

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-K**

(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, 2005**

or

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

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

Commission file number 000-14242

**CELSION CORPORATION**

(Exact Name of Registrant as Specified in Its Charter)

**DELAWARE**  
(State or Other Jurisdiction of  
Incorporation or Organization)

52-1256615  
(I.R.S. Employer  
Identification No.)

10220-L OLD COLUMBIA ROAD  
COLUMBIA, MARYLAND  
(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:**

Title of Each Class	Name of Each Exchange on Which Registered
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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act YES  NO

Indicate by check mark if the Registrant is not required to file pursuant to Section 13 or Section 15(d) of the Act. YES  No

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

Indicate by check mark 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 a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one)

Large Accelerated Filer  Accelerated Filer  Non-accelerated Filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

As of March 15, 2006, 10,726,127 shares of the Registrant's Common Stock were issued and outstanding.

As of June 30, 2005, the aggregate market value of voting common stock held by non-affiliates of the Registrant was approximately \$47,389,349, 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 2006 Annual Meeting of Stockholders, scheduled for May 23, 2006, are incorporated by reference into Part III hereof, as indicated herein.

---

## Table of Contents

CELSION CORPORATION  
FORM 10-K  
TABLE OF CONTENTS

<u>PART I</u>	
<u>ITEM 1. BUSINESS</u>	2
<u>FORWARD-LOOKING STATEMENTS</u>	2
<u>GENERAL</u>	2
<u>THERMODOX (DOXORUBICIN ENCAPSULATED IN HEAT-ACTIVATED LIPOSOME)</u>	3
<u>Liver Cancer Overview</u>	4
<u>Celsion's Approach</u>	4
<u>Liver Cancer Phase I Trial</u>	4
<u>Recurrent Chest Wall Breast Cancer Overview</u>	4
<u>Breast Cancer Phase I Trial</u>	5
<u>PROLIEVE THERMODILATATION SYSTEM</u>	5
<u>Focused Heat Treatment</u>	5
<u>Marketing, Distribution and Supply</u>	5
<u>RESEARCH AND DEVELOPMENT</u>	6
<u>CONDUCT OF CLINICAL TRIALS</u>	6
<u>FDA REGULATION</u>	6
<u>Research and Development</u>	6
<u>Post Approval Requirements</u>	7
<u>Inspections</u>	7
<u>Recalls</u>	8
<u>Other FDA Regulations</u>	8
<u>OTHER FEDERAL REGULATIONS</u>	8
<u>PRODUCT LIABILITY AND INSURANCE</u>	9
<u>EMPLOYEES</u>	9
<u>SEASONALITY</u>	9
<u>COMPETITION</u>	9
<u>Prolieve</u>	9
<u>ThermoDox™</u>	9
<u>LICENCES, PATENTS AND TRADEMARKS</u>	9
<u>ITEM 1A. RISK FACTORS</u>	10
<u>ITEM 1B. UNRESOLVED STAFF COMMENTS</u>	18
<u>ITEM 2. PROPERTIES</u>	18
<u>ITEM 3. LEGAL PROCEEDINGS</u>	18
<u>ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	18
<u>PART II</u>	18
<u>ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	19
<u>MARKET PRICE FOR OUR COMMON STOCK</u>	19
<u>DIVIDEND POLICY</u>	19
<u>ISSUANCE OF SHARES WITHOUT REGISTRATION</u>	19
<u>ITEM 6. SELECTED FINANCIAL DATA</u>	20
<u>ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	22

## Table of Contents

<u>OVERVIEW</u>	22
<u>Development Pipeline</u>	23
<u>Recent Events</u>	24
<u>CRITICAL ACCOUNTING POLICIES AND ESTIMATES</u>	25
<u>RESULTS OF OPERATIONS</u>	26
<u>COMPARISON OF FISCAL YEAR ENDED DECEMBER 31, 2005 AND FISCAL YEAR ENDED DECEMBER 31, 2004</u>	26
<u>COMPARISON OF FISCAL YEAR ENDED DECEMBER 31, 2004 AND FISCAL YEAR ENDED DECEMBER 31, 2003</u>	27
<u>LIQUIDITY AND CAPITAL RESOURCES</u>	27
<u>ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	28
<u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA AND FINANCIAL DISCLOSURE</u>	28
<u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	29
<u>ITEM 9A. CONTROLS AND PROCEDURES</u>	29
<u>ITEM 9B. OTHER INFORMATION</u>	29
<u>PART III</u>	29
<u>ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS</u>	30
<u>ITEM 11. EXECUTIVE COMPENSATION</u>	30
<u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	30
<u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS</u>	31
<u>ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	31
<u>ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	31
<u>1 FINANCIAL STATEMENTS</u>	31
<u>2 FINANCIAL STATEMENT SCHEDULES</u>	31
<u>3 EXHIBITS</u>	32

**PART I**

**ITEM 1. BUSINESS**

**FORWARD-LOOKING STATEMENTS**

Certain of the statements contained in this Annual Report on Form 10-K 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.

**GENERAL**

Founded in 1982 as Cheung Laboratories, with a vision of using thermotherapy to treat cancer and other diseases, Celsion Corporation ("Celsion" or "the Company or "we") is a biotechnology company. The Company initially focused research efforts on the treatment of breast cancer. Celsion's core business activity is the development of products to treat cancer and other diseases and to commercialize those products to generate a return on investment for its stockholders through one of several means including (a) selling products directly to end users; (b) selling products through a distributor (as is the case with its Prolieve product); (c) licensing its technology to third parties and generating income through royalties and milestone payments.

In 2001 the Company narrowed its focus and concentrated its resources on commercializing a second generation treatment system for Benign Prostatic Hyperplasia (BPH) with the ultimate goal of using the funds generated from that product to develop cancer treatment drugs based on a heat activated liposome technology licensed from Duke University.

The Prolieve Thermomodulation® system for the treatment of BPH was approved by the FDA in 2004 and is being marketed by Celsion's exclusive distributor Boston Scientific Corporation. Boston Scientific also has a

## [Table of Contents](#)

five year (expiring in February 2009) option to purchase the Prolieve® assets for \$60 million. The funds generated to date from sales of Prolieve have been used in the development of the Company's first drug, ThermoDox™. Celsion is currently engaged in a Phase I, dose escalation study, in the treatment of primary liver cancer and expects to start enrolling patients in a second Phase I study to treat recurrent chest wall breast cancer during the second quarter of 2006.

In 2005 the Company made a strategic decision to discontinue the development of new thermotherapy devices and has since initiated a program to dispose of its device development business. In November 2005 the Company reached an agreement to sell its heat activated gene technology and in January 2006 the Company sold its breast cancer treatment device to its founder and former Chief Executive Officer, Dr. Augustine Cheung.

The Company intends to focus on developing drugs for the treatment of various cancer indications. The first of these development projects involves ThermoDox, our proprietary heat activated liposome containing doxorubicin. The Company plans to develop ThermoDox for multiple cancer indications where it believes that ThermoDox may enhance the therapeutic benefit offered by existing thermotherapy devices. For certain indications the Company may seek licensing partners to share in the development and commercialization costs. The Company will also evaluate licensing products from third parties for cancer treatments involving novel drugs or drug-delivery systems to expand its development pipeline.

Our principal offices are located at 10220-L Old Columbia Road, Columbia, Maryland and our telephone numbers are (410) 290-5490 and (800) 262-0394.

The Company makes available free of charge through its website, [www.celsion.com](http://www.celsion.com), its annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. In addition, copies of our annual report on Form 10-K will be made available free of charge upon written request. The SEC also maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file periodic and other reports electronically with the Securities and Exchange Commission. The address of that site is [www.sec.gov](http://www.sec.gov). The material on our website is not a part of this Annual Report on Form 10-K.

### **THERMODOX (DOXORUBICIN ENCAPSULATED IN HEAT-ACTIVATED LIPOSOME)**

Conventional liposomes are manufactured lipid spheres that can carry drugs and delay their elimination by the body, allowing the drugs to remain in the bloodstream for extended periods of time. However, the currently available liposome drug delivery products used to treat cancer do not provide for active targeting of organ specific tumors.

A team of Duke University scientists has developed heat-sensitive liposomes comprised of lipid molecules that rapidly change structure when heated to a specific temperature (40° to 42° C), creating openings in the liposome allowing it to release its drug rapidly.

In 1999, Celsion obtained an exclusive commercialization license from Duke University to this proprietary heat-sensitive liposome technology for the delivery of a wide range of drugs. In partnership with Duke University, Celsion has encapsulated doxorubicin, an approved and frequently used cancer drug, in its investigational heat-activated liposome product, ThermoDox. Celsion intends to use various available focused-heat technologies to provide localized heating of tumors to trigger the release of doxorubicin from ThermoDox after intravenous administration. As these liposomes circulate within the tumor tissue and tumor vasculature, the locally applied heat will cause the rapid release of doxorubicin within the targeted tumor. Celsion believes that this approach can deliver greater concentrations of drug directly to the tumor, while potentially improving the tolerability problems associated with conventional chemotherapy.

Animal studies have demonstrated that the intravenous administration of ThermoDox in combination with targeted heat to the tumor can produce tumor tissue concentrations higher than that achieved in the same experiments with traditional or non-heat sensitive liposomal doxorubicin formulations when given at the same dose as ThermoDox.

## [Table of Contents](#)

Celsion is pursuing primary liver cancer as its lead indication for ThermoDox. The Company is also evaluating the possibility of using ThermoDox or other chemotherapeutic agents encapsulated in its heat activated liposome to treat other cancers.

### **Liver Cancer Overview**

Primary liver cancer (Hepatocellular carcinoma or HCC) is one of the most common and deadliest forms of cancer worldwide. It is estimated that up to 90% of liver cancer patients will die within five years of diagnosis. There are approximately 19,000 new cases per year of HCC in the U.S. With the inclusion of liver metastases from other cancers (e.g. colon, lung, breast, etc) the total number of cases of liver cancer in the U.S. increases significantly.

Although the standard treatment for liver cancer is surgical excision of the tumor, 80 to 90% of patients are ineligible for surgery at time of diagnosis as early stage liver cancer generally has few symptoms and when finally detected the tumor frequently is too large for surgery. There are few alternative treatments, since radiation therapy and chemotherapy are largely ineffective. For tumors generally up to about two inches in diameter, radiofrequency ablation (RFA) is a commonly utilized treatment approach which directly destroys the tumor tissue through the application of high temperatures by a probe inserted into the core of the tumor.

### **Celsion's approach**

While RFA uses extremely high temperatures (80°-100° C) to ablate the tumor, it may fail to treat micrometastases in the outer margins of ablated tumors because temperatures in the periphery may not be high enough to destroy the cancer cells. Local recurrence can be a problem especially for tumors greater than about one inch in diameter. Celsion's ThermoDox treatment approach is designed to utilize the ability of RFA devices to ablate the center of the tumor while simultaneously thermally activating the ThermoDox liposome to release its encapsulated doxorubicin to kill remaining viable cancer cells throughout the heated region, including the tumor ablation margins. This treatment is intended to deliver the drug directly to those cancer cells that survive RFA. This approach will also increase the delivery of the drug at the desired tumor site while potentially reducing drug exposure distant to the tumor site.

### **Liver Cancer Phase I Trial**

A Phase I single dose escalation study is underway which is investigating ThermoDox in combination with RFA for the treatment of liver cancer. The study is currently being performed at the National Cancer Institute (NCI), which is part of the National Institutes of Health (NIH). The Company treated its first patient on February 14, 2005, and expects to complete treatment of all patients in the Phase I study by the middle of 2006. The Company is currently planning a Phase II/III study which it hopes to initiate in late 2006 or early 2007.

### **Recurrent Chest Wall Breast Cancer Overview**

Studies at Duke University and other centers have indicated that heat may improve the therapeutic action of non temperature sensitive liposomal doxorubicin formulations in advanced loco-regional breast cancer. Celsion, in collaboration with Duke University, has decided to explore the potential of ThermoDox to treat a population of advanced breast cancer patients with loco-regional chest wall disease or Recurrent Chest Wall Breast Cancer (RCW).

RCW cancer is a condition which afflicts patients that have undergone a mastectomy, surgery to remove a cancerous breast, and occurs in about 15,000 patients annually in the United States. There is currently no generally effective therapeutic approach for this condition with the result that many of these patients die within two years of the local recurrence of their breast cancer.

As in the liver cancer program, we are using a commercially available thermotherapy device to activate ThermoDox at the desired target site. In the case of RCW tumors, however, the heat source will be a microwave device which is designed to heat the target tissue to a temperature adequate to activate ThermoDox but not ablate the tissue as with RFA.

## [Table of Contents](#)

### **Breast Cancer Phase I Trial**

Celsion has provided a research grant to Duke University and will provide clinical supplies of ThermoDox to support a Phase I, open label study of the safety and pharmacokinetics in RCW patients. Duke expects to start enrollment in the second quarter of 2006.

### **PROLIEVE THERMODILATATION SYSTEM**

#### **Focused Heat Treatment**

Celsion's minimally invasive transurethral microwave system, the Prolieve Thermodilatation system, combines heat transmitted through a transurethral microwave thermotherapy device with pressure applied by a unique balloon catheter to produce a natural stent to reopen the urethra. At the same time, the microwave applied heat kills prostate cells outside the wall of the urethra, creating space for the enlarged natural opening.

It is a relatively painless, rapid outpatient procedure, requiring no sedation, generally no post-operative catheterization, and delivering rapid symptomatic relief.

The procedure is eligible for Medicare/Medicaid and insurance reimbursement averaging \$4,000. The market for minimally invasive procedures is currently approximately \$75 million and growing rapidly. Management believes the potential for Prolieve could be greater than \$125 million.

As mentioned above, Celsion has granted Boston Scientific exclusive marketing rights to the Prolieve Thermodilatation System. In addition, Celsion has also granted Boston Scientific the option to purchase the assets and technology relating to Prolieve for a period of five years from its launch (February 2004) for a price of \$60 million less any principal and accrued interest outstanding under a \$15 million loan from Boston Scientific. At December 31, 2005 the outstanding principal and interest amounted to \$6.2 million.

#### **Marketing, Distribution and Supply**

Celsion markets the Prolieve system through an exclusive Distribution Agreement with Boston Scientific Corporation, pursuant to which Celsion granted Boston Scientific exclusive rights to market and distribute Prolieve and its component parts for the treatment of BPH. Under the terms of this agreement Boston Scientific markets and distributes Prolieve in the United States and has a license to market and distribute the product worldwide, with the exception of Greater China, Mexico and Central and South America. Boston Scientific through its urology sales force launched the product in the United States in February 2004 targeting Urology practices throughout the country. Trial of the system is generated through the placement of control units in physician's offices for an evaluation period at the end of which the physician either acquires the machine or returns it to Boston Scientific. Since approval in February 2004 Prolieve has been sold exclusively in the United States generating revenues of \$2,506,000 in the year ended December 31, 2004 and \$12,320,000 in the year ended December, 31 2005. As of December 31, 2005 approximately 15,000 treatments had been performed using the Prolieve system.

Under the terms of the Distribution Agreement Celsion is responsible for supplying control units and disposables to Boston Scientific. Celsion supplies an inventory of control units to Boston Scientific. Boston places these machines as evaluation units for eventual sale or sells the units directly to physicians. Celsion records a sale when Boston Scientific ultimately sells control units to end users. Celsion sells control units to Boston Scientific at its fully loaded cost plus half of any profit generated on the sale. Celsion sells disposable kits, which includes a catheter, a heat exchanger, a tubing set and a bag of sterile water, to Boston Scientific at 50% of the average selling price generated by sales of the disposable kits during the preceding six month period ending on December 31 and June 30 of each year. Boston Scientific is responsible for maintaining an inventory of disposable kits.

Celsion has contracted out the manufacturing of both the control units and the catheter kits. Prolieve<sup>®</sup> Control units are manufactured under a Medical Product Manufacturing Services Agreement by Sanmina-SCI. During 2005 we purchased disposable catheter kits from Catheter Research, Inc., pursuant to a Development and Supply Agreement. Beginning in October 2005, we initiated supply from an additional manufacturer, Accellant (formerly Venusa) Corporation, for the production of catheters and disposables under a Medical Product Manufacturing Services Agreement.

## **RESEARCH AND DEVELOPMENT**

Celsion engages in a limited amount of research and development in its own facilities, and instead sponsors the majority of the research programs in partnership with various research institutions including Duke University. Our expenditures for research and development were \$10,081,000, \$11,533,000 and \$9,191,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

## **CONDUCT OF CLINICAL TRIALS**

During 2004, Celsion shifted from monitoring its clinical trials using Celsion employees to contracting with contract research organizations, or CROs, to monitor its trials. Use of CROs enables Celsion to perform high quality clinical trials without the need to hire staff and build infrastructure to support such trials and to retain all rights to, and control over, its product candidates. We have instituted a formal process for requesting and reviewing proposals from, and interviewing, prospective CROs in advance of the initiation of each of our clinical trials. Following such process, in December 2004 we retained Theradex® as our CRO in connection with the ThermoDox/RFA Phase I liver cancer study and in February 2005 we retained INC Research, Inc. in connection with the Prolieve post-market study.

## **FDA REGULATION**

### **Research and Development**

Our research and development activities, pre-clinical tests and clinical trials and, ultimately, the manufacturing, marketing and labeling of our products, are subject to extensive regulation by the FDA. The Federal Food, Drug and Cosmetic Act, the Public Health Service Act and the regulations promulgated by the FDA govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising, promotion, import and export of our products.

Under these statutes, our Prolieve system is regulated as a class III medical device, our heat-activated liposomes may be regulated as a new drug and our Cancer Repair Inhibitors may be regulated as a biological product. The steps ordinarily required before such products can be marketed in the U.S. include (a) pre-clinical and clinical studies; (b) the submission to the FDA of an application for an Investigational Device Exemption (IDE) or approval as an Investigational New Drug (IND) which must become effective before human clinical trials may commence; (c) adequate and well-controlled human clinical trials to establish the safety and efficacy of the product; (d) the submission to the FDA of an application for premarketing approval (PMA), a New Drug Application (NDA), or a Biological License Application (BLA); and (e) FDA approval of the application, including approval of all product labeling.

Pre-clinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product. Pre-clinical safety tests must be conducted by laboratories that comply with FDA regulations regarding Good Laboratory Practice. The results of pre-clinical tests are submitted to the FDA as part of an IDE or IND and are reviewed by the FDA before the commencement of human clinical trials. Submission of an IDE or IND will not necessarily result in FDA authorization to commence clinical trials and the absence of FDA objection to an IDE or IND does not necessarily mean that the FDA will ultimately approve a PMA or that a product candidate otherwise will come to market.

Clinical trials involve the administration of therapy to humans under the supervision of a qualified principal investigator. Clinical trials must be conducted in accordance with Good Clinical Practices under protocols submitted to the FDA as part of an IDE or IND. Also, each clinical trial must be approved and conducted under the auspices of an internal review board, or IRB, and with patient informed consent. An IRB will consider, among other things, ethical factors, and the safety of human subjects and the possible liability of the institution conducting the clinical trials.

Clinical trials are typically conducted in two or three sequential phases, but the phases may overlap. Phase I clinical trials involve the initial introduction of the therapy to a small number of subjects. Phase II trials are

## [Table of Contents](#)

generally larger trials conducted in the target population. For devices such as our Prolieve system, Phase II studies may serve as the pivotal trials, providing the demonstration of safety and effectiveness required for approval. However, as in the case of the PMA for Prolieve, the FDA has required additional, post-market trials as a condition of approval. In the case of drugs and biological products, Phase II clinical trials generally are conducted in a target patient population to gather evidence about the pharmacokinetics, safety and biological or clinical efficacy of the drug for specific indications, to determine dosage tolerance and optimal dosage and to identify possible adverse effects and safety risks. When a drug or biological compound has shown evidence of efficacy and an acceptable safety profile in Phase II evaluations, Phase III clinical trials are undertaken to serve as the pivotal trials to demonstrate clinical efficacy and safety in an expanded patient population.

There can be no assurance that any of our clinical trials will be completed successfully, within any specified time period or at all. Either the FDA or we may suspend clinical trials at any time, if either the FDA or we conclude that clinical subjects are being exposed to an unacceptable health risk or for other reasons. The FDA inspects and reviews clinical trial sites, informed consent forms, data from the clinical trial sites (including case report forms and record keeping procedures) and the performance of the protocols by clinical trial personnel to determine compliance with Good Clinical Practices. The FDA also examines whether there was bias in the conduct of clinical trials. The conduct of clinical trials is complex and difficult, especially in pivotal Phase II or Phase III trials. There can be no assurance that the design or the performance of the pivotal clinical trial protocols or any of our current or future product candidates will be successful.

The results of pre-clinical studies and clinical trials, if successful, are submitted in an application for FDA approval to market the device, drug or biological product for a specified use. The testing and approval process requires substantial time and effort, and there can be no assurance that any approval will be granted for any product at any time, according to any schedule, or at all. The FDA may refuse to accept or approve an application if it believes that applicable regulatory criteria are not satisfied. The FDA may also require additional testing for safety and efficacy. Moreover, if regulatory approval is granted, the approval will be limited to specific indications. There can be no assurance that any of our current product candidates will receive regulatory approvals for marketing or, if approved, that approval will be for any or all of the indications that we request.

The FDA is authorized to require various user fees including NDA fees (currently up to \$767,400) and PMA application fees (currently ranging from \$7,103 up to \$98,648). The FDA is also authorized to require annual user fees for approved products and for companies with establishments at which finished products are manufactured, which fees may increase from year to year. The FDA may waive or reduce such user fees under special circumstances. We seek waivers or reductions of user fees where possible, but we cannot be assured that we will be eligible for any such waiver or reduction.

### **Post Approval Requirements**

Even after receipt of necessary regulatory approvals for initial manufacturing and sale of our product candidates, our manufacturing facilities and products are subject to ongoing review and periodic inspection. Each U.S. device, drug and biologic manufacturing establishment must be registered with the FDA. Manufacturing establishments in the U.S. and abroad are subject to inspections by the FDA and must comply with the FDA's QSR regulations. Medical devices also must comply with the FDA's QSR regulations. In order to ensure full technical compliance with such regulations, manufacturers must expend funds, time and effort in the areas of production and quality control. In addition, the FDA may impose post-approval requirements on us, including the requirement that we conduct specified post-marketing studies.

### **Inspections**

We are subject to the periodic inspection of our clinical trials, facilities, procedures and operations and/or the testing of our products by the FDA to determine whether our systems and processes are in compliance with FDA regulations. Following such inspections, the FDA may issue notices on Form 483 and warning letters that could cause us to modify certain activities identified during the inspection. A Form 483 notice is generally issued at the conclusion of an FDA inspection and lists conditions the FDA inspectors believe may violate FDA regulations. FDA guidelines specify that a warning letter only is to be issued for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

---

[Table of Contents](#)

**Recalls**

The FDA has the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. A governmentally mandated recall, or a voluntary recall by us, could result from a number of events or factors, including component failures, manufacturing errors, design defects or defects in labeling.

**Other FDA Regulations**

We are also subject to recordkeeping and reporting regulations, including the FDA's mandatory Medical Device Reporting, or MDR, regulations. These regulations require, among other things, the reporting to the FDA of adverse events alleged to have been associated with the use of a product or in connection with certain product failures.

Labeling and promotional activities also are regulated by the FDA and, in certain instances, by the Federal Trade Commission (FTC). We must also comply with record keeping requirements as well as requirements to report certain adverse events involving our products. The FDA can impose other post-marketing controls on us as well as our products including, but not limited to, restrictions on sale and use, through the approval process, regulations and otherwise.

**OTHER FEDERAL REGULATIONS**

The Federal Communications Commission (FCC) regulates the frequencies of microwave and radio-frequency emissions from medical and other types of equipment to prevent interference with commercial and governmental communications networks. The FCC has approved the frequency of 915 MHZ for medical applications, and machines utilizing that frequency do not require shielding to prevent interference with communications. Our products utilize the 915 MHZ frequency.

## [Table of Contents](#)

### **PRODUCT LIABILITY AND INSURANCE**

Our business exposes us to potential product liability risks that are 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, 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 out of our own limited resources.

### **EMPLOYEES**

As of March 15, 2006, we employed 29 full-time employees and also utilized the services of part-time consultants from time to time. None of our employees are covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

### **SEASONALITY**

Customer purchasing patterns do not show significant predictable seasonal variation.

### **COMPETITION**

#### **Prolieve**

BPH has traditionally been treated either surgically using a procedure in which the prostatic urethra and surrounding tissue in the prostate are trimmed with a telescopic knife, thereby reopening the urethral channel for urine flow. Procedures have been developed as alternatives to TURPs using interstitial Radiofrequency or laser ablation to remove the obstructing portion of the prostate. The condition can also be treated with one of two classes of drugs. Alpha-blockers, are one such class of drug, the most commonly prescribed of which are Hytrin® and Flowmax®. These drugs work by relaxing muscles surrounding the urethra, thereby easing urinary flow. The alternate drug type is Proscar® which is designed to shrink the enlarged gland. However for a number of reasons these treatments may be inadequate due to side effects or lack of effectiveness. This inadequacy has led to the development of transurethral microwave treatments (TUMT) which ablate the tissue surrounding the prostatic urethra removing the blockage. These TUMT systems include devices marketed by Urologix (NASDAQ:ULGX) and American Medical Systems Holdings, Inc. ((NASDAQ:AMMD), or AMS (which acquired TherMatrx in July 2004), as well as Prolieve. Celsion believes and market experience to date has confirmed that the Prolieve's combined attributes of rapid relief, as demonstrated by its low level of post treatment catheterization, low pain and minimal side effects make Prolieve more than competitive in this market.

#### **ThermoDox**

Although there are many drugs and devices marketed and under development for the treatment of cancer, the Company is not aware of any other heat activated drug delivery product either being marketed or under clinical development.

### **LICENSES, PATENTS AND TRADEMARKS**

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.

## [Table of Contents](#)

In 1996, the Company entered into a patent license agreement with MIT, pursuant to which the Company obtained exclusive rights to use 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.

On November 10, 1999, the Company entered into a license agreement with Duke University under which the Company received exclusive rights (subject to certain exceptions) to commercialize and use Duke's thermo-liposome technology. In January 2003, Celsion purchased these rights from Duke upon the issuance 3,805,366 shares of the Company's Common Stock with a value of \$2,175,014, subject to any agreement to pay a royalty based upon future sales.

The Company's rights under the license agreement with Duke University extend for the longer of 20 years or the end of any 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 expires 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, the Company's license rights are worldwide, with various patent rights covering the United States, Canada, the United Kingdom, France, Germany and Japan.

The Company entered into a license agreement with Sloan-Kettering in November 2000 by which the Company 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 Company's 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.

In addition to the rights available to the Company under completed or pending license agreements, the Company relies on its own proprietary know-how and experience in the development and use of heat for medical therapies, which the Company seeks to protect, in part, through proprietary information agreements with employees, consultants and others. The Company cannot offer assurances that these information agreements will not be breached, that the Company will have adequate remedies for any breach or that these agreements, even if fully enforced, will be adequate to prevent third-party use of the Company's proprietary technology. Similarly, the Company cannot guarantee that technology rights licensed to it by others will not be successfully challenged or circumvented by third parties, or that the rights granted will provide the Company with adequate protection.

### **ITEM 1A. RISK FACTORS**

The following is a summary of the risk factors that we believe are most relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ significantly from anticipated or historical results. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events, or otherwise. You are advised, however, to consult any further disclosure we make on related subjects in our reports on forms 10-Q and 8-K filed with the SEC.

#### **WE HAVE A HISTORY OF SIGNIFICANT LOSSES 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 \$82,903,000 at December 31, 2005, including losses of \$8,685,000 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

## [Table of Contents](#)

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 liver cancer and recurrent chest wall breast cancer treatment systems, as well as other potential new products. We expended approximately \$13,500,000 in the 12-month period ended December 31, 2005. As of that date, we had available a total of approximately \$8,300,000 in cash, cash equivalents and short term investments 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, either directly or through other strategic alliances and distribution arrangements with third parties. There can be no assurance that we will be able to enter into third-party marketing or distribution arrangements on advantageous terms or at all. To the extent that we do enter into such arrangements, we will be dependent on our marketing and distribution partners. In entering into third-party marketing or distribution arrangements, we expect to incur significant additional expense. There can be no assurance that, to the extent that we sell products directly or we enter into any commercialization arrangements with third parties, such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for our products and services.

**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 or limited 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 29 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 an exclusive license agreement 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-sensitive liposome technology. The MMTC and, Duke University 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.

## [Table of Contents](#)

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.

We are subject to the periodic inspection of our clinical trials, facilities, procedures and operations and/or the testing of our products by the FDA to determine whether our systems and processes are in compliance with FDA regulations. Following such inspections, the FDA may issue notices on Form 483 and warning letters that could cause us to modify certain activities identified during the inspection. A Form 483 notice is generally issued at the conclusion of an FDA inspection and lists conditions the FDA inspectors believe may violate FDA regulations. FDA guidelines specify that a warning letter is issued only for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

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

We are also subject to 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.

## [Table of Contents](#)

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

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

Failure to comply with applicable 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 development projects using ThermoDox plus RFA or microwave heating, are currently in the early stages of Phase I clinical trials. Any or all of these projects may prove not to be effective in practice. If testing and clinical practice do not confirm the safety and efficacy of our systems or, even if further testing and practice produce positive results but the medical community does not view these new forms of treatment as effective and desirable, our efforts to market our new products may fail, with material adverse consequences to our business.

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

Various methods for treating cancer currently are, and in the future 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 various technologies, both for prostate disease and cancer treatment products that seek treatment outcomes similar to those that we are pursuing. We believe that the level of interest by others in investigating the potential of possible competitive treatments and alternative technologies will continue and may increase. Potential competitors engaged in all areas of prostate and cancer treatment research in the United States and other countries include, among others, major pharmaceutical, specialized technology companies, and universities and other research institutions. Most of our competitors and potential competitors have substantially greater financial, technical, human and other

## [Table of Contents](#)

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.**

The following information reflects the 15:1 reverse stock split effected February 27, 2006.

As of December 31, 2005, we had outstanding and exercisable warrants and options to purchase a total of 1,643,552 shares of our Common Stock, including 3,740 shares issuable upon exercise of preferred stock warrants and the subsequent conversion of the preferred shares to Common Stock, at exercise prices ranging from \$3.75 to \$75.00 per share (and a weighted average exercise price of approximately \$11.10 per share). In addition, we had outstanding but unexercisable and unvested options to purchase a total of 611,768 shares of our Common Stock at exercise prices ranging from \$4.05 to \$22.50 per share. Some of the prices are below the current market price of our Common Stock, which has ranged from a low of \$3.90 to a high of \$4.80 over the 20 trading days ending December 31, 2005 and from a low of \$3.75 to a high of \$4.29 over the 20 trading days ending March 15, 2006. 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.

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 would likely to have a material 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 \$0.62 and a low price of \$0.25 in the 52-week period ending December 31, 2005. Factors such as announcements of technological innovations or new products by us or by our competitors, government regulatory action, litigation, patent or proprietary rights developments and market conditions for medical and high technology stocks in general can have a significant impact on the market for our Common Stock

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

While our Common Stock is listed on the 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.

**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

## [Table of Contents](#)

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 1B. UNRESOLVED STAFF COMMENTS**

None.

### **ITEM 2. PROPERTIES**

We lease premises consisting of approximately 13,891 square feet of administrative office, laboratory and workshop space at 10220-L Old Columbia Road, Columbia, Maryland 21046-2364 from an unaffiliated party under a seven-year lease that expires on October 31, 2010. Rent expense for the year ended December 31, 2005 was \$275,771. Future minimum lease obligations are as follows:

2006	\$ 211,873
2007	\$ 222,039
2008	\$ 206,217
2009	\$ 210,379
2010	\$ 179,657

Celsion has adequate office and laboratory space for the foreseeable future.

### **ITEM 3. LEGAL PROCEEDINGS**

None.

### **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None.

**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****MARKET PRICE FOR OUR COMMON STOCK**

Our Common Stock trades on The American Stock Exchange. The following table sets forth the high and low sales prices for our Common Stock reported by The American Stock Exchange. The quotations set forth below do not include retail markups, markdowns or commissions.

	<u>High</u>	<u>Low</u>
<b>YEAR ENDED DECEMBER 31, 2004</b>		
First Quarter (January 1 - March 31, 2004)	\$2.10	1.10
Second Quarter (April 1 - June 30, 2004)	\$1.33	0.42
Third Quarter (July 1 - September 30, 2004)	\$0.75	0.45
Fourth Quarter (October 1 - December 31, 2004)	\$0.70	0.40
<b>YEAR ENDED DECEMBER 31, 2005</b>		
First Quarter (January 1 - March 31, 2005)	\$0.62	\$0.32
Second Quarter (April 1 - June 30, 2005)	\$0.50	\$0.25
Third Quarter (July 1 - September 30, 2005)	\$0.50	\$0.32
Fourth Quarter (October 1 - December 31, 2005)	\$0.38	\$0.26

On March 16, 2006, the last reported sale price for our Common Stock on The American Stock Exchange was \$4.00 (Reflects 15:1 reverse stock split effective February 27, 2006). As of March 15, 2006, there were approximately 1,400 holders of record of our Common Stock.

**DIVIDEND POLICY**

We have never declared or paid any cash dividends on our Common Stock or other securities and do not currently anticipate paying cash dividends in the foreseeable future.

**ISSUANCE OF SHARES WITHOUT REGISTRATION**

On February 23, 2005 we issued 98,684 shares of common stock, valued at \$44,408, to Dr. Max Link as a retainer for his services as Chairman of the Board of Directors. These shares are restricted stock, and the certificates representing such shares are endorsed with the Celsion's standard restricted stock legend, with a stop transfer instruction recorded by the transfer agent. Accordingly, Celsion views the shares issued as exempt from registration under Sections 4(2) and/or 4(6) of the Securities Act of 1933, as amended.

See also "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters—Equity Compensation Plan Information."

[Table of Contents](#)

Period	Issuer Purchases of Equity Securities			
	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Number of Shares Available for Purchase under Publicly Announced Programs
October 1 –31, 2005	—	—	—	—
November 1 –30, 2005	—	—	—	—
December 1 –31, 2005	—	—	—	—
Total	—	—	—	—

The Company has never entered into a stock repurchase program.

**ITEM 6. SELECTED FINANCIAL DATA**

The following table contains certain financial data for Celsion for the five fiscal years ended December 31, 2005, is qualified in its entirety by, and should be read in conjunction with, “Item 8. Financial Statements and Supplementary Data and Financial Disclosure” and “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.” In December 2003, the Board of Directors acted to change Celsion’s fiscal year end from September 30 to December 31, effective with the year ended December 31, 2003. Therefore, the information for prior periods had been restated consistent with a December 31 year end.

[Table of Contents](#)

	YEAR ENDED DECEMBER 31,				
	2001 (unaudited)	2002 (unaudited)	2003 (unaudited)	2004	2005
	(Amounts in Thousands, Except Per Share Amounts)				
STATEMENT OF OPERATIONS DATA:					
Revenues	\$ —	\$ —	\$ —	\$ 2,506	\$12,320
Cost of sales	—	—	—	2,101	8,113
Gross profit	—	—	—	405	4,207
Other costs and expenses:					
Research and development	4,642	4,979	9,191	11,533	10,081
Selling, general and administrative	2,822	5,132	5,143	3,471	3,406
Total operating expenses	7,464	10,111	14,334	15,004	13,487
Loss from operations	(7,464)	(10,111)	(14,334)	(14,599)	(9,280)
Other income (expense), net	(189)	(384)	(137)	384	475
Interest income net of interest expense	217	38	47	230	120
Net loss	\$ (7,436)	\$ (10,457)	\$ (14,424)	\$ (13,985)	\$ (8,685)
Net loss per share <sup>1</sup>	\$ (1.47)	\$ (1.80)	\$ (1.75)	\$ (1.32)	\$ (0.81)
Weighted average shares outstanding <sup>1</sup>	5,052	5,794	8,257	10,584	10,725

<sup>1</sup> Adjusted to reflect 15:1 reverse stock split effected on February 27, 2006

[Table of Contents](#)

	AS OF DECEMBER 31,				
	2001	2002	2003	2004	2005
	(unaudited)	(unaudited)			
	(Amounts in Thousands, Except Per Share Amounts)				
<b>BALANCE SHEET DATA:</b>					
Cash and cash equivalents and short term investments	\$ 4,335	\$ 1,051	\$ 12,272	\$ 10,484	\$ 8,313
Working Capital	4,457	993	12,582	12,019	8,495
Total Assets	4,848	2,640	14,440	15,909	17,052
Debt	—	500	—	—	6,178
Deferred revenue-license fee	—	—	—	2,952	2,381
Other liabilities	—	—	—	—	30
Redeemable preferred stock:					
Series A 10% Convertible Preferred Stock	1,064	1,153	—	—	—
Series B 8% Convertible Preferred Stock	—	1,427	—	—	—
Accumulated deficit	(35,286)	(45,808)	(60,232)	(74,217)	(82,903)
Total stockholders' equity	4,805	1,218	13,453	11,971	3,425

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

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

## [Table of Contents](#)

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 heat activated liposomal encapsulation of doxorubicin, for the treatment of liver cancer and breast cancer.

### Development pipeline

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

<u>Product</u>	<u>Status</u>
<ul style="list-style-type: none"><li>• Prolieve Thermodilatation system for the treatment of BPH</li></ul>	We received premarketing approval (PMA) for the Prolieve system from the FDA on February 19, 2004. Since that time, we have been commercializing the Prolieve system through Boston Scientific. Boston Scientific has an option to purchase the Prolieve assets (expiring February 2009) for \$60 million.
<ul style="list-style-type: none"><li>• ThermoDox (Doxorubicin-laden thermo-liposome) plus heat for the treatment of cancer</li></ul>	We are conducting a Phase I clinical trial in collaboration with the National Institutes of Health and Queen Mary's Hospital in Hong Kong using ThermoDox in conjunction with radio frequency ablation in the treatment of liver cancer. We have also funded a study investigating the use ThermoDox for the treatment of recurrent chest wall breast cancer. Patient enrollment for this study being performed by Duke University is expected to commence in the first half of 2006.

We anticipate that, in the near term (up to 12 months), the source of our revenues will be from sales of our Prolieve system and related disposables. In the longer term (beyond 12 months), we expect to seek to develop new revenue streams from our current work with Duke University in targeted drug delivery systems. 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 throughout the body or from the sale of one or more of these technologies.

From 1995 to 2004, we 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 million under our agreement with Boston Scientific, the distributor of our Prolieve system. During the portion of 2004 and 2005 subsequent to receipt of the PMA, sales of Prolieve products generated revenues of \$14.8 million. 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 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.

## [Table of Contents](#)

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 ThermoDox plus heat and certain ongoing studies related to our Prolieve system; and the costs of development and design of other products and
- Corporate overhead.

Our research and development activities, pre-clinical tests and clinical trials, and the manufacturing, marketing and labeling of each of our products, are subject to extensive regulation by the FDA. We may not bring to market any product without approval, in the form of a premarketing approval from the FDA. We received such premarketing approval for our Prolieve system on February 19, 2004. We are currently conducting basic research and development activities, pursuing prototype products through clinical testing and regulatory approval. Our ultimate objective is to commercialize those products to generate a return on investment for 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) or (c) licensing the technology to third parties and generating income through royalties and milestone payments.

### **Recent Events**

On January 16, 2006, Celsion contributed to its wholly-owned subsidiary, Celsion (Canada) Limited (“Canada”), all of the Company’s assets relating to its Adaptive Phased Array (“APA”) technology for the treatment of breast cancer. Also on that date, the Company entered into a Stock Purchase Agreement with the Company’s founder and former officer and director, Dr. Augustine Y. Cheung, whereby the Company sold to Dr. Cheung all of the issued and outstanding shares of capital stock of Canada. The Company also agreed to provide certain services to Canada pursuant to a Transition Services Agreement between the Company and Canada.

Under the Stock Purchase Agreement all of the capital stock of Canada was transferred to Dr. Cheung in exchange for a promissory note made by Dr. Cheung in favor of the Company in the principal amount of \$1,500,000 to be paid over a period of up to 78 months and secured by a pledge of 1,508,050 shares of Celsion common stock owned by Dr. Cheung and his wife; and the commitment of Canada to pay a 5 percent royalty on the net sales of certain products sold by and patent royalties received by Canada and its successors and assigns, of up to \$18,500,000.

Under the Transition Services Agreement Celsion will sublease space in the Company’s offices for use by Canada to carry on its business, for a period of up to six (6) months from the date of the agreement; provide administrative support services as needed in the operation of Canada’s business for the period of the sublease and advance funds to pay salary and health and dental insurance of each of certain employees of Canada and expenses reasonably incurred in connection with the operation of Canada’s business up to \$100,000 for the shorter of the period ending June 30, 2006 and the date of closing by Canada of a transaction involving the merger of Canada into a newly created Canadian Capital Pool Company and a simultaneous funding through a private placement of shares under terms approved by the Toronto Stock Exchange (the “Canada Transaction”). Within ten days after the closing of the Canada Transaction Canada will pay the Company all amounts due under the Transition Services Agreement. If Canada fails to close the Canada Transaction, Celsion will not be paid under this agreement.

On February 27, 2006, the Company effected a one-for-15 reverse split of the Company’s issued and outstanding shares of common stock (the “Common Stock”). As of that date, each fifteen shares of the Company’s issued and outstanding shares of Common Stock were automatically combined, converted and changed into one share of Common Stock of the Company (the “Reverse Split”). No fractional shares were issued as a result of the Reverse Split. Instead, the Company will pay cash in lieu of fractional shares based on

## [Table of Contents](#)

the average closing price of the Company's Common Stock for the five trading days prior to the effective date of the Reverse Split. Unless otherwise noted herein, all share numbers and per share financial information in this Annual Report on Form 10-K is provided on a pre-reverse stock split basis.

As of March 2006 the Company had enrolled ten patients in its ThermoDox/RFA liver cancer Phase I study. Celsion, in collaboration with the National Institutes of Health ("NIH") and Queen Mary's Hospital, Hong Kong, and is aggressively recruiting patients eligible for enrollment in the study both at the NIH and Queen Mary's Hospital. In order to facilitate enrollment of patients, the Company is adding an additional clinical site in the U.S.

### **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

Our financial statements, which appear at Item 8 to this Annual Report on Form 10-K, 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 to Boston Scientific.
- 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.
- 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 FASB issued SFAS No.123R *Share-Based Payment* which replaces SFAS No. 123 *Accounting for Stock-Based Compensation* and supersedes APB Opinion No. 25 *Accounting for Stock Issued to Employees*. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values and provides that the pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. The company is required to adopt SFAS No. 123R in the first quarter of fiscal year 2006.

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, 2005 AND FISCAL YEAR ENDED DECEMBER 31, 2004

Net sales for 2005 were \$12,320,000, an increase of \$9,814,000 or 392%, compared to \$2,506,000 in 2004. Product sales consist of sales of our Prolieve products and are comprised of two elements – sales of control units and sales of disposable catheter kits, all to our exclusive distributor, Boston Scientific Corporation. The increase in revenues during the year ended December 31, 2005 compared to the year ended December 31, 2004 reflects a partial period (commencing with grant of the PMA on February 19, 2004) in 2004, as well as the progress of commercialization and marketing efforts.

Research and development expenses for the year ended December 31, 2005 of \$10,081,000 were \$1,452,000 or 13%, lower than expenses incurred in the year ended December 31, 2004 of \$11,533,000. The decrease in expenses was due to the non-recurrence of expenses associated with receipt of the PMA for the Prolieve system, cash bonuses paid to employees in connection with receipt of the PMA offset by 2004 performance bonus payments (\$375,000) and a reduction in consulting support related to development and approval of the Prolieve system (\$851,000). The reduction is also attributable to non-recurrence of costs related to personnel matters (\$1,102,000); a reduction in clinical costs due to the closure of our heat-alone breast cancer clinical study and suspension of our prostate cancer clinical study (\$400,000); write-off of product development costs (\$379,000) and costs related to consultants hired to aid in clinical compliance (\$217,000), offset by adjustments in stock related compensation expense, in 2004, due to decreases in the market price of our Common Stock (\$622,000), patent expenses (\$236,000), preclinical and clinical costs associated with our liver cancer clinical studies (\$574,000) and the first installment of the grant to Duke University related to the recurrent chest wall breast cancer study (\$275,000).

General and administrative expenses in the twelve months ended December 31, 2005 were \$3,406,000 a reduction of \$65,000, or 2%, compared to \$3,471,000 for the twelve months ended December 31, 2004. There were, however, a number of changes in the expenses making up total general and administrative costs. Compensation costs increased as a result of adjustments in stock related compensation expense, in 2004, due to decreases in the market price of our Common Stock (\$464,000) and provision for costs related to personnel matters (\$308,000) offset by non-recurrence of expenses arising due to the approval of the Prolieve system in February 2004, principally consisting of a payment to Legg Mason for investment banking services rendered in connection with negotiation of our strategic relationship with Boston Scientific in 2003 which became due upon receipt of the PMA (\$410,000); cash bonuses paid to employees in connection with receipt of the PMA offset by 2004 performance bonus payments (\$85,000), and changes in investor relations programs and consultants (\$188,000).

The net decrease of \$1,517,000 in operating expenditures during the twelve months ended December 31, 2005 compared to the comparable period during 2004, combined with income generated (gross margin) from the sale of Prolieve products during the year ended December 31, 2005, resulted in a decrease in the loss from operations for the year ended December 31, 2005 of \$5,319,000 or 36%, to \$9,280,000 from \$14,599,000 in the year ended December 31, 2004.

Interest income, which is reflected net of any interest expense, decreased by 48%, or \$110,000 for the year ended December 31, 2005 compared to the year ended December 31, 2004. The decrease was due to interest accrued on a loan from Boston Scientific which closed on August 8, 2005.

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

Product sales for 2004 in the amount of \$2,506,000 all of which were generated subsequent to the receipt of the PMA for its Prolieve system on February 19, 2004, consisted 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 increase of \$2,342,000 (25.4%) in research and development expense during the year ended December 31, 2004 was due primarily to costs related to personnel matters (\$1,262,000); 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 approval for the Prolieve system (\$554,000); an increase in salaries and recruiting and relocation expenses for new hires (\$550,000) as we filled critical positions; increased costs related to consultants hired to aid in clinical compliance efforts (\$227,000) and an initial payment to the CRO that was 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 \$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 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 \$183,000 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 period, as well as payments to us in connection with the sale of our Common Stock to and licensing fees from Boston Scientific.

## 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, income generated from licensing agreements 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 \$82,903,000 at December 31, 2005. We have incurred negative cash flows from operations since our inception and have funded our operations primarily through the sale of equity securities.

## [Table of Contents](#)

In 2005, 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. These expenditures are discussed above at “Results of Operations.” As a result, net cash used in operating activities during the year ended December 31, 2005—otherwise referred to as the “cash burn”—was \$8,062,000, representing a decrease of \$5,879,000 from the fiscal year ended December 31, 2004. This net cash requirement was funded from cash on hand at the beginning of the year, together the first \$6 million installment of a loan from Boston Scientific. Under the loan agreement, which was effective on August 8, 2005, Boston Scientific has agreed to lend the Company up to \$15 million disbursed in three installments. The first installment, in the amount of \$6 million, was disbursed on August 17, 2005. The second installment of \$4.5 million was disbursed on February 6, 2006 and the third disbursement is expected to occur on or about May 1, 2006 subject to the Company making continuing progress, to the reasonable satisfaction of Boston Scientific, with respect to the development of the Company’s Prolieve product. The loan, which has a term expiring on February 20, 2009 and bears interest at a rate of prime plus 1 percent, due on the first to occur of (i) February 20, 2009, (ii) upon repayment of the principal amount and accrued interest in full, (iii) upon Boston Scientific’s exercise of its option, described below, to purchase certain assets and technology, or (iv) on conversion of the principal amount plus accrued interest, if any, to shares of Company common stock. The Company has the right to prepay the loan at any time without penalty.

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

For fiscal year 2006, we expect to expend approximately \$15,000,000 to commercialize our Prolieve system and for clinical testing of our prostate cancer, liver cancer and breast cancer treatment systems, as well as corporate overhead, all of which we expect to fund from our current resources, consisting of funds on hand and revenues anticipated from the sale of our Prolieve system and related disposables. The foregoing is an estimate, based upon assumptions as to the scheduling of institutional clinical research and testing personnel, the timing of clinical trials and other factors, not all of which are fully predictable.

The following is a summary of our future minimum payments under contractual obligations as of December 31, 2005:

	<u>Total</u>	<u>&lt;1 year</u>	<u>1-3 years</u>	<u>4-5 years</u>	<u>Thereafter</u>
Operating leases—Property	\$1,030,165	\$211,873	\$428,256	\$390,036	\$—
Loan Payable	\$6,000,000	\$—	\$—	\$6,000,000	\$—

### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We do not currently hold any derivative instruments and do not engage in hedging activities and currently do not enter into any transactions denominated in a foreign currency. Thus, our exposure to interest rate and foreign exchange fluctuations is minimal.

### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA AND FINANCIAL DISCLOSURE**

The financial statements, supplementary data and report of independent public accountants are filed as part of this report on pages F-2 through F-25.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. 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 principal executive officer and principal financial officer. Based on that evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2005, which is the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures are effective.

There have been no changes in our internal controls over financial reporting in the fiscal quarter ended December 31, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**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 23, 2006, 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, 2005.

**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 23, 2006, 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, 2005.

**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” Celsion’s Definitive Proxy Statement in connection with the Annual Meeting of Stockholders to be held on May 23, 2006, 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, 2005.

**Equity Compensation Plan Information as of December 31, 2005**

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights (b)</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)</u>
Equity compensation plans approved by security holders	10,231,290 <sup>(1)</sup>	0.68	8,028,128
Equity compensation plans not approved by security holders	13,248,479 <sup>(2)</sup>	0.67	— <sup>(2)</sup>
<b>Total</b>	23,479,769	0.67	8,028,128

<sup>(1)</sup> Includes both vested and unvested options to purchase Common Stock issued to employees, officers, and 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.

## [Table of Contents](#)

- (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 23, 2006, 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, 2005.

### **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this item is incorporated by reference to the information set forth under the captions “Proposal No. 3: Ratification of Independent Public Accountants—Fees,” “—Services by Employees of Stegman & Company” and “—Audit Committee Policy on Approval of Audit and Non-Audit Services” in Celsion’s Definitive Proxy Statement in connection with the Annual Meeting of Stockholders to be held on May 23, 2006, 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, 2005.

### **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 registered public accountants.

	<u>Page</u>
<a href="#">Management’s Report on Internal Control over Financial Reporting</a>	F-1
<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-2
<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-3
<b>CONSOLIDATED FINANCIAL STATEMENTS</b>	
<a href="#">Balance Sheets</a>	F-4
<a href="#">Statements of Operations</a>	F-6
<a href="#">Statements of Changes in Stockholders’ Equity</a>	F-8
<a href="#">Statements of Cash Flows</a>	F-10
<a href="#">NOTES TO CONSOLIDATED FINANCIAL STATEMENTS</a>	F-12

#### **2. FINANCIAL STATEMENT SCHEDULES**

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

## [Table of Contents](#)

### 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	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.
3.1.3	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.
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 Quarterly 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).
10.7.1*	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.
10.11	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.

## Table of Contents

- 10.12 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.
- 10.13 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.
- 10.14\* Employment Agreement Effective January 1, 2004 between the Company and Anthony P. Deasey. Incorporated herein by reference to the Current Report on Form 8-K of the Company filed December 8, 2004.
- 10.15\* 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.
- 10.16\* Stock Option Grant Agreement effective July 29, 2005 between Celsion Corporation and Lawrence S. Olanoff on Form 8K of the Company filed July 29, 2005
- 10.17 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).
- 10.18 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.
- 10.19 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.
- 10.20 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).
- 10.21 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.
- 10.22 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.
- 10.23 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.
- 10.24 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.
- 10.25 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.
- 10.26 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.
- 10.27 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.
- 10.28 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.
- 10.29.1 Transaction Agreement effective as of January 20, 2003 by and between Celsion Corporation and Boston Scientific Corporation, incorporated herein by reference to the Current Report on Form 8-K filed January 22, 2003. (Confidential treatment requested)
- 10.29.2 First Amendment to Transaction Agreement effective as of August 8, 2005, between Celsion Corporation and Boston Scientific Corporation, incorporated herein by reference to the Current Report on Form 8-K filed August 9, 2005.

## Table of Contents

10.29.3	Convertible Secured Promissory Note dated as of August 8, 2005, incorporated herein by reference to the Current Report on Form 8-K of the Company filed August 9, 2005
10.30*	Employment Agreement Effective July 29, 2005, between the Company and Lawrence S. Olanoff, incorporated herein by reference to the Current report on Form 8-K of the Company filed May 19, 2005.
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 registered 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.
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.

^ Furnished herewith.

\* Management contract or compensatory plan furnished herewith.

**SIGNATURES**

Pursuant to the requirement of Section 13 or 159(d) of the Securities Exchange Act of 1934, the Registrant has duly caused its annual report on Form 10-K to be signed on its behalf by the undersigned thereunto duly authorized.

March 17, 2006

CELSION CORPORATION

By: /s/ Lawrence S. Olanoff  
Lawrence S. Olanoff  
President and Chief Executive Officer

By: /s/ Anthony P. Deasey  
Anthony P. Deasey  
Executive Vice President – Chief Operating Officer,  
Chief Financial Officer

Pursuant to the requirement of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ Lawrence Olanoff</u> Lawrence Olanoff	President and Chief Executive Officer (Principle Executive Officer)	March 17, 2006
<u>/s/ Anthony P. Deasey</u> Anthony P. Deasey	Executive Vice President – Chief Operating Officer, Chief Financial Officer (Principle Financial and Accounting Officer)	March 17, 2006
<u>/s/ Max E. Link</u> Max E. Link	Chairman of the Board	March 17, 2006
<u>/s/ Gary W. Pace</u> Gary W. Pace	Director	March 17, 2006
<u>/s/ Claude Tihon</u> Claude Tihon	Director	March 17, 2006
<u>/s/ Kris Venkat</u> Kris Venkat	Director	March 17, 2006
<u>/s/ Gregory Weaver</u> Gregory Weaver	Director	March 17, 2006

## 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 as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America (GAAP). The Company's internal control over financial reporting includes those policies and procedures that:

- (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions of the Company;
- (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP and that receipts and expenditures of the Company are being made only in accordance with authorization of management and directors of the Company; and
- (iii) 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.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2005. In making this assessment, management 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 and those criteria, management has concluded that, as of December 31, 2005, the Company's internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

The Company's independent registered public accountants, Stegman & Company, have issued an attestation report on management's assessment of the Company's internal control over financial reporting. The report of Stegman & Company appears on the following page.

**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, 2005, 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, 2005 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, 2005, based on criteria established in *Internal Control—Integrated Framework* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2005 and 2004 and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the years ended December 31, 2005 and 2004, the three months ended December 31, 2003 and the fiscal year ended September 30, 2003 and our report dated February 28, 2006, expressed an unqualified opinion on those financial statements.

/s/ Stegman & Company

Baltimore, Maryland  
February 28, 2006

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
Celsion Corporation  
Columbia, Maryland

We have audited the accompanying consolidated balance sheets of Celsion Corporation (the "Company") as of December 31, 2005 and 2004, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the years ended December 31, 2005 and 2004, the three months ended December 31, 2003 and for the fiscal year ended September 30, 2003. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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, 2005 and 2004, and the results of its operations and its cash flows for the years ended December 31, 2005 and 2004, the three months ended December 31, 2003 and for the fiscal year ended September 30, 2003, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2005, based on the criteria established in *Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)* and our report dated February 28, 2006 expressed an unqualified opinion on management's assessment of internal control over financial reporting and an unqualified opinion on the effectiveness of internal control over financial reporting.

/s/ Stegman & Company

Baltimore, Maryland  
February 28, 2006

**CELSION CORPORATION**  
CONSOLIDATED BALANCE SHEETS  
DECEMBER 31, 2005 AND DECEMBER 31, 2004  
ASSETS

	<u>December 31,</u> <u>2005</u>	<u>December 31,</u> <u>2004</u>
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 2,313,430	\$ 586,376
Short term investments	6,000,000	9,897,440
Accounts receivables– trade	715,714	691,938
Other receivables	49,799	91,101
Inventories	3,325,640	2,201,663
Prepaid expenses	436,521	679,237
Total current assets	<u>12,841,104</u>	<u>14,147,755</u>
<b>Property and Equipment–at cost:</b>		
Furniture and office equipment	182,171	176,666
Computer hardware and software	304,522	264,774
Laboratory and shop equipment	656,676	607,418
Leasehold improvements	132,148	120,101
	<u>1,275,517</u>	<u>1,168,959</u>
Less: Accumulated depreciation	704,662	486,861
Net value of property and equipment	<u>570,855</u>	<u>682,098</u>
<b>Other Assets:</b>		
Investment in Celsion China, Ltd.	11,994	107,797
Escrow account–license fee	2,053,153	2,007,002
Deposits	432,335	17,706
Prepaid inventory development costs	—	58,214
Patent licenses (net of accumulated Amortization of \$189,950 and \$158,585, respectively)	—	31,365
Total other assets	<u>2,497,482</u>	<u>2,222,084</u>
<b>Total Assets</b>	<u>\$ 15,909,441</u>	<u>\$ 17,051,937</u>

See accompanying notes.

## LIABILITIES AND STOCKHOLDERS' EQUITY

	December 31, 2005	December 31, 2004
<b>Current Liabilities:</b>		
Accounts payable–trade	\$ 1,996,159	\$ 819,168
Accrued noncash compensation	10,132	53,543
Other accrued liabilities	1,317,876	684,550
Current portion of deferred revenue	571,428	571,428
Total current liabilities	<u>3,895,595</u>	<u>2,128,689</u>
<b>Long Term Liabilities:</b>		
Deferred revenue–license fee	2,380,953	2,952,382
Loan Payable - Principal	6,000,000	—
Loan Payable - Interest	177,625	—
Other Liabilities	29,773	—
Total long-term liabilities	<u>8,588,351</u>	<u>2,952,382</u>
Total Liabilities	<u>12,483,946</u>	<u>5,081,071</u>
<b>Stockholders' Equity:</b>		
Common stock - \$.01 par value; 250,000,000 shares authorized at December 31, 2005 and December 31, 2004, 160,901,600 and 160,749,497 shares issued and outstanding at December 31, 2005 and December 31, 2004, respectively.	1,609,015	1,607,494
Additional paid-in capital	84,719,064	84,580,637
Accumulated deficit	(82,902,584)	(74,217,265)
Total stockholders' equity	<u>3,425,495</u>	<u>11,970,866</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 15,909,441</u>	<u>\$ 17,051,937</u>

See accompanying notes.

**CELSION CORPORATION**

CONSOLIDATED STATEMENTS OF OPERATIONS  
FOR THE YEARS ENDED DECEMBER 31, 2005, DECEMBER 31, 2004, AND SEPTEMBER 30, 2003  
AND THE THREE MONTHS ENDED DECEMBER 31, 2003

	<u>Year Ended December 31,</u>		<u>Year Ended</u>	<u>Three Months Ending</u>
	<u>2005</u>	<u>2004</u>	<u>September 30,</u>	<u>December 31,</u>
			<u>2003</u>	<u>2003</u>
<b>Revenues:</b>				
Sales of equipment and parts	\$12,458,863	\$ 2,506,228	\$ —	\$ —
Returns and allowances	138,722	—	—	—
Total revenues	<u>12,320,141</u>	<u>2,506,228</u>	<u>—</u>	<u>—</u>
<b>Cost of Sales</b>	<u>8,112,760</u>	<u>2,100,888</u>	<u>—</u>	<u>—</u>
<b>Gross Profit</b>	<u>4,207,381</u>	<u>405,340</u>	<u>—</u>	<u>—</u>
<b>Operating Expenses:</b>				
Research and development	10,081,483	11,533,421	8,178,680	2,109,795
Selling, general and administrative	3,405,409	3,470,869	5,125,769	856,968
Total operating expenses	<u>13,486,892</u>	<u>15,004,290</u>	<u>13,304,449</u>	<u>2,966,763</u>
<b>Loss from Operations</b>	<u>(9,279,511)</u>	<u>(14,598,950)</u>	<u>(13,304,449)</u>	<u>(2,966,763)</u>
License Fee Income Amortization	571,429	476,191	—	—
Interest Income	299,245	229,914	30,378	—
Interest Expense	(179,591)	—	—	—
Loss from Investment in Celsion China, Ltd.	(95,803)	(92,203)	—	—
Loss from Disposal of Property and Equipment	(1,088)	—	—	(5,791)
Rental income	—	—	—	18,720
<b>Net Loss</b>	<u>(8,685,319)</u>	<u>(13,985,048)</u>	<u>(13,274,071)</u>	<u>(2,953,834)</u>
<b>Beneficial Conversion Feature and Dividends on Preferred Stock</b>	<u>—</u>	<u>—</u>	<u>(184,231)</u>	<u>—</u>
<b>Net Loss Attributable to Common Stockholders</b>	<u>\$ (8,685,319)</u>	<u>\$ (13,985,048)</u>	<u>\$ (13,458,302)</u>	<u>\$ (2,953,834)</u>
<b>Basic and Diluted Net Loss per Common Share<sup>(1)</sup></b>	<u>\$ (0.81)</u>	<u>\$ (1.32)</u>	<u>\$ (1.78)</u>	<u>\$ (0.31)</u>
<b>Basic and Diluted Weighted Average Number of Common Shares Outstanding<sup>(1)</sup></b>	<u>10,725,091</u>	<u>10,583,772</u>	<u>7,578,686</u>	<u>9,610,182</u>

(1) Adjusted to reflect 15:1 reverse split 2/27/06.

See accompanying notes.

## CELSION CORPORATION

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
FOR THE YEARS ENDED DECEMBER 31, 2005, DECEMBER 31, 2004 AND SEPTEMBER 30, 2003  
AND FOR THE THREE MONTHS ENDED DECEMBER 31, 2003

	Common Stock		Series A 10% Convertible Preferred Stock	
	Shares	Amount	Shares	Amount
<b>Balances at September 30, 2002</b>	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	—	—	—	—
<b>Balances at September 30, 2003</b>	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	—	—	—	—
<b>Balances at December 31, 2003</b>	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	—	—	—	—
<b>Balances at December 31, 2004</b>	160,749,497	1,607,494	—	—
Sale of common stock	—	—	—	—
Exercise of common stock warrants and options	—	—	—	—
Stock-based compensation expense	152,104	1,521	—	—
Effect of repriced options	—	—	—	—
Net loss	—	—	—	—
<b>Balances at December 31, 2005</b>	160,901,601	\$1,609,015	—	\$ —

See accompanying notes

**CELSION CORPORATION**

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
FOR THE YEARS ENDED DECEMBER 31, 2005, DECEMBER 31, 2004 AND SEPTEMBER 30, 2003  
AND FOR THE THREE MONTHS ENDED DECEMBER 31, 2003

	Series B 8% Convertible Preferred Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
<b>Balances at September 30, 2002</b>	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)
<b>Balances at September 30, 2003</b>	—	—	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)
<b>Balances at December 31, 2003</b>	—	—	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)
<b>Balances at December 31, 2004</b>	—	—	84,580,637	(74,217,265)	11,970,866
Sale of common stock	—	—	—	—	—
Exercise of common stock warrants and options	—	—	—	—	—
Stock-based compensation expense	—	—	138,427	—	139,948
Effect of repriced options	—	—	—	—	—
Net loss	—	—	—	(8,685,319)	(8,685,319)
<b>Balances at December 31, 2005</b>	—	\$ —	\$84,719,064	\$(82,902,584)	\$ 3,425,495

See accompanying notes.

**CELSION CORPORATION**

STATEMENTS OF CASH FLOWS  
FOR THE YEARS ENDED DECEMBER 31, 2005, DECEMBER 31, 2004, SEPTEMBER 30, 2003  
AND THREE MONTHS ENDED DECEMBER 31, 2003

	Year Ended December 31,		Year Ended September 30,	Three Months Ended December 31,
	2005	2004	2003	2003
<b>Cash Flows from Operating Activities</b>				
Net loss	\$(8,685,319)	\$(13,985,048)	\$(13,274,071)	\$ (2,953,834)
Noncash items included in net loss:				
Depreciation and amortization	250,037	200,515	100,532	31,149
Amortization of deferred revenue—license fee	(571,429)	(476,191)	—	—
Loss from investment in Celsion. China, Ltd.	95,803	92,203	—	219,115
Common stock issued for operating expenses	78,539	200,760	2,561,600	—
Stock options issued for operating expenses	17,997	496,221	281,266	—
Executive repriced options	—	(1,030,684)	967,374	647,656
Loss from disposal of property and equipment	1,088	—	—	5,791
Other liabilities	29,773	—	—	—
Net changes in:				
Accounts receivable—trade	(23,776)	(691,938)	—	—
Other receivables	41,302	(74,348)	(6,434)	74,174
Inventories	(1,123,977)	(1,283,953)	(375,183)	(92,919)
Prepaid expenses	242,716	(317,270)	(31,587)	(283,125)
Escrow account—license fee	(46,151)	(2,007,002)	—	—
Prepaid inventory development costs	58,214	359,239	69,384	(235)
Accounts payable—trade	1,176,991	188,071	388,568	(252,121)
Accrued interest payable	177,625	—	—	—
Accrued noncash compensation	—	(99,773)	125,395	—
Deposits	(414,629)	5,916	—	—
Deferred revenue—license fee	—	4,000,000	—	—
Other accrued liabilities	633,326	482,124	104,577	(154,539)
Net cash used in operating activities	<u>(8,061,870)</u>	<u>(13,941,158)</u>	<u>(9,088,579)</u>	<u>(2,758,888)</u>
<b>Cash Flows from Investing Activities:</b>				
Investment in Celsion China, Ltd.	—	(200,000)	—	—
Purchase of short-term investments	(6,000,000)	(4,897,438)	—	(5,000,000)
Sale of short-term investments	9,900,440	—	—	—
Purchase of property and equipment	(108,516)	(484,056)	(111,850)	(184,493)
Net cash provided (used) in investing activities	<u>3,791,924</u>	<u>(5,581,494)</u>	<u>(111,850)</u>	<u>(5,184,493)</u>
<b>Cash Flows from Financing Activities:</b>				
Issuance of notes payable	6,000,000	—	500,000	—
Payment on notes payable	—	—	(500,000)	—
Proceeds of stock issuances	—	12,836,621	19,682,143	3,805,255
Net cash provided by financing activities	<u>6,000,000</u>	<u>12,836,621</u>	<u>19,682,143</u>	<u>3,805,255</u>
<b>Net Increase (Decrease) in Cash and Cash Equivalents</b>	<u>1,730,054</u>	<u>(6,686,031)</u>	<u>10,481,714</u>	<u>(4,138,126)</u>
<b>Cash and Cash Equivalents at Beginning of Period</b>	<u>586,376</u>	<u>7,272,407</u>	<u>928,819</u>	<u>11,410,533</u>
<b>Cash and Cash Equivalents at the End of Period</b>	<u>\$ 2,313,430</u>	<u>\$ 586,376</u>	<u>\$ 11,410,533</u>	<u>\$ 7,272,407</u>

**CELSION CORPORATION**

NOTES TO FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2005, DECEMBER 31, 2004 AND SEPTEMBER 30, 2003  
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.

Celsion (Canada) Limited

Celsion (Canada) Limited is a wholly-owned subsidiary of Celsion Corporation formed on August 25, 2005 to hold all the assets related to its Adaptive Phase Array (“APA”) technology. There was no financial activity for the year ended December 31, 2005, but for purposes of financial reporting, these financial statements are considered consolidated. On January 16, 2006 the APA technology was sold through an all stock transaction whereby all the outstanding shares of Celsion (Canada) were sold to Dr. Augustine Cheung.

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 not covered by FDIC insurance.

Short Term Investments

The Company invests in auction rate securities as part of its cash management strategy. In 2005, the Company concluded that it was appropriate to classify its holdings of auction rate securities as short-term investments. Previously, such investments had been classified as cash and cash equivalents. Accordingly, the Company has revised the classification to report these securities as short term investments in its consolidated balance sheets. The Company has also made corresponding adjustments to its consolidated statements of cash flows to reflect the gross purchases and sales of these securities as investing activities rather than as a component of cash and cash equivalents. This change in classification does not affect previously reported cash flows from operations in the Company’s consolidated statements of cash flows or the Company’s previously reported consolidated statements of operations for any period.

The Company classifies its investments in marketable securities with readily determinable fair values as investments available-for-sale in accordance with Statement of Financial Accounting Standards (“SFAS”)

## Table of Contents

No. 115, "Accounting for Certain Investments in Debt and Equity Securities". Available-for-sale securities consist of debt and equity securities not classified as trading securities or as securities to be held to maturity. The Company has classified all investments as available-for-sale. Unrealized holding gains and losses on available-for-sale securities are reported as a net amount in accumulated other comprehensive gain or loss in stockholders' equity until realized. Gains and losses on the sale of available-for-sale securities are determined using the specific identification method.

The Company's short term investments are in Auction Rate Certificates and Auction Preferred Securities. Auction Rate Certificates are municipal bonds which pay interest at a floating rate set periodically, usually 7, 28 or 35 days. Auction Preferred Securities are issued by closed end bond funds and pay dividends every 7, 28 or 35 days. Increases or withdrawals from investments can take place every 7, 28 or 35 days. Both investment vehicles are rated A1P1 commercial paper equivalents, trade at par and do not have significant market fluctuations.

### Accounts Receivable

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. Accounts receivable are not pledged as collateral for any borrowings. No allowance for doubtful accounts is established, as Celsion uses the direct write-off method.

### 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. Reserve balances of \$39,706 and \$153,384 were recorded for years ended December 31, 2005 and December 31, 2004, respectively.

### 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.

Effective January 12, 2006 Celsion made an additional \$25,000 investment to purchase from Asia Pacific Life Science Group, Ltd. equity, bringing Celsion's total equity position to 71.3%.

Celsion accounts for this investment under the equity method. Due to the increased equity position future accounting for this investment will be under the fully consolidated method. No foreign currency adjustment was necessary during the year ended December 31, 2005.

An additional cash advance in the amount of \$84,123 in form of a loan was made to Celsion China, Ltd. on January 27, 2006.

### 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.

## Table of Contents

### 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 \$218,762 and \$190,793 for years ended December 31, 2005 and December 31, 2004 and \$84,703 for the year ended September 30, 2003 and \$20,707 for the three months ended December 31, 2003.

### Deposits

Real property security and deposits which are contractually required and of a long-term nature comprise the balance of this account. Approximately, \$373,000 of this balance is deposits made with a clinical research organization with respect to Celsion's BPH PMA study. The study is anticipated to take 5 years to complete and the deposits are held against final billings.

### Prepaid Inventory 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 were amortized on a straight-line basis over the remaining life of the related patent and the remaining balance was written off in the year ended December 31, 2005.

### Loan Payable

On August 8, 2005 we entered into a loan agreement with BSC whereby BSC will lend the Company up to \$15 million. The loan, which has a term expiring on February 20, 2009 and will bear interest at a rate of prime plus 1 percent, will be disbursed in three installments. The first installment, in the amount of \$6 million, was disbursed on August 17, 2005. The second installment of \$4.5 million was disbursed on February 2, 2006 and the third disbursement which maybe drawn at the Company's discretion is expected to occur on or about May 1, 2006. The third disbursement is subject to the Company making continuing progress, to the reasonable satisfaction of BSC, with respect to the development of the Company's Prolieve product.

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

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

### 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.

### Comprehensive Income

SFAS No. 130, "Reporting Comprehensive Income," establishes standards for the reporting and display of comprehensive income and its components in the Company's consolidated financial statements. The objective of SFAS No. 130 is to report a measure (comprehensive income (loss)) of all changes in equity of an enterprise that result from transactions and other economic events in a period other than transactions with owners.

## Table of Contents

The Company had no unrealized gains or losses on short-term investments available-for-sale for the years ended December 31, 2005 and December 31, 2004.

### 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. Warranty reserves were \$15,000 and \$0 as of years ended December 31, 2005 and December 31, 2004, respectively.

### 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 diluted weighted average common shares outstanding, as the effect would be antidilutive. Net loss per common stock has been adjusted to reflect the 15:1 reverse split, effective February 27, 2006.

### 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.

## Table of Contents

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, 2005	Year Ended December 31, 2004	Year Ended September 30, 2003	Three Months Ended December 31, 2003
Net loss, attributable to common stockholders, as reported	<u>\$ (8,658,319)</u>	<u>\$ (13,985,048)</u>	<u>\$ (13,458,302)</u>	<u>\$ (2,953,834)</u>
Stock-based employee compensation (income) expense included in reported net loss	—	(1,030,684)	967,376	647,656
Total stock-based employee compensation (expense) income determined using the fair value based method for all awards	(914,507)	559,585	(1,187,722)	(711,910)
Pro forma net loss	<u>\$ (9,572,826)</u>	<u>\$ (14,456,147)</u>	<u>\$ (13,678,648)</u>	<u>\$ (3,018,088)</u>
Loss per share:				
Basic - as reported <sup>(1)</sup>	<u>\$ (0.81)</u>	<u>\$ (1.32)</u>	<u>\$ (1.78)</u>	<u>\$ (0.31)</u>
Basic - pro forma <sup>(1)</sup>	<u>\$ (0.89)</u>	<u>\$ (1.37)</u>	<u>\$ (1.80)</u>	<u>\$ (0.31)</u>

(1) Adjusted to reflect 15:1 reverse split February 27, 2006.

### Fair Value of Financial Instruments

The carrying values of financial instruments approximate fair value.

### 2. RECENT ACCOUNTING PRONOUNCEMENTS

In May 2005, the FASB issued Statement of Financial Accounting Standard ("SFAS") No. 154, *Accounting Changes and Error Corrections*, which changes the accounting for and reporting of a change in accounting principle. This statement applies to all voluntary changes in accounting principle and changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. This statement requires retrospective application to prior period financial statements of changes in accounting principle, unless it is impractical to determine either the period-specific or cumulative effects of the change. SFAS 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005. The adoption of this standard is not expected to have a material effect on financial condition, results of operations, or liquidity.

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.

## [Table of Contents](#)

In December 2004, the FASB issued SFAS No. 123R *Share-Based Payment* which replaces SFAS No. 123 *Accounting for Stock-Based Compensation* and supersedes APB Opinion No. 25 *Accounting for Stock Issued to Employees*. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values and provides that the pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. The Company is required to adopt SFAS No. 123R in the first quarter of fiscal year 2006.

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

In December 2004, the FASB issued SFAS No. 153, *Exchange of Nonmonetary Assets*. SFAS No. 153 amends APB No. 29, *Accounting for Nonmonetary Transactions*, to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The Company 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 \$83 million as of December 31, 2005. 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, and 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, 2005 and income generated from sale of Prolieve control units and catheter kits to fund operations as least through the end of 2007.

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

## [Table of Contents](#)

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:

	<u>December 31,</u> <u>2005</u>	<u>December 31,</u> <u>2004</u>
Components	\$ 535,253	\$ 739,645
Work-in-process	—	—
Finished goods	<u>2,830,093</u>	<u>1,615,402</u>
	3,365,346	2,355,047
Less: Reserve	<u>39,706</u>	<u>153,384</u>
	<u>\$3,325,640</u>	<u>\$2,201,663</u>

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, 2005 reflected the following:

Cash	\$ 12,754
Inventory	62,500
Prepaid expense	17,439
Prepaid Insurance	6,000
Due from Celsion Corporation	<u>6,344</u>
Total current assets	105,037
Fixed assets, net	<u>286</u>
Total assets	<u>\$105,323</u>
Due to Celsion Corporation	\$ 74,949
Equity	<u>30,374</u>
Total liabilities and equity	<u>\$105,323</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, 2005. The loss from this unconsolidated investee for the year ended December 31, 2005 can be recalculated as follows and is comprised of only general and administrative costs. Celsion China, Ltd. had no commercial sales for the year.

## [Table of Contents](#)

Annual deficit	\$(209,864)
Ownership percentage	45.65%
Loss recorded for the year	<u>\$ (95,803)</u>

Celsion Corporation's balance sheet at December 31, 2005 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	(188,006)%
Net investment carrying value	<u>\$ 11,994</u>

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, 2005, December 31, 2004 and September 30, 2003 respectively, and three months ended December 31, 2003 is as follows:

	Year Ended December 31, 2005	Year Ended December 31, 2004	Year Ended September 30, 2003	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)
	<u>0%</u>	<u>0%</u>	<u>0%</u>	<u>0%</u>

As of December 31, 2005, the Company had net operating loss carry forwards of approximately \$72 million for federal income tax purposes that are available to offset future taxable income through the year 2024.

The components of the Company's deferred tax asset as of December 31, 2005 and 2004 are as follows:

	December 31, 2005	December 31, 2004
Net operating loss carry forwards	\$ 27,700,000	\$ 24,200,000
Valuation allowance	(27,700,000)	(24,200,000)
	<u>\$ —</u>	<u>\$ —</u>

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.

## Table of Contents

### 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.

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 permitted 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, 2005, 583,791 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, 2005 options to purchase 8,028,128 shares were available from the 10,743,266 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.

## [Table of Contents](#)

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

Following is additional information with respect to options and warrants outstanding at December 31, 2005:

	<u>Options Outstanding</u>	<u>Weighted Average Exercise Price</u>	<u>Warrants Outstanding</u>	<u>Weighted Average Exercise Price</u>
<b>Outstanding at September 30, 2002</b>	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	<u>(100,000)</u>	\$ 0.64	<u>(206,100)</u>	\$ 1.03
<b>Outstanding at September 30, 2003</b>	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	<u>(30,000)</u>	\$ 0.47	<u>0</u>	\$
<b>Outstanding at December 31, 2003</b>	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	<u>(664,850)</u>	\$ 0.78	<u>(91,000)</u>	\$ 0.91
<b>Outstanding at December 31, 2004</b>	11,457,408	\$ 0.71	14,895,598	\$ 1.02
Granted	8,520,250	\$ 0.40	582	\$ 0.25
Exercised	0	\$ —	0	\$ —
Expired/cancelled	<u>(826,669)</u>	\$ 0.70	<u>(291,471)</u>	\$ 1.82
<b>Outstanding at December 31, 2005</b>	<u>19,150,989</u>	\$ 0.58	<u>14,604,709</u>	\$ 0.92

## [Table of Contents](#)

	Exercise Price from \$0.25 to \$0.60	Exercise Price from \$0.61 to \$1.01	Exercise Price from \$1.02 to \$5.00
<b>Common Stock Options</b>			
<b>Outstanding at December 31, 2005:</b>			
Number of options	11,342,124	5,582,200	2,226,666
Weighted average exercise price	\$ 0.40	0.73	1.22
Weighted average remaining contractual life in years	8.21	6.00	3.70
<b>Exercisable at December 31, 2005:</b>			
Number of options	3,130,625	5,090,525	1,890,001
Weighted average exercise price	\$ 0.40	0.73	1.22
Weighted average remaining contractual life in years	4.30	5.81	3.06
	Exercise Price from \$0.25 to \$0.60	Exercise Price from \$0.61 to \$1.01	Exercise Price from \$1.02 to \$5.00
<b>Common Stock Warrants</b>			
<b>Outstanding at December 31, 2005:</b>			
Number of warrants	5,537,022	2,556,955	6,510,731
Weighted average exercise price	\$ 0.42	0.73	1.46
Weighted average remaining contractual life in years	1.25	1.99	2.51
<b>Exercisable at December 31, 2005:</b>			
Number of warrants	5,537,022	2,556,955	6,510,731
Weighted average exercise price	\$ 0.42	0.73	1.46
Weighted average remaining contractual life in years	1.25	1.99	2.51

### 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 \$0, \$(1,030,684) and \$967,374 for the years ended December 31, 2005, December 31, 2004, September 30, 2003 respectively, and \$647,656 for the three months ended December 31, 2003.

## Table of Contents

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:

	<u>Year Ended December 31, 2005</u>	<u>Year Ended December 31, 2004</u>	<u>Year Ended September 30, 2003</u>	<u>Three Months Ended December 31, 2003</u>
Risk-free interest rate	4.15%	3.21%	2.88%	3.2%
Expected volatility	88.7%	94.0%	96.4%	94.3%
Expected option life in years	6	7	5	7

Based upon these valuations, the Company recognized \$17,997, \$496,221, and \$281,266 of expense associated with its issuance of options in lieu of cash for services to consultants, for the years ended December 31, 2005, December 31, 2004, September 30, 2003 and \$0 for 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, 2005, December 31, 2004 and September 30, 2003 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:

	<u>Year Ended December 31, 2005</u>	<u>Year Ended December 31, 2004</u>	<u>Year Ended September 30, 2003</u>	<u>Three Months Ended December 31, 2003</u>
Risk-free interest rate	4.21%	3.62%	2.88%	3.20%
Expected volatility	87.3%	93.4%	96.4%	94.3%
Expected option life in years	7	6	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.

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 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.

## Table of Contents

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. COMMITMENTS AND CONTINGENCIES

#### Lease Commitments

The following is a summary of our future minimum payments under contractual obligations as of December 31, 2005:

2006	\$ 211,873
2007	\$ 222,039
2008	\$ 206,217
2009	\$ 210,379
2010	\$ 179,657
Thereafter	\$ -0-

Rent expense was \$275,771, \$236,020 and \$367,288 for the years ended December 31, 2005 and December 31, 2004 and September 30, 2003 respectively, and \$70,782 for the three months ended December 31, 2003.

Effective February 1, 2006 Celsion entered into a lease agreement for 1,250 square feet of laboratory space in conjunction with the research and development activities of the liposome technology. The lease will expire on January 31, 2008. Celsion has adequate office space for the foreseeable future.

#### 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 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.

## [Table of Contents](#)

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 Accellant Corporation as a catheter supplier.

### Contingent Purchase Commitment

Sanmina-SCI (“Sanmina”) and Celsion entered into a Medical Product Manufacturing Services Agreement on April 2, 2003 for the production of the Company’s Prolieve™ Thermodilatation control units. It is stipulated in this agreement that Celsion may from time to time require Sanmina to acquire component inventories in excess of current demand. Any such inventory of components purchased and held by Sanmina will be designated as “excess” inventory, Celsion is responsible to reimburse Sanmina for the delivered cost of those components. As of December 31, 2005 Celsion and Sanmina have agreed that the excess components can be valued at \$499,244. In lieu of payment in full Celsion has and will pay a 1.5% monthly inventory carrying charge, beginning October 1, 2005. The amount paid for the year ended December 31, 2005 was \$18,099 and is included in cost of sales.

### 12. CONCENTRATIONS OF CREDIT RISK

As of December 31, 2005, 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.

### 13. 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.

[Table of Contents](#)

## 14. 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.

15. SELECTED QUARTERLY FINANCIAL INFORMATION FOR THE YEARS ENDED DECEMBER 31, 2005 AND DECEMBER 31, 2004  
(UNAUDITED)

	2005			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Sales	\$ 1,870,153	\$ 2,896,350	\$ 3,205,829	\$ 4,347,808
Cost of sales	1,271,849	1,926,707	2,186,640	2,727,563
Gross profit on sales	598,304	969,643	1,019,189	1,620,245
Research and development expenses	(2,218,590)	(2,485,328)	(2,293,562)	(3,084,003)
General and administrative expenses	(766,300)	(1,071,703)	(810,244)	(757,162)
Other income/expense	183,221	183,463	130,752	96,756
Net loss	<u>\$ (2,203,365)</u>	<u>\$ (2,403,925)</u>	<u>\$ (1,953,865)</u>	<u>\$ (2,124,164)</u>
Net loss per share—basic and diluted <sup>(1)</sup>	<u>\$ (0.21)</u>	<u>\$ (0.22)</u>	<u>\$ (0.18)</u>	<u>\$ (0.20)</u>

(1) Adjusted to reflect 15:1 reverse split February 27, 2006

	2004			
	First Quarter	Second Quarter	Third Quarter	Fourth 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	<u>\$ (6,065,680)</u>	<u>\$ (1,471,586)</u>	<u>(3,310,583)</u>	<u>(3,137,199)</u>
Net loss per share - basic and diluted <sup>(1)</sup>	<u>\$ (0.59)</u>	<u>\$ (0.14)</u>	<u>(0.31)</u>	<u>(0.29)</u>

(1) Adjusted to reflect 15:1 reverse split February 27, 2006

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the registration statements on Forms S-8 (File Nos. 333-127045, 333-116435 and 333-67508) and on Form S-3 (File Nos. 333-115890, 333-108318, 333-100638, 333-82450 and 333-64710) of Celsion Corporation (the "Company") of our report dated February 28, 2006, relating to the consolidated balance sheets of the Company as of December 31, 2005 and 2004, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years ended December 31, 2005 and 2004, the three months ended December 31, 2003 and for the fiscal year ended September 30, 2003 and our report dated February 28, 2006, relating to management's assessment of the effectiveness of internal control over financial reporting and the effectiveness of the Company's internal control over financial reporting as of December 31, 2005, which appear in the Company's Form 10-K for the year ended December 31, 2005.

/s/ Stegman & Company

Baltimore, Maryland

March 17, 2006

**CELSION CORPORATION**  
**CERTIFICATION**

I, Lawrence S. Olanoff, certify that:

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 17, 2006

/s/ Lawrence S. Olanoff

Lawrence S. Olanoff  
Chief Executive Officer  
Celsion Corporation

**CELSION CORPORATION**  
**CERTIFICATION**

I, Anthony P. Deasey, certify that:

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

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 17, 2006

/s/ Anthony P. Deasey

Anthony P. Deasey  
Chief Financial Officer

Celsion Corporation

CELSION CORPORATION  
CERTIFICATION  
PURSUANT TO 18 UNITED STATES CODE § 1350  
AS ADOPTED PURSUANT TO  
§ 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Celsion Corporation (the "Company") on Form 10-K for the period ended December 31, 2005, as filed with the Securities and Exchange Commission on or about March 16, 2006 (the "Report"), I, Lawrence S. Olanoff, Chief Executive Officer of the Company, certify, pursuant to 10 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 17, 2006

/s/ Lawrence S. Olanoff

---

Lawrence S. Olanoff  
Chief Executive Officer

CELSION CORPORATION  
CERTIFICATION  
PURSUANT TO 18 UNITED STATES CODE § 1350  
AS ADOPTED PURSUANT TO  
§ 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Celsion Corporation (the "Company") on Form 10-K for the period ended December 31, 2005, as filed with the Securities and Exchange Commission on or about March 16, 2006 (the "Report"), I, Anthony P. Deasey, Chief Financial Officer of the Company, certify, pursuant to 10 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 17, 2006

/s/ Anthony P. Deasey

Anthony P. Deasey  
Chief Financial Officer