CELSION CORP
Form 10-Q/A
November 09, 2005
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT #1

TO FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2005

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 x No ¨

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

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

As of November 7, 2005 the Registrant had outstanding 160,901,600 shares of Common Stock, $.01 par value.

Table of Contents

This amendment is filed solely for the purpose of correcting a typographical error in Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations, relating to the number of machines in service at September 30, 2005.

TABLE OF CONTENTS

Table of Contents

PART I

FINANCIAL INFORMATION

Item 1. Financial Statements.

Index to Financial Statements

Table of Contents

CELSION CORPORATION

BALANCE SHEETS

September 30, 2005 and December 31, 2004

ASSETS

	September 30, 2005 (Unaudited)	December 31, 2004
Current assets:		
Cash	$ 9,254,653	$ 10,483,816
Account receivable trade	851,838	691,938
Other receivables	23,802	91,101
Inventories	4,008,126	2,201,663
Prepaid expenses	509,939	679,237
Total current assets	14,648,358	14,147,755
Property and equipment - at cost:		
Furniture and office equipment	178,282	176,666
Computer hardware and software	298,867	264,774
Laboratory, shop and production equipment	643,704	607,418
Leasehold improvements	124,026	120,101
	1,244,879	1,168,959
Less accumulated depreciation	651,625	486,861
Net value of property and equipment	593,254	682,098
Other assets:		
Investment in Celsion China, Ltd.	41,196	107,797
Escrow account license fee	2,036,269	2,007,002
Deposits	17,706	17,706
Prepaid inventory development costs	17,450	58,214
Patent licenses (net of amortization)	24,490	31,365
Total other assets	2,137,111	2,222,084
Total assets	$ 17,378,723	$ 17,051,937

Table of Contents

LIABILITIES AND STOCKHOLDERS EQUITY

	September 30, 2005	December 31, 2004
	(Unaudited)	
Current liabilities:		
Accounts payable trade	$ 1,622,412	$ 819,168
Accrued non-cash compensation	71,391	53,543
Other accrued liabilities	1,056,104	684,550
Current portion of deferred revenue	571,428	571,428
Total current liabilities	3,321,335	2,128,689
Loan Payable	6,055,458	
Deferred revenue license fee	2,523,810	2,952,382
Total liabilities	11,900,603	5,081,071
Stockholders equity:		
Common Stock $0.01 par value: 250,000,000 shares authorized, 160,901,600 and 160,749,497 shares issued and outstanding, at September 30, 2005 and December 31, 2004, respectively	1,609,016	1,607,494
Additional paid-in capital	84,647,524	84,580,637
Accumulated deficit	(80,778,420)	(74,217,265)
Total stockholders equity	5,478,120	11,970,866
Total liabilities and stockholders equity	$ 17,378,723	$ 17,051,937

See accompanying notes.

Table of Contents

CELSION CORPORATION

STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	**2004**	**2005**	**2004**
Revenue:				
Sales	$ 3,205,829	$ 539,549	$ 7,972,332	$ 1,082,494
Cost of sales	2,186,640	472,837	5,385,196	896,540
Gross margin	1,019,189	66,712	2,587,136	185,954
Operating expenses:				
Research and development	2,293,562	2,973,522	6,997,480	8,945,864
General and administrative	810,244	601,966	2,648,247	2,538,515
Total operating expenses	3,103,806	3,575,488	9,645,727	11,484,379
Loss from operations	(2,084,617)	(3,508,776)	(7,058,591)	(11,298,425)
License fee income amortization	142,857	142,857	428,571	333,333
Interest income	65,838	65,830	191,077	165,444
Interest expense	(55,611)		(55,611)	
Loss from investment in Celsion China, Ltd	(22,332)	(10,494)	(66,601)	(48,201)
Loss before income taxes	(1,953,865)	(3,310,583)	(6,561,155)	(10,847,849)
Income taxes				
Net Loss	$ (1,953,865)	$ (3,310,583)	$ (6,561,155)	$ (10,847,849)
Net loss per common share (basic and diluted)	$ (0.01)	$ (0.02)	$ (0.04)	$ (0.07)
Weighted average shares outstanding	160,901,600	160,639,842	160,867,950	158,062,867

See accompanying notes.

Table of Contents

CELSION CORPORATION

STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,	
	2005	**2004**
Cash flows from operating activities:		
Net loss	$ (6,561,155)	$ (10,847,849)
Non-cash items included in net loss:		
Depreciation and amortization	172,509	142,499
Amortization of deferred revenue license fee income	(428,572)	(333,333)
Loss from investment in Celsion China, Ltd	66,601	48,201
Loss from disposal of assets	1,088	
Common Stock and stock options issued for compensation and other operating expenses	86,257	
Stock based employee compensation		(380,420)
Net changes in:		
Trade receivable	(159,900)	(576,048)
Other receivables	67,299	(51,324)
Inventories	(1,806,463)	(2,264,813)
Prepaid expenses	169,298	255,850
Escrow account license fee	(29,267)	(2,002,687)
Prepaid inventory development costs	40,764	392,951
Accounts payable-trade	803,244	723,698
Other accrued liabilities.	371,554	383,620
Deposits		5,916
Deferred revenue license fee		4,000,000
Net cash used by operating activities	(7,206,743)	(10,503,739)
Cash flows from investing activities:		
Investment in Celsion China, Ltd		200,000
Purchase of property and equipment	(77,878)	(452,583)
Net cash used by investing activities	(77,878)	(652,583)
Cash flows from financing activities:		
Proceeds of stock issuances.		12,836,624
Proceeds from loan payable	6,055,458	
Net cash provided by financing activities	6,055,458	12,836,624
Net (decrease) increase in cash	(1,229,163)	1,680,302
Cash at beginning of period	10,483,816	12,272,407
Cash at end of the period	$ 9,254,653	$ 13,952,709

See accompanying notes.

Table of Contents

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, 2005 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, 2004.

Note 2. Common Stock Outstanding and Per Share Information

For the three and nine-month periods ended September 30, 2005 and 2004, per share data is based on the weighted average number of shares of common stock, par value $0.01 per share (Common Stock), outstanding during the respective periods. Outstanding warrants and options that can be converted into Common Stock are not included, as their effect is anti-dilutive. The total number of outstanding warrants and options for the periods ended September 30, 2005 and 2004 were 34,232,850 and 26,409,104 respectively.

Note 3. New Accounting Pronouncements

In November 2004, the Financial Accounting Standard Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 151, *Inventory Costs*. SFAS No. 151 amends Accounting Research Bulletin No. 43, Chapter 4, to clarify that abnormal amounts of idle facility expense, freight, handling costs and wasted materials (spoilage) should be recognized as current-period charges. In addition, SFAS No. 151 requires that allocation of fixed production overhead to inventory be based on the normal capacity of the production facilities. The Company is required to adopt SFAS No. 151 beginning January 1, 2006. The Company is currently assessing the impact that SFAS No. 151 will have on its results of operations, financial position and cash flow.

In December 2004, the FASB issued SFAS No.123R *Share-Based Payment* which replaces SFAS No. 123 *Accounting for Stock-Based Compensation* and supersedes APB Opinion No. 25 *Accounting for Stock Issued to Employees*. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values and provides that the pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. The original effective date for SFAS No. 123R was the first interim or annual period after June 15, 2005, with early adoption encouraged. On April 21, 2005, the Securities and Exchange Commission amended Rule 4-01(a) under Regulation S-X to provide that each registrant that is not a small business issuer is required to comply with SFAS No. 123R beginning with the first annual or interim reporting period of the registrant s first fiscal year beginning on or after June 15, 2005. In the Company s case, this means that compliance is required

beginning in the first quarter of fiscal year 2006.

The pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. Under SFAS No. 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. The Company is evaluating the requirements of SFAS No. 123R. However, the Company expects that the adoption of SFAS No. 123R will not have a material impact on its results of operations and earnings per share. The Company has not yet determined the method of adoption or the effect of adopting SFAS No. 123R, and it has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123. The Company also has not yet determined the impact of SFAS No. 123R, if any, on its compensation policies or plans.

In December 2004, the FASB issued SFAS No. 153, *Exchange of Nonmonetary Assets.* SFAS No. 153 amends APB No. 29, *Accounting for Nonmonetary Transactions,* to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The Company was required to adopt SFAS No. 153, on a prospective basis, for nonmonetary exchanges after June 15, 2005. SFAS No. 153 has not had an impact on the Company s results of operations or financial position.

Table of Contents

Note 4. 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. Celsion has elected to follow APB 25 and the related interpretations in accounting for its employee stock options, pending mandatory compliance with SFAS No. 123R, as discussed above.

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,	
	2005	2004	2005	2004
Net loss attributable to common stockholders, as reported	$ (1,953,865)	$ (3,310,583)	$ (6,561,155)	$ (10,847,849)
Adjust for stock-based employee compensation expense included in reported net loss				(1,030,684)
Adjust for total stock-based employee compensation expense determined using the fair value-based method for all awards	(273,160)	(156,009)	(646,824)	617,277
Pro forma net loss	(2,227,025)	(3,466,592)	(7,207,979)	(11,261,256)
Loss per share:				
Basic as reported	$ (0.01)	$ (0.02)	$ (0.04)	$ (0.07)
Basic pro forma	$ (0.01)	$ (0.02)	$ (0.04)	$ (0.07)

Table of Contents

Note 5. Investment in Celsion China, Ltd.

We have formed a joint venture with Asia Pacific Life Science Group, Ltd., a group of Hong Kong-based investors, to develop our technologies and distribute our products in Greater China. We announced the joint venture on December 15, 2003 and 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, 2005 and December 31, 2004 reflected the following:

	September 30, 2005	December 31, 2004
Cash	$ 76,311	$ 289,551
Inventory	62,500	0
Prepaid expense	17,465	1,602
Total current assets	156,276	291,153
Fixed assets, net	375	375
Total assets	$ 156,651	$ 291,528
Liabilities	$ 62,500	$ 52,369
Equity	442,023	441,137
Accumulated deficit	(347,872)	(201,978)
Total liabilities and equity	$ 156,651	$ 291,528

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. The loss from this unconsolidated investee at September 30, 2005 and December 31, 2004 can be recalculated as follows and is comprised of only general and administrative costs. Celsion China, Ltd. had no commercial sales as of September 30, 2005.

	September 30, 2005	September 30, 2004
Quarterly deficit	$ (48,920)	$ (22,987)
Ownership percentage	45.65%	45.65%
Loss recorded for the quarter	(22,332)	(10,494)

Celsion Corporation s balance sheet at September 30, 2005 and December 31, 2004 reflects the investment in Celsion China in the account entitled Investment in Celsion China, Ltd., the components of which are as follows:

	September 30, 2005	December 31, 2004
Initial cash investment	$ 200,000	$ 200,000
45.65% accumulated loss	(158,804)	(92,203)
Net investment carrying value	$ 41,196	$ 107,797

Note 6. Licensing Agreement

The Distribution Agreement dated January 21, 2003 between Celsion Corporation and Boston Scientific Corporation (BSC or Boston Scientific) entitled Celsion to a $4,000,000 licensing fee, effective upon the occurrence of certain events, 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. All of the conditions were met, and we received cash from BSC during the quarter ended March 31, 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 occurring during the 36-month term of the escrow. The escrow is held in an interest-bearing account, with interest accruing for the benefit of Celsion, but subject to the escrow. 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 licensing fee ratably, at the rate of approximately $47,600 per month, over the seven-year term of the Distribution Agreement.

Table of Contents

Note 7. Inventory

Inventory is comprised of Prolieve Thermodilatation system control units, parts inventory and associated disposable treatment kits. Inventory is stated at the lower of cost or market. Inventory on hand at September 30, 2005 and December 31, 2004 was as follows:

	September 30, 2005	December 31, 2004
Material	$ 840,432	$ 739,645
Work in Progress		
Finished Goods	3,192,694	1,615,402
	4,033,126	2,355,047
Less: reserve	(25,000)	(153,384)
	$ 4,008,126	$ 2,201,663

Note 8. Loan Payable

On August 8, 2005 we entered into a loan agreement with BSC whereby BSC will lend the Company up to $15 million The loan, which has a term expiring on February 20, 2009 and will bear interest at a rate of prime plus 1 percent, will be disbursed in three installments. The first installment, in the amount of $6 million, was disbursed on August 17, 2005. The second and third disbursements which may be drawn down at the Company s discretion are expected to occur on or about January 1, 2006 and May 1, 2006, respectively. The second and third disbursements are subject to the Company making continuing progress, to the reasonable satisfaction of BSC, with respect to the development of the Company s Prolieve product.

Interest is due on the first to occur of (i) February 20, 2009, (ii) upon repayment of the principal amount in full, (iii) upon BSC s exercise of its option described below, to purchase certain assets and technology or (iv) on conversion of the principal amount plus accrued interest, if any, to shares of Company s common stock. The Company has the right to prepay the loan at any time without penalty.

The principal balance of this loan, together with then all unpaid and accrued interest, is due and payable in full on February 29, 2009.

Note 9. Contingent Purchase Commitment

Sanmina-SCI (Sanmina) and Celsion entered into a Medical Product Manufacturing Services Agreement on April 2, 2003 for the production of the Company s Prolieve Thermodilatation control units. It is stipulated in this agreement that Celsion may from time to time require Sanmina to acquire component inventories in excess of current demand. Any such inventory of components purchased and held by Sanmina will be designated as excess inventory, Celsion is responsible to reimburse Sanmina for the delivered cost of those components. As of September 30, 2005 Celsion and Sanmina have agreed that the excess components can be valued at $407,000. In lieu of payment in full Celsion has and will

pay a 1.5% monthly inventory carrying charge, beginning October 1, 2005. The amount paid for October 2005 was $6,110.

Table of Contents

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

Forward-Looking Statements

Statements and terms such as expect , anticipate , estimate , plan , believe and words of similar import regarding the Company s expectations a 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, 2004 and its Quarterly Reports on Form 10-Q for the quarters ended March 31, 2005 and June 30, 2005, 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 December 31, 2004 and in the Quarterly Report on Form 10-Q for the quarter ended March 31, 2005 and June 30, 2005 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 Reports on Form 10-Q for the quarters ended March 31, 2005 and June 30, 2005 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 biotechnology company dedicated to furthering the development and commercialization of treatment systems for cancer and other diseases using focused heat energy in combination with other therapeutic devices, heat-activated drugs or heat-activated genes.

On February 19, 2004, we received premarketing approval, or a PMA, from the Food and Drug Administration, or the FDA, for our Prolieve Thermodilatation system for the treatment of Benign Prostatic Hyperplasia, or BPH, a chronic condition of enlargement of the prostate common in older men. We currently are marketing the Prolieve system under a distribution arrangement with our marketing partner, Boston Scientific Corporation.

Table of Contents

Our product portfolio 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 our distribution agreement with Boston Scientific.
ThermoDox (Doxorubicin-laden thermo-liposome) plus heat for the treatment of cancer	We currently are conducting a single-site Phase I clinical trial in collaboration with the National Institutes of Health using ThermoDox in conjunction with radio frequency ablation in the treatment of liver cancer. We are evaluating additional study sites and expect to add one such site in China and one U.S. site in order to accelerate patient accrual. On November 8, 2005 the Company announced that it will sponsor, through a research grant, a Phase I Dose escalation study at Duke University, for the treatment of advanced breast cancer which has recurred in the chest wall. The heating source for this study will be the BSD 500 a device which is currently approved and marketed. We continue to evaluate the feasibility of re-initiating a study in combination with a modified Prolieve device to treat prostate cancer. The Company has determined that in future it will focus resources on the development of cancer drugs based on its heat activated liposome technology. The Company will no longer develop heating devices.
Breast cancer treatment system	During 2004, we terminated both branches of our pivotal Phase II trials using our advanced phased array technology in the treatment of small and late-stage breast cancer tumors. We continue to explore possible strategic alternatives and relationships involving our heat-only treatment system.
Cancer Repair Inhibitor (CRI)	Pre-clinical studies at Sloan-Kettering involving our CRI technology are ongoing. We are exploring possible strategic transactions and relationships to further the development of this technology.

Since 1995, we have generated only modest revenues and have funded our operations primarily through private placements of our equity securities. During the most recently completed fiscal year, following FDA premarketing approval of our Prolieve Thermodilatation system, we received one-time licensing fees of $4,000,000 under our agreement with BSC, the distributor of our Prolieve system. During the first nine months of 2005, sales of Prolieve products generated revenues of $7,972,332 compared to $1,082,494 for the portion of the first nine months of 2004 subsequent to FDA approval. 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 the 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.

Table of Contents

The Prolieve system consists of a microwave generator and conductors, along with a computer and software programs that control the focusing and application of heat (control units), plus a specially designed, one-time-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 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 expect 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 a 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, ultimately, 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. until we have received permission to do so, in the form of a premarketing approval, from the FDA. 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 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.

During the second quarter of 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. 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. While we could incur additional expenditures of this nature during 2005, we do not expect that such expenditures will be material. 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 CROs. This outsourcing effort will significantly increase the costs of our clinical trials.

As of September 30, 2005 the Company had enrolled the first two cohorts of patients in its ThermoDox/RFA liver cancer Phase I study. Celsion, in collaboration with the National Institutes of Health, is aggressively recruiting patients eligible for enrollment in the study. The Company also is evaluating additional study sites and expects to add one such site in China and one U.S. site in order to accelerate patient accrual. The Company anticipates that enrollment in the Phase I study could be completed around the end of 2005. Celsion is currently considering whether to re-initiate its Phase I ThermoDox/modified Prolieve prostate cancer study.

14

Table of Contents

Results of Operations

Comparison of Three Months Ended September 30, 2005 and Three Months Ended September 30, 2004

	Actual Results			
	Three Months Ended September 30,		Change	
	2005	2004	Dollars	Percent
Revenue:				
Sales	$ 3,205,829	$ 539,549	2,666,280	494
Cost of sales	2,186,640	472,837	1,713,803	363
Gross margin	1,019,189	66,712	952,477	1,428
Operating expenses:				
Research and development	2,293,562	2,973,522	(679,960)	(29)
General and administrative	810,244	601,966	208,278	35
Total operating expenses	3,103,806	3,575,488	(471,682)	(13)
Loss from operations	$ (2,084,617)	$ (3,508,776)	1,424,159	(41)
Interest income, net	$ 10,227	$ 65,830	(55,603)	(84)

Product sales consist of sales of our Prolieve products and are comprised of two elements sales of control units and sales of disposable catheter kits, all to our exclusive distributor, Boston Scientific Corporation. Celsion recognizes revenues on sales of control units upon sale of such units by Boston Scientific to ultimate end users. Celsion recognizes sales of catheter kits upon shipment to Boston Scientific. Catheter kits are inventoried by Boston Scientific for ultimate sale and shipment to end users.

Sales for the quarter ended September 30, 2005 were $3,205,829 compared to $539,549 in the comparable quarter of 2004, representing an increase of 494%. The increase in revenues during the current quarter was the result of expanded distribution as the product roll out continues following FDA PMA approval of the product on February 19, 2004. Our Prolieve system is distributed under a seven year distribution agreement with Boston Scientific Corporation through which Boston Scientific also acquired a five year option to purchase the Prolieve assets. In the event that Boston Scientific terminates or elects not to extend the distribution agreement Celsion would be required to establish alternate distribution arrangements with a potentially disruptive impact on sales. Should Boston Scientific exercise its purchase option sales of Prolieve would terminate.

Additionally, during the quarter ended September 30, 2005, control units were shipped to Boston Scientific on a consignment basis and were placed at urologists offices for evaluation. Under Boston Scientific s arrangements with end users, such units are either converted to sales or returned to Boston at the end of the evaluation period, which typically does not exceed 90 days. At September 30, 2005 a total of 247 control units (including both units sold to end users and evaluation units) were in service. In the current quarter 46 control units were sold by Boston Scientific to end users and Celsion recognized revenues on the sale of these units compared with 14 control unit sales during the third quarter of

2004.

The decrease of $679,960 (29%) in research and development expense during the third quarter of 2005 in comparison to the quarter ended September 30, 2004 was due primarily to non-recurrence of one-time costs occurring in the quarter ended September 30, 2004, specifically the write-off of product development costs ($379,000) and provision for costs related to personnel matters ($130,000); and costs related to consultants hired to aid in clinical compliance ($217,000). In addition to the non recurrence of those items, there were reductions in expenses associated with consulting costs related to the commercial introduction of Prolieve ($383,000); clinical costs associated with the suspended Prostate cancer study ($78,000); recruiting and relocation ($52,000); FDA user fees ($21,000) and clinical costs related to the Phase II APA studies ($24,000). These reductions were offset by pre-clinical and clinical costs related to development costs associated with the liver cancer phase I clinical study ($360,000); Prolieve post market study clinical costs ($161,000) and intellectual property costs ($104,000).

Table of Contents

The $208,278 (35%) increase in general and administrative expense during the quarter ended September 30, 2005 as compared to the comparable period during 2004 was attributable to costs related to the hiring of the new Chief Executive Officer ($76,000); increased legal fees due to engagement of external counsel as a result of in-house counsel leaving the company in June 2005 ($72,000); provision for costs related personnel matters ($60,000); and increased directors fees and expenses and accounting fees ($35,000); offset by a reduction in professional fees for consulting and public/investor relations ($43,000).

The net decrease of $471,682 in operating expenditures during the quarter ended September 30, 2005 when compared to the quarter ended September 30, 2004, 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, 2005 of $1,424,159 or 41%, to $2,084,617 from $3,508,776 in the comparable period during the prior fiscal year.

Interest income, which is reflected net of any interest expense, decreased by 84%, or $55,603, for the quarter ended September 30, 2005 from the comparable quarter in 2004. The decrease was due to interest expense accrued on a loan from Boston Scientific which closed on August 8, 2005.

Comparison of Nine Months Ended September 30, 2005 and Nine Months Ended September 30, 2004

	Actual Results			
	Nine Months Ended September 30		Change	
	2005	2004	Dollars	Percent
Revenue:				
Sales	$ 7,972,332	$ 1,082,494	6,889,838	637
Cost of sales	5,385,196	896,540	4,488,656	501
Gross margin	2,587,136	185,954	2,401,182	1,291
Operating expenses:				
Research and development	6,997,480	8,945,864	(1,948,384)	4
General and administrative	2,648,247	2,538,515	109,732	(22)
Total operating expenses	9,645,727	11,484,379	(1,838,652)	(16)
Loss from operations	$ (7,058,591)	$ (11,298,425)	4,239,834	(38)
Interest income, net	$ 135,466	$ 165,444	(29,978)	(18)

Sales for the nine months ended September 30, 2005 were $7,972,332, an increase of $6,889,838, or 637%, compared to $1,082,494 in the first nine months of 2004. Product sales consist of sales of our Prolieve products and are comprised of two elements sales of control units and sales of disposable catheter kits, all to our exclusive distributor, Boston Scientific Corporation. The increase in revenues during the first nine months was the result of a full selling period in 2005 compared to a partial period (commencing with grant of the PMA on February 19, 2004) in 2004,

as well as the progress of commercialization and marketing efforts during the 16 months since the launch of the Prolieve system.

Research and development expenses in the nine months ended September 30, 2005 of $6,997,480 were $1,948,384, or 22%, lower than expenses incurred in the comparable nine months of 2004. The decrease in expenses was due to the non-recurrence of expenses associated with receipt of the PMA for the Prolieve system, cash bonuses paid to employees in connection with receipt of the PMA offset by 2004 performance bonus payments ($375,000) and a reduction in consulting support related to development and approval of the Prolieve system ($851,000). The reduction is also attributable non recurrence of provision for costs related to personnel matters ($1,102,000); a reduction in clinical costs due to the closure of our heat-alone breast cancer clinical study and suspension of our prostate cancer clinical study ($400,000); write-off of product development costs ($379,000) and costs related to consultants hired to aid in clinical compliance ($217,000), offset by adjustments in stock related compensation expense, in 2004, due to decreases in the market price of our Common Stock ($622,000), patent expenses ($236,000) and preclinical and clinical costs associated with our liver cancer clinical studies ($574,000).

Table of Contents

General and administrative expenses increased by $109,732, or 4%, to $2,648,247 in the nine months ended September 30, 2005 compared to $2,538,515 in the nine months ended September 30, 2004. The increase was primarily due to adjustments in stock related compensation expense, in 2004, due to decreases in the market price of our Common Stock ($464,000) and provision for costs related to personnel matters ($308,000) offset by non-recurrence of expenses arising due to the approval of the Prolieve system in February 2004, principally consisting of a payment to Legg Mason for investment banking services rendered in connection with negotiation of our strategic relationship with Boston Scientific in 2003 which became due upon receipt of the PMA ($410,000); cash bonuses paid to employees in connection with receipt of the PMA offset by 2004 performance bonus payments ($85,000), and changes in investor relations programs and consultants ($188,000).

The net decrease of $1,838,652 in operating expenditures during the nine months ended September 30, 2005 when compared to the comparable period during 2004, combined with income generated (gross margin) from the sale of Prolieve products during the first nine months of 2005, resulted in a decrease in the loss from operations for the nine-month period ended September 30, 2005 of $4,239,834 or 38%, to $7,058,591 from $11,298,425 in the comparable period during the prior fiscal year.

Interest income, which is reflected net of any interest expense, decreased by 18%, or $29,978, for the quarter ended September 30, 2005 from the comparable quarter in 2004. The decrease was due to interest accrued on a loan from Boston Scientific which closed on August 8, 2005.

Liquidity and Capital Resources

Since inception, our expenses have significantly exceeded our revenues, resulting in an accumulated deficit of $80,778,420 at September 30, 2005. 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, 2005, we received an amount of $6,000,000 from Boston Scientific in the form of the first installment of the loan discussed below. As of September 30, 2005, we had total current assets of $14,648,358, including cash of $9,254,653, compared with current liabilities of $3,321,335, resulting in a working capital surplus of $11,327,023. As of December 31, 2004, we had $10,483,816 in cash and total current assets of $14,147,755 compared with current liabilities of $2,128,689, which resulted in working capital of $12,019,066 at the fiscal year end. Net cash used in the Company s operating activities for the nine months ended September 30, 2005 was $7,206,743 compared to $10,503,739 for the nine months ending September 30, 2004.

On August 8, 2005 we entered into a loan agreement with BSC whereby BSC will lend the Company up to $15 million. The loan, which has a term expiring on February 20, 2009 and will bear interest at a rate of prime plus 1 percent, will be disbursed in three installments. The first installment, in the amount of $6 million, was disbursed on August 17, 2005. The second and third disbursements are expected to occur on or about January 1, 2006 and May 1, 2006, respectively. The second and third disbursements are subject to the Company making continuing progress, to the reasonable satisfaction of BSC, with respect to the development of the Company s Prolieve product.

Interest is due on the first to occur of (i) February 20, 2009, (ii) upon repayment of the principal amount and accrued interest in full, (iii) upon BSC s exercise of its option, described below, to purchase certain assets and technology, or (iv) on conversion of the principal amount plus accrued interest, if any, to shares of Company s common stock. The Company has the right to prepay the loan at any time without penalty.

BSC has a continuing security interest in the Company s right, title and interest in the BPH Business and the BPH Assets (as those terms are defined in the Transaction Agreement), together with all proceeds with respect thereto.

BSC may at any time convert in whole or in part the outstanding principal plus accrued interest into shares of the Company s common stock at a minimum conversion price of $0.61 per share. Additionally, BSC may apply the outstanding principal plus accrued interest toward the option exercise price if BSC decides to exercise the option granted by the Company under the Transaction Agreement to purchase for $60 million the assets and technology relating to the manufacture, marketing, sale, distribution and/or research and development of products using thermal therapy for the treatment of BPH for $60 million. There can be no assurance when, if ever, Boston Scientific will exercise its right to purchase. In the event that Boston Scientific does exercise its option, the Company will receive an immediate infusion of cash but will cease to receive revenues from the sale of Prolieve systems and related disposables.

Table of Contents

We anticipate that our available cash on hand (including revenues received from sales of Prolieve products) and future installments of the loan from Boston Scientific discussed above will be sufficient to fund our activities through the first quarter of 2007. Our dependence on Prolieve revenues and on raising additional capital beyond that date will continue at least until we are able to begin marketing our other technologies. Our future capital requirements and the adequacy of our funding depend upon numerous factors, including the successful commercialization of our Prolieve 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 these 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 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 30,2005, which is the end of the period covered by this 10-Q, 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 9d) of Exchange Act Rule 13a-15 that occurred during the quarter ended September 30, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II

OTHER INFORMATION

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

	Issuer Purchases of Equity Securities			
Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Number of Shares Available for Purchase under Publicly Announced Programs
July 1 July 31, 2005				
August 1 August 31, 2005				
September 1 September 30, 2005				
Total				

The company has never entered into a stock repurchase program.

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 Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (Filed herewith)
32.1	Certification 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 Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. (Furnished herewith)

Table of Contents

SIGNATURES

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

November 9, 2005

CELSION CORPORATION
Registrant

By: /s/ Lawrence S. Olanoff

Lawrence S. Olanoff
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)