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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, 2004

or

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

For the transition period from _____ to _____

Commission file number 000-14242

CELSION CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

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

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

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 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 an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ☒ No ☐

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

DOCUMENTS INCORPORATED BY REFERENCE

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

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

PART I

ITEM 1. BUSINESS

GENERAL

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

In addition, we are currently conducting;

- Phase I clinical trials of a treatment for *liver cancer*, using a combination of ThermoDox™, our proprietary encapsulation of doxorubicin, a common cancer-treating drug, in a heat-activated liposome, which we license exclusively from Duke University and Radio Frequency Ablation, or RFA;
- Phase I clinical trials of a treatment for *prostate cancer*, using a combination of ThermoDox and heat from a modified Prolieve device; and
- Discussions with Duke University regarding possible breast cancer treatments using a combination of ThermoDox and the Adaptive Phased Array technology that we license exclusively from the Massachusetts Institute of Technology (MIT) or the advanced phased array radio frequency heating technology that we license from Duke.

In addition, our gene-based Cancer Repair Inhibitor (CRI), licensed from Memorial Sloan-Kettering Cancer Center (Sloan-Kettering), is in late-stage pre-clinical development.

The Company was organized under the laws of the State of Maryland under the name “Cheung Laboratories” in 1982 and in 1998 changed its name to Celsion Corporation. In 2000 we changed our state of incorporation from Maryland to Delaware. 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, 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. The material on our website is not a part of this Report on Form 10-K.

BPH TREATMENT SYSTEM

Benign Prostatic Hyperplasia

Millions of aging men experience symptoms resulting from BPH, a non-cancerous urological disease in which the prostate enlarges and constricts the urethra. The prostate is a walnut-sized gland surrounding the male urethra that produces seminal fluid and plays a key role in sperm preservation and transportation. The prostate frequently enlarges with age. As the prostate expands, it compresses or constricts the urethra, thereby restricting the normal passage of urine. This restriction may require a patient to exert excessive bladder pressure to urinate. Because urination is one of the body’s primary means of cleansing impurities, the inability to urinate adequately increases the possibility of infection and bladder and kidney damage.

Prevalence of BPH

BPH is an age-related disorder the incidence of which increases with maturation of the population. Industry estimates suggest that nine million men in the United States experience BPH symptoms and that more than 26 million men are affected by BPH worldwide. As the U.S. population continues to age, the prevalence of BPH can be expected to continue to increase. It is generally estimated that approximately 50% of all men over the age of 55 and 90% of all men over 75 will have BPH symptoms at various times. Industry studies estimate the overall costs of BPH therapy for those patients currently seeking treatment to be approximately $2.5 to $3.0 billion annually in the United States and $8.0 to $10.0 billion worldwide.

Treatment Alternatives for BPH

BPH, like some cancerous tumors, historically has been treated by surgical intervention or by drug therapy. The primary treatment for BPH currently is transurethral resection of the prostate, or TURP, a surgical procedure in which the prostatic urethra and surrounding diseased tissue in the prostate are trimmed with a telescopic knife, thereby widening the urethral channel for urine flow. While the TURP procedure generally has been considered the most effective treatment available for the relief of BPH symptoms, the procedure has shortcomings. In the first instance, TURP generally requires from one to three days of post-operative hospitalization. In addition, a substantial percentage of patients who undergo TURP encounter significant complications, which can include painful urination, infection, retrograde ejaculation, impotence, incontinence and excessive bleeding. Furthermore, the cost of the TURP procedure and the related hospitalization is high, ranging from $8,000 to $12,000. This cost does not take into account the costs of lost work time, which could amount to several weeks, or the costs related to adverse effects on patients' quality of life.

Other, less radical, surgical procedures, generally categorized as "minimally invasive" or MI therapies, are available as alternatives to the TURP procedure. The primary MI treatment, known as TUMT, uses microwave heating to treat BPH by ablating (destroying) the obstructing portion of the prostate. TUMT involves sedation, catheterization and high levels of heat. Two other MI therapies—interstitial RF therapy and laser therapy—employ, respectively, concentrated radio frequency, or RF, waves or laser radiation to reduce prostate swelling by cauterizing tissue instead of removing it with a surgical knife. However, these procedures require puncture incisions in order to insert cauterizing RF or laser probes into the affected tissue and, therefore, also involve the use of a full operating facility and anesthesia, as well as the burning of prostate tissue by the probes. Although these procedures result in less internal bleeding and damage to the urethra than the TURP procedure and may decrease the adverse effects and costs associated with surgery, anesthesia and post-operative recovery, they do not entirely eliminate these adverse consequences.

Finally, drug therapy has emerged as an alternative to surgery for the treatment of BPH in the last several years. There are several drugs available for BPH treatment, the two most widely prescribed being Hytrin® and Proscar®. Hytrin works by relaxing certain involuntary muscles surrounding the urethra, thereby easing urinary flow, and Proscar is intended actually to shrink the enlarged gland. However, industry studies have asserted that drug therapy costs $500 to $800 per year or more, must be maintained for life and does not offer consistent relief to a large number of BPH patients. In fact, studies have shown that 45% of patients who begin drug therapy for BPH drop out within the first year, primarily due to the ineffectiveness of currently available drug therapies. All of the currently available BPH drugs also have appreciable side effects.

Accordingly, neither drug therapies nor the surgical alternatives appear to provide fully satisfactory, cost-effective treatment solutions for BPH sufferers.

Celsion BPH Treatment System

We have developed a BPH treatment system—the Prolieve Thermodilatation system—that combines our microwave thermotherapy capability with a proprietary balloon compression technology licensed from MMTC, Inc. The system consists of a microwave generator and conductors and a computer and computer software programs that control the focusing and application of heat, plus a specially designed balloon catheter, and consists of two fundamental elements:

- computer-controlled transurethral microwave heating directly to the prostate at temperatures greater than 44º C (111º F); and

- Simultaneous pressure on the walls of the urethra from the inside outward as the balloon inflates the device, while the surrounding prostate tissue is heated.

The combined effect of this “heat plus compression” therapy is twofold: first, the heat denatures the proteins in the wall of the urethra, causing a stiffening of the opening created by the inflated balloon. Second, the heat serves effectively to kill off prostate cells outside the wall of the urethra, thereby creating sufficient space for the enlarged natural opening.

Pre-clinical animal studies demonstrated that a natural “stent,” or reinforced opening, in the urethra forms after the combined heat plus compression treatment. In addition, the BPH system’s temperature (43º C to 45º C) appears to be sufficient to kill prostatic cells surrounding the urethra wall, thereby creating space for the enlargement of the urethra opening. However, the relatively low temperature is not sufficient to cause swelling in the urethra.

Celsion’s Prolieve system is designed to overcome the limitations of all three of the current treatment methods. It is designed to be a relatively painless, rapid procedure that delivers the efficacy of surgical treatments without significant risks and the potential for life-altering side effects. The potential benefits of the Prolieve system include walk-in, outpatient treatment that can be completed in less than an hour; no required sedation; generally no post-operative catheterization; and rapid symptomatic relief from BPH.

Ultimate FDA approval for a device such as our equipment typically requires two phases of clinical testing. The purpose of Phase I testing is to show feasibility and safety. Phase I testing involves a small group of patients. Phase II testing may involve as many as 160 patients and is designed to show safety and efficacy. In June 1998, the FDA approved an Investigational Device Exemption, or IDE, to allow clinical testing of our BPH system and we completed initial Phase I clinical feasibility human trials of the BPH system at Montefiore Medical Center in May 1999. In the Phase I trials, the combination of computer-controlled microwave heat and balloon catheter expansion was able to increase peak flow rates and to provide immediate relief of symptoms caused by BPH. In addition, we undertook an expanded Phase I study to test an accelerated treatment protocol, which was completed in May 2000 at Montefiore Medical Center. In July 2000, the FDA approved the commencement of multiple-site Phase II studies to collect the safety and efficacy data necessary for FDA premarketing approval for commercialization. All 160 patients required to be treated under the Phase II trial were treated as of November 29, 2001. We submitted the last documentation required in support of the PMA to the FDA on March 24, 2003 and the FDA accepted this filing on August 18, 2004.

On February 19, 2004, the FDA granted us a PMA for the Prolieve system and thereafter we commenced commercial introduction of the Prolieve system through Boston Scientific Corporation. As of December 31, 2004, we had sold a total of 57 Prolieve control units, with an additional 44 in the field for evaluation and more than 2,400 patients had undergone Prolieve treatments.

Based on our experience to date, the Prolieve system has delivered a treatment that is performed in approximately 45 minutes on an outpatient basis, generally does not require post-treatment catheterization and provides symptomatic relief and an increase in urinary flow rates promptly after completion of the procedure.

As a condition to the PMA, the FDA is requiring that Celsion conduct a post-marketing study to evaluate the long-term safety and effectiveness of the Prolieve system. Celsion currently is recruiting clinical sites for this study, a secondary objective of which will be to assess the safety and effectiveness of re-treatment with Prolieve. The study is designed to follow patients for five years following treatment.

APA TECHNOLOGY

In 1993, we began working with researchers at MIT who had developed, originally for the United States Defense Department, the microwave control technology known as “Adaptive Phased Array”, or APA. This technology permits properly designed microwave equipment to focus and concentrate energy targeted at

diseased tissue areas deep within the body and to heat them selectively, without adverse impact on surrounding healthy tissue. In 1996, MIT granted us an exclusive worldwide license to use this technology for medical applications and since that time we have concentrated on developing equipment capable of focusing microwave energy on specific tissue areas. We have incorporated the APA technology in our microwave therapy equipment.

THERMODOX (DOXORUBICIN ENCAPSULATED IN HEAT-ACTIVATED LIPOSOME)

Background

Targeting drugs to a specific area within the body, ideally to a tumor, is the major goal of drug delivery. However, significant toxicity limits the dosage of many of today's chemotherapeutic agents. Therefore, it is desirable to deliver chemotherapeutic agents directly to tumor sites in order to minimize systemic toxicity. Delivering anti-cancer drugs by encapsulating them in biodegradable delivery vehicles may reduce systemic toxicity and improve localized targeting.

Liposomes are manmade, microscopic spheres with a liquid membrane, primarily composed of lipids (fatty or oily organic compounds that are not soluble in water), that can be produced in stable biodegradable formulations. Liposomes have been used to encapsulate chemotherapeutic drugs such as doxorubicin (Doxil™, Myocet™ (not available in the U.S.) and Evocet™) and these encapsulations have been shown to limit toxicity while improving accumulation in tumors. However, with presently available technology, it often takes up to four hours for such liposomes to accumulate in and release their drug contents to the tumors. This long period for accumulation and release severely limits the clinical efficacy of liposome chemotherapy treatments. Therefore, it would be desirable to increase site-specific liposome accumulation and triggered release of encapsulated drugs. Duke University has achieved these ends using temperature-sensitive liposomes that can be triggered to release encapsulated drugs when exposed to temperatures of 39.5° C to 42° C.

Celsion holds the exclusive license for Duke University's heat-activated liposome technology. We view this technology, in conjunction with heat delivered via our focused-heat technology or other heating sources, as a highly promising modality for the delivery of medicines used to combat cancer and other serious diseases. By heating the specific area and encapsulating chemotherapeutics in thermo-sensitive liposomes, the drug can be delivered directly to the area where it is needed, as opposed to being distributed through the entire circulatory system. This, in turn can increase the local concentration of the drug, while reducing the toxic side effects that accompany large systemic dosing.

Development of Thermo-Sensitive Liposomes

Duke's heat-sensitive liposomes are comprised of materials that rapidly change porosity when heated to a specific temperature range. As the heat-sensitive liposomes circulate within the small arteries, arterioles and capillaries, the drug contents of the liposomes are released at significantly higher levels in those tissue areas that have been heated than in areas that do not receive heat. In animal trials, it has been determined that up to 25 times more drug was deposited at a specific heated tissue site by heat-sensitive liposomes, when compared to systemic use of the same chemotherapeutic agent and significantly more than conventional liposomes. We have been a sponsor of this research, which is part of a larger Duke University project to develop new temperature-sensitive liposomes, temperature-sensitive gene promoters and related compounds.

In Duke's preliminary tumor growth delay studies, the heat-activated liposomes, which encapsulate chemotherapeutic agents, were injected into the bloodstream where they remain encapsulated until they release their drug payload inside the heated tumor. In these studies, tumor-bearing mice received a single intravenous injection of the liposome with a 5 mg per kilogram doxorubicin concentration. This was immediately followed by heating of the tumor to 42° C for one hour. The result of the study was a complete regression of the tumors in 11 out of 11 mice. These animals remained disease free through the 60-day study.

In November 2001, we completed large animal toxicity studies involving ThermoDox at the Roswell Park Cancer Institute, a cancer research organization in Buffalo, New York, and at Dartmouth Hitchcock Medical Center, a teaching hospital associated with Dartmouth Medical College. As discussed elsewhere herein, we currently are conducting Phase I clinical trials for the treatment of liver cancer using ThermoDox in

combination with an FDA-approved RFA device and for the treatment of prostate cancer using ThermoDox in combination with heat provided by a modified version of our Prolieve equipment. In addition, we are exploring the possibility of commencing trials using ThermoDox for the treatment of breast cancer in combination with a heating device incorporating the APA technology that we license exclusively from the MIT or the advanced phased array radio frequency heating technology that we license exclusively from Duke, often referred to as the "booby jacuzzi". See "—Liver Cancer Treatment Program," "—Prostate Cancer Treatment Program" and "—Prospective Breast Cancer Treatment Program."

Production of Heat-Sensitive Liposomes

We have established a relationship with British Columbia Cancer Agency of Vancouver, Canada to provide Quality System Regulation, or QSR (formerly Good Manufacturing Practices, or GMP), production of our heat-activated liposome for our completed large animal toxicity studies and our planned Phase I clinical studies in humans. BCCA is a leading drug formulation and discovery company that specializes in liposome drug development. In November 2002, Celsion engaged Northern Lipids Limited, a Vancouver, Canada-based liposome consulting firm, to develop a scaled-up manufacturing process for this product and, in September 2003, we engaged Baxter Pharmaceuticals to produce the liposomes on a large scale.

The current formulation of ThermoDox requires the compounding of three ingredients—a heat-activated liposome, doxorubicin and a buffer. These ingredients must be stored frozen, refrigerated and at room temperature, respectively, and must be compounded immediately prior to use at the clinical site's pharmacy. The storage and transportation characteristics of these ingredients, together with a highly sensitive compounding process could be problematic in the context of a multi-site clinical study or in commercial use. Celsion is pursuing several drug manufacturing initiatives to develop a formulation that is more suitable for efficient use in a clinical setting and more commercially viable. These initiatives include producing ThermoDox as a pre-compounded drug for commercial delivery frozen, refrigerated or at room temperature, and in a lyophilized (powder) form. Successful completion of one or all of these initiatives could ameliorate actual and potential problems in compounding and storage and increase the quality of the formulated drug. In addition to the eventual commercial and operational benefits from these initiatives we expect that revising the formulation process will also permit simplification of the manufacturing process, resulting in cost reductions.

LIVER CANCER TREATMENT PROGRAM

Prevalence of Liver Cancer

Liver cancer is a highly recurrent and lethal cancer that occurs either as a primary cancer (cancer that starts in the liver) or as a metastatic cancer (cancer that starts within another organ and spreads to the liver). The incidence of primary liver cancer in the United States currently is relatively low—approximately 11,000 new cases annually, with nearly the equivalent number of deaths. However, it is the fifth most prevalent cancer worldwide, with nearly 500,000 new cases, as well as near equivalent number of deaths, each year. The incidence of liver cancer is correlated with the incidence of chronic Hepatitis B, Hepatitis C and cirrhosis, all of which currently are more prevalent in the developing world than in the west, and all of which are becoming increasingly prevalent. Given the growing incidence of these diseases, and the aging of immigrant populations more likely to suffer from them, the incidence of liver cancer in the U.S. and the west, as well as worldwide, is expected to increase significantly.

Metastatic liver cancer accounts for over 240,000 U.S. cases annually, but accurate estimates of global incidence are unavailable. Because the liver is a vital organ, the success of the treatment of the liver cancer often determines the patient's survival. The most common metastatic liver cancers originate from colorectal cancer (estimated 50% of total metastatic liver cancer), as well as from cancers of the breast, lung, pancreas and stomach.

Current Treatment Alternatives

There presently is no adequate standard of care for liver cancer, and there have been no significant breakthroughs in its treatment. Current treatment options include liver transplantation, surgical removal of the cancer (hepatic resection), chemotherapy, radiation therapy, and minimally invasive treatments such as heat therapy (RFA) or freezing therapy (cryotherapy).

While liver transplantation may offer a cure, particularly in cases of early diagnosis, it is a viable option for relatively few patients due to the small number of available organs, limited donor compatibility and strict inclusion/exclusion criteria for the procedure. In light of its promise, however, the medical community is seeking local control therapies that, if effective, would extend the period of time that transplant candidates could wait for a compatible donor organ.

Surgical removal of the cancer, or hepatic resection, also is available to a limited number of patients. Because victims of early stage liver cancer often experience few symptoms, detection and diagnosis frequently are delayed. When the cancer ultimately is diagnosed, tumors often are too large to permit surgical intervention.

Chemotherapy has been the common alternative to transplantation and surgery for liver cancer, but has had limited effectiveness due to the systemic nature of current delivery techniques. That is, only a small dose of a chemotherapeutic agent can be delivered to the liver without causing side effects that significantly impact the patient's overall health and quality of life. In recent years there have been advances in the localized delivery of drugs through hepatic arterial injection, or HAI. However, even with HAI, delivery to the complete liver is not assured due to the complex, vascularized structure of the liver. While additional anti-cancer drugs presently are under clinical development, in light of the systemic limitations on chemotherapeutics, these drugs are expected to have the same limitations as currently available chemotherapeutic agents.

Except as a palliative or adjuvant, radiation therapy has proven largely ineffective for liver cancer, and is not a standard treatment as a stand alone therapy.

In recent years, researchers have been investigating minimally invasive treatment options. Cryotherapy, which works by freezing the liver tumor to sub-zero temperatures, is generally effective, but to date high capital equipment and maintenance costs, as well as potential severe side effects including hemorrhage and renal failure, have limited its use.

Radio Frequency Ablation (RFA) is emerging as the standard of care among minimally invasive treatments for liver cancer. A number of devices are now FDA-approved for this indication and a growing body of literature supports RFA as a viable option for both primary and metastatic liver cancer. The liver has high regenerative capabilities and the ability to withstand very high temperatures. Therefore, RFA, which can heat to over 100° C at the center of the tumor in as little as 15 minutes, causes near-instant necrosis. RFA is gaining acceptance among medical specialists including interventional radiologists, surgical oncologists and hepatologists.

One of the demonstrated limitations of current RFA treatments is the limited distance from the center of the tumor that can be heated sufficiently to induce necrosis. That is, while RFA generates very high temperatures to ablate the primary tumor, it is ineffective in eliminating cancerous cells at the tumor margins because the temperatures at the margins are not high enough to destroy the cells. Therefore, tumor recurrence is frequent at the lesion margins. In addition, RFA alone is ineffective in treating larger liver tumors and multi-focal liver cancer, where there is more than a single lesion.

Celsion Multi-Modal Liver Cancer Treatment System—Localized Heat Plus ThermoDox

Celsion is developing a unique approach to treating primary and metastatic liver cancer through the use of a drug-device combination. Celsion's approach is to build on the demonstrated effectiveness of FDA-approved RFA devices in killing cancer cells at or near the center of a tumor by increasing the "kill zone" around the tumor through the simultaneous delivery of doxorubicin, delivered via ThermoDox. While the heating capacity of RFA is insufficient to ablate tumor cells at the tumor margins, it is more than sufficient to heat tumor margins to at least 39.5° C, which is the release point for the doxorubicin encapsulated in ThermoDox. By combining

heat from RFA with the doxorubicin delivered by ThermoDox, Celsion expects that a significant amount of doxorubicin will be delivered throughout the tumor region, including to the margins of the tumor, thereby reducing recurrence rates from "missed" cells in tumor margins. Reduced recurrence should improve long-term survival as well as the quality of life for patients by reducing the severe side effects associated with the delivery of free doxorubicin.

Phase I Clinical Trial

On August 21, 2004, the FDA cleared Celsion's Investigational New Drug application, or IND, for a Phase I clinical trial investigating the use of ThermoDox in combination with RFA for the treatment of primary and metastatic liver cancer. Since that time, Celsion and the National Cancer Institute (NCI) of the National Institutes of Health (NIH) have been engaged in initiating the trial, which is being conducted at the NIH Clinical Center in Bethesda, Maryland. The first patient was treated on February 14, 2005 and Celsion expects that enrollment in the study will be completed by the end of 2005.

The trial is designed to determine the maximum safely tolerated dose and pharmacokinetic profile of ThermoDox when used in combination with RFA in the treatment of liver cancer. The study will utilize RFA (100°C or above) to ablate the center of the tumor and to activate the ThermoDox liposome thermally to release its encapsulated doxorubicin to kill remaining viable cancer cells throughout the heated area, including the tumor margins.

The study is being conducted pursuant to a Clinical Research and Development Agreement (CRADA) between Celsion and NIH. Pursuant to the CRADA, Celsion is responsible for providing ThermoDox, clinical support, regulatory services, and specified financial support, while NCI is responsible for enrolling and treating patients.

PROSTATE CANCER TREATMENT PROGRAM

Background

Prostate cancer is the most common cancer in males (approximately 230,000 new cases per year in the U.S. alone) and the second leading cause of all cancer deaths in males (approximately 37,000 per year). Current treatment options for localized prostate cancer include observation, radiation and surgical therapy. Currently, the most effective treatments are radical prostatectomy (surgical removal of the prostate) and brachytherapy (radiation therapy in which radioactive pellets are implanted in the tumor region), which effectively achieve local control and have roughly equivalent overall survival rates in low and moderate grade prostate tumors. However, these therapies are often associated with side effects, such as impotence, that have a deleterious impact on the patient's quality of life.

Current Treatment Alternatives

Despite optimal techniques of external beam and brachytherapy, progressive disease following local irradiation continues, causing additional clinical problems (e.g. bladder outlet obstruction, urethral obstruction, local pain/discomfort and base of bladder invasion).

Devising locally effective, palliative therapies is an important goal in prostate cancer therapeutics. Further, while still a theoretical consideration, experimental evidence from various studies demonstrates that destruction of a local tumor mass, in situ, may "induce" a systemic immunologic response.

Phase I Study

On June 27, 2002 Celsion was cleared by the FDA to proceed with human clinical trials for its investigational therapy for the treatment of prostate cancer. Celsion's treatment combines localized heat from a modified version of its Prolieve Thermodilatation system with ThermoDox. The Phase I study is designed to determine the maximum safely tolerated dose and pharmacokinetic profile of ThermoDox when used in combination with the modified Prolieve device. Thirteen patients initially were treated in this study. The maximum tolerated dose has not yet been reached. In response to issues raised in the aftermath of a warning letter from the FDA in connection with our Prolieve pivotal study, we voluntarily suspended the study and applied to the FDA to restart the study under a new protocol. The FDA has cleared the Company to restart this study and we are in

the process of recruiting new clinical sites to undertake the study. We expect to resume treating patients once we have received necessary regulatory and administrative clearances.

PROSPECTIVE BREAST CANCER TREATMENT PROGRAM

Background

Breast cancer currently is the most common cancer in women in the United States and is responsible for over 40,000 deaths annually, second only to lung cancer. Over 216,000 new cases of invasive breast cancer were detected in the U.S. during 2004 and worldwide over 1.1 million cases were diagnosed and accounted for approximately 330,000 deaths. In the U.S annual expenditures of over $7 billion are focused on detection, diagnosis and treatment of breast cancer.

Treatment for breast cancer on a global basis is diverse. In the U.S., surgery, radiation and chemotherapy are commonly employed as the standard of care to attempt to arrest the disease and prevent recurrence. While detection following mammography and treatment at the early stage is generally accepted as providing a good prognosis, with a greater than 95 percent survival rate 10 years post-diagnosis, there are still a large number (>25 percent) of women who present at later stages of the disease. For a variety of reasons many patients will undergo a mastectomy or extensive breast tissue removal as their primary treatment even though this has not been demonstrated to provide an improved survival over less extensive breast conserving surgery. Despite a wide array of hormonal, cytotoxic and biologic approaches, a significant number (10 percent) of tumors will recur in the chest wall and axillary area following primary treatment. In the U.S. it is estimated that as many as 11,000 patients a year are seen with a recurrence of their original breast cancer at the chest wall, skin flap or surgical scar. A high proportion of these diagnosed patients will die in less than 12 months. During this period patients will experience pain, discomfort and lack of mobility due to the chest wall lesions.

Prognosis for patients presenting with a reoccurrence of breast cancer at the chest wall following mastectomy is generally regarded as poor. Comprehensive re-irradiation following reoccurrence at the chest wall after mastectomy currently offers the best chance of local control and reduces further reoccurrence from >60 percent to <35 percent. In some studies survival at five years following radiation treatment for reoccurrence at the chest wall following mastectomy is improved from <20 percent to <50 percent.

The addition of heat or hyperthermia to radiation has been the subject of significant scientific attention and the addition of hyperthermia to radiotherapy has been demonstrated to provide significantly improved results over radiotherapy alone. The medical rationale for the augmentation of the radiation effect is based on direct cytotoxic effect of hyperthermia on cancer cells, radiosensitization of cancer cells, inhibition of the cell repair mechanism and selective destruction of tumor microcirculation.

Localized Heat Plus ThermoDox

Clinicians currently combine the use of small molecules, hormones and monoclonal antibodies as systemic therapy to prevent, treat and reduce recurrence of breast cancer. These treatments tend to be delivered using a systemic route and, as such, clinical effectiveness is often reduced due to toxicities or inability to target efficacious doses to the tumor cells. Therefore, a major focus of chemotherapy and drug delivery is to identify drugs and technology that enable the clinician to target the tumor without widespread systemic toxicity.

It is evident that drug delivery to the tumor site plays an important role in the therapy of isolated recurrences and the idea of improved anti-tumor efficacy with increased drug delivery is the subject of intense pre-clinical and clinical research. Chemotherapy delivery in breast cancer has been demonstrated to play an important role in tumor kill and the use of mild hyperthermia with systemic free doxorubicin has been shown to increase therapeutic efficacy of chemotherapy. In many cases attempts to improve targeting have involved the delivery of chemotherapy using liposomes. Such commercial liposome products are Doxil and Myocet. These non-thermo-sensitive liposomes are used to carry cytotoxic drugs around the body in order to reduce the toxic effect on non-target tissue, with the hypothesis being that the liposome will accumulate in the target tumor tissue due to pores in the vascular tissue associated with tumors.

In clinical trials at Duke University non-thermo-sensitive liposomal encapsulations of doxorubicin (Doxil and Myocet) plus localized heat provided by a microwave device were shown to be safe. However, although safe, the application with Doxil was not efficacious. It is believed that hyperthermia likely augmented liposomal drug delivery to the site, but that it had no effect on the release of drug from the liposome, thus limiting efficacy. There was some efficacy demonstrated in a Phase I/II study using a combination of Evacet and paclitaxel and hyperthermia.

Other clinical trials using doxorubicin encapsulated in non-thermo-sensitive liposomes, although showing similar disease response rates to systemic doxorubicin, have shown marked reduction in cardiotoxicity and myelosuppression normally associated with doxorubicin. A further study using Doxil supported this observation of reduced cardiotoxicity associated with liposomal versus free doxorubicin.

Celsion Multi-Modal Breast Cancer Treatment System—Localized Heat Plus ThermoDox

As discussed above, Celsion has licensed a liposome formulation that releases its encapsulated contents when exposed to temperatures between 39.5° C and 42° C. This liposome has been used to encapsulate doxorubicin, a well known anthracycline cytotoxic drug used in treatment of breast cancer. Celsion's liposome-drug combination is ThermoDox. See "—ThermoDox (Doxorubicin Encapsulated in Heat-Activated Liposome)."

In contrast to results using non-thermo-sensitive liposomal (NTSL) encapsulated chemotherapeutics such as Doxil, Myocet or Evacet, results with low temperature thermo-sensitive liposomes (LTSL), such as ThermoDox in combination with hyperthermia, have consistently shown a better anti-tumor effect pre-clinically. In specific tumor growth studies, the growth delay obtained using LTSL was superior to NTSL. In pre-clinical studies hyperthermia increased delivery (up to 25 times more drug delivered than with standard free doxorubicin) and anti-tumor effect, compared to liposomal formulations of chemotherapy alone or hyperthermia with free doxorubicin.

Celsion presently is in discussions with Duke University regarding development of a treatment for breast cancer that would use this low temperature-sensitive liposome to achieve therapeutic drug concentrations in the target tissue by activating the liposome to release its contents of doxorubicin by raising the temperature of the target tumor to 41° C. This local temperature increase could be achieved using either a modification of Celsion's earlier hyperthermia device, developed with technology licensed from MIT, or Duke's advanced phased array radio frequency heating system, both of which are discussed below.

Allied Heating Technologies

In 1989 Celsion was granted a PMA by the FDA for use of its microwave hyperthermia device in conjunction with radiotherapy to treat superficial and subcutaneous cancers. Further development of this PMA system and the incorporation of Adaptive Phased Array microwave focusing technology licensed from MIT enabled Celsion to obtain approval of a Supplement to the PMA from the FDA.

Following approval of the PMA Supplement, Celsion developed a device to treat small tumors with focused hyperthermia alone and large tumors in association with systemic chemotherapy. These two treatments were the subject of a number of clinical trials which supported the rationale that (1) focused microwaves can cause significant necrosis in small tumors and reduce the potential of positive margins associated with lumpectomy and (2) in association with systemic chemotherapy, hyperthermia can assist in the downsizing of inoperable breast tumors to permit lumpectomy rather than mastectomy.

On July 18, 2003, we entered into a license agreement with Duke University, pursuant to which we have obtained exclusive rights to an advanced phased array radio frequency heating system designed specifically for use with chemotherapeutic drugs for the treatment of locally advanced breast cancer. The system, developed by engineers at Duke University, uses Radio Frequency (RF) energy to warm a woman's breast to approximately 42° C to enhance the effectiveness of liposomal chemotherapeutic compounds. During the treatment, the breast is immersed in a pool of distilled water, which helps distribute the heat evenly around the breast, thus preventing skin burns and "hot spots," which often create pain. Skin burns and hot spots have, up to now, limited the use of RF hyperthermia as an effective means for treatment of breast cancer.

This heating system is currently being clinically evaluated at Duke. A Phase I trial has been completed and a Phase II trial is underway. The combination of trials was designed to demonstrate the system's ability to enhance the combined therapeutic effect of liposomal encapsulations of doxorubicin plus traditional paclitaxel (Taxol®) in the management of locally advanced breast cancer. Results of the Phase I study, which included 21 women, indicated that tumor growth was halted in all of the women participating in the trial and that 50 percent of the treated tumors were reduced in size. Eleven percent of the trial participants had complete pathologic responses, meaning no cancer was found in the breast tissue upon analyzing its surgical remains, and 33 percent of patients had complete clinical responses, meaning visible signs of the tumor could no longer be detected. An additional 17 percent of trial participants were converted from mastectomy candidates to lumpectomy candidates. Celsion intends to work with Duke to explore the potential for using this heating system in combination with ThermoDox to treat breast cancer.

HEAT-ACTIVATED, GENE-BASED CANCER REPAIR INHIBITORS

Background

Cancer cells have the ability to repair themselves after radiation or chemotherapy. Thus, patients require repeated treatments to destroy substantially all of the cancer cells. Celsion has licensed from Sloan-Kettering a biomedical innovation that promises significant improvements in cancer therapy. Sloan-Kettering has developed a biological modifier that inhibits cancer cells' ability to repair themselves. Activated by focused heat, this Cancer Repair Inhibitor, or CRI, temporarily disables the repair mechanism of cancer cells, making it possible to reduce significantly the number of radiation/chemotherapy treatments and/or lower the treatment dosage.

A standard approach to treating cancer is radiation therapy combined with chemotherapy. High doses of radiation kill cancer cells or keep them from dividing, but produce chronic or acute side effects, including fatigue, neutropenia, anemia and leucopenia. In addition, depending on the location of the tumor, other acute side effects may occur, including diarrhea, alopecia and various foreign ulcers. Chemotherapy presents comparable or more serious side effects.

Oncologists are looking for ways to mitigate these side effects. In radiation therapy, these mitigating techniques include hyperfractionated radiation, intra-operative radiation, three-dimensional radiation, stereotactic radiosurgery and the use of radio-labeled monoclonal antibodies and radio sensitizers. CRI falls into this latter category because it "sensitizes" a cancer cell for treatment by making it more susceptible to DNA-damaging agents such as heat, chemicals or radiation. A product of advances in the understanding of the biology of cancer, CRI is one of a new class of "biologics" that we expect may become part of the cancer treatment protocol.

Celsion Multi-Modal Treatment System—CRI Plus Focused Heat

CRI can be activated in tumors by minimally invasive focused heat in the range of 41º C (106º F). This focused heat may be generated by Celsion's Adaptive Phased Array microwave technology or other heating systems. Having increased the susceptibility of cancer cells to DNA-damaging agents, radiation and chemotherapy treatment may then be administered with less frequency and/or at lower doses than currently is possible. CRI would then deactivate and the patient would resume normal post-treatment care.

In September 2001, scientists at Sloan-Kettering successfully completed pre-clinical laboratory feasibility demonstrations to assess safety and biological activity of CRI. In December 2001, a small animal feasibility study was completed by Sloan-Kettering' to assist in drug formulation. At such time as we determine safety and dosage in our preliminary studies, we expect to form partnership(s) with one or more drug companies to scale up manufacturing for larger pivotal studies.

In May 2000, we entered into an exclusive worldwide agreement with Sloan-Kettering for the commercial rights to the heat-activated gene therapy technology developed by Sloan-Kettering. In the June 15, 2003 issue of *Cancer Research*, a Sloan-Kettering scientist summarized the scientific and clinical rationale leading to the successful development of the heat-activated anti-sense genetic modifier and the pre-clinical evaluations, which demonstrated the feasibility of its use as a potent radiation sensitizer for the treatment of cancer.

In addition, in the July 1, 2000 issue of Cancer Research, a Duke University research scientist reported on his initial use of heat to activate gene therapy and to increase the production in animals of Interleukin-12, a genetic protein, in order to delay tumor growth. On August 8, 2000, we entered into an agreement with Duke University under which Celsion has the right to negotiate an exclusive license for this technology. This agreement expires on February 7, 2006.

On September 3, 2003, Celsion entered into an exclusive license with the National Institutes of Health, or NIH, for NIH's patent-pending technology for heat-activated gene expression. This is a broad, umbrella patent which, Celsion believes, will enhance the value of the technologies licenses from Duke and Sloan-Kettering.

DEVELOPMENT, MARKETING AND SALES STRATEGY

OVERVIEW AND GOALS

Along with our distributor, Boston Scientific, we are focusing our efforts on ensuring the successful introduction of our Prolieve Thermodilatation system. We are also developing and testing other technologies in our pipeline. Our strategic plan is based upon our expertise and experience in the medical application of focused microwave heat and our relationships with and license rights from our institutional research partners. Our goal has been to employ these resources to develop minimally invasive or non-invasive treatment technologies with efficacy significantly exceeding that available from other treatment methods. We currently are focusing on the following goals:

- Short-Term Goals—12 to 24 Months:
  - complete commercialization and monetization of our Prolieve system;
  - complete ThermoDox/RFA liver cancer Phase I study;
  - restart ThermoDox/ modified Prolieve prostate cancer Phase I study; and
  - initiate ThemoDox/APA breast cancer program with Duke University and MIT.
- Longer-Term Goals—Beyond 24 Months:
  - Initiate ThermoDox/RFA liver cancer Phase II study**;**
  - Complete ThermoDox/modified Prolieve prostate cancer Phase I study and seek a development partner;
  - Continue ThermoDox/APA breast cancer program with Duke University and MIT; and
  - Establish development plan for gene technologies licensed from Sloan-Kettering, Duke and NIH.

THE PROLIEVE SYSTEM

Effective January 21, 2003, we entered in to a 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 BPH. See "—Strategic Alliances, License Agreements and Proprietary Rights." The marketing plan calls for eventual marketing to the approximately two million readily identifiable BPH sufferers currently employing drug therapies, as well as the estimated seven million men in the United States afflicted with BPH who are not currently being treated—the "watchful waiters"—with a focused message designed to encourage these BPH sufferers to take advantage of a solution that will relieve their symptoms and help to restore the quality of their lives. This marketing effort includes the following elements:

- Reimbursement. Prolieve treatments are covered under the TUMT reimbursement code for Medicare patients.

- Targeting Key Constituencies:
  - Urology Practices. Boston Scientific presently is targeting large urology practices, starting with the practices that participated in our Phase II trial. Our Prolieve system is being sold to urologists, who purchase unique disposable catheter kits for each treatment. We believe that urology practices have experienced a loss of revenue to primary care physicians as a result of new drug therapies introduced to treat BPH and other urological disorders and that urologists will be favorably disposed toward our Prolieve system, which could offer them a significant new revenue source. Urologists have the opportunity to evaluate Prolieve units for up to 60 days, and then make a decision whether to purchase the equipment.
  - Patients. In the future, Boston Scientific also expects to target BPH sufferers, through aggressive use of promotional and advertising media. Due to the specificity of the target patient audience (males 50 years and older) and the geographic concentration of retirees, we expect that specific media in well-defined and discrete markets will generate a high level of awareness of the availability of, and interest in, our treatment system. We also expect that the Internet and other electronic methods will be utilized to direct prospective patients to urology offices equipped to perform the Prolieve procedure.

This marketing approach has been designed to bypass primary care physicians, whom we believe to be the most significant barrier to the success of our Prolieve system. Generally, under current managed care protocols, a patient must first visit his primary care physician who, after reviewing the patient's symptoms, may either treat him or refer him to a specialist. With increasing availability of drug therapies to treat urological disorders, the number of referrals to urologists has been declining. The marketing strategy calls for ensuring that BPH sufferers are aware of our Prolieve system so that they are in a position to insist that they be referred to a urologist to obtain treatment.

STRATEGIC ALLIANCES, LICENSE AGREEMENTS AND PROPRIETARY RIGHTS

We have 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 our 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 the Launch Date (February 21, 2004). In return, and upon meeting certain conditions, Celsion was entitled to a $4 million licensing fee. All of the conditions were met, and we received a payment from Boston Scientific during the second quarter of 2004. Pursuant to the terms of the Distribution Agreement, the parties share gross sales (less certain defined costs and expenses) attributable to the product. The Company and Boston Scientific also entered into a Transaction Agreement effective January 20, 2003, pursuant to which, upon attainment of specified milestones, Boston Scientific made equity investments in the Company through the purchase of our common stock, par value $0.01 per share (Common Stock) at a premium to the market price for such stock over various measurement periods. On January 21, 2003, Boston Scientific purchased 9,375,354 shares of our Common Stock for $5 million, on March 2, 2004, Boston Scientific purchased 2,083,333 shares of our Common Stock for $4 million and on April 7, 2004, Boston Scientific purchased 1,273,885 shares of Common Stock for $2 million. In addition, 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. This option is exercisable for a period of five years, with the option price being calculated based on worldwide sales of the product subject to the Distribution Agreement, subject to a minimum price of $60 million. Additionally, for a period of up to seven years, the Company has granted Boston Scientific the right to (i) match any unsolicited offer that the Company may receive for any other product developed by the Company and (ii) make a written offer to the Company in the event the Company desires to sell, license or distribute any product developed by it.

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

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

In 1996, we entered into a patent license agreement with MIT, pursuant to which we 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, Europe, Canada and Japan. The term of our 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 our rights continue on a non-exclusive basis for the life of the MIT patents.

We entered into license agreements with MMTC in 1996 and 2002, pursuant to which we currently have exclusive worldwide rights to MMTC's patents related to its balloon compression technology for the treatment of prostatic disease in humans. Our 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, we entered into a license agreement with Duke University under which we 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.

Our rights under our 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, we have 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, our license rights are worldwide, with various patent rights covering the United States, Canada, the United Kingdom, France, Germany and Japan.

We 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. Our 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 us under completed or pending license agreements, we rely on our own proprietary know-how and experience in the development and use of heat for medical therapies, which we seek to protect, in part, through proprietary information agreements with employees, consultants and others. We cannot offer assurances that these information agreements will not be breached, that we will have adequate remedies for any breach or that these agreements, even if fully enforced, will be adequate to prevent third-party use of our proprietary technology. Similarly, we cannot guarantee that technology rights licensed to

us by others will not be successfully challenged or circumvented by third parties, or that the rights granted will provide us with adequate protection.

MANUFACTURING

On April 2, 2003, we entered into a Medical Product Manufacturing Services Agreement, referred to herein as the Sanmina Agreement, with Sanmina-SCI for the manufacture of Prolieve control units. The Sanmina Agreement, which was for an initial term of one year, renews automatically for additional consecutive one-year terms unless terminated by either party. Under the Sanmina Agreement, Celsion has the right to cause Sanmina to produce, and thereafter to purchase, Prolieve control units and related items in the quantities and at the prices set forth therein, subject to upward adjustment if Celsion fails to purchase product in specified volumes. Prices are also subject to annual adjustment to the extent that actual increases in product costs exceed 3 percent. In addition, the parties are obligated to implement a cost reduction program to reduce product cost by 5 percent during each annual term, with such cost reductions shared equally by the parties. The Sanmina Agreement provides for a one-year warranty on defects in workmanship (as defined) on Sanmina's products (up to 15 months from the date of manufacture) and a pass-through to Celsion of manufacturers' warranties on component products, and contains other customary terms.

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 and disposables, 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. Celsion provided notice of its intent to terminate on October 29, 2003. However, in order to secure our supply chain, we intend to retain CR as a second, back-up source following approval of Venusa Corporation as a catheter supplier.

In anticipation of the termination of our Supply Agreement with CR, on March 12, 2004, we contracted with Venusa Corporation for the production of catheters and disposables under a Medical Product Manufacturing Services Agreement, referred to herein as the Venusa Agreement. The Venusa Agreement, which was for an initial term of one year, renews automatically for additional consecutive one-year terms unless terminated by either party. Under the Venusa Agreement, Celsion has the right to cause Venusa to produce, and thereafter to purchase, catheter kits and related disposable items in the quantities and at the prices set forth therein, subject to upward adjustment if Celsion fails to purchase product in specified volume and to downward adjustment if Celsion purchases in greater volume. Prices are also subject to quarterly adjustment to the extent of actual increases in basic material costs. The Venusa Agreement provides for a one-year warranty on manufacturing defects and nonconformances.

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 (GMP). We are currently working toward FDA approval of Venusa as a supplier of our disposables. Although there can be no assurances, we currently anticipate that Venusa will begin to supply catheters and related disposables by September 2005.

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 one or more of our single-source suppliers could have a material adverse effect on our business.

We believe we are best suited to conduct basic research and development activities, to pursue a prototype product through clinical testing and regulatory approval, and to engage in initial manufacturing and marketing activities during product launch. Accordingly, we do not intend to engage in large-scale manufacturing with respect to our breast cancer treatment system or other future products, but instead intend generally to outsource the manufacture of final commercial products, components and disposables. Based on past experience, we do not anticipate any significant obstacles in identifying and contracting with qualified suppliers and manufacturers.

THIRD-PARTY REIMBURSEMENT

We believe that satisfactory third-party reimbursement arrangements will likely be essential to commercial acceptance of our products and overall cost-effectiveness and physician advocacy will be keys to obtaining such reimbursement.

We believe that our Prolieve system can be used to deliver treatment at substantially lower total cost than surgical treatments for BPH or cancer or than continuous drug therapy. Consequently, we believe that third-party payors seeking procedures that provide quality clinical outcomes at relatively lower cost will help drive acceptance of our products. For BPH, our strategy is to use reimbursement codes currently approved for TUMT in the United States With the increasing use of managed care and capitation as means to control health care costs in the United States, we believe that physicians may view our products as a tool to treat BPH patients at a lower total cost, thus providing them with a competitive advantage when negotiating managed care contracts. This is especially important in the United States, where a significant portion of the aging, Medicare-eligible population is moving into a managed care system. Physicians submit insurance claims for reimbursement of covered procedures to third-party payors, such as Medicare carriers, Medicaid carriers, health maintenance organizations and private insurers. In the United States and in international markets, third-party reimbursement is generally available for existing therapies used to treat cancer and BPH. The availability and level of reimbursement from such payors for the use of our new products will be a significant factor in our ability to commercialize these systems.

We expect that new regulations regarding third-party reimbursement for certain investigational devices in the United States will allow us to pursue early reimbursement from Medicare with individual clinical sites prior to receiving FDA approval. However, FDA approval likely will be necessary to obtain a national coverage determination from Medicare. The national coverage determination for third-party reimbursement will depend on the determination of the Centers for Medicare and Medicaid Service, or CMS (formerly known as the United States Health Care Financing Administration, or HCFA), which establishes national coverage policies for Medicare carriers, including the amount to be reimbursed, for coverage of claims submitted for reimbursement related to specific procedures. Private insurance companies and health maintenance organizations make their own determinations regarding coverage and reimbursement based upon “usual and customary” fees. Reimbursement experience with a particular third-party payor does not reflect a formal reimbursement determination by the third-party payor. New outpatient procedure codes were instituted on August 1, 2000. Our ability to petition successfully for these new reimbursement codes will ultimately determine the degree of success we achieve in implementing our business model.

Internationally, we expect to seek reimbursement approvals for procedures utilizing our new products on a country-by-country basis. We expect to use clinical studies and physician advocacy to support reimbursement requests in countries in which there is currently no reimbursement for such procedures.

RESEARCH AND DEVELOPMENT

Celsion does not directly engage in research and development activities except with respect to development of certain devices. Instead, we underwrite sponsored research in partnership with various research institutions including Duke University, Sloan-Kettering, NIH and MIT. Our expenditures for research and development were $11,533,000, $9,191,000 and $4,979,000 for the years ended December 31, 2004, 2003 and 2002, 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 trails. 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.

REGULATION OF SALES IN THE UNITED STATES

FDA REGULATION—RESEARCH AND APPROVAL

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 are 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, 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 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 demonsration of safety and effectiveness required for approval. However, as in the case of the PMA for Prolieve, the FDA may require 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 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 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 $672,000) and PMA application fees (currently up to $3,502). 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.

FDA REGULATION—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.

FDA REGULATION—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 adequately and promptly to achieve correction may be expected to result in an enforcement action.

On May 7, 2004, Celsion received a warning letter from the FDA regarding the Phase I and Phase II clinical trials of the Prolieve system, which had been completed in January 2002. The warning letter, which was based upon an inspection conducted in December 2003, addressed four general areas—monitoring, investigator agreements, provision of information to investigators, and FDA reporting—in connection with the Prolieve studies. Since receipt of the warning letter, we have initiated short- and long-term corrective and compliance measures to address fully the issues raised by the FDA, including adding additional senior personnel with significant clinical experience. Following receipt of the warning letter, Celsion retained consultants to assist in bringing the Company into compliance with FDA regulations and ensuring ongoing compliance with those regulations. In addition, in order to ensure prompt and continuing compliance with FDA regulations in the conduct of our clinical trials, we have elected to replace our in-house monitoring staff with CROs. If the FDA is not satisfied with our follow-up and corrective actions, it could require us to take additional actions or could take regulatory action against us, which could include fines, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of product applications, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted product approvals. Although we have internal compliance programs, if these programs do not meet regulatory agency standards or if our compliance is deemed deficient in any significant way, such findings and related actions by the FDA could have a material adverse effect on the Company.

FDA REGULATION—RECALLS

The FDA has the authority to require the recall of our products in the event of material definiencies 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 labelling. In August 2004, we conducted a voluntary Class II recall and field correction of our Prolieve system to correct a potential software malfunction that occurred if a procedure using the Prolieve system was ongoing when the system's computer clock transitioned through midnight. A Class II recall is a situation in which use of the product in question may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. In contrast, a Class I recall is a situation in which there is a reasonable probability that use of the product will cause serious adverse health consequences or death. No injuries have been reported in connection with use of the Prolieve system. The Company developed a software upgrade to eliminate the potential for the malfunction, applied the upgrade to all existing Prolieve units and incorporateed it into the software package for all newly manufactured units.

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 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.

REGULATION OF FOREIGN SALES

Sales of domestically produced drugs, biologics and medical devices outside of the U.S. are subject to United States export requirements and foreign regulatory controls. Drugs, biologics, and devices that are subject to PMA requirements and have not received FDA marketing approval cannot be exported unless they are approved in the European Union (EU), in a country in the EU or the European Free Trade Association, or in certain other countries specified in the U.S. Food, Drug and Cosmetic Act.

Products approved in these countries may be exported to other countries in which they are legal for marketing. Such products must bear labeling that complies with both the country of approval and the country to which the product is exported. In the case of drugs and biologics, there must also be a valid marketing authorization by a responsible authority and FDA must make detailed determinations regarding the adequacy of the statutory or regulatory requirements of the importing country.

Exported products that are not approved in the U.S. are subject to other FDA regulatory requirements as well, including substantial compliance with good manufacturing practice requirements. The FDA may prohibit export if there is a determination that the exportation of the product presents an imminent hazard to the public health of the importing country or to the U.S. if reimported.

Upon exportation, our products would 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. In the EU, the harmonization of standards has caused a shift from a country-by-country regulatory system towards a single EU-wide regulatory system. However, many members of the EU have imposed additional country-specific regulations/requirements. The approval procedure varies from member state to member state, and the time required may be longer or shorter than that required for FDA approval. There can be no assurance that the changes in the regulatory schemes imposed by the EU, supranational agencies or individual countries affecting our products will not have a material adverse effect on the our ability to sell our products in countries other than the U.S.

Failure to comply with foreign regulatory requirements can result in, among other things, warning letters, fines, injunctions and other equitable remedies, civil penalties, recall orders or seizure of products, total or partial suspension of production, refusal of the health authorities to grant desired approvals, the withdrawal of approvals and criminal prosecution.

Legal restrictions on the sale of imported medical devices vary from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ.

COMPETITION

Many companies and institutions are engaged in research and development of thermotherapy technologies for both cancer and prostate disease products that seek treatment outcomes similar to those we are pursuing. In addition, a number of companies and institutions are pursuing alternative treatment strategies through the use of RF, laser and ultrasound energy sources. Potential competitors engaged in all areas of cancer and prostate treatment research in the U.S. and other countries include, among others, major pharmaceutical and chemical companies, specialized technology companies, universities and other research institutions. See “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations—Risk Factors.”

There currently are three principal competitors in the minimally invasive market for BPH treatment systems: Medtronic (NYSE:MDT), Urologix (NASDAQ:ULGX) and American Medical Systems Holdings, Inc. ((NASDAQ:AMMD), or AMS (which acquired TherMatrx in July 2004). These companies utilize one of two major approaches to BPH treatment:

- Transurethral needle ablation, or TUNA, which uses radio frequency ablation and is offered by Medtronic; and
- TUMT, which uses microwave heating to ablate tissue within the prostate and is offered by the remaining companies.

TUNA technology is labor intensive for the physician and requires a significant learning curve prior to perfecting the technique. Patients require post-treatment catheterization and significant pre-medication is common.

TUMT technology is currently the dominant minimally invasive alternative. Urologix is the market leader in TUMT systems. Urologix’ technology uses a “water cooled” catheter, which is designed to use high microwave energy without damaging the urethral lining. AMS/TherMatrx takes a simpler approach, offering a low power machine that does not require cooling. The catheter used in conjunction with this equipment sells in the same range as the Urologix catheter. Both Urologix’ and AMS/TherMatrx’ products require pre-medication, are more difficult for the physician to administer than is the Prolieve system and require post-treatment catheterization of the patient.

We believe that our technology represents a significant advancement of microwave therapy. The addition of balloon compression within the prostatic portion of the urethra allows for immediate relief to the patient and in most cases can avoid post treatment catheterization. Thus, Celsion’s technology allows for the type of rapid relief for the patient normally associated with drug therapies while avoiding the side effects and significant delays in patient symptomatic relief associated with other minimally invasive therapies.

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, 2005, we employed 33 full-time employees and also utilize 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.

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, 2004 was $236,000. Future minimum lease obligations are as follows:

2005	$187,000
2006	$193,000
2007	$198,000
2008	$204,000
2009	$210,000
2010	$180,000

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 AND RELATED STOCKHOLDER MATTERS

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.

	High	Low
YEAR ENDED DECEMBER 31, 2003		
First Quarter (January 1 - March 31, 2003)	$0.76	$0.39
Second Quarter (April 1 - June 30, 2003)	$1.45	$0.39
Third Quarter (July 1 - September 30, 2003)	$1.29	$0.84
Fourth Quarter (October 1 - December 31, 2003)	$1.45	$0.94
YEAR ENDED DECEMBER 31, 2004		
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

On March 15, 2005, the last reported sale price for our Common Stock on The American Stock Exchange was $0.37. As of March 15, 2005, there were approximately 1,300 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 October 28, 2004, we issued a total of 70,166 shares of Common stock to three consultants for services valued at $36,501. 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."

ITEM 6. SELECTED FINANCIAL DATA

The following table contains certain financial data for Celsion for the five fiscal years ended December 31, 2004, 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.

	YEAR ENDED DECEMBER 31,				
	2000 (unaudited)	2001 (unaudited)	2002 (unaudited)	2003 (unaudited)	2004
	(Dollar Amounts in Thousands, Except Per Share Amounts)				
STATEMENT OF OPERATIONS DATA:					
Revenues:					
Product Sales (Net)	$ 3	$ —	$ —	$ —	$ 2,506
Research and development contracts	—	—	—	—	—
Total revenues	3	—	—	—	2,506
Cost of sales	—	—	—	—	2,101
Gross profit on product sales	3	—	—	—	405
Other costs and expenses:					
Selling, general and administrative	3,107	2,822	5,132	5,143	3,471
Research and development	2,439	4,642	4,979	9,191	11,533
Total operating expenses	5,546	7,464	10,111	14,334	15,004
(Loss) from operations	(5,543)	(7,464)	(10,111)	(14,334)	(14,599)
Other income (expense)	(324)	(189)	384	(137)	(384)
Interest income	456	217	38	46	230
Net (loss)	$ (5,411)	$ (7,436)	$ (10,457)	$ (14,425)	$ (13,985)
Net loss per share	$ (0.09)	$ (0.10)	$ (0.12)	$ (0.12)	$ (0.09)
Weighted average shares outstanding	62,022,814	75,775,722	89,603,812	123,847,007	158,756,580

	AS OF DECEMBER 31,				
	2000 (unaudited)	2001 (unaudited)	2002 (unaudited)	2003	2004
	(Dollar Amounts in Thousands, Except Per Share Amounts)				
BALANCE SHEET DATA:					
Cash and cash equivalents	$ 7,481	$ 4,335	$ 1,051	$ 12,272	$ 10,484
Working Capital	7,307	4,457	993	12,582	12,019
Total Assets	8,051	4,848	2,640	14,440	17,052
Long-term debt, less current maturities	—	—	500	—	—
Deferred revenue-license fee					2,952
Redeemable preferred stock:					
Series A 10% Convertible Preferred Stock	5,176	1,064	1,153	—	—
Series B 8% Convertible Preferred Stock	—	—	1,427	—	—
Accumulated deficit	(27,822)	(35,286)	(45,808)	(60,232)	(74,217)
Total stockholders' equity	7,568	4,805	1,218	13,453	11,971

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

FORWARD-LOOKING STATEMENTS

Certain of the statements contained in this Annual Report on Form 10-K, including certain in this section, are forward-looking and constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, from time to time we may publish forward-looking statements relating to such matters as anticipated financial performance, business prospects, technological developments, new products, research and development activities and other aspects of our present and future business operations and similar matters that also constitute such forward-looking statements. These statements involve known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among other things, unforeseen changes in the course of research and development activities and in clinical trials; possible changes in cost and timing of development and testing, capital structure, and other financial items; changes in approaches to medical treatment; introduction of new products by others; possible acquisitions of other technologies, assets or businesses; possible actions by customers, suppliers, strategic partners, potential strategic partners, competitors and regulatory authorities, as well as those listed under "Risk Factors" below and elsewhere in this Annual Report on Form 10-K. In some cases, you can identify forward-looking statements by terminology such as "expect", "anticipate", "estimate", "plan", "believe" and words of similar import regarding the Company's expectations. Forward-looking statements are only predictions. Actual events or results may differ materially. Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our industry, business and operations, we cannot guarantee that actual results will not differ materially from our expectations. In evaluating such forward-looking statements, you should specifically consider various factors, including the risks outlined under "Risk Factors." The discussion of risks and uncertainties set forth in this Annual Report on Form 10-K is not necessarily a complete or exhaustive list of all risks facing the Company at any particular point in time. We operate in a highly competitive, highly regulated and rapidly changing environment and our business is in a state of evolution. Therefore, it is likely that new risks will emerge, and that the nature and elements of existing risks will change, over time. It is not possible for management to predict all such risk factors or changes therein, or to assess either the impact of all such risk factors on our business or the extent to which any individual risk factor, combination of factors, or new or altered factors, may cause results to differ materially from those contained in any forward-looking statement. We disclaim any obligation to revise or update any forward-looking statement that may be made from time to time by us or on our behalf.

BASIS OF PRESENTATION

Overview and Recent Events

Celsion is a biotechnology company dedicated to furthering the development and commercialization of treatment systems for cancer and other diseases using focused heat energy in combination with other therapeutic devices, heat-activated drugs or heat-activated genes. In 1989, we obtained premarketing approval (PMA) from the FDA to use our microwave-based Microfocus 1000 heat therapy system on surface and subsurface tumors in conjunction with radiation therapy. We marketed this system until 1995. From 1995 until early in 2004 we engaged in research and development of new treatment systems. On February 19, 2004, we obtained a PMA for our Prolieve Thermodilatation system for the treatment of BPH and thereafter our marketing partner, Boston Scientific, commenced commercial sales of the Prolieve system. In addition, we are engaged in the development of treatment systems using a combination of heat and ThermoDox, our proprietary liposomal encapsulation of doxorubicin, for the treatment of prostate and liver cancer and are exploring the possibility of using such a combination to treat breast cancer.

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

Product	Status
• Prolieve Thermodilatation system for the treatment of BPH	We received premarketing approval for the Prolieve system from the FDA on February 19, 2004. Since that time, we have been commercializing the Prolieve system through Boston Scientific.
• ThermoDox (Doxorubicin-laden thermo-liposome) plus heat for the treatment of cancer	We are conducting a single-site Phase I clinical trial in collaboration with the National Institutes of Health using ThermoDox in conjunction with radio frequency ablation in the treatment of liver cancer. In addition, ThermoDox, in conjunction with modified Prolieve equipment, is currently the subject of a multi-site Phase I clinical trial for the treatment of prostate cancer. We also are evaluating the feasibility of initiating studies using ThermoDox in combination with APA or advanced phased array radio frequency heating technology for the treatment of breast cancer.
• Breast cancer treatment system	During 2004, we terminated both branches of our pivotal Phase II trials using our advanced phase array technology in the treatment of small and late-stage breast cancer tumors. As noted above, we currently are exploring the use of ThermoDox in combination with APA or advanced phased array radio frequency technology to treat breast cancer. In addition, we are exploring possible strategic transactions and relationships involving our heat-only treatment system.
• Cancer Repair Inhibitor (CRI)	Pre-clinical studies at Sloan-Kettering involving our CRI technology are ongoing. We are exploring possible strategic transactions and relationships to further the development of this technology.

Since 1995, we have generated only minimal revenues and have funded our operations primarily through private placements of our equity securities. During 2004, following FDA premarketing approval of our Prolieve Thermodilatation system, we received a one-time licensing fee of $4,000,000 under our agreement with Boston Scientific, the distributor of our Prolieve system. During the portion of 2004 subsequent to receipt of the

PMA, sales of Prolieve products generated revenues of $2,506,228. Until such time, if any, as we are able to complete development and testing of, and gain necessary regulatory approvals for, one or more of our other products, sales of Prolieve products will represent our only source of revenue. We presently do not have any committed sources of financing. Therefore, we are reliant on revenues from the sale of our Prolieve products and from funds generated through the sale of our securities to fund our ongoing operations.

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

Our principal costs consist of:

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

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

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

On May 7, 2004, Celsion received a warning letter from the FDA regarding the Phase I and Phase II clinical trials of the Prolieve system, which had been completed in January 2002. The warning letter addressed four

general areas—monitoring, investigator agreements, provision of information to investigators, and FDA reporting—in connection with the Prolieve studies. Since receipt of the warning letter, we have initiated short- and long-term corrective and compliance measures to address fully the issues raised by the FDA, including adding additional senior personnel with significant clinical experience. Following receipt of the warning letter, Celsion retained consultants to assist in bringing the Company into compliance with FDA regulations and ensuring ongoing compliance with those regulations. Through December 31, 2004, Celsion had expended $227,000 in connection with such compliance consultants. While we anticipate additional expenditures of this nature, we do not expect that such expenditures during 2005 will be material. In addition, in order to ensure prompt and continuing compliance with FDA regulations in the conduct of our clinical trials, we have elected to replace our in-house monitoring staff with CROs. This outsourcing effort will significantly increase the costs of our clinical trials.

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

In August 2004 Celsion conducted a voluntary Class II recall and field correction of the Prolieve system to correct a potential software malfunction that occurred if a procedure using the Prolieve system was ongoing when the system's computer clock transitioned through midnight. A Class II recall is a situation in which use of the product in question may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. In addition, the Company has developed, and, with FDA approval has implemented, a software upgrade to eliminate the potential for the malfunction. This upgrade applied to all Prolieve units in the field as well as all newly manufactured units. The costs of the recall, field correction and software upgrade were not material.

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

- We state our inventories at the lower of cost or market. We track Prolieve control units by serial number and cost is the actual cost of each unit. We carry catheter kits at average cost. Carrying value does not include any general and administrative costs. We have established an inventory reserve to reflect the estimated value of excess and obsolete inventory.
- We recognize revenue on the sale of Prolieve control units as they are sold to ultimate customers by Boston Scientific. Prolieve control units shipped to Boston Scientific but not yet sold to ultimate customers are reflected in Finished Goods inventory. We recognize revenue on the sale of catheter kits upon shipment.
- We include in the cost of sales the inventory carrying value of items sold, shipping and handling, miscellaneous production costs, excess and obsolescence costs and warranty expenses.
- We warrant Prolieve control units for a period of 12 months from date of delivery to the end user and catheter kits until the date of expiration. Warranty exposure is reviewed and accruals, if any, are included in cost of sales.
- We have long-term compensation plans that permit the granting of incentive awards in the form of stock options. We have adopted the disclosure-only provisions of Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation (SFAS No. 123), which allows us to measure compensation costs for stock options granted to employees using the value-based method of accounting prescribed by APB Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). In December 2004, the Financial Accounting Standards Board issued SFAS No.123R, which replaces SFAS No. 123 and requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first interim or annual period after June 15, 2005. Under SFAS No. 123R, the Company will be required to determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. We are evaluating the requirements of SFAS No. 123R and expect that its adoption will have a material impact on our consolidated results of operations and earnings per share. We have not yet determined the impact, if any, of SFAS No. 123R on our compensation policies or plans.

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

RESULTS OF OPERATIONS

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

The Company received a PMA for its Prolieve system from the FDA on February 19, 2004 and since that time has been engaged in the commercial introduction of the system through a distribution arrangement with Boston Scientific. Product sales for 2004 in the amount of $2,506,000, all of which were generated subsequent to February 19, 2004, consist of the sale of control units, catheter kits and miscellaneous parts to Boston Scientific and Celsion China. There were no product sales during the comparable period in 2003, which predated the commercial introduction of our Prolieve system.

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

The increase of $2,342,000 (25.4%) in research and development expense during the year ended December 31, 2004 was due primarily to costs with respect to the Separation and Release Agreement with Mr. Daniel S. Reale in connection with Mr. Reale’s resignation as Executive Vice President and President of our Oncology Division, as reflected in our Report on Form 8-K filed with the SEC on March 1, 2004 ($972,000); the value of certain payments in connection with the departure of William Gannon, former Medical Director ($130,000); the value of certain payments in connection with the departure of David Braitman, former Senior Vice President—Product Development ($160,000); a termination fee payment in connection with migration of manufacturing of the catheter kits for our Prolieve system to a new supplier ($350,000); a write-off of amounts previously classified as prepaid inventory costs related to the production of the catheter kits ($379,000); cash bonuses granted to our employees in connection with receipt of the PMA for the Prolieve system ($554,000); an increase in salaries and recruiting and relocation expenses for new hires ($550,000) as we continue to fill critical positions; increased costs related to consultants hired to aid in clinical compliance efforts ($227,000) and an initial payment to the CRO that has been engaged to monitor the Prolieve post-market study which must be completed by Celsion as a condition of the PMA for the Prolieve system ($293,000). These additional expenses were partially offset by a decrease of $1,006,000 in compensation expense as a result of a reduction in the cumulative value of re-priced stock options. During the year ended December 31, 2004 substantially all of the net increase in operating expenses not due to the unusual items discussed above was attributable to increased personnel and consulting costs in connection with completion of the PMA process and commercialization of the Prolieve system.

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

Interest income increased by 400% or $184,000 for the year ended December 31, 2004 compared to the year ended December 31, 2003. The increase was due to a combination of higher average cash balances and a higher rate of return on account balances. The higher cash balances were, in turn, the result of private placements of our equity securities during the last 12 months, as well as payments to us in connection with the sale of our Common Stock to and licensing fees from Boston Scientific, as discussed elsewhere herein.

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

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

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

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

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

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

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

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

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

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

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

LIQUIDITY AND CAPITAL RESOURCES

Since inception, our expenses have significantly exceeded our revenues, resulting in an accumulated deficit of $74,217,000 at December 31, 2004. We have incurred negative cash flows from operations since our inception and have funded our operations primarily through the sale of equity securities. As of December 31, 2004, we had cash of $10,484,000 and total current assets of $14,148,000, compared with current liabilities of $2,129,000, resulting in a working capital surplus of $12,019,000. As of December 31, 2003, we had $12,272,000 in cash and total current assets of $13,569,000, compared with current liabilities of $987,000, which resulted in a working capital surplus of $12,582,000 at fiscal year end. The decrease in working capital at December 31, 2004, as compared to December 31, 2003 was due to the fact that, during the past fiscal year, funding received from private placements of our equity securities, sales of our equity securities to Boston Scientific, exercises of options and warrants and revenues generated from the sale of our Prolieve Thermodilatation system were insufficient to offset cost of sales and operating expenses incurred during the year.

We do not have any bank financing arrangements and have funded our operations primarily through private placements of our equity securities. On January 31, 2004, we issued 2,727,273 shares of Common Stock and associated warrants to purchase 818,182 shares of Common Stock in connection with a private placement offering. The private placement was made exclusively to one institutional “accredited investor” as that term is defined in Rule 501 under the Securities Act of 1933, as amended (the Securities Act). These securities were issued at a price of $1.10 per share and associated fractional warrant. The warrants issued to the investor entitle the investor to purchase that number of shares of Common Stock equal to 30% of the number of shares of Common Stock initially issued to the investor in the offering. The warrants are exercisable at $1.50 per share of Common Stock, subject to call under certain circumstances. In connection with the private placement, the Company issued warrants to a finder to purchase 283,636 shares of Common Stock at an exercise price of $1.10 per share. The Company realized gross proceeds in the amount of $3,000,000 and paid a cash finder’s fee in the amount of $240,000 in connection with the sale of these securities. On March 2, 2004, the Company issued 2,083,333 shares of its Common Stock to Boston Scientific for cash consideration of $4,000,000 pursuant to the Transaction Agreement between the Company and Boston Scientific. On April 7, 2004, the Company issued 1,273,885 shares of its Common Stock to Boston Scientific for cash consideration of $2,000,000 pursuant to the Transaction Agreement. In addition, during the 12 months ended December 31, 2004, the Company issued a total of 4,762,667 shares of its Common Stock for cash consideration of $2,986,000 upon exercise of outstanding stock purchase warrants. The warrants were exercised in accordance with their respective terms at prices ranging from $0.39 to $1.75 per share. The Company also issued 1,641,466 shares of its Common Stock for cash consideration of $1,091,000 upon exercise of stock options.

For fiscal year 2005, 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.

Our available cash on hand, together with anticipated Prolieve revenues, are expected to be sufficient to fund our activities through February 2006. Our dependence on Prolieve revenues and on raising additional capital beyond that date will continue at least until we are able to begin marketing our other technologies. Our future capital requirements and the adequacy of our financing depend upon numerous factors, including the successful commercialization of our Prolieve systems, progress in product development efforts, progress with pre-clinical studies and clinical trials, the cost and timing of production arrangements, the development of effective sales and marketing activities, the cost of filing, prosecuting, defending and enforcing intellectual property rights, competing technological and market developments and the development of strategic alliances for the marketing of our products. In the future we will be required to obtain additional funding through equity or debt

financing, strategic alliances with corporate partners and others, or through other sources not yet identified. We do not have any committed sources of additional financing, and cannot guarantee that additional funding will be available in a timely manner, on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, scale back or eliminate certain aspects of our operations or attempt to obtain funds through unfavorable arrangements with partners or others that may require us to relinquish rights to certain of our technologies, product candidates, products or potential markets or which otherwise may be materially unfavorable to us. Furthermore, if we cannot fund our ongoing development and other operating requirements, particularly those associated with our obligation to conduct clinical trials under our licensing agreements, we will be in breach of our commitments under these licensing agreements and could therefore lose our license rights, which could have material adverse effects on our business.

Under our Transaction Agreement with Boston Scientific, we have 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. This option is exercisable until February 2008, with the option price being calculated based on worldwide sales of the product subject to the Distribution Agreement to which Boston Scientific and Celsion are parties, subject to a minimum price of $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.

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

	Total	< 1 year	1 - 3 years	4 – 5 years	Thereafter
Operating leases–Property	$1,172,000	$187,000	$391,000	$414,000	$180,000

OFF-BALANCE SHEET ARRANGEMENTS

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

RISK FACTORS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

On May 7, 2004, Celsion received a warning letter from the FDA regarding the Phase I and Phase II clinical trials of the Prolieve system, which had been completed in January 2002. The warning letter, which was based upon an inspection conducted in December 2003, addressed four general areas—monitoring, investigator agreements, provision of information to investigators, and FDA reporting—in connection with the Prolieve studies. Since receipt of the warning letter, we have initiated short- and long-term corrective and compliance measures to address fully the issues raised by the FDA. If the FDA is not satisfied with our follow-up and corrective actions, it could require us to take additional actions or could take regulatory action against us, which could include fines, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of product applications, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted product approvals. Although we have internal compliance programs, if these programs do not meet regulatory agency standards or if our compliance is deemed deficient in any significant way, it could have a material adverse effect on the company. Any such action is likely to have a material adverse effect on our business and financial condition.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our Certificate of Incorporation and Bylaws may discourage, delay or prevent a merger or acquisition that a stockholder may consider favorable by authorizing the issuance of "blank check" preferred stock. This preferred stock may be issued by the Board of Directors, on such terms as it determines, without further stockholder approval. Therefore, the Board may issue such preferred stock on terms unfavorable to a potential bidder in the event that is 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 o f $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 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-1 through F-22.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

CONCLUSION OF MANAGEMENT REGARDING THE EFFECTIVENESS OF DISCLOSURE CONTROLS AND PROCEDURES

We have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) under the supervision, and with the participation, of our management, including our Chief Executive Officer and Chief Financial Officer. Based on that evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that, subject to the limitation set forth below, our disclosure controls and procedures were effective as of December 31, 2004 to ensure that information required to be disclosed in reports that Celsion files or submits under the Exchange Act is recorded, processed, summarized and reported in a timely manner. There have not been any significant changes in our internal controls or in other factors subsequent to the date of the evaluation that could significantly affect such controls and no corrective actions have been required with regard to significant deficiencies and material weaknesses.

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

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The Sarbanes-Oxley Act of 2002 (the SOX Act) imposed many requirements regarding corporate governance and financial reporting. Beginning with this Annual Report on Form 10-K, Section 404 of the SOX Act requires that management report on the Company's internal controls over financial reporting and that our independent registered public accountants attest to this report. In late November 2004, the Securities and Exchange Commission issued an exemptive order providing a 45-day extension for the filing of these reports and attestations by eligible companies. We have elected to avail ourselves of this extension. Therefore, this Annual Report on Form 10-K does not include management's report or our accountant's attestation thereon. These reports will be included in an amended Form 10-K expected to be filed in April 2005. During 2004, we applied significant financial and human resources in analyzing, documenting and testing our system of internal controls. We are not aware of any material weaknesses in our internal controls over financial reporting and related disclosures as of December 31, 2004.

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 At of 1934, as Amended” and “Code of Ethics” in Celsion’s Definitive Proxy Statement in connection with the Annual Meeting of Stockholders to be held on May 19, 2005, which has been, or will be, filed with the Securities and Exchange Commission within 120 days after the end of our fiscal year ended December 31, 2004.

ITEM 11. EXECUTIVE COMPENSATION

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

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

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

Equity Compensation Plan Information as of December 31, 2004

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	8,977,709(1)	$ 0.72	9,284,475
Equity compensation plans not approved by security holders	7,886,965(2)	$ 0.96	— (2)
Total	16,864,674	$ 0.83	9,284,475

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

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

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

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

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

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

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. FINANCIAL STATEMENTS

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

2. FINANCIAL STATEMENT SCHEDULES

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

3. EXHIBITS

The following documents are included as exhibits to this report:

EXHIBIT NO.	DESCRIPTION
3.1.1	Certificate of Incorporation of Celsion (the "Company"), as amended, incorporated herein by reference to Exhibit 3.1.1 to the Quarterly Report on Form 10-Q of the Company for the Quarter Ended June 30, 2004.
3.1.2	Intentionally omitted.
3.1.3	Certificate of Ownership and Merger of Celsion Corporation (a Maryland Corporation) into Celsion (Delaware) Corporation (inter alia, changing the Company's name to "Celsion Corporation" from "Celsion (Delaware) Corporation), incorporated herein by reference to Exhibit 3.1.3 to the Annual Report on Form 10-K of the Company for the Year Ended September 30, 2000.
3.1.4	Intentionally omitted
3.1.5	Certificate of Designations of Series C Junior Participating Preferred Stock of Celsion Corporation, incorporated herein by reference to Exhibit 4.4 to the Form S-3 Registration Statement (File No. 333-100638) filed October 18, 2002.

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

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

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

EXHIBIT NO.	DESCRIPTION
32.1+	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2+	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

+ Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused its annual report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

CELSION CORPORATION

March 14, 2005

By: /s/ Augustine Y. Cheung
Augustine Y. Cheung
President and Chief Executive Officer
(Principal Executive Officer)

March 15, 2005

By: /s/ Anthony P. Deasey
Anthony P. Deasey
Chief Financial Officer
(Principal Financial and
Accounting Officer)

Pursuant to the requirements 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:

SIGNATURE	TITLE	DATE
/s/ Augustine Y. Cheung Augustine Y. Cheung	Director, President and Chief Executive Officer (Principal Executive Officer)	March 14, 2005
/s/ Anthony P. Deasey Anthony P. Deasey	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 15, 2005
/s/ Max E. Link Max E. Link	Chairman of the Board	March 12, 2005
Gary W. Pace	Director	
/s/ Dudleigh C. Stone Dudleigh C. Stone	Director	March 15, 2005
/s/ Claude Tihon Claude Tihon	Director	March 15, 2005
/s/ Kris Venkat Kris Venkat	Director	March 14, 2005

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Celsion Corporation
Columbia, Maryland

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

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

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

/s/ Stegman & Company

Baltimore, Maryland
March 10, 2005

CELSION CORPORATION
BALANCE SHEETS
DECEMBER 31, 2004, DECEMBER 31, 2003 AND SEPTEMBER 30, 2003

ASSETS

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

See accompanying notes.

LIABILITIES AND STOCKHOLDERS' EQUITY

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

See accompanying notes.

CELSION CORPORATION
STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED
DECEMBER 31, 2004, DECEMBER 31, 2003, SEPTEMBER 30, 2003 AND SEPTEMBER 30, 2002

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

See accompanying notes.

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

	Three Months Ended December 31,	
	2003	**2002**
		(unaudited)
Revenues:		
Sales of equipment and parts	$ —	$ —
Returns and allowances	—	—
Total revenues	—	—
Cost of Sales	—	—
Gross Profit	—	—
Operating Expenses:		
Selling, general and administrative	856,968	840,044
Research and development	2,109,795	1,097,428
Total operating expenses	2,966,763	1,937,472
Loss from operations	2,966,763	1,937,472
License Fee Income Amortization	—	—
Interest Income	—	—
(Loss) from Investment in Celsion China, Ltd.	—	—
(Loss) from Disposal of Property and Equipment	(5,791)	—
Rental income	18,720	2,651
Net (Loss)	(2,953,834)	(1,934,821)
Beneficial Conversion Feature and Dividends on Preferred Stock	—	(53,313)
Net Loss Attributable to Common Stockholders	$ (2,953,834)	$ (1,988,134)
Basic and Diluted Net Loss per Common Share	$ (0.02)	$ (0.02)
Basic and Diluted Weighted Average Number of Common Shares Outstanding	144,152,732	95,128,667

See accompanying notes.

CELSION CORPORATION
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2004, SEPTEMBER 30, 2003 AND SEPTEMBER 30, 2002 AND
FOR THE THREE MONTHS ENDED DECEMBER 31, 2003

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

See accompanying notes.

CELSION CORPORATION
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2004, SEPTEMBER 30, 2003 AND SEPTEMBER 30, 2002
AND FOR THE THREE MONTHS ENDED DECEMBER 31, 2003

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

See accompanying notes.

CELSION CORPORATION
STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2004, DECEMBER 31, 2003,
SEPTEMBER 30, 2003 AND SEPTEMBER 30, 2002

	Year Ended December 31,		Year Ended September 30,	
	2004	2003	2003	2002
		(unaudited)		
Cash Flows from Operating Activities				
Net loss	$(13,985,048)	$(14,293,084)	$(13,274,071)	$(9,751,082)
Noncash items included in net loss:				
Depreciation and amortization	200,515	106,806	100,532	82,437
Amortization of deferred revenue–license fee	(476,191)	—	—	—
Loss from investment in Celsion. China, Ltd.	92,203	—	—	—
Stock-based compensation	(333,703)	4,544,054	3,810,240	492,573
Warrants issued for legal settlement	—	—	—	476,724
Loss from disposal of property and equipment	—	5,791	—	1,825
Net changes in:				
Accounts receivable–trade	(691,938)	—	—	—
Other receivables	(74,348)	(16,753)	(6,434)	(83,288)
Inventories	(1,283,953)	(296,354)	(375,183)	(449,608)
Prepaid expenses	(317,270)	(118,171)	(31,587)	(47,255)
Escrow account–license fee	(2,007,002)	—	—	—
Other current assets	—	—	—	150,000
Prepaid inventory development costs	359,239	36,769	69,384	(486,602)
Accounts payable and accrued interest payable	188,071	(162,607)	388,568	349,130
Accrued noncash compensation	(99,773)	125,395	125,395	—
Deposits	5,916	—	—	—
Deferred revenue–license fee	4,000,000	—	—	—
Other accrued liabilities	482,124	101,606	104,577	153,388
Net cash used in operating activities	(13,944,158)	(9,966,548)	(9,088,579)	(9,111,758)
Cash Flows from Investing Activities:				
Investment in Celsion China, Ltd.	(200,000)	—	—	—
Increase (decrease) in deposits	—	—	—	5,915
(Decrease) increase in security deposit liability	—	—	—	(15,203)
Purchase of property and equipment	(484,056)	(296,049)	(111,850)	(89,329)
Net cash used in investing activities	(684,056)	(296,049)	(111,850)	(98,617)
Cash Flows from Financing Activities:				
Issuance of notes payable	—	—	500,000	—
Payment on notes payable	—	(500,000)	(500,000)	—
Proceeds of stock issuances	12,836,621	21,984,398	19,682,143	7,629,058
Net cash provided by financing Activities	12,836,621	21,484,398	19,682,143	7,629,058
Net (Decrease) Increase in Cash	(1,788,591)	11,221,801	10,481,714	(1,581,317)
Cash at Beginning of Period	12,272,407	1,050,606	928,819	2,510,136
Cash at the End of Period	$ 10,483,816	$ 12,272,407	$ 11,410,533	$ 928,819

See accompanying notes

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

	Three Months Ended December 31,	
	2003	**2002**
		(unaudited)
Cash Flows from Operating Activities		
Net loss	$ (2,953,834)	$ (1,934,821)
Noncash items included in net loss:		
Depreciation and amortization	31,149	24,875
Amortization of deferred revenue–license fee	—	—
Loss from investment in Celsion China, Ltd.	219,115	132,957
Stock-based compensation	647,656	—
Warrants issued for legal settlement	—	—
Loss from disposal of property and equipment	5,791	—
Net changes in:		
Accounts receivable–trade	—	—
Other receivables	74,174	84,493
Inventories	(92,919)	(171,748)
Prepaid expenses	(283,125)	(196,541)
Escrow account–license fee	—	—
Other current assets	—	—
Prepaid inventory development costs	(235)	32,380
Accounts payable and accrued interest payable	(252,121)	299,054
Accrued noncash compensation	—	—
Deposits	—	—
Deferred revenue–license fee	—	—
Other accrued liabilities	(154,539)	(151,568)
Net cash used in operating activities	(2,758,888)	(1,880,919)
Cash Flows from Investing Activities:		
Investment in Celsion China, Ltd.	—	—
Increase (decrease) in deposits	—	—
(Decrease) increase in security deposit liability	—	—
Purchase of property and equipment	(184,493)	(294)
Net cash used in investing activities	(184,493)	(294)
Cash Flows from Financing Activities:		
Issuance of notes payable	—	500,000
Payment on notes payable	—	—
Proceeds of stock issuances	3,805,255	1503,000
Net cash provided by financing activities	3,805,255	2,003,000
Net Increase (Decrease) in Cash	861,874	121,787
Cash at Beginning of Period	11,410,533	928,819
Cash at the End of Period	$ 12,272,407	$ 1,050,606

See accompanying notes.

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Celsion Corporation, referred to herein as Celsion or the Company, a Delaware corporation based in Columbia, Maryland, is a biotechnology company dedicated to furthering the development and commercialization of treatment systems for cancer and other diseases using focused heat energy in combination with other therapeutic devices, heat-activated drugs or heat-activated genes.

On February 19, 2004 Celsion received premarketing approval (PMA), from the Food and Drug Administration (FDA), for its Prolieve™ Thermodilatation system for the treatment of Benign Prostatic Hyperplasia (BPH), a chronic condition of enlargement of the prostate common in older men. The Prolieve system is currently being marketed through our licensed distributor, Boston Scientific Corporation.

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

Cash and Cash Equivalents

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

Accounts Receivable

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

Inventories

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

Investment in Celsion China, Ltd.

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

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

Escrow account–license fee

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

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

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

Property and Equipment

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

Prepaid 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 are amortized on a straight-line basis over the remaining life of the related patent.

Revenue Recognition

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

Cost of Sales

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

Product Warranties

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

Research and Development

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

Net Loss Per Common Share

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

Nonmonetary Transactions

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

Use of Estimates

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

Stock-Based Employee Compensation

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

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

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

Fair Value of Financial Instruments

The carrying values of financial instruments approximate fair value.

2. RECENT ACCOUNTING PRONOUNCEMENTS

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

In December 2004, the FASB issued SFAS No.123R, which replaces SFAS No. 123 and supersedes APB No. 25. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first interim or annual period after June 15, 2005, with early adoption encouraged. The pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. The Company is required to adopt SFAS No. 123R beginning July 1, 2005. Under SFAS No. 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. The Company is evaluating the requirements of SFAS No. 123R. However, the Company expects that the adoption of SFAS No. 123R will have a material impact on its consolidated results of operations and earnings per share. The Company has not yet determined the method of adoption or the effect of adopting SFAS No. 123R, and it has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123. The Company also has not yet determined the impact of SFAS No. 123R on its compensation policies or plans, if any.

In December 2004, the FASB issued SFAS No. 153, *Exchange of Nonmonetary Assets.* SFAS No. 153 amends APB No. 29, *Accounting for Nonmonetary Transactions*, to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do

not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The Company is required to adopt SFAS No. 153, on a prospective basis, for nonmonetary exchanges beginning after June 15, 2005. The Company has not yet determined if SFAS No. 153 will have an impact on its results of operations or financial position.

3. FINANCIAL CONDITION

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

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

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

4. INVENTORIES

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

	December 31, 2004	December 31, 2003	September 30, 2003
Materials	$ 739,645	$ 838,992	$ 732,225
Work-in-process	—	37,308	51,156
Finished goods	1,615,402	41,410	41,410
	2,355,047	917,710	824,791
Less: Reserve	153,384	—	—
	$2,201,663	$ 917,710	$ 824,791

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

5. INVESTMENT IN CELSION CHINA, LTD.

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

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

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

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

Annual deficit	$(201,978)
Ownership percentage	45.65%
Loss recorded for the year	$ (92,203)

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

Initial cash investment	$200,000
45.65% accumulated loss	(92,203)
Net investment carrying value	$107,797

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

6. INCOME TAXES

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

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

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

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

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

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

7. CELSION EMPLOYEE BENEFIT PLANS

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

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

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

9. STOCK OPTIONS AND WARRANTS

2001 Stock Option Plan

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

2004 Stock Incentive Plan

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

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

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

	Options/ Warrants Outstanding	Weighted Average Exercise Price
Outstanding at September 30, 2001	15,105,218	$ 0.94
Granted	31,307,874	$ 0.52
Exercised	(1,471,250)	$ 0.03
Expired/cancelled	(10,258,049)	$ 0.91
Outstanding at September 30, 2002	34,683,793	$ 0.61
Granted	9,013,765	$ 0.74
Exercised	(15,209,291)	$ 0.38
Expired/cancelled	(306,100)	$ 0.90
Outstanding at September 30, 2003	28,182,167	$ 0.78
Granted	2,417,065	$ 1.13
Exercised	(201,500)	$ 0.60
Expired/cancelled	(30,000)	$ 0.47
Outstanding at December 31, 2003	30,367,732	$ 0.80
Granted	3,137,940	$ 1.05
Exercised	(6,396,816)	$ 0.61
Expired/cancelled	(755,850)	$ 0.68
Outstanding at December 31, 2004	26,353,006	$ 0.88

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

	Exercise Price from $.25 to $.60	Exercise Price from $.61 to $1.01	Exercise Price from $1.02 to $5.00
Outstanding at December 31, 2004:			
Number of options/warrants	8,750,399	8,567,875	9,034,732
Weighted average exercise price	$ 0.48	$ 0.73	$ 1.41
Weighted average remaining contractual life in years	3.54	5.44	3.91
Exercisable at December 31, 2004:			
Number of options/warrants	8,088,733	7,965,791	8,024,731
Weighted average exercise price	$ 0.48	$ 0.74	$ 1.43
Weighted average remaining contractual life in years	3.14	5.14	3.31

Option Repricing

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 a compensation expense adjustment of $(1,030,684), $967,376 and $0 for the years ended December 31, 2004, September 30, 2003 and 2002 and $647,656 for the three months ended December 31, 2003, respectively.

Options Issued to Non-Employees for Services

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

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

Based upon these valuations, the Company recognized $406,660, $259,171 and $ 219,115 of expense associated with its issuance of options in lieu of cash for services to consultants, for the years ended December 31, 2004, September 30, 2003 and 2002 and the three months ended December 31, 2003.

Employee Stock Options

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

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

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

10. LICENSE AGREEMENTS AND PROPRIETARY RIGHTS

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

Through the Company's license agreements with Massachusetts Institute of Technology (MIT) MMTC, Inc. (MMTC), Duke University (Duke) and the 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.

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 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, 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. These rights under the agreement with Sloan-Kettering will terminate at the later of 20 years after the date of the agreement or the last expiration date of any patent rights covered by the agreement.

11. LITIGATION SETTLEMENT

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

12. COMMITMENTS AND CONTINGENCIES

Lease Commitments

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

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

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

Contract Termination Commitments

We currently purchase our Prolieve catheters and related disposables from Catheter Research, Inc., or CR, under a Development and Supply Agreement dated December 11, 2001 and amended October 29, 2003. Under the Supply Agreement, CR is the exclusive provider of Prolieve catheter kits and disposables, 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 kids to third-party end users. As of the date hereof, Celsion has met its obligation to purchase 2,000 catheter kits. CR warrants the catheter kits to be free from defects relating to or arising from the design, manufacture, materials or sterilization techniques that result in the failure of CR products and the Supply Agreement contains other customary terms. Celsion provided notice of its intent to terminate on October 29, 2003. However, in order to secure our supply chain, we intend to retain CR as a second, back-up source following approval of Venusa Corporation as a catheter supplier.

13. CONCENTRATIONS OF CREDIT RISK

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

14. AGREEMENT WITH BOSTON SCIENTIFIC CORPORATION

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

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

The Company has also granted Boston Scientific the exclusive right to purchase the assets and technology relating to the manufacture, marketing sale, distribution and/or research and development of products using thermal therapy for the treatment of BPH.

Celsion also is a party to a Distribution Agreement dated January 21, 2003 with BSC. Under the Distribution Agreement, Celsion was entitled to a $4,000,000 licensing fee, effective upon the occurrence of a triggering event, in return for granting BSC a seven-year, royalty-free, exclusive right to market, distribute, import, export, use, sell and offer to sell Celsion’s Prolieve Thermodilatation system worldwide, with the exception of China, Taiwan, Hong Kong, Macao, Mexico and Central and South America. The condition was met and Celsion received a payment from Boston Scientific during the quarter ended June 30, 2004 in the amount of $2,000,000. The remaining $2,000,000 was placed in an escrow account, pursuant to the terms of the Distribution Agreement. The escrow is designed to provide available funds for payment in the event of certain contingencies during the 36-month term of the escrow. The escrow is held in an interest-bearing account. Interest on the escrowed funds accrues for the benefit of Celsion, but becomes part of the balance of the account. All amounts held in the account at the end of the term of the escrow are payable to Celsion. However, Celsion bears full responsibility for payment of claims subject to the escrow in excess of available escrowed funds. The Company is recognizing the entire $4,000,000 licensing fee at the rate of $47,619 per month over a seven-year term which began March 1, 2004.

15. YEAR END CHANGE

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

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

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
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	163,266
Net loss	$(6,065,680)	$(1,471,586)	$(3,310,583)	$(3,137,199)
Net loss per share - basic and diluted	$ (.04)	$ (.01)	$ (.02)	$ (.02)

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the inclusion of our report dated March 10, 2005, relating to the balance sheets of Celsion Corporation (the "Company") as of December 31, 2004 and 2003 and as of September 30, 2003 and the related statements of operations, changes in stockholders' equity and cash flows for the year ended December 31, 2004, the three months ended December 31, 2003 and for both fiscal years in the period ended September 30, 2003 in the Company's Form 10-K for the year ended December 31, 2004.

/s/ Stegman & Company

Baltimore, Maryland
March 15, 2005

Exhibit 31.1

CELSION CORPORATION
CERTIFICATION

I, Augustine Y. Cheung, 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)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2005

/s/ Augustine Y. Cheung
Augustine Y. Cheung
Chief Executive Officer
Celsion Corporation

Exhibit 31.2

CELSION CORPORATION
CERTIFICATION

I, Anthony P. Deasey, certify that

1. I have reviewed this 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)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2005

/s/ Anthony P. Deasey
Anthony P. Deasey
Chief Financial Officer
Celsion Corporation

Exhibit 32.1

CELSION CORPORATION
CERTIFICATION
PURSUANT TO 18 UNITED STATES CODE § 1350
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, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Augustine Y. Cheung. 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.

/s/ Augustine Y. Cheung
Augustine Y. Cheung
Chief Executive Officer

March 14, 2005

Exhibit 32.2

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, 2004, as filed with the Securities and Exchange Commission on the date hereof (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.

/s/ Anthony P. Deasey
Anthony P. Deasey
Chief Financial Officer

March 15, 2005