical testing and clinical trials. Preclinical testing and clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. It will take us several years to complete clinical studies. The start or end of a clinical study 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 or our own financial constraints. The failure of one or more of our drug candidates could have a material adverse effect on our business, financial condition and results of operations.

If we do not obtain or maintain FDA and international 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 international 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 international regulatory agencies may require us to perform additional trials beyond those we planned. This process generally takes a number of years and requires the expenditure of substantial resources. The time required for completing testing and obtaining approvals is uncertain, and the FDA and foreign regulatory agencies have substantial discretion, at any phase of development, to terminate clinical studies, require additional clinical development or other testing, delay or withhold registration and marketing approval and mandate product withdrawals, including recalls.

In addition, undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities. Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

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

We have devoted our resources to developing a new generation of products and will not be able to market these products until we have completed clinical testing and obtain all necessary governmental approvals. In addition, our products are still in various stages of development and testing and cannot be marketed until we have completed clinical testing and obtained necessary governmental approval. Accordingly, our revenue sources are, and will remain, extremely limited until and if our products are clinically tested, approved by the FDA and successfully marketed. Currently Yakult Honsha Co. is our only collaboration partner. Under our development, product supply and commercialization agreement with Yakult, which was amended in January 2011, we may receive certain milestone payments as well as royalties on the sale of ThermoDox® in Japan, when and if any such sales occur. In May 2012, we entered into a technology agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. (Hisun), pursuant to which Hisun will manufacture and supply certain quantities of ThermoDox® to us for sale in mainland China, Hong Kong and Macau upon approval of ThermoDox® by the State Food and Drug Administration of the PRC. We cannot guarantee that any of our products will be successfully tested, approved by the FDA or foreign regulatory agencies 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 September 30, 2012, we had approximately \$22.7 million in cash, cash equivalents and short-term investments and related accrued interest on the short term investments. To complete the development and commercialization of our products, we will need to raise substantial amounts of additional capital to fund our operations. We do not have any committed sources of financing and cannot assure you that alternate funding will be available in a timely manner, on acceptable terms or at all. We may need to pursue dilutive equity financings, such as the issuance of shares of common stock, convertible debt or other convertible or exercisable securities. Such dilutive equity financings would dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock. In addition, a financing could result in the issuance of new securities that may have rights, preferences or privileges senior to those of our existing stockholders.

If we cannot raise additional capital, we may be required to delay, reduce or eliminate certain aspects of our operations or attempt to obtain funds through unfavorable arrangements with partners or others that may force us to relinquish rights to certain of our technologies, products or potential markets or that could impose onerous financial or other terms. Furthermore, if we cannot fund our ongoing development and other operating requirements, particularly

those associated with our obligations to conduct clinical trials under our licensing agreements, we will be in breach of these licensing agreements and could therefore lose our license rights, which could have material adverse effects on our business.

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

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

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

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

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

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

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

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

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

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

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

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

Failure to comply with 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 in the future, may do business, or in which our products may be sold, 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 payers 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. healthcare system.

The success of our products may be harmed if the government, private health insurers and other third-party payors 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 payers. 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 payers 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 payers 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.

Our cancer treatment development projects using ThermoDox® plus RFA or microwave heating, are currently in clinical trials. Any or all of these projects 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, with material adverse consequences to our business.

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 estimate 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 payer 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.

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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.

## RISKS RELATED TO OUR COMMON STOCK

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. 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 prospects. Our closing price of our common stock had a high price of \$4.23 and a low price of \$1.69 in the 52-week period ended December 31, 2011 and a high price of \$5.91 and a low price of \$1.64 in the first nine months of 2012. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this “Risk Factors” section and other factors, including:

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

- variance in our financial performance from the expectations of investors;

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

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

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

- conditions and trends in the markets we serve;

- changes in general economic, industry and market conditions;

- success of competitive products and services;

- changes in market valuations or earnings of our competitors;

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

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

- changes in legislation or regulatory policies, practices, or actions;

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

- recruitment or departure of key personnel;

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

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

the trading volume of our common stock.

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

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.

In April 2011 we received notice from The NASDAQ Listing Qualifications Department that we were not in compliance with the minimum Market Value of Listed Securities (MVLS) requirement for continued listing on The NASDAQ Capital Market, as set forth in NASDAQ Listing Rule 5550(b)(2) (the Rule), which requires a listed company to maintain a minimum MVLS of \$35 million. On May 10, 2011, we received a letter from NASDAQ stating that our MVLS had been \$35 million or greater for the previous ten consecutive business days (from April 26, 2011 to May 9, 2011) and that we had regained compliance with the Rule.

We cannot guarantee that our MVLS will remain at or above \$35 million and if our MVLS again drops below \$35 million, the stock could become subject to delisting again. 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.

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.

We have not paid dividends on our common stock in the past and do not intend to do so for the foreseeable future.

We have never 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.

In connection with the first tranche (the Term A Loan) under our Loan and Security Agreement (the Credit Agreement) with Oxford Finance LLC (Oxford) and Horizon Technology Finance Corporation (Horizon), on June 27, 2012, we issued warrants (the Warrants) to Oxford and Horizon. (For more information on the Credit Agreement, please see the disclosure set forth under Part I, Item 2 “Management’s Discussion and Analysis of Financial Condition and Results of Operations -- Financial Condition, Liquidity and Capital Resources”.)

The Warrants were issued in connection with the Credit Agreement, and no separate consideration was paid for the Warrants. The Warrants have not been registered under the Securities Act of 1933, as amended, and were issued pursuant to the exemptions from registration provided by Section 4(2) of the Securities Act of 1933 and/or Regulation D and/or Regulation S promulgated thereunder. The shares issued or issuable thereunder are restricted in accordance with Rule 144 under the Securities Act of 1933.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

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. (Filed herewith)

31.2 Certification of Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (Filed herewith)

32.1\* Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (Furnished herewith)

101\*\* The following materials from the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, 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.

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.

November 9, 2012

CELSION CORPORATION

Registrant

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

By: /s/ Gregory Weaver  
Gregory Weaver  
Senior Vice President and Chief Financial  
Officer