Celsion CORP Form 10-Q November 10, 2009

## UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

## FORM 10-Q

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

For the quarterly period ended September 30, 2009

OR

o 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 (I.R.S. Employer

of

incorporation or Identification No.)

organization)

10220-L Old Columbia 21076

Road

Columbia, Maryland (Address of principal (Zerecutive offices)

(Zip Code)

(410) 290-5390 (Registrant's telephone number, including area code) None

(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 xNo o

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 oNo o

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

Large accelerated filer o

Accelerated filer o

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

Smaller reporting company x

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

As of November 9, 2009 the Registrant had 2,117,967 shares outstanding of Common Stock, \$.01 par value per share.

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## PART I FINANCIAL INFORMATION CELSION CORPORATION BALANCE SHEETS

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Item 1.	Financial Statemen	te
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item 1. Financial Statements.			
		September 30,	December
ASSETS		2009 (Unaudited)	31, 2008
Current assets			
Cash and cash equivalents	\$	12,098,472 \$	3,456,225
Short term investments available for sale		4,204,126	4,061,320
Due from Boston Scientific Corporation		-	15,000,000
Prepaid expenses and other receivables		439,568	305,888
Total current assets		16,742,166	22,823,433
Property and equipment (at cost less accumulated depreciation o	f		
\$837,701 and \$771,624, respectively)		204,674	222,638
3		,	,
Other assets			
Deposits		744,038	362,651
Note receivable (net of allowance and discount of \$1,128,821 at		,	2 32,32 2
December 31, 2008)		_	221,179
Other assets		52,500	58,125
Total other assets		796,538	641,955
Total other assets		770,330	071,755
Total assets	\$	17,743,378 \$	23,688,026
Total assets	Ψ	17,743,576 ψ	23,000,020
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities			
Accounts payable - trade		\$ 2,839,814 \$	1,186,511
Indemnity reserve		φ 2,039,014 φ	
Other accrued liabilities		1 202 757	1,053,357
		1,292,757	1,459,391
Note payable - current portion		4 120 571	234,735
Total current liabilities		4,132,571	3,933,994
W 1 11.		1 550 (7)	
Warrant liability		1,553,676	- 27.642
Other liabilities – noncurrent		18,893	27,643
Total liabilities		5,705,140	3,961,637
0. 11 11 1 2			
Stockholders' equity			
Common stock - \$0.01 par value (75,000,000 and 250,000,000			
shares authorized; 12,874,241 and 10,816,088 shares issued:			
12,113,967 and 10,156,350 shares outstanding at September 30,		100 740	100 161
2009 and December 31, 2008, respectively)		128,742	108,161
Additional paid-in capital		94,775,750	89,183,549
Accumulated deficit			(66,923,972)
Subtotal		15,114,908	22,367,738
Less: Treasury stock, at cost (760,274 and 659,738 shares at			
September 30, 2009 and December 31, 2008, respectively)		(3,076,670)	(2,641,349)

Total stockholders' equity	12,038,238	19,726,389
Total liabilities and stockholders' equity	\$ 17,743,378 \$	23,688,026

See accompanying notes to the financial statements.

## CELSION CORPORATION STATEMENTS OF OPERATIONS (Unaudited)

			Months		e Months
		2009	ptember 30, 2008	2009	eptember 30, 2008
0		2009	2008	2009	2008
Operating expenses:					
Research and		Φ 2.502.064	ф 2.020.051.d	10.675.506	Φ 0.400.140
development		\$ 3,503,064	\$ 3,839,951 \$	5 10,675,506	\$ 8,422,143
General and		1 222 700	<b>7</b> 00 <b>7</b> 04	0.711.071	4.506.000
administrative		1,223,709	509,794	2,514,351	1,586,322
Total operating					
expenses		4,726,773	4,349,745	13,189,857	10,008,465
Loss from operations		(4,726,773)	(4,349,745)	(13,189,857)	(10,008,465)
Other income					
(expense):					
Other income (expense	e)	(100)	(57,287)	322,843	(896,377)
Interest income		9,619	81,419	36,490	185,543
Interest expense		-	(14,457)	(94,920)	(132,778)
Total other income					
(expense), net		9,519	9,675	264,413	(843,612)
Net loss before income					
taxes		(4,717,254)	(4,340,070)	(12,925,444)	(10,852,077)
Income taxes		-	-	-	_
Net Loss	\$	(4,717,254)\$	(4,340,070)\$	(12,925,444)	\$ (10,852,077)
		( ), , , , , ,	( )= = ; = ; = ;	( ) /	( 2)22 )211)
Basic and diluted net					
loss per common share	\$	(0.47)§	(0.43)\$	(1.27)\$	(1.07)
ross per common snare	Ψ	(0.17)4	(σ. 13)φ	(1.27)\$	(1.07)
Basic and diluted					
weighted average share	es.				
outstanding	,,,	10,117,750	10,149,055	10,166,360	10,146,339
outstanding		10,117,750	10,147,033	10,100,300	10,140,337



See accompanying notes to the financial statements.

## CELSION CORPORATION STATEMENTS OF CASH FLOWS (Unaudited)

	Nine Months Ended September 30,	
	2009	2008
Cash flows from operating activities	Φ (12.025.111)	Φ (10.053.077)
Net loss for the period	\$ (12,925,444)	\$ (10,852,077)
Non-cash items included in net loss:		
Depreciation and amortization	66,077	90,038
Loss on disposal of assets	-	523
Accretion of discount on note receivable	-	(21,319)
Amortization of indemnity reserve	(1,053,357)	(1,575,365)
Stock based compensation - options	675,011	612,930
Stock based compensation - restricted		
stock	137,808	66,717
Amortization of patent license fee	5,625	5,625
Shares issued in exchange for services	-	14,720
(Reversal of) provision for bad debts	(214,142)	895,854
Net changes in:		
Accounts receivable-trade	-	156,262
Due from Boston Scientific	15,000,000	15,000,000
Prepaid expenses and other receivables	(133,680)	115,805
Deposits and other assets	(381,387)	(219,134)
Accounts payable	1,653,303	606,711
Income taxes payable	-	(546,000)
Other accrued liabilities	(175,384)	(739,354)
Net cash provided by operating	( 1 - ) - )	(121)22
activities	2,654,430	3,611,936
dell'illes	2,00 1,100	2,011,720
Cash flows from investing activities		
Purchases of short-term investments	(5,422,723)	(11,687,638)
Sales of short-term investments	5,339,749	6,515,226
Advances under Celsion Canada transition services	5,555,715	0,010,220
agreement	_	(7,666)
Purchase of property and equipment	(48,113)	(47,535)
Net cash used in investing activities	(131,087)	(5,227,613)
Net eash used in investing activities	(131,007)	(3,227,013)
Cash flows from financing activities		
Net proceeds from equity offering	6,353,639	_
Extension of warrants	-	400
Payments on note payable	(234,735)	(503,840)
Net cash provided by (used in)	(234,733)	(505,010)
financing activities	6,118,904	(503,440)
inidicing activities	0,110,704	(303,770)

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Net increase (decrease) in cash and		9 642 247	(2.110.117)
cash equivalents		8,642,247	(2,119,117)
Cash and cash equivalents at beginning			
of period		3,456,225	2,937,373
Cash and cash equivalents at end of			
period	\$	12,098,472	\$ 818,256
Cash paid for:			
Interest	\$	94,920	\$ 45,882
Income taxes	\$-		\$ 546,000

See accompanying notes to the financial statements.

# CELSION CORPORATION NOTES TO FINANCIAL STATEMENTS (UNAUDITED) For the Three and Nine Months Ended September 30, 2009 and 2008

#### Note 1. Business Description

Celsion Corporation ("Celsion" or the "Company" or "we") 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, effective, targeted chemotherapeutic oncology drugs based on our proprietary heat-activated liposomal technology. The promise of this drug technology is to maximize efficacy of known therapeutics 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 and a Phase II study for recurrent chest wall breast cancer. ThermoDox® is a liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. Localized mild hyperthermia (39.5-42 degrees Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

Celsion has also demonstrated feasibility for a product pipeline of cancer drugs that employ its 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. Additionally, we have formed a joint research agreement with Royal Phillips Electronics to evaluate the combination of Phillips' high intensity focused ultrasound with Celsion's ThermoDox® to determine the potential of this combination to treat a broad range of cancers.

#### Note 2. Basis of Presentation

The accompanying unaudited financial statements of Celsion have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. 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 months ended September 30, 2009 are not necessarily indicative of the results that may be expected for any other interim period(s) or for any full year. For further information, refer to the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 filed with the Securities and Exchange Commission on March 27, 2009.

Further, in connection with preparation of the condensed consolidated financial statements and in accordance with the FASB Accounting Standards Codification 855, Subsequent Events (ASC 855), the Company evaluated subsequent events after the balance sheet date of September 30, 2009 through November 9, 2009.

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

## Note 3. New Accounting Pronouncements

In May 2009, we adopted authoritative guidance issued by the FASB on subsequent events. The guidance establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. Adoption of the new guidance did not materially impact the Company's financial statements.

On July 1, 2009, the FASB's GAAP Codification became effective as the sole authoritative source of GAAP. This codification was issued under FASB Statement No. 168, "The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles—a replacement of FASB Statement No. 162." This Codification reorganizes current GAAP for non-governmental entities into a topical index to facilitate accounting research and to provide users additional assurance that they have referenced all related literature pertaining to a given topic. Existing GAAP prior to the Codification was not altered in compilation of the GAAP Codification. Statement 168 is effective for all interim and annual periods ending after September 15, 2009.

In October 2009, the FASB issued Accounting Standards Update ("ASU") Number 2009-13, "Revenue Recognition (ASC 605) Multiple-Deliverable Revenue Arrangements a consensus of the FASB Emerging Issues Task Force." This ASU establishes a new selling price hierarchy to use when allocating the sales price of a multiple element arrangement between delivered and undelivered elements. This ASU is generally expected to result in revenue recognition for more delivered elements than under current rules. We are required to adopt this ASU prospectively for new or materially modified agreements as of January 1, 2011. We are evaluating the impact of this ASU, but do not expect adoption to have a material impact on our financial statements.

## Note 4. Common Stock Outstanding and Per Share Information

Basic earnings per share is computed by dividing net income by the weighted average number of common shares outstanding. Diluted earnings per share is computed 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, 2009 and 2008, diluted loss per common share was the same as basic loss per common share as all options, warrants and restricted stock awards that were convertible into shares of the Company's common stock were excluded from calculation of diluted earnings per share as their effect would have been anti-dilutive. The total number of potentially dilutive common shares represented by outstanding warrants, options and restricted stock as of September 30, 2009 and 2008 were 3,142,978 and 2,057,080 respectively.

#### Note 5. Short Term Investments Available For Sale

Short term investments available for sale of \$4,204,126 and \$4,061,320 as of September 30, 2009 and December 31, 2008, respectively, consist of corporate debt securities, government agency debt securities and equity securities. 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. The Company had no such charge to its financial results in the three or nine months ended September 30, 2009.

September	December
30,	31,
2009	2008

Bonds - government agencies	\$ 309,957\$ 1,400,101
Bonds - corporate issuances	3,730,390 2,661,219
Equity securities (see note 9)	163,779 -
Total short-term investments, available for sale	\$ 4,204,126\$ 4,061,320

## Note 6. Fair Values of Financial Instruments

FASB Statement No. 157 establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1: Quoted prices (unadjusted) of identical assets or liabilities traded 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.

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 by 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 company did not have any assets valued using the measuring criteria of Level 2 or Level 3. Assets measured at fair value on a recurring basis are summarized below:

	Quoted
	prices in
	active
	markets for
Total	identical
Short-term	assets
Investments	(Level 1)

Short term investments available for sale at September 30, \$ 4,204,126\$ 4,204,126 2009

Short term investments available for sale at December 31, \$ 4,061,320\$ 4,061,320 2008

A summary of the cost, fair value and maturities of the Company's short term investments is as follows:

	September	30, 2009	December	r 31, 2008
		Fair		Fair
	Cost	Value	Cost	Value
Short term investments				
Bonds - government agencies	\$ 309,957\$	309,957\$	1,400,101\$	1,400,101
Bonds - corporate issuances	3,730,390	3,730,390	2,661,219	2,661,219
Subtotal bonds	4,040,347	4,040,347	4,061,320	4,061,320

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Equity securities (see note 9)	108,373	163,779 -	-
Total investments available for sale\$	4,148,720\$	4,204,126\$ 4,061,320\$	4,061,320
Bond maturities			
Within 3 months \$	1,459,533\$	1,459,533\$ 2,962,978\$	2,962,978
Between 3-12 months	2,165,944	2,165,944 1,098,342	1,098,342
Between 1-2 years	414,870	414,870 -	-
Total investments available for sale\$	4,040,347\$	4,040,347\$ 4,061,320\$	4,061,320

#### Note 7: Prepaid Expenses

Under its ThermoDox® licensing agreement for the Japanese territory with Yakult Honsha ("Yakult") (see Note 13), Yakult is obligated to fund all the development and clinical trial costs necessary to obtain regulatory approval in Japan. Accordingly, Celsion will be reimbursed for Research and Development costs it incurrs in connection with Japanese patients treated in the global Phase III clinical trial. For the quarter ended September 30, 2010, Celsion has recorded a benefit of \$449,651 on the Research and Development expense line of the Statement of Operations and of this amount, Celsion has invoiced and collected \$90,721 from Yakult, with the balance of \$358,830 recorded as a prepaid expense to be invoiced to Yakult.

#### Note 8. Note Receivable

In January, 2006, Celsion contributed to its wholly-owned subsidiary, Celsion (Canada) Limited ("Canada"), all of the Company's assets relating to its Adaptive Phased Array ("APA") microwave technology for the treatment of breast cancer. Also on that date, the Company entered into a Stock Purchase Agreement with the Company's founder and former officer and director, Dr. Augustine Y. Cheung, whereby the Company sold to Dr. Cheung all of the issued and outstanding shares of capital stock of Canada for \$20,000,000 as discussed below. The Company also agreed to provide certain services to Canada pursuant to a Transition Services Agreement between the Company and Canada.

Under the Stock Purchase Agreement, all of the capital stock of Canada was transferred to Dr. Cheung in exchange for a promissory note made by Dr. Cheung in favor of the Company in the principal amount of \$1,500,000 to be paid over a period of up to 78 months and secured by a pledge of 100,536 restricted shares of Celsion common stock owned by Dr. Cheung and his wife and the commitment of Canada, including its successors, to pay a 5% royalty on the net sales of Canada up to \$18,500,000. In November 25, 2008, Medifocus, Inc. ("Medifocus"), a company listed on the Toronto Exchange Company (TSXV-MFS), announced that it completed a transaction with Canada to purchase 100% of the issued and outstanding shares of Canada.

The terms of the note receivable from Dr. Cheung only specify an interest charge in the event that scheduled payments are in arrears. The \$1,500,000 note was therefore discounted at the prime rate in effect January 16, 2006 (7.25%) plus 1.0%, or 8.25%, and the balance, net of discount, of \$1,146,428 was recorded in the financial statements above. Interest income based on this receivable of \$21,320 and \$40,045 was recorded for the three and nine months ended September 30, 2008, respectively. No interest income was recognized during 2009.

The Company previously evaluated the likelihood that the receivable would be fully collected and as a result, an allowance was placed against the note to reduce the balance to the estimated net realizable value of the collateral underlying the note. As of December 31, 2008 and March 31, 2009, the Company reduced the carrying value of the note to \$221,179. In June 2009, the Company's management determined the note was uncollectable, wrote off the balance of \$221,179 and retained the 100,536 restricted shares of Celsion common stock that was pledged as collateral. The 100,536 shares of common stock were valued at \$435,321, or \$4.33 per share, and were transferred to treasury stock at cost. The treasury stock's cost value of \$435,321 exceeded the net carrying value of the \$221,179 note receivable and in June 2009 the Company recorded the difference of \$214,142 as other income.

Note 9. Other Assets

In June 2009, the Company recorded in other assets and other income an amount due of \$108,373 from Medifocus as a result of a March 2006 amendment to the Transition Services Agreement between Celsion Canada and Celsion. The \$108,273 asset value reflected the estimated net realizable value of 903,112 equity units due from Medifocus (each equity unit represents one common share of stock and one warrant to purchase one common share of stock). In the third quarter of 2009, Medifocus delivered 903,112 shares of common stock to Celsion and the value of this investment was reclassified from other assets to short investments. See Footnotes 5 and 6 above.

## Note 10. Equity (including warrants)

On September 30, 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 \$6.4 million. The Company sold 2,018,153 units at a price of \$3.50 per unit. Each unit consisted of one share of common stock and a warrant to purchase 0.5 shares of common stock. 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 Statement of Financial Accounting Standards No. 133 (SFAS No. 133), Accounting for Derivative Instruments and Hedging Activities and Emerging Issues Task Force No. 00-19 (EITF 00-19), Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock, the warrants are recorded as a liability and then marked to market each period through Statement of Operations in other income or expense. As of September 30, 2009, the Company recorded a warrant liability of \$1.6 million based on the fair value offset by a reduction in additional-paid in-capital. 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, 2009 was calculated using the Black-Scholes option-pricing model with the following assumptions:

	September
	30, 2009
Risk-free interest rate	2.75%
Expected volatility	77.4%
Expected life (in years)	3.25
Expected forfeiture rate	0%
Expected dividend yield	0.00%

#### Treasury Stock

In 2007, the Company purchased 659,738 shares of its Common Stock held by Boston Scientific Corporation. The purchase price was \$2.64 million, which was \$4.00 per share. The Treasury Stock was accounted for under the cost method and is shown as a reduction of stockholders' equity. During the second quarter of 2009, the Company retained collateral pursuant to an uncollectible notes receivable (see Note 8) of 100,536 shares of common stock that were transferred to treasury stock at a cost of \$435,321, or \$4.33 per share

Note 11. Stock Based Compensation

**Employee Stock Options** 

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.

#### 2007 Stock Incentive Plan

In 2007, the Company adopted the Celsion Corporation 2007 Stock Incentive Plan (the "2007 Plan") under which 1,000,000 shares was 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.

Prior to the adoption of the 2007 Plan, the Company previously 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 can be rolled into the 2007 Plan. Stock certificates will be issued for any options exercised under these plans.

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 nonqualified 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, 2009	Nine months ended September 30, 2008
Risk-free interest rate	1.21% to 2.17%	2.18 to 3.54%
		77.28% to
Expected volatility	72.3% to 77.2%	79.24%
Expected life (in years)	2.7 to 6.25	5.5 to 6.0
Expected forfeiture rate	0% to 10%	0% to 10%
Expected dividend yield	0.00%	0.00%
Expected volatility Expected life (in years) Expected forfeiture rate	72.3% to 77.2% 2.7 to 6.25 0% to 10%	77.28% to 79.24% 5.5 to 6.0 0% to 10%

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 strips 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 2009 grants was generated using the simplified method as allowed under Securities and Exchange Commission Staff Accounting Bulletin No. 107.

Total compensation cost charged related to employee stock options and restricted stock awards was \$261,089 and \$148,240 for the three months ended September 30, 2009 and 2008, respectively and was \$812,819 and \$694,276 for

the nine months ended September 30, 2009 and 2008, respectively. No compensation cost related to share-based payments arrangements was capitalized as part of the cost of any asset at June 30, 2009 and 2008.

A summary of the Company's Common Stock options and restricted stock awards are follows:

	Stock Options Restricted Awa		rds	Weighted Average	
		Remaining Contractual			
	Weighted			Grant	Terms of
		Average Restricted			Equity
	Options	Exercise		Date Fair	Awards
Equity Awards	Awarded	Price	Awarded	Value	(in years)
Equity awards outstanding at					•
December 31, 2008	1,255,880	\$4.38	89,500	\$2.76	
Equity awards granted	430,000	\$2.88	60,600	\$3.09	
Equity awards issued/exercised	-	-	(15,000)	\$2.88	
Equity awards					
forfeited/cancelled/expired	(63,900)	\$4.77	(5,000)	3.39	
Equity awards outstanding at					
September 30, 2009	1,621,980	\$3.97	130,100	\$2.88	7.4
Aggregate intrinsic value of outstanding awards at					
September 30, 2009	\$812,275		\$456,651		
Equity awards exercisable September 30, 2009	657,064	\$4.74	-	-	7.0
Aggregate intrinsic value of vested awards at September 30, 2009	\$251,350				

Collectively for all the option plans as of September 30, 2009, there were a total of 2,708,624 shares reserved which were comprised of outstanding 1,752,080 equity award granted and 956,544 equity awards still available for future issuance.

As of September 30, 2009, there was \$1.7 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 values of the options granted during the nine months ended September 30, 2009 was \$2.88 and the weighted average grant-date fair values of the restricted stock awards during the nine months ended September, 2009 was \$3.09.

#### Warrants

At September 30, 2009, Celsion had outstanding warrants for the exercise of 1,032,410 shares of common stock. In addition to warrants for the exercise of 1,009,076 common shares that were issued in connection with the September 2009 financing (see Note 10), the Company has warrants outstanding exercisable of for 23,334 shares of the common stock at a weighted average exercise price of \$9.86 with a remaining weighted average life of 0.4 years. At December 31, 2008, warrants exercisable for 96,789 common shares were outstanding of which 73,455 expired during

the nine months ended September 30, 2009. No warrants were issued nor exercised during the nine months ended December 31, 2008. The warrants exercisable for 23,334 shares were originally prior to 2007. The compensation expense associated with these warrants was recognized prior to 2008 and no unrecognized expense existed for the warrants outstanding at September 30, 2009.

## Note 12. Licenses of Intellectual Property and Patents

On November 10, 1999, the Company entered into a license agreement with Duke University under which the Company received worldwide exclusive rights (subject to certain exceptions) to commercialize and use Duke's thermally sensitive liposome technology. The license agreement contains annual royalty and minimum payment provisions due on net sales. The agreement also required milestone-based royalty payments measured by various events, including product development stages, FDA applications and approvals, foreign marketing approvals and achievement of significant sales. However, in lieu of such milestone-based cash payments, Duke agreed to accept shares of the Company's Common Stock to be issued in installments at the time each milestone payment is due, with each installment of shares to be calculated at the average closing price of the Common Stock during the 20 trading days prior to issuance. The total number of shares issuable to Duke under these provisions is subject to adjustment in certain cases, and Duke has piggyback registration rights for public offerings taking place more than one year after the effective date of the license agreement. On January 31, 2003, the Company issued 253,691 shares of Common Stock to Duke University valued at \$2.2 million as payment for milestone based royalties under this license agreement. An amendment to the Duke license agreement contains certain development and regulatory milestones, and other performance requirements that the Company has met with respect to the use of the licensed technologies. The Company will be obligated to make royalty payments based on sales to Duke upon commercialization, until the last of the Duke patents expire. For the three and nine months ended September 30, 2009 and 2008, the Company has not incurred any expense under this agreement and will not incur any future liabilities until commercial sales commence.

Under the Nov. 10, 1999 license agreement with Duke, the Company has rights to the thermally sensitive liposome technology, including Duke's US patents covering the technology as well as all foreign counter parts and related pending applications. Foreign counterpart applications have been issued in Europe, Hong Kong and Australia, have been allowed in Canada and remain pending in Japan. The European patent has been validated in Austria, Belgium, France, Germany, Great Britain, Italy, Luxembourg, Monaco, Spain and Switzerland. In addition, the Duke license agreement provides the Company with rights to multiple issued and pending US patents related to the formulation and use of heat sensitive liposomes. The Company's rights under the license agreement with Duke University extend for the life of the last-to-expire of the licensed patents.

The Company has licensed from Valentis, CA certain global rights covering the use of pegylation for temperature sensitive liposomes.

In addition to the rights available to the Company under completed or pending license agreements, the Company is actively pursing patent protection for technologies developed by the Company. Among these patents is a family of pending US and international patent applications which seek to protect the Company's proprietary method of storing ThermoDox® which is critical for world wide distribution channels.

The Company has received a registered trade mark on ThermoDox® in the United States. In addition, the Company has filed for trademark protection for ThermoDox® in the European Communities, plus over twenty five additional countries world-wide.

Finally, through proprietary information agreements with employees, consultants and others, the Company seeks to protect its own proprietary know-how and trade secrets. The Company cannot offer assurances that these confidentiality agreements will not be breached, that the Company will have adequate remedies for any breach, or that these agreements, even if fully enforced, will be adequate to prevent third-party use of the Company's proprietary technology. Similarly, the Company cannot guarantee that technology rights licensed to it by others will not be successfully challenged or circumvented by third parties, or that the rights granted will provide the Company with adequate protection.

## Note 13. ThermoDox® Licensing Agreement

In December 2008, the Company entered into a licensing agreement with Yakult Honsha ("Yakult") under which Yakult was granted the exclusive right to commercialize and market ThermoDox® for the Japanese market. Celsion was paid a \$2.5 million up-front, non refundable licensing fee which was recorded as licensing revenue in the fourth quarter of 2008. Celsion has the potential to receive an additional \$18 million upon receipt of marketing approval by the Japanese Ministry of Health, Labor and Welfare and additional milestone payments tied to the achievement of certain levels of sales and approval for new indications. If marketing approval is obtained in Japan, Celsion will receive double digit escalating royalties on the sale ThermoDox® in Japan. Celsion also will be the exclusive supplier of ThermoDox® to Yakult.

## Note 14. Note Payable

In July 2007, the Company entered into a Premium Finance Agreement with Flatiron Capital Corporation ("Flatiron") whereby Flatiron funded certain insurance premiums in the amount of \$1,313,250 on behalf of the Company. In exchange, the Company was required to make 21 installment payments of approximately \$59,000 beginning in August 2007. Interest accrues at a rate of 5.98% on outstanding balances. As of June 30, 2009, the outstanding balance was paid off.

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 Company's expectations as to the development and effectiveness of its 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 this Quarterly Report on Form 10-Q and the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 including, 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 such forward-looking statements, including those set forth in Part II, "Item 1A. Risk Factors" of this Quarterly Report on Form 10-Q and Part I,"Item 1A. Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

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

#### Overview

Celsion Corporation ("Celsion" or the "Company" or "we") 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, effective, targeted chemotherapeutic oncology drugs based on our proprietary heat-activated liposomal technology. The promise of this drug technology is to maximize efficacy of known therapeutics 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 and a Phase II study for recurrent chest wall breast cancer. ThermoDox is a liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. Localized mild hyperthermia (39.5-42 degrees Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

Celsion has also demonstrated feasibility for a product pipeline of cancer drugs that employ its 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. Additionally, we have formed a joint research agreement with Royal Phillips Electronics to evaluate the combination of Phillips' high intensity focused ultrasound with Celsion's ThermoDox® to determine the potential of this combination to treat a broad range of cancers.

## **Results of Operations**

Comparison of Three and Nine Months Ended September 30, 2009 and 2008.

	Three Months Ended September 30,						
	(\$ amounts in 000's)			Increase (Decrease)			
	2009		2008	\$	%		
Operating expenses:							
Research and development	\$ 3,503	\$	3,840\$	(337)	(9)%		
General and administrative	1,224		510	714	140%		
Total operating expenses	4,727	\$	4,350	377	9%		
Loss from operations	\$ (4,727)	\$	(4,350)\$	(377)	(9)%		
	Nine Months Ended September 30, (\$ amounts in 000's) Increase (Decrease)						
	2009		2008	\$	%		
Operating expenses:							
D 1 1 1 1 .							
Research and development	\$ 10,676	\$	8,422\$	2,254	27%		
General and administrative	\$ 10,676 2,514	\$	8,422\$ 1,586	2,254 928	27% 59%		
*	\$ 	\$		•			
General and administrative	\$ 2,514	·	1,586	928	59%		

Comparison of the three months ended September 30, 2009 and 2008

## Research and Development Expenses

Research and development expenses decreased by \$0.3 million to \$3.5 million for the three months ended September 30, 2009 from \$3.8 million for the three months ended September 30, 2009. For the quarter ended September 30, 2009, costs for the primary liver cancer clinical trial decreased by \$0.3 million as compared to the same period in 2008. Clinical trial costs for the recurrent chest wall breast cancer study increased by \$0.2 million for the third quarter of 2009 as compared to the same period in 2008 as a result of the start up of this study during 2009. Manufacturing costs for the production of ThermoDox for clinical trials decreased by \$0.2 million in the third quarter of 2009 compared to the same period of 2008.

#### General and Administrative Expenses

General and administrative expenses increased by \$0.7 million to \$1.2 million for the third quarter of 2009 from \$0.5 million in the same period of 2008. The \$0.7 million increase is primarily the result of a \$0.5 million non-cash benefit recorded in the third quarter of 2008 for a reduction in an indemnity reserve that was established when the Prolieve medical device assets were sold to Boston Scientific in 2007. The indemnity reserve was fully amortized as of June 30, 2009 upon receipt of the final \$15 million payment from Boston Scientific, therefore, for the third quarter of 2009, there was no similar non-cash expense benefit recorded. During the third quarter of 2008, \$0.5 million of the indemnity reserve was amortized.

Other Income, Expense, Net

Other income was insignificant in the third quarter 2009 compared to other expense of \$0.1 million in the same period of 2008. In 2008, the Company wrote down the carrying value of a note receivable.

Interest Income

Interest income was insignificant in the third quarter 2009 compared to interest income of \$0.1 million in the same period of 2008. The decrease is attributable to lower interest rates.

Interest Expense

Interest expense was insignificant in the third quarters of 2009 and 2008.

Comparison of the nine months ended September 30, 2009 and 2008

Research and Development Expenses

Research and development expenses increased by \$2.3 million to \$10.7 million for the first nine months of 2009 from \$8.4 million for the same period of 2008. Clinical trial costs for the primary liver cancer study increased by \$1.1 million for the first nine months of 2009 compared to the same period of 2008 due to start up costs for opening additional clinical trial sites, costs for treating patients and costs associated with the transition to a new contract research organization. Clinical trial costs for the recurrent chest wall breast cancer study increased by \$0.8 million for the first nine months of 2009, compared to the same period of 2008 due to the start up of the clinical trial in 2009. Manufacturing costs to produce ThermoDox for clinical trials increased by \$0.5 million for the first nine months of 2009, compared to same period in 2008, due a higher production volume of ThermoDox to meet the needs of the clinical trials.

General and Administrative Expenses

General and administrative expenses increased by \$0.9 million to \$2.5 million for the first nine months of 2009 from \$1.6 million for the same period of 2008. For the first nine months of 2009, costs increased by \$0.5 million due to a reduction in a non-cash benefit from the amortization of the indemnity reserve, which was fully amortized as of June 30, 2009. For the nine months ended September 30, 2009, \$1.1 million of the indemnity reserve was amortized as compared to \$1.6 million for the same period of 2008. Other factors increasing cost include an increase in non-cash stock compensation of \$0.1 million, an increase in consulting expenses of \$0.1 million and an increase in legal expenses of \$0.1 million.

Other Income, Expense, Net

Other income was \$0.3 million for the nine months ended September 30, 2009, compared to other expense of \$0.9 million for the same period of 2008. In 2008, the Company wrote down the carrying value of a note receivable by

\$0.9 million. In the second quarter of 2009, the Company wrote off the note receivable and retained the collateral for this note. At the time of the retention of the collateral, its value increased by \$0.2 million which was recorded in other income.

## Interest Income

Interest income decreased by \$149,000 from \$185,000 in the first nine months of 2008 to \$36,000 in the same period of 2009. The decrease is attributable to lower interest rates.

## Interest Expense

Interest expense remained relatively unchanged at \$0.1 million during the first nine months of 2009 compared to the same period of 2008.

## Financial Condition, Liquidity and Capital Resources

Since inception, excluding the net aggregate payments from Boston Scientific of \$43 million (\$13 million received in June 2007 and \$15 million received in each of 2008 and 2009), we have incurred negative cash flows from operations. We have financed our operations primarily through the sale of equity and through the divestiture of the medical device business. On September 30, 2009, the Company closed a registered direct offering raising gross proceeds of approximately \$7.1 million realizing net proceeds of \$6.4 million. Our expenses have significantly and regularly exceeded our revenues, and we have an accumulated deficit of \$79.8 million at September 30, 2009.

At September 30, 2009 we had total current assets of \$16.7 million (including cash and short term investments of \$16.3 million) and current liabilities of \$4.1 million, resulting in a working capital surplus of \$12.6 million. At December 31, 2008, we had total current assets of \$22.8 million (including cash and short term investments of \$7.5 million) and current liabilities of \$3.9 million, resulting in a working capital surplus of \$18.9 million.

Net cash provided by operating activities for the nine months ended September 30, 2009 was \$2.7 million. The \$2.7 million in net cash from operations was mainly the result of the Company collecting \$14.9 million from Boston Scientific and a \$1.6 million increase in accounts payable. These items offset the net loss from operations of \$13.1 million the Company incurred for the first nine months of 2009. Net cash provided by financing activities was \$6.2 million for the nine months ended September 30, 2009 which represents net proceeds of \$6.4 million from the September 30, 2009 sale of stock and warrants partially offset by \$0.2 million payments made on notes payable.

At September 30, 2009, the Company had cash, cash equivalents and short term investments of \$16.3 million. The \$16.3 million of cash resources is expected to be adequate to fund operations through the end of 2010. The Company will need substantial additional capital to complete its clinical trials, obtain marketing approvals and to commercialize its products.

Item 3. Quantitative and Qualitative Disclosure about Market Risk.

Not required.

#### 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 concluded that as of September 30, 2009, which is the end of the period covered by this report, our disclosure controls and procedures are effectiv