

CELSION CORP
Form 10-K/A
August 01, 2005

OMB APPROVAL
OMB Number: 3235-0063
Expires January 31, 2008
Estimated average burden hours
per response: 1,647.00

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K/A
(Amendment No. 2)

(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004

or

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

For the transition period from _____ to _____

Commission file number 000-14242

CELSION CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE (State or Other Jurisdiction)	52-1256615 (I.R.S. Employer
of Incorporation or Organization)	Identification No.)
10220-L OLD COLUMBIA ROAD	
COLUMBIA, MARYLAND (Address of Principal Executive Offices)	21046-2364 (Zip Code)

(410) 290-5390

Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
COMMON STOCK, PAR VALUE \$.01 PER SHARE	AMERICAN STOCK EXCHANGE

Securities registered pursuant to Section 12(g) of the Act:

Not Applicable

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 check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. "

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

Edgar Filing: CELSION CORP - Form 10-K/A

As of March 15, 2005, 160,879,542 shares of the Registrant's Common Stock were issued and outstanding. As of March 15, 2005, the aggregate market value of voting common stock held by non-affiliates of the Registrant was approximately \$53,125,351, based on the closing price for the Registrant's Common Stock on that date as quoted on The American Stock Exchange.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement in connection with its 2005 Annual Meeting of Stockholders, scheduled for May 19, 2005, are incorporated by this reference into Part III hereof, as indicated herein.

**Persons who respond to the collection of information contained
In this form are not required to respond unless the form
SEC 1673 (3-05) displays A currently valid OMB control number.**

EXPLANATORY NOTE:

Celsion Corporation (the Company) is filing this Amendment No. 2 on Form 10-K/A (this Amendment) to its Annual Report on Form 10-K for the year ended December 31, 2004, originally filed with the Securities and Exchange Commission (the Commission) on March 16, 2005 (the Original Form 10-K) and amended by Amendment No. 1 on April 12, 2005 (collectively with the Original Form 10-K, the Amended Form 10-K). This Amendment reflects modification that we have made in light of comments from the staff of the Commission in connection with its review of the Amended Form 10-K and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2005.

Item 7 and Item 9A contained in Part II, and Footnotes 9 and 16 to the Financial Statements which appear as part of Item 15 in Part III, are amended hereby. In addition, pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, as amended, the certifications pursuant to Section 302 and 906 of the Sarbanes-Oxley Act of 2002 filed as exhibits to the Amended Form 10-K, have been reexecuted as of the date of, and are refiled as part of, this Amendment as Exhibits 31.1, 31.2, 32.1 and 32.2. Finally, an additional Consent of Independent Registered Public Accounting Firm dated June __, 2005 is filed as part of this Amendment.

Except for the items describe above or contained in Amendment No. 1, this Amendment continues to speak as of the date of the Original Form 10-K, and does not modify, amend or update in any way the financial statements or any other item or disclosures in the Amended Form 10-K.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

FORWARD-LOOKING STATEMENTS

Certain of the statements contained in this Annual Report on Form 10-K, including certain in this section, are forward-looking and constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, from time to time we may publish forward-looking statements relating to such matters as anticipated financial performance, business prospects, technological developments, new products, research and development activities and other aspects of our present and future business operations and similar matters that also constitute such forward-looking statements. These statements involve known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among other things, 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; possible actions by customers, suppliers, strategic partners, potential strategic partners, competitors and regulatory authorities, as well as those listed under Risk Factors below and elsewhere in this Annual Report on Form 10-K. In some cases, you can identify forward-looking statements by terminology such as expect, anticipate, estimate, plan, believe and words of similar import regarding the Company's expectations. Forward-looking statements are only predictions. Actual events or results may differ materially. 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, you should specifically consider various factors, including the risks outlined under Risk Factors. The discussion of risks and uncertainties set forth in this Annual Report on Form 10-K 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.

BASIS OF PRESENTATION

Overview and Recent Events

Celsion 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. In 1989, we obtained premarketing approval (PMA) from the 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. From 1995 until early in 2004 we engaged in research and development of new treatment systems. On February 19, 2004, we obtained a PMA for our Prolieve Thermodilatation system for the treatment of BPH and thereafter our marketing partner, Boston Scientific, commenced commercial sales of the Prolieve system. In addition, we are engaged in the development of treatment systems using a combination of heat and ThermoDox, our proprietary liposomal encapsulation of doxorubicin, for the treatment of prostate and liver cancer and are exploring the possibility of using such a combination to treat breast cancer.

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	We 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. In addition, ThermoDox, in conjunction with modified Prolieve equipment, is currently the subject of a multi-site Phase I clinical trial for the treatment of prostate cancer. We also are evaluating the feasibility of initiating studies using ThermoDox in combination with APA or advanced phased array radio frequency heating technology for the treatment of breast cancer.
Breast cancer treatment system	During 2004, we terminated 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. As noted above, we currently are exploring the use of ThermoDox in combination with APA or advanced phased array radio frequency technology to treat breast cancer. In addition, we are exploring possible strategic transactions 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 minimal revenues and have funded our operations primarily through private placements of our equity securities. During 2004, following FDA premarketing approval of our Prolieve Thermodilatation system, we received a one-time licensing fee of \$4,000,000 under our agreement with Boston Scientific, the distributor of our Prolieve system. During the portion of 2004 subsequent to receipt of the

PMA, sales of Prolieve products generated revenues of \$2,506,228. 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 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.

We anticipate that, in the near term (up to 24 months), the source of our revenues will be from sales of our Prolieve system and related disposables. In the longer term (beyond 24 months), we expect to seek to develop new revenue streams from our current work with Duke University in targeted drug delivery systems and with Sloan-Kettering in gene therapy. We anticipate that revenues will come from the licensing of these technologies to pharmaceutical manufacturers and major institutional health care providers who would employ these technologies to deliver drug regimens or gene therapy throughout the body or from the sale of one or more of these technologies. Also, because these technologies are used in conjunction with heating equipment, including our Prolieve system and systems using our APA technology, we expect that the acceptance of these technologies could generate demand for our equipment which, in turn, would create equipment sales revenues.

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.

Edgar Filing: CELSION CORP - Form 10-K/A

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 December 31, 2004, Celsion had expended \$227,000 in connection with such compliance consultants. While we anticipate additional expenditures of this nature, we do not expect that such expenditures during 2005 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.

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.

In August 2004 Celsion conducted a voluntary Class II recall and field correction of the Prolieve system to correct a potential software malfunction that occurred if a procedure using the Prolieve system was ongoing when the system's computer clock transitioned 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 has implemented, a software upgrade to eliminate the potential for the malfunction. This upgrade applied to all Prolieve units in the field as well as all newly manufactured units. The costs of the recall, field correction and software upgrade were not material.

As of March 2005 the Company had enrolled one patient 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. In order to ensure timely enrollment of patients, the Company also has initiated a search for additional sites. The Company anticipates that enrollment in the Phase I study will be completed by the end of 2005. Celsion is also actively recruiting new clinical sites at which to resume its Phase I ThermoDox/modified Prolieve prostate cancer study.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Management's Discussion of Financial Condition and Results of Operations is based on our financial statements, which appear at Item 8 to this Annual Report on Form 10-K. The financial statements have been prepared in accordance with accounting principles generally accepted in the United States, which require that the Company make certain assumptions and estimates and, in connection therewith, adopt certain accounting policies. Our significant accounting policies are set forth in Note 1 to our financial statements. Of those policies, we believe that the following may involve a higher degree of judgment and may be more critical to an accurate reflection of our financial condition and results of operations:

We state our inventories at the lower of cost or market. We track Prolieve control units by serial number and cost is the actual cost of each unit. We carry catheter kits at average cost. Carrying value does not include any general and administrative costs. We have established an inventory reserve to reflect the estimated value of excess and obsolete inventory.

We recognize revenue on the sale of Prolieve control units as they are sold to ultimate customers by Boston Scientific. Prolieve control units shipped to Boston Scientific but not yet sold to ultimate customers are reflected in Finished Goods inventory. We recognize revenue on the sale of catheter kits upon shipment.

We include in the cost of sales the inventory carrying value of items sold, shipping and handling, miscellaneous production costs, excess and obsolescence costs and warranty expenses.

Edgar Filing: CELSION CORP - Form 10-K/A

We warrant Prolieve control units for a period of 12 months from date of delivery to the end user and catheter kits until the date of expiration. Warranty exposure is reviewed and accruals, if any, are included in cost of sales.

We have long-term compensation plans that permit the granting of incentive awards in the form of stock options. We have adopted the disclosure-only provisions of Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation (SFAS No. 123), which allows us 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). In December 2004, the Financial Accounting Standards Board issued SFAS No.123R, which replaces SFAS No. 123 and 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 beginning with the first interim or annual period after June 15, 2005. Under SFAS No. 123R, the Company will be required to 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. We are evaluating the requirements of SFAS No. 123R and expect that its adoption will not have a material impact on our consolidated results of operations and earnings per share. We have not yet determined the impact, if any, of SFAS No. 123R on our compensation policies or plans.

We review our financial reporting and disclosure practices and accounting policies on an ongoing basis to ensure that our financial reporting and disclosure system provides accurate and transparent information relative to the current economic and business environment. As part of the process, the Company reviews the selection, application and communication of critical accounting policies and financial disclosures. The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires that our management make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We review our estimates and the methods by which they are determined on an ongoing basis. However, actual results could differ from our estimates.

RESULTS OF OPERATIONS

COMPARISON OF FISCAL YEAR ENDED DECEMBER 31, 2004 AND FISCAL YEAR ENDED DECEMBER 31, 2003

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 2004 in the amount of \$2,506,000, all of which were generated subsequent to February 19, 2004, consist of the sale of control units, catheter kits and miscellaneous parts to Boston Scientific and Celsion China. There were no product sales during the comparable period in 2003, which predated the commercial introduction of our Prolieve system.

The \$1,672,000 (33%) decrease in general and administration expense during the year ended December 31, 2004 compared to the year ended December 31, 2003 was attributable primarily to a reduction in compensation expense (\$1,639,000) as a result of a decrease in the cumulative value of re-priced stock options issued under our employee stock option plan; a reduction in legal fees (\$117,000) attributable to the retention of in-house counsel in May 2004; savings from a new building lease effective November 1, 2003 (\$122,000) and various other reductions including reductions in investor relations costs, partially offset by a net increase of \$179,000 in payments to Legg Mason for investment banking services rendered in connection with negotiation of our strategic relationship with Boston Scientific, which became due with receipt of the PMA for the Prolieve system.

The increase of \$2,342,000 (25.4%) in research and development expense during the year ended December 31, 2004 was due primarily to costs with respect to the Separation and Release Agreement with Mr. Daniel S. Reale in connection with Mr. Reale's resignation as 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 (\$972,000); the value of certain payments in connection with the departure of William Gannon, former Medical Director (\$130,000); the value of certain payments in connection with the departure of David Braitman, former Senior Vice President Product Development (\$160,000); a termination fee payment in connection with migration of manufacturing of the catheter kits for our Prolieve system to a new supplier (\$350,000); a write-off of amounts previously classified as prepaid inventory costs related to the production of the catheter kits (\$379,000); cash bonuses granted to our employees in connection with receipt of the PMA for the Prolieve system (\$554,000); an increase in salaries and recruiting and relocation expenses for new hires (\$550,000) as we continue to fill critical positions; increased costs related to consultants hired to aid in clinical compliance efforts (\$227,000) and an initial payment to the CRO that has been engaged to monitor the Prolieve post-market study which must be completed by Celsion as a condition of the PMA for the Prolieve system (\$293,000). These additional expenses were partially offset by a decrease of \$1,006,000 in compensation expense as a result of a reduction in the cumulative value of re-priced stock options. During the year ended December 31, 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 commercialization of the Prolieve system.

The net increase of \$670,000 in operating expenditures during the year ended December 31, 2004 compared to the year ended December 31, 2003, as discussed above, was partially offset by revenues generated from the sale of Prolieve products during the year ended December 31, 2004, and resulted in an increase in the loss from operations for the year ended December 31, 2004 of \$265,000 or 1.8%, to \$14,599,000 from \$14,334,000 in the year ended December 31, 2003.

Interest income increased by 400% or \$184,000 for the year ended December 31, 2004 compared to the year ended December 31, 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.

**COMPARISON OF THREE MONTHS ENDED DECEMBER 31, 2003 AND THREE MONTHS ENDED DECEMBER 31, 2002
(BASED UPON UNAUDITED FINANCIAL INFORMATION)**

There were no product sales for the three month periods ended December 31, 2003 or 2002. No product revenues were expected until the Company's equipment incorporating new technologies received the necessary approvals from governmental regulatory agencies and the Company began to market such equipment.

General and administrative expense did not change materially for the three months ended December 31, 2003, compared to the comparable period in 2002.

Research and development expense increased by 92% to \$2,110,000 for the quarter ended December 31, 2003 from \$1,097,000 for the three months ended December 31, 2002. The increase of \$1,013,000 in the more recent quarter was the result of recognition of compensation expense related to employee stock options, salary, recruiting and relocation expenses associated with new employees and increased business development expenses for BPH and our liposome and gene therapy technologies.

The net increase in expenditures discussed above resulted in an increase in the loss from operations for the three-month period ended December 31, 2003 of \$1,029,000, or 53%, to \$2,967,000 from \$1,937,000 in the comparable period during the prior fiscal year.

COMPARISON OF FISCAL YEAR ENDED SEPTEMBER, 2003 AND FISCAL YEAR ENDED SEPTEMBER 30, 2002

We generated no revenues during either the fiscal year ended September 30, 2003 or the fiscal year ended September 30, 2002.

Research and development expenditures in the year ended September 30, 2003 were \$8,179,000, an increase of \$3,174,000, or 63%, compared to the fiscal year ended September 30, 2002. The increase was primarily the result of (1) a payment of \$2,175,000 to Duke University pursuant to an obligation under the License Agreement between the Company and Duke University, which was satisfied by the issuance of 3,805,366 shares of the Company's Common Stock to Duke University on January 16, 2003; (2) recognition of compensation expense related to employee stock options; and (3) increased production costs related to the scale-up of liposome production.

Selling, general and administrative expense increased by 6%, to \$5,126,000 for the fiscal year ended September 30, 2003 compared to \$4,833,000 for the fiscal year ended September 30, 2002. The increase was due primarily to compensation expense related to employee stock options, offset by the absence of costs associated with the 2002 settlement of litigation brought by the Company's former Chief Financial Officer and others.

Edgar Filing: CELSION CORP - Form 10-K/A

The increase in operating expenses described above, together with the absence of revenues during the relevant periods, resulted in a loss from operations of \$13,304,000 for the year ended September 30, 2003 compared to a loss \$9,838,000 for the year ended September 30, 2002, an increase of \$3,466,000.

Interest income net of interest expense decreased by \$18,000 to \$30,000 for the fiscal year ended September 30, 2003 compared to \$48,000 for the fiscal year ended September 30, 2002. This decrease is the result of a combination of lower average funds available for investment and lower interest rates in fiscal 2003.

LIQUIDITY AND CAPITAL RESOURCES

Celsion's core business activity is the development of products to treat cancer and other diseases and to commercialize those products to generate a return on investment for its stockholders through one of several means including (a) selling products directly to end users; (b) selling product through a distributor (as is the case with its Prolieve products); (c) licensing its technology to third parties and generating income through royalties and milestone payments; (d) outright sale of a technology directly or, ultimately, through the sale of the entire Company. This business model will generate uneven cash flows, inasmuch as continuing development expenditures will not necessarily be matched by revenues from one of the above sources. In the event that annual development expenditures are not covered by current revenues, funding will be provided from other sources including any cash on hand, revenues provided as above and debt or equity funding raised in the capital markets. Since inception, our expenses have significantly exceeded our revenues, resulting in an accumulated deficit of \$74,217,000 at December 31, 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 2004, although the Company generated revenues from sale of its Prolieve products pursuant to a distribution agreement with Boston Scientific, these revenues were not sufficient to cover cash expenditures, which showed an increase over prior years due to one-time expenditures incurred either as a result of receipt of the PMA for Prolieve or the separation from Celsion of certain senior employees. These expenditures are discussed above at Results of Operations. As a result, net cash used in operating activities during the year ended December 31, 2004 otherwise referred to as the cash burn was \$13,944,158, representing an increase of \$3,978,000 from the fiscal year ended December 31, 2003. This net cash requirement was funded from cash on hand at the beginning of the year, together with funds generated from Common Stock sales to Boston Scientific pursuant to milestone commitments triggered by the approval of Prolieve, other private equity investments and the exercise of options and warrants to purchase Celsion Common Stock.

As of December 31, 2004, we had cash on hand of \$10,484,000 and total current assets of \$14,148,000, compared with current liabilities of \$2,129,000, resulting in a working capital surplus of \$12,019,000. As of December 31, 2003, we had \$12,272,000 in cash and total current assets of \$13,569,000, compared with current liabilities of \$987,000, which resulted in a working capital surplus of \$12,582,000 at fiscal year end.

With an annual cash burn expected to be around \$15,000,000 for 2005, the Company anticipates that cash on hand at the beginning of the year, plus revenues generated from the sale of its Prolieve products, will be sufficient to fund operations for the next 12 months; however, future funding will be required from other sources. While Prolieve revenues could provide a continuing source of funding in 2006 and beyond they are unlikely to be sufficient to maintain current development programs. Additionally since Boston Scientific has an option to purchase the Prolieve assets at any time until February 2009, Prolieve revenues could cease at any time as a consequence of such a purchase. In the event that Boston Scientific exercises its option, the proceeds of at least \$60 million potentially could fund development of Celsion's other technologies to the point where they could be the source of additional revenues. Until either Boston Scientific exercises its option or Celsion develops other products to the point of revenue generation, the Company will be dependent on the capital markets for funding. However the Company cannot guarantee that additional funding will be available in a timely manner, on acceptable terms, or at all.

The following is a summary of our future minimum payments under contractual obligations as of December 31, 2004:

	<u>Total</u>	<u>< 1 year</u>	<u>1 - 3 years</u>	<u>4 - 5 years</u>	<u>Thereafter</u>
Operating leases Property	\$ 1,173,000	\$ 187,000	\$ 391,000	\$ 415,000	\$ 180,000

OFF-BALANCE SHEET ARRANGEMENTS

The Company does not engage in any off-balance sheet financing arrangements. In particular, we do not have any interest in so-called limited purpose entities, which include special purpose entities (SPEs) and structured finance entities.

RISK FACTORS

Among numerous risk factors that may affect our future performance and our ability to achieve profitable operations are the following:

WE HAVE A HISTORY OF SIGNIFICANT LOSSES AND EXPECT TO CONTINUE SUCH LOSSES FOR THE FORESEEABLE FUTURE.

Since Celsion's inception in 1982, our expenses have substantially exceeded our revenues, resulting in continuing losses and an accumulated deficit of \$74,217,000 at December 31, 2004, including losses of \$13,985,000 for the 12 months then ended. Because we presently have only limited revenues from sales of our Prolieve system and related disposables and we are committed to continuing our product research, development and commercialization programs, we will continue to experience significant operating losses unless and until we complete the commercialization of Prolieve, as well as the development of other new products and these products have been clinically tested, approved by the FDA and successfully marketed.

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

Since 1995 we have devoted our resources to developing a new generation of products, but have not been able to market these products until we completed clinical testing and obtained all necessary governmental approvals. On February 19, 2004, we received a PMA from the FDA for the first of our new generation of thermotherapy products our Prolieve Thermodilatation system for the treatment of BPH and, since that time, our distributor Boston Scientific has begun commercial introduction of the Prolieve system. However, we can give no assurance as to how much revenue will be generated by Prolieve sales or when sales of Prolieve systems may occur. In addition, at the present time our other products are still in various stages of development and testing and cannot be marketed until we have completed clinical testing and obtained necessary governmental approval. Accordingly, our revenue sources are, and will remain extremely limited until and unless our Prolieve system is marketed successfully and/or until our other new products are clinically tested, approved by the FDA and successfully marketed. We cannot guarantee that any or all of our products will be successfully tested, approved by the FDA or marketed, successfully or otherwise, at any time in the foreseeable future or at all.

IF WE ARE NOT ABLE TO OBTAIN NECESSARY FUNDING, WE WILL NOT BE ABLE TO COMPLETE THE DEVELOPMENT, TESTING AND COMMERCIALIZATION OF OUR TREATMENT SYSTEMS.

We will need substantial additional funding in order to complete the development, testing and commercialization of our prostate and liver cancer treatment systems, as well as other potential new products. We expended approximately \$15,000,000 in the 12-month period ended December 31, 2004. As of that date, we had available a total of approximately \$10,500,000 to fund our operations. We have made a significant commitment to our heat-activated liposome research and development projects and it is our intention at least to maintain, or increase the pace and scope of these activities. The commitment to these new projects could require additional external funding, at least until we are able to generate sufficient cash flow from sale of one or more of our products to support our continued operations. We do not have any committed sources of financing and cannot offer any assurances that additional funding will be available in a timely manner, on acceptable terms or at all.

If adequate funding is not available, we may be required to delay, scale back or eliminate certain aspects of our operations or attempt to obtain funds through unfavorable arrangements with partners or others that may force us to relinquish rights to certain of our technologies, products or potential markets or that could impose onerous financial or other terms. Furthermore, if we cannot fund our ongoing development and other operating requirements, particularly those associated with our obligations to conduct clinical trials under our licensing agreements, we will be in breach of these licensing agreements and could therefore lose our license rights, which could have material adverse effects on our business.

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

Currently our only source of revenues is from the sale of Prolieve control units and disposables to Boston Scientific which, in turn, distributes these products to the market. Consequently, we are dependent upon Boston Scientific for the successful introduction and marketing of our Prolieve system. There can be no assurance that Boston Scientific will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for our Prolieve system. Disruption of our relationship with Boston Scientific, or Boston Scientific's sales of Prolieve products, would reduce our revenues and, if such reduction were material, it would have a material adverse effect on our business and financial condition.

We intend to market our other products, if and when such products are approved for commercialization by the FDA, through other strategic alliances and distribution arrangements with third parties. There can be no assurance that we will be able to enter into third-party marketing or distribution arrangements on advantageous terms or at all. To the extent that we do enter into such arrangements, we will be dependent on our marketing and distribution partners. In entering into third-party marketing or distribution arrangements, we expect to incur significant additional

expense. There can be no assurance that, to the extent we enter into any commercialization arrangements with third parties, such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for our products and services.

WE DEPEND ON THIRD-PARTY SUPPLIERS TO MANUFACTURE OUR PRODUCTS AND MAY NOT BE ABLE TO OBTAIN THESE PRODUCTS ON FAVORABLE TERMS OR AT ALL.

We currently contract for the manufacture of both our Prolieve control units and disposables from single source suppliers. The FDA must approve the vendors that supply us with Prolieve control units and disposables, and both our suppliers and the suppliers of our suppliers must comply with FDA regulations including good manufacturing practices. Accordingly, we are dependent upon our contract manufacturers to comply with FDA requirements.

In the event a supplier should lose its regulatory status as an approved source, or otherwise would cease to supply us, we would attempt to locate an alternate source. However, we may not be able to obtain the required products or components in a timely manner, at commercially reasonable prices or at all. To the extent that alternative sources of supply are not available on a timely basis and at reasonable cost, the loss of any of our suppliers could have a material adverse effect on our business. The loss of any of these suppliers would require that we obtain a replacement supplier, which would result in delays and additional expense in being able to meet our supply commitments to Boston Scientific. In addition, our suppliers are in turn dependent upon single or limited-source suppliers for critical components of our products. Although we believe that alternative sources of supply ultimately would be available both to us and to our suppliers if the need arose, the need to identify and qualify such alternative suppliers pursuant to FDA requirements would entail significant time and expense.

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

We currently have only 33 full-time employees. We rely, and expect to continue to rely, on third-party CROs to conduct all of our clinical trials. We have contracted with Theradex to conduct our Phase I liver cancer trial and with INC Research, Inc. to conduct our Prolieve post-market study. Because we do not conduct our own clinical trials, we must rely on the efforts of others and cannot always control or predict accurately the timing of such trials, the costs associated with such trials or the procedures that are followed for such trials. We do not anticipate significantly increasing our personnel in the foreseeable future and therefore, expect to continue to rely on third parties to conduct all of our future clinical trials. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they do not carry out the trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become prohibitively expensive, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

OUR BUSINESS DEPENDS ON LICENSE AGREEMENTS WITH THIRD PARTIES TO PERMIT US TO USE PATENTED TECHNOLOGIES. THE LOSS OF ANY OF OUR RIGHTS UNDER THESE AGREEMENTS COULD IMPAIR OUR ABILITY TO DEVELOP AND MARKET OUR PRODUCTS.

Our success will depend, in substantial part, on our ability to maintain our rights under license agreements granting us rights to use patented technologies. We have entered into exclusive license agreements with MIT, for APA technology and with MMTC, a privately owned developer of medical devices, for microwave balloon catheter technology. We have also entered into license agreements with Duke University, under which we have exclusive rights to commercialize medical treatment products and procedures based on Duke's thermo-liposome technology, an advanced phased array radio frequency (RF) heating system designed specifically for use with chemotherapeutic drugs for the treatment of locally advanced breast cancer. In addition, we have entered into a license agreement with Sloan-Kettering under which we have rights to commercialize certain cancer repair inhibitor products. The MIT, MMTC, Duke University and Sloan-Kettering license agreements each contain license fee, royalty and/or research support provisions, testing and regulatory milestones, and other performance requirements that we must meet by certain deadlines. If we

were to breach these or other provisions of the license and research agreements, we could lose our ability to use the subject technology, as well as compensation for our efforts in developing or exploiting the technology. Any such loss of rights and access to technology could have a material adverse effect on our business.

Further, we cannot guarantee that any patent or other technology rights licensed to us by others will not be challenged or circumvented successfully by third parties, or that the rights granted will provide adequate protection. We are aware of published patent applications and issued patents belonging to others, and it is not clear whether any of these patents or applications, or other patent applications of which we may not have any knowledge, will require us to alter any of our potential products or processes, pay licensing fees to others or cease certain activities. Litigation, which could result in substantial costs, may also be necessary to enforce any patents issued to or licensed by us or to determine the scope and validity of others' claimed proprietary rights. We also rely on trade secrets and confidential information that we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants. We cannot guarantee that these agreements will not be breached, that, even if not breached, that they are adequate to protect our trade secrets, that we will have adequate remedies for any breach or that our trade secrets will not otherwise become known to, or will not be discovered independently by, competitors.

OUR BUSINESS IS SUBJECT TO NUMEROUS AND EVOLVING STATE, FEDERAL AND FOREIGN REGULATIONS AND WE MAY NOT BE ABLE TO SECURE THE GOVERNMENT APPROVALS NEEDED TO DEVELOP AND MARKET OUR PRODUCTS.

Our research and development activities, pre-clinical tests and clinical trials, and ultimately the manufacturing, marketing and labeling of our products, all are subject to extensive regulation by the FDA and foreign regulatory agencies. Pre-clinical testing and clinical trial requirements and the regulatory approval process typically take years and require the expenditure of substantial resources. Additional government regulation may be established that could prevent or delay regulatory approval of our product candidates. Delays or rejections in obtaining regulatory approvals would adversely affect our ability to commercialize any product candidates and our ability to generate product revenues or royalties.

The FDA and foreign regulatory agencies require that the safety and efficacy of product candidates be supported through adequate and well-controlled clinical trials. If the results of pivotal clinical trials do not establish the safety and efficacy of our product candidates to the satisfaction of the FDA and other foreign regulatory agencies, we will not receive the approvals necessary to market such product candidates.

Even if regulatory approval of a product candidate is granted, the approval may include significant limitations on the indicated uses for which the product may be marketed. In addition, we are subject to inspections and regulations by the FDA. Medical devices must also continue to comply with the FDA's Quality System Regulation, or QSR. Compliance with such regulations requires significant expenditures of time and effort to ensure full technical compliance. The FDA stringently applies regulatory standards for manufacturing.

In August 2004, Celsion conducted a voluntary Class II recall and field correction of the Prolieve system to correct a potential software malfunction that occurred if a procedure using the Prolieve system was ongoing when the system's computer clock transitioned through midnight. The Company has developed, and, with FDA approval has implemented, a software upgrade to eliminate the potential for the malfunction. This upgrade applied to all Prolieve units in the field as well as all newly manufactured units. While this recall did not have a material adverse effect on our business, a future recall could divert management time and attention and could require that we incur significant costs. In addition, a recall may harm our reputation and adversely affect future sales.

We are subject to the periodic inspection of our clinical trials, facilities, procedures and operations and/or the testing of our products by the FDA to determine whether our systems and processes are in compliance with FDA regulations. Following such inspections, the FDA may issue notices on Form 483 and warning letters that could cause us to modify certain activities identified during the inspection. A Form 483 notice is generally issued at the conclusion of an FDA inspection and lists conditions the FDA inspectors believe may violate FDA regulations. FDA

Edgar Filing: CELSION CORP - Form 10-K/A

guidelines specify that a warning letter is issued only for violations of regulatory significance for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

Failure to comply with FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of product applications, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted product approvals. Although we have internal compliance programs, if these programs do not meet regulatory agency standards or if our compliance is deemed deficient in any significant way, it could have a material adverse effect on the company.

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, which was based upon an inspection conducted in December 2003, 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. If the FDA is not satisfied with our follow-up and corrective actions, it could require us to take additional actions or could take regulatory action against us, which could include fines, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of product applications, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted product approvals. Although we have internal compliance programs, if these programs do not meet regulatory agency standards or if our compliance is deemed deficient in any significant way, it could have a material adverse effect on the company. Any such action is likely to have a material adverse effect on our business and financial condition.

We are also subject to record keeping and reporting regulations, including FDA's mandatory Medical Device Reporting, or MDR, regulation. Labeling and promotional activities are regulated by the FDA and, in certain instances, by the Federal Trade Commission.

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

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

The EU has a registration process that includes registration of manufacturing facilities (known as ISO certification) and product certification (known as a CE Mark). We have obtained ISO certification for our existing U.S. facilities. However, there is no guarantee that we will be successful in obtaining European certifications for new facilities or for our products, or that we will be able to maintain our existing certifications in the future. Foreign government regulation may delay marketing of our new products for a considerable period of time, impose costly procedures upon our activities and provide an advantage to larger companies that compete with us. There can be no assurance that we will be able to obtain necessary regulatory approvals, on a timely basis or at all, for any products that we develop. Any delay in obtaining, or failure to obtain, necessary approvals would materially and adversely affect the marketing of our contemplated products subject to such approvals and, therefore, our ability to generate revenue from such products.

Even if regulatory authorities approve our product candidates, such products and our facilities, including facilities located outside the EU, may be subject to ongoing testing, review and inspections by the European health regulatory authorities. After receiving premarketing approval, in order to manufacture and market any of our products in the EU, we will have to comply with regulations and requirements governing manufacture, labeling and advertising on an ongoing basis.

Edgar Filing: CELSION CORP - Form 10-K/A

Failure to comply with applicable domestic and foreign regulatory requirements, can result in, among other things, warning letters, fines, injunctions and other equitable remedies, civil penalties, recall or seizure of

products, total or partial suspension of production, refusal of the government to grant approvals, pre-market clearance or pre-market approval, withdrawal of approvals and criminal prosecution of the Company and its employees, all of which would have a material adverse effect on our business.

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

There have been a number of federal and state proposals during the last few years to subject the pricing of health care goods and services to government control and to make other changes to the United States health care system. It is uncertain which legislative proposals, if any, will be adopted (or when) or what actions federal, state, or private payors for health care treatment and services may take in response to any health care reform proposals or legislation. We cannot predict the effect health care reforms may have on our business and we can offer no assurances that any of these reforms will not have a material adverse effect on our business.

THE SUCCESS OF OUR PRODUCTS MAY BE HARMED IF THE GOVERNMENT, PRIVATE HEALTH INSURERS AND OTHER THIRD-PARTY PAYORS DO NOT PROVIDE SUFFICIENT COVERAGE OR REIMBURSEMENT.

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

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

Although we have received a PMA from the FDA for our Prolieve system for the treatment of BPH, we can offer no assurance that the Prolieve system will be accepted by the medical community widely or at all. Our cancer treatment systems using ThermoDox plus RFA or a modified version of our Prolieve system, currently are in the early stages of Phase I clinical trials and we are still exploring the possibility of commencing Phase I trials using ThermoDox and heat delivered by APA or advanced phased array radio frequency heating technology for the treatment of breast cancer. Any or all of these treatment systems may prove not to be effective in practice. If testing and clinical practice do not confirm the safety and efficacy of our systems or, even if further testing and practice produce positive results but the medical community does not view these new forms of treatment as effective and desirable, our efforts to market our new products may fail, with material adverse consequences to our business.

TECHNOLOGIES FOR THE TREATMENT OF CANCER ARE SUBJECT TO RAPID CHANGE AND THE DEVELOPMENT OF TREATMENT STRATEGIES THAT ARE MORE EFFECTIVE THAN OUR TECHNOLOGIES COULD RENDER OUR TECHNOLOGIES OBSOLETE.

Edgar Filing: CELSION CORP - Form 10-K/A

Various methods for treating cancer currently are, and in the future may be expected to be, the subject of extensive research and development. Many possible treatments that are being researched, if successfully developed, may not require, or may supplant, the use of our technologies. The successful development and acceptance of any one or more of these alternative forms of treatment could render our technology obsolete as a cancer treatment method.

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

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

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

Our business strategy contemplates growth and diversification. Our ability to manage growth effectively will require that we continue to expend funds to improve our operational, financial and management controls, reporting systems and procedures. In addition, we must effectively expand, train and manage our employees. We will be unable to manage our businesses effectively if we are unable to alleviate the strain on resources caused by growth in a timely and successful manner. There can be no assurance that we will be able to manage our growth and a failure to do so could have a material adverse effect on our business.

WE FACE INTENSE COMPETITION AND THE FAILURE TO COMPETE EFFECTIVELY COULD ADVERSELY AFFECT OUR ABILITY TO DEVELOP AND MARKET OUR PRODUCTS.

There are many companies and other institutions engaged in research and development of thermotherapy technologies, both for prostate disease and cancer treatment products that seek treatment outcomes similar to those that we are pursuing. In addition, a number of companies and other institutions are pursuing alternative treatment strategies through the use of microwave, infrared, radio frequency, laser and ultrasound energy sources, all of which appear to be in the early stages of development and testing. We believe that the level of interest by others in investigating the potential of thermotherapy and alternative technologies will continue and may increase. Potential competitors engaged in all areas of prostate and cancer treatment research in the United States and other countries include, among others, major pharmaceutical and chemical companies, specialized technology companies, and universities and other research institutions. Most of our competitors and potential competitors have substantially greater financial, technical, human and other resources, and may also have far greater experience, than do we, both in pre-clinical testing and human clinical trials of new products and in obtaining FDA and other regulatory approvals. One or more of these companies or institutions could succeed in developing products or other technologies that are more effective than the products and technologies that we have been or are developing, or which would render our technology and products obsolete and non-competitive. Furthermore, if we are permitted to commence commercial sales of any of our products, we will also be competing, with respect to manufacturing efficiency and marketing, with companies having substantially greater resources and experience in these areas.

WE MAY BE SUBJECT TO SIGNIFICANT PRODUCT LIABILITY CLAIMS AND LITIGATION.

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human therapeutic products. We presently have product liability insurance limited to \$5,000,000 per incident and \$5,000,000 annually. If we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim with our own limited resources, which could have a material adverse effect on our business. In addition, liability or alleged liability could harm the business by diverting the attention and resources of our management and by damaging our reputation.

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

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

THE EXERCISE OF OUR OUTSTANDING OPTIONS AND WARRANTS COULD RESULT IN SIGNIFICANT DILUTION OF OWNERSHIP INTERESTS IN OUR COMMON STOCK OR OTHER CONVERTIBLE SECURITIES.

As of December 31, 2004, we had outstanding and exercisable warrants and options to purchase a total of 24,135,353 shares of our Common Stock, including 56,098 shares issuable upon exercise of preferred stock warrants and the subsequent conversion of the preferred shares to Common Stock, at exercise prices ranging from \$0.25 to \$5.00 per share (and a weighted average exercise price of approximately \$0.88 per share). In addition, we had outstanding but unexercisable and unvested options to purchase a total of 2,273,751 shares of our Common Stock at exercise prices ranging from \$0.40 to \$1.50 per share. Some of the prices are below the current market price of our Common Stock, which has ranged from a low of \$0.40 to a high of \$0.68 over the 20 trading days ending December 31, 2004 and from a low of \$0.33 to a high of \$0.51 over the 20 trading days ending March 15, 2005. If holders choose to exercise such warrants and options at prices below the prevailing market price for the Common Stock, the resulting purchase of a substantial number of shares of our Common would have a dilutive effect on our stockholders and could adversely affect the market price of our issued and outstanding Common Stock and convertible securities. In addition, holders of these options and warrants who have the right to require registration of the Common Stock under certain circumstances and who elect to require such registration, or who exercise their options or warrants and then satisfy the one-year holding period and other requirements of Rule 144 of the Securities Act, will be able to sell in the public market shares of Common Stock purchased upon such exercise.

IF THE PRICE OF OUR SHARES REMAINS LOW, WE MAY BE DELISTED BY THE AMERICAN STOCK EXCHANGE AND BECOME SUBJECT TO SPECIAL RULES APPLICABLE TO LOW PRICED STOCKS.

Our Common Stock currently trades on The American Stock Exchange (the Amex). The Amex, as a matter of policy, will consider the suspension of trading in, or removal from listing of, any stock when, in the opinion of the Amex, (i) the financial condition and/or operating results of an issuer appear to be unsatisfactory; (ii) it appears that the extent of public distribution or the aggregate market value of the stock has become so reduced as to make further dealings on the Amex inadvisable; (iii) the issuer has sold or otherwise disposed of its principal operating assets; or (iv) the issuer has sustained losses which are so substantial in relation to its overall operations or its existing financial condition has become so impaired that it appears questionable, in the opinion of the Amex, whether the issuer will be able to continue operations and/or meet its obligations as they mature. For example, the Amex will consider suspending dealings in or delisting the stock of an issuer if the issuer has sustained losses from continuing operations and/or net losses in its five most recent fiscal years. Another instance where the Amex would consider suspension or delisting of a stock is if the stock has been selling for a substantial period of time at a low price per share and the issuer fails to effect a reverse split of such stock within a reasonable time after being notified that the Amex deems such action to be appropriate. We have sustained net losses for our last five fiscal years (and beyond) and our Common Stock has been trading at relatively low prices. At our Annual Meeting of on May 19, 2005, our stockholders will be asked to grant the Board of Directors the authority to effect a reverse split of our Common Stock without further approval from the stockholders of the Company. If approved, the Board may in its discretion effect a reverse split, at one of nine ratios between 1 for 7 and 1 for 15, at any time prior to the next annual meeting of stockholders in 2006. There can be no assurance that the stockholders will grant the necessary authority to the Board, that the Board will act to effect a reverse stock split or, even if the Board does effect a reverse stock split, that the market price of our Common Stock will rise in any amount, for any period, or at all.

Upon a delisting from the Amex, the Common Stock would become subject to the penny stock rules of the SEC, which generally are applicable to equity securities with a price of less than \$5.00 per share (other than securities registered on certain national securities exchanges or quoted on the Nasdaq system, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the SEC

that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with bid and ask quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that, prior to a transaction in a penny stock that is not otherwise exempt from such rules; the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements are likely to have a material and adverse effect on price and the level of trading activity in the secondary market for a stock that becomes subject to the penny stock rules. If our Common Stock were to become subject to the penny stock rules it is likely that the price of the Common Stock would decline and that our stockholders would be likely to find it more difficult to sell their shares.

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

Market prices for our Common Stock and the securities of other medical, high technology companies have been volatile. Our Common Stock has had a high price of \$2.10 and a low price of \$0.40 in the 52-week period ending December 31, 2004. Factors such as announcements of technological innovations or new products by us or by our competitors, government regulatory action, litigation, patent or proprietary rights developments and market conditions for medical and high technology stocks in general can have a significant impact on the market for our Common Stock. The fact that we are seeking stockholder approval for a reverse split, as well as such a split if one is effected, also could make our stock price volatile.

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

While our Common Stock is listed on the Amex, the volume of trading historically has been relatively light. Although trading volume has increased recently, there can be no assurance that this increased trading volume, our historically light trading volume, or any trading volume whatsoever will be sustained in the future. Therefore, there can be no assurance that our stockholders will be able to sell their shares of our Common Stock at the time or at the price that they desire, or at all. In the event that our stockholders authorize the Board of Directors to effect a reverse stock split and the Board acts to do so, the number of shares outstanding could decrease by as much as a factor of 15. Such reverse stock split would decrease the liquidity of our stock by decreasing the number of shares outstanding.

ANTI-TAKEOVER PROVISIONS IN OUR CHARTER DOCUMENTS AND DELAWARE LAW COULD PREVENT OR DELAY A CHANGE IN CONTROL.

Our Certificate of Incorporation and Bylaws may discourage, delay or prevent a merger or acquisition that a stockholder may consider favorable by authorizing the issuance of blank check preferred stock. This preferred stock may be issued by the Board of Directors, on such terms as it determines, without further stockholder approval. Therefore, the Board may issue such preferred stock on terms unfavorable to a potential bidder in the event that it opposes a merger or acquisition. In addition, our classified Board of Directors may discourage such transactions by increasing the amount of time necessary to obtain majority representation on the Board. We also have implemented a stockholder rights plan and distributed rights to our stockholders. When these rights become exercisable, these rights entitle their holders to purchase one share of our Series C Junior Participating Preferred Stock at a price of \$4.46 per one ten-thousandth of a share of Series C Preferred Stock. If any person or group acquires more than 15% of our Common Stock, the holders of rights (other than the person or group crossing the 15% threshold) will be able to purchase, in exchange for the \$4.46 exercise price, \$8.92 of our Common Stock or the stock of any company into which we are merged. Because these rights may substantially dilute stock ownership by a person or group seeking to take us over without the approval of our Board of Directors, our rights plan could make it more difficult for a person or group to take us over (or acquire significant ownership interest in us) without negotiating with our Board regarding such a transaction. Certain other provisions of our Bylaws and of Delaware law may also discourage, delay or prevent a third party from acquiring or merging with us, even if such action were beneficial to some, or even a majority, of our stockholders.

ITEM 9A. CONTROLS AND PROCEDURES

CONCLUSION OF MANAGEMENT REGARDING THE EFFECTIVENESS OF DISCLOSURE 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, and with the participation, of our management, including our Chief Executive Officer and Chief Financial Officer. Based on that evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that, subject to the limitation set forth below, our disclosure controls and procedures were effective as of December 31, 2004 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. There have not been any significant changes in our internal controls or in other factors subsequent to the date of the evaluation that could significantly affect such controls and no corrective actions have been required with regard to significant deficiencies and material weaknesses.

Because of their inherent limitations, our disclosure controls and procedures may not prevent or detect misstatements. A control system, no matter how well designed or implemented, can provide only reasonable, and not absolute, assurance that the objectives of the control systems were met in all cases. Because of the limitations inherent in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected.

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The management of Celsion Corporation is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is a process designed to provide reasonable assurance to the Company's management and Board of Directors regarding the reliability and preparation of published financial statements in accordance with accounting principles generally accepted in the United States of America. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2004. In making this assessment, the Company used the criteria set forth in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on management's assessment, the Company believes that, as of December 31, 2004, the Company's internal control over financial reporting is effective based on the criteria established in *Internal Control - Integrated Framework*.

The Company's independent registered public accountants, Stegman & Company, have audited and issued their attestation report on management's assessment of the Company's internal control over financial reporting. The report of Stegman & Company appears below in this Item 9A.

CHANGES IN INTERNAL CONTROLS OVER FINANCIAL REPORTING

Edgar Filing: CELSION CORP - Form 10-K/A

There was no change in the Company's internal control over financial reporting that occurred during the quarter ended December 31, 2004 that has materially affected, or is likely to materially affect, the Company's internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

of Celsion Corporation

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that Celsion Corporation (the Company) maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)*. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in *Internal Control Integrated Framework* issued by COSO. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control Integrated Framework* issued by COSO.

Edgar Filing: CELSION CORP - Form 10-K/A

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets as of December 31, 2004 and 2003 and September 30, 2003 and the related statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2004, the three months ended December 31, 2003 and for both fiscal years in the period ended September 30, 2003 of Celsion Corporation, and our report dated March 10, 2005, expressed an unqualified opinion on those financial statements.

/s/ Stegman & Company

Baltimore, Maryland

April 11, 2005

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS

The information required by this item is incorporated by reference to the information set forth under the captions "Directors and Executive Officers," "Compliance with Section 16(a) of the Securities Exchange Act of 1934, as Amended" and "Code of Ethics" in Celsion's Definitive Proxy Statement in connection with the Annual Meeting of Stockholders to be held on May 19, 2005, which has been, or will be, filed with the Securities and Exchange Commission within 120 days after the end of our fiscal year ended December 31, 2004.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to the information set forth under the caption "Executive Compensation" in Celsion's Definitive Proxy Statement in connection with the Annual Meeting of Stockholders to be held on May 19, 2005, which has been, or will be, filed with the Securities and Exchange Commission within 120 days after the end of our fiscal year ended December 31, 2004.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Certain information required by this item is incorporated by reference to the information set forth under the caption "Security Ownership of Certain Beneficial Owners and Management" in Celsion's Definitive Proxy Statement in connection with the Annual Meeting of Stockholders to be held on May 19, 2005, which has been, or will be, filed with the Securities and Exchange Commission within 120 days after the end of our fiscal year ended December 31, 2004.

Equity Compensation Plan Information as of December 31, 2004

<u>Plan category</u>	<u>(a)</u>	<u>(b)</u>	<u>(c)</u>
	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	8,977,709 ⁽¹⁾	\$ 0.72	9,284,475

Edgar Filing: CELSION CORP - Form 10-K/A

Equity compensation plans not approved by security holders	7,886,965 ⁽²⁾	\$ 0.96	⁽²⁾
Total	16,864,674	\$ 0.83	9,284,475

(1) Includes both vested and unvested options to purchase Common Stock issued to employees, officers, directors and outside consultants under the Company's 2001 Stock Option Plan and 2004 Stock Option Plan (the Plans). Certain of these options to purchase Common Stock were issued under the Plan in connection with employment agreements.

(2) Certain of the securities exercisable to purchase Common Stock set forth in column (a) of this row have price protection or antidilution rights that entitle the holders to reduce the exercise price of such securities if the Company issues additional stock, options, warrants or other convertible securities below the exercise price of the subject securities.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is incorporated by reference to the information set forth under the captions "Certain Transactions" in Celsion's Definitive Proxy Statement in connection with the Annual Meeting

of Stockholders to be held on May 19, 2005, which has been, or will be, filed with the Securities and Exchange Commission within 120 days after the end of our fiscal year ended December 31, 2004.

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. FINANCIAL STATEMENTS

The following is a list of the financial statements of Celsion Corporation filed with this Annual Report on Form 10-K, together with the report of our independent public accountants.

	<u>Page</u>
<u>Report of Independent Registered Public Accounting Firm</u>	F-1
FINANCIAL STATEMENTS	
<u>Balance Sheets</u>	F-2
<u>Statements of Operations</u>	F-4
<u>Statements of Changes in Stockholders' Equity</u>	F-6
<u>Statements of Cash Flows</u>	F-8
<u>NOTES TO FINANCIAL STATEMENTS</u>	F-10

2. FINANCIAL STATEMENT SCHEDULES

No schedules are provided because of the absence of conditions under which they are required.

3. EXHIBITS

The following documents are included as exhibits to this report:

<u>EXHIBIT NO.</u>	<u>DESCRIPTION</u>
3.1.1	Certificate of Incorporation of Celsion (the Company), as amended, incorporated herein by reference to Exhibit 3.1.1 to the Quarterly Report on Form 10-Q of the Company for the Quarter Ended June 30, 2004.
3.1.2	Intentionally omitted.
3.1.3	Certificate of Ownership and Merger of Celsion Corporation (a Maryland Corporation) into Celsion (Delaware) Corporation (inter alia, changing the Company's name to Celsion Corporation from Celsion (Delaware) Corporation), incorporated herein by reference to Exhibit 3.1.3 to the Annual Report on Form 10-K of the Company for the Year Ended September 30, 2000.
3.1.4	Intentionally omitted

Edgar Filing: CELSION CORP - Form 10-K/A

3.1.5

Certificate of Designations of Series C Junior Participating Preferred Stock of Celsion Corporation, incorporated herein by reference to Exhibit 4.4 to the Form S-3 Registration Statement (File No. 333-100638) filed October 18, 2002.

<u>EXHIBIT NO.</u>	<u>DESCRIPTION</u>
3.2	By-laws of the Company, as amended, incorporated herein by reference to Exhibit 3.2 to the Quarterly Report on Form 10-Q of the Company for the Quarter Ended June 30, 2004.
4.1	Form of Common Stock Certificate, par value \$0.01, incorporated herein by reference to Exhibit 4.1 to the Annual Report on Form 10-K of the Company for the Year Ended September 30, 2001.
4.2	Celsion Corporation and American Stock Transfer & Trust Company Rights Agreement dated as of August 15, 2002, incorporated by reference to Exhibit 99.1 to the Current Report on Form 8-K of the Company filed August 21, 2002.
4.2.1	Amendment adopted January 16, 2003 to Rights Agreement between Celsion Corporation and American Stock Transfer & Trust Company. Incorporated herein by reference to Exhibit 4.1 to the Report on Form 10-Q of the Company for the quarter ended June 30, 2004.
10.1	Patent License Agreement between the Company and Massachusetts Institute of Technology dated June 1 1996, incorporated herein by reference to Exhibit 10.1 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996 (Confidential Treatment Requested).
10.2	License Agreement between the Company and MMTC, Inc. dated August 23, 1996, incorporated herein by reference to Exhibit 10.2 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996 (Confidential Treatment Requested).
10.3	Patent License Agreement between the Company and Massachusetts Institute of Technology dated October 17, 1997, incorporated herein by reference to Exhibit 10.7 to the Annual Report on Form 10-K (amended) of the Company for the year ended September 30, 1998. (Confidential Treatment Requested).
10.4	Amendment dated November 25, 1997 to the License Agreement between the Company and MMTC, Inc. dated August 23, 1996, incorporated herein by reference to Exhibit 10.8 to the Annual Report on Form 10-K (amended) of the Company for the year ended September 30, 1998. (Confidential Treatment Requested).
10.5	Patent License Agreement between the Company and Duke University dated November 10, 1999, incorporated herein by reference to Exhibit 10.9 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1999 (Confidential Treatment Requested).
10.6	Amendment dated March 23, 1999 to the License Agreement between the Company and MMTC, Inc. dated August 23, 1996, incorporated herein by reference to Exhibit 10.10 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1999. (Confidential Treatment Requested).
10.7	Celsion Corporation 2001 Stock Option Plan. Incorporated herein by reference to Exhibit 10.23 to the Annual Report on Form 10-K of the Company for the year ended September 30, 2001.
10.7.1	Celsion Corporation 2004 Stock Incentive Plan. Incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2004.
10.8	Form of Series 200 Warrant issued to certain employees, directors and consultants to Purchase Common Stock of the Company, Incorporated herein by reference to Exhibit 10.11 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1998.
10.9	Form of Series 250 Warrant issued to DunnHughes Holding, Inc. to Purchase Common Stock of the Company, incorporated herein by reference to Exhibit 10.12 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1998.
10.10	Form of Series 300 Warrant issued to Nace Resources, Inc. to purchase Common Stock of the Company, incorporated herein by reference to Exhibit 10.13 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1998.

<u>EXHIBIT NO.</u>	<u>DESCRIPTION</u>
10.11	Intentionally omitted.
10.12	Form of Series 500 Warrant to Purchase Common Stock of the Company pursuant to the Private Placement Memorandum dated January 6, 1997, as amended, incorporated herein by reference to Exhibit 10.15 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1998.
10.13	Intentionally omitted.
10.14	Form of Series 600 Warrant issued to Certain Employees and Directors on May 16, 1996 to Purchase Common Stock of the Company, incorporated herein by reference to Exhibit 10.17 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1998.
10.15	License Agreement between the Company and Sloan-Kettering Institute for Cancer Research dated May 19, 2000, incorporated herein by reference to Exhibit 10.18 to the Annual Report on Form 10-K of the Company for the year ended September 30, 2000.
10.16	Employment Agreement between the Company and Anthony P. Deasey dated November 27, 2000, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-K of the Company for the quarter ended June 30, 2001.
10.16.1	Employment Agreement Effective January 1, 2004 between the Company and Anthony P. Deasey. Incorporated herein by reference to the Report on Form 8-K of the Company dated December 8, 2004.
10.17	Amended and Restated Executive Employment Agreement between the Company and Augustine Y. Cheung, effective January 1, 2000, incorporated herein by reference to Exhibit 10.17 to the Annual Report on Form 10-K of the Company for the Year Ended September 30, 2002.
10.17.1	Employment Agreement Effective January 1, 2004 between the Company and Augustine Y. Cheung. Incorporated herein by reference to the Report on Form 8-K of the Company dated December 8, 2004.
10.18	Amended and Restated Executive Employment Agreement between the Company and John Mon, effective June 8, 2000, incorporated herein by reference to Exhibit 10.18 to the Annual Report on Form 10-K of the Company for the Year Ended September 30, 2002.
10.19	Amended and Restated Executive Employment Agreement between the Company and Dennis Smith, dated effective May 19, 2000, incorporated herein by reference to Exhibit 10.19 to the Annual Report on Form 10-K of the Company for the Year Ended September 30, 2002.
10.20	Option Agreement between the Company and Duke University dated August 8, 2000, incorporated herein by reference to Exhibit 10.23 to the Annual Report on Form 10-K of the Company for the year ended September 30, 2000.
10.21	Intentionally omitted.
10.22	Service Agreement between the British Columbia Cancer Agency, Division of Medical Oncology, Investigational Drug Section, Propharma Pharmaceutical Clean Room and the Company dated September 20, 2000, incorporated herein by reference to Exhibit 10.24 to the Annual Report on Form 10-K of the Company for the year ended September 30, 2000 (Confidential Treatment Requested).
10.23	Form of Warrant to Purchase Common Stock of the Company pursuant to the Private Placement Memorandum dated October 11, 2001, incorporated herein by reference to Exhibit 10.23 to the Annual Report on Form 10-K of the Company for the year ended September 30, 2001.
10.24	Advisory Agreement between the Company and Dr. Kris Venkat dated August 1, 2001, incorporated herein by reference to Exhibit 10.24 to the Annual Report on Form 10-K of the Company for the Year Ended September 30, 2001.

<u>EXHIBIT NO.</u>	<u>DESCRIPTION</u>
10.25	Amendment dated May 23, 2002 to the Patent License Agreement between the Company and Massachusetts Institute of Technology dated October 17, 1997, incorporated herein by reference to Exhibit 10.25 to the Annual Report on Form 10-K of the Company for the Year Ended September 30, 2002. (Confidential Treatment Requested).
10.26	Amendment dated September 17, 2002 to the License Agreement between the Company and MMTC, Inc. dated August 23, 1996, incorporated herein by reference to Exhibit 10.26 to the Annual Report on Form 10-K of the Company for the Year Ended September 30, 2002.
10.27	Employment Agreement between the Company and William W. Gannon, Jr. dated January 15, 2002, incorporated herein by reference to Exhibit 10.27 to the Annual Report on Form 10-K of the Company for the Year Ended September 30, 2002.
10.28	Form of Warrant to Purchase Common Stock Units of the Company issued to Placement Agents pursuant to the Private Placement Memorandum dated October 18, 2001, incorporated herein by reference to Exhibit 4.4 to the Registration Statement on Form S-3 of the Company (File No. 333-82450) filed February 8, 2002.
10.29	Form of Warrant to Purchase Common Stock of the Company pursuant to private placement by the Company which closed on June 3, 2002, incorporated herein by reference to Exhibit 4.6 to the Form S-3 Registration Statement of the Company (File No. 333-100638) filed October 18, 2002.
10.30	Letter dated May 8, 2002, from Legg Mason Wood Walker, Incorporated (Legg Mason) to the Company regarding retention of Legg Mason as financial advisor, incorporated herein by reference to Exhibit 10.30 to the Annual Report on Form 10-K of the Company for the Year Ended September 30, 2002.
10.31	Letter Agreement with Goldpac Investment Partners dated October 17, 2001, incorporated herein by reference to Exhibit 4.5 to the Form S-3 Registration Statement (File No. 333-82450) filed February 8, 2002.
10.32	Letter Agreement with Equity Communications, dated November 5, 2001, incorporated herein by reference to Exhibit 4.6 to the Form S-3 Registration Statement (File No. 333-82450) filed February 8, 2002.
10.33	Form of Warrant to Purchase Common Stock pursuant to the Private Placement Memorandum (the PPM) of the Company dated May 30, 2003 as supplemented, incorporated herein by reference to Exhibit 4.3 to the Form S-3 Registration Statement of the Company (File No. 333-108318) filed on August 28, 2003.
10.34	Form of Warrant issued to the Placement Agents pursuant to the PPM, incorporated herein by reference to Exhibit 4.3 to the Form S-3 Registration Statement of the Company (File No. 333-108318) filed on August 28, 2003.
10.35	License Agreement dated July 18, 2003 between the Company and Duke University. (Confidential treatment requested.), incorporated herein by reference to Exhibit 4.3 to the Form S-3 Registration Statement of the Company (File No. 333-108318) filed on August 28, 2003.
14.1	Code of Ethics and Business Conduct, incorporated herein by reference to Exhibit 14.1 to the Annual Report on Form 10-K of the Company for the Year Ended September 30, 2003.
23.1+	Consent of Stegman & Company, independent public accounting firm for the Company.
31.1+	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

EXHIBIT

NO.

DESCRIPTION

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.

+ Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this annual report to be signed on its behalf by the undersigned, thereunto duly authorized.

	CELSION CORPORATION
August 1, 2005	By: /s/ Augustine Y. Cheung Augustine Y. Cheung
	President and Chief Executive Officer
	(Principal Executive Officer)
August 1, 2005	By: /s/ Anthony P. Deasey Anthony P. Deasey
	Chief Financial Officer
	(Principal Financial and Accounting Officer)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

Celsion Corporation

Columbia, Maryland

We have audited the accompanying balance sheets of Celsion Corporation (the Company) as of December 31, 2004 and 2003 and as of September 30, 2003, and the related statements of operations, changes in stockholders' equity, and cash flows for the year ended December 31, 2004, the three months ended December 31, 2003 and for both fiscal years in the period ended September 30, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Celsion Corporation as of December 31, 2004 and 2003 and as of September 30, 2003 and the results of its operations and its cash flows for the year ended December 31, 2004, the three months ended December 31, 2003 and for both fiscal years in the period ended September 30, 2003 in conformity with accounting principles generally accepted in the United States of America.

/s/ Stegman & Company

Baltimore, Maryland

March 10, 2005

CELSION CORPORATION

BALANCE SHEETS

DECEMBER 31, 2004, DECEMBER 31, 2003 AND SEPTEMBER 30, 2003

ASSETS

	December 31, 2004	December 31, 2003	September 30, 2003
Current Assets:			
Cash and cash equivalents	\$ 10,483,816	\$ 12,272,407	\$ 11,410,533
Accounts receivables - trade	691,938		
Other receivables	91,101	16,753	90,927
Inventories	2,201,663	917,710	824,791
Prepaid expenses	679,237	361,967	78,842
Total current assets	14,147,755	13,568,837	12,405,093
Property and Equipment at cost:			
Furniture and office equipment	176,666	146,508	138,592
Computer hardware and software	264,774	218,758	189,812
Laboratory and shop equipment	607,418	212,379	172,006
Leasehold improvements	120,101	107,258	12,275
	1,168,959	684,903	512,685
Less: Accumulated depreciation	486,861	296,068	275,361
Net value of property and equipment	682,098	388,835	237,324
Other Assets:			
Investment in Celsion China, Ltd.	107,797		
Escrow account - license fee	2,007,002		
Deposits	17,706	23,622	23,622
Prepaid inventory development costs	58,214	417,453	417,218
Patent licenses (net of accumulated Amortization of \$158,585, \$148,863 and \$144,906, respectively)	31,365	41,087	45,044
Total other assets	2,222,084	482,162	485,884
Total Assets	\$ 17,051,937	\$ 14,439,834	\$ 13,128,301

See accompanying notes.

LIABILITIES AND STOCKHOLDERS EQUITY

	December 31, 2004	December 31, 2003	September 30, 2003
Current Liabilities:			
Accounts payable trade	\$ 819,168	\$ 631,097	\$ 883,218
Accrued noncash compensation	53,543	153,316	125,395
Other accrued liabilities	684,550	202,426	384,886
Current portion of deferred revenue	571,428		
Total current liabilities	2,128,689	986,839	1,393,499
Long Term Liabilities:			
Deferred revenue license fee	2,952,382		
Total Liabilities	5,081,071	986,839	1,393,499
Stockholders Equity:			
Common stock - \$.01 par value; 250,000,000 shares authorized at December 31, 2004, 200,000,000 shares authorized at December 31, 2003 and September 30, 2003, 160,749,497, 148,034,473 and 143,101,134 shares issued and outstanding at December 31, 2004, December 31, 2003, and September 30, 2003, respectively	1,607,494	1,480,344	1,431,011
Additional paid-in capital	84,580,637	72,204,868	67,582,174
Accumulated deficit	(74,217,265)	(60,232,217)	(57,278,383)
Total stockholders equity	11,970,866	13,452,995	11,734,802
Total Liabilities and Stockholders Equity	\$ 17,051,937	\$ 14,439,834	\$ 13,128,301

See accompanying notes.

CELSION CORPORATION
STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED

DECEMBER 31, 2004, DECEMBER 31, 2003, SEPTEMBER 30, 2003 AND SEPTEMBER 30, 2002

	Year Ended December 31,		Year Ended September 30,	
	2004	2003	2003	2002
		(unaudited)		
Revenues:				
Sales of equipment and parts	\$ 2,506,228	\$	\$	\$
Returns and allowances				
Total revenues	2,506,228			
Cost of Sales	2,100,888			
Gross Profit	405,340			
Operating Expenses:				
Selling, general and administrative	3,470,869	5,142,693	5,125,769	4,833,005
Research and development	11,533,421	9,191,047	8,178,680	5,004,687
Total operating expenses	15,004,290	14,333,740	13,304,449	9,837,692
Loss from operations	14,598,950	14,333,740	13,304,449	9,837,692
License Fee Income Amortization	476,191			
Interest Income	229,914	46,447	30,378	48,321
(Loss) from Investment in Celsion China, Ltd.	(92,203)			
(Loss) from Disposal of Property and Equipment		(5,791)		
Rental income				38,289
Net (Loss)	(13,985,048)	(14,293,084)	(13,274,071)	(9,751,082)
Beneficial Conversion Feature and Dividends on Preferred Stock		(130,918)	(184,231)	(391,888)
Net (Loss) Attributable to Common Stockholders	\$ (13,985,048)	\$ (14,424,002)	\$ (13,458,302)	\$ (10,142,970)
Basic and Diluted Net Loss per Common Share	\$ (0.09)	\$ (0.12)	\$ (0.12)	\$ (0.12)
Basic and Diluted Weighted Average Number of Common Shares Outstanding	158,756,580	123,847,007	113,680,286	87,257,672

See accompanying notes.

CELSION CORPORATION
STATEMENTS OF OPERATIONS
FOR THE THREE MONTHS ENDED
DECEMBER 31, 2003 AND 2002

	Three Months Ended December 31,	
	2003	2002
		(unaudited)
Revenues:		
Sales of equipment and parts	\$	\$
Returns and allowances		
Total revenues		
Cost of Sales		
	_____	_____
Gross Profit		
	_____	_____
Operating Expenses:		
Selling, general and administrative	856,968	840,044
Research and development	2,109,795	1,097,428
	_____	_____
Total operating expenses	2,966,763	1,937,472
	_____	_____
Loss from operations	2,966,763	1,937,472
License Fee Income Amortization		
Interest Income		
(Loss) from Investment in Celsion China, Ltd.		
(Loss) from Disposal of Property and Equipment	(5,791)	
Rental income	18,720	2,651
	_____	_____
Net (Loss)	(2,953,834)	(1,934,821)
Beneficial Conversion Feature and Dividends on Preferred Stock		(53,313)

Net Loss Attributable to Common Stockholders	\$ (2,953,834)	\$ (1,988,134)
	_____	_____
Basic and Diluted Net Loss per Common Share	\$ (0.02)	\$ (0.02)
	_____	_____
Basic and Diluted Weighted Average Number of Common Shares Outstanding	144,152,732	95,128,667
	_____	_____

See accompanying notes.

CELSION CORPORATION

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

FOR THE YEARS ENDED DECEMBER 31, 2004, SEPTEMBER 30, 2003 AND SEPTEMBER 30, 2002 AND

FOR THE THREE MONTHS ENDED DECEMBER 31, 2003

	Series A 10% Convertible			
	Common Stock		Preferred Stock	
	Shares	Amount	Shares	Amount
Balances at September 30, 2001	76,876,761	\$ 768,768	1,099	\$ 1,099,584
Sale of preferred and common stock	12,500,000	125,000		
Conversion of shares of Series A 10% convertible, preferred stock plus accrued dividends	143,836	1,438	(58)	(58,972)
Conversion of shares of Series B 8% convertible preferred stock plus accrued dividends	918,000	9,180		
Exercise of common stock warrants and options	1,471,250	14,713		
Preferred stock dividend			90	89,888
Beneficial conversion feature				
Stock-based compensation expense	507,709	5,077		
Net loss				
	<u>92,417,556</u>	<u>924,176</u>	<u>1,131</u>	<u>1,130,500</u>
Balances at September 30, 2002	92,417,556	924,176	1,131	1,130,500
Sale of preferred and common stock	24,418,399	244,184	10	10,050
Conversion of shares of Series A 10% convertible, preferred stock plus accrued dividends	2,996,814	29,968	(1,231)	(1,230,595)
Conversion of shares of Series B 8% convertible preferred stock plus accrued dividends	3,370,453	33,704		
Exercise of common stock warrants and options	15,209,291	152,093		
Preferred stock dividend			90	90,045
Stock-based compensation expense	4,688,621	46,886		
Net loss				
	<u>143,101,134</u>	<u>1,431,011</u>		
Balances at September 30, 2003	143,101,134	1,431,011		
Sale of common stock	4,550,000	45,500		
Exercise of common stock warrants and options	201,500	2,015		
Stock-based compensation expense	181,839	1,818		
Effect of repriced options				
Net loss				
	<u>148,034,473</u>	<u>1,480,344</u>		
Balances at December 31, 2003	148,034,473	1,480,344		
Sale of common stock	6,084,491	60,845		
Exercise of common stock warrants and options	6,404,133	64,041		
Stock-based compensation expense	226,400	2,264		
Effect of repriced options				
Net loss				
	<u>160,749,497</u>	<u>\$ 1,607,494</u>		<u>\$</u>
Balances at December 31, 2004	160,749,497	\$ 1,607,494		\$

See accompanying notes.

F-6

CELSION CORPORATION

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

FOR THE YEARS ENDED DECEMBER 31, 2004, SEPTEMBER 30, 2003 AND SEPTEMBER 30, 2002

AND FOR THE THREE MONTHS ENDED DECEMBER 31, 2003

	Series B 8% Convertible				
	Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balances at September 30, 2001			\$ 34,729,646	\$ (33,928,781)	\$ 2,669,217
Sale of preferred and common stock	2,000	2,000,000	5,454,532		7,579,532
Conversion of shares of Series A 10% convertible, preferred stock plus accrued dividends			57,534		
Conversion of shares of Series B 8% convertible preferred stock plus accrued dividends	(459)	(402,375)	393,195		
Exercise of common stock warrants and options			34,814		49,527
Preferred stock dividend	50	50,330		(140,218)	
Beneficial conversion feature		(251,670)	251,670		
Stock-based compensation expense			964,219		969,296
Net loss				(9,751,082)	(9,751,082)
Balances at September 30, 2002	1,591	1,396,285	41,885,610	(43,820,081)	1,516,490
Sale of preferred and common stock			13,656,290		13,910,524
Conversion of shares of Series A 10% convertible, preferred stock plus accrued dividends			1,200,627		
Conversion of shares of Series B 8% convertible preferred stock plus accrued dividends	(1,685)	(1,490,471)	1,456,767		
Exercise of common stock warrants and options			5,619,526		5,771,619
Preferred stock dividend	94	94,186		(184,231)	
Stock-based compensation expense			3,763,354		3,810,240
Net loss				(13,274,071)	(13,274,071)
Balances at September 30, 2003			67,582,174	(57,278,383)	11,734,802
Sale of common stock			3,638,180		3,683,680
Exercise of common stock warrants and options			119,560		121,575
Stock-based compensation expense			217,298		219,116
Effect of repriced options			647,656		647,656
Net loss				(2,953,834)	(2,953,834)
Balances at December 31, 2003			72,204,868	(60,232,217)	13,452,995
Sale of common stock			8,699,155		8,760,000
Exercise of common stock warrants and options			4,012,581		4,076,622
Stock-based compensation expense			694,717		696,981
Effect of repriced options			(1,030,684)		(1,030,684)
Net loss				(13,985,048)	(13,985,048)
Balances at December 31, 2004		\$	\$ 84,580,637	\$ (74,217,265)	\$ 11,970,866

See accompanying notes.

F-7

CELSION CORPORATION

STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31, 2004, DECEMBER 31, 2003,

SEPTEMBER 30, 2003 AND SEPTEMBER 30, 2002

	Year Ended December 31,		Year Ended September 30,	
	2004	2003	2003	2002
	(unaudited)			
Cash Flows from Operating Activities				
Net loss	\$ (13,985,048)	\$ (14,293,084)	\$ (13,274,071)	\$ (9,751,082)
Noncash items included in net loss:				
Depreciation and amortization	200,515	106,806	100,532	82,437
Amortization of deferred revenue license fee	(476,191)			
Loss from investment in Celsion. China, Ltd.	92,203			
Common stock issued for operating expenses	200,760	2,629,302	2,561,600	233,401
Stock options issued for operating expenses	496,221	299,722	281,266	259,172
Executive repriced options	(1,030,684)	1,615,030	967,374	
Warrants issued for legal settlement				476,724
Loss from disposal of property and equipment		5,791		1,825
Net changes in:				
Accounts receivable trade	(691,938)			
Other receivables	(74,348)	(16,753)	(6,434)	(83,288)
Inventories	(1,283,953)	(296,354)	(375,183)	(449,608)
Prepaid expenses	(317,270)	(118,171)	(31,587)	(47,255)
Escrow account license fee	(2,007,002)			
Other current assets				150,000
Prepaid inventory development costs	359,239	36,769	69,384	(486,602)
Accounts payable and accrued interest payable	188,071	(162,607)	388,568	349,130
Accrued noncash compensation	(99,773)	125,395	125,395	
Deposits	5,916			
Deferred revenue license fee	4,000,000			
Other accrued liabilities	482,124	101,606	104,577	153,388
Net cash used in operating activities	(13,944,158)	(9,966,548)	(9,088,579)	(9,111,758)
Cash Flows from Investing Activities:				
Investment in Celsion China, Ltd.	(200,000)			
Increase (decrease) in deposits				5,915
(Decrease) increase in security deposit liability				(15,203)
Purchase of property and equipment	(484,056)	(296,049)	(111,850)	(89,329)
Net cash used in investing activities	(684,056)	(296,049)	(111,850)	(98,617)
Cash Flows from Financing Activities:				
Issuance of notes payable			500,000	
Payment on notes payable		(500,000)	(500,000)	
Proceeds of stock issuances	12,836,621	21,984,398	19,682,143	7,629,058

Edgar Filing: CELSION CORP - Form 10-K/A

Net cash provided by financing Activities	12,836,621	21,484,398	19,682,143	7,629,058
Net (Decrease) Increase in Cash	(1,788,591)	11,221,801	10,481,714	(1,581,317)
Cash at Beginning of Period	12,272,407	1,050,606	928,819	2,510,136
Cash at the End of Period	\$ 10,483,816	\$ 12,272,407	\$ 11,410,533	\$ 928,819

See accompanying notes

F-8

CELSION CORPORATION

STATEMENTS OF CASH FLOWS

FOR THE THREE MONTHS ENDED DECEMBER 31, 2003 AND 2002

	Three Months Ended December 31,	
	2003	2002
	(unaudited)	
Cash Flows from Operating Activities		
Net loss	\$ (2,953,834)	\$ (1,934,821)
Noncash items included in net loss:		
Depreciation and amortization	31,149	24,875
Amortization of deferred revenue license fee		
Loss from investment in Celsion China, Ltd.	219,115	132,957
Executive repriced options	647,656	
Warrants issued for legal settlement		
Loss from disposal of property and equipment	5,791	
Net changes in:		
Accounts receivable trade		
Other receivables	74,174	84,493
Inventories	(92,919)	(171,748)
Prepaid expenses	(283,125)	(196,541)
Escrow account license fee		
Other current assets		
Prepaid inventory development costs	(235)	32,380
Accounts payable and accrued interest payable	(252,121)	299,054
Accrued noncash compensation		
Deposits		
Deferred revenue license fee		
Other accrued liabilities	(154,539)	(151,568)
	(2,758,888)	(1,880,919)
Net cash used in operating activities		
Cash Flows from Investing Activities:		
Investment in Celsion China, Ltd.		
Increase (decrease) in deposits		
(Decrease) increase in security deposit liability		
Purchase of property and equipment	(184,493)	(294)
	(184,493)	(294)
Net cash used in investing activities		
Cash Flows from Financing Activities:		
Issuance of notes payable		500,000
Payment on notes payable		
Proceeds of stock issuances	3,805,255	1503,000
	3,805,255	2,003,000
Net cash provided by financing activities		
Net Increase (Decrease) in Cash	861,874	121,787
Cash at Beginning of Period	11,410,533	928,819

Cash at the End of Period	<u>\$ 12,272,407</u>	<u>\$ 1,050,606</u>
----------------------------------	----------------------	---------------------

See accompanying notes.

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2004 AND SEPTEMBER 30, 2003 AND

2002 AND THE THREE MONTHS ENDED DECEMBER 31, 2003

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Celsion Corporation, referred to herein as Celsion or the Company, a Delaware corporation based in Columbia, Maryland, 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 Celsion received premarketing approval (PMA), from the Food and Drug Administration (FDA), for its Prolieve Thermodilatation system for the treatment of Benign Prostatic Hyperplasia (BPH), a chronic condition of enlargement of the prostate common in older men. The Prolieve system is currently being marketed through our licensed distributor, Boston Scientific Corporation.

In addition, Celsion is currently conducting Phase I clinical trials of (i) a treatment for liver cancer using a combination of ThermoDox, a proprietary encapsulation of doxorubicin, a common cancer-treating drug, in a heat-activated liposome which Celsion licenses exclusively from Duke University, and Radio Frequency Ablation, or RFA and (ii) a treatment for prostate cancer using a combination of ThermoDox and heat from a modified Prolieve device.

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand and investments purchased with an original maturity of three months or less. These funds are on deposit with UBS Financial Services (UBS) and are not covered by FDIC insurance. Cash equivalents include a U.S. Treasury Bill, face value \$650,000, which collateralizes a \$500,000 standby letter of credit, issued by UBS for the benefit of Sanmina-SCI, the Celsion subcontractor responsible for the manufacture of Prolieve Thermodilatation control units. These funds are restricted from use by Celsion until expiration of the letter of credit, which currently expires on June 30, 2005.

Accounts Receivable

Edgar Filing: CELSION CORP - Form 10-K/A

Amounts due Celsion from the sale of Prolieve control units and catheter kits comprise the entire balance of accounts receivable. These amounts are due from Boston Scientific. All amounts are collectible and no allowance for doubtful accounts is required. Accounts receivable are not pledged as collateral for any borrowings.

Inventories

Inventories are stated at the lower of cost or market. Prolieve control units are tracked by serial number and cost is the actual cost of each unit. Catheter kits are carried at average cost. There are no general and administrative costs included in carrying value. Inventory is not pledged as collateral for any borrowings. An inventory reserve has been established to reflect the estimated value of excess and obsolete inventory.

F-10

Investment in Celsion China, Ltd.

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

Celsion accounts for this investment under the equity method. No foreign currency adjustment was necessary during the year ended December 31, 2004.

Escrow Account License Fee

Celsion entered into a Distribution Agreement, dated as of January 21, 2003 with Boston Scientific, pursuant to which the Company granted Boston Scientific exclusive rights to market and distribute the Prolieve system and its component parts for the treatment of BPH in all territories other than China, Taiwan, Hong Kong, Macao, Mexico and Central and South America for a period of seven years., beginning on February 21, 2004, in return for \$4 million licensing fee.

Pursuant to the Distribution Agreement, \$2 million of the licensing fee was to be placed in an interest bearing escrow account for a period of 36 months beginning February 21, 2004 for payment of any legal expenses, settlements, license fees, royalties, damages or judgments incurred by Celsion or Boston Scientific in connection with any patent litigation related to alleged infringement of third party patents.

Interest income generated by the escrow account is recognized monthly and increases the carrying value of the account. All accrued interest and the \$2 million principal balance will be released to Celsion from the escrow account, less any expenditures, on February 21, 2007.

Property and Equipment

Property and equipment is stated at cost. Depreciation is provided over the estimated useful lives of the related assets three to seven years using the straight-line method. Major renewals and improvements are capitalized at cost and ordinary repairs and maintenance are charged against operations as incurred. Depreciation expense was \$190,793 for the year ended December 31, 2004; \$84,703, and \$66,608, respectively, for the years ended September 30, 2003 and 2002, and \$20,707, for the three months ended December 31, 2003.

Prepaid Development Costs

The balance in prepaid development costs represents funds advanced to a vendor for the purchase of long-lead items consumed in the production of catheter kits. These amounts are subject to rebate as catheters and their components are produced.

Patent Licenses

The Company has purchased several licenses for rights to patented technologies. Patent license costs are amortized on a straight-line basis over the remaining life of the related patent.

Revenue Recognition

Revenue is recognized on Prolieve control units as they are sold to ultimate customers by Boston Scientific. Prolieve control units shipped to Boston Scientific but not yet sold to ultimate customers are reflected in Finished Goods inventory. Revenue on the sale of catheter kits is recognized upon shipment.

F-11

Cost of Sales

Cost of sales includes the inventory carrying value of items sold, shipping and handling, miscellaneous production costs, excess and obsolescence costs and warranty expenses.

Product Warranties

Celsion warrants ProLieve control units for a period of 12 months from date of delivery to the end user and catheter kits until the date of expiration. Warranty exposure is reviewed and accruals, if any, are included in cost of sales. As of December 31, 2004, the Company has recorded no warranty reserves.

Research and Development

Research and development costs are expensed as incurred. Equipment and facilities acquired for research and development activities that have alternative future uses are capitalized and charged to expense over their estimated useful lives.

Net Loss Per Common Share

Basic and diluted net loss per common share was computed by dividing net loss attributable to common stockholders by the weighted average number of shares of Common Stock outstanding during each period. The impact of Common Stock equivalents has been excluded from the computation of weighted average common shares outstanding, as the effect would be antidilutive.

Nonmonetary Transactions

Nonmonetary transactions are accounted for in accordance with Accounting Principles Board (APB) Opinion No. 29, *Accounting for Nonmonetary Transactions*, which provides that the transfer or distribution of a nonmonetary asset or liability generally is based on the fair value of the asset or liability that is received or surrendered, whichever is more clearly evident.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Stock-Based Employee Compensation

The Company has long-term compensation plans that permit the granting of incentive awards in the form of stock options. The Company had adopted the disclosure-only provisions of Statement of Financial Accounting Standard (SFAS) No. 123, *Accounting for Stock-Based Compensation* (Statement 123), which allows 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 Company has repriced certain stock options, which has resulted in an adjustment of compensation costs.

F-12

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of Statement 123, using the assumptions described in Note 9, to its stock-based employee plans:

	Year Ended December 31, 2004	Year Ended December 31, 2003 (unaudited)	Year Ended September 30, 2003	Year Ended September 30, 2002	Three Months Ended December 31, 2003	Three Months Ended December 31, 2002 (unaudited)
Net loss, attributable to common stockholders, as reported	\$ (13,985,048)	\$ (14,424,002)	\$ (13,458,302)	\$ (10,142,970)	\$ (2,953,834)	\$ (1,988,134)
Add stock-based employee compensation expense (reduction) included in reported net loss	(1,030,684)	1,615,032	967,376		647,656	
Deduct total stock-based employee compensation expense determined using the fair value based method for all awards	559,585	1,700,015	1,187,722	980,962	711,910	199,617
Pro forma net loss	\$ (14,456,147)	\$ (14,508,985)	\$ (13,678,648)	\$ (11,123,932)	\$ (3,018,088)	\$ (2,187,751)
Loss per share:						
Basic - as reported	\$ (0.09)	\$ (0.12)	\$ (0.12)	\$ (0.12)	\$ (0.02)	\$ (0.02)
Basic - pro forma	\$ (0.10)	\$ (0.12)	\$ (0.12)	\$ (0.13)	\$ (0.02)	\$ (0.02)

Fair Value of Financial Instruments

The carrying values of financial instruments approximate fair value.

2. RECENT 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, which replaces SFAS No. 123 and supersedes APB No. 25. 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

Edgar Filing: CELSION CORP - Form 10-K/A

values beginning with the first interim or annual period after June 15, 2005, with early adoption encouraged. The pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. The Company is required to adopt SFAS No. 123R beginning July 1, 2005. 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 consolidated 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 on its compensation policies or plans, if any.

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 is required to adopt SFAS No. 153, on a prospective basis, for nonmonetary exchanges beginning after June 15, 2005. The Company has not yet determined if SFAS No. 153 will have an impact on its results of operations or financial position.

3. FINANCIAL CONDITION

Since inception, the Company has incurred substantial operating losses, principally from expenses associated with the Company's research and development programs, the clinical trials conducted in connection with the Company's treatment systems and applications and submission to the Food and Drug Administration. The Company believes these expenditures are essential for the commercialization of its technologies. As a result of these expenditures, as well as related general and administrative expenses the Company had an accumulated deficit of \$74 million as of December 31, 2004. The Company expects such operating losses to continue in the near term and for the foreseeable future as it continues its product development efforts, and undertakes marketing and sales activities. The Company's ability to achieve profitability is dependent upon its ability to obtain governmental approvals, produce, market and sell its new products. There can be no assurance that the Company will be able to commercialize its technology successfully or that profitability will ever be achieved. The operating results of the Company have fluctuated significantly in the past. The Company expects that its operating results will fluctuate significantly in the future and will depend on a number of factors, many of which are outside the Company's control.

The Company will need substantial additional funding in order to complete the development, testing and commercialization of its cancer treatment products. Celsion has made a significant commitment to heat-activated liposome research and development projects and it is the Company's intention at least to maintain, or increase, the pace and scope of these activities. The commitment to these new projects could require additional external funding, at least until the Company is able to generate sufficient cash flow from sale of one or more of its products to support our continued operations. Management believes that adequate funding is available from cash resources on hand at December 31, 2004 and income generated from sale of Prolieve control units and catheter kits to fund operations as least through the end of 2005.

If adequate funding is not available, the Company may be required to delay, scale back or eliminate certain aspects of its operations or attempt to obtain funds through unfavorable arrangements with partners or others that may force it to relinquish rights to certain of its technologies, products or potential markets or that could impose onerous financial or other terms. Furthermore, if the Company cannot fund its ongoing development and other operating requirements, particularly those associated with our obligations to conduct clinical trials under its licensing agreements, it will be in breach of these licensing agreements and could therefore lose its license rights, which could have material adverse effects on its business. Management is continuing its efforts to obtain additional funds so that the Company can meet its obligations and sustain operations.

4. INVENTORIES

Inventories are stated at the lower of cost or market and consist of the following:

	December 31, 2004	December 31, 2003	September 30, 2003
Materials	\$ 739,645	\$ 838,992	\$ 732,225
Work-in-process		37,308	51,156
Finished goods	1,615,402	41,410	41,410
	2,355,047	917,710	824,791
Less: Reserve	153,384		

	<u> </u>	<u> </u>	<u> </u>
	\$ 2,201,663	\$ 917,710	\$ 824,791
	<u> </u>	<u> </u>	<u> </u>

F-14

We have increased inventory levels to meet expected commercial sales requirements for both Prolieve Thermodilatation system control units and associated kits (catheters).

5. INVESTMENT IN CELSION CHINA, LTD.

On December 15, 2003, the Company 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 Celsion's products in greater China. On February 5, 2004, the Company purchased a 45.65% equity position in Celsion China, Ltd. for \$200,000.

The financial records, in U.S. Dollars, of Celsion China, Ltd. as of December 31, 2004 reflected the following:

Cash	\$ 289,551
Deposits	
Prepaid expense	1,602
	<u> </u>
Total current assets	291,153
Fixed assets, net	375
	<u> </u>
Total assets	<u>\$ 291,528</u>
	<u> </u>
Liabilities	\$ 52,369
Equity	239,159
	<u> </u>
Total liabilities and equity	<u>\$ 291,528</u>

Celsion accounts for its investment in Celsion China, Ltd. under the equity method. The investee's functional currency is the Hong Kong Dollar. No foreign currency adjustment was necessary during the year ended December 31, 2004. The loss from this unconsolidated investee for the year ended December 31, 2004 can be recalculated as follows and is comprised of only general and administrative costs. Celsion China, Ltd. had no commercial sales for the year.

Annual deficit	\$ (201,978)
Ownership percentage	45.65%
	<u> </u>
Loss recorded for the year	<u>\$ (92,203)</u>

Celsion Corporation's balance sheet at 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:

Initial cash investment	\$ 200,000
45.65% accumulated loss	(92,203)
	<u> </u>

Net investment carrying value	\$ 107,797
-------------------------------	------------

During the year ended December 31, 2004, Celsion sold two Prolieve units to Celsion China, Ltd. for \$35,000. The units were used for regulatory and display purpose and have been expensed. Celsion has a \$35,000 receivable due from Celsion China, Ltd. from this sale, classified as an other receivable.

6. INCOME TAXES

A reconciliation of the Company's statutory tax rate to the effective rate for the years ended December 31, 2004 and September 30, 2003 and 2002 respectively, and three months ended December 31, 2003 is as follows:

	Year Ended December 31, 2004	Year Ended September 30, 2003	Year Ended September 30, 2002	Three Months Ended December 31, 2003
Federal statutory rate	34.0%	34.0%	34.0%	34.0%
State taxes, net of federal tax benefit	4.6	4.6	4.6	4.6
Valuation allowance	(38.6)	(38.6)	(38.6)	(38.6)
	0%	0%	0%	0%

As of December 31, 2004, the Company had net operating loss carryforwards of approximately \$63 million for federal income tax purposes that are available to offset future taxable income through the year 2023.

The components of the Company's deferred tax asset as of December 31, 2004 and 2003 and September 30, 2003 are as follows:

	December 31, 2004	December 31, 2003	September 30, 2003
Net operating loss carryforwards	\$ 24,200,000	\$ 18,700,000	\$ 18,200,000
Valuation allowance	(24,200,000)	(18,700,000)	(18,200,000)
	\$	\$	\$

The evaluation of the realizability of such deferred tax assets in future periods is made based upon a variety of factors that affect the Company's ability to generate future taxable income, such as intent and ability to sell assets and historical and projected operating performance. At this time, the Company has established a valuation reserve for all of its deferred tax assets. Such tax assets are available to be recognized and benefit future periods.

7. CELSION EMPLOYEE BENEFIT PLANS

Celsion maintains a defined-contribution plan under Section 401(k) of the Internal Revenue Code. The plan covers substantially all employees over the age of 21. Participating employees may defer a portion of their pretax earnings, up to the Internal Revenue Service annual contribution limit. No employer contributions have been made to the plan since its inception.

Edgar Filing: CELSION CORP - Form 10-K/A

Celsion also has established Flexible Spending and Dependent Care Accounts allowing voluntary participation. Participating employees can elect to use pretax dollars, for preset, capped payroll deductions. These deductions are to be utilized by the employee for qualified out-of-pocket medical expenses and qualified dependent care expenses.

8. PREFERRED STOCK

The Company had preferred stock known as Series A 10% convertible preferred stock. As of the end of the year ended September 30, 2003 all of this preferred stock had been converted to Common Stock. Holders of shares of preferred stock were entitled to receive, as and if declared by the Company's Board of Directors, dividends at the annual rate of 10% per share payable semi-annually on March 31 and September 30. Such dividends were payable in shares and fractional shares of preferred stock, valued for this purpose at \$1,000 per share. The shares of Series A preferred stock were subject to exchange and conversion privileges upon the occurrence of major events, including a public offering of the Company's securities or the Company's merger into another public company. In addition, the holders of the Series A preferred stock were entitled to convert their preferred shares into shares of Common Stock at a conversion price of \$0.41 per share of Common Stock, subject to certain adjustments.

The Company also had preferred stock known as Series B 8% Convertible Preferred Stock. All of this preferred stock was converted to Common Stock during the year ended September 30, 2003. Holders of shares of Series B preferred stock were entitled to receive, as and if declared by the Company's Board of Directors, dividends at the

annual rate of 8% per share payable semi-annually on June 30 and December 31. Such dividends were payable in shares and fractional shares of Series B preferred stock, valued for this purpose at \$1,000 per share.

9. STOCK OPTIONS AND WARRANTS

2001 Stock Option Plan

The purpose of the 2001 Plan is to promote long-term growth and profitability of Celsion Corporation by providing key people with incentives to improve stockholder value and to contribute to the growth and financial success of Celsion and enabling the company to attract, retain and reward the best available persons for positions of substantial responsibility. The 2001 Plan permits the granting of stock options (including nonqualified stock options and incentive stock options qualifying under Section 422 of the Code) and stock appreciation rights or any combination of the foregoing. During the year that ended December 31, 2004, 159,475 options became available under the 2001 Plan and were rolled into the 2004 Stock Incentive Plan.

2004 Stock Incentive Plan

The purpose of the 2004 Plan is to promote the long-term growth and financial success of the Company and enable the Company to attract, retain and reward the best available persons for positions of substantial responsibility. The 2004 Plan permits the granting of awards in the form of incentive stock options, restricted stock, restricted stock units, stock appreciation rights, phantom stock, and performance awards, or in any combination of the foregoing. At December 31, 2004 options to purchase 9,284,475 shares were available from the 10,159,475 authorized under the 2004 Plan.

The Company has issued stock options and warrants to employees, directors, vendors and debt holders. Options and warrants are generally granted at market value at the date of the grant.

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

	Options Outstanding	Weighted Average Exercise Price	Warrants Outstanding	Weighted Average Exercise Price
Outstanding at September 30, 2001	7,860,000	\$ 1.13	7,245,218	\$ 0.75
Granted	7,860,625	\$ 0.72	23,447,249	\$ 0.44
Exercised	(16,250)	\$ 0.52	(1,455,000)	\$ 0.03
Expired/cancelled	(5,293,751)	\$ 1.38	(4,964,298)	\$ 0.31
Outstanding at September 30, 2002	10,410,624	\$ 0.70	24,273,169	\$ 0.58
Granted	1,636,000	\$ 0.42	7,377,765	\$ 0.81
Exercised	(318,333)	\$ 0.52	(14,890,958)	\$ 0.38
Expired/cancelled	(100,000)	\$ 0.64	(206,100)	\$ 1.03

Edgar Filing: CELSION CORP - Form 10-K/A

Outstanding at September 30, 2003	11,628,291	\$ 0.66	16,553,876	\$ 0.86
Granted	310,000	\$ 1.11	2,107,065	\$ 1.13
Exercised	(5,000)	\$ 0.40	(196,500)	\$ 0.61
Expired/cancelled	(30,000)	\$ 0.47	0	
Outstanding at December 31, 2003	11,903,291	\$ 0.68	18,464,441	\$ 0.90
Granted	1,987,500	\$ 0.89	1,150,440	\$ 1.35
Exercised	(1,768,533)	\$ 0.66	(4,628,283)	\$ 0.62
Expired/cancelled	(664,850)	\$ 0.78	(91,000)	\$ 0.91
Outstanding at December 31, 2004	11,457,408	\$ 0.71	14,895,598	\$ 1.02

Weighted Average Fair Value of Options Granted for periods ending:

September 30, 2002	\$ 0.59
September 30, 2003	\$ 0.50
December 30, 2003	\$ 0.90
December 30, 2004	\$ 0.72

Following is additional information with respect to options and warrants outstanding at December 31, 2004:

Common Stock Options	Exercise	Exercise	Exercise
	Price from \$0.25 to \$0.60	Price from \$0.61 to \$1.01	Price from \$1.02 to \$5.00
Outstanding at December 31, 2004:			
Number of options	3,263,958	5,833,450	2,360,000
Weighted average exercise price	\$ 0.40	\$ 0.73	\$ 1.21
Weighted average remaining contractual life in years	5.75	9.23	5.20
Exercisable at December 31, 2004:			
Number of options	2,602,292	5,231,366	1,349,999
Weighted average exercise price	\$ 0.38	\$ 0.74	\$ 1.17
Weighted average remaining contractual life in years	5.06	6.46	2.65

Common Stock Warrants	Exercise	Exercise	Exercise
	Price from \$0.25 to \$0.60	Price from \$0.61 to \$1.01	Price from \$1.02 to \$5.00
Outstanding at December 31, 2004:			
Number of warrants	5,486,441	2,734,425	6,674,732
Weighted average exercise price	\$ 0.53	\$ 0.73	\$ 1.48
Weighted average remaining contractual life in years	2.23	2.63	3.45
Exercisable at December 31, 2004:			
Number of warrants	5,486,441	2,734,425	6,674,732
Weighted average exercise price	\$ 0.53	\$ 0.73	\$ 1.48
Weighted average remaining contractual life in years	2.23	2.63	3.45

Option Repricing

On March 25, 2002, in order to provide meaningful continuing stock-based incentives for members of management, and in recognition of the decline in the market price of the Company's Common Stock, the Compensation Committee of the Board of Directors approved the cancellation of options to purchase a total of 3,625,000 shares of Common Stock held by certain key executives and issued new options to purchase a total of 3,150,000 shares, resulting in a net decrease of options to purchase 475,000 shares. The cancelled options had been issued to the Company's executives pursuant to their respective employment contracts at exercise prices in excess of the current market price of the Company's Common Stock. These options consisted of certain options vested at the time of cancellation, as well as options with vesting dates through April of 2003, and with expiration dates through April of 2011. The new options consist of currently vested compensatory options, bonus options, one-third of which were currently vested and the remainder of which vested on March 31, 2003 and 2004, and performance-based awards that vest, if at all, upon achievement, by the Company, of certain specified milestones, all of which expire in May of 2012. All of the new options were issued pursuant to the Company's 2001 Stock Option Plan, at exercise prices at or in excess of the market price for the common stock on the date of grant.

The Company accounts for the repriced options using variable accounting under FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation-An Interpretation of APB Opinion No. 25*. Consequently, during each reporting period the Company adjusts compensation expense relating to the vested portion of the repriced options to the extent that the fair market value of the Company's Common Stock exceeds the exercise price of such options. The Company recognized compensation expense adjustments of \$(1,030,684), \$967,374 and \$0 for the years ended December 31, 2004, September 30, 2003 and September 30, 2002, respectively, and \$647,656 for the three

months ended December 31, 2003.

The compensation expense adjustment for the year ending December 31, 2004 was negative due to a decline in the market value of the Company's Common Stock., which was \$1.31 at the beginning of the year, \$1.24 at March 31, 2004, \$0.63 at June 30, 2004, \$0.50 at September 30, 2004 and \$0.57 at December 31, 2004. Since the exercise prices of the repriced options range from \$0.64 to \$0.92, all previous compensation expense adjustments were reversed during 2004.

Options Issued to Non-Employees for Services

The Company enters into agreements with consultants in which the consultants received stock options in exchange for services. The fair value of these options is estimated at the date of the grant using a Black-Scholes option pricing model. The Black-Scholes option pricing model was developed for use in estimating the fair value of options. It requires the use of certain somewhat subjective inputs. These inputs are listed below along with the weighted average of the values used by the Company:

	Year Ended December 31, 2004	Year Ended September 30, 2003	Year Ended September 30, 2002	Three Months Ended December 31, 2003
Risk-free interest rate	3.21%	2.88%	5.0%	3.2%
Expected volatility	94.0%	96.4%	50%	94.3%
Expected option life in years	7	5	5	7

Based upon these valuations, the Company recognized \$496,221, \$281,266 and \$ 259,172 of expense associated with its issuance of options in lieu of cash for services to consultants, for the years ended December 31, 2004, September 30, 2003 and 2002 and \$299,722 for the three months ended December 31, 2003.

Employee Stock Options

The Company has long-term compensation plans that permit the granting of incentive awards in the form of stock options. Generally, the terms of these plans require that the exercise price of the options may not be less than the fair market value of Celsion's Common Stock on the date the options are granted. Options generally vest over various time frames or upon milestone accomplishments. Some vest immediately. Others vest over a period between one to five years. The Company's options generally expire ten years from the date of the grant.

The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (Statement No. 123), but applies Accounting Principles Board Opinion No. 25 and related interpretations. No compensation expense related to the granting of stock options to employees or directors was recorded during the years ended December 31, 2004, September 30, 2003 and 2002 and the three months ended December 31, 2003. The fair value of these equity awards was estimated at the date of grant using a Black-Scholes option pricing model. The inputs used along with the weighted average of the values used were as follows:

	Year Ended December 31, 2004	Year Ended September 30, 2003	Year Ended September 30, 2002	Three Months Ended December 31, 2003
Risk-free interest rate	3.62%	2.88%	5.0%	3.2%
Expected volatility	93.4%	96.4%	50%	94.3%
Expected option life in years	6	3 - 5	3 - 5	5

10. LICENSE AGREEMENTS AND PROPRIETARY RIGHTS

The Company owns six United States patents, which are directed to its adaptive phased array methods of treating breast cancer, prostate cancer and BPH. Additionally, the Company has four United States patents pending, all of which have been filed internationally. Three of the pending United States patent applications are directed to the prostate cancer and BPH treatment system, and one is directed to a monopole deep tumor treatment system.

Through the Company's license agreements with Massachusetts Institute of Technology (MIT), MMTC, Inc. (MMTC), Duke University (Duke) and the Memorial Sloan-Kettering Cancer Institute (Sloan-Kettering), the Company has exclusive rights, within defined fields of use of nine United States patents. Three of these patents relate to the treatment of BPH, four relate to thermotherapy for cancer, one relates to heat-sensitive liposomes and one relates to gene therapy.

The MIT, MMTC, Duke and Sloan-Kettering license agreements each contains license fee, royalty and/or research support provisions, testing and regulatory milestones, and other performance requirements that the Company must meet by certain deadlines with respect to the use of the licensed technologies. In conjunction with the patent holders, the Company intends to file international applications for certain of the United States patents.

In 1996, the Company entered into a patent license agreement with MIT, pursuant to which the Company obtained exclusive rights to use of MIT's patented APA technology in conjunction with application of heat to breast tumor conditions, the application of heat to prostate conditions and all other medical uses. MIT has retained certain rights in the licensed technology for non-commercial research purposes. MIT's technology has been patented in the United States and MIT has patents pending for its technology in China and Europe. The term of the Company's exclusive rights under the MIT license agreement expires on the earlier of ten years after the first commercial sale of a product using the licensed technology or October 24, 2009, but the rights continue on a non-exclusive basis for the life of the MIT patents.

The Company entered into license agreements with MMTC in 1996 and 2002, for exclusive worldwide rights to MMTC's patents related to its balloon compression technology for the treatment of prostatic disease in humans. The exclusive rights under the MMTC license agreements extend for the life of MMTC's patents. MMTC currently has patents in the United States and Canada. The terms of these patents expire at various times from April 2008 to November 2014. In addition, MMTC also has patent applications pending in Japan and Europe.

Edgar Filing: CELSION CORP - Form 10-K/A

On November 10, 1999, the Company entered into a license agreement with Duke under which the Company received exclusive rights (subject to certain exceptions) to commercialize and use Duke's thermo-liposome technology. The license agreement contains annual royalty and minimum payment provisions and also requires milestone-based royalty payments measured by various events, including product development stages, FDA applications and approvals, foreign marketing approvals and achievement of significant sales. However, in lieu of

F-19

such milestone-based cash payments, Duke agreed to accept shares of the Company Common Stock to be issued in installments at the time each milestone payment is due, with each installment of shares to be calculated at the average closing price of the Common Stock during the 20 trading days prior to issuance. The total number of shares issuable to Duke under these provisions is subject to adjustment in certain cases, and Duke has piggyback registration rights for public offerings taking place more than one year after the effective date of the license agreement.

On January 31, 2003, the Company issued 3,805,366 shares of Common Stock to Duke University valued at \$2,175,000 as payment under this licensing agreement, which has been included in research and development expenses for the year ending September 30, 2003.

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

The Company has entered into a license agreement with Sloan-Kettering in November 2000 by which we obtained exclusive rights to Sloan-Kettering's United States patent and to patents that Sloan-Kettering may receive in the future for its heat-sensitive gene therapy in Japan, Canada and Europe, where it has patent applications pending. The rights under the agreement with Sloan-Kettering will terminate at the later of 20 years after the date of the agreement or the last expiration date of any patent rights covered by the agreement.

11. LITIGATION SETTLEMENT

During the year ended September 30, 2002 the Company settled litigation with a former director and a related investment group related to the issuance of Common Stock purchase warrants. In settlement of this litigation, the Company agreed to pay the lesser of certain legal costs or \$265,000 and to adjust the exercise price of 6,325,821 warrants originally issued to the investment group. Expense related to this settlement totaled \$741,724 and is included in selling, general and administrative expenses for the year ended September 30, 2002.

12. COMMITMENTS AND CONTINGENCIES

Lease Commitments

The following is a summary of our future minimum payments under contractual obligations as of December 31, 2004:

2005	\$ 186,926
2006	\$ 192,529
2007	\$ 198,364
2008	\$ 204,244
2009	\$ 210,379
Thereafter	\$ 179,657

Edgar Filing: CELSION CORP - Form 10-K/A

Rent expense for the years ended December 31, 2004, September 30, 2003 and September 30, 2002 was \$236,020, \$367,288 and \$359,206 , respectively, and \$70,782 for the three months ended December 31, 2003.

Contract Termination Commitments

We currently purchase our Prolieve catheters and related disposables from Catheter Research, Inc., or CR, under a Development and Supply Agreement dated December 11, 2001 and amended October 29, 2003. Under the Supply Agreement, CR is the exclusive provider of Prolieve catheter kits, subject to stated

F-20

minimum annual purchase obligations, at the price and on the terms set forth therein. The Supply Agreement provides for an initial term of three years from the receipt of the Prolieve PMA from the FDA, with annual automatic renewals thereafter, subject to the right of either party to terminate upon six months notice. However, Celsion may terminate the Supply Agreement at any time following notice to CR upon payment of termination fees in the amount of \$700,000, \$350,000 heretofore has been paid and the remaining \$350,000 is due and payable upon FDA approval of an alternative catheter manufacturer following purchase of at least 2,000 catheter kits at an agreed upon price, as well as certain fees based on the average annual selling price of catheter kits to third-party end users. As of the date hereof, Celsion has met its obligation to purchase 2,000 catheter kits. CR warrants the catheter kits to be free from defects relating to or arising from the design, manufacture, materials or sterilization techniques that result in the failure of CR products and the Supply Agreement contains other customary terms. Celsion provided notice of its intent to terminate on October 29, 2003. However, in order to secure our supply chain, we intend to retain CR as a second, back-up source following approval of Venusa Corporation as a catheter supplier.

13. CONCENTRATIONS OF CREDIT RISK

As of December 31, 2004, the Company had a concentration of credit represented by cash balances in one large financial institution that is not insured by the Federal Deposit Insurance Corporation. Additionally, the Company has a concentration of credit risk as a result of accounts receivable primarily consisting of amounts due from one company.

14. AGREEMENT WITH BOSTON SCIENTIFIC CORPORATION

On January 21, 2003, the Company and Boston Scientific Corporation (BSC) entered into a distribution agreement pursuant to which the Company has granted BSC certain rights to market and distribute the Company's BPH technology.

The Company and BSC also entered into a transaction agreement on January 21, 2003. Pursuant to this agreement, upon attainment of specified milestones by Celsion, BSC was obligated to make equity investments in Celsion through the purchase of the Company's Common Stock. On January 21, 2003, BSC purchased 9,375,354 shares of the Company's Common Stock for \$5,000,000. On March 2, 2004, BSC purchased 2,083,330 shares of the Company's Common Stock for \$4,000,000. On April 7, 2004 BSC purchased 1,273,885 shares of the Company's Common Stock for \$2,000,000.

The Company has also granted Boston Scientific the exclusive right to purchase 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.

Celsion also is a party to a Distribution Agreement dated January 21, 2003 with BSC. 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 Celsion received a payment from Boston Scientific 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.

15. YEAR END CHANGE

In December 2003, the Company's Board of Directors approved a change in the Company's fiscal year end from September 30 to December 31.

16. SELECTED QUARTERLY FINANCIAL INFORMATION FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003
(UNAUDITED)

	2004			
	First	Second	Third	Fourth
	Quarter	Quarter	Quarter	Quarter
Sales	\$ 100,000	\$ 442,945	\$ 539,549	\$ 1,423,734
Cost of sales	74,787	348,916	472,837	1,204,348
Gross profit on sales	25,213	94,029	66,712	219,386
General and administrative expenses	(1,569,388)	(367,161)	(601,966)	(932,354)
Research and development expenses	(4,586,084)	(1,386,258)	(2,973,522)	(2,587,557)
Other income/expense	64,579	187,804	198,193	163,326
Net loss	\$ (6,065,680)	\$ (1,471,586)	\$ (3,310,583)	\$ (3,137,199)
Net loss per share - basic and diluted	\$ (.04)	\$ (.01)	\$ (.02)	\$ (.02)
	2003			
	First	Second	Third	Fourth
	Quarter	Quarter	Quarter	Quarter
Sales				
Cost of sales				
Gross profit on sales				
General and administrative expenses	\$ (1,141,021)	\$ (925,279)	\$ (2,219,425)	\$ (856,968)
Research and development expenses	(3,652,560)	(1,929,435)	(1,499,257)	(2,109,795)
Other income/expense	(45,989)	(44,298)	(12,904)	12,929
Net loss	\$ (4,839,570)	\$ (2,899,012)	\$ (3,731,586)	\$ (2,953,834)
Net loss per share - basic and diluted	\$ (.04)	\$ (.03)	\$ (.03)	\$ (.02)