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 (State or other jurisdiction of incorporation or organization)	52-1256615 (I.R.S. Employer Identification No.)
10220-L Old Columbia Road Columbia, Maryland (Address of principal executive offices)	21076 (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.

TABLE OF CONTENTS

Table of Contents

PART I
FINANCIAL INFORMATION
CELSION CORPORATION
BALANCE SHEETS

Item 1. Financial Statements.

ASSETS		September 30, 2009 (Unaudited)	December 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 of $837,701 and $771,624, respectively)		204,674	222,638
Other assets			
Deposits		744,038	362,651
Note receivable (net of allowance and discount of $1,128,821 at December 31, 2008)		-	221,179
Other assets		52,500	58,125
Total other assets		796,538	641,955
Total assets	$	17,743,378	$ 23,688,026
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities			
Accounts payable - trade	$	2,839,814	$ 1,186,511
Indemnity reserve		-	1,053,357
Other accrued liabilities		1,292,757	1,459,391
Note payable - current portion		-	234,735
Total current liabilities		4,132,571	3,933,994
Warrant liability		1,553,676	-
Other liabilities – noncurrent		18,893	27,643
Total liabilities		5,705,140	3,961,637
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, 2009 and December 31, 2008, respectively)		128,742	108,161
Additional paid-in capital		94,775,750	89,183,549
Accumulated deficit		(79,789,584)	(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.

Table of Contents

CELSION CORPORATION
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Operating expenses:				
Research and development	$ 3,503,064	$ 3,839,951	$ 10,675,506	$ 8,422,143
General and 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)	(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)
Basic and diluted net loss per common share	$ (0.47)	$ (0.43)	$ (1.27)	$ (1.07)
Basic and diluted weighted average shares outstanding	10,117,750	10,149,055	10,166,360	10,146,339

See accompanying notes to the financial statements.

Table of Contents

CELSION CORPORATION
STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2009	2008
Cash flows from operating activities		
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 activities	2,654,430	3,611,936
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 agreement	-	(7,666)
Purchase of property and equipment	(48,113)	(47,535)
Net cash used in investing activities	(131,087)	(5,227,613)
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) financing activities	6,118,904	(503,440)

Net increase (decrease) in cash and 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.

Table of Contents

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.

Table of Contents

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 30, 2009	December 31, 2008
Short term investments - at fair value		

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

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) 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:

	Total Short-term Investments	Quoted prices in active markets for identical assets (Level 1)
Short term investments available for sale at September 30, 2009	$ 4,204,126	$ 4,204,126
Short term investments available for sale at December 31, 2008	$ 4,061,320	$ 4,061,320

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

	September 30, 2009		December 31, 2008	
	Cost	Fair Value	Cost	Fair 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

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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%
Expected volatility	72.3% to 77.2%	77.28% to 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 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.

Table of Contents

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

	Stock Options		Restricted Stock Awards		
Equity Awards	Options Awarded	Weighted Average Exercise Price	Restricted Stock Awarded	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Terms of Equity Awards (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.

Table of Contents

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.

Table of Contents

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.

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 t 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.

Table of Contents

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:				
Research and development	$ 10,676	$ 8,422	$ 2,254	27%
General and administrative	2,514	1,586	928	59%
Total operating expenses	13,190	$ 10,008	3,182	32%
Loss from operations	$ (13,190)	$ (10,008)	$ (3,182)	(32)%

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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 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 nine months ended September 30, 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 $79.8 million at September 30, 2009. For the nine months ended September 30, 2009, we incurred a loss from continuing operations of $13.2 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 RAISE ADDITIONAL CAPITAL, WE MAY NOT BE ABLE TO COMPLETE THE DEVELOPMENT, TESTING AND COMMERCIALIZATION OF OUR TREATMENT SYSTEMS.

As of September 30, 2009, we had approximately $16.3 million in cash, cash equivalents, and short term investments. To complete the development and commercialization of our product, we will need to raise substantial amounts of additional capital. 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 we can not raise additional capital, 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 20 full-time employees. We rely, and expect to continue to rely, on third-party Clinical Research Organizations to conduct a significant portion of our clinical trials. Because of this, 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

WE RELY ON A SOLE SOURCE FOR THE MANUFACTURING OF THERMODOX®. THE FAILURE OF THIS MANUFACTURER TO PROPERLY PERFORM ITS OBLIGATIONS TO SUPPLY THERMODOX® COULD HALT OR DELAY OUR CLINICAL TRIALS.

We are dependent on a single contract manufacturer to produce ThermoDox® for clinical trials. This contract manufacturer is subject to ongoing periodic inspection by the FDA and corresponding foreign agencies to ensure strict compliance with current good manufacturing practices and other governmental regulations and standards. We have limited control over our contract manufacturer and its ability to maintain adequate quality control, quality assurance and qualified personnel. We are in the process of establishing a second source manufacturer as a back up facility; however, we have not yet manufactured ThermoDox® at this second source manufacturer. Failure by our sole source contract manufacturer to produce ThermoDox® batches that meet specifications or failure to comply with or maintain any of the required international quality standards could adversely affect our ability to complete clinical trials and obtain regulatory approval for ThermoDox® and would adversely impact our business.

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.

Table of Contents

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

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

LEGISLATIVE AND REGULATORY CHANGES AFFECTING THE 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.

Table of Contents

WE MAY NOT BE ABLE TO HIRE OR RETAIN KEY OFFICERS OR EMPLOYEES THAT WE NEED TO IMPLEMENT OUR BUSINESS STRATEGY AND DEVELOP OUR PRODUCTS AND BUSINESS.

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

OUR SUCCESS WILL DEPEND IN PART ON OUR ABILITY TO GROW AND DIVERSIFY, WHICH IN TURN WILL REQUIRE THAT WE MANAGE AND CONTROL OUR GROWTH EFFECTIVELY.

Our business strategy contemplates growth and diversification. Our ability to manage growth effectively will require that we continue to expend funds to improve our operational, financial and management controls, reporting systems and procedures. In addition, we must effectively expand, train and manage our employees. We will be unable to manage our 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.

Table of Contents

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 $5.18 and a low price of $2.00 in the 52-week period ending September 30, 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.

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.

Table of Contents

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.

Table of Contents

Item 6. Exhibits.

10.1	Placement Agency Agreement dated September 25, 2009 among Celsion Corporation and Needham & Company, LLC., incorporated herein by reference to Exhibit 1.1 to the Current Report on Form 8-K of the Company, filed September 28, 2009.
10.2	Form of Common Stock Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company, filed September 28, 2009.
10.3	Form of Subscription Agreement, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed September 28, 2009.
10.4	Escrow Agreement by and between JPMorgan Chase Bank, N.A., Celsion Corporation, and Needham & Company, LLC., incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of the Company, filed September 28, 2009.
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.

November 10, 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

Table of Contents