

Celsion CORP  
Form 10-Q  
May 12, 2009  
Table of Contents

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

**FORM 10-Q**

**x**

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

**For the quarterly period ended March 31, 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**

(State or other jurisdiction of  
incorporation or organization)

**10220-L Old Columbia Road  
Columbia, Maryland**

(Address of principal executive offices)

**52-1256615**

(I.R.S. Employer  
Identification No.)

**21076**

(Zip Code)

Edgar Filing: Celsion CORP - Form 10-Q

(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  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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

As of May 11, 2009 the Registrant had 10,847,297 shares outstanding of Common Stock, \$.01 par value per share.

Table of Contents

**TABLE OF CONTENTS**

		<b>Page(s)</b>
<b><u>PART I: FINANCIAL INFORMATION</u></b>		
<b><u>Item 1.</u></b>	<b><u>Financial Statements and Notes (Unaudited)</u></b>	<b>3 - 12</b>
	<u>Balance Sheets</u>	3
	<u>Statements of Operations</u>	4
	<u>Statements of Cash Flows</u>	5
	<u>Notes to Financial Statements</u>	6 - 12
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	15
<u>Item 4T.</u>	<u>Controls and Procedures</u>	15
<b><u>PART II: OTHER INFORMATION</u></b>		
<u>Item 1.</u>	<u>Legal Proceedings</u>	16
<u>Item 1A.</u>	<u>Risk Factors</u>	16 - 21
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	21
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	21
<u>Item 4.</u>	<u>Submission of Matters to a vote of Security Holders</u>	21
<u>Item 5.</u>	<u>Other Information</u>	21
<u>Item 6.</u>	<u>Exhibits</u>	21
	<u>SIGNATURES</u>	22

Table of Contents

**PART I**

**FINANCIAL INFORMATION**

**CELSION CORPORATION**

**BALANCE SHEETS**

**Item 1. Financial Statements.**

	March 31, 2009 (unaudited)	December 31, 2008
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 1,920,079	\$ 3,456,225
Short term investments available for sale	2,346,304	4,061,320
Due from Boston Scientific Corporation	15,000,000	15,000,000
Prepaid expenses and other receivables	161,156	305,888
Total current assets	19,427,539	22,823,433
Property and equipment (at cost less accumulated depreciation of \$793,651 and \$771,624 respectively)	206,952	222,638
<b>Other assets</b>		
Note receivable (net of allowance and discount of \$1,128,820)	221,179	221,179
Deposits and other assets	346,632	362,651
Patent licensing fees (net of accumulated amortization of \$16,875 and \$15,000, respectively)	56,250	58,125
Total other assets	624,061	641,955
<b>Total assets</b>	<b>\$ 20,258,552</b>	<b>\$ 23,688,026</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable - trade	\$ 1,861,536	\$ 1,186,511
Indemnity reserve	526,679	1,053,357
Other accrued liabilities	1,375,613	1,459,391
Note payable - current portion	59,117	234,735
Total current liabilities	3,822,945	3,933,994
Other liabilities - noncurrent	26,671	27,643
Total liabilities	3,849,616	3,961,637
<b>Stockholders equity</b>		
Common stock - \$0.01 par value (250,000,000 shares authorized; 10,856,088 and 10,816,088 shares outstanding at March 31, 2009 and December 31, 2008, respectively)	108,161	108,161
Additional paid-in capital	89,482,863	89,183,549
Accumulated deficit	(70,540,739)	(66,923,972)
Subtotal	19,050,285	22,367,738
Less: Treasury stock - at cost	(2,641,349)	(2,641,349)
Total stockholders equity	16,408,936	19,726,389

<b>Total liabilities and stockholders equity</b>	\$	20,258,552	\$	23,688,026
--	----	------------	----	------------

See accompanying notes to the financial statements.

Table of Contents

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

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Operating expenses:</b>		
Research and development	\$ 2,942,727	\$ 2,967,111
General and administrative	688,209	1,175,977
Total operating expenses	3,630,936	4,143,088
<b>Loss from operations</b>	<b>(3,630,936)</b>	<b>(4,143,088)</b>
<b>Other income (expense):</b>		
Other (expense) income	(7)	94
Interest income	20,998	75,510
Interest expense	(6,822)	(14,358)
Total other income (expense), net	14,169	61,246
<b>Net loss before income taxes</b>	<b>(3,616,767)</b>	<b>(4,081,842)</b>
Income taxes		
<b>Net Loss</b>	<b>\$ (3,616,767)</b>	<b>\$ (4,081,842)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.35)</b>	<b>\$ (0.40)</b>
<b>Basic and diluted weighted average shares outstanding</b>	<b>10,190,489</b>	<b>10,143,442</b>

See accompanying notes to the financial statements.

Table of Contents

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

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Cash flows from operating activities</b>		
Net loss for the period	\$ (3,616,767)	\$ (4,081,842)
Non-cash items included in net loss:		
Depreciation and amortization	22,027	31,818
Accretion of discount on note receivable		(21,319)
Amortization of indemnity reserve	(526,678)	(526,678)
Stock based compensation - Options	226,471	251,679
Stock based compensation - Restricted Stock	72,843	39,514
Amortization of deferred license fee	1,875	1,875
Shares issued in exchange for services		50
Provision for bad debts		680,360
Net changes in:		
Accounts receivable-trade		13,322
Prepaid expenses and other receivables	144,732	9,710
Deposits and other assets	16,019	(103,989)
Accounts payable	675,025	658,673
Income taxes payable		(546,000)
Other accrued liabilities	(84,750)	(618,664)
<b>Net cash used in operating activities</b>	<b>(3,069,203)</b>	<b>(4,211,491)</b>
<b>Cash flows from investing activities</b>		
Purchases of short-term investments	(1,253,290)	
Sale of short-term investments	2,968,306	3,000,000
Advances under Celsion Canada transition services agreement		(9,377)
Purchase of property and equipment	(6,341)	(7,932)
<b>Net cash provided by investing activities</b>	<b>1,708,675</b>	<b>2,982,691</b>
<b>Cash flows from financing activities</b>		
Payments on note payable	(175,618)	(165,448)
<b>Net cash used by financing activities</b>	<b>(175,618)</b>	<b>(165,448)</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(1,536,146)</b>	<b>(1,394,248)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>3,456,225</b>	<b>2,937,373</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 1,920,079</b>	<b>\$ 1,543,125</b>
<b>Cash paid for:</b>		
Interest	\$ 6,882	\$ 12,807
Income taxes	\$	\$ 546,000

See accompanying notes to the financial statements.





**Table of Contents**

**CELSION CORPORATION**

**NOTES TO FINANCIAL STATEMENTS (UNAUDITED)**

**For the Three Months Ended March 31, 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 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 8 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 month period ended March 31, 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.

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

**Note 3. New Accounting Pronouncements**

In June 2008, the Financial Accounting Standards Board ( FASB ) ratified Emerging Issue Task Force (EITF) Issue No. 07-5, *Determining Whether an Instrument (or an Embedded Feature) is Indexed to an Entity's Own Stock* (EITF 07-5). This issue provides guidance for determining whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock. EITF 07-5 applies to any freestanding financial instrument or embedded feature that has all the characteristics of a derivative under paragraphs 6-9 of Statement of Financial Accounting Standards No. 133, *Accounting for Derivative Instruments and Hedging Activities*, (SFAS 133) for purposes of determining whether that instrument or embedded feature qualifies for the first part of the scope exception under paragraph 11(a) of SFAS 133. EITF 07-5 also applies to any freestanding financial instrument that is potentially settled in an entity's own stock, regardless of whether the instrument has all the characteristics of a derivative under paragraphs 6-9 of SFAS 133, for purposes of determining whether the instrument is within the scope of EITF Issue 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, (Issue 00-19) which provides accounting guidance for instruments that are indexed to, and potentially settled in, the issuer's own stock. EITF 07-5 is effective for fiscal years beginning after December 15, 2008. We have concluded that application of EITF 07-5 does not have a material impact on the Company's financial statements.

Table of Contents

In May 2008, FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS 162). SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements. SFAS No. 162 was effective November 15, 2008. The adoption of SFAS 162 did not have a material impact on our financial position, results of operations or cash flows.

In May 2008, the FASB issued FASB Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). Under the new rules for convertible debt instruments that may be settled entirely or partially in cash upon conversion, an entity should separately account for the liability and equity components of the instrument in a manner that reflects the issuer's economic interest cost. Previous guidance provided for accounting of this type of convertible debt instruments entirely as debt. For instruments subject to the scope of FSP APB 14-1, higher interest expense may result through the accretion of the discounted carrying value of the convertible debt instruments to their face amount over their term. FSP APB 14-1 will be effective for fiscal years beginning after December 15, 2008, and for interim periods within those fiscal years, with retrospective application required. Early adoption is not permitted. As of the date of these financial statements, we do not have any instruments outstanding that would be subject to FSP APB 14-1, but any instruments that we may issue in the future will be subject to this pronouncement.

**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 months ended March 31, 2009 and 2008, 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 calculation of diluted earnings per share as their effect would have been anti-dilutive. The total number of outstanding warrants and options for the periods ended March 31, 2009 and 2008 were 1,796,785 and 2,402,302, respectively.

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

Short term investments available for sale of \$2,346,304 and \$4,061,320 as of March 31, 2009 and December 31, 2008, respectively, consist of commercial paper, corporate debt securities, and government agency debt 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.

	March 31, 2009	December 31, 2008
Short term investments - at fair value		

Edgar Filing: Celsion CORP - Form 10-Q

Bonds - government agencies	\$	749,072	\$	1,400,101
Bonds - corporate issuances		1,597,232		2,661,219
Total short-term investments, available for sale	\$	2,346,304	\$	4,061,320

Table of Contents**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) 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.

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 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:

	<b>Total Short-term Investments</b>	<b>Quoted prices in active markets for identical assets (Level 1)</b>
Short term investments available for sale at March 31, 2009	\$ 2,346,304	\$ 2,346,304
Short term investments available for sale at December 31, 2008	\$ 4,061,320	\$ 4,061,320

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

	<b>March 31, 2009</b>		<b>December 31, 2008</b>	
	<b>Cost</b>	<b>Fair Value</b>	<b>Cost</b>	<b>Fair Value</b>
<b>Short term investments</b>				
Bonds - government agencies	\$ 749,072	\$ 749,072	\$ 2,661,219	\$ 2,661,219
Bonds - corporate issuances	1,597,232	1,597,232	1,400,101	1,400,101

Edgar Filing: Celsion CORP - Form 10-Q

<b>Total investments available for sale</b>	\$	2,346,304	\$	2,346,304	\$	4,061,320	\$	4,061,320
<b>Maturities</b>								
Within 3 months	\$	899,667	\$	899,667	\$	2,962,978	\$	2,962,978
Between 3-12 months		1,446,637		1,446,637		1,098,342		1,098,342
Between 1-2 years								
<b>Total investments available for sale</b>	\$	2,346,304	\$	2,346,304	\$	4,061,320	\$	4,061,320

8

---

Table of Contents

**Note 7. Note Receivable**

On January 16, 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 ) 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. 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 shares of Celsion common stock owned by Dr. Cheung and his wife and the commitment of Canada to pay a 5% royalty on the net sales of certain products sold by, and patent royalties received by, Canada and its successors and assigns, of up to \$18,500,000.

The terms of the note receivable 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 was recorded for the three months ended March 31, 2008. No interest income was recognized during the three months ended March 31, 2009.

The Company 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 noted above, 100,536 shares of Celsion common stock are pledged as collateral to the note. As of December 31, 2008, the Company reduced the carrying value of the note to \$221,179 based on a closing price at that date of \$2.20. The closing price of Celsion's common stock on March 31, 2009 was \$3.60, which results in a total collateral value of approximately \$362,000, however, the Celsion's Management has decided not to increase the carrying value of the collateral as of that date.

**Note 8. Stock Based Compensation**

Treasury Stock

In 2007, the Company purchased 659,738 shares of its Common Stock that was held by Boston Scientific Corporation. The purchase price was \$2.64 million, which is \$4.00 per share. The Treasury Stock was accounted for under the cost method and is shown as a reduction of stockholders' equity.

Employee Stock Options

## Edgar Filing: Celsion CORP - Form 10-Q

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 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.

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.



Table of Contents

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:

	Three months ended March 31, 2009	Three months ended March 31, 2008
Risk-free interest rate	1.83%	2.18% to 2.81%
Expected volatility	73%	282% to 283%
Expected life (in years)	6	6
Expected forfeiture rate	10%	10%
Expected dividend yield	0.00%	0.00%

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 amounted to \$299,314 and \$291,193 for the three months ended March 31, 2009 and 2008, respectively. No compensation cost related to share-based payments arrangements was capitalized as part of the cost of any asset at March 31, 2009 and 2008.

As of March 31, 2009, there was \$2.0 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 2.4 years. The weighted average grant-date fair values of the options granted during the three months ended March 31, 2009 was \$1.75 and the weighted average grant-date fair values of the restricted stock awards during the three months ended March 31, 2009 was \$2.88.

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

	Stock Options		Restricted Stock Awards		Weighted Average Contractual Terms of Equity Awards (in years)
	Options Awarded	Weighted Average Exercise Price	Restricted Stock Awarded	Weighted Average Exercise Price	
Equity Awards					
Equity awards outstanding at December 31, 2008	1,255,880	\$ 4.38	61,871	\$ 2.40	
Equity awards granted	350,000	\$ 2.72	45,000	\$ 2.88	

Edgar Filing: Celsion CORP - Form 10-Q

Equity awards issued/exercised				(40,000)	\$	2.69	
Equity awards forfeited/cancelled/expired	(5,000)	\$	4.05				
Equity awards outstanding at March 31, 2009	1,600,880	\$	4.02	66,871	\$	2.55	7.5
Aggregate intrinsic value of outstanding awards at March 31, 2009	\$	2,275,784		\$	170,521		
Equity awards exercisable at March 31, 2009	645,214	\$	4.71	66,871	\$	2.55	6.4
Aggregate intrinsic value of vested awards at March 31, 2009	\$	1,361,848		\$	170,521		

Table of Contents

Collectively for all the option plans as of March 31, 2009, there were a total of 2,658,495 shares reserved which were comprised of outstanding 1,667,751 equity award granted and 990,744 equity awards still available for future issuance.

Warrants

Celsion has warrants outstanding at March 31, 2009 enabling the holders thereof to purchase up to 23,334 shares of the Company's Common Stock at a weighted average exercise price of \$9.86 and a weighted average remaining life of 0.9 years. At December 31, 2008, 96,789 warrants were outstanding of which 73,455 expired in the three months ended March 31, 2009. No warrants were issued nor exercised during this same period. The warrants were originally issued in exchange for consulting and financing services provided prior to 2007, including prior private placements of equity securities. Any compensation or other expense associated with these warrants was recognized prior to 2008 and no unrecognized expense existed at March 31, 2009 related to the warrants outstanding.

**Note 9. Licensing Agreements**

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 has the potential to receive 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.

On November 10, 1999, the Company entered into a license agreement with Duke University under which the Company received exclusive rights (subject to certain exceptions) to commercialize and use Duke's thermo-liposome technology. The license agreement contains annual royalty and minimum payment provisions and also requires 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 under this licensing agreement.

With regard to Liposome patents licensed from Duke University, the Company has filed two additional patents related to the formulation and use of liposomes. Further, in relation to the patents licensed from Duke, the Company has licensed from Valentis, CA certain global rights covering the use of pegylation for temperature sensitive liposomes.

The Duke license agreement contains a license fee, royalty and/or research support provisions, testing and regulatory milestones, and other performance requirements that the Company must meet by certain deadlines with respect to the use of the licensed technologies. In conjunction

## Edgar Filing: Celsion CORP - Form 10-Q

with the patent holders, the Company intends to file international applications for certain of the United States patents. For the year ended December 31, 2008, and thus far in 2009, the Company has not incurred any expense under this agreement but upon commercialization will be obligated to make royalty payments until the Duke patents expire.

The Company's rights under our license agreement with Duke University extend for the longer of 20 years or the term for which any relevant patents are issued by the United States Patent and Trademark Office. Currently, the Company has rights to Duke's patent for its thermo-liposome technology in the United States, which expire in 2018, and to future patents received by Duke in Canada, Europe, Japan and Australia, where it has patent applications pending. The European application can result in coverage in the United Kingdom, France and Germany. For this technology, license rights are worldwide, with various patent rights covering the United States, Canada, the United Kingdom, France, Germany and Japan.

Table of Contents

**Note 10. 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 March 31, 2009, the outstanding balance owed was \$59,117 and is expected to be paid in the second quarter of 2009.

Table of Contents

**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 the 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 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 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 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.

## Edgar Filing: Celsion CORP - Form 10-Q

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.

Table of Contents

**Results of Operations**





## Edgar Filing: Celsion CORP - Form 10-Q

*Comparison of Three Months Ended March 31, 2009 and 2008.*

	Three Months Ended March 31, (\$ amounts in 000 s)		\$	Change	
	2009	2008			%
<b>Operating expenses:</b>					
Research and development	\$ 2,943	\$ 2,967	\$ (24)		(0.8)%
General and administrative	688	1,176	(488)		(41.5)%
Total operating expenses	\$ 3,631	\$ 4,143	\$ (512)		(12.4)%
<b>Loss from operations</b>	\$ (3,631)	\$ (4,143)	\$ (512)		(12.4)%

### *Comparison of the three months ended March 31, 2009 and 2008*

#### *Research and Development Expenses*

Research and development expenses ( R&D ) decreased by \$24 thousand from \$2.967 million in the first quarter of 2008 to \$2.943 million in the same period of 2009. Costs associated with the recurrent chest wall breast cancer clinical trials increased, including the employee headcount associated with R&D. This increase was offset by a decrease in the costs of liver cancer clinical trials.

#### *General and Administrative Expenses*

General and administrative expenses ( G&A ) decreased by \$488 thousand, from \$1.176 million in the first quarter of 2008 to \$688 thousand in the same period of 2009. In the first quarter of 2008, the Company recognized a write-down of a note receivable of \$680 thousand. This decrease is partially offset by an increase in business development costs of approximately \$124 thousand and an increase in G&A salaries.

#### *Interest income*

Interest income decreased by \$55 thousand from \$76 thousand in the first quarter of 2008 to \$21 thousand in the same period of 2009. The decrease is attributable to lower interest rates.

#### *Interest expense*

Interest expense was insignificant at \$7 thousand in the first quarter of 2009 compared to \$14 thousand in the same period of 2008.

**Financial Condition, Liquidity and Capital Resources**

Since inception, excluding the \$15 million payments from Boston Scientific received in 2008 and to be received in June 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. Our expenses have significantly and regularly exceeded our revenues, and we have an accumulated deficit of \$70.5 million at March 31, 2009.

At March 31, 2009 we had total current assets of \$19.4 million (including cash and short term investments of \$4.3 million) and current liabilities of \$3.8 million, resulting in a working capital surplus of \$15.6 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.

Table of Contents

Net cash used in operating activities for the quarter ended March 31, 2009 was \$3.1 million. The \$3.1 million net cash requirement was funded from cash on hand and the \$7.3 million short term investments held at the beginning of the year. Net cash used in financing activities was \$176 thousand for the quarter ended March 31, 2009 which represents the payments made on notes payable.

At March 31, 2009, the Company had cash, cash equivalents and short term investments of \$4.3 million and \$15 million due from Boston Scientific in June 2009. The \$19.3 million of cash resources is expected to be adequate to fund operations to mid 2010. The Company will need substantial additional capital to complete its clinical trials, obtain marketing approvals and to commercialize the products.

**Item 3. Quantitative and Qualitative Disclosure about Market Risk.**

Not required.

**Item 4T. 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 March 31, 2009, which is the end of the period covered by this report, our disclosure controls and procedures are effective.

There has been no change in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Securities Exchange Act of 1934, as amended that occurred during the three months ended March 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

**PART II**

**OTHER INFORMATION**

**Item 1. Legal Proceedings**

None.

**Item 1A. Risk Factors.**

The following is a summary of the risk factors 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. 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. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events, or otherwise. You are advised, however, to consult any further disclosure we make on related subjects in our reports on forms 10-Q and 8-K filed with the SEC.

**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 \$70.5 million at March 31, 2009. For the quarter ended March 31, 2009, we incurred a loss from continuing operations of \$3.6 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.

**WE DO NOT EXPECT TO GENERATE SIGNIFICANT REVENUE FOR THE FORESEEABLE FUTURE.**

We have devoted our resources to developing a new generation of products but 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 our products are clinically tested, approved by the FDA and successfully marketed. We cannot guarantee that any or all of our products will be successfully tested, approved by the FDA or marketed, successfully or otherwise, at any time in the foreseeable future or at all.

**IF WE DO NOT COLLECT THE RECEIVABLES FROM BOSTON SCIENTIFIC CORPORATION, WE MAY NOT BE ABLE TO COMPLETE THE DEVELOPMENT, TESTING AND COMMERCIALIZATION OF OUR TREATMENT SYSTEMS.**

As of March 31, 2009, we had approximately \$4.3 million in cash, cash equivalents, and short term investments. We also had \$15.0 million in receivables due to us from Boston Scientific in June 2009. Should Boston Scientific default on its obligations, we would need substantial additional funding in order to complete the development, testing and commercialization of our liver cancer and recurrent chest wall breast cancer treatment systems, as well as other potential new products. Other than the \$15.0 million due from Boston Scientific, we do not have any committed sources of financing and cannot offer any assurances that alternate funding will be available in a timely manner, on acceptable terms or at all.

In the event of a default by Boston Scientific and alternate, adequate funding is not available, we may be required to delay, scale back 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.

Table of Contents

**WE HAVE NO INTERNAL SALES OR MARKETING CAPABILITY AND MUST ENTER INTO ALLIANCES WITH OTHERS POSSESSING SUCH CAPABILITIES TO COMMERCIALIZE OUR PRODUCTS SUCCESSFULLY.**

We intend to market our products, if and when such products are approved for commercialization by the FDA, either directly or through other strategic alliances and distribution arrangements with third parties. There can be no assurance that we will be able to enter into third-party marketing or distribution arrangements on advantageous 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. There can be no assurance that, to the extent that we sell products directly or we enter into any commercialization arrangements with third parties, 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 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. If we were to breach these or other provisions of the license and research agreements, we could 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 are aware of published patent applications and issued patents belonging to others, and it is not clear whether any of these patents or applications, or other patent applications of which we may not have any knowledge, will require us to alter any of our potential products or processes, pay licensing fees to others or cease certain activities. 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 also 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 guarantee that these agreements will not be breached, that, even if not breached, that they are adequate to protect our trade secrets, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known to, or will not be discovered independently by, competitors.

**WE RELY ON THIRD PARTIES TO CONDUCT ALL OF OUR CLINICAL TRIALS. IF THESE THIRD PARTIES DO NOT SUCCESSFULLY CARRY OUT THEIR CONTRACTUAL DUTIES, COMPLY WITH BUDGETS AND OTHER FINANCIAL OBLIGATIONS OR MEET EXPECTED DEADLINES, WE MAY NOT BE ABLE TO OBTAIN REGULATORY APPROVAL FOR OR COMMERCIALIZE OUR PRODUCT CANDIDATES IN A TIMELY OR COST-EFFECTIVE MANNER.**

We currently have 19 full-time employees. We rely, and expect to continue to rely, on third-party Clinical Research Organizations to conduct all of 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 anticipate significantly increasing our personnel in the foreseeable future and therefore, expect to continue to rely on third parties to conduct all

of our future clinical trials. If these third parties do not successfully carry out their contractual duties or obligations 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 prohibitively expensive, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.



Table of Contents

**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, all are 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 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.

Table of Contents

**LEGISLATIVE AND REGULATORY CHANGES AFFECTING THE HEALTH CARE INDUSTRY COULD ADVERSELY AFFECT OUR BUSINESS.**

There have been a number of federal and state proposals during the last few years to subject the pricing of health care goods and services to government control and to make other changes to the United States health care system. It is uncertain which legislative proposals, if any, will be adopted (or when) or what actions federal, state, or private payors for health care treatment and services may take in response to any health care reform proposals or legislation. We cannot predict the effect health care 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.

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

**OUR PRODUCTS MAY NOT ACHIEVE SUFFICIENT ACCEPTANCE BY THE MEDICAL COMMUNITY TO SUSTAIN OUR BUSINESS.**

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 systems or, even if further testing and 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.

**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.

Table of Contents

**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 businesses 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 \$10.0 million per incident and \$10.0 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 material adverse effect on our business. In addition, liability or alleged liability could harm the business by diverting the attention and resources of our management and by damaging our reputation.

**WE HAVE NOT PAID DIVIDENDS IN THE PAST AND DO NOT INTEND TO DO SO FOR THE FORESEEABLE FUTURE.**

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. Therefore, our stockholders cannot achieve any degree of liquidity with respect to their shares of Common Stock except by selling such shares.

**OUR STOCK PRICE HAS BEEN, AND COULD BE, VOLATILE.**

Market prices for our Common Stock and the securities of other medical, high technology companies have been volatile. Our Common Stock had a high price of \$6.00 and a low price of \$1.60 in the 52-week period ending March 31, 2009. Factors such as announcements of technological innovations or new products by us or by our competitors, government regulatory action, litigation, patent or proprietary rights developments and market conditions for medical and high technology stocks in general can have a significant impact on the market for our Common Stock.

**OUR STOCK HISTORICALLY HAS BEEN THINLY TRADED. THEREFORE, STOCKHOLDERS MAY NOT BE ABLE TO SELL THEIR SHARES FREELY.**

While our Common Stock is listed on The NASDAQ Stock Market, LLC (and previously on the American Stock Exchange), the volume of trading historically has been relatively light. There can be no assurance that our historically light trading volume, or any trading volume whatsoever, will be sustained in the future. Therefore, there can be no assurance that our stockholders will be able to sell their shares of our Common Stock at the time or at the price that they desire, or at all.

Table of Contents

**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 the Board of Directors (the Board), on such terms as it determines, without further stockholder approval. Therefore, the Board may issue such preferred stock on terms unfavorable to a potential bidder in the event that the Board opposes a merger or acquisition. In addition, our classified Board may discourage such transactions by increasing the amount of time necessary to obtain majority representation on the Board. We also have implemented a stockholder rights plan and distributed rights to our stockholders. When these rights become exercisable, these rights entitle their holders to purchase one share of our Series C Junior Participating Preferred Stock at a price of \$66.90 per one ten-thousandth of a share of Series C Preferred Stock. If any person or group acquires more than 15% of our Common Stock, the holders of rights (other than the person or group crossing the 15% threshold) will be able to purchase, in exchange for the \$66.90 exercise price, \$133.80 of our Common Stock or the stock of any company into which we are merged. Because these rights may substantially dilute stock ownership by a person or group seeking to take us over without the approval of our Board, our rights plan could make it more difficult for a person or group to take us over (or acquire significant ownership interest in us) without negotiating with our Board regarding such a transaction. Certain other provisions of our Bylaws and of Delaware law may also discourage, delay or prevent a third party from acquiring or merging with us, even if such action were beneficial to some, or even a majority, of our stockholders.

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

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Submission of Matters to a Vote of Security Holders.**

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



Table of Contents

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

May 12, 2009

CELSION CORPORATION  
Registrant

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

By: */s/ Sean Moran*  
Sean Moran  
Senior Vice President & Chief Financial Officer