

Celsion CORP  
Form 10-Q  
November 14, 2008  
Table of Contents

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2008

or

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

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

Commission file number 000-14242

---

**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 21046

Edgar Filing: Celsion CORP - Form 10-Q

(Address of Principal Executive Offices) (Zip Code)

**(410) 290-5390**

(Registrant's telephone number, including area code)

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 is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "accelerated filer", "large 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

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

As of November 1, 2008 the Registrant had 10,149,850 shares outstanding of Common Stock, \$.01 par value per share.

---

Table of Contents

**TABLE OF CONTENTS**

**PART I:**      **FINANCIAL INFORMATION**



**Item 1.**

**Financial Statements and Notes (Unaudited)**

Balance Sheets

Edgar Filing: Celsion CORP - Form 10-Q

Statements of Operations  
Statement of Changes in Stockholders' Equity  
Statements of Cash Flows  
Notes to Financial Statements

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Item 4. Controls and Procedures

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

Item 1A. Risk Factors

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

Item 3. Defaults Upon Senior Securities

Item 4. Submission of Matters to a vote of Security Holders

Item 5. Other Information

Item 6. Exhibits

SIGNATURES





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

### EXHIBITS

- 11 Statement Re: Computation of Earnings Per Share. (Filed herewith)
  - 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (Filed herewith)
  - 31.2 Certification of Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (Filed herewith)
  - 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (Furnished herewith)
  - 32.2 Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (Furnished herewith)
-

Table of Contents

**PART I**  
**FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

Index to Financial Statements

	<b>Page</b>
<u>Balance Sheets as of September 30, 2008 (Unaudited) and December 31, 2007</u>	4 - 5
<u>Statements of Operations (Unaudited) for the Three and Nine Month Periods Ended September 30, 2008 and 2007</u>	6
<u>Statement of Changes in Stockholders' Equity (Unaudited) for the Nine Months Ended September 30, 2008</u>	7
<u>Statements of Cash Flows (Unaudited) for the Nine Months Ended September 30, 2008 and 2007</u>	8
<u>Notes to Financial Statements (Unaudited)</u>	9 - 16

Table of Contents**CELSION CORPORATION**

## BALANCE SHEETS

September 30, 2008 and December 31, 2007

	September 30, 2008 (Unaudited)	December 31, 2007
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 818,256	\$ 2,937,373
Short term investments available for sale, at fair value	8,151,090	3,000,000
Accounts receivable - trade	13,182	183,043
Other receivables	54,657	47,110
Due from Boston Scientific Corporation	15,000,000	15,000,000
Prepaid expenses	141,069	256,874
Total current assets	24,178,254	21,424,400
<b>Property and equipment - at cost</b>		
Furniture and office equipment	198,434	194,200
Computer hardware and software	314,096	338,349
Laboratory and shop equipment	324,501	305,340
Leasehold improvements	132,148	132,148
	969,179	970,037
Less: Accumulated depreciation	744,324	702,156
Net value of property and equipment	224,855	267,881
<b>Other assets</b>		
Advances under Celsion (Canada), Ltd.		
Transition Services Agreement (net of allowance of \$649,891 and \$442,225 respectively)		200,000
Note receivable (net of discount of \$147,154 and \$168,473, respectively, and an allowance of \$882,136 and \$0, respectively)	320,710	1,181,527
Due from Boston Scientific Corporation - Non Current		15,000,000
Deposits with CROs and other assets	1,118,402	899,268
Patent licensing fees (net of accumulated amortization of \$15,000 and \$9,375, respectively)	60,000	65,625
Total other assets	1,499,112	17,346,420
<b>Total assets</b>	<b>\$ 25,902,221</b>	<b>\$ 39,038,701</b>

Table of Contents**CELSION CORPORATION**

## BALANCE SHEETS (Continued)

September 30, 2008 and December 31, 2007

	September 30, 2008 (Unaudited)	December 31, 2007
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable - trade	\$ 2,237,168	\$ 1,830,457
Other accrued liabilities	2,745,848	5,056,380
Income taxes payable		546,000
Accrued non-cash compensation	8,910	8,910
Note payable - current portion	407,761	676,859
Total current liabilities	5,399,687	8,118,606
<b>Long-term liabilities</b>		
Note payable		234,742
Other liabilities	30,051	34,238
Total long-term liabilities	30,051	268,980
Total liabilities	5,429,738	8,387,586
<b>Stockholders equity</b>		
Common stock - \$0.01 par value per share (250,000,000 shares authorized; 10,809,588 and 10,783,922 shares issued as of September 30, 2008 and December 31, 2007, respectively.)	108,096	107,839
Additional paid-in capital	89,014,495	88,319,985
Accumulated other comprehensive loss	(21,322)	
Accumulated deficit	(65,989,834)	(55,137,757)
Subtotal	23,111,435	33,290,067
Less: 659,738 shares of treasury stock - at cost	(2,638,952)	(2,638,952)
Total stockholders equity	20,472,483	30,651,115
<b>Total liabilities and stockholders equity</b>	<b>\$ 25,902,221</b>	<b>\$ 39,038,701</b>

See accompanying notes.

Table of Contents**CELSION CORPORATION**

## STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Operating expenses:				
Research and development	\$ 3,839,951	\$ 1,958,671	\$ 8,422,143	\$ 6,078,520
General and administrative	509,794	1,860,531	1,586,322	4,826,087
Total operating expenses	4,349,745	3,819,202	10,008,465	10,904,607
Loss from operations	(4,349,745)	(3,819,202)	(10,008,465)	(10,904,607)
Other (expense) / income:				
Other expense	(57,287)	(23,754)	(896,377)	(439,211)
Interest income	81,419	204,143	185,543	505,174
Interest expense	(14,457)	(11,899)	(132,778)	(677,324)
Loss from continuing operations	\$ (4,340,070)	\$ (3,650,712)	\$ (10,852,077)	\$ (11,515,968)
Discontinued Operations (Note 12)				
Income from discontinued operations		33,054		50,029,211
Income tax expense				(274,000)
Income from discontinued operations		33,054		49,755,211
Net (loss) / income	\$ (4,340,070)	\$ (3,617,658)	\$ (10,852,077)	\$ 38,239,243
Net loss from continuing operations per common share - basic	\$ (0.43)	\$ (0.34)	\$ (1.07)	\$ (1.07)
Net loss from continuing operations per common share - diluted	\$ (0.43)	\$ (0.34)	\$ (1.07)	\$ (1.07)
Net income from discontinued operations per common share - basic	\$	\$ 0.00	\$	\$ 4.62
Net income from discontinued operations per common share - diluted	\$	\$ 0.00	\$	\$ 4.32
Net (loss) / income per common share - basic	\$ (0.43)	\$ (0.34)	\$ (1.07)	\$ 3.55
Net (loss) / income per common share - diluted	\$ (0.43)	\$ (0.34)	\$ (1.07)	\$ 3.32
Weighted average shares outstanding - basic	10,149,055	10,774,497	10,146,339	10,764,878
Weighted average shares outstanding - diluted (1)	10,149,055	10,774,497	10,146,339	11,526,717

Edgar Filing: Celsion CORP - Form 10-Q

(1) Potentially dilutive securities are excluded from the computation of earnings per share for periods in which there is a loss as their effect would be anti-dilutive.

See accompanying notes.

Table of Contents**CELSION CORPORATION**

## STATEMENTS OF CHANGES IN STOCKHOLDERS EQUITY

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2008

(Unaudited)

	Nine Months Ended September 30, 2008							
	Common Stock Shares	Common Stock Total	Additional Paid-in Capital	Treasury Stock Shares	Treasury Stock Total	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
Balance at January 1, 2008	10,783,922	\$ 107,839	\$ 88,319,985	659,738	\$ (2,638,952)	\$	\$ (55,137,757)	\$ 30,651,115
Stock-based compensation expense related to employee stock options			612,930					612,930
Stock based compensation - restricted stock			39,217					39,217
Issuance of restricted stock upon vesting	16,666	167	(167)					
Shares issued to employees	9,000	90	42,130					42,220
Extension of warrants			400					400
Change in fair value of investments						(21,322)		(21,322)
Net loss							(10,852,077)	(10,852,077)
Balance at September 30, 2008	10,809,588	\$ 108,096	\$ 89,014,495	659,738	\$ (2,638,952)	\$ (21,322)	\$ (65,989,834)	\$ 20,472,483



Table of Contents

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

	Nine Months Ended September 30,	
	2008	2007
<b>Cash flows from operating activities</b>		
Net (loss) / income for the year	\$ (10,852,077)	\$ 38,239,243
Non-cash items included in net loss:		
Depreciation and amortization	90,038	136,463
Accretion of discount on note receivable	(21,319)	(78,979)
Gain on the sale of Prolieve		(48,029,793)
Loss on disposal of fixed assets	523	10,488
Stock based compensation - Options	612,930	714,053
Stock based compensation - Stock grants	66,717	58,560
Amortization of deferred license fee		(269,840)
Exercise of common stock options		2,718
Shares issued in exchange for services	14,720	56,255
Amortization of patent license	5,625	59,731
Allowance for bad debts	895,854	428,722
Net changes in:		
Accounts receivable-trade	169,861	1,653,023
Other receivables	(13,599)	17,873
Due from Boston Scientific Corporation	15,000,000	
Inventories		5,792
Prepaid expenses	115,805	170,351
Escrow account-license fee		1,824,740
Deposits and other assets	(219,134)	(607,586)
Accounts payable - trade and accrued interest	606,711	(295,846)
Income taxes payable	(546,000)	68,500
Other accrued liabilities	(2,314,719)	(1,212,541)
<b>Net cash provided by / (used in) operating activities</b>	<b>3,611,936</b>	<b>(7,048,073)</b>
<b>Cash flows from investing activities</b>		
Purchase of short term investments	(11,640,470)	(5,000,000)
Sale of short-term investments	6,507,355	4,100,000
Proceeds from the sale of the Prolieve assets		9,958,615
Advances under Celsion Canada transition services agreement	(7,666)	(45,400)
Amortization of premium on investments	7,871	
Accretion of discount on investments	(12,499)	
Accrued interest on investments	(34,669)	
Payment of licensing fee		(1,600,000)
Purchase of property and equipment	(47,535)	(87,043)
<b>Net cash (used in) / provided by investing activities</b>	<b>(5,227,613)</b>	<b>7,326,172</b>
<b>Cash flows from financing activities</b>		
Extension of warrants	400	
Draws on line of credit	3,000,000	
Repayment of line of credit	(3,000,000)	
Proceeds from note payable		1,181,925
Payments on note payable	(503,840)	(107,324)

Edgar Filing: Celsion CORP - Form 10-Q

<b>Net cash (used in) / provided by financing activities</b>	(503,440)	1,074,601
<b>Net (decrease) / increase in cash and cash equivalents</b>	(2,119,117)	1,352,700
<b>Cash and cash equivalents at beginning of period</b>	2,937,373	1,032,674
<b>Cash and cash equivalents at end of period</b>	\$ 818,256	\$ 2,385,374
<b>Cash paid for:</b>		
Interest	\$ 45,882	\$ 13,637
Income taxes	\$ 546,000	\$ 205,500

See accompanying notes.



Table of Contents

**CELSION CORPORATION**

## NOTES TO FINANCIAL STATEMENTS (UNAUDITED)

For the Three and Nine Month Periods Ended September 30, 2008 and 2007

**Note 1. Basis of Presentation**

The accompanying unaudited financial statements of Celsion Corporation (which we sometimes refer to as "Celsion", the "Company", "we" or "us") have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") 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 month periods ended September 30, 2008 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, 2007 filed with the Securities and Exchange Commission on March 28, 2008.

**Note 2. 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 quarter ended September 30, 2008, the 2,097,913 options and warrants that were convertible into shares of the Company's common stock were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive. For the quarter ended September 30, 2007, 844,791 options and warrants that were convertible into shares of the Company's common stock were excluded from the calculation of diluted earnings per share as their effect would have been anti-dilutive. The total number of outstanding warrants and options for the periods ended September 30, 2008 and 2007 were 2,057,080 and 2,062,467 respectively. Additionally, shares of unvested restricted stock were excluded from the calculation. The total number of shares of unvested stock as of September 30, 2008 and 2007 was 40,833 and 56,400, respectively.

Information relating to the calculation of earnings per share is summarized as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net loss from continuing operations - basic and diluted	\$ (4,340,070)	\$ (3,650,712)	\$ (10,852,077)	\$ (11,515,968)
Net income from discontinued operations - basic and diluted	\$	\$ 33,054	\$	\$ 49,755,211

Edgar Filing: Celsion CORP - Form 10-Q

Net (loss) / income - basic and diluted	\$	(4,340,070)	\$	(3,617,658)	\$	(10,852,077)	\$	38,239,243
Weighted average shares outstanding - basic		10,149,055		10,774,497		10,146,399		10,764,878
Dilutive securities - options and warrants								761,839
Adjusted weighted average shares outstanding - dilutive		10,149,055		10,774,497		10,146,399		11,526,717
Net loss from continuing operations per common share - basic	\$	(0.43)	\$	(0.34)	\$	(1.07)	\$	(1.07)
Net loss from continuing operations per common share - diluted	\$	(0.43)	\$	(0.34)	\$	(1.07)	\$	(1.07)
Net income from discontinued operations per common share - basic	\$		\$	0.00	\$		\$	4.62
Net income from discontinued operations per common share - diluted	\$		\$	0.00	\$		\$	4.32
Net (loss) / income per common share - basic	\$	(0.43)	\$	(0.34)	\$	(1.07)	\$	3.55
Net (loss) / income per common share - diluted	\$	(0.43)	\$	(0.34)	\$	(1.07)	\$	3.32

Table of Contents

**Note 3. New Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board issued SFAS No. 157 *Fair Value Measurements*, which defines fair value, establishes a framework for consistently measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 became effective for the Company on January 1, 2008 and did not have an impact on the Company's financial statements.

In November 2007, the Emerging Issues Task Force (EITF) issued Issue No. 07-1 (EITF 07-1), *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*. Companies may enter into arrangements with other companies to jointly develop, manufacture, distribute, and market a product. Often the activities associated with these arrangements are conducted by the collaborators without the creation of a separate legal entity (that is, the arrangement is operated as a virtual joint venture). The arrangements generally provide that the collaborators will share, based on contractually defined calculations, the profits or losses from the associated activities. Periodically, the collaborators share financial information related to product revenues generated (if any) and costs incurred that may trigger a sharing payment for the combined profits or losses. EITF 07-1 requires collaborators in such an arrangement to present the result of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. EITF 07-1 is effective for collaborative arrangements in place at the beginning of the annual period beginning after December 15, 2008. The Company does not currently expect the adoption of EITF 07-1 to have a material impact on its financial statements.

In February 2007, the Financial Accounting Standards Board issued SFAS No. 159 *The Fair Value Option for Financial Assets and Financial Liabilities* including an amendment of FASB Statement No. 115. SFAS No. 159 permits entities to choose to measure eligible items at fair value at specified election dates and report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS No. 159 became effective for the Company on January 1, 2008 and did not have an impact on the Company's financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities* an amendment of FASB Statement No. 133 (SFAS 161), which requires enhanced disclosures about an entity's derivative and hedging activities and thereby improves the transparency of financial reporting. SFAS 161 is effective for fiscal years beginning after November 15, 2008. The Company does not expect that the adoption of SFAS 161 will have a significant impact on its financial statements.

In April 2008, the FASB issued FASB Staff Position No. 142-3, *Determination of the Useful Life of Intangible Assets* (FSP No. 142-3) to improve the consistency between the useful life of a recognized intangible asset (under SFAS No. 142) and the period of expected cash flows used to measure the fair value of the intangible asset (under SFAS No. 141(R)). FSP No. 142-3 amends the factors to be considered when developing renewal or extension assumptions that are used to estimate an intangible asset's useful life under SFAS No. 142. The guidance in the new staff position is to be applied prospectively to intangible assets acquired after December 31, 2008. In addition, FSP No. 142-3 increases the disclosure requirements related to renewal or extension assumptions. The Company is currently assessing the impact of the adoption of FSP No. 142-3 on its financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS 162). SFAS 162 is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements in conformity with GAAP for nongovernmental entities. The statement establishes that the GAAP hierarchy should be

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

directed to entities because it is the entity (not its auditor) that is responsible for selecting accounting principles for financial statements that are presented in conformity with GAAP. This statement is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board's amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. The Company does not believe implementation of SFAS 162 will have a material impact on its financial statements.

In June 2008, the FASB issued FASB Staff Position EITF No. 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities* ( FSP EITF No. 03-6-1 ). Under FSP EITF No. 03-6-1, unvested share-based payment awards that contain rights to receive non-forfeitable dividends (whether paid or unpaid) are participating securities, and should be included in the two-class method of computing earnings per share ( EPS ). FSP EITF No. 03-6-1 is



Table of Contents

effective for fiscal years beginning after December 15, 2008, and the Company does not expect it to have a material impact on the Company's financial statements.

**Note 4. 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 generally vest over various time frames or upon milestone accomplishments. Some vest immediately. Others vest over a period between one and five years. The Company's options generally expire ten years from the date of the grant.

2001 Stock Option Plan

The purpose of the 2001 Plan is to promote the long-term growth and profitability of Celsion by providing key associates with incentives to improve stockholder value and to contribute to the growth and financial success of Celsion and to enable the Company to attract, retain and reward the best available persons for positions of substantial responsibility. The 2001 Plan permitted the granting of stock options (including nonqualified stock options and incentive stock options qualifying under Section 422 of the Internal Revenue Code) and stock appreciation rights or any combination of the foregoing. During the year that ended December 31, 2007, 195,043 options were canceled or expired. During the nine months ended September 30, 2008, 13,333 options expired. All of the 208,376 canceled and expired options under the 2001 Plan became available for issue under the 2007 Plan.

2004 Stock Incentive Plan

The purpose of the 2004 Plan is to promote the long-term growth and financial success of the Company and enable the Company to attract, retain and reward the best available persons for positions of substantial responsibility. The 2004 Plan permits the granting of awards in the form of incentive stock options, restricted stock, restricted stock units, stock appreciation rights, phantom stock, and performance awards, or in any combination of the foregoing. During the year that ended December 31, 2007, 90,379 options were canceled or expired. During the nine months ended September 30, 2008, 24,333 options were canceled or expired. All of the 114,712 canceled and expired options under the 2004 Plan became available for issue under the 2007 Plan.

2007 Stock Incentive Plan

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

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 permitted the granting of 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. During the year ended December 31, 2007, 103,500 options were issued. No options were canceled or expired under the plan for the year ended December 31, 2007. During the nine months ended September 30, 2008, 345,000 options were issued and 24,000 options were canceled. Additionally, 9,000 shares of stock were issued under the plan as performance awards during the quarter ended September 30, 2008. On September 30, 2008, there were 566,500 shares available out of 1,000,000 shares authorized and available under the 2007 Plan. All canceled and expired options under the 2001 Plan and the 2004 Plan became available for issue under the 2007 Plan.

### Options and Restricted Stock Issued to Consultants for Services

The Company enters into agreements with consultants in which the consultants receive restricted stock and stock options in exchange for services. 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 and restricted stock generally vest over various time frames or upon milestone accomplishments. Some vest immediately. Others vest over a period between one and five years. The Company's options generally expire ten years from the date of the grant. During the nine months ended September 30, 2008, 5,000 shares of restricted stock were issued to a consultant as part of a consulting agreement. There were no options granted to non-employees for the nine months ended September 30, 2008.

Table of Contents

A summary of the Company's Common Stock option and warrant activity and related information is as follows:

<b>Stock Options</b>	<b>Options Outstanding</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (in years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at December 31, 2007	1,498,841	\$ 6.17		
Granted	345,000	5.44		
Exercised				
Canceled or expired	(61,667)	(7.72)		
Outstanding at September 30, 2008	1,782,174	\$ 5.97	7.2	\$ 336,625
Exercisable at September 30, 2008	998,550	\$ 7.21	5.9	\$ 87,167

<b>Warrants</b>	<b>Warrants Outstanding</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (in years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at December 31, 2007	568,461	\$ 15.59		
Granted				
Exercised				
Canceled or expired	(293,555)	(14.17)		
Outstanding at September 30, 2008	274,906	\$ 17.12	0.6	\$
Exercisable at September 30, 2008	274,906	\$ 17.12	0.6	\$

A summary of the Company's Restricted Stock activity and related information is as follows:

<b>Restricted Stock</b>	<b>Outstanding</b>	<b>Weighted Average Exercise Price</b>
Non-vested stock awards at December 31, 2007	50,000	\$ 2.42
Granted	7,500	4.89
Vested	(16,667)	2.42
Forfeited		
Non-vested stock awards at September 30, 2008	40,833	\$ 2.87

Table of Contents

The following is additional information with respect to options granted during the nine months ended September 30, 2008:

	<b>Nine Months Ended September 30, 2008</b>
Risk-free interest rate	2.18% to 3.54%
Dividend Yield	0.0%
Expected volatility	77.28% to 79.24%
Expected option life in years	6.0

For all of the Company's stock-based compensation plans, the fair value of each grant was estimated at the date of grant using the Black-Scholes option pricing model. Black-Scholes utilizes assumptions related to volatility, the risk-free interest rate, the dividend yield and employee exercise behavior. 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 2008 grants was generated using the simplified method as allowed under Securities and Exchange Commission Staff Accounting Bulletin No. 107.

Stock based compensation expense totaled \$148,240 and \$694,276 during the three and nine months ended September 30, 2008 and \$345,326 and \$772,613 during the three and nine months ended September 30, 2007. Stock based compensation is recognized ratably over the requisite service period for all awards. Unrecognized stock based compensation expense related to stock options totaled \$1,799,674 at September 30, 2008 while the unrecognized stock based compensation expense related to non-vested restricted stock awards was \$78,150 at September 30, 2008. These unrecognized expenses will be recognized in the income statement at various rates up to the next four years.

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

Short term investments available for sale of \$8,151,090 as of September 30, 2008 and \$3,000,000 as of December 31, 2007 consist of money market funds, commercial paper, corporate debt securities, and government agency debt securities. They are valued at estimated fair value, with unrealized gains and losses reported as a separate component of stockholders' equity in Accumulated Other Comprehensive Loss.

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.

<b>Short term investments - at fair value</b>	<b>September 30 2008</b>	<b>December 31, 2007</b>
Money market funds and commercial paper	\$ 3,441,082	\$ 3,000,000
Bonds - government agencies	2,423,707	

Edgar Filing: Celsion CORP - Form 10-Q

Bonds - corporate issuances		2,286,301		
Total	\$	8,151,090	\$	3,000,000

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).

Assets measured at fair value on a recurring basis are summarized below:

	Fair value measurements at September 30, 2008 using			
	September 30, 2008	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Short term investments available for sale	\$ 8,151,090	\$	\$ 8,151,090	\$

**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

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

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 of \$21,319 and \$60,624 was recorded in the nine months ended September 30, 2008 and 2007, respectively.

During the month of May 2008, the borrower approached the Company and requested that the terms of the note be extended and/or restructured. As of the filing of this Form 10-Q, an agreement between the parties had not been reached. As a result, the collectibility of the note receivable became doubtful. Accordingly, 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. The closing price of Celsion's common stock on September 30, 2008 was \$3.19, which results in a total collateral value of \$320,710. Therefore, the carrying value of the note was reduced to \$320,710 as of September 30, 2008.

Table of Contents

**Note 8. Advances under Celsion (Canada) Limited Transition Services Agreement**

In conjunction with the sale of Canada, a Transition Services Agreement was entered into whereby (i) Celsion sublet space in the Company's offices for use by Canada to carry on its business, for a period of up to six (6) months from the date of the agreement; (ii) Celsion provided administrative support services as needed in the operation of Canada's business for the period of the sublease; and (iii) Celsion advanced funds to pay salary and health and dental insurance of each of certain employees of Canada and the expenses reasonably incurred in connection with the operation of Canada's business up to \$100,000 for the shorter of the period ending June 30, 2006 or the date of closing by Canada of a transaction involving the merger of Canada into a newly created Canadian Capital Pool Company and a simultaneous funding through a private placement of shares under terms approved by the Toronto Stock Exchange (the Canada Transaction). Within ten days after the closing of the Canada Transaction, Canada is obligated to pay the Company all amounts due under the Transition Services Agreement.

The Transition Services Agreement was amended on March 28, 2006 to advance Canada an additional \$200,000 to fund reasonable operating expenses. This additional advance is repayable under the same terms as the Transition Services Agreement. The cumulative balance advanced under the Transition Services Agreement, as amended, at September 30, 2008 was \$649,891.

When the Canada Transaction did not close by December 31, 2006, Celsion management established, based on discussions with Canada management, that diligent efforts were being made by Canada management to close the Canada Transaction on a timely basis and agreed to extend the due date for repayment of the loan to the earlier of the closing of the Canada Transaction or June 30, 2007. Canada did not close the transaction nor had it paid the amounts due as of the June 30, 2007 due date. Accordingly, during the quarter ended June 30, 2007, the Company placed an allowance against this receivable and recorded the estimated net realizable value of the receivable as \$200,000, which was guaranteed by Dr. Cheung. Given the collectibility concern of Dr. Cheung's note described in Note 7 above, the Company has increased its allowance to \$649,891 as of September 30, 2008 and recorded the estimated net realizable value of the receivable as zero.

**Note 9. Licensing Agreement**

Celsion entered into a Distribution Agreement with Boston Scientific Corporation (Boston Scientific or BSC) on January 20, 2003 pursuant to which the Company granted Boston Scientific exclusive rights to market and distribute the Prolieve Thermomodilatation® system and its component parts for the treatment of BPH in all territories other than China, Taiwan, Hong Kong, Macao, Mexico and Central and South America. The agreement was terminated upon the sale of the Prolieve assets to Boston Scientific on June 21, 2007 (as more fully described in Note 12). The Distribution Agreement had a seven-year term commencing on February 21, 2004. The parties previously shared gross sales (less costs and expenses) attributable to the product.

Celsion received a \$4,000,000 licensing fee under the Distribution Agreement, \$2,000,000 of which was placed in an interest bearing escrow account for a period of 36 months ending February 21, 2007 for payment of any legal expenses, settlements, license fees, royalties, damages or judgments incurred by Celsion or Boston Scientific in connection with any patent litigation related to alleged infringement of third party patents. Interest on the funds was retained in the escrow account and accrued to the benefit of Celsion. The balance remaining in the escrow was released to Celsion on February 20, 2007 and applied to settlement of a patent infringement lawsuit with American Medical Systems, Inc. and AMS Research Corporation (together referred to as AMS).



The Company recognized the licensing fee at a rate of \$47,619 per month over the seven-year term of the Distribution Agreement which began February 21, 2004. Upon the sale of the Prolieve assets on June 21, 2007, the remaining balance of the fee was recorded as income and included in the gain on the sale of the Prolieve assets during the quarter ended June 30, 2007.

**Note 10. Secured Line of Credit**

On November 9, 2007, the Company entered into a Loan and Security Agreement (the Agreement ) with Manufacturers and Traders Trust Company ( M&T ) pursuant to which M&T agreed to provide a draw-down credit facility to the Company (the Credit Facility ). The Company was able to request advances under the Credit Facility at a rate not to exceed \$1.5 million per month, up to a maximum principal amount under the Credit Facility of \$6.5 million. Each

Table of Contents

advance was subject to, among other customary conditions, a determination by M&T in its good faith discretion that the Company owned less than \$0.5 million in cash and other property readily convertible into cash, excluding a \$1.0 million cash collateral account held at M&T. Amounts borrowed by the Company under the Credit Facility and repaid could not be re-advanced to the Company.

The Credit Facility was secured by (i) the \$1.0 million cash collateral account and (ii) substantially all of the Company's assets. The Credit Facility bore interest on the outstanding balance at a rate of the London Interbank Offered Rate plus 2.75%. Accrued interest on the outstanding balance was payable monthly. The total outstanding principal and accrued interest balance on the Credit Facility was fully repaid on June 6, 2008.

Upon receipt of the second \$15 million installment due from Boston Scientific under the Asset Purchase Agreement (discussed below in Note 12) on June 6, 2008, the credit facility was closed.

**Note 11. Note Payable**

On July 23, 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 will make 21 monthly installments of \$59,418 beginning on August 23, 2007. Interest accrues at a rate of 5.98% on outstanding balances.

**Note 12. Discontinued Operations**

On April 17, 2007, the Company and Boston Scientific entered into an asset purchase agreement to reflect the exercise by Boston Scientific of its option to purchase all of the Prolieve assets of the Company (the Asset Purchase Agreement ). The Board of Directors of the Company approved the Asset Purchase Agreement and the transactions contemplated thereby, and the Company's stockholders ratified the sale at the annual meeting on June 13, 2007. Pursuant to the Asset Purchase Agreement, Boston Scientific purchased the Prolieve assets for an aggregate purchase price of \$60 million, subject to reduction in accordance with the terms and conditions of the Asset Purchase Agreement. The transaction closed on June 21, 2007, and the Company recorded a gain on the sale in the amount of \$48 million.

The gain on the sale of Prolieve was calculated as follows:

Sales Price	\$	60,000,000
Transaction fees and legal costs		(1,460,165)
Indemnity guarantee costs		(5,000,000)
Licensing fee		(3,100,000)
Adjusted Sales Price		50,439,835

Net assets sold

Inventories		(2,824,757)
-------------	--	-------------

Edgar Filing: Celsion CORP - Form 10-Q

Laboratory and shop equipment	(150,503)
AMS License Fee	(1,545,893)
<u>Liabilities Transferred</u>	
Amortization of License Fee	2,111,111
Gain on Sale	\$ 48,029,793

As previously disclosed, the Company and Boston Scientific entered into a Transaction Agreement effective January 20, 2003 (the Transaction Agreement). As part of the consideration in the Transaction Agreement, the Company granted Boston Scientific an exclusive option to purchase the Prolieve assets for a price equal to the greater of \$60 million or a multiple of sales, exercisable for a period of five years and expiring in February 2009. As previously disclosed, on August 8, 2005, the Company and Boston Scientific entered into the First Amendment pursuant to which Boston Scientific agreed to lend the Company up to \$15 million to be evidenced by one or more convertible secured promissory notes (the Notes). The first installment of \$6 million was disbursed on August 17, 2005, the second and third installments, each of \$4.5 million, were disbursed on February 2, 2006, and July 28, 2006, respectively. The First Amendment also fixed the purchase option price at \$60 million (eliminating the multiple of sales).

Table of Contents

The Asset Purchase Agreement reflects the agreement by the Company and Boston Scientific to further modify the terms of the purchase option granted to Boston Scientific on January 20, 2003 and amended on August 8, 2005. The revised terms provided for the aggregate purchase price of \$60 million to be paid in three installments consisting of \$30 million at closing on June 20, 2007 and \$15 million on each of the first and second anniversaries of the closing. The revised terms also provided that the \$30 million first installment was reduced at closing by approximately \$17 million, representing the principal and accrued interest due on the Notes.

In addition to the other indemnification provisions, such as indemnification for breaches of representations, warranties and covenants contained in the Asset Purchase Agreement, the Company has agreed to indemnify Boston Scientific for a period of two years from the closing, in an amount up to \$15 million of incurred costs, in the event of unforeseen intellectual property claims related to the Prolieve assets. In accordance with FASB interpretation No. 45 ( FIN 45 ), *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* an interpretation of FASB Statements No. 5, 57, and 107 and rescission of FASB interpretation No. 34, the Company recorded an estimate for the fair value of standing ready to perform under the indemnification guarantee of \$5,000,000. This estimate was consistent with the fair value of insurance premiums to cover the entire \$15 million indemnity. On July 23, 2007, the Company purchased an insurance policy to cover \$10 million of the indemnity guarantee. The premium for this policy was \$1,313,250 and was recorded as a reduction of the accrued liability. The Company will continue to evaluate the accrued liability on a quarterly basis and reduce it as the risk of the indemnity decreases. As of September 30, 2008, the balance of this accrued liability was \$1,580,037.

**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, 2007 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 Management s Discussion and Analysis of Financial Condition and Results of Operations Risk Factors contained in the Annual Report on Form 10-K for the fiscal year ended December 31, 2007.*

*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 is a biotechnology company dedicated to furthering the development and commercialization of oncology drugs including tumor-targeting treatments using focused heat energy in combination with heat activated drug delivery. We are

Table of Contents

currently engaged in the development of treatment systems using a combination of heat and drugs developed on our proprietary heat activated liposomal technology platform. Our first drug, ThermoDox®, an encapsulation of doxorubicin, a common oncology drug, in our heat activated liposome, is in clinical studies for the treatment of liver cancer and breast cancer.

From 1995 until early in 2004, we engaged in research and development of new treatment systems. On January 16, 2006, we transferred all of our rights to the Microfocus 1000, together with all associated technology, to Celsion (Canada) Ltd. and on the same day sold all the stock of Celsion (Canada) to our founder and former officer and director, Dr. Augustine Cheung.

On February 19, 2004, we obtained pre-marketing approval ( PMA ) for the Prolieve Thermodilatation System from the Food and Drug Administration (the FDA ) for the treatment of Benign Prostatic Hyperplasia ( BPH ). From 2004 through June 2007, Prolieve was marketed and sold through our commercial distributor, Boston Scientific Corporation ( BSC or Boston Scientific ). On June 21, 2007, we sold all of our Prolieve assets to Boston Scientific.

**Development pipeline**

Our pipeline presently consists of the following product, in the indicated stage of development:

**Product**

ThermoDox® (doxorubicin encapsulated in our heat activated liposome) plus heat for the treatment of cancer

**Status**

We began a Phase III study during the second quarter of 2008 to determine the efficacy of ThermoDox® in combination with RFA in the treatment of primary liver cancer. The study will incorporate approximately 40 clinical sites in North America, Italy, China, Taiwan, Hong Kong, and Korea and is planned to enroll a total of 600 patients.

We expect to commence an Open Label, Single Arm Phase II study in patients with Recurrent Chest Wall cancer ( RCW ) during the 4th quarter of 2008. The study will test the efficacy of ThermoDox® in combination with hyperthermia.

We are currently conducting a confirmatory Phase I clinical study for our single vial formulation of ThermoDox® used in conjunction with RFA in the treatment of liver cancer. This study is being performed at the North Shore Long Island Jewish Health System.

We have recently completed a Phase I clinical study to establish the maximum tolerable dose, the safety, and the pharmacokinetics of

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

ThermoDox® used in conjunction with radio frequency ablation ( RFA ) in the treatment of liver cancer. The study was conducted at the National Cancer Institute of the National Institutes of Health and Queen Mary 's Hospital in Hong Kong.

In addition to ThermoDox®, the Company is currently exploring alternative drugs that may be used in conjunction with its heat sensitive liposomal technology. Feasibility studies are being conducted on a liposomal Docetaxel and a liposomal Carboplatin. The Company is also exploring the use of its ThermoDox® drug enhanced with a ligand that targets epidermal growth factor receptors.

From 1995 to 2004, we generated only minimal revenues and funded our operations primarily through private placements of our equity securities. During 2004, following FDA premarketing approval of the Prolieve Thermodilatation System, we received a one-time licensing fee of \$4 million under our agreement with Boston Scientific, the former distributor of our Prolieve system. From 2004 through June 2007, sales of Prolieve products generated revenues of approximately \$29 million. The proceeds from the sale of the Prolieve assets to BSC, along with raising additional equity, is anticipated to

Table of Contents

generate sufficient funding until such time as we are able to complete development and testing of, and gain necessary regulatory approvals for, one or more of our products.

While the Company is currently funded from the available cash resources and amounts due from the sale of the Prolieve assets, we anticipate that in the longer term revenues will be generated from licensing fees paid for our technologies by pharmaceutical manufacturers and royalties generated from eventual product sales to major institutional health care providers. In the event that such licensing fees are not forthcoming and/or the Company elects to make investments in additional drug development and/or commercial opportunities, funding will be generated from the sale of our equity securities.

Our principal costs consist of:

- Research and development costs, including licensing fees due in connection with various of our technologies, the costs of sponsored research and pre-clinical and clinical trials for ThermoDox® , the costs of development and design of other products;
- Research and development costs, including payments to investigators, acquisition of materials, and preclinical work associated with the feasibility analysis of three new heat sensitive liposomal anticancer formulations including Liposomal Docetaxel, Liposomal Carboplatin, and ThermoDox® enhanced with a ligand having an affinity for epidermal growth factor receptors (EGFR); and
- Corporate overhead.

Our research and development activities, preclinical tests and clinical trials, and the manufacturing, marketing and labeling of each of our products, are subject to extensive regulation by the FDA. We may not bring to market any product in the U.S. without a premarketing approval from the FDA. We are currently conducting basic research and development activities, pursuing prototype products through clinical testing and regulatory approval. Our ultimate objective is to commercialize those products to generate a return on investment for our stockholders through one of several means including: (a) selling products directly to end users; (b) selling products through a distributor; or (c) licensing the technology to third parties and generating income through royalties and milestone payments.

**Recent Events**

In January 2008, the FDA provided written agreement with the Company's application for a Special Protocol Assessment for its Pivotal Phase III Primary Liver Cancer Trial. The study is designed to demonstrate the efficacy of ThermoDox® in combination with RFA. The study incorporates approximately 40 clinical sites in North America, Italy, China, Taiwan, Hong Kong, and Korea and is planned to enroll a total of 600 patients. The Company enrolled the first patient in the study during the second quarter of 2008. Currently, 21 patients have begun treatments under the study.



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

On January 15, 2008, the FDA provided a favorable written response to Celsion on its proposed Open Label, Single Arm Phase II study in patients with RCW. The agency agreed with the patient population as defined by Celsion, an objective response endpoint, and confirmed, that depending on the final data obtained, this study could be used to support a New Drug Application ( NDA ) submission. In light of this positive response from the FDA, Celsion is planning and working diligently to enable this Phase II study to commence as soon as a safe dose for multiple ThermoDox® treatments per patient, in this patient population, is determined from the Phase I study. Celsion believes that this Phase II study will commence enrollment late in 2008 and will be completed in 2009.

On February 8, 2008, the Company voluntarily moved the listing of its Common Stock from the American Stock Exchange to The NASDAQ Stock Market, LLC. On June 30, 2008, the Company changed its NASDAQ ticker symbol from CLN to CLSN.

On August 18, 2008, the Company executed a letter of intent with Yakult Honsha Co., Ltd. relating to the commercialization of ThermoDox® for the Japanese markets, which is subject to the execution of definitive agreements. Under the terms of the pending agreement, Yakult would commence pre-clinical and clinical studies of ThermoDox® to support requirements for drug registration in Japan. As of the filing of this 10-Q, the final definitive agreements had not yet been executed.

On October 16, 2008, the Company and Royal Philips Electronics entered into a joint research agreement focusing on a new cancer treatment that combines Philips' ultrasound technology with the Company's drug delivery platform to target

Table of Contents

tumors with high concentrations of a cancer-fighting drug. Under the terms of the agreement, Philips and Celsion will collaborate to explore the potential for using Philips' investigational magnetic resonance imaging (MRI)-guided high intensity focused ultrasound (HIFU) system in combination with Celsion's leading drug candidate, ThermoDox®, to treat a broad range of cancers. The research uses the HIFU system to position doxorubicin, an approved and frequently used anti-cancer drug, and to create a mild hyperthermia that releases the drug directly into the tumor. The result would be the ability to treat tumors that would otherwise be inaccessible.

**Results of Operations**

*Comparison of the Three Months Ended September 30, 2008 and 2007.*

	Three Months Ended September 30,		Change Dollars	Percent
	2008	2007		
Operating expenses:				
Research and development	\$ 3,839,951	\$ 1,958,671	\$ 1,881,280	96%
General and administrative	509,794	1,860,531	(1,350,737)	-73%
Total operating expenses	4,349,745	3,819,202	530,543	14%
Interest income, net	66,962	192,244	(125,282)	-65%
Other expense, net	(57,287)	(23,754)	(33,533)	141%
Loss from continuing operations	(4,340,070)	(3,650,712)	(689,358)	19%
Discontinued Operations (Note 12)				
Income from discontinued operations		33,054	(33,054)	-100%
Net loss	\$ (4,340,070)	\$ (3,617,658)	\$ (722,412)	20%

The increase of \$1,881,280, or 96%, increase in research and development expense during the third quarter of 2008 in comparison to the third quarter of 2007 was primarily due to:

• Increase in CRO and clinical costs related to the Phase III HCC study Progressing and Phase II RCW start up costs	\$ 1,642,000
• Increase in drug manufacturing costs to support clinical trials and additional formulation studies	118,000
• Increase in travel costs due to visits to clinical sites and site initiations	79,000
• Increase in recruiting and relocation costs related to clinical positions	75,000
• Increase in salaries due to clinical staff additions	41,000
• Increase in marketing/advertising costs related to patient recruitment	35,000
• Decrease in consulting fees	(143,000)

The \$1,350,737, or 73%, decrease in general and administrative expense during the quarter ended September 30, 2008 as compared to the same period of 2007 was primarily attributable to:

Edgar Filing: Celsion CORP - Form 10-Q

• Decrease in salaries, benefits, and relocation costs due to head count reductions	\$	(693,000)
• Decrease in the indemnity reserve related to the sale of the Prolieve Assets (see Note 12 to the Financial Statements)		(527,000)
• Decrease in consulting fees due to the termination of certain strategic business advisors		(115,000)
• Decrease in board of directors fees and related expenses		(63,000)
• Decrease in corporate insurances due to the elimination of the product liability insurance related to the sale of the Prolieve assets		(20,000)
• Increase in Public Relations/Investor Relations costs		45,000

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

### Table of Contents

Net interest income for the quarter ended September 30, 2008 was \$66,962, compared to \$192,244 for the quarter ended September 30, 2007. The decrease was due to the higher average cash and short term investment balances in 2007 than in 2008.

The discontinued operations reflect the income and expense of the former Prolieve division. These assets were sold to Boston Scientific Corporation on June 21, 2007 for \$60 million. See Note 12 to the financial statements for further detail on the discontinued operations.

### *Comparison of the Nine Months Ended September 30, 2008 and 2007.*

	Nine Months Ended September 30,		Change Dollars	Percent
	2008	2007		
<b>Operating expenses:</b>				
Research and development	\$ 8,422,143	\$ 6,078,520	\$ 2,343,623	39%
General and administrative	1,586,322	4,826,087	(3,239,765)	-67%
Total operating expenses	10,008,465	10,904,607	(896,142)	-8%
Interest income / (expense), net	52,765	(172,150)	224,915	-131%
Other expense, net	(896,377)	(439,211)	(457,166)	104%
Loss from continuing operations	(10,852,077)	(11,515,968)	663,891	-6%
<b>Discontinued Operations (Note 12)</b>				
Income from discontinued operations (including gain on sale of \$48,029,793)		50,029,211	(50,029,211)	-100%
Income tax expense		(274,000)	274,000	-100%
Income from discontinued operations		49,755,211	(49,755,211)	-100%
Net (loss) / income	\$ (10,852,077)	\$ 38,239,243	\$ (49,091,320)	-128%

The increase of \$2,343,623, or 39%, in research and development expense during the nine months ended September 30, 2008 in comparison to 2007 was primarily due to:

- Increase in CRO and clinical costs related to the Phase III HCC study \$ 2,242,000
- Increase in drug development and manufacturing costs due to increase in supplies of ThermoDox® for clinical trials 246,000
- Increase in travel expenses due to site visits related to the Phase III Primary Liver Cancer trial 122,000
- Increase in salaries and benefits due to clinical staff additions 109,000
- Decrease in legal fees due to the non-recurrence of patent and trademark costs (149,000)
- Decrease in consulting fees (307,000)

The \$3,239,765, or 67%, decrease in general and administrative expense during the quarter ended September 30, 2008 as compared to the same period of 2007 was primarily attributable to:

•	Decrease in the indemnity reserve related to the sale of the Prolieve Assets (see Note 12 to the Financial Statements)	\$	(1,576,000)
•	Decrease in salaries, benefits, and relocation costs due to head count reductions		(1,196,000)

Table of Contents

• Decrease in consulting fees due to the non-recurrence of financial consultants used in the first quarter of 2007 as a result of the then controller's departure and the termination of certain strategic business advisors	(361,000)
• Decrease in legal fees due to the non-recurrence of the fees associated with the American Medical Systems lawsuit	(124,000)
• Decrease in stockholder costs due to the non-recurrence of proxy solicitation costs in 2007	(114,000)
• Decrease in corporate insurances due to the elimination of the product liability insurance related to the sale of the Prolieve assets	(82,000)
• Increase in investor/public relation costs	110,000
• Increase in occupancy costs due to higher taxes and utilities	19,000

Net interest income for the nine months ended September 30, 2008 was \$52,765, compared to a net expense of \$172,150 for the nine months ended September 30, 2007. This change was due to the repayment of the loan to Boston Scientific Corporation during the quarter ended June 30, 2007.

The discontinued operations reflect the income and expense of the former Prolieve division. These assets were sold to Boston Scientific Corporation on June 21, 2007 for \$60 million. See Note 12 to the financial statements for further detail on the discontinued operations.

*Comparison of Discontinued Operations for the three months ended September 30, 2008 and 2007.*

	Three Months Ended September 30,		Dollars	Change Percent
	2008	2007		
Revenues				
Net sales of equipment and parts	\$	\$	\$	0%
Cost of Sales				0%
Gross Profit				0%
Operating expenses:				
Research and development		(33,054)	33,054	-100%
Total operating expenses		(33,054)	33,054	-100%
Income from operations		33,054	(33,054)	-100%
Gain on sale of Prolieve assets				
Other income, net				0%
Net income before taxes	\$	\$ 33,054	\$ (33,054)	-100%
Income tax expense				0%
Net income from discontinued operations	\$	\$ 33,054	\$ (33,054)	-100%

The Prolieve assets were sold to Boston Scientific Corporation on June 21, 2007. There were no ongoing activities related to the Prolieve business during 2008. The negative research and development costs of \$33,054 for the quarter ended September 30, 2007 represent the expense reimbursements from Boston Scientific Corporation under the transition services agreement.

*Comparison of Discontinued Operations for the nine months ended September 30, 2008 and 2007.*

Table of Contents

	Nine Months Ended September 30,		Change Dollars	Percent
	2008	2007		
<b>Revenues</b>				
Net sales of equipment and parts	\$	\$ 5,995,821	\$ (5,995,821)	-100%
Cost of Sales		3,018,765	(3,018,765)	-100%
Gross Profit		2,977,056	(2,977,056)	-100%
<b>Operating expenses:</b>				
Research and development		1,247,479	(1,247,479)	-100%
Total operating expenses		1,247,479	(1,247,479)	-100%
Income from operations		1,729,577	(1,729,577)	100%
Gain on sale of Prolieve assets		48,029,793	(48,029,793)	100%
Other income, net		269,841	(269,841)	-100%
Net income before taxes		50,029,211	(50,029,211)	100%
Income tax expense		274,000	(274,000)	100%
Net income from discontinued operations	\$	\$ 49,755,211	\$ (49,755,211)	100%

The Prolieve assets were sold to Boston Scientific Corporation on June 21, 2007. There were no ongoing activities related to the Prolieve business during 2008.

**Financial Condition, Liquidity and Capital Resources**





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

Celsion's core business activity is the development of products to treat cancer and other diseases and to commercialize those products to generate a return on investment for its stockholders through one of several means including: (a) selling products directly to end users; (b) selling products through a distributor; or (c) licensing its technology to third parties and generating income through royalties and milestone payments. This business model will generate uneven cash flows, inasmuch as continuing development expenditures will not necessarily be matched by revenues from one of the above sources. In the event that annual development expenditures are not covered by current revenues, funding will be provided from other sources including any cash on hand, revenues provided as above, income generated from licensing agreements and debt or equity funding raised in the capital markets.

### *Working Capital*

<b>Working Capital</b>	<b>September 30, 2008</b>	<b>December 31, 2007</b>
Cash and short term investments	\$ 8,969,346	\$ 5,937,373
Total current assets	24,178,254	21,424,400
Total current liabilities	5,399,687	8,118,606
Working capital	18,778,567	13,305,794

The increase in cash and short term investments during the nine months ended September 30, 2008 is due to the collection of the \$15 million receivable from Boston Scientific, less amounts used in the Company's operations. The decrease in current liabilities is primarily the result of the decrease in the indemnity reserve (see Note 12) and the payment of accrued income taxes.

Table of Contents**Cash Flow**

Since inception, our expenses have significantly exceeded our revenues, resulting in an accumulated deficit of \$65,989,834 at September 30, 2008. We have incurred negative cash flows from operations since our inception and have funded our operations primarily through the sale of equity securities and more recently through the sale of our Prolieve assets.

Cash Flows	Nine months ended September 30,	
	2008	2007
Cash provided by / (used in) operating activities	\$ 3,611,936	\$ (7,048,073)
Cash flow (used in) / provided by investing activities	(5,227,613)	7,326,172
Cash flow (used in) / provided by financing activities	(503,440)	1,074,601

The net cash provided by the Company's operating activities for the nine months ended September 30, 2008 was largely attributable to the collection of the \$15,000,000 receivable from Boston Scientific offset by the loss for the period of \$10,852,077. For the nine months ended September 30, 2007, the cash used in operating activities was the result of the loss from continuing operations of \$11,515,968 offset by net collections on accounts receivable of \$1,653,023 and the reduction of an escrow account liability of \$1,824,740.

The net cash used in the Company's investing activities for the nine months ended September 30, 2008 was primarily due to the net purchases of short term investments of \$5,133,115. For the nine months ended September 30, 2007, the cash provided by investing activities was the result of the \$9,958,615 in proceeds from the sale of the Prolieve Assets less the payment of a licensing fee in the amount of \$1,600,000 and the net purchase of short term investments in the amount of \$900,000.

The net cash used in financing activities for the nine months ended September 30, 2008 was primarily the result of payments on the note payable of \$503,840. For the same period in 2007, the cash provided by financing activities were the result of the proceeds on the note payable of \$1,181,925, less payments on the note of \$107,324.

For the balance of fiscal year 2008, we expect to expend approximately \$3,000,000 for clinical testing of liver cancer and breast cancer treatment systems as well as corporate overhead, all of which we expect to fund from cash on hand. The foregoing is an estimate, based upon assumptions as to the scheduling of institutional clinical research and testing personnel, the timing of clinical trials and other factors, not all of which are fully predictable.

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

We are exposed to interest rate risk on investments of our excess cash. The primary objective of our investment activities is to preserve capital. To achieve this objective and minimize the exposure due to adverse shifts in interest rates, we invest in high quality short-term maturity commercial paper, municipal bonds, and money market funds operated by reputable financial institutions in the United States. Due to the nature

of our investments, we believe that we do not have a material interest rate risk exposure.

**Item 4. Controls and Procedures**



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

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, 2008, 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

Table of Contents

quarter ended September 30, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II  
OTHER INFORMATION**

**Item 1. Legal Proceedings**

None.

**Item 1A. Risk Factors.**

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2007, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K are not the only risks facing the Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

**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.**

- 11 Statement Re: Computation of Earnings Per Share. (Filed herewith)
- 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 Interim Chief Accounting 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 of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (Furnished herewith)
- 32.2 Certification of Interim Chief Accounting Officer pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (Furnished herewith)

**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 14, 2008

**CELSION CORPORATION**

Registrant

By: */s/ Michael H. Tardugno*

Michael H. Tardugno  
President and Chief Executive Officer

By: */s/ Paul B. Susie*

Paul B. Susie  
Chief Accounting Officer  
Principal Financial Officer