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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, 2004

or

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

Commission file number 000-14242

CELSION CORPORATION
(Exact Name of Registrant as Specified in its Charter)

Delaware	**52-1256615**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. employer identification no.)**

10220-L Old Columbia Road, Columbia, Maryland 21046-2364
(Address of Principal Executive Offices) (Zip Code)

(410) 290-5390
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 10, 2004, the Registrant had outstanding 160,714,497 shares of Common Stock, $.01 par value.

SEC 1296 (10-04) **Potential persons who are to respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB control number.**

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PART I
FINANCIAL INFORMATION

Item 1. Financial Statements.

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CELSION CORPORATION
BALANCE SHEETS
September 30, 2004 and December 31, 2003

ASSETS

	September 30, 2004	December 31, 2003
	(Unaudited)	(Unaudited) (1)
Current assets:		
Cash	$ 13,952,709	$ 12,272,407
Account receivable – trade	576,049	—
Other receivables	68,077	16,753
Materials	1,365,397	838,992
Work-in-process	—	37,308
Finished goods	1,817,126	41,410
Prepaid expenses	106,118	361,967
Total current assets	17,885,476	13,568,837
Property and equipment - at cost:		
Furniture and office equipment	174,818	146,508
Computer hardware and software	256,822	218,758
Laboratory, shop and production equipment	585,745	212,379
Leasehold improvements	120,101	107,258
	1,137,486	684,903
Less accumulated depreciation	431,137	296,068
Net value of property and equipment	706,349	388,835
Other assets:		
Investment in Celsion China, Ltd.	151,799	—
Escrow account – license fee	2,002,687	—
Deposits	17,706	23,622
Prepaid inventory development costs	24,500	417,453
Patent licenses (net of amortization)	33,657	41,087
Total other assets	2,230,349	482,162
Total assets	$ 20,822,174	$ 14,439,834

LIABILITIES AND STOCKHOLDERS' EQUITY

	September 30, 2004	December 31, 2003
	(Unaudited)	(Unaudited) (1)
Current liabilities:		
Accounts payable – trade	$ 1,354,795	$ 631,097
Accrued non-cash compensation	35,696	153,316
Other accrued liabilities	703,667	202,426
Current portion of deferred revenue	571,428	—
Total current liabilities	2,665,586	986,839
Deferred revenue – license fee	3,095,239	—
Stockholders' equity:		
Common Stock $0.01 par value: 200,000,000 and 250,000,000 shares authorized, 160,679,331 and 148,034,473 shares issued and outstanding, at September 30, 2004 and December 31, 2003, respectively	1,606,793	1,480,345
Additional paid-in capital	84,534,622	72,204,867
Accumulated deficit	(71,080,066)	(60,232,217)
Total stockholders' equity	15,061,349	13,452,995
Total liabilities and stockholders' equity	$ 20,822,174	$ 14,439,834

See accompanying notes.

(1) During the last quarter of calendar year 2003, the Company changed its fiscal year end from September 30 to December 31. The balance sheet at September 30, 2003 was audited but the balance sheet at December 31, 2003 was not audited.

CELSION CORPORATION
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Revenue:				
Sales	$ 539,549	$ —	$ 1,082,494	$ —
Cost of sales	436,100	—	810,804	—
Gross margin	103,449	—	271,690	—
Other manufacturing and distribution costs	36,737	—	85,736	—
Operating expenses:				
General and administrative	601,966	1,499,257	2,538,515	3,565,557
Research and development.	2,973,522	2,219,425	8,945,864	7,801,420
Total operating expenses	3,575,488	3,718,682	11,484,379	11,366,977
Loss from operations	(3,508,776)	(3,718,682)	(11,298,425)	(11,366,977)
License fee income	142,857	—	333,333	—
Interest income	65,830	15,915	165,444	27,727
Loss from Investment in Celsion China, Ltd	(10,494)	—	(48,201)	—
Loss before income taxes	(3,310,583)	(3,702,767)	(10,847,849)	(11,339,250)
Income taxes	—	—	—	—
Net Loss	$ (3,310,583)	$ (3,702,767)	$ (10,847,849)	$ (11,339,250)
Dividends on preferred stock	—	(28,819)	—	(130,918)
Net loss attributable to common stockholders	$ (3,310,583)	$ (3,731,586)	$ (10,847,849)	$ (11,470,168)
Net loss per common share (basic and diluted)	$ (0.02)	$ (0.03)	$ (0.07)	$ (0.10)
Weighted average shares outstanding	160,639,842	136,135,077	158,062,867	119,818,566

See accompanying notes.

CELSION CORPORATION

STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2004	2003
Cash flows from operating activities:		
Net loss	$(10,847,849)	$ (11,339,250)
Non-cash items included in net loss:		
Depreciation and amortization	142,499	75,657
Amortization of deferred revenue – license fee income	(333,333)	—
Loss from investment in Celsion China, Ltd	48,201	—
Stock-based compensation	(380,420)	3,677,283
Net changes in:		
Trade receivable	(576,048)	—
Other receivables	(51,324)	(90,927)
Inventories	(2,264,813)	(203,435)
Prepaid expenses	255,850	164,954
Escrow account – license fee	(2,002,687)	—
Prepaid inventory development costs	392,951	37,004
Accounts payable-trade	723,698	89,514
Other accrued liabilities.	383,620	381,540
Deposits	5,916	—
Deferred revenue – license fee	4,000,000	—
Net cash used by operating activities	(10,503,739)	(7,207,660)
Cash flows from investing activities:		
Investment in Celsion China, Ltd	(200,000)	—
Purchase of property and equipment	(452,583)	(111,556)
Net cash used by investing activities	(652,583)	(111,556)
Cash flows from financing activities:		
Proceeds of stock issuances.	12,836,624	18,179,143
Payment of note payable	—	(500,000)
Net cash provided by financing activities	12,836,624	17,679,143
Net increase in cash	1,680,302	10,359,927
Cash at beginning of period	12,272,407	1,050,606
Cash at end of the period	$ 13,952,709	$ 11,410,533

See accompanying notes.

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS

Note 1. Basis of Presentation

The accompanying unaudited condensed 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 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-month and nine-month periods ended September 30, 2004 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 September 30, 2003. On December 3, 2003, the Company filed with the Securities and Exchange Commission (SEC) a Current Report on Form 8-K reporting, under Item 5, that, effective December 31, 2003, it was changing its fiscal year end from September 30 to December 31.

Note 2. Common Stock Outstanding and Per Share Information

For the nine-month periods ended September 30, 2004 and 2003, per share data is based on the weighted average number of shares of common stock, par value $0.01 per share (Common Stock), outstanding. Outstanding warrants and options that can be converted into Common Stock are not included, as their effect is anti-dilutive.

Note 3. Fair Value Accounting for Stock Plans

The Company has long-term compensation plans that permit the granting of incentive awards in the form of stock options. The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standard No. 123 (SFAS 123), which allow companies to continue to measure compensation costs for stock options granted to employees using the value-based method of accounting prescribed by APB Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). Celsion has elected to follow APB 25 and the related interpretations in accounting for its employee stock options.

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS 123 to its stock-based employee plans:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net loss attributable to common stockholders, as reported	$ (3,310,583)	$ (3,731,586)	$(10,847,849)	$(11,470,168)
Adjust for stock-based employee compensation expense included in reported net loss	—	184,126	(1,030,684)	967,376
Adjust for total stock-based employee compensation expense determined using the fair value-based method for all awards	(156,009)	(89,389)	617,277	(988,105)
Pro forma net loss	$ (3,466,592)	$ (3,636,849)	$(11,261,256)	$(11,490,897)
Loss per share:				
Basic–as reported	$ (0.02)	$ (0.03)	$ (0.07)	$ (010)
Basic–pro forma	$ (0.02)	$ (0.03)	$ (0.07)	$ (0.10)

Note 4. Investment in Celsion China, Ltd.

On December 15, 2003, we announced the formation of a joint venture with Asia Pacific Life Science Group, Ltd., a Hong Kong-based investment company, to develop our technologies and distribute our products in greater China. We made a $200,000 investment to purchase a 45.65% equity position in Celsion China, Ltd. on February 5, 2004.

The financial records of Celsion China, Ltd. as of September 30, 2004 reflected the following:

	US$
Cash	$ 333,514
Deposits	—
Prepaid expense	108
Total current assets	333,622
Fixed assets, net	449
Total assets	$ 334,071
Liabilities	$ —
Equity	439,658
Accumulated deficit	(105,587)
Total liabilities and equity	$ 334,071

Celsion accounts for its investment in Celsion China, Ltd. under the equity method. The investees' functional currency is the Hong Kong Dollar. No foreign currency adjustment was necessary during the quarter ended September 30, 2004. The loss from this unconsolidated investee for the quarter can be recalculated as follows and is comprised of only general and administrative costs. Celsion China, Ltd. had no commercial sales for the quarter.

Quarterly deficit	$(22,987)
Ownership percentage	45.65%
Loss recorded for the quarter	$(10,494)

Celsion Corporation's balance sheet at September 30, 2004 reflects the investment in Celsion China in the account entitled "Investment in Celsion China, Ltd.," the components of which are as follows:

Initial cash investment	$200,000
45.65% accumulated loss	(48,201)
Net investment carrying value	$151,799

Note 5. Licensing Agreement

Celsion is a party to a Distribution Agreement dated January 21, 2003 with Boston Scientific Corporation (BSC or Boston Scientific). Under the Distribution Agreement, Celsion was entitled to a $4,000,000 licensing fee, effective upon the occurrence of a triggering event, in return for granting BSC a seven-year, royalty-free, exclusive right to market, distribute, import, export, use, sell and offer to sell Celsion's Prolieve™ Thermodilatation system worldwide, with the exception of China, Taiwan, Hong Kong, Macao, Mexico and Central and South America. The

condition was met and we received a payment from BSC during the quarter ended June 30, 2004 in the amount of $2,000,000. The remaining $2,000,000 was placed in an escrow account, pursuant to the terms of the Distribution Agreement. The escrow is designed to provide available funds for payment in the event of certain contingencies during the 36-month term of the escrow. The escrow is held in an interest-bearing account. Interest on the escrowed funds accrues for the benefit of Celsion, but becomes part of the balance of the account. All amounts held in the account at the end of the term of the escrow are payable to Celsion. However, Celsion bears full responsibility for payment of claims subject to the escrow in excess of available escrowed funds. The Company is recognizing the entire $4,000,000 licensing fee at the rate of $47,619 per month over a seven-year term which began March 1, 2004.

Note 6. Inventory

We have increased inventory levels to meet expected commercial sales requirements for both Prolieve Thermodilatation system control units and associated kits (catheters). September 30, 2004 and December 31, 2003 inventory balances are as follows:

	September 30, 2004	December 31, 2003
Control units	$ 1,856,347	$ 41,410
Kit components	1,124,343	791,467
Other parts and work-in-progress	201,833	84,833
Total inventory	$ 3,182,523	$ 917,710

Note 8. Accounts Payable

Accounts payable increased to $1,354,795 at the close of the current quarter, from $631,097, at December 31, 2003. The various categories of items that comprise accounts payable are as follows:

Control units	$ 537,374
Kit components	217,552
Other parts	805
Legal fees	54,527
Liposome costs	60,740
Patents	2,855
Recruiting	38,750
Travel	4,210
Consulting	261,175
Other	176,807
	$1,354,795

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 September 30, 2003 and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2004, as well as this Quarterly Report on Form 10-Q, 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 September 30, 2003 and in the Quarterly Report on Form 10-Q for the quarter ended March 31, 2004, as well as those set forth below and elsewhere in this Report.

The discussion of risks and uncertainties set forth in this Report and in our most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q for the quarter ended March 31, 2004, 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 and Recent Events

Celsion Corporation is a medical technology company applying proprietary focused-heat technology in the development and commercialization of products to treat cancer and other diseases. In 1989, we obtained premarketing approval (PMA) from the United States Food and Drug Administration (FDA) to use our microwave-based Microfocus 1000 heat therapy system on surface and subsurface tumors in conjunction with radiation therapy. We marketed this system until 1995. Since that time, we have been engaged in research and development of new treatment systems.

Our pipeline presently consists of the following products, in the indicated stages of development:

Product	Status
• Prolieve Thermodilatation system for the treatment of BPH	We received premarketing approval for the Prolieve system from the FDA on February 19, 2004. Since that time, we have been commercializing the Prolieve system through Boston Scientific.
• ThermoDox™ (Doxorubicin- laden thermo-liposome) plus heat for the treatment of cancer	Currently the subject of multi-site Phase I clinical trials, in conjunction with the Prolieve system (modified), for the treatment of prostate cancer. In addition, we have received an Investigational New Drug (IND) approval from the FDA to enable us to commence Phase I clinical trials in collaboration with the National Institutes of Health using ThermoDox in conjunction with radio frequency ablation in the treatment of liver cancer.
• Breast cancer treatment system	We have elected to terminate both branches of our pivotal Phase II trials using our advanced phase array technology in the treatment of small and late-stage breast cancer tumors. We currently are evaluating the feasibility of initiating studies with this product, either alone or in combination with ThermoDox or other chemotherapeutic agents.
• Cancer Repair Inhibitor (CRI)	Currently the subject of pre-clinical studies at Sloan-Kettering Cancer Institute.

Since 1995, we have generated only minimal revenues and have funded our operations primarily through private placements of our equity securities. During the quarter ended June 30, 2004, following FDA premarketing approval of our Prolieve Thermodilatation system on February 19, we received one-time licensing fees of $4,000,000 under our agreement with Boston Scientific, the distributor of our Prolieve system. During the quarter ended September 30, 2004, sales of Prolieve products generated revenues of $539,549. Until such time, if any, as we are able to complete development and testing of, and gain necessary regulatory approvals for, one or more of our other products, sales of Prolieve products will represent our only source of revenue. We presently do not have any committed sources of financing. Therefore, we are reliant on revenues from the sale of our Prolieve products and from funds generated through the sale of our securities to fund our ongoing operations.

The Prolieve system consists of a microwave generator and conductors, along with a computer and computer software programs that control the focusing and application of heat (control units), plus a specially designed, single-use catheter kit. We expect to continue to generate revenues from sales of control units and catheter kits. Under our agreement with Boston Scientific, we are entitled to receive our costs plus 50% of the "profit"—measured as the difference between such costs and the average selling price (determined in accordance with the agreement) for each control unit—and 50% of the revenue generated from the sale of catheter kits, for which Celsion bears the cost of goods sold. During the introduction of the Prolieve system, we anticipate that sales of both control units and catheter kits will increase. However, over time we expect that sales will level off.

Our principal costs consist of:

- Cost of sales, relating to the production and sale of Prolieve control units and catheter kits, which are being marketed by Boston Scientific under s seven-year agreement (expiring in 2011);
- 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 our ThermoDox plus heat and Cancer Repair Inhibitor systems and certain ongoing studies related to our Prolieve system, including the costs of contracting with Contract Research Organizations (CROs) for the management of our clinical trials, which costs are directly related to the number and size of ongoing studies; and the costs of development and design of other products and equipment; and
- Corporate overhead.

Our research and development activities, pre-clinical 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 until we have received permission to do so, in the form of a premarketing approval from the FDA. We received such premarketing approval for our Prolieve system on February 19, 2004. As we believe we are best suited to conduct or oversee basic research and development activities, to pursue a prototype product through clinical testing and regulatory approval, and to engage in initial manufacturing and marketing activities during product launch, we do not intend to engage in large-scale manufacturing or marketing with respect to our products. Instead, for the foreseeable future, we intend generally to outsource the manufacture of final commercial products, components and disposables, as well as the marketing of our products. Therefore, in connection with the approval and commercialization of each product, we will be required to identify and negotiate production and marketing arrangements with third parties, as we have done in connection with our Prolieve system.

On May 7, 2004, Celsion received a Warning Letter from the FDA regarding the Phase I and Phase II clinical trials of the Prolieve system, which had been completed in January 2002. The Warning Letter addressed four general areas—monitoring, investigator agreements, provision of information to investigators, and FDA reporting—in connection with the Prolieve studies. Since receipt of the Warning Letter, we have initiated short- and long-term

corrective and compliance measures to address fully the issues raised by the FDA, including adding additional senior personnel with significant clinical experience. Following receipt of the Warning Letter, Celsion retained consultants to assist in bringing the Company into compliance with FDA regulations and ensuring ongoing compliance with those regulations. Through September 30, 2004, Celsion had expended $254,744 in connection with such compliance consultants. While we anticipate additional expenditures of this nature during the fourth quarter of 2004, we do not expect to continue to make significant expenditures in this area during 2005. In addition, in order to ensure prompt and continuing compliance with FDA regulations in the conduct of our clinical trials, we have elected to replace our in-house monitoring staff with Contract Research Organizations (CROs). This outsourcing effort, which we expect to complete for our existing trials during the fourth quarter of 2004, will significantly increase the costs of our clinical trials although, as of the date of this Report, we are not able to quantify the increase.

The Company anticipates that, going forward, the increased costs associated with use of CROs in connection with clinical trials will be substantially offset by increasing revenues from sales of Prolieve products.

During the quarter ended September 30, 2004, Celsion conducted a voluntary “Class II” recall and field correction of the Prolieve system to correct a potential software malfunction that occurs if a procedure using the Prolieve system is ongoing when the system’s computer clock transitions through midnight. A Class II recall is a situation in which use of the product in question may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. In addition, the Company has developed, and, with FDA approval currently is implementing, a software upgrade that will eliminate the potential for the malfunction. This upgrade will apply to all Prolieve units currently in the field as well as all newly manufactured units. The costs of the recall and field correction were not, and the costs of the software upgrade are not expected to be, material.

Results of Operations

Comparison of Three Months Ended September 30, 2004 and Three Months Ended September 30, 2003

	Actual Results			
	Three Months Ended September 30,		Change	
	2004	2003	Dollars	Percent
Revenue:				
Sales	$ 539,549	$ —	$ 539,549	N/A
Cost of sales	436,100	—	436,100	N/A
Gross margin	103,449	—	103,449	N/A
Other manufacturing and distribution costs	36,737	—	36,737	N/A
Operating expenses:				
General and administrative	601,966	1,499,257	(897,291)	-41%
Research and development	2,973,522	2,219,425	754,097	26%
Total operating expenses	3,575,488	3,718,682	(143,194)	-4%
Loss from operations	$(3,508,776)	$(3,718,682)	$(209,906)	-6%
Interest income	$ 65,830	$ 15,915	$ 49,915	314%

The Company received a PMA for its Prolieve system from the FDA on February 19, 2004 and since that time has been engaged in the commercial introduction of the system through a distribution arrangement with Boston Scientific Corporation. Product sales for the current quarter are comprised of sales of Prolieve systems, catheter kits and miscellaneous parts to Boston Scientific. There were no product sales during the comparable quarter in 2003, which predated the commercial introduction of our Prolieve system.

Other manufacturing and distribution costs represent freight charges and incidental manufacturing costs.

The $897,291 (41%) decrease in general and administrative expense during the quarter ended September 30, 2004 as compared to the comparable period during 2003 was primarily attributable to a reduction in compensation expense ($73,873) as a result of a decrease in the cumulative value of repriced options issued under our employee stock option plan; a reduction in legal fees ($101,000) attributable to the retention of in-house counsel in May 2004; the timing of directors' fees and expenses and year-end accounting fees ($116,000) related to the fiscal year end change from September 30 to December 31; a reduction in professional fees for consulting and public/investors relations due to recording the cost of issuing warrants/options for services ($266,570); and various other reductions, including savings from a new building lease effective November 1, 2003.

The increase of $754,097 (26%) in research and development expense during the current quarter in comparison to the quarter ended September 30, 2003 was due primarily to the write-off of amounts previously classified as prepaid inventory costs ($379,000) related to the transfer of production for catheter kits to a new vendor; increase in staff and related recruiting and relocation expenses ($221,685) as we continue to fill critical positions; the value of certain payments in connection with the departure of William Gannon, former Medical Director ($129,984); and costs related to consultants hired to aid in clinical compliance efforts ($254,744), partially offset by various reductions, including a reduction in compensation expenses ($110,000) as a result of a decrease in the cumulative value of repriced options issued under our employee stock option plan

The net decrease of $143,194 in operating expenditures during the quarter ended September 30, 2004 when compared to the quarter ended September 30, 2003, as discussed above, combined with gross profit generated from the sale of Prolieve products during the most recent quarter, resulted in a decrease in the loss from operations for the three-month period ended September 30, 2003 of $209,906 or 6%, to $3,508,776 from $3,718,682 in the comparable period during the prior fiscal year.

Interest income increased by 314%, or $49,515, for the quarter ended September 30, 2004 from the comparable quarter in 2003. The increase was due to a combination of higher average cash balances and a higher rate of return on account balances. The higher cash balances were, in turn, the result of private placements of our equity securities during the last 12 months, as well as payments to us in connection with the sale of our Common Stock to and licensing fees from Boston Scientific, as discussed elsewhere in this Report.

Comparison of Nine Months Ended September 30, 2004 and Nine Months Ended September 30, 2003

	Actual Results			
	Nine Months Ended September 30,		Change	
	2004	2003	Dollars	Percent
Revenue:				
Sales	$ 1,082,494	$ —	$ 1,082,494	N/A
Cost of sales	810,804	—	810,804	N/A
Gross margin	271,690	—	271,690	N/A
Other manufacturing and distribution costs	85,736	—	85,736	N/A
Operating expenses:				
General and administrative	2,538,515	3,565,557	(1,027,042)	-29%
Research and development	8,945,864	7,801,420	1,144,444	15%
Total operating expenses	11,484,379	11,366,977	117,402	1%
Loss from operations	$(11,298,425)	$(11,366,977)	$ (68,552)	-1%
Interest income	$ 165,444	$ 27,727	$ 137,717	497%

The Company received a PMA for its Prolieve system from the FDA on February 19, 2004 and since that time has been engaged in the commercial introduction of the system through a distribution arrangement with Boston Scientific. Product sales for the nine months ended September 30, 2004, all of which were generated subsequent to

February 19, 2004, consist of the sale of catheter kits and miscellaneous parts to Boston Scientific. There were no product sales during the comparable period in 2003, which predated the commercial introduction of our Prolieve system.

Other manufacturing and distribution costs represent freight charges and incidental manufacturing costs.

The $1,027,042 (29%) decrease in general and administrative expense during the nine months ended September 30, 2004 as compared to the nine months ended September 30, 2003 was attributable primarily to a reduction in compensation expense ($537,675) as a result of a decrease in the cumulative value of repriced options issued under our employee stock option plan; a reduction in legal fees ($178,000) attributable to the retention of in-house counsel in May 2004; the timing of directors' fees and expenses and year-end accounting fees ($116,000) related to the fiscal year end change from September 30 to December 31; a reduction in professional fees for consulting and public/investor relations due to recording the value of options issued for services ($266,570); and various other reductions including savings from a new building lease effective November 1, 2003, partially offset by a $410,000 payment to Legg Mason paid in the quarter ended March 31, 2004 for investment banking services rendered in connection with negotiation of our strategic relationship with Boston Scientific, which became due with receipt of the PMA.

The increase of $1,144,444 (15%) in research and development expense during the nine months ended September 30, 2004 was due primarily to costs in the approximate amount of $972,000 recorded with respect to the Separation and Release Agreement with Mr. Daniel S. Reale in connection with Mr. Reale's resignation as an Executive Vice President and President of our Oncology Division, as reflected in our Report on Form 8-K filed with the SEC on March 1, 2004; a termination fee payment in the amount of $350,000 in connection with migration of manufacturing of the catheter kits for our Prolieve system to a new supplier; the write-off of amounts previously classified as prepaid inventory costs ($379,000) related to the production of catheter kits; cash bonuses in the approximate amount of $554,000 granted to our employees in connection with receipt of the PMA for the Prolieve system; an increase in salaries, recruiting and relocation expenses for new hires ($221,685) as we continue to fill critical positions; the value of certain payments in connection with the departure of William Gannon, former Medical Director ($129,984); and increased costs related to consultants hired to aid in clinical compliance efforts ($254,744). These additional expenses during the most recent nine-month period were substantially offset by a decrease of $1,517,000 in compensation expense as a result of a reduction in the cumulative value of repriced employee stock options. During the nine months ended September 30, 2004 substantially all of the net increase in operating expenses not due to the unusual items discussed above was attributable to increased personnel and consulting costs in connection with completion of the PMA process and the commencement of commercialization of the Prolieve system.

In contrast, our expenses for the nine months ended September 30, 2003 included an unusual, nonrecurring payment in the amount of $2,175,000 to Duke University in January 2003 under our licensing arrangements for our thermo-liposome technology.

The net increase of $117,402 in operating expenditures during the nine months ended September 30, 2004 when compared to the comparable period during 2003, as discussed was partially offset by revenues generated from the sale of Prolieve products during the first nine months of 2004, and resulted in an increase in the loss from operations for the nine-month period ended September 30, 2004 of $68,552 or 1%, to $11,298,425 from $11,366,977 in the comparable period during the prior fiscal year.

Interest income increased by 497%, or $137,717, for the nine months ended September 30, 2004 from the comparable period in 2003. The increase was due to a combination of higher average cash balances and a higher rate of return on account balances. The higher cash balances were, in turn, the result of private placements of our equity securities during the last 12 months, as well as payments to us in connection with the sale of our Common Stock to and licensing fees from Boston Scientific, as discussed elsewhere herein.

Liquidity and Capital Resources

Since inception, our expenses have significantly exceeded our revenues, resulting in an accumulated deficit of

$71,080,066 at September 30, 2004. We have incurred negative cash flows from operations since our inception and have funded our operations primarily through the sale of equity securities. In addition, during the nine months ended September 30, 2004, we received aggregate payments in the amount of $10,000,000 (of which $2,000,000 remains subject to escrow, as discussed elsewhere herein) from Boston Scientific in the form of payments for shares of our Common Stock and of licensing fees for our Prolieve system. As of September 30, 2004, we had total current assets of $17,885,476, including cash of $13,952,709, compared with current liabilities of $2,665,586, resulting in a working capital surplus of $15,219,890. As of December 31, 2003, we had $12,272,407 in cash and total current assets of $13,568,837, compared with current liabilities of $986,839, which resulted in a working capital surplus of $12,581,998 at the fiscal year end. Net cash used in the Company's operating activities was $10,503,739 for the nine months ending September 30, 2004, compared to $7,207,660 for the nine months ended September 30, 2003.

On January 31, 2004, the Company issued 2,727,273 shares of its Common Stock and associated warrants to purchase 818,182 shares of its Common Stock in connection with a private placement offering. The private placement was made exclusively to one institutional "accredited investor" as that term is defined in Rule 501 under the Securities Act of 1933, as amended (the Securities Act). These securities were issued at a price of $1.10 per share and associated fractional warrant. The warrants issued to the investor entitle the investor to purchase that number of shares of Common Stock equal to 30% of the number of shares of Common Stock initially issued to the investor in the offering. The warrants are exercisable at $1.50 per share of Common Stock, subject to call under certain circumstances. In connection with the private placement, the Company issued warrants to a finder to purchase 283,636 shares of its Common Stock at an exercise price of $1.10 per share. The Company realized gross proceeds in the amount of $3,000,000 and paid a cash finder's fee in the amount of $240,000 in connection with the sale of these securities. On March 2, 2004, the Company issued 2,083,333 shares of its Common Stock to Boston Scientific Corporation for cash consideration of $4,000,000 pursuant to the Transaction Agreement between the Company and Boston Scientific (the Transaction Agreement). On April 7, 2004, the Company issued 1,273,885 shares of its Common Stock to Boston Scientific for cash consideration of $2,000,000 pursuant to the Transaction Agreement. In addition, during the nine months ended September 30, 2004, the Company issued a total of 4,762,667 shares of its Common Stock for cash consideration of $2,985,909 upon exercise of outstanding stock purchase warrants. The warrants were exercised in accordance with their respective terms at prices ranging from $0.39 to $1.20 per share. The Company also issued 1,641,466 shares of its Common Stock for cash consideration of $1,090,715 upon exercise of stock options.

During the nine months ended September 30, 2004, we expended approximately $11,370,902 (including research and development outlays, compensation expenses, including recruitment and relocation expenses for new employees and increased business development costs for BPH, liposome and gene therapy products) for clinical testing of our breast cancer and prostate cancer treatment systems, as well as corporate overhead. For fiscal year ending December 31, 2004, we expect to expend a total of approximately $14,000,000 for clinical testing of our breast cancer, prostate cancer and liver cancer treatment systems, as well as corporate overhead, all of which we have funded, or expect to fund, from our current resources. On February 19, 2004, we received FDA approval for our Prolieve Thermodilatation system, clearing the path for Celsion and Boston Scientific to introduce the BPH treatment system. We anticipate that sales of Prolieve control units and catheter kits will generate revenues on a going-forward basis, although it is not possible for us to predict the timing or amount of such revenues. The foregoing amounts are estimates based upon assumptions as to the scheduling of institutional clinical research and testing personnel, the timing of clinical trials and other factors that are not fully predictable or within our control.

On January 5, 2004, we issued an Irrevocable Letter of Credit (LOC) in the amount of $500,000 to Sanmina-SCI Corporation (Sanmina), the manufacturer for our Prolieve Thermodilatation system. The LOC, which by its terms expired on June 30, 2004, was renewed through December 31, 2004 at the request of Sanmina. The LOC is collateralized by $650,000 of U.S. Treasury Bills. Until the LOC termination date, we are restricted from use of these funds.

We anticipate that our available cash on hand (without regard to the $2,000,000 plus interest being held in escrow under our agreement with Boston Scientific) will be sufficient to fund our activities through December 2005. However, our dependence on raising additional capital will continue at least until we are able to generate significant sales of our Prolieve system and related kits, as well as of products based on our other new technologies. Our future capital requirements and the adequacy of our financing depend upon numerous factors, including the successful

commercialization of our Prolieve Thermodilatation system, progress in product development efforts, progress with pre-clinical studies and clinical trials, the cost and timing of production arrangements, the development of effective sales and marketing activities, the cost of filing, prosecuting, defending and enforcing intellectual property rights, competing technological and market developments and the development of strategic alliances for the marketing of our products. We will be required to obtain additional funding through equity or debt financing, strategic alliances with corporate partners and others, or through other sources not yet identified. We do not have any committed sources of additional financing, and cannot guarantee that additional funding will be available in a timely manner, on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, scale back or eliminate certain aspects of our operations or attempt to obtain funds through unfavorable arrangements with partners or others that may require us to relinquish rights to certain of our technologies, product candidates, products or potential markets or which otherwise may be materially unfavorable to us. Furthermore, if we cannot fund our ongoing development and other operating requirements, particularly those associated with our obligation to conduct clinical trials under our licensing agreements, we will be in breach of our commitments under those licensing agreements and could therefore lose our license rights, which could have material adverse effects on our business.

Item 3. Quantitative and Qualitative Disclosure About Market Risk.

Not applicable.

Item 4. Controls and Procedures

We have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) under the supervision of our Chief Executive Officer and Chief Financial Officer as of the end of the fiscal quarter covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2004, our disclosure controls and procedures were effective to ensure that information required to be disclosed in reports that Celsion files or submits under the Exchange Act is recorded, processed, summarized and reported in a timely manner. In designing, implementing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and implemented, may not be effective in all circumstances. However, we believe that our disclosure controls and procedures provide reasonable assurance of achieving the desired disclosure control objectives.

There have not been any significant changes in our internal controls or in other factors subsequent to the date the evaluation was completed that could significantly affect such controls and no corrective actions have been required with regard to significant deficiencies and material weaknesses.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings.

Not applicable.

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

During the fiscal quarter ended September 30, 2004 the Company issued a total of 52,264 shares of its Common Stock to three outside consultants for services valued at $37,140. These shares are restricted stock, endorsed with the Company's standard restricted stock legend, with stop transfer instructions recorded by the transfer agent. Accordingly, the Company views the shares issued as exempt from registration under Sections 4(2) and/or 4(6) of the Securities Act.

During nine months ended September 30, 2004 the Company issued a total of 52,264 shares of its Common Stock to consultants for services valued at $37,140. These shares are restricted stock, endorsed with the Company's standard restricted stock legend, with stop transfer instructions recorded by the transfer agent. Accordingly, the Company views the shares issued as exempt from registration under Sections 4(2) and/or 4(6) of the Securities Act.

Item 3. Defaults upon Senior Securities.

Not applicable.

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

None.

Item 5 Other Information.

Not applicable.

Item 6. Exhibits.

11	Statement Re. Computation of Earnings Per Share.
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.
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.
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.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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.

DATE: November 12, 2004

CELSION CORPORATION
Registrant

By: /s/ Augustine Y. Cheung

Augustine Y. Cheung
President and Chief Executive Officer

By: /s/ Anthony P. Deasey

Anthony P. Deasey
Chief Operating Officer and Chief Financial Officer
(Principal Financial and Chief Accounting Officer)

Exhibit 11

CELSION CORPORATION
COMPUTATION OF EARNINGS PER SHARE

CELSION CORPORATION
COMPUTATION OF EARNINGS PER SHARE

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net loss attributable to common stockholders	$ (3,310,583)	$ (3,731,586)	$ (10,847,849)	$ (11,470,168)
Net (loss) income per common share*	$ (0.02)	$ (0.03)	$ (0.07)	$ (0.10)
Weighted average shares outstanding	160,639,842	136,135,077	158,062,867	119,818,566

* Common stock equivalents have been excluded from the calculation of net loss per share as their inclusion would be anti-dilutive.

Exhibit 31.1

CELSION CORPORATION
CERTIFICATION

I, Augustine Y. Cheung, certify that:

1. I have reviewed this report on Form 10-Q of Celsion Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2004

/s/ Augustine Y. Cheung

Augustine Y. Cheung
Chief Executive Officer
Celsion Corporation

Exhibit 31.2

CELSION CORPORATION
CERTIFICATION

I, Anthony P. Deasey, certify that

1. I have reviewed this report on Form 10-Q of Celsion Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2004

/s/ Anthony P. Deasey

Anthony P. Deasey
Chief Financial Officer
Celsion Corporation

Exhibit 32.1

CELSION CORPORATION
CERTIFICATION
PURSUANT TO 18 UNITED STATES CODE § 1350

The undersigned hereby certifies that the Quarterly Report on Form 10-Q for the period ended September 30, 2004 of Celsion Corporation (the Company) filed with the Securities and Exchange Commission on the date hereof fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Augustine Y. Cheung

Augustine Y. Cheung
Chief Executive Officer

November 12, 2004

Exhibit 32.2

CELSION CORPORATION
CERTIFICATION
PURSUANT TO 18 UNITED STATES CODE § 1350

The undersigned hereby certifies that the Quarterly Report on Form 10-Q for the period ended September 30, 2004 of Celsion Corporation (the Company) filed with the Securities and Exchange Commission on the date hereof fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Anthony P. Deasey

Anthony P. Deasey
Chief Financial Officer

November 12, 2004