

# CELSION CORP

## FORM 10-K (Annual Report)

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Industry	Medical Equipment & Supplies
Sector	Healthcare
Fiscal Year	09/30

**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 September 30, 1999

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)

Maryland -----	52-1256615 -----
State or other jurisdiction of incorporation or organization	(I.R.S. Employer Identification No.)
10220-I Old Columbia Road Columbia, Maryland -----	21046-1705 -----
(Address of principal executive offices)	(Zip Code)
Registrant's telephone number, including area code:	(410) 290-5390 -----

**Securities registered pursuant to Section 12(b) of the Act: None:**

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

Common Stock, par value \$.01 per share

(Title of Class)

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

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Indicate by check mark if disclosure of delinquent filers pursuant to

Item 405 of Regulation S-K (ss. 229.405 of this chapter) 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.

As of December 9, 1999, 53,580,448 shares of the Registrant's Common Stock were issued and outstanding. As of December 9, 1999, the aggregate market value of voting stock held by non-affiliates of the Registrant was approximately \$43,894,740 based on the closing price for the Registrant's Common Stock as quoted on the Over-the-Counter Bulletin Board.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the following documents are incorporated by reference in this Report on Form 10-K: None.

## **PART I**

### **ITEM 1. BUSINESS**

#### **General**

Celsion Corporation (the "Company") was incorporated in the State of Maryland in 1982 under the name A.Y. Cheung Associates, Inc. The Company changed its name to Cheung Laboratories, Inc. on June 31, 1984 and to Celsion Corporation on May 1, 1998. The Company is a biomedical research and development company headquartered in Columbia, Maryland, dedicated to creating and marketing medical treatment systems for cancer, benign prostatic hyperplasia ("BPH") and other diseases using focused heat energy.

#### **Breast Cancer Treatment**

##### **Current Treatment for Breast Cancer**

According to statistics published in the American Cancer Society's A Cancer Journal for Clinicians, there were an average of 183,000 newly diagnosed breast cancer cases in each of the years from 1995 through 1997, and breast cancer is one of the leading causes of death among U.S. women. This form of cancer is presently treated by mastectomy, the surgical removal of the entire breast, or by lumpectomy, the surgical removal of the tumor and surrounding tissue. Both procedures are often followed by radiation therapy or chemotherapy. In addition, the more severe forms of surgical intervention for breast cancer can result in disfigurement and a need for extended prosthetic and rehabilitation therapy.

##### **Heat Therapy in Conjunction with Radiation; Earlier Celsion Equipment**

Heat therapy (also known as hyperthermia or thermotherapy), is an historically recognized method of treatment of various medical conditions, and heat therapy has been used in the past to treat malignant tumors in conjunction with radiation and chemotherapy. As summarized in the Fourth Edition of Radiobiology for the Radiologist, published in 1994 by J.B. Lippincott Company, in 24 independent studies on an aggregate of 2,234 tumors, it was reported that treatment consisting of heat plus radiation resulted in an average doubling of the complete response rate of tumors, compared to the use of radiation alone, with the complete response rate being defined as the total absence of a treated tumor for a minimum of two years. Comparable increases in the complete response rate were reported to have occurred with the use heat combined with chemotherapy. In addition, it has been demonstrated on numerous occasions that properly applied heat, alone and without the concurrent use of radiation, can also kill cancer cells.

In 1989, Celsion obtained pre-marketing approval from the Food and Drug Administration ("FDA") for its microwave-based Microfocus 1000 heat therapy machine for use on surface and subsurface tumors in conjunction with radiation therapy. Until 1995, the Company marketed its Microfocus 1000 units for such use in 23 countries, but microwave heat therapy was not widely accepted in the U.S. medical community as an effective cancer treatment. Moreover, due to the limitations of microwave technology available at that time, it was difficult to deliver a controlled amount of heat to internal tumors without burning surrounding healthy tissue.

## **New Microwave Technology from MIT**

In 1993, the Company began working with researchers at Massachusetts Institute of Technology ("MIT") who had developed, originally for the U.S. 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 the Company an exclusive worldwide license to use this technology for medical applications, and Celsion concentrated its efforts on developing a second generation of Microfocus equipment capable of focusing microwave energy on specific tissue areas. Celsion has now incorporated the APA technology in its second-generation microwave therapy equipment.

### **Celsion Breast Cancer Treatment System**

Using the APA technology, Celsion has developed a prototype breast cancer treatment system intended to destroy localized breast tumors through the application of heat alone. The system consists of a microwave generator and conductors, a computer and computer software programs which control the focusing, application and duration of the thermotherapy, and a specially designed patient treatment table.

In 1998 Celsion completed pre-clinical animal testing of its prototype system at the Massachusetts General Hospital, a teaching hospital for Harvard Medical School in Boston, Massachusetts. Using breast tissue-equivalent phantoms and tumors in live animals, such studies verified that Celsion's system is capable of selectively heating tumors at temperatures up to 46 (degrees) Celsius without damage to surrounding healthy tissues. Such high temperatures maintained for 8-10 minutes can cause complete tumor necrosis leading to the death of viable cancer cells within the tumor and in its immediate vicinity. A second prototype clinical breast cancer treatment system at Oxford University in England was used to demonstrate successfully the ability of the Celsion equipment to focus heat deep into animal tissue at precise locations and in a small target area. In the Company's view, such animal tests demonstrate that it is possible to ablate (kill) tumors by heat alone and without the use of radiation.

### **Testing and FDA Approval Process**

The Company has obtained an Investigational Device Exemption ("IDE") for the new equipment from the FDA, and has also obtained approval to commence Phase I human trials at Harbor UCLA Medical Center in Torrance, California and Columbia Hospital, West Palm Beach, Florida. The procedure for which Celsion's equipment is being clinically tested will be performed on female breast tumors on a minimally invasive basis and is expected to require a single application of precisely controlled and targeted heat. Patient testing has recently begun.

Ultimate FDA approval for a device requires two phases. The purpose of Phase I testing is to show feasibility and safety and involves a small group of patients. Phase II testing may involve as many as 100 patients and is designed to show safety and efficacy. Assuming successful completion of Phase I, the Company will undertake multi-site Phase II clinical trials to obtain the necessary safety and efficacy data. If Phase II tests are successful, the Company will apply to add a "tumor ablation" indication to the existing FDA pre-marketing approval for Celsion's Microfocus equipment, denoting that the system can be used to destroy cancerous tumors and viable cancer cells within

the human breast through the application of focused microwave heat energy alone. If testing and approvals proceed as planned, Celsion expects the breast cancer system will be available for marketing in 2001 through a strategic partner to be identified and selected as the approval process nears completion.

## **BPH Treatment System**

### **Benign Prostatic Hyperplasia**

Millions of aging males experience symptoms resulting from a non-cancerous urological disease in which the prostate enlarges and constricts the urethra, a condition known medically as benign prostatic hyperplasia, or "BPH". 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. In many adult males, the prostate enlarges with age, and as the prostate expands, it compresses or constricts the urethra, thereby restricting the normal passage of urine. This restriction of the urethra may require a patient to exert excessive bladder pressure to urinate. Since the urination process 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**

Because BPH is an age-related disorder, its incidence increases with maturation of the population. Industry estimates suggest that more than 17 million U.S. males aged 50 and over experience BPH symptoms and that more than 26 million men in similar age categories are affected by BPH worldwide. As the population continues to age, it is expected that the prevalence of BPH will continue to increase. It is generally estimated that approximately 50% of all men over 55 and 75% of all men over 80 will have BPH symptoms at various times. One survey of the medical urology market indicates that at least \$3 billion is spent on BPH treatment annually in the U.S. and \$9 billion worldwide, although Celsion believes the market may be even larger, because many men with BPH symptoms do not opt for treatment.

### **Current Treatment Alternatives for BPH**

Like cancerous tumors, BPH historically has been treated by surgical intervention or by drug therapy. The primary treatment for BPH 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, thereby widening the urethral channel for urine flow. While the TURP procedure typically has been considered the most effective treatment available for the relief of BPH symptoms, the procedure has shortcomings. A large number of patients who undergo TURP encounter significant complications, which can include painful urination, infection, 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. Also, this high cost fails to reflect the cost of lost work time, which could amount to several weeks, and a reduction in quality of life. Other less radical surgical procedures are available in addition to the TURP procedure. For example, Interstitial RF Therapy and Laser Therapies are procedures which employ, respectively, concentrated radio frequency waves or laser radiation to reduce prostate swelling by cauterization of tissue instead of removal of tissue with a surgical knife. However, these procedures require puncture incisions to be made in a patient in order to insert cauterizing RF or

laser probes into the affected tissue, and therefore also may involve the use of a full operating facility and anaesthesia, as well as the burning of tissue by the probes. While these procedures result in less internal bleeding and damage to the urethra compared with TURP procedures, they do not completely eliminate the adverse effects and costs associated with hospital surgery, anaesthesia and post-operative tissue recovery.

Drug therapy has emerged as an alternative to surgery in the last several years. There are several drugs available for BPH treatment, the two most widely prescribed drugs being Hytrin and Proscar. Hytrin works by relaxing certain involuntary muscles surrounding the urethra, thereby easing urinary flow, and Proscar is intended to actually shrink the enlarged gland. However, industry studies have asserted that drug therapy costs \$500 to \$800 per year or more, and does not offer consistent relief to a large number of BPH patients, with the best of the drugs being estimated to be only 50% as effective as the TURP procedure. Since both surgical and drug treatment alternatives involve appreciable side effects and high costs, the Company believes there is a substantial opportunity for a less invasive and lower-cost treatment option.

Thermotherapy involving high heat treatment using microwaves is another new alternative treatment approach. In May 1996, the FDA approved a microwave-based BPH treatment device manufactured by EDAP Technomed, Inc. ("Technomed"), called Prostatron. The FDA has recently approved another similar microwave treatment device manufactured by Urologix, another thermotherapy company. However, based on information obtained by the Company at trade shows, from the manufacturers and from urologists who have considered acquiring the equipment, the relatively higher treatment temperatures used in such equipment appear to create initial swelling in the tissues surrounding the urethra for a substantial portion of the patients treated. This can result in no immediate symptomatic relief and in a need for post-treatment catheterization of the urethra in order to relieve blockage for a number of patients undergoing such treatment.

### **Celsion BPH Treatment System**

The Company has developed a BPH treatment system which combines Celsion's microwave thermotherapy capability with a proprietary balloon compression technology licensed from MMTC, Inc. ("MMTC"). The treatment system deals with the problem of enlarged prostates in two ways. A catheter incorporating a balloon enlargement device delivers computer-controlled transurethral microwave heating which damages and kills the enlarged prostate cells constricting the wall of the urethra. Simultaneously, the balloon device inflates and expands to press the walls of the urethra from the inside outward as the surrounding prostate tissue is heated.

In pre-clinical animal studies, a natural "stent," or reinforced opening in the urethra of the animals tested, was shown to be formed after the combined heat plus compression treatment. Also, the system's relatively low temperature (43(degree)C to 45(degree)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 temperature is not high enough to cause swelling in the urethra.

The FDA approved an IDE for Celsion's BPH system in June 1998, and initial Phase I clinical feasibility human trials of the BPH system were completed 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. The Company has received FDA approval to conduct an expanded Phase I study to test a shortened treatment protocol. Patient testing has recently begun. Assuming additional FDA approval, Celsion will undertake multiple-site Phase II studies to collect the safety and efficacy data necessary to obtain an FDA pre-marketing approval for commercialization. If Phase II produces anticipated results, the Company intends to begin marketing the BPH system by the end of 2000, using a strategic partner to be identified and selected at that time.

Based on its information to date, the Company believes that its BPH system, assuming continued positive clinical test results, could deliver a treatment that is performed in one hour or less on an outpatient basis, would not require post-treatment catheterization, and would deliver symptomatic relief and an increase in urinary flow rates.

### **Thermo-Liposomes; Duke University Technology**

Liposomes are man-made microscopic spheres with a liquid membrane, developed in the 1980's to encapsulate drugs for targeted delivery. Commercial liposomes can now encapsulate chemotherapeutic drugs, enabling them to evade destruction by the body's immune system, and allowing them to accumulate in tumors. However, with presently available technology, it often takes 18 to 24 hours for commercially available liposomes to release their drug contents to the tumors, severely limiting the clinical efficacy of liposome chemotherapy treatments.

A team of Duke University scientists has developed heat-sensitive liposomes comprised of materials that rapidly change porosity when heated to a specific point. For application to mammalian tissue, the heat-sensitive liposomes are injected into the blood stream. As the heat-sensitive liposomes circulate repeatedly within the small arteries, arterioles, and capillaries, the drug contents of the liposomes are released in significantly higher levels in those tissue areas which have been heated for 30 to 60 minutes, than in areas that do not receive heat. In animal trials, it has been determined that 50 times the amount of drugs carried by heat-sensitive liposomes were deposited at a specific heated tissue site, as compared to conventional liposomes. Celsion has 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.

The Company and Duke University are pursuing further development work and pre-clinical studies aimed at using the new thermo-liposome technology in conjunction with Celsion's APA focused heat technology for a variety of applications, including cancer chemotherapy. The Company views the Duke thermo-liposome technology as a highly promising improvement in the delivery of medicines used to combat serious diseases. For example, the drugs used in chemotherapy regimens to fight cancer are often toxic when administered in large quantities, and produce nausea, vomiting, and exhaustion - all side effects of the body being poisoned. However, if such a drug can be delivered directly to a tissue area where it is needed, as opposed to being distributed through the entire circulatory system, the local concentration of the drug could be increased without the side effects that accompany large systemic dosing.

On November 10, 1999, the Company entered into a License Agreement with Duke University, under which Duke has granted the Company exclusive rights (subject to certain exceptions) to commercialize and use Duke's patented thermo-liposome technology. See "Business -- License Agreements and Proprietary Rights - Duke University"

## **Sloan-Kettering / Celsion - Heat-Activated Gene Therapy Compounds**

Celsion has also been working with Memorial Sloan-Kettering Cancer Center ("Sloan-Kettering") on the development of a thermo-genetic technology for cancer treatment that employs a heat-activated, genetic modifier. The modifier is designed to improve the effectiveness of, and lower the treatment dose for, chemotherapy, heat, and radiation treatment of localized cancers, by suppressing the action of the protein responsible for DNA damage repair in tumor cells. Once heated, the genetic modifier multiplies rapidly in the cancer cells. The genetic modifier deletes the repairing protein from the cancer cells, rendering them temporarily incapable of reversing DNA damage incurred during chemotherapy, heat, and radiation treatment. Preclinical studies in vitro suggest that the genetic modifier has the potential to significantly reduce the levels of a radiation or chemotherapy dose required to destroy a tumor, thus decreasing the toxicity and associated side effects of such treatment on other areas of the body.

Celsion and scientists from Sloan-Kettering are planning to conduct initial preclinical tests to evaluate the safety and efficacy of the modifier technology in an animal model. Celsion has been holding discussions with Sloan-Kettering on finalizing terms and conditions for an exclusive license agreement for such modifier technology. See "Business - License Agreements and Proprietary Rights - Sloan-Kettering"

### **Development, Marketing and Sales Strategy**

Celsion is not currently engaged in marketing and sales, and is focusing its activities on the development and testing of its products. The Company's strategic plan is based upon (i) its expertise and experience in the medical application of focused microwave heat and (ii) its relationships with and license rights from its institutional research partners. Celsion's goal has been to employ these resources to develop minimally-invasive or non-invasive, non-toxic treatment technologies with efficacy significantly exceeding that available from other sources. Using its management and staff, scientific advisory personnel, and available financial resources, Celsion is focusing its efforts on the following goals:

#### **Short-Term Goals; 12 to 24 Months**

1. Completing the development, testing, and commercialization of its second-generation technology for the eradication of cancerous breast tumors when used alone or combined with radiation or chemotherapy;
2. Completing the clinical testing and commercialization of its BPH treatment system; and
3. Pursuing the development and testing of targeted drug delivery via heat sensitive liposomes for the purpose of concentrating chemotherapeutic drugs at tumor sites.

#### **Longer-Term Goals; 18 Months and Longer**

4. Continuing with the development of gene therapy to significantly improve the effectiveness of radiation and chemotherapy on tumors; and

5. Initiating, either alone or with partners, the development of cost-effective enhancements and variations of its technology base. These include a version of its Microfocus equipment for treating prostate and other cancers, and additional potential applications for heat-sensitive liposome therapy and heat-activated gene therapy in the treatment of inflammatory, infectious and genetic diseases.

Assuming successful completion of its product development efforts, the Company plans to place its new products with hospitals, clinics, health maintenance organizations and pharmaceutical companies at modest initial cost. The emphasis of the Company's marketing strategy for its breast cancer and BPH systems will be to create ongoing cash flow by selling disposable medical procedure kits for each patient use and by charging a per-usage fee to recoup its costs and generate profits. The Company intends to stimulate demand for its treatment systems by educating patients through various forms of media publicity, consistent with FDA regulations.

The Company's planning anticipates that, in the near term (up to 24 months), the source of the Company's revenues will be its proprietary technology for BPH and for treatment of breast cancer and deep-seated tumors through the use of focused microwave heat therapy equipment, after the necessary testing and regulatory approval processes are completed. The Company intends to generate initial sales through a combination of direct marketing and development of marketing alliances.

In the longer term (from 18 months to 36 months and beyond), the Company will seek to generate new revenue streams from its current development work with Duke University in targeted drug delivery systems and with Sloan-Kettering in gene therapy. It is anticipated that such revenues will come from the licensing of such technology to pharmaceutical manufacturers and major institutional health care providers who would employ these technologies to deliver drug regimens or gene therapy throughout the body. Also, since such technology is designed to be used in conjunction with the Company's APA-improved microwave equipment, the Company expects that the acceptance of such technology will mean demand for such equipment, which, in turn, is expected to create equipment sales revenues. To prepare for future marketing of its heat sensitive drug delivery systems, the Company intends to explore the possibilities of forming alliances with pharmaceutical companies, major hospitals and health maintenance organizations.

### **License Agreements and Proprietary Rights**

The Company owns no patents. Through the Company's license agreements with MIT, MMTC, Haim Bitcher Cancer Institute and Duke University, the Company has exclusive rights within defined fields of use to various U.S. patents. The patents relate to the cancer equipment and to the BPH equipment. The patents expire at various times from May, 1999 to November, 2014. The Company, in conjunction with the patent holders, has filed or intends to file international applications for certain of the U.S. patents. A summary of the Company's various agreements follows.

#### **MIT**

The material terms of the MIT license agreement provide for a grant of exclusive rights for the permitted uses under a number of U.S. patents and various U.S. and foreign pending patent applications, along with two copyrighted software programs. The grant includes the right to sublicense for end-users, and the license term expires at the earlier of 10 years after the first commercial

sale of a licensed product or 12 years after the date of the license agreement, which expiration date may be extended with the consent of MIT. The agreement contains various milestone requirements and payments, provides for certain minimum sales, and may be terminated (i) by the Company at any time upon at least six months notice and payment of all amounts which may then be owed to MIT, and (ii) by MIT upon the occurrence of a breach by the Company.

### **MMTC**

The Company's exclusive rights under the MMTC license agreements extend for the life of MMTC's patents. The patent terms expire at various times from May 2011 to November 2014. The MMTC license agreement contains, license fee, royalty and/or research support provisions, testing and regulatory milestones, and other performance requirements which the Company must meet by certain deadlines with respect to the use of the licensed technologies.

### **Duke University**

On November 10, 1999, the Company entered into a License Agreement with Duke University, under which Duke has granted the Company exclusive rights (subject to certain exceptions) to commercialize and use Duke's thermo-liposome technology. The license is for a term which is the longer of 20 years or the end of any term for which any relevant patents are issued by the U.S. Patent and Trademark Office, and includes the right to sublicense. For portions of the technology, Celsion's rights are worldwide, and, for various patent rights, the license covers the United States, Canada, the United Kingdom, France, Germany and Japan, and other countries in which Celsion desires to seek patent protection, provided that Celsion will be responsible for the costs of obtaining such protection.

The License Agreement contains annual royalty and minimum payment provisions, and also requires the Company to make milestone-based royalty payments measured by such events as 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 has agreed to accept shares of Celsion 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 such 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. As a result of the foregoing provisions, the Company expects that, over time, Duke University will become a significant shareholder of Celsion.

### **Sloan-Kettering**

Under the Company's research agreement with Sloan-Kettering, the Company had an option to negotiate the terms of an exclusive license agreement to commercialize the results of the Sloan-Kettering research sponsored by Celsion concerning patented thermo-genetic modifier technology. Celsion exercised its option to commence such negotiations on November 9, 1999, and has until February 9, 2000 to negotiate the terms of a final license agreement. Celsion has been holding discussions with Sloan-Kettering on such terms, and anticipates that the terms will be finalized by the February 9, 2000 expiration date.

In addition to the rights available to it under completed or pending license agreements, the Company also relies upon its own proprietary know-how and experience in the development and use of microwave thermotherapy equipment, which it seeks to protect, in part, through proprietary information agreements with employees, consultants and others. The Company cannot guarantee that such information agreements will not be breached, that the Company would have adequate remedies for any such breach or that such agreements, even if fully enforced, would be adequate to prevent third party use of the Company's proprietary technology. Similarly, the Company cannot guarantee that technology rights licensed to the Company by others will not be successfully challenged or circumvented by third parties, or that the rights granted will provide adequate protection to the Company. The Company is aware of patent applications and issued patents belonging to other companies, and it is uncertain whether any of these, or patent applications filed of which the Company may not have any knowledge, will require the Company to alter its potential products or processes, pay licensing fees, or cease certain activities.

### **Manufacturing of Products**

The Company believes it is best suited to conduct basic research and development activities, to pursue a prototype product through clinical testing and regulatory approval, and to market the final product. The Company does not intend to engage in manufacturing, but intends to out source the manufacture of final commercial products, components and disposable patient use kits. Based on past experience, the Company does not anticipate any significant obstacles in identifying and contracting with qualified suppliers and manufacturers.

### **Third Party Reimbursement**

The Company believes that third party reimbursement will be essential to commercial acceptance of the Deep Focused Heat Systems and Microfocus BPH System procedures, and that overall cost effectiveness and physician advocacy will be keys to obtaining such reimbursement. The Company believes that its procedures can be performed for substantially lower total cost than surgical treatments for BPH or cancer or continuous drug therapy. Consequently, the Company believes that third party payers seeking procedures that provide quality clinical outcomes at lower cost will help drive acceptance of the Company's products.

The Company's strategy for obtaining reimbursement in the United States is to obtain appropriate reimbursement codes and perform studies in conjunction with clinical studies to establish the efficacy and cost effectiveness of the procedures as compared to surgical and drug treatments for BPH and cancer. The Company plans to use this information when approaching health care payers to obtain reimbursement authorizations.

With the increasing use of managed care and capitation as a means to control health care costs in the United States, the Company believes that physicians may view the Company's products as a tool to treat efficaciously BPH and cancer 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 population appears to be moving into a managed care system.

Subject to regulatory approval for the Deep Focused Heat Systems to treat cancer and the new Microfocus BPH System to treat BPH, it is anticipated that physicians will submit insurance claims for reimbursement for the procedure to third party payers, such as Medicare carriers, Medicaid carriers, HMOs, and private insurers. In the United States, third party reimbursement is generally available for existing therapies used to treat cancer and BPH. The availability and level of reimbursement from such payers for the use of the Company's new Deep Focus Heat Systems and the new Microfocus BPH System will be a significant factor in the Company's ability to commercialize these systems.

The Company believes that new regulations regarding third party reimbursement for certain investigational devices in the United States will allow it to pursue early reimbursement from Medicare with individual clinical sites prior to receiving FDA approval. However, the Company believes that FDA approval 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 United States Health Care Financing Administration ("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 HMOs make their own determinations regarding coverage and reimbursement based upon "usual and customary" fees. Reimbursement experience with a particular third party payer does not reflect a formal reimbursement determination by the third party payer.

Internationally, reimbursement approvals for procedure utilizing the Company's new products will be sought on an individual country basis. Some countries currently have established reimbursement authorizations for transurethral microwave therapy. Clinical studies and physician advocacy will be used to support reimbursement requests in countries where there is currently no reimbursement for such procedures.

### **United States Regulation**

In the United States, the FDA regulates the sale and use of medical devices, which include the Company's thermotherapy systems for both cancer and BPH. A company introducing a medical device in the United States must go through a two-step process. The company must first obtain an IDE permit from the FDA. An IDE is granted upon the manufacturer's adequately demonstrating the safety and feasibility of the device for patient use. Receipt of the IDE allows the use of the device on patients for the purpose of obtaining safety and efficacy confirmation. An FDA pre-marketing approval is granted upon compilation of sufficient clinical data to establish safety and efficacy for the indicated use of the device. This process is not only time consuming but is also expensive. Obtaining pre-marketing approval is a significant barrier to entry into the thermotherapy market. Firms which lack pre-marketing approval face significant impediments to the successful marketing of their thermotherapy equipment because, under applicable regulations, customers can only obtain reimbursement from Medicare, Medicaid and health insurers for treatment with products which have received such pre-marketing approval.

The Federal Communications Commission (the "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 frequency of 915 MHZ has been approved by the FCC for medical applications, and machines utilizing that frequency do not require

shielding to prevent interference with communications. The Company's Microfocus and BPH treatment products utilize the 915 MHZ frequency.

In December 1984, the HCFA approved reimbursement under Medicare and Medicaid for thermotherapy treatment when used in conjunction with radiation therapy for the treatment of surface and subsurface tumors. At this time, most of the large medical insurance carriers in the United States have approved reimbursement for such thermotherapy treatment under their health policies. Thermotherapy treatment administered using equipment which has received pre-marketing approval is eligible for such reimbursement.

The Company and its facilities are subject to inspection by the FDA at any time to insure compliance with FDA regulations in the production and sale of medical products. The Company believes that it is substantially in compliance with FDA regulations governing the manufacturing and marketing of medical devices. The Company previously received pre-marketing approval from the FDA for its original Microfocus 1000 cancer treatment equipment for treatment of surface and sub-surface tumors in conjunction with radiation therapy. The Company has also received a supplemental pre-marketing approval to add the APA technology from MIT to the Microfocus 1000 equipment. The Company is seeking a new indication of use to enable its improved Microfocus equipment with APA to be used for breast tumor ablation using heat alone. In connection with this new indication of use, the Company has received Phase I approval from the FDA to conduct clinical trials.

Celsion has also received approval to conduct an expanded Phase I study using its BPH treatment system. The purpose of the expanded Phase I study is to test a revised protocol, which is intended both to significantly shorten the BPH treatment time for each patient application and to lower the manufacturing cost for a disposable device used during the treatment.

### **Regulation of Foreign Sales**

Sales of medical devices outside of the United States are subject to United States export requirements and foreign regulatory controls. Export sales of investigational devices that are subject to PMA requirements and have not received FDA marketing approval generally may be subject to FDA export permit requirements under the Federal Food, Drug and Cosmetic Act ("FDC Act") depending upon, among other things, the purpose of the export (investigational or commercial) and on whether the device has valid marketing authorization in a country listed in the FDA Export Reform and Enhancement Act of 1996. In order to obtain such a permit, when required, the Company must provide the FDA with documentation from the medical device regulatory authority of the country in which the purchaser is located, stating that the device has the approval of such country. In addition, the FDA must find that export of the device is not contrary to public health and safety of such country.

The Company sold its original product, Microfocus 1000, in approximately 23 countries in Asia, Europe, and South America. Meeting the registration requirements within these countries has been the responsibility of the distributors in each of these countries. 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. The timing for obtaining such approvals is not presently known.

## Competition

### (1) Thermotherapy For Cancer

The Company believes that there are at least six other domestic firms, as well as a number of foreign firms, producing, or designing and intending to produce, thermotherapy systems to treat cancer. Of those firms, at least four have obtained PMA for their machines and several have obtained IDE for their machines. Some, and possibly all of those firms, have greater resources than those which the Company now has or may reasonably be expected to have in the near future. Other firms not presently in competition with the Company may decide to produce thermotherapy systems which compete with those of the Company. At least some of those firms may reasonably be expected to have resources greater than those of the Company. As acceptance of thermotherapy as a cancer treatment increases, the Company expects that the competition will also increase. The two main competitors of the Company are BSD Medical Corporation in Salt Lake City, Utah ("BSD"), and Labthermics Technology, Inc. in Champaign, Illinois ("Labthermics"), each of which manufactures thermotherapy machines competitive with the Company's current Microfocus 1000. The major factors in competition for sales of thermotherapy equipment are product performance, product service, and product cost. The system manufactured by BSD uses microwave technology. Labthermics uses ultrasound technology to heat the cancer site.

BSD received its FDA approval in 1983 and was allowed to begin marketing its system at that time. To date, BSD has sold approximately 200 thermotherapy systems worldwide and has a much larger presence in the thermotherapy market than has the Company.

### (2) Thermotherapy For Prostatic Diseases

The Company believes there are as many as 10 companies in the USA and as many as 15 companies worldwide that are planning to enter or already active in the prostatic device market marketplace.

In 1996, the FDA for the first time approved a microwave-based BPH treatment device manufactured by EDAP Technomed, Inc. ("Technomed"), called "Prostatron." In addition, Urologix and Dornier recently received FDA approval on their BPH systems. These approvals should enhance market acceptance of microwave BPH treatment systems both in the United States and abroad, but gives Technomed a competitive advantage of being first to the market in the United States. The Company's new BPH system has not been approved by the FDA for sale in the United States. The Company has obtained an IDE approval from the FDA for conducting clinical trials of the Company's BPH system at the Montefiore Medical Center.

Large companies such as Dornier, Olympus, and Technomed are expected to spend large amounts of resources for marketing and development of BPH products. In addition to the above companies, the following are companies offering BPH thermotherapy systems in the worldwide marketplace: BSD, Direx Medical, Technomatix (Primus), Lund Science, Quantum, GENEMED, Bruker, and Meditherm. There are several other companies which have not yet brought their products to the international marketplace. Presently, Technomed is considered the market leader with its Prostatron system. The Prostatron unit is a high cost system which sells for approximately U.S. \$300,000. Other companies are marketing their systems in the range of US \$100,000 to \$300,000. To date, it is believed there are over 600 installed BPH Systems worldwide of which Technomed and Direx have

the largest share of approximately 30% combined. There are approximately 75 of the Company's older Microfocus BPH Systems installed worldwide.

### **Product Service, Warranty and Training**

Service in the thermotherapy business includes maintenance of the thermotherapy machines to minimize downtime as well as training for personnel who will utilize the machines to render treatment to patients. The Company has warranty and service policies which are competitive within the industry. The Company's warranty for the Microfocus 1000 is for a period of 12 months and the Company offers a service policy following expiration of the warranty. The Company no longer markets the Microfocus 1000, and its warranty obligations on virtually all Microfocus 1000 machines previously sold have expired. On the Company's new products, it plans to offer warranties substantially similar to the warranties and service policies offered by competitors. The Company has provided, and will in the future, three to four days of training for the personnel who will be operating each machine that the Company places at a treatment center. The Company also has provided, and will provide in the future training programs at its facility in Maryland for doctors who desire to receive training on the Company's products. Both training courses are helpful in marketing the Company's products, because users who become familiar with one machine have a reluctance to switch to another machine which would require additional training. For this reason, the Company will seek to increase the frequency of its training sessions given at its facility in Maryland.

### **Product Liability and Insurance**

The business of the Company entails the risk of product liability claims. Although the Company has not experienced any product liability claims to date, any such claims could have an adverse impact on the Company. In the past, the Company had not maintained product liability insurance. Recently, the Company has secured product liability insurance in the amount of \$5,000,000 and directors and officers insurance in the amount of \$3,000,000. There is no assurance, however, that claims will be covered by such insurance and will not exceed such insurance coverage limits.

### **Employees**

The Company utilizes the services of 16 individuals on a regular basis, including seven full-time employees and nine full or part-time consultants. In addition, Celsion's Scientific Advisory Board actively assists the Company's management with advice on numerous projects. None of the Company's employees is represented by a collective bargaining organization, and the Company considers its relations with its employees to be good.

## **ITEM 2. PROPERTIES**

The Company's facilities consists of approximately 6,000 square feet of administrative office, laboratory and workshop space at 10220-I Old Columbia Road, Columbia, Maryland 21046-1705. The Company leases the premises from an unaffiliated party under a three- year lease which will expires May 31, 2000. Monthly rent is \$5,887.07

**ITEM 3. LEGAL PROCEEDINGS**

The Company is not a party to any legal proceedings.

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

The Company did not have a stockholders meeting during the fiscal year ended September 30, 1999.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON

#### EQUITY AND RELATED STOCKHOLDER MATTERS

The Company's Common Stock is traded on the over-the-counter market. Prices for the Company's shares are quoted in the Electronic Bulletin Board operated by NASDAQ. The quotations set forth below do not include retail markups, markdowns or commissions, and may not necessarily represent actual transactions. There were approximately 1,208 holders of record of the Common Stock as of December 8, 1999. The Company has never paid cash dividends on its stock and does not expect to pay any cash dividends in the foreseeable future.

Period -----	September 30 -----			
	1998 ----		1999 ----	
	High ----	Low ---	High ----	Low ---
1st Quarter (Oct.1 to Dec. 31)	1.13	0.75	0.34	0.23
2nd Quarter (Jan. 1 to March 31)	1.03	0.69	2.26	0.25
3rd Quarter (April 1 to June 30)	0.90	0.36	0.84	0.75
4th Quarter (July 1 to Sept. 30)	0.52	0.21	1.21	0.81

#### Issuance of Shares Without Registration

During the fourth quarter of the fiscal year ended September 30, 1999, the Company issued the following securities without registration under the Securities Act of 1933, as amended (the "Securities Act"):

1. On August 21, 1999, the Company called its Series 700 Warrants for redemption pursuant to the terms thereof. The Series 700 Warrants had previously been issued in a private placement offering to accredited investors under Regulation D, and permitted the holders to purchase shares of Common Stock at an exercise price of \$0.50 per share. In response to the redemption call, holders elected to exercise their warrants to the extent of 2,293,000 shares of Common Stock. As a result, the Company received total proceeds of \$1,146,500 and issued a total of 2,293,000 shares of Common Stock to the exercising warrant holders. The shares issued to such holders were endorsed with the Company's standard restricted stock legend, and a stop transfer instruction was recorded by the transfer agent. Accordingly, the Company views the shares issued as exempt from registration under Sections 4(2) and/or 4(6) of the Securities Act.
2. During the quarter, the Company issued 15,400 shares to a finder in lieu of paying a cash finder's fee of \$7,700. The shares issued to the finder were endorsed with the Company's standard restricted stock legend, and a stop transfer instruction was recorded by the transfer agent. Accordingly, the Company views the shares issued as exempt from registration under Sections 4(2) and/or 4(6) of the Securities Act.

3. The Company issued a total of 187,500 shares of Common Stock upon the exercise of certain options and warrants, for a total cash consideration of \$46,875 or an exercise price of \$0.25 per share. The shares issued to the holders of such options and warrants were endorsed with the Company's standard restricted stock legend, and a stop transfer instruction was recorded by the transfer agent. Accordingly, the Company views the shares issued as exempt from registration under Sections 4(2) and/or 4(6) of the Securities Act.

4. During the quarter, the Company issued a total of 66,666 shares to its current directors in lieu of cash fees for services rendered as directors during the prior fiscal year. In addition, the Company issued 50,000 shares to a non-director consultant for services performed over the past two years. All of such shares were valued at a total of \$83,613. The shares issued to the directors and non-director consultant were endorsed with the Company's standard restricted stock legend, and a stop transfer instruction was recorded by the transfer agent. Accordingly, the Company views the shares issued as exempt from registration under Sections 4(2) and/or 4(6) of the Securities Act.

## ITEM 6. SELECTED FINANCIAL DATA

The following table contains certain financial data for the Company for the five fiscal years ended September 30, 1999 is qualified in its entirety by, and should be read in conjunction with, the Company's Financial Statements and the related Notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	Year Ended September 30,				
	1995	1996	1997	1998	1999
Statement of Operations Data:					
Revenues:					
Product Sales (Net)	\$ 157,618	\$ 74,006	\$ 121,257	\$ 174,182	--
Research and development contracts	--	--	--	--	--
Total revenues	\$ 157,618	\$ 74,006	\$ 121,257	\$ 174,182	--
Cost of sales	67,350	64,406	46,734	136,500	--
Gross profit on product sales	90,268	9,600	74,523	37,682	--
Other costs and expenses:					
Selling, general and administrative	1,386,854	1,321,361	2,283,245	2,515,822	1,371,161
Research and development	18,546	94,012	185,974	1,534,872	1,019,941
Total operating expenses	1,405,400	1,415,373	2,469,219	4,050,694	2,391,102
(Loss) from operations	(1,315,132)	(1,405,773)	(2,394,696)	(4,013,012)	(2,391,102)
Other income (expense)	8,620	(442,192)	(471,631)	11,870	15,744
Interest income (expense)	(90,805)	(85,506)	(185,562)	(199,346)	(60,834)
Net (loss)	\$ (1,397,317)	\$ (1,933,471)	\$ (3,051,889)	\$ (4,200,488)	\$ (2,436,192)
Net loss per share	(\$ .06)	(\$ 0.05)	(\$ 0.11)	(0.12)	(0.05)
Weighted average shares outstanding	23,466,070	39,499,650	28,386,145	34,867,001	45,900,424

September 30,

	1995	1996	1997	1998	1999
Balance Sheet Data:					
Working Capital	(1,101,136)	(646,754)	(2,645,908)	(2,000,351)	906,926
Total Assets	9,710,742	9,321,600	823,209	330,738	1,558,684
Long-term debt, less current maturities	2,000	1,213,000	--	--	--
Accumulated deficit	(10,278,162)	(12,211,633)	(15,263,522)	(19,464,010)	(21,900,202)
Total stockholders' equity (deficit)	8,128,768	6,755,874	(2,460,646)	(1,851,067)	1,037,125

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

**Forward-Looking Statements**

Statements and terms such as "expect," "anticipate," "estimate," "plan," "believe" and words of similar import, regarding the Company's expectations as to the development and effectiveness of its technology, the potential demand for its products and other aspects of its present and future business, constitute forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Although the Company believes that its expectations are based on reasonable assumptions within the bounds of its knowledge of its business and operations, it cannot guarantee that actual results will not differ materially from its expectations. Factors which could cause actual results to differ from expectations include, but are not limited to, those set forth under "Risk Factors."

**General**

Since inception, the Company has incurred substantial operating losses. The Company expects operating losses to continue and possibly increase in the near term and for the foreseeable future as it continues its product development efforts, conducts clinical trials and undertakes marketing and sales activities for new products. The Company's ability to achieve profitability is dependent upon its ability to successfully integrate new technology into its thermotherapy systems, conduct clinical trials, obtain governmental approvals, and manufacture, market and sell its new products. Major obstacles facing the Company over the last several years have included inadequate funding, a negative net worth, and the slow development of the thermotherapy market due to technical shortcomings of the thermotherapy equipment previously available commercially. The Company has not continued to market its older thermotherapy system, principally because of the system's inability to provide precise and consistent heat treatment for other than surface and sub-surface tumors.

The operating results of the Company have fluctuated significantly in the past on an annual and a quarterly basis. The Company expects that its operating results will fluctuate significantly from quarter to quarter in the foreseeable future and will depend on a number of factors, many of which are outside the Company's control.

**Material Non-Operating Transactions and Losses in 1997**

For the year ended September 30, 1997, the Company had a non-operating loss of \$(438,803) resulting from its 1996 investment in Ardex Equipment, LLC ("Ardex"). The Ardex investment arrangements were originally made with persons who were then directors of the Company and principals of Ardex, as described under "Certain Relationships and Related Transactions".

After Ardex experienced financial difficulties, the Company reviewed the financial status of Ardex and determined that the entire amount due from Ardex, including accrued interest, was uncollectible as of September 30, 1997. See Note 9 of Notes to Financial Statements.

## **Results of Operations**

### **Comparison of Fiscal Year Ended September 30, 1999 to Fiscal Year Ended September 30, 1998**

There were no product sales for the year ended September 30, 1999, compared with sales of \$174,182 for the year ended September 30, 1998, which represented re-orders of the Company's older equipment. Product revenues are not expected until development of the Company's second generation equipment incorporating APA technology is completed and such equipment is clinically tested and receives necessary approvals from governmental regulatory agencies.

There was no cost of sales for the current year, as compared with the cost of sales for the year ended September 30, 1999 of \$136,500.

Research and development expense decreased substantially to \$1,019,941 for the year ended September 30, 1999 from \$1,534,872 for the prior year. The difference in expenditure levels reflects the fact that the major portion of development work on the Company's new equipment took place in the 1998 period. However, the Company expects research and development expenses to increase over the next several months as BPH clinical trials and Phase I breast cancer testing begin.

Selling, general and administrative expense decreased substantially to \$1,371,161 for the year ended September 30, 1999 from \$2,515,822 for the previous year. The decrease was due to the absence in fiscal 1999 of the following expenses which were recorded in the earlier period: incentive stock issued to the Company's President, recorded on the Company books in the amount of \$700,640; consulting fees and expenses paid to Stearns Management, a company affiliated with a former officer and director, in the amount of \$195,297; legal fees in the amount of \$145,000; and a write-off of approximately \$112,000 of inventory stocked as replacement parts for older equipment sold in prior years by the Company.

Due mainly to the absence of expenditures for equipment development and for clinical trials for the year ended September 30, 1999 and the decrease in executive bonus, legal, and consulting fees, the net loss decreased by \$1,764,296 to \$(2,436,192) from \$(4,200,488) in the prior year.

### **Comparison of Fiscal Year Ended September 30, 1998 to Fiscal Year Ended September 30, 1997**

Product sales for the fiscal year ended September 30, 1998 were \$174,182. These sales occurred due to limited re-orders of the Company's older equipment. During the prior fiscal year, gross product sales, taking returns and allowances into consideration, were \$121,257. Significant product revenues are not expected until development of equipment incorporating the Company's new technologies is completed and such equipment is clinically tested and receives necessary approvals from governmental regulatory agencies.

Cost of sales increased to \$136,500 in fiscal 1998 from \$46,734 in fiscal 1997. Cost of sales as a percentage of sales increased over the prior period because newer components and enhancements were added to existing inventory in conjunction with upgrading the Company's products to incorporate new technology.

Research and development expense grew substantially to \$1,534,872 in fiscal 1998 from \$185,974 in fiscal 1997. During fiscal 1998, the Company increased its research and development efforts to enhance its products and to incorporate APA and other technological advances into its equipment. The increases included \$ 561,238 for engineering work performed outside the Company on the breast cancer treatment device, \$289,868 for animal studies for the improved BPH system, \$245,976 for animal studies and other development work on the new breast cancer equipment and \$76,000 for work at Duke University in connection with the development of targeted drug delivery and gene-therapy technology. In addition, after a review of the Company's inventory, approximately \$175,000 of components and parts acquired in the course of developing older equipment, including slower, DOS-based electronic components, were deemed to be unusable for the development of the Company's newer models, and were therefore classified as obsolete and written off as additional research and development expense during fiscal 1998. The Company expects to continue its higher levels of expenditures for research and development in order to continue to enhance its products.

Selling, general and administrative expense increased to \$2,515,822 in fiscal 1998 from \$2,283,245 in fiscal 1997. Such increased expense included a write-off of approximately \$112,000 of inventory stocked as replacement parts for older equipment sold in prior years by the Company, which inventory was being carried at the lower of cost or market value and which was determined to have no appreciable market value at year-end because of the absence of demand. The remainder of the increase was attributable to a combination of somewhat higher outside consulting, advertising and administrative expenses. The Company expects selling and marketing expense to increase substantially as it completes the development and testing of its new thermotherapy systems and expands its related advertising, and promotional and marketing activities.

Due mainly to the ramping up of research and development activities in the 1998 fiscal year, the loss from operations increased by \$1,618,316 to \$(4,013,012) from \$(2,394,696) in the prior year. However, the increase in the 1998 loss before income taxes was not as large compared with 1997 because of the non-operating losses reflected in the earlier year as described above.

### **Liquidity and Capital Resources**

Since inception, the Company's expenses have significantly exceeded its revenues, resulting in an accumulated deficit of \$21,900,202 at September 30, 1999. The Company has incurred negative cash flows from operations since its inception, and has funded its operations primarily through the sale of equity securities. As of September 30, 1999, the Company had cash of \$1,357,464 and total current assets of \$1,424,058 compared with current liabilities of \$517,132, resulting in a working capital surplus of \$906,926. As of September 30, 1998, the Company had only \$54,920 in cash and total current assets of \$175,735 compared with current liabilities of \$2,176,086, which resulted in a working capital deficit of \$(2,200,351) at September 30, 1998. The improvement in the Company's working capital was due to several factors, including receipt of gross proceeds of approximately \$2,300,000 from two private placements, the receipt of \$1,146,500 from the exercise of Series 700 Warrants called for redemption, and the conversion of debt, accrued interest payable, and accrued compensation through the issuance of restricted shares of Common Stock in the total amount of \$1,511,205.

The Company also received several concessions on certain accounts payable and debt previously recorded on the books of the Company. Net cash used in the Company's operating activities was \$2,282,951 for the year ended September 30, 1999.

The Company does not have any bank financing arrangements and has funded its operations in recent years primarily through private placement offerings. For all of fiscal year 2000, the Company expects to expend a total of about \$4 million for breast cancer and BPH clinical testing and for corporate overhead. The foregoing amounts are estimates based upon assumptions as to the availability of funding, the scheduling of institutional personnel, the timing of clinical trials and other factors, not all of which are fully predictable. Accordingly, estimates and timing concerning projected expenditures and programs are subject to change.

The Company expects to meet its funding needs for fiscal year 2000 through a private placement offering to accredited investors under Regulation D, which has commenced and is anticipated to be either consummated or to expire in January 2000.

The Company's dependence on raising additional capital will continue at least until the Company is able to begin marketing its new technologies. The Company's future capital requirements and the adequacy of its financing depend upon numerous factors, including the successful commercialization of the thermotherapy systems, progress in its product development efforts, progress with preclinical 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 its products. The Company will be required to obtain such funding through equity or debt financing, strategic alliances with corporate partners and others, or through other sources not yet identified. The Company does not have any committed sources of additional financing, and cannot guarantee that additional funding will be available on acceptable terms, if at all. If adequate funds are not available, the Company may be required to delay, scale-back or eliminate certain aspects of its operations or attempt to obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, product candidates, products or potential markets.

### **Year 2000 Compliance**

The Company previously adopted a plan to address the potential impact of what is commonly referred to as Year 2000 or Y2K issues, concerning the inability of certain information systems to properly recognize and process dates containing the year 2000 and beyond. Management has undertaken assessment and testing of the Company's newer Microfocus and BPH treatment equipment, which equipment incorporates software designed to be Y2K compliant. Testing included operating such medical treatment systems by moving internal timekeeping functions beyond December 31, 1999 and printing out sufficient records to indicate full functioning of the systems beyond January 1, 2000. Similar testing has been carried out for Celsion's accounting, record-keeping and other internal computer systems, and has also indicated that such systems are fully Y2K compatible.

Nevertheless, as a standard precautionary step, software data generated by the Company is backed-up on a daily basis. The worst case scenario, if the

Company experienced computer equipment failure due to Y2K, would be that, once the failed equipment was fixed, the backed-up data would have to be reinstalled onto any fixed system. Concerning the actual operation of the machinery, the worst case scenario would be distorted patient data recorded on the machinery's storage unit. However, the machine would continue to operate properly with distorted patient records, but would require the operator of the machinery to re-enter corrected patient information. As previously reported, the Company's older medical treatment equipment, including the Microfocus equipment sold several years ago, virtually all of which is no longer under warranty, are not date driven and are "stand alone" systems which are not required to be linked with other computers in order to function. The Company has notified users of such older equipment that they can elect either (i) to purchase from the Company, at modest cost, software upgrades to make their existing machines fully Y2K compliant and capable of printing patient records with contemporaneous Year 2000 dating, or (ii) to operate such older equipment by making a one-time entry of a date sometime before Year 2000, in which case such equipment will continue to operate but will generate records printed with an invalid date. Also as previously reported, the Company prepared and sent out a Y2K survey directed to its vendors and suppliers. On the basis of the survey and follow-up contacts by the Company, management believes that all of the Company's essential vendors and suppliers, including utilities, are Y2K compliant. The Y2K compliance of vendors who are non-essential is being followed up by the Company's Controller. At this time, Celsion's management does not foresee significant Y2K risks resulting from its dealings with vendors or suppliers. All Y2K compliance costs of the Company to date, which have been modest, have been funded and paid by it. Celsion does not anticipate incurring any further significant costs related to Y2K issues. Although the Company does not anticipate that Y2K will have a material impact on the Company's financial condition or its ability to operate at current levels, it cannot guarantee that the steps taken in preparation for the year 2000 will be sufficient to avoid any adverse impact on the Company.

## **Risk Factors**

Among numerous risk factors which may affect the future performance of the Company and its ability to achieve profitable operations are the following:

### **Continuing Losses and Accumulated Deficit; Limited Working Capital**

Since inception, the Company's expenses have substantially exceeded its revenues, resulting in continuing losses and an accumulated deficit of \$(21,900,202) at September 30, 1999, including losses of \$(2,436,192) for the year ended September 30, 1999. Since the Company presently has no significant source of revenues and is committed to continuing its product research and development program, operating losses will continue until development of new products is completed and such products have been clinically tested, approved by the FDA, and successfully marketed. In addition, the Company has funded its operations for many years primarily through the sale of Company securities, and has not had sufficient working capital for its desired product development and other activities.

## **Limited Revenue History and Lack of Current Revenues and Profits**

The Company previously marketed and sold its original microwave thermotherapy products which produced modest revenues from 1990 to 1994, when the Company effectively ceased marketing such older products. The Company has devoted its resources in recent years to developing a new generation of thermotherapy products, but such products cannot be marketed until clinical testing is completed and governmental approvals have been obtained. Accordingly, there is no current source of revenues, much less profits, to sustain the Company's present operations, and no revenues will be available until and unless the new products are clinically tested, approved by the FDA and successfully marketed, an outcome which the Company is not able to guarantee.

## **Need for Medical Acceptance of Heat Therapy and Prior History**

In 1989 the Company received FDA pre-marketing approval for its first generation Microfocus 1000 equipment, which included a permitted use of the equipment to apply microwave-generated heat in conjunction with radiation for the treatment of surface and subsurface tumors. The FDA approval had been based on test data supplied by the Company, which indicated 50% fewer tumor reoccurrences over a two-year period in instances where microwave heat was applied along with radiation, as opposed to use of radiation alone. However, after the Company had begun to market the Microfocus 1000 in 1989, a study by the Radiation Oncology Therapy Group ("ROTG") was published in 1990, which purported to show that thermotherapy in conjunction with radiation was only marginally effective. The study was based on the use of a variety of equipment from a number of manufacturers, some custom-made, and included numerous attempts to treat tumors too large or too deep for the equipment used. Such equipment was not able to focus heat accurately on internal organs, and the study combined the relatively poor results from the use of such other equipment to treat internal tumors with the more positive results from the Company's equipment and from studies concerning surface and subsurface cancers, resulting in the study's conclusion that thermotherapy in conjunction with radiation was of questionable value. The study was widely publicized, and the U.S. Healthcare Financing Administration subsequently established a low medical reimbursement rate for all thermotherapy equipment designed to be used in conjunction with radiation. Such low reimbursement rate effectively hampered sales of the Microfocus 1000 in the U.S. Despite the ROTG study results, the Company was able to market its Microfocus systems in Europe and Asia and derived modest revenues from continuing sales of the product until 1995.

In 1996, overseas studies conducted at Hammersmith Hospital in London on breast cancer and at the Danish Cancer Society on Melanoma in Denmark confirmed that thermotherapy in conjunction with radiation significantly increased the tumor response rate as compared to radiation alone.

As indicated above, microwave heat therapy has not been widely accepted in the U.S. medical community as an effective cancer treatment, with or without the concurrent use of radiation. The Company believes that this has been due primarily to the inability of earlier technology to adequately focus and control heat directed at specific tissue locations and to the conclusions which were improperly drawn from the widely publicized ROTG study. While the Company feels its new technology is capable of overcoming such prior limitations, the medical community may not embrace the perceived advantages of APA-focused heat therapy without more extensive testing and clinical experience than the Company will be able to provide. Also, the Company's new cancer treatment technology has only been tested on animals, and its new BPH system has been subjected to only Phase I testing on humans.

Accordingly, it is possible that the Company's technology will not be as effective in practice as the Company anticipates based on preliminary testing. If further testing and clinical practice do not confirm the efficacy of the Company's technology, or, even if such testing and practice produce positive results but the medical community does not view such new form of heat therapy as effective and desirable, the efforts of the Company to market its new products may fail, with serious adverse consequences to the Company.

### **Need for Substantial Additional Funds**

The Company will need substantial additional funding in order to complete the development, testing and commercialization of its products and to continue its operations. The Company's cash requirements may vary materially because of results of research and development, results of pre-clinical testing, relationships with collaborators, changes in the focus and direction of the Company's research and development programs, competitive and technological advances, the FDA's regulatory process, and other factors. The Company is dependent on raising new capital to fund operations to commercialize its products and to satisfy the commitments made by the Company for its fiscal year and 2000, as revenues are not expected to begin until late 2000 at the earliest, with early year 2001 being more likely. The Company does not have any committed sources of financing, and cannot guarantee that additional funding will be available on acceptable terms, if at all.

If adequate funds are not available, the Company may be required to delay, scale-back or eliminate certain aspects of its operations or to attempt to obtain funds through onerous arrangements with partners or others that may force the Company to relinquish rights to certain of its technologies, products or potential markets. Furthermore, if the Company cannot fund its development and other operating requirements, and particularly those associated with its obligation to conduct clinical trials under its licensing agreements, it will be in breach of its commitments under such licensing agreements and could therefore lose its license rights, with material adverse effects on the Company.

### **No Assurance of FDA Approval; Government Regulation**

The FDA and comparable agencies in foreign countries impose substantial requirements upon the introduction of medical products through lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years or more and varies substantially based upon the type, complexity, and novelty of the product. For medical systems such as Celsion's breast cancer treatment product, the FDA will require data from a Phase-I clinical feasibility and safety demonstration using 10- 20 patients, and then a Phase II patient study which establishes safety and efficacy (60-100 patients) before commercialization approval is granted. Similarly, the BPH treatment system will require data from an expanded Phase I study and from a Phase II study.

The effect of government regulation may be to delay marketing of new products for a considerable period of time, to impose costly procedures upon the Company's activities, and to provide an advantage to larger companies that compete with the Company. There can be no assurance that FDA or other regulatory approval for any products developed by the Company will be granted on a timely basis or at all. Any such delay in obtaining, or failure to obtain, such approvals would materially and adversely affect the marketing of any contemplated products and the ability to earn product revenue. Further, regulation of manufacturing facilities by state, local, and other authorities is subject to change. Any additional regulation could result in limitations or restrictions on the Company's ability to utilize any of its technologies, thereby adversely affecting the Company's operations.

## **License Agreements; Uncertain Ability to Protect Technology**

The Company's success will depend, in substantial part, on its ability to maintain its rights under license agreements granting it rights to use patented technology. The Company has entered into exclusive license agreements with MIT for APA technology, with MMTC for balloon catheter technology and with Duke University for thermo-liposome technology. In addition, Celsion is negotiating, and also expects to finalize in the near future, an exclusive license with Sloan-Kettering for the commercialization of thermo-genetic modifier technology. The MIT, MMTC and the Duke University agreements each contain, and the Sloan-Kettering agreement is expected to contain, license fee, royalty and/or research support provisions, testing and regulatory milestones, and other performance requirements which the Company must meet by certain deadlines with respect to the use of the licensed technologies. If the Company were to breach these or other provisions of its license and research agreements, the Company would lose its ability to use the applicable technology and would also not receive compensation for its efforts in developing or exploiting the technology. Also, loss of the Company's rights under the MIT license agreement would prevent the Company from proceeding with most of its current product development efforts, which are dependent on licensed APA technology.

Also, the Company cannot guarantee that any patent or other technology rights licensed to the Company by others will not be successfully challenged or circumvented by third parties, or that the rights granted will provide adequate protection to the Company. The Company is aware of patent applications and issued patents belonging to other companies, and it is uncertain whether any of these, or patent applications filed of which the Company may not have any knowledge, will require the Company to alter its potential products or processes, pay licensing fees, or cease certain activities. Litigation, which could result in substantial cost to the Company, may also be necessary to enforce any patents issued to or licensed by the Company or determine the scope and validity of others' claimed proprietary rights. The Company also relies on trade secrets and confidential information that it seeks to protect, in part, by confidentiality agreements with its corporate partners, collaborators, employees, and consultants. The Company cannot guarantee that these agreements will not be breached, that the Company will have adequate remedies for any such breach, or that the Company's trade secrets will not otherwise become known or be independently discovered by competitors. See "Business-License Agreements and Proprietary Rights."

## **Technological Change and Obsolescence**

Various modalities for the treatment of cancer are the subject of extensive research and development. Many possible treatments which are being researched, if successfully developed, may not require, or may supplant, the use of the Company's thermotherapy technology for an effective cure. Such alternate treatment strategies include the use of radio frequency, laser and ultrasound energy sources, and the successful development and acceptance of any such forms of treatment could render the Company's technology obsolete.

## **Dependence upon Key Personnel**

The Company's success depends (i) on the continued contributions of its executive officers, scientific and technical personnel, and consultants, and  
(ii) on the Company's ability to attract new personnel as the Company seeks to

implement its business strategy. During the Company's operating history, many key responsibilities within the Company have been assigned to a relatively small number of individuals. The competition for qualified personnel is intense, and the loss of services of certain key personnel could adversely affect the business of the Company. Of the Company's personnel, Spencer J. Volk, the Company's Chief Executive Officer and President, has an existing employment agreement, and an employment agreement has been negotiated and is expected to be finalized in January 2000 with Dr. Augustine Y. Cheung, the Company's Chairman and Chief Scientific Officer. See "Executive Compensation - Executive Employment Agreements."

### **Uncertain Availability and Amounts of Health Care Reimbursement**

The Company's ability to commercialize its thermotherapy technology 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. Significant uncertainty exists as to the reimbursement status of newly-approved medical products. The Company cannot guarantee that adequate third-party insurance coverage will be available for the Company to establish and maintain price levels sufficient for realization of an appropriate return on its 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 the Company's products, the market acceptance of these products would be adversely affected if the amount of reimbursement available for the use of the Company's therapies proved to be unprofitable for health care providers.

### **Effects of Outstanding Options and Warrants; Possible Dilution and Additional Trading Shares; Registration Rights**

As of September 30, 1999, the Company had outstanding commitments to issue shares to management, and outstanding options and warrants to purchase shares in, an aggregate amount of approximately 16,653,770 shares of Common Stock, a significant portion of which are exercisable at exercise prices substantially below the current market price. If holders choose to exercise such warrants and options, the resulting purchase of a substantial number of shares of Common Stock at prices below the current market price of the Common Stock could have the effect of adversely affecting the market price of the issued and outstanding Common Stock of the Company. Accordingly, the issuance of shares of Common Stock upon exercise of the options or warrants may result in dilution of the equity represented by the then-outstanding shares of Common Stock held by other stockholders. Also, while the shares of Common Stock to be issued upon any such exercise will not be registered and will initially be restricted securities, the holders of warrants and options for the purchase of approximately 15,000,000 shares have various registration rights, which, if exercised, would require the Company to register such shares for sale in the public market. Furthermore, even without such registration, holders of the warrants and options who are able, after the exercise of such warrants and options, to satisfy the one-year holding period and other requirements of Rule 144 of the Securities and Exchange Commission, will be able to sell shares of Common Stock purchased upon the exercise of such warrants and options in the public market. Future sales of significant numbers of shares of Common Stock in the public market could adversely affect the prevailing market price of the Common Stock and also could impair the Company's ability to raise capital through subsequent offerings of securities.

## **Competitive Risks**

There are many companies and institutions that are engaged in research and development on thermotherapy technologies for both cancer and prostate disease products, and such activities seek treatment outcomes similar to those being pursued by the Company. In addition, a number of companies and institutions are pursuing alternative treatment strategies through the use of radio frequency, laser and ultrasound energy sources, all of which appear to be in the early stages of development and testing. The Company believes 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 cancer and prostate treatment research in the United States and other countries include, among others, major pharmaceutical and chemical companies, specialized technology companies, universities and other research institutions. Many of these have substantially greater financial, technical, human, and other resources, and may also have far greater experience than the Company both in undertaking preclinical testing and human clinical trials of new products and in obtaining FDA and other regulatory approvals. There is always a possibility that one or more of such companies or institutions will succeed in developing products or other technologies that are more effective than any which have been or are being developed by the Company, or which would render the Company's technology and products obsolete and non-competitive. Furthermore, if the Company is permitted to commence commercial sales of products, it will also be competing, with respect to manufacturing efficiency and marketing, with companies having greater resources and experience in these areas.

There are several U.S. and overseas companies, such as BSD Medical Corporation and Labthermics Technology, Inc., which have marketed equipment using heat produced by microwaves or ultrasound to treat surface and subsurface cancer, either with or without the concurrent use of radiation or chemotherapy. To the Company's knowledge, among such entities, BSD Medical Corporation has had the longest business history and has sold the largest number of microwave thermotherapy units for the treatment of surface and subsurface cancer, but the Company does not believe that BSD Medical Corporation has a dominant competitive position or that its equipment has been widely accepted for use in the treatment of cancer. The Company believes BSD Medical Corporation is attempting to develop more advanced versions of its equipment for use in treating deep-seated tumors.

In the treatment of BPH, EDAP TMS S.A., a French company, has marketed a device named the "Prostatron," both in the U.S. and overseas, which uses microwave-generated heat to destroy enlarged prostate tissue. Also, Urologix, Inc., a domestic company, has introduced a BPH medical device similar to that of the Prostatron. While Celsion's management believes these devices have not been widely used or accepted by providers of medical treatment for BPH, there is no guarantee that EDAP or Urologix will not seek to introduce improved equipment for the treatment of BPH.

### **Uncertainty Related to Health Care Reform Measures**

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 health care system of the United States. It is uncertain which legislative proposals will be adopted 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.

The Company cannot predict the effect health care reforms may have on its business, and there is no guarantee that any such reforms will not have a material adverse effect on the Company.

### **Limited Product Liability Insurance**

The Company's business exposes it to potential product liability risks which are inherent in the testing, manufacturing, and marketing of human therapeutic products. The Company presently has product liability insurance limited to \$5,000,000 per incident, and, if the Company were to be subject to a claim in excess of such coverage and such claim succeeded, the Company would be required to pay such claim out of its own limited resources, which could have a serious adverse effect on the Company.

### **Importance of Suppliers; Future Dependence**

The Company is not currently manufacturing any products but is using its facilities to assemble prototypes of its new equipment for research and development purposes. Certain specialized microwave and thermometry components and applicator materials, and the catheter unit used for the Company's BPH equipment, are now purchased only from single or limited source suppliers because of the small quantities involved. While the Company has not experienced any significant difficulties in obtaining such components, the loss of an important current supplier could require the Company to obtain a replacement supplier, which might result in delays and additional expense in being able to make prototype equipment available for clinical trials and other research purposes. Also, in the event the Company should succeed in marketing its products, it will most likely use outside contractors to supply components and to assemble finished equipment, at which time the Company will become dependent on key vendors.

### **Possible Volatility of Share Price**

Market prices for the Company's Common Stock, and the securities of other medical and high technology companies have been volatile. Factors such as announcements of technological innovations or new products by the Company or its 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 any future market for the Common Stock.

### **Absence of Dividends**

The Company has never paid cash dividends on Common Stock, and does not intend to do so in the foreseeable future.

### **Potential Effect of Future Issuances of Common Stock**

The Company as of September 30, 1999 has a total of approximately 53,580,448 shares of Common Stock issued, excluding shares which may be issued pursuant to outstanding warrants and options.

The Company's Board of Directors has the authority to issue additional shares of Common Stock and other classes of capital stock and to issue options and warrants to purchase shares of Common Stock and other stock without

stockholder approval. Future issuance of shares of Common Stock and/or preferred stock could be at values below prevailing market prices and therefore could represent further dilution to investors.

### **NASDAQ Listing Requirements; Risks of Low-Priced Stocks**

The Company's Common Stock is currently traded through the OTC Electronic Bulletin Board. In the future, when it anticipates that it would be able to meet listing requirements, the Company intends to apply have its Common Stock listed on the NASDAQ SmallCap Market. At the present time, such a listing application would require, among other criteria, net tangible assets of at least \$4 million, a market capitalization of at least \$50 million, or net income of at least \$750,000, while the Company had, as of September 30, 1999, a net tangible surplus of \$1,037,125, market capitalization of only approximately \$45 million, and a net loss of \$(2,436,192). Accordingly, the Company can not offer any assurances that they will meet these listing requirements. If the Company is unable to satisfy NASDAQ's initial listing criteria in the future, its securities will continue to be traded through the Electronic Bulletin Board or the Pink Sheets.

The Securities Enforcement and Penny Stock Reform Act of 1990 requires additional disclosure in connection with trades in any stock defined as a penny stock. Regulations generally define a penny stock to be any equity security that has a market price of less than \$5.00 per share, subject to certain exceptions. Such exceptions include any equity security listed on NASDAQ and any equity security issued by an issuer that has (i) net tangible assets of at least \$2,000,000, if such issuer has been in continuous operation for three years, (ii) net tangible assets of at least \$5,000,000, if such issuer has been in continuous operation for less than three years, or (iii) average annual revenue of at least \$6,000,000, if such issuer has been in continuous operation for less than three years.

If the Company's securities are not quoted on NASDAQ, or the Company does not have \$2,000,000 in net tangible assets, trading in the Company's securities will continue to be covered by Rules 15g-1 through 15g-6 promulgated under the Exchange Act for non-NASDAQ and non-exchange listed securities. Under such rules, broker-dealers who recommend such securities to persons (other than established customers and accredited investors) must make a special written suitability determination that the penny stock is a suitable investment for the purchaser and must receive other information from the purchaser.

### **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-17.

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

No change of accountants and/or disagreements on any matter of accounting principles or financial statement disclosures have occurred within the last two years.

### PART III

#### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS

Directors are elected for staggered terms of three years each. The following table sets forth the names and ages of the members of the Company's Board of Directors and executive officers, and sets forth the position with the

Company held by each:

Name ----	Age ---	Position -----
Augustine Y. Cheung+	52	Chairman of the Board of Directors, Chief Scientific Officer
Spencer J. Volk+	65	President, Chief Executive Officer and Director
Max E. Link+	58	Director
LaSalle D. Leffall, Jr.*	70	Director
Claude Tihon **	55	Director
John Mon*	47	Secretary, Treasurer/General Manager and Director
Walter B. Herbst**	61	Director

\* Term as director expires at 1999 annual meeting

\*\* Term as director expires at 2000 annual meeting

+ Term as director expires at 2001 annual meeting

Augustine Y. Cheung. Dr. Cheung is Chairman of the Board of Directors

and has served as a director, principal executive officer and Chief Scientific Officer of the Company since 1982. Dr. Cheung was the founder of the Company and served as President from 1982 to 1986 and Chief Executive Officer from 1982 to 1996. From 1982 to 1985, Dr. Cheung was a Research Associate Professor of the Department of Electrical Engineering and Computer Science at George Washington University and from 1975 to 1981 was a Research Associate Professor and Assistant Professor at the Institute for Physical Science and Technology and the Department of Radiation Therapy at the University of Maryland. Dr. Cheung holds a Ph.D. and Masters Degree from the University of Maryland. Dr. Cheung is the brother-in-law of John Mon, a director and officer of the Company.

Spencer J. Volk. Mr. Volk has been a director, President, and Chief Executive Officer of the Company since May 22, 1997. From 1994 to 1996, Mr. Volk was President and Chief Operating Officer of Sunbeam International. From 1991 to 1993, Mr. Volk was President and Chief Executive Officer of the Liggett Group, Inc. From 1989 to 1991, he was the President and Chief Operating Officer of Church and Dwight (Arm and Hammer), and from 1984 to 1986, he was the President and Chief Executive Officer of Tropicana Products, Inc. Prior to that, he spent thirteen years in various staff and management positions at Pepsico, ultimately as Senior Vice President for the Western Hemisphere. Mr. Volk holds an Honors BA in Economics and Math from Queens University in Ontario, Canada and a BA in Economics from Royal Military College in Ontario, Canada.

Max E. Link. Dr. Link has been a director of the Company since September 23, 1997. Dr. Link currently provides consulting and advisory services to a number of pharmaceutical and biotechnology companies. From 1993 to 1994,

Dr. Link served as Chief Executive Officer of Corange, Ltd., a medical diagnostics company acquired by Hoffman-LaRoche. From 1971 to 1993, Dr. Link served in numerous positions with Sandoz Pharma AG culminating in his appointment as Chairman of the Board of Directors in 1992. Dr. Link serves on the Board of Directors of the following publicly held companies: Human Genome Sciences; Alexion Pharmaceuticals; Cell Therapeutics; Access Pharmaceuticals; Protein Design Laboratories; Osiris Therapeutics; Procept, Inc.; Discovery Laboratories Inc. and Cytrx Corp. Dr. Link holds a Ph.D. in economics from the University of St. Gallen (Switzerland).

La Salle D. Leffall, Jr. Dr. Leffall has served as Professor of Surgery at Howard University College of Medicine since 1970, and in 1992, was named the Charles R. Drew Professor of Surgery. Dr. Leffall also served as Chairman of the College's Department of Surgery from 1970 to 1985. He is also a Professional Lecturer in Surgery at Georgetown University. Dr. Leffall holds a B.S. from Florida A&M and a medical degree from Howard University. Dr. Leffall is a director of Warner Lambert, Mutual of America, Chevy Chase Bank and the Charles A. Dana Foundation. He is a former President of the American College of Surgeons and the American Cancer Society. He is also a consultant for the National Cancer Institute, a diplomat of the American Board of Surgery and a fellow of the American College of Surgeons.

Claude Tihon. Dr. Tihon is currently President and Chief Executive Officer of Contimed, Inc., a medical device company for developing urological products to manage women's stress incontinence and men's prostate obstruction. From 1987 to 1995, Dr. Tihon served in numerous positions with Pfizer, Inc., culminating in his appointment as Vice President of Research and Technology Assessment of American Medical Systems, Inc., a Pfizer Co. subsidiary. From 1983 to 1987, Dr. Tihon served as Director of Cellular Diagnostics Development of Miles Scientific, a division of Miles Laboratories. From 1979 to 1983, Dr. Tihon served as Senior Research Scientist and Assistant Director of Clinical Cancer Research of Bristol Laboratories, a division of Bristol Myers Squibb Co. Dr. Tihon holds a Ph.D. in Pathology from Columbia University.

John Mon. Mr. Mon has been employed by the Company since 1986, and has served as Treasurer and General Manager of the Company since 1989, and also as Secretary and a director since June 1997. During the first two years of his employment with the Company, Mr. Mon was responsible for the Company's FDA filings, which resulted in obtaining pre-marketing approval for the Microfocus 1000. From 1983 to 1986, he was an economist with the U.S. Department of Commerce in charge of forecasting business sales, inventory and prices for all business sectors in the estimation of Gross National Product. Mr. Mon holds a B.S. degree from the University of Maryland. Mr. Mon is the brother-in-law of Dr. Cheung.

Walter B. Herbst. Mr. Herbst has been a director of the Company since May 28, 1997. Mr. Herbst is the Chairman and a director of Herbst Lazar Bell, Inc., the engineering firm he founded in 1962. Mr. Herbst also serves as a faculty fellow in industrial design at the Northwestern University McCormick School of Engineering and Applied Sciences, teaching materials and process. Additionally, he serves on the faculty at Northwestern University's Kellogg Graduate School teaching a course in product development. Mr. Herbst holds a Bachelors Degree in Industrial Design from the University of Illinois and a Master Degree in Management from the Kellogg Graduate School of Northwestern University.

## **Committees of the Board of Directors**

The Board of Directors presently maintains an Audit Committee, a Compensation Committee, and a Research and Development Oversight Committee. The Audit Committee's principal responsibilities are to recommend annually a firm of independent auditors to the Board of Directors, to review the annual audit of the Company's Financial Statements and to meet with the independent auditors of the Company from time to time in order to review the Company's general policies and procedures with respect to audits and accounting and financial controls.

The principal responsibilities of the Compensation Committee are to establish compensation policies for the executive officers of the Company and the administration of the Company's incentive plans. The Research and Development Oversight Committee is responsible for reviewing the performance, scheduling and cost-effectiveness of the Company's research and development programs. Messrs. Mon and Tihon serve on the Audit Committee, Messrs. Volk and Herbst comprise the Compensation Committee, and Dr. Cheung and Mr. Herbst are the members of the Research and Development Oversight Committee.

## **Compensation Committee Interlocks and Insider Participation**

No interlocking relationship exists between the Compensation Committee or the Board of Directors and any other company's board of directors or compensation committee. Spencer J. Volk, President and Chief Executive Officer, is party to an employment agreement with the Company and has made loans and advances to the Company which were repaid through conversion into Common Stock. See "Certain Relationships and Related Transactions." The employment and compensation arrangements for Mr. Volk were established prior to the formation of the Compensation Committee. The Committee believes that Mr. Volk's compensation package aligns his interests with those of the stockholders. See "Employment Agreements" below.

## **Directors Compensation**

For the year ended September 30, 1999, the four members of the Board of Directors who are not officers of the Company were entitled to directors fees at the annual rate of \$20,000 each. In lieu of a cash payment of such directors fees, each outside director was paid in shares of Common Stock, valued at a price of \$0.88 per share, the closing price on September 30, 1999. Accordingly, Dr. Max E. Link and Walter B. Herbst each received 22,727 shares, while Dr. La Salle D. Leffall and Dr. Claude Tihon each received 7,576 shares reflecting pro-rated compensation for the service of Messrs. Leffall and Tihon as directors beginning May 27, 1999. In addition, Mr. Herbst received an option to purchase 15,000 shares of Common Stock of the Company at \$0.50 per share, exercisable during the period from October 1, 1999 through September 30, 2004, for prior service on the Board of Directors. The Company has agreed also that Dr. Link will receive an option to purchase 50,000 shares of Common Stock of the Company, exercisable at \$0.75 per share, which will vest if Dr. Link is still serving as a director after December 31, 1999 and will terminate on December 30, 2004, and that Dr. Tihon and Dr. Leffall will each receive options to purchase 50,000 shares, exercisable at \$0.74 per share, which will vest on May 27, 2000 (if each is then serving as a director) and will terminate May 26, 2005.

Officers of the Company who also act as directors each receive 2000 shares of Common Stock for a full year of service on the Board.

## **Key Consultant**

The Company regularly uses the services of Robert Barnett, M.D., as a consultant on matters relating to oncological surgery. Dr. Barnett, currently the Oncology Surveyor for the American College of Surgeons, holds an American Board of Surgery Diplomate, and is the former President of the Maryland Chapter of the American Cancer Society.

## **Scientific Advisory Board**

The Company currently has a scientific advisory board ("SAB") which is chaired by Dr. Cheung, the Company's Chief Scientific Officer, and is comprised of the persons listed below. The main purpose of the SAB is to assist management of the Company in identifying and developing technology trends and business opportunities within the Company's industry. The SAB members operate as consultants and not as officers or directors of the Company.

Donald Beard. Mr. Beard is a retired businessman and is the former senior program manager for the United States Department of Energy. Mr. Beard consults with the Company in connection with technology and business development matters.

Mark Dewhirst, Ph.D. Dr. Dewhirst currently serves as a Professor of Radiology and Oncology and the Director of the Tumor Microcirculation Laboratories in the Department of Radiation & Oncology at Duke University. Dr. Dewhirst consults with the Company in connection with research on temperature sensitive liposomes.

Gloria Li, Ph.D. Dr. Li currently serves as the Director of the Radiation Biology Laboratory at Memorial Sloan-Kettering Hospital. Dr. Li consults with the Company on heat shock and gene therapy.

Arnold Melman, M.D. Dr. Melman currently serves as the Chairman of the Department of Urology at Albert Einstein College of Medicine. Dr. Melman consults with the Company on clinical studies in urology and is the Company's primary investigator on BPH.

David Needham, Ph.D. Dr. Needham currently serves as the Director of Cell and Micro-carrier Research and as an Associate Professor in the Duke University Department of Mechanical Engineering and Materials Science. Dr. Needham consults with the Company in connection with research on temperature sensitive liposomes.

Thomas Ripley, Ph.D. Dr. Ripley currently serves as Director of Operations for the Grace Biomedical Division at W.R. Grace & Co. Dr. Ripley consults with the Company on technology and business development.

Mays Swicord, Ph.D. Dr. Swicord currently serves as Director of Research at Motorola, Inc. Dr. Swicord consults with the Company on the biological effects of microwave technology.

All members of the SAB serve at the discretion of the Board of Directors. Each member of the SAB, other than Dr. Cheung and Dr. Swicord, received an option to purchase 5,000 shares of the Common Stock of the Company at the time they were appointed. The options are exercisable for a five-year term at \$.50 per share. In addition, each member of the SAB will receive an option exercisable over a five-year term to purchase 3,000 shares of the Common Stock of the Company for each 12 months served by such member on the SAB, exercisable at the market price of the Common Stock on the date of grant. During fiscal year 1999, each member of the SAB, other than Messrs. Cheung and Swicord, received an option to purchase 3,000 shares of the Common Stock of the Company at \$0.74 per share. In addition, members of the SAB (except for Dr. Cheung) are compensated at the rate of \$125 per hour or a maximum of \$1,000 per day, together with expenses, on consulting matters undertaken by such member.

### **Company Performance and Chief Executive Officer Compensation**

The compensation of Spencer Volk was established prior to organization of the Compensation Committee. The Committee believes that Spencer Volk's compensation package aligns his interests with those of the stockholders.

### **Compliance with Section 16(a) of the Exchange Act**

Section 16(a) of the Securities Exchange Act of 1934 requires the Company's officers and directors, and persons who own more than ten percent of a registered class of the Company's equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange Commission and the National Association of Securities Dealers. Officers, directors and greater than ten-percent shareholders are required by Securities and Exchange Commission regulations to furnish the Company with copies of all Section 16(a) forms they file. Based solely on a review of the copies of such forms furnished to the Company between October 1, 1998 and September 30, 1999, and on discussions with directors and officers, the Company believes during the last fiscal year all applicable 16(a) filing requirements were met.

## **ITEM 11. EXECUTIVE COMPENSATION**

### **Executive Compensation**

The following table sets forth the aggregate cash compensation paid for services rendered to the Company in all capacities during each year of the three-year period ended September 30, 1998 to the Company's Chief Executive Officer and to each of the Company's other executive officers listed in Item 10 whose annual combined salary and bonus for the most recent fiscal year exceeded \$100,000 (the "Named Executive Officers").

Summary Compensation Table

Name and Principal Position	Fiscal Year	Annual Compensation			Long-Term Compensation		
		Salary (\$)	Bonus (\$)	Other Annual Compensation (\$)	Awards		All Other Compensation (\$)
					Restricted Stock Awards (\$)	Stock Options (#)	
Spencer J. Volk, President and Chief Executive Officer	1999	\$240,000			\$ 1,760 (1)		
	1998	\$240,000			\$700,640 (1)(2)		
	1997	\$ 96,923 (3)			\$281,995 (1)(2)		
Augustine Y. Cheung, Chairman of the Board of Directors	1999	\$180,000			\$ 1,760 (1)		
	1998	\$125,000			\$ 640 (1)		
	1997	\$125,000			\$ 2,120 (1)		
John Mon Treasurer, Secretary, and General Manager	1999	\$90,000			\$ 28,760 (1)		
	1998	\$78,000			\$ 640 (1)		
	1997	\$78,000			\$ 844 (1)		

(1) In each of fiscal years 1997, 1998 and 1999, Dr. Cheung received 2,000 shares of the Common Stock of the Company for his services as a member of the Board of Directors of the Company. For his service on the Board, Mr. Volk received 701 shares of Common Stock for fiscal year 1997 and 2,000 shares of Common Stock for fiscal year 1998 and 1999. John Mon received 2,000 shares of Common Stock of the company for his services as a member of the Board of Directors in each of fiscal years 1997, 1998, and 1999. In the past fiscal year, John Mon also received a one-time bonus of 100,000 shares of the Common Stock of the Company for his services as an employee of the company.

(2) Pursuant to his 1997 employment agreement, Mr. Volk was granted 500,000 shares of Common Stock in fiscal year 1997 and has the right to receive up to 1,400,000 additional shares of the Common Stock of the Company if the Company meets certain financing goals during his tenure and if he is employed by the Company after one year. As of September 30, 1999, Mr. Volk had received 1,000,000 shares of such amount. See "Executive Employment Agreements."

(3) Reflects compensation for a portion of the fiscal year; Mr. Volk became President and Chief Executive Officer of the Company on May 11, 1997.

#### Aggregate Option Exercises and Year-End Option Values in 1999

The following table summarizes for each of the Named Executive Officers the number of stock options held at September 30, 1999 and the aggregate dollar value of in-the-money unexercised options. The value of unexercised, in-the-money options at September 30, 1999 is the difference between exercise price and the fair market value of the underlying stock on September 30, 1999, which was \$0.88 per share based on the closing price of the Common Stock of the Company on September 30, 1999. The options described have not been and may never be exercised, and actual gains, if any, on exercise will depend on the value of the Common Stock of the Company on the actual date of exercise. No options were exercised by any Named Executive Officer in fiscal 1999.

Name	Shares Acquired on Exercise	Value Realized	Number of Unexercised		Value of Unexercised	
			Options at		In-the-Money Options at	
			Exercisable	Unexercisable	Exercisable	Unexercisable
			9/30/99		9/30/99	
		(\$)				
Augustine Y. Cheung	0	\$0	400,000	0	\$252,000	\$0
Spencer J. Volk	0	\$0	0	0	\$0	\$0
John Mon	0	\$0	600,000	0	\$378,000	\$0

### Stock Option Plans

At the annual meeting held on April 27, 1998, the stockholders approved an omnibus stock option plan. The plan commits up to 2,000,000 shares for option grants to directors, employees and consultants. The Company has agreed to allow Spencer J. Volk to recommend the recipients of options for up to 1,570,000 shares under the option plan, to be reviewed by the Board of Directors. To date, options for a total of 190,000 of such shares have been granted upon the recommendation of Mr. Volk.

### Executive Employment Agreements

In May 1997, the Company and Spencer J. Volk, President and Chief Executive Officer, entered into a one-year executive employment agreement, automatically renewable annually unless terminated by either party at least 90 days prior to the end of each one-year period. The agreement provides for an annual salary of \$240,000, which was to be increased to at least \$360,000 upon the Company's successful raising of an aggregate of at least \$5,000,000 in additional capital. In addition, under the provisions of the agreement, Mr. Volk was awarded incentive compensation of 500,000 shares of Common Stock at commencement and had the right to receive up to an additional 1,400,000 shares based on the Company's increased capital base and Mr. Volk's continued employment. As of September 30, 1999, Mr. Volk had received only 1,000,000 of such additional shares and had agreed, at the request of the Company to defer the issuance of the remaining 400,000 shares to a later date. In addition, and at the further request of the Company, Mr. Volk agreed to waive any salary increase due him for any period prior to September 30, 1999.

With regard to such 400,000 shares, on November 11, 1999, Mr. Volk agreed to waive his right under his existing employment agreement to receive such shares, in consideration of (i) the Company's concurrent grant to him of an option to purchase 400,000 shares of restricted Common Stock at a price equal to two-thirds of the average closing price of Common Stock during the prior three trading days (which closing price amounted to approximately \$.75 per share) and (ii) the Company's issuance to him of 100,000 shares of Common Stock at a price of \$.01 per share prior to February 15, 2000.

Also, in order to provide for continuity and stability of management at a critical point in the development of the Company's business, the Company has requested that Mr. Volk enter into a new three-year employment agreement in place of his existing annually renewable agreement, and that Augustine Y. Cheung, Chairman and Chief Scientific Officer, also enter into a three-year employment agreement, such agreements to be concluded by approximately January 10, 2000. Mr. Volk has consented to terminate his existing agreement and to enter into a new agreement.

at an initial annual salary of \$240,000, with future increases to be commensurate with those set forth in his existing agreement, if his new contract contains bonus and performance-based option terms substantially similar to those being negotiated in connection with Dr. Cheung's pending employment agreement.

The Company and Dr. Cheung have been negotiating the terms of a three-year executive employment agreement, which is expected to be signed and to commence in January 2000. The agreement will provide for a salary of \$240,000 per year, except that, until a final closing of the Company's next financing, Dr. Cheung's salary installments will be computed and paid at his former salary rate of \$180,000, with the unpaid salary differential to be accrued as a Company obligation to Dr. Cheung and to be paid when the Company's working capital position permits. Such employment agreement will also provide that, as a form of annual bonus, Dr. Cheung will be permitted to purchase shares of Common Stock at a nominal price equal to par value (\$.01 per share), in three separate installments of 100,000 shares each, with the first installment to be purchasable after March 15, 2000, the next installment after October 1, 2001, and the final installment after October 1, 2002. The annual bonus shares will be subject to restrictions on transfer for a minimum period of two years, and each installment will be purchasable only if Dr. Cheung continues to be employed by the Company on the applicable installment date. Furthermore, the employment agreement will provide for the issuance in installments, during the term of employment, of performance-based options to purchase up to a maximum aggregate limit of 700,000 shares of Common Stock, at exercise prices ranging from a low of \$.80 to a high of \$1.60 per share, on achieving five significant corporate milestones. An option for a specified portion of the incentive shares would become issuable and exercisable only after reaching various, specific performance objectives, such as obtaining final FDA approval for Company products, consummating alliances with strategic marketing and distribution partners, and attaining annual pre-tax earnings of at least \$1,000,000 for the Company.

The new agreements for each executive will provide for continued payment of salary and benefits during the full terms of the agreements in the event of a change of control of the Company. A change of control is defined as a merger, asset sale, tender offer or other substantial change in voting control, or the election of a new majority of the Board of Directors or of three or more directors whose election is opposed by a majority of the Board. In addition, the agreements will provide for restrictive covenants and for confidentiality and other protections in the form generally included in employment agreements for senior management.

Other than as set forth above, there are no employment contracts, termination of employment or change in control arrangements.

### **Report of the Compensation Committee on Executive Compensation**

The Company formed a Compensation Committee in June 1997, consisting of Spencer J. Volk, President and Chief Executive Officer and a director, and Walter Herbst, a non-employee director. The Committee is responsible for establishing and administering the compensation policies applicable to the Company's officers and key personnel. The Committee's responsibilities include, establishing general compensation policy and recommending compensation arrangements to the Board of Directors. The Committee also evaluates the performance of and makes compensation recommendations for senior management.

The Committee and the Board have adopted the following executive compensation approaches:

## **Executive Compensation Philosophy**

The Company attempts to design executive compensation to achieve two principal objectives. First, the program is intended to be fully competitive so that the Company may attract, motivate and retain talented executives. Second, the program is intended to create an alignment of interests between the Company's executives and stockholders such that a significant portion of each executive's compensation varies with business performance.

The Committee's philosophy is to pay competitive annual salaries, coupled with an incentive system which, through stock compensation, that pays more than competitive total compensation for superior performance reflected in increases in the Company's stock price.

Based on assessments by the Board and the Committee, the Committee believes that the Company's compensation program for its senior executive officers has the following characteristics that serve to align executive interests with long-term stockholder interests:

- \* Emphasizes "at risk" pay such as options and grants of restricted stock;
- \* Emphasizes long-term compensation through options and restricted stock awards; and
- \* Rewards financial results and promotion of Company objectives rather than individual performance against individual objectives.

### **Annual Salaries**

Salary ranges and increases for executives are established annually (unless subject to longer term contracts) based on competitive data. Within those ranges, individual salaries vary based upon the individual's work experience, performance, level of responsibility, impact on the business, tenure and potential for advancement within the organization. Annual salaries for newly-hired executives are determined at time of hire taking into account the above factors other than tenure.

### **Long-Term Incentives**

The grant of restricted stock or options to key employees encourages equity ownership and closely aligns management interests with the interests of stockholders. The amount and nature of any option or restricted stock award is determined by the Committee on a case by case basis, depending upon the individual's perceived future benefit to the Company and the perceived need to provide additional incentive to align performance with the objectives of the shareholders.

## **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth information regarding shares of voting securities of the Company beneficially owned as of September 30, 1999, determined in accordance with Rule 13d-3 under the Securities Exchange Act of 1934, by: (i) each person known by the Company to beneficially own 5% or more of the outstanding voting securities; (ii) by each current director, (iii) by each

current executive officer and (iv) by all current directors and executive officers of the Company as a group.

Name and Addresses of Officers, Directors and Principal Shareholders	Amount of Common Shares	Percentage of Voting Securities(1)
Augustine Y. Cheung (2)	7,031,176	13.2%
Spencer J. Volk (3)	2,795,485	5.2%
John Mon (4)	1,008,288	1.9%
Walter B. Herbst (5)	326,595	**
Max E. Link (6)	184,765	**
LaSalle D. Leffall, Jr.	7,576	**
Claude Tihon (7)	18,576	**
Executive Officers and Directors as a group (7 individuals)	11,346,309	21.3%
** Less than 1%.		

(1) Except as noted, the above table does not give effect to outstanding options and warrants for the purchase of approximately 16,653,770 shares of Common Stock. Outstanding options and warrants do not carry voting rights.

(2) Includes 400,000 shares purchasable under an option exercisable through May 16, 2001.

(3) Does not include an additional 400,000 shares of Common Stock that may be earned by Mr. Volk pursuant to his employment agreement upon the occurrence of certain events. See "Management-Executive Employment Agreements." Includes 100,000 shares of Common Stock purchasable under a warrant exercisable through December 10, 2001.

(4) Includes 400,000 shares of Common Stock purchasable under an option exercisable through May 16, 2001 and 200,000 shares of Common Stock purchasable under an option exercisable through March 31, 2002.

(5) Includes options to purchase an aggregate of 115,000 shares of Common Stock exercisable during various periods through September 30, 2004. Does not include options to purchase 20,000 shares of Common Stock exercisable through October 30, 2002, and 1,322,898 shares of Common Stock, both owned by Herbst, Lazar, Bell, Inc. ("HLB"), a company of which Mr. Herbst is a director. Mr. Herbst disclaims beneficial ownership of the options and shares of Common Stock owned by HLB.

(6) Includes an option to purchase 50,000 shares of Common Stock exercisable through December 31, 2003 and an option which vests as to the purchase of 50,000 shares of Common Stock on December 31, 1999.

(7) Includes options to purchase 11,000 shares of Common Stock exercisable through May 15, 2003.

The address of each of the named principal stockholders is c/o Celsion Corporation, 10220-I Old Columbia Road, Columbia, MD 21046-1705

## **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

### **Compensation to Warren C. Stearns**

Warren C. Stearns, a former director and financial consultant to the Company, was previously engaged to provide services to Celsion for a two-year period beginning May 1996 under a consulting agreement between Celsion and Mr. Stearns' company, SMC. Pursuant to the agreement, Mr. Stearns was to perform various services related to financing and capital structure, including locating and soliciting sources of funding for Celsion. In consideration for such services, the agreement provided for the issuance to SMC's designees of five-year warrants (the "Stearns Warrants") to purchase approximately 4.8% of the Company's Common Stock at an initial exercise price of \$0.41 per share, subject to anti-dilution provisions intended to maintain such equity interest and to a provision permitting renewal of the Stearns Warrants for an additional period of five-years. Such warrants were issued but have not been exercised. Also, SMC was paid approximately \$266,666 in cash compensation and \$38,824 for reimbursement of expenses during the 1997 fiscal year and approximately \$95,297 for additional compensation and expenses in the 1998 fiscal year. At the time Mr. Stearns resigned, the Company agreed to settle, for \$100,000, claims which he made for additional consulting fees and expenses, and such amount was subsequently paid.

On the basis of a review of the circumstances surrounding the issuance of the Stearns Warrants and the consulting agreement between SMC and the Company, the Company believes that the issuance of the Stearns Warrants may be a voidable transaction under provisions of the Securities Exchange Act of 1934. While the Company has commenced discussions with Mr. Stearns in order to seek an amicable settlement without litigation, the Company is prepared to contest the Stearns Warrants if settlement efforts are not successful.

### **George T. Horton Trust Loan**

The Company was obligated under a secured note to the George T. Horton Trust in the original principal amount of \$220,000, which bore interest at 1% per month, was payable December 15, 1997, and was secured by certain equipment and software. The George T. Horton Trust is a part equity owner of SMC. In full satisfaction of such note, the Company paid \$120,000 and issued 200,000 shares of the Common Stock.

### **HLB**

The Company previously used the services of HLB, an engineering firm, to assist in the development of commercial versions of its new breast cancer and BPH treatment systems. Walter B. Herbst, a director of the Company, was the founder and is a director of HLB. In the 1998 fiscal year, HLB billed the Company \$561,238 for extensive engineering and design work it performed, on terms which, in the judgment of the Board of Directors, were comparable to terms which would be available from a non-affiliated vendor. Of this amount, HLB was paid \$106,500 in cash, and on September 23, 1998, HLB converted \$250,000 of the amount owed into 833,334 shares of restricted Common Stock at the then market price of \$.30 per share. On June 16, 1999 HLB converted the remaining balance of \$204,738 into 409,476 shares of restricted Common Stock at \$.50 a share.

Promissory Notes and Conversions into  
Common Stock; Purchase of Common Stock

From 1987 through 1998, the Company borrowed sums needed for working capital at various times from related parties, and issued promissory notes as follows:

A note dated January 26, 1987 payable to Dr. Augustine Cheung, accruing interest at the rate of twelve percent (12%) per annum, in the principal amount of \$78,750 due December 31, 1998.

A note dated June 30, 1994 payable to Dr. Augustine Cheung, accruing interest at the rate of ten percent (10%) per annum, in the principal amount of \$42,669 due December 31, 1998.

A note dated June 23, 1998 payable to Spencer J. Volk, accruing interest at the rate of eight percent (8%) per annum, in the principal amount of \$50,000 due September 30, 1998.

All of such notes and accrued interest have been converted into Common Stock at prices equal to fair market value at the time of conversion. In addition to conversion of the foregoing notes, on September 23, 1998, Mr. Volk converted \$50,134 of amounts owed him by the Company for unpaid expense reimbursements into 167,114 shares of the Common Stock at \$0.30 per share.

On June 16, 1999 the various officers converted accrued salary payable to them into restricted Common Stock as follows. Spencer J. Volk converted \$289,884 into 579,768 shares at \$ .50 a share. Dr. Augustine Cheung converted \$177,884 into 355,768 shares at \$ .50 a share. John Mon converted \$68,538 into 137,076 shares.

On June 3, 1997, Spencer J. Volk purchased 243,902 shares of restricted Common Stock at a price of \$.41 per share or a total of \$100,000, paid by Mr. Volk to the Company. The funds were intended as working capital, and were primarily used to pay Mr. Volk's salary under his employment agreement. At the time of the purchase, the Company was conducting a private placement of 8% Convertible Notes, convertible at \$.41 per share, and consummated the sale of \$1,505,000 aggregate principal amount of such Notes to investors.

Agreement with Gao Yu Wen

On February 16, 1995, Gao Yu Wen executed a subscription agreement with the Company to purchase 20,000,000 shares of Common Stock at \$0.50 per share or a total of \$10,000,000. This amount was paid \$2,000,000 in cash and by transferring to the Company 9.5% of the outstanding equity of Aestar Fine Chemical Company ("Aestar"), valued at \$8,000,000 by the parties based on Aestar's assets, revenues and earnings.

In 1996, the Company and Mr. Gao entered into agreements under which the Company returned all of its shares in Aestar to Mr. Gao and Gao returned 16,000,000 out of the 20,000,000 shares of the Company's Common Stock originally purchased by him, and the Company received the right to repurchase the remaining four million shares for \$2.2 million, which the Company did not elect to exercise.

In a related transaction, on April 26, 1995, the Company entered into an Investment Agreement with Mr. Gao whereby the Company transferred \$700,000 to Gao to invest as agent of the Company at the rate of no less than 17% per annum. Mr. Gao repaid \$190,000 by September 30, 1996. The balance owed to the Company by Mr. Gao was offset against a claim by Mr. Gao and Aestar for \$470,000 advanced them to start a cosmetics division with the Company, which was abandoned.

### **Rescission of Ardex Acquisition**

On or about March 31, 1995, the Company paid \$400,000 to Ardex Equipment, LLC ("Ardex") and \$50,000 to Charles C. Shelton and Joseph Colino in exchange for an aggregate 19.25% interest in Ardex. At the time Messrs. Shelton and Colino were directors of Celsion. In 1996, the Company received a \$50,000 distribution from Ardex.

On August 2, 1996, the Company and Ardex entered into an agreement rescinding the Company's investment in Ardex (the "Rescission Agreement"). Pursuant to the Rescission Agreement, the Company was to receive a 5-year negotiable promissory note for \$350,000 bearing interest at 8% per annum. Interest only was to be paid until the principal became due. Principal was due upon the first of the following events to occur: (i) completion of public or private offerings by Ardex in the aggregate of \$1,500,000 or more; (ii) 90 days following the year end in which sales have been or exceed \$3,000,000; (iii) Ardex having a cash balance of \$800,000 or more from operations; or (iv) five years from the date of the note. The note was to be secured by a limited guarantee of Charles C. Shelton, Joseph Colino and John Kohlman but only to the extent of their interest in Ardex and their options in the Company. In addition, Messrs. Shelton, Colino and Kohlman were to deliver their personal promissory notes for a total of \$50,000.

The terms of the Rescission Agreement were not performed by Ardex and Messrs. Shelton, Colino and Kohlman, and Celsion was advised by Ardex and such persons that they could not honor the terms of the Rescission Agreement because Ardex had not been successful and the Ardex individuals were in financial difficulties. The Company is no longer continuing with its efforts to obtain the documents contemplated by the Rescission Agreement.

On September 30, 1998, the Company and Charles Shelton entered into a settlement agreement pursuant to which the Company released any claims against Mr. Shelton and Mr. Shelton waived his right to an option to purchase 420,000 shares of the Common Stock of the Company at a price of \$.35 per share and his claim for approximately \$110,000 against the Company in exchange for 50,000 shares of Common Stock of the Company. At the time of such settlement, the Company's shares were trading at a price of approximately \$.30 per share.

**PART IV**

**ITEM 14. EXHIBITS, FINANCIAL STATEMENTS,  
SCHEDULES AND REPORTS ON FORM 8-K**

(a)(1) Index to Financial Statements and Supplemental Schedules

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Statements of Operations	F-6
Statements of Changes in Stockholders' Equity	F-7
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**CELSION CORPORATION**

**REPORT ON AUDITS OF  
FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED  
SEPTEMBER 30, 1999, 1998 AND 1997**

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## INDEPENDENT AUDITORS' REPORT

The Board of Directors and Stockholders  
Celsion Corporation  
Columbia, Maryland

We have audited the accompanying balance sheets of Celsion Corporation as of September 30, 1999 and 1998, and the related statements of operations, changes in stockholders' equity (deficit), and cash flows for each of the three years in the period ended September 30, 1999. 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 generally accepted auditing standards. 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 September 30, 1999 and 1998, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 1999 in conformity with generally accepted accounting principles.

*/s/ Stegman & Co.*  
-----  
*Stegman & Co.*  
*Baltimore, Maryland*  
*November 1, 1999*

**CELSION CORPORATION**

**BALANCE SHEETS  
SEPTEMBER 30, 1999 AND 1998**

**ASSETS**

	1999	1998
	-----	-----
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$1,357,464	\$ 54,920
Accounts receivable - trade	1,812	1,812
Inventories	22,059	42,059
Prepaid expenses	3,520	76,944
Other current assets	39,203	--
	-----	-----
Total current assets	1,424,058	175,735
	-----	-----
<b>PROPERTY AND EQUIPMENT - at cost:</b>		
Furniture and office equipment	203,156	195,794
Laboratory and shop equipment	47,983	47,048
	-----	-----
	251,139	242,842
Less accumulated depreciation	224,874	212,029
	-----	-----
Net value of property and equipment	26,265	30,813
	-----	-----
<b>OTHER ASSETS:</b>		
Patent licenses (net of accumulated amortization of \$81,589 and \$65,760 in 1999 and 1998,		
respectively)	108,361	124,190
	-----	-----
<b>TOTAL ASSETS</b>	<b>\$1,558,684</b>	<b>\$ 330,738</b>
	=====	=====

See accompanying notes.

LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)

	1999	1998
	-----	-----
CURRENT LIABILITIES:		
Accounts payable - trade	\$ 130,792	\$ 1,034,767
Notes payable ? other	114,778	132,778
Notes payable - related parties	10,000	146,041
Accrued interest payable - related parties	13,800	150,020
Accrued interest payable - other	155,373	127,538
Accrued compensation	91,009	470,220
Accrued professional fees	--	100,000
Other accrued liabilities	88	13,639
Capital lease ? current	1,292	1,083
	-----	-----
Total current liabilities	517,132	2,176,086
LONG-TERM LIABILITIES:		
Capital lease ? long-term	4,427	5,719
	-----	-----
Total liabilities	521,559	2,181,805
	-----	-----
STOCKHOLDERS' EQUITY (DEFICIT):		
Common stock - \$.01 par value; 100,000,000 shares authorized, 53,370,498 and 39,945,826 issued and outstanding for 1999 and 1998, respectively	533,705	399,458
Additional paid-in capital	22,403,622	17,213,485
Accumulated deficit	(21,900,202)	(19,464,010)
	-----	-----
Total stockholders' equity (deficit)	1,037,125	(1,851,067)
	-----	-----
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	\$ 1,558,684	330,738
	=====	=====

See accompanying notes.

CELSION CORPORATION  
STATEMENTS OF OPERATIONS  
FOR THE YEARS ENDED SEPTEMBER 30, 1999, 1998 AND 1997

	1999	1998	1997
	-----	-----	-----
REVENUES:			
Equipment sales and parts	\$       --	\$   174,182	\$   121,257
Returns and allowances	--	--	--
	-----	-----	-----
Total revenues	--	174,182	121,257
COST OF SALES	--	136,500	46,734
	-----	-----	-----
GROSS PROFIT	--	37,682	74,523
	-----	-----	-----
OPERATING EXPENSES:			
Selling, general and administrative	1,371,161	2,515,822	2,283,245
Research and development	1,019,941	1,534,872	185,974
	-----	-----	-----
Total operating expenses	2,391,102	4,050,694	2,469,219
	-----	-----	-----
LOSS FROM OPERATIONS	(2,391,102)	(4,013,012)	(2,394,696)
LOSS ON FUNDS HELD IN INVESTMENT CONTRACT	--	--	(40,000)
LOSS ON WRITE-OFF OF ARDEX EQUIPMENT, L.L.C. NOTES RECEIVABLE AND RELATED ACCRUED INTEREST RECEIVABLE	--	--	(438,803)
OTHER INCOME	15,744	11,870	7,172
INTEREST EXPENSE	(60,834)	(199,346)	(185,562)
	-----	-----	-----
LOSS BEFORE INCOME TAXES	(2,436,192)	(4,200,488)	(3,051,889)
INCOME TAXES	--	--	--
	-----	-----	-----
NET LOSS	\$ (2,436,192)	\$ (4,200,488)	\$ (3,051,889)
	=====	=====	=====
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$       (.05)	\$       (.12)	\$       (.11)
	=====	=====	=====
BASIC AND DILUTED WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	45,900,424	34,867,001	28,386,145
	=====	=====	=====

See accompanying notes.

CELSION CORPORATION

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)  
FOR THE YEARS ENDED SEPTEMBER 30, 1999, 1998 AND 1997

	Common Stock		Additional	Deficit	Total
	Shares	Amount	Paid-In Capital		
Balances at October 1, 1996	41,206,360	\$ 412,063	\$ 18,555,444	\$(12,211,633)	\$ 6,755,874
Sale of common stock	1,409,902	14,099	668,901	--	683,000
Issuance of 2,479,071 shares of common stock as payment of indebtedness and expenses	2,479,071	24,791	1,127,578	--	1,152,369
Retirement of shares	(16,000,000)	(160,000)	(7,840,000)	--	(8,000,000)
Net loss	--	--	--	(3,051,889)	(3,051,889)
Balances at September 30, 1997	29,095,333	290,953	12,511,923	(15,263,522)	(2,460,646)
Sale of common stock	4,315,000	43,150	1,981,850	--	2,025,000
Issuance of 6,535,493 shares of common stock as payment of indebtedness and expenses	6,535,493	65,355	2,719,712	--	2,785,067
Net loss	--	--	--	(4,200,488)	(4,200,488)
Balances at September 30, 1998	39,945,826	399,458	17,213,485	(19,464,010)	(1,851,067)
Sale of common stock	9,545,500	95,455	3,517,420	--	3,612,875
Issuance of 3,879,172 shares of common stock as payment of indebtedness and expenses	3,879,172	38,792	1,672,717	--	1,711,509
Net loss	--	--	--	(2,436,192)	(2,436,192)
Balances at September 30, 1999	53,370,498	\$ 533,705	\$ 22,403,622	\$(21,900,202)	\$ 1,037,125

See accompanying notes.

CELSION CORPORATION

STATEMENTS OF CASH FLOWS  
FOR THE YEARS ENDED SEPTEMBER 30, 1999, 1998 AND 1997

	1999	1998	1997
	-----	-----	-----
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$(2,436,192)	\$(4,200,488)	\$(3,051,889)
Noncash items included in net loss:			
Funds held under investment contract used for cosmetic division expenses	--	--	40,000
Depreciation and amortization	28,674	24,291	24,169
Bad debt expense	--	--	120,865
Loss on disposal of property and equipment	--	45,180	--
Inventory valuation	20,000	287,682	--
Write-off of Ardex Equipment - note receivable and accrued interest	--	--	438,803
Common stock issued for operating expenses	200,304	796,745	297,542
Net changes in:			
Accounts receivable	--	4,079	
Inventories	--	--	(58,789)
Accrued interest receivable - related parties	--	--	(33,470)
Prepaid expenses	73,424	5,430	--
Other current assets	(21,594)	10,085	--
Accounts payable and accrued interest payable	(223,255)	903,900	837,172
Accrued compensation	189,239	168,732	145,256
Accrued professional fees	(100,000)	(156,300)	179,950
Other accrued liabilities	(13,551)	(1,865)	(85,401)
	-----	-----	-----
Net cash used in operating activities	(2,282,951)	(2,112,529)	(1,154,751)
	-----	-----	-----
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of patent licenses	--	(10,000)	--
Purchase of property and equipment	(8,297)	(21,935)	(3,807)
	-----	-----	-----
Net cash used in investing activities	(8,297)	(31,935)	(3,807)
	-----	-----	-----
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from notes payable	--	50,000	615,000
Payment on notes payable - related parties	--	(63,240)	(24,020)
Payment on notes payable - other	(18,000)	(79,254)	(95,000)
Payment on capital lease obligation	(1,083)	(475)	--
Proceeds of stock issuances	3,612,875	2,025,000	683,000
	-----	-----	-----
Net cash provided by financing activities	3,593,792	1,932,031	1,178,980
	-----	-----	-----
NET INCREASE (DECREASE) IN CASH	1,302,544	(212,433)	20,422
CASH AT BEGINNING OF YEAR	54,920	267,353	246,931
	-----	-----	-----
CASH AT END OF YEAR	\$ 1,357,464	\$ 54,920	\$ 267,353
	=====	=====	=====

Celsion Corporation

Statements of Cash Flows (Continued)  
 For the Years Ended September 30, 1999, 1998 and 1997

	1999	1998	1997
	-----	-----	-----
Schedule of noncash investing and financing transactions:			
Rescission of a 9.5% interest in the Aestar Fine Chemical Company in exchange for 16,000,000 shares of common stock	\$ -- =====	\$ -- =====	\$ (8,000,000) =====
Conversion of accounts payable, debt and accrued interest payable through issuance of common stock	\$ 1,511,205 =====	\$ 1,988,322 =====	\$ 854,826 =====
Equipment reacquired for internal use	\$ -- =====	\$ -- =====	\$ 30,000 =====
Acquisition of equipment:			
Cost of equipment	\$ --	\$ 7,277	\$ --
Capital lease payable	--	(7,277)	--
	-----	-----	-----
Cash down payment for equipment	\$ -- =====	\$ -- =====	\$ -- =====
Payment on notes payable:			
Decrease in notes payable	\$ --	\$ 16,670	\$ --
Offset of accounts receivable	--	(16,670)	--
	-----	-----	-----
Net cash paid	\$ -- =====	\$ -- =====	\$ -- =====
Cash paid during the year for interest	\$ 21,356 =====	\$ 103,470 =====	\$ -- =====

See accompanying notes.

# CELSION CORPORATION

## NOTES TO FINANCIAL STATEMENTS FOR THE YEARS ENDED SEPTEMBER 30, 1999, 1998 AND 1997

### 1. DESCRIPTION OF BUSINESS

Celsion Corporation (the "Company") was incorporated in the State of Maryland in 1982 under the name A.Y. Cheung Associates, Inc. The Company changed its name to Cheung Laboratories, Inc. on June 30, 1984 and to Celsion Corporation on May 1, 1998. The Company is a biomedical research and development company headquartered in Columbia, Maryland, dedicated to creating and marketing medical treatment systems for cancer, benign prostatic hyperplasia and other diseases using focused heat energy.

### 2. 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 thermotherapy systems and applications for submission to the Food and Drug Administration. The Company believes these expenditures are essential for the commercialization of its technologies. The Company has experienced significant operating losses and as of September 30, 1999 had an accumulated deficit of approximately \$21 million. The Company expects such operating losses to continue and possibly increase 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 successfully obtain governmental approvals, produce, market and sell its new technology and integrate such technology into its thermotherapy systems. The Company has not been able to successfully market its older thermotherapy cancer treatment system because of its inability to provide heat treatment for other than surface and sub-surface tumors. There can be no assurance that the Company will be able to successfully commercialize its newer technology 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 from quarter to quarter in the future and will depend on a number of factors, many of which are outside the Company's control.

The Company's dependence on raising additional capital will continue at least until the Company is able to begin marketing its new technologies. The Company's future capital requirements and the adequacy of its financing depend upon numerous factors, including the successful commercialization of the thermotherapy systems, progress in its product development efforts, progress with preclinical 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 its products. The Company will be required to obtain such funding through equity or debt financing, strategic alliances with corporate partners and others, or through other sources not yet identified. The Company does not have any committed sources of additional financing, and cannot guarantee that additional funding will be available on acceptable terms, if at all. If adequate funds are not available, the Company may be required to delay, scale-back or eliminate certain aspects of its

operations or attempt to obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, product candidates, products or potential markets.

### 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### **Cash and Cash Equivalents**

The Company classifies highly liquid investments with original maturities of 90 days or less to be cash equivalents. Cash equivalents are stated at cost, which approximates market value.

#### **Inventories**

Inventories are stated at the lower of cost or market. Cost is determined using the average cost method.

#### **Property and Equipment**

Property and equipment is stated at cost. Depreciation is provided over the estimated useful lives of the related assets of three to seven years using the straight-line method. Major renewals and betterments are capitalized at cost and ordinary repairs and maintenance are charged against operations as incurred. Depreciation expense was \$12,845, \$11,910 and \$8,119 for the years ended 1999, 1998 and 1997, respectively.

#### **Patent Licenses**

The Company has purchased several licenses to use the rights to patented technologies. Patent license costs are amortized straight-line over the remaining patent life.

#### **Revenue Recognition**

Revenue is recognized when systems, products or components are shipped and when consulting services are rendered. Deferred revenue is recorded for customer deposits received on contingent sale agreements.

#### **Research and Development**

Research and development costs are expensed as incurred. Equipment and facilities acquired for research and development activities which 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 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 anti-dilutive.

#### **Non-monetary Transactions**

Non-monetary transactions are accounted for in accordance with Accounting Principles Board Opinion No. 29 "Accounting for Non-monetary

Transactions" which requires that the transfer or distribution of a non-monetary 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 generally accepted accounting principles 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.

### **Financial Institutions**

For most financial instruments, including cash, accounts payable and accruals, management believes that the carrying amount approximates fair value, as the majority of these instruments are short-term in nature.

#### 4. INVENTORIES

Inventories are comprised of the following:

	1999	1998
	-----	-----
Materials	\$ 5,059	\$ 5,059
Finished products	17,000	37,000
	-----	-----
	\$22,059	\$42,059
	=====	=====

During the year ended September 30, 1998, management completed a thorough review of all its components inventory. As a result of this review the Company identified and wrote off approximately \$287,000 of parts and components inventory acquired in the course of developing older equipment now considered to be obsolete. This includes approximately \$175,000 of components and parts acquired in the course of developing the Company's older equipment, which was deemed unusable in the Company's newer models that incorporate advanced microwave technology, and \$112,000 of replacement parts inventory for older equipment sold in prior years by the Company which was determined to have no appreciable market value because of absence of demand. The write off of \$175,000 is included in research and development expenses and the write off of \$112,000 is included in operating expenses. During the year ended September 30, 1999 an additional \$20,000 reduction was made to the carrying value of the inventory account. The write-off is included in operating expense.

## 5. RELATED PARTY TRANSACTIONS

### Note Payable - Related Parties

Note payable to related parties as of September 30 are comprised of the following:

	1999 -----	1998 -----
Demand note payable to relative of an officer and stockholder of the Company, accruing interest at 12% per annum	\$ --	\$ 36,041
Term notes payable to interested parties of the Company accruing interest at 12% per annum	10,000	10,000
Term note payable to an officer and stockholder of the Company accruing interest at 8% per annum	--	50,000
Term note payable to stockholder of the Company accruing interest at 10% per annum payable in monthly payments of \$2,000 for 25 months. The note is secured by all accounts receivable and general intangibles of the Company	--	50,000
	-----	-----
Less current portion	10,000	146,041
	-----	-----
Long-term portion - due in 1998	\$ --	\$ --
	=====	=====

Accrued interest payable on these notes amounted to \$13,800 and \$150,020 at September 30, 1998 and 1997, respectively.

### **Stock Based Compensation Plan**

As part of the Company's employment agreement with its current chief executive officer (CEO), the Company has granted to the CEO 1,900,000 shares of the Company's capital stock which vests in certain milestones throughout the term of employment. The shares become fully vested provided that the CEO remains with the Company through the term of the contract. Under the Plan there was no compensation expense recognized in the year ended September 30, 1999, and \$699,375 and \$280,000 of compensation expense was recognized in the years ended September 30, 1998 and 1997, respectively.

## 6. NOTES PAYABLE - OTHER

Notes payable - other consist of the following as of September 30:

	1999 -----	1998 -----
Term note with interest accruing at 24% per annum, compounded monthly. The note matured April 30, 1996	\$114,778	\$114,778
Term note with accrued interest payable each month at 12% per annum. The note was secured by inventory and property. The note matured December 18, 1997	--	18,000
	-----	-----
	\$114,778	\$132,778
	=====	=====

Accrued interest payable on these notes amounted to \$155,373 and \$127,538 at September 30, 1999 and 1998, respectively.

## 7. RETIREMENT PLAN

The Company provides a SAR-SEP savings plan to which eligible employees may make pretax payroll contributions up to 15% of compensation. The Company does not make contributions to the plan.

## 8. INVESTMENT IN AESTAR FINE CHEMICAL COMPANY - AT COST

During 1995, the Company acquired a 9.5% equity interest in Aestar Fine Chemical Company (Aestar) in exchange for 16,000,000 shares of its common stock. The investment was carried at cost, as measured by the \$.50 per share fair market value of the 16,000,000 shares of the Company's common stock. The Company subsequently rescinded this investment during the year ended September 30, 1997 by exchanging its interest in Aestar for the 16,000,000 shares of its common stock.

## 9. INVESTMENT IN ARDEX EQUIPMENT, L.L.C. - AT EQUITY

The Company purchased a 19.25% equity interest in Ardex Equipment, L.L.C. (Ardex) during the year ended September 30, 1995. The investment was carried at cost, adjusted for the Company's proportionate share of Ardex's loss from the purchase date through September 30, 1995. During the year ended September 30, 1996, the Company agreed to rescind its purchase of the interest in Ardex through the conversion of its equity investment into a note receivable from Ardex and its principals, a conversion which did not result in a gain or loss because the amount of the note was equal to the carrying amount of the investment. During the year ended September 30, 1997, Ardex experienced financial difficulties and the receivable plus accrued interest totaling \$438,803 was written-off as being uncollectible and is reported separately in the statement of operations.

## 10. LICENSE AGREEMENTS

The Company has exclusive license agreements with Massachusetts Institute of Technology (the "MIT Agreement") and MMTC, Inc. (the "MMTC Agreement") for the use of certain patented technologies. The MIT Agreement and the MMTC Agreement each contain license fee and royalty requirements and other performance requirements which the Company must meet by certain deadlines with respect to the use of the patented technologies. If the Company were to breach the MIT Agreement or the MMTC Agreement, the Company would lose its rights to the respective licensed technology and would not receive compensation for its efforts in developing or exploiting the technology.

In March 1998, the Company entered into two sponsored research agreements with Duke University pursuant to which the Company has agreed to pay Duke University for all direct and indirect costs incurred in the performance of the research contemplated under such agreements not to exceed \$625,062 and Duke University has agreed to grant to the Company an option to acquire an exclusive, worldwide, royalty bearing license of Duke University's rights to any invention, development, or discovery resulting from the subject research. The sponsored research agreements were terminated, and, on November 10, 1999, the Company entered into a License Agreement with Duke University, under which Duke has granted the Company exclusive rights (subject to certain exceptions) to commercialize and use Duke's patented thermo-liposome technology. For portions of the technology, Celsion's rights are worldwide, and, for various patent rights, the license covers the United States, Canada, the United Kingdom, France, Germany and Japan, and other countries in which Celsion desires to seek patent protection, provided that Celsion will be responsible for the costs of obtaining such protection. The License Agreement contains annual royalty and minimum payment provisions, and also requires the Company to make milestone-based royalty payments measured by such events as 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 has agreed to accept shares of Celsion Common Stock to be issued in installments at the time each milestone payment is due.

Under the Company's research agreement with Sloan-Kettering, the Company had an option to negotiate the terms of an exclusive license agreement to commercialize the results of the Sloan-Kettering research sponsored by Celsion concerning patented thermo-genetic modifier technology. Celsion exercised its option to commence such negotiations on November 9, 1999, and has until February 9, 2000 to negotiate the terms of a final license agreement.

Celsion has been holding discussions with Sloan-Kettering on such terms, and anticipates that the terms will be finalized by the February 9, 2000 expiration date.

## 11. INCOME TAXES

A reconciliation of the Company's statutory tax rate to the effective rate for the years ended September 30 is as follows:

	1999	1998	1997
Federal statutory rate	34.0%	34.0%	34.0%
State taxes, net of federal tax benefit	4.6	4.6	4.6
Valuation allowance	(38.6)	(38.6)	(38.6)
	.0%	.0%	.0%
	=====	=====	=====

As of September 30, 1999, the Company had net operating loss carryforwards of approximately \$21,300,000 for federal income tax purposes that are available to offset future taxable income through the year 2019.

The components of the Company's deferred tax asset for the years ended September 30 is as follows:

	1999	1998
	-----	-----
Net operating loss carryforwards	\$7,893,000	\$ 6,952,000
Valuation allowance	(7,893,000)	(6,952,000)
	\$ --	\$ --
	-----	-----

The evaluation of the realizability of such deferred tax assets in future periods is made based upon a variety of factors for generating 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.

## 12. COMMON STOCK

During the year ended September 30, 1999, the Company issued an aggregate of 9,545,500 shares of common stock for net or gross cash of \$3,612,875. In addition, a total of 3,343,976 shares were issued to extinguish debt, and 535,196 shares were issued as payment for various operating expenses.

During the year ended September 30, 1998, the Company issued a total of 4,315,000 shares of common stock for \$2,025,000. In addition, 5,274,961 shares were issued to extinguish debt, and 1,260,532 shares were issued as payment for various operating expenses.

During the year ended September 30, 1997, the Company issued 1,409,902 shares of common stock for \$683,000; also 1,317,143 shares were issued to extinguish debt, and 1,161,828 shares were issued as payments for various operating expenses. Additionally, the Company retired 16,000,000 shares of common stock in connection with the rescission in its investment in Aestar.

### 13. STOCK OPTIONS AND WARRANTS

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

A summary of the Company's stock option activity and related information for the years ended September 30, 1999, 1998 and 1997 is as follows:

	1999		1998		1997	
	Common Stock Options	Weighted Average Exercise Price	Common Stock Options	Weighted Average Exercise Price	Common Stock Options	Weighted Average Exercise Price
Outstanding at beginning of year	2,745,000	\$.41	3,565,000	\$.38	3,050,000	\$.34
Granted	-	-	-	-	515,000	.61
Exercised	(587,500)	.25	(125,000)	.45	-	-
Expired/cancelled	(10,000)	.69	(695,000)	.25	-	-
Outstanding at end of year	2,147,500	\$.45	2,745,000	\$.41	3,565,000	\$.38

Additionally, the Company has issued warrants to purchase the Company's stock as follows:

	1999		1998		1997	
	Common Stock Options	Weighted Average Exercise Price	Common Stock Options	Weighted Average Exercise Price	Common Stock Options	Weighted Average Exercise Price
Outstanding at beginning of year	7,858,983	\$.45	3,276,818	\$.35	2,218,035	\$.29
Issued	6,749,627	.81	4,582,165	.52	1,058,783	.48
Expired/cancelled	(102,340)	.50	-	-	-	-
Outstanding at end of year	14,506,270	\$.59	7,858,983	\$.45	3,276,818	\$.35

The following summarizes information about options and warrants at September 30, 1999:

Range of Exercise Prices	Options/Warrants Outstanding		Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Options/Warrants Exercisable	
	Number				Number	Weighted Average Exercise Price
\$0.16 - \$3.00	16,653,770		4.63 years	\$0.57	12,898,659	\$0.60

Additionally, certain agreements with stockholders have antidilutive provisions which require that additional shares and options be issued under certain circumstances.

The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS No. 123), but applies Accounting Principles Board Opinion No. 25 and related interpretations. No compensation expense related to the granting of stock options was recorded during the three years ended September 30, 1999. The fair value of these equity awards was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted average assumptions for 1999, 1998 and 1997: risk-free interest rate of 5.71%, 5.75% and 6.50% for 1999, 1998 and 1997, respectively; expected volatility of 50%; expected option life of 3 to 5 years from vesting and an expected dividend yield of 0.0%. If the Company had elected to recognize cost based on the fair value at the grant dates consistent with the method prescribed by SFAS No. 123, net loss and loss per share would have been changed to the pro forma amounts as follows:

	Year Ended September 30,		
	1999	1998	1997
Net loss	\$ (5,477,762)	\$ (5,272,699)	\$ (3,476,159)
Net loss per common share - basic	(.09)	(.12)	(.12)

#### 14. COMMITMENTS AND CONTINGENCIES

##### Potential Liability and Insurance

In the normal course of business, the Company may be subject to warranty and product liability claims on its hyperthermia equipment. Although the Company has obtained liability insurance, assertion of any product liability claim against the Company, in excess of such insurance limits, may have an adverse effect on its financial condition. As of September 30, 1999, no product warranty claims or other liabilities against the Company have been asserted.

#### 15. LEASE OBLIGATIONS

During the year ended September 30, 1997, the Company entered into a three-year lease for their facilities in Columbia, Maryland. Future minimum lease obligations are as follows:

Year ended September 30:

2000 \$ 55,877

Total amounts charged to rent expense for 1999, 1998 and 1997 were \$67,796, \$75,018 and \$64,594, respectively.

#### 16. CONCENTRATIONS OF CREDIT RISK

As of September 30, 1999, the Company has a concentration of credit represented by cash balances in one large commercial bank in amounts which exceed current federal deposit insurance limits. The financial stability of this institution is continually reviewed by senior management.

## 17. CAPITAL LEASE COMMITMENTS

The Company leases a telephone system under an agreement classified as a capital lease. The cost and accumulated depreciation for the equipment as of September 30, 1999 was \$7,276 and \$2,183, respectively, and as of September 30, 1998 was \$7,276 and \$728, respectively.

The following is a schedule of future minimum lease payments under the capital lease together with the present value of the next minimum lease payments as of September 30, 1999:

Year Ending September 30:	
2000	\$ 2,206
2001	2,206
2002	2,206
2003	1,103
	-----
Total future minimum lease payments	7,721
Amount representing interest	(2,002)
Present value of future minimum lease payments	5,719
Current portion	(1,292)
	-----
Long-term portion	\$ 4,427
	=====

Total interest expense on the long-term capital lease obligation for the years ended September 30, 1999 and 1998 was \$1,123 and \$629, respectively.

(a)(2) No schedules are provided because of the absence of conditions under which they are required.

(b) Reports on Form 8-K.

The Company filed no reports on Form 8-K during the fourth quarter of its fiscal year ended September 30, 1998.

(c) Exhibits.

The following documents are included as exhibits to this report:

Exhibit Number -----	Description -----
3.1	Articles of Incorporation of the Company as filed on May 19, 1982 with the State of Maryland Department of Assignments and Taxation, incorporated herein by reference to the exhibits to the Company's Registration Statement on Form S-1, as amended, originally filed with the Securities and Exchange Commission on October 17, 1984, Registration No. 2-93826-W.
3.1.1	Articles of Amendment and Restatement to the Articles of Incorporation of the Company as filed on June 21, 1984 with the State of Maryland Department of Assignments and Taxation, incorporated herein by reference to Exhibit 3.1.1 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.
3.1.2	Articles of Amendment to the Articles of Incorporation of the Company as filed on December 14, 1994 with the State of

Maryland Department of Assignments and Taxation, incorporated herein by reference to Exhibit 3.1.2 to the Annual Report on Form 10-K of the Company for the year

3.1.3	ended September 30, 1996 Certificate of Amendment to Certificate of Incorporation as filed on May 1, 1998 with the State of Maryland Department of Assignment and Taxation, incorporated herein by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 30, 1998.
3.2	By-laws, incorporated herein by reference to Exhibit 3.2 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.
3.2.1	Amendment to the By-laws of the Company adopted December 9, 1994, incorporated herein by reference to Exhibit 3.2.1 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.

Exhibit Number -----	Description -----
3.2.2	Amendment to the By-laws of the Company adopted April 27, 1998, incorporated herein by reference to Exhibit 3.2 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 30, 1998.
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	Letter Agreement between the Company and H.B.C.I., Inc., dated September 17, 1996, incorporated herein by reference to Exhibit 10.3 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.
10.4	Letter Agreement between the Company and Herbst, Lazar, Bell, Inc. dated October 4, 1996, incorporated herein by reference to Exhibit 10.4 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.
10.5	Sponsored Research Agreement dated March 17, 1998 between the Company and Duke University and Sponsored Research Agreement dated February 26, 1998 between the Company and Duke University.
10.6	Engagement Letter dated August 6, 1998 between the Company and Josephberg Grosz & Co., Inc.
10.7	Patent License Agreement between the Company and Massachusetts Institute of Technology dated October 17, 1997 (Confidential Treatment Requested).
10.8	Amendment dated November 25, 1997 to the License Agreement between the Company and MMTC, Inc. dated August 23, 1996 (Confidential Treatment Requested).
10.9	Patent License Agreement between the Company and Duke University dated November 10, 1999 (Confidential Treatment Requested).+
10.10	Amendment dated March 23, 1999 to the License Agreement between the Company and MMTC, Inc. dated August 23, 1996 (Confidential Treatment Requested).+
10.11	Option Agreement between the Company and Sloan-Kettering Institute for Cancer Research dated February 26, 1999 (Confidential Treatment Requested).+
10.12	Amendment Letter dated August 31, 1999 to the Option Agreement between the Company and Sloan-Kettering Institute for Cancer Research dated February 26, 1999.+
10.13	Omnibus Stock Option Plan, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 30, 1998.
10.14	Letter of Intent between the Company and Mr. Sun Shou Yi, representative of Mr. Gao Yu Wen, dated May 27, 1996 and Redemption Agreement between the Company and Mr. Sun Shou Yi., representative of Mr. Gao Yu Wen, dated June 6, 1996, incorporated herein by reference to Exhibit 10.8 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.

Exhibit Number -----	Description -----
10.15	Amendment among the Company, Sun Shou Yi, Ou Yang An, Gao Yu Wen, dated October 23, 1996, 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, 1996.
10.16	Unsecured Promissory Note, dated June 23, 1998, in the amount of \$50,000 and bearing interest at the rate of eight percent, payable to Spencer J. Volk.
10.17	Form of Series 200 Warrant issued to certain employees, directors, and consultants to Purchase Common Stock of the Company.
10.18	Form of Series 250 Warrant Issued to DunnHughes Holding, Inc. to Purchase Common Stock of the Company.
10.19	Form of Series 300 Warrant Issued to Nace Resources, Inc. and George T. Horton Trust to Purchase Common Stock of the Company.
10.20	Form of Series 400 Warrant Issued to Stearns Management Company Assignees to Purchase Common Stock of the Company.
10.21	Form of Series 500 Warrant to Purchase Common Stock of the Company pursuant to the Private Placement Memorandum of the Company dated January 6, 1997, as amended.
10.22	Form of Series 550 Warrant to Purchase Common Stock of the Company pursuant to the Private Placement Memorandum of the Company dated January 6, 1997, as amended.
10.23	Form of Series 600 Warrant Issued to Certain Employees and Directors on May 16, 1996 to Purchase Common Stock of the Company.
10.24	Form of Series 700 Warrant to Purchase Common Stock of the Company pursuant to the Private Placement Memorandum of the Company dated September 10, 1998, as amended.
10.25	Form of Series 800 Warrant to Purchase Common Stock of the Company pursuant to the Private Placement Memorandum of the Company dated February 23, 1999, as amended.+
10.26	Form of Registration Rights Agreement pursuant to the Private Placement Memorandum of the Company dated January 6, 1997, as amended.
10.27	Form of Registration Rights Agreement pursuant to the Private Placement Memorandum of the Company dated September 10, 1998, as amended.
21.1	Subsidiaries of the Registrant, incorporated herein by reference to Exhibit 21.1 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1996.
23.1	Consent of Stegman & Company, independent public accountants of the Company.+
27.1	Financial Data Schedule.+

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+ Denotes exhibits filed with this Form 10-K

## 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

December 28, 1999

By: /s/ Spencer J. Volk

-----  
Spencer J. Volk  
Chief Executive Officer and President

By: /s/ John Mon

-----  
John Mon  
Chief Accounting Officer, General  
Manager, Secretary and Treasurer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Registrant's annual report on Form 10-K 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/ Spencer J. Volk ----- Spencer J. Volk	Chief Executive Officer, President and Director	December 28, 1999
/s/ John Mon ----- John Mon	General Manager, Treasurer, Secretary and Director	December 28, 1999
/s/ Augustine Y. Cheung ----- Dr. Augustine Y. Cheung	Chairman, Director	December 28, 1999
/s/ Walter Herbst ----- Walter Herbst	Director	December 28, 1999
/s/ Claude Tihon ----- Claude Tihon	Director	December 28, 1999
/s/ LaSalle D. Leffall, Jr. ----- LaSalle D. Leffall, Jr.	Director	December 28, 1999
/s/ Max E. Link ----- Max E. Link	Director	December 28, 1999

**EXHIBIT 10.9**

**LICENSE AGREEMENT**

THIS AGREEMENT made and entered into as of the tenth day of November, 1999 (this "AGREEMENT"), by and between DUKE UNIVERSITY, a North Carolina not-for-profit corporation organized under the laws of North Carolina (the "LICENSOR"), having its principal office at Durham, North Carolina 27708, and CELSION CORPORATION, a corporation organized under the laws of Maryland (the "LICENSEE"), having its principal office at Columbia, MD.

WHEREAS, David Needham and Mark Dewhirst (the "DISCLOSERS"), employees of LICENSOR, have filed an Invention Disclosure Form that has been assigned Duke University Office of Science and Technology file number 1544 relating to a method whereby encapsulated chemotherapeutic drugs and other agents can be caused to be released by the local application of heat; and

WHEREAS, LICENSOR represents that it is the sole owner of the entire right, title and interest in and to the HEAT TRIGGERED DELIVERY TECHNOLOGY (as hereinafter defined) and PATENT RIGHTS related thereto (as hereinafter defined); and

WHEREAS, LICENSOR has the right to grant licenses to said HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS and wishes to have the HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS utilized in the public interest; and

WHEREAS, LICENSEE represents that it owns proprietary technology that may allow it to develop HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS into products that will be useful in the treatment of disease; and

WHEREAS, LICENSEE wishes to obtain a license to develop the HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS into such useful products;

NOW THEREFORE, in consideration of the premises and the faithful performance of the covenants herein contained, IT IS AGREED:

**ARTICLE 1 - DEFINITIONS**

1.01 - For the purposes of this AGREEMENT, and solely for that purpose, the terms and phrases set forth hereinafter in capital letters shall be defined as follows:

a. "AFFILIATE" shall mean any corporation, partnership or other entity at least fifty percent (50%) of whose voting or other capital stock is owned or controlled, directly or indirectly, by a party.

b. "FIELD" shall mean the use of the HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS in thermally sensitive formulations designed to release, activate, or express pharmaceutically active agents locally, such release, activation, or expression being initiated by local application of heat and being made for the purpose of treating any disease or altering a physiological process in animals, including, without restriction, in humans.

c. "HEAT TRIGGERED DELIVERY TECHNOLOGY" shall mean PATENT RIGHTS and know-how related to the use in the FIELD of liposomes that contain pharmacologically active agents at normal body temperature and that can be induced to release said agents locally by the local application of heat as heretofore conceived and/or reduced to practice by DISCLOSERS as evidenced by written records, including, without limitation, Duke University Office of Science & Technology File #1544.

d. "PATENT RIGHTS" shall mean all existing and presently being drafted US and Foreign patent applications relating to Duke University Office of Science and Technology file number 1544. The parties agree that all such existing and presently being drafted applications are US Patent Application Serial #09/099688 and PCT application US99/12964 designating all countries of the EPO, Australia, Canada, and Japan. In addition PATENT RIGHTS shall mean all U.S. and foreign patent application(s) hereafter issuing on any such existing patent application, substitutes, continuations, divisionals, or reissues thereof.

e. "LICENSED PRODUCT" shall mean any product which is produced or sold by or on behalf of LICENSEE, its AFFILIATES or sublicensees that utilizes the HEAT TRIGGERED DELIVERY TECHNOLOGY or PATENT RIGHTS or that is covered by one or more claims of the PATENT RIGHTS, and which is intended for use in, or is used in, the FIELD.

f. "ALLIANCE FEES" shall include upfront cash fees, sublicensing fees, periodic maintenance fees, and other cash payments or non-cash consideration actually received by LICENSEE pursuant to the formation, maintenance, extension or continuation of a DEVELOPMENT ALLIANCE. ALLIANCE FEES shall not include amounts received by LICENSEE in the form of research and development funding, equity investments, performance-based research milestones, royalties on net sales, sales bonuses, commercialization or development milestones, or fees for hiring subcontractors to manufacture all or components of the LICENSED PRODUCTS.

g. "DEVELOPMENT ALLIANCE" shall mean any strategic alliance, partnership, joint venture, sublicense arrangement, manufacturing arrangement, or other business relationship between LICENSEE and another commercial party or parties which involves the development of LICENSED PRODUCTS based on HEAT TRIGGERED DELIVERY TECHNOLOGY or the PATENT RIGHTS.

h. "NETSALES" shall mean the aggregate United States dollar equivalent of gross revenues paid LICENSEE, its AFFILIATES and sublicensees from or on account of the sale or distribution of LICENSED PRODUCTS to third parties who are not AFFILIATES of LICENSEE, less a provision, determined under generally accepted accounting principles in the United States for, first, shipping, handling, trade, cash, prompt payment and/or quantity discounts or rebates (other than price discounts granted at the time of invoicing and which are included in the determination of gross revenues from sales); and, second, credits or allowances, if any, actually made or granted (prospectively or retroactively) on account of price adjustments, recalls, rejection or return of, or on account of uncollectible amounts on, LICENSED PRODUCT previously sold, including Medicare or other similar rebates or discounts; and, third, credits or allowances given or made for wastage replacement or indigent patient programs;

NET SALES shall not include any transfer between LICENSEE, its AFFILIATES or sublicensees, on the one hand, and any of their AFFILIATES or sublicensees, on the other hand, for resale, but shall include the resale price to a third party payable to such AFFILIATES or sublicensees.

If LICENSEE or any of its AFFILIATES or sublicensees sells any LICENSED PRODUCT to a distributor which is not an AFFILIATE of LICENSEE, the gross revenues derived by or payable to LICENSEE, such AFFILIATE or sublicensee on account of such sale shall be the gross revenues received by LICENSEE or such AFFILIATE or sublicensee from the sale of such LICENSED PRODUCTS to such distributor. If such distributor is an AFFILIATE of LICENSEE, then gross revenues derived by or payable to LICENSEE, such AFFILIATE or sublicensee from the sale of such LICENSED PRODUCTS shall be those received from the sale of such LICENSED PRODUCTS to the first third party which is not an AFFILIATE of LICENSEE.

If any LICENSED PRODUCT is sold as part of a system, package or combination product wherein other components are or have been sold as separate products not dependent on such LICENSED PRODUCT, NET SALES for the purpose of calculating payments under Section 4.01 hereof shall be calculated by multiplying the NET SALES of the combination product by the fraction A/B, where "A" is the average unit price of such LICENSED PRODUCT when sold separately and "B" is the average unit price of the combination product. If such LICENSED PRODUCT is not sold separately, the NET SALES of such combination product shall be negotiated in good faith by the Parties.

Notwithstanding the foregoing, no transfer of any LICENSED PRODUCT for testing, pre-clinical, clinical or development purposes or as samples shall be considered a sale hereunder for accounting purposes and for payments under Section 4.01 hereof.

i. "FDA" shall mean the Food and Drug Administration of the United States of America.

j. "MAJOR MARKET COUNTRY" shall mean the United States of America, Canada, the United Kingdom, France, Germany, and Japan.

k. "EFFECTIVE DATE" shall mean November 20, 1999.

## **ARTICLE 2 - LICENSE**

2.01 - LICENSOR hereby grants to LICENSEE and LICENSEE hereby accepts from LICENSOR, upon the terms and conditions herein specified, an exclusive, sublicensable license under the HEAT TRIGGERED DELIVERY TECHNOLOGY and the PATENT RIGHTS to practice the INVENTIONS and to, directly or indirectly, make, import, export, use, lease, sell or otherwise dispose of LICENSED PRODUCTS for a period of (i) twenty (20) years or (ii) until the full end of the term or terms for which a patent is issued by the U.S. Patent and Trademark Office in respect of the PATENT RIGHTS, whichever is longer, unless sooner terminated as hereinafter provided. With regard to HEAT TRIGGERED DELIVERY TECHNOLOGY, this license shall be world-wide; with regard to PATENT RIGHTS, this license shall extend to the United States of America, MAJOR MARKET COUNTRIES, and DESIGNATED COUNTRIES as defined and specified under ARTICLE 7 hereof.

2.02 - LICENSEE shall have the right to grant sublicenses. Any such sub-licenses shall be subject to the terms of this AGREEMENT. LICENSEE agrees to be responsible for the performance hereunder by its sub-licensees, if any, but not to be a guarantor for such sublicensees. If, for any reason, this AGREEMENT is terminated, LICENSEE hereby agrees to assign all such sublicenses directly to LICENSOR, to the extent permitted by such sublicenses.

2.03 - It is agreed that, notwithstanding anything to the contrary contained herein, LICENSOR is free to use the HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS for its own non-commercial educational, teaching, research and clinical purposes without restriction and without payment of royalties or other fees, provided that LICENSOR discloses in connection with such use that the HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS are licensed to LICENSEE pursuant to the terms of this AGREEMENT.

2.04 - If LICENSEE, acting alone or together with any of its officers, directors, employees, agents or sublicensees, makes any modification, enhancement or improvement to the HEAT TRIGGERED DELIVERY TECHNOLOGY and/or the PATENT RIGHTS (the "IMPROVEMENTS") then LICENSEE shall own all right, title and interest in and to such IMPROVEMENTS and shall be responsible for patent and other intellectual property protection thereon.

2.05 - LICENSOR shall provide reasonable opportunities for LICENSEE'S personnel to have access to DISCLOSERS so that DISCLOSERS can provide training and information with respect to the HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS. Once available information concerning HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS has been transmitted to LICENSEE, DISCLOSERS shall be entitled to be compensated by LICENSEE if additional training or consulting is necessary. Such arrangement shall be made between DISCLOSERS and LICENSEE and shall comply with all regulations and policies of LICENSOR governing faculty consulting relationships.

### **ARTICLE 3 - ROYALTIES, RECORDS AND REPORTS**

3.01 - LICENSEE shall pay to LICENSOR a running royalty (i) during the term of this AGREEMENT up to the date on which the U.S. Patent and Trademark Office shall issue a patent in respect of the PATENT RIGHTS, at the rate of [Confidential Treatment Requested] percent ([Confidential Treatment Requested]%) of NET SALES of LICENSED PRODUCTS and (ii) during the terms of this Agreement from and after the date on which the U.S. Patent and Trademark Office shall issue a patent in respect of the PATENT RIGHTS at the rate of (Confidential Treatment Requested) percent ([Confidential Treatment Requested]%) of NET SALES of LICENSED PRODUCTS. If LICENSEE demonstrates through written records (i) that it has been necessary to license additional technology from third parties in order to commercialize the LICENSED PRODUCTS (the "NECESSARY TECHNOLOGY") and (ii) that such additional license for NECESSARY TECHNOLOGY obligates LICENSEE to

pay royalties on NET SALES of LICENSED PRODUCTS such that the aggregates royalties on NET SALES due to third parties exceeds [Confidential Treatment Requested] percent ([Confidential Treatment Requested]%) of NET SALES, then LICENSEE shall be permitted to reduce the royalty due LICENSOR under this AGREEMENT by one-half of any such additional royalties payable to third parties in excess of [Confidential Treatment Requested] percent ([Confidential Treatment Requested]%) percent of NET SALES of LICENSED PRODUCTS; provided, however, in no case shall the royalty rate payable by LICENSEE to LICENSOR pursuant to this Section 3.01 from and after the date on which the U.S. Patent and Trademark Office shall issue a patent in respect of the PATENT RIGHTS, when reduced by any royalties due to third parties for NECESSARY TECHNOLOGY, be less than [Confidential Treatment Requested] percent ([Confidential Treatment Requested]%) **of NET SALES.**

3.02 - Beginning with the year that ensues on the second January 1 after the approval of the first LICENSED PRODUCT by the FDA or a comparable regulatory authority in a MAJOR MARKET COUNTRY, LICENSEE shall pay to LICENSOR a minimum annual royalty of [Confidential Treatment Requested]dollars (\$[Confidential Treatment Requested]). For avoidance of doubt, this means that should the running royalties due under Section 3.01 hereof for a calendar year not equal [Confidential Treatment Requested] dollars (\$[Confidential Treatment Requested]), LICENSEE shall pay to LICENSOR an additional amount so that the total royalties paid to LICENSOR for such calendar year shall be [Confidential Treatment Requested]dollars (\$[Confidential Treatment Requested]).

3.03 - LICENSEE shall render to LICENSOR prior to February 28th and August 31st of each year during the term of this AGREEMENT a written account of the NET SALES of LICENSED PRODUCTS subject to royalty payments hereunder made during the prior six month periods ending December 31st and June 30th, respectively, and shall simultaneously pay to LICENSOR the royalties due on such NET SALES in United States Dollars. Minimum annual royalties, if any, which are due LICENSOR for any calendar year, shall be paid by LICENSEE along with the written report due on February 28 of each year.

3.04- Specified reports shall be submitted on the forms giving the same information and having substantially the same layout as the sample form in EXHIBIT A of this AGREEMENT.

3.05 - LICENSEE will make all payments on or before the later of the date required by the terms of this AGREEMENT, or within [Confidential Treatment Requested] ([Confidential Treatment Requested]) days of any invoice date on invoices received from LICENSOR. If LICENSEE has not paid any uncontested amount due to LICENSOR in accordance with this Article 3, LICENSOR shall increase the amount due (in US Dollars) by an annual percentage rate equal to [Confidential Treatment Requested] percent ([Confidential Treatment Requested]%) on such unpaid amount. Such increase(s) shall compound monthly until such time as LICENSEE has met the full financial obligation due at the time of the next payment or invoice due date.

3.06 - LICENSEE shall keep full, true and accurate books of accounts and other records containing all particulars which may be necessary to properly ascertain and verify the royalties payable by it hereunder. Upon [Confidential Treatment Requested] ([Confidential Treatment Requested]) days advance notice by

LICENSOR, LICENSEE shall permit an independent Certified Public Accountant selected by LICENSOR (except one to whom LICENSEE has some reasonable objection) to have access during ordinary business hours to such of LICENSEE's records as may be necessary to determine, in respect of any quarter ending not more than two (2) years prior to the date of such request, the correctness of any report and/or payment made under this AGREEMENT, provided that such access shall not interfere unreasonably with the business and affairs of LICENSEE, and provided further that such audits are conducted no more than once during each calendar year or portion thereof during the term hereof.

3.07 - During the term of this AGREEMENT, LICENSEE will submit annual progress reports to LICENSOR by February 28 of each year which discuss the progress and results, as well as ongoing plans, with respect to the HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS. LICENSOR shall have the right to request one meeting per year at times and places mutually agreed upon between LICENSOR and LICENSEE to discuss the progress and results, as well as ongoing plans, with respect to the evaluation and development of the HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS; provided, however, that should LICENSOR's personnel be required by LICENSEE to meet with LICENSEE outside of Durham, North Carolina, LICENSEE will reimburse reasonable travel and living expenses for two (2) individuals incident thereto.

#### **ARTICLE 4 - MILESTONE-BASED ROYALTIES**

4.01 - LICENSEE will pay royalties (each, a "MILESTONE-BASED ROYALTY"; collectively, the "MILESTONE-BASED ROYALTIES") to LICENSOR upon the attainment of the commercial milestones specified below by LICENSOR, LICENSEE, an AFFILIATE of LICENSOR or LICENSEE or any other person or entity with whom LICENSEE has formed a DEVELOPMENT ALLIANCE. Unless specifically noted, no MILESTONE-BASED ROYALTIES shall be credited towards other royalties or minimum royalties due to LICENSOR under any other Article of this AGREEMENT:

- a. Execution of this AGREEMENT, [Confidential Treatment Requested]United States Dollars (\$[Confidential Treatment Requested]);
- b. Filing of the first Investigational New Drug (IND) application or comparable foreign application for a LICENSED PRODUCT, [Confidential Treatment Requested]United States Dollars (\$[Confidential Treatment Requested]);
- c. First demonstration of the efficacy of a LICENSED PRODUCT in a clinical trial using the definition of efficacy determined at the outset of the trial, [Confidential Treatment Requested] United States Dollars (\$[Confidential Treatment Requested]);
- d. Filing of the first New Drug Application (NDA), Biologic Licensing Application (BLA) or comparable foreign applications for marketing approval of a LICENSED PRODUCT, [Confidential Treatment Requested]United States Dollars (\$[Confidential Treatment Requested]);
- e. Approval of the first NDA, BLA or comparable foreign application for marketing approval of a Licensed Product, [Confidential Treatment Requested]United States Dollars (\$[Confidential Treatment Requested]);

f. Approval of each second, third and fourth NDA, BLA or comparable foreign applications for marketing approval for additional LICENSED PRODUCTS, [Confidential Treatment Requested] United States Dollars (\$[Confidential Treatment Requested]);

g. Approval of each additional NDA, BLA or comparable foreign application for marketing approval for new indications of an already approved LICENSED PRODUCT:

second indication, [Confidential Treatment Requested]United States Dollars(\$[Confidential Treatment Requested]) third indication, [Confidential Treatment Requested]United States Dollars (\$[Confidential Treatment Requested]) fourth indication, [Confidential Treatment Requested]United States Dollars (\$[Confidential Treatment Requested]);

h. First attainment of total aggregate Net Sales of all LICENSED PRODUCTS of [Confidential Treatment Requested] United States Dollars (\$[Confidential Treatment Requested]) in a single calendar year, [Confidential Treatment Requested]United States Dollars (\$[Confidential Treatment Requested]); and

i. First attainment of total aggregate Net Sales of all LICENSED PRODUCTS of [Confidential Treatment Requested]United States Dollars (\$[Confidential Treatment Requested]) in a single calendar year, [Confidential Treatment Requested]United States Dollars (\$[Confidential Treatment Requested]).

4.02. a. Notwithstanding anything to the contrary contained herein, LICENSOR and LICENSEE hereby agree that, in lieu of paying any such MILESTONE-BASED ROYALTY in cash, LICENSEE may issue and LICENSOR shall accept shares of the Common Stock of LICENSEE. The number of shares of the Common Stock of LICENSEE to be issued at the time that such MILESTONE-BASED ROYALTY is due and payable with respect to each such MILESTONE-BASED ROYALTY shall be determined by dividing the amount of such MILESTONE BASED ROYALTY by the average closing price of the Common Stock of LICENSEE during the twenty (20) trading days immediately preceding the date that such MILESTONE-BASED ROYALTY became due and payable.

b. Within ten (10) days after the first anniversary of the EFFECTIVE DATE, LICENSEE shall determine, in good faith, the market value of the shares of Common Stock issued by LICENSEE to LICENSOR hereunder as of the first anniversary of the EFFECTIVE DATE (the "FIRST ANNIVERSARY MARKET VALUE") by multiplying the number of shares of Common Stock of LICENSEE issued by LICENSEE to LICENSOR hereunder prior to the first anniversary of the EFFECTIVE DATE by the average closing price of the Common Stock of LICENSEE during the twenty (20) trading days immediately preceding the first anniversary of the EFFECTIVE DATE. In the event that the FIRST ANNIVERSARY MARKET VALUE of such shares of Common Stock is less than the aggregate amount of the MILESTONE-BASED ROYALTIES that LICENSEE would have been required to pay to LICENSOR on or before the first anniversary of the EFFECTIVE DATE had LICENSEE chosen to make such MILESTONE -BASED ROYALTIES in cash rather than in shares of Common Stock of LICENSEE (the "AGGREGATE FIRST ANNIVERSARY CASH VALUE") then LICENSEE shall issue to LICENSOR and LICENSOR shall accept additional shares of the Common Stock of LICENSEE, the number of which shall be determined by dividing (i) the difference between the

AGGREGATE FIRST ANNIVERSARY CASH VALUE and the FIRST ANNIVERSARY MARKET VALUE by (ii) the average closing price of the Common Stock of LICENSEE during the twenty (20) trading days immediately preceding the first anniversary of the EFFECTIVE DATE.

c. Within ten (10) days after the second anniversary of the EFFECTIVE DATE, LICENSEE shall determine, in good faith, the aggregate market value of the shares of Common Stock issued by LICENSEE to LICENSOR hereunder prior to the second anniversary of the EFFECTIVE DATE (the "SECOND ANNIVERSARY AGGREGATE MARKET VALUE"). For the purposes hereof, the "market value" of each share of Common Stock of LICENSEE issued by LICENSEE to LICENSOR pursuant to Section 4.02(a) hereof with respect to any MILESTONE-BASED ROYALTY due hereunder shall be equal to the average closing price of the Common Stock of LICENSEE during the twenty (20) trading days immediately preceding the date that such MILESTONE -BASED ROYALTY became due and payable and the "market value" of each share of Common Stock of LICENSEE issued by LICENSEE to LICENSOR pursuant to Section 4.02(b) hereof shall be equal to the average closing price of the Common Stock of LICENSEE during the twenty (20) trading days immediately preceding the first anniversary of the EFFECTIVE DATE. In the event that SECOND ANNIVERSARY MARKET VALUE of such shares of Common Stock is less than the aggregate amount of the MILESTONE-BASED ROYALTIES that LICENSEE would have been required to pay to LICENSOR on or before the second anniversary of the EFFECTIVE DATE had LICENSEE chosen to pay such MILESTONE-BASED ROYALTIES in cash rather than in shares of Common Stock of LICENSEE (the "Aggregate Second Anniversary Cash Value") then LICENSEE shall issue to LICENSOR and LICENSOR shall accept additional shares of the Common Stock of LICENSEE, the number of which shall be determined by dividing (i) the difference between the AGGREGATE SECOND ANNIVERSARY CASH VALUE and the SECOND ANNIVERSARY MARKET VALUE by (ii) the average closing price of the Common Stock of LICENSEE during the twenty (20) trading days immediately preceding the second anniversary of the EFFECTIVE DATE.

d. In addition, (i) LICENSOR may not sell, transfer or assign any shares of the Common Stock of LICENSEE issued to LICENSOR hereunder as MILESTONE-BASED ROYALTIES on or before the first anniversary of the EFFECTIVE DATE until the first anniversary of the EFFECTIVE DATE and (ii) LICENSOR shall be prohibited from selling, transferring or assigning any shares of the Common Stock of LICENSEE issued to LICENSOR hereunder with respect to milestones during the period commencing on the first anniversary of the EFFECTIVE DATE and ending on the second anniversary of the EFFECTIVE DATE until the second anniversary of the EFFECTIVE DATE.

e. In the event that, on or before the second anniversary of the EFFECTIVE DATE, (i) LICENSEE forms a subsidiary to which LICENSEE's rights under this AGREEMENT are assigned (the "SUBSIDIARY") and (ii) the SUBSIDIARY undertakes an initial public offering of its Common Stock or otherwise registers its Common Stock with the Securities and Exchange Commission (the "SEC") so as to permit a public trading market to develop for such Common Stock, LICENSOR shall have a one-time right to exchange all or any portion of the Common Stock of LICENSEE which LICENSOR received under this AGREEMENT and which LICENSOR is then holding for shares of the Common Stock of the SUBSIDIARY. Such right may be exercised by LICENSOR's written notice to LICENSEE, to be given not earlier than ninety (90) and not later than one hundred eighty (180) days after the Common Stock of LICENSEE first becomes publicly traded, which notice shall specify the number of shares of the Common Stock of LICENSEE to be so exchanged for Common Stock of the SUBSIDIARY. Within ten (10) days after receipt of such notice (the

"NOTICE DATE"), LICENSEE shall notify LICENSOR of the number of shares of the Common Stock of the SUBSIDIARY which will be issued in such exchange, and shall include in such notification the computation of such number, which computation shall be based on an exchange price which incorporates a thirty percent (30%) discount from the then market price of the Common Stock of the SUBSIDIARY, and which shall be determined in accordance with the following formula:

$AP \times LS \text{ divided by } .7 \text{ (APS)} = \text{No. of SS,}$

where "AP" means the average closing price of the Common Stock of LICENSEE over the twenty (20) trading days immediately preceding the NOTICE DATE;

"LS" means the number of shares of the Common Stock of LICENSEE which LICENSOR desires to exchange;

"APS" means the average closing price of the Common Stock of the Subsidiary over the twenty (20) trading days immediately preceding the NOTICE DATE; and

"No. of SS" means the number of shares of the Common Stock of the SUBSIDIARY to be issued in exchange for the shares of the Common Stock of LICENSEE being tendered for exchange by LICENSOR.

Within ten (10) days after notice from LICENSEE, LICENSOR shall deliver a certificate or certificates for the shares of LICENSEE to be exchanged, accompanied by a validly executed stock power and free and clear of all liens, charges and encumbrances, and LICENSEE shall cause the SUBSIDIARY to deliver a certificate for shares of the Common Stock of the SUBSIDIARY, which shares shall be duly and validly issued, fully paid and free and clear of all liens, charges and encumbrances.

f. In the event that, on or before the second anniversary of the EFFECTIVE DATE, (i) LICENSEE does not form the SUBSIDIARY or (ii) the SUBSIDIARY does not undertake an initial public offering of its Common Stock or otherwise register its Common Stock with the SEC so as to permit a public trading market to develop for such Common Stock, LICENSOR, at its option, may by written notice given to LICENSEE within thirty (30) days after the second anniversary of the EFFECTIVE DATE, require LICENSEE to pay to LICENSOR, within thirty (30) days after receipt by LICENSEE of such notice, the amount of all previously unpaid, unearned MILESTONE-BASED ROYALTIES in shares of the Common Stock of LICENSEE; it being understood, however, that by doing so, LICENSOR waives any and all right it may have pursuant to Section 4.02(e) hereof or otherwise to exchange all or any portion of the Common Stock of LICENSEE which LICENSOR received under this AGREEMENT and which LICENSOR is holding for shares of the Common Stock of the SUBSIDIARY. The number of shares of the Common Stock of LICENSEE to be issued under this Section 4.02(f) shall be determined by dividing the amount of all previously unpaid, unearned MILESTONE-BASED ROYALTIES by the average closing price of the Common Stock of LICENSEE during the twenty (20) trading days immediately preceding the date of receipt by LICENSEE of such notice.

g. LICENSOR acknowledges that the securities which may be issued under this AGREEMENT are not being initially registered and therefore are "restricted securities" under the federal securities laws inasmuch as they are being acquired from LICENSEE in a transaction not involving a public offering, and that, under such laws and applicable regulations, such securities may not be

transferred or resold without registration under the Securities Act of 1933, as amended (the "SECURITIES ACT"), or pursuant to an exemption therefrom. In this connection, LICENSOR represents that it is familiar with Rule 144 under the SECURITIES ACT, as presently in effect, and understands the resale limitations imposed thereby and by the SECURITIES ACT. LICENSOR is acquiring the shares of Common Stock subscribed solely for investment purposes and not with a view to a distribution of all or any part thereof. LICENSOR has the financial ability to bear the economic risk of its investment for an indefinite period, and has adequate means of providing for its current needs and anticipated contingencies without reference to the liquidity of the securities which may be issued to it. LICENSOR is a not-for-profit organization with more than (\$ Confidential Treatment Requested) in total assets. LICENSOR has such knowledge and experience in financial and business matters that it is fully capable of evaluating the merits and risks of an investment in LICENSEE.

h. If LICENSEE intends to make an underwritten public offering of its Common Stock solely for cash at any time after the first anniversary of the EFFECTIVE DATE, and files a registration statement in connection therewith, LICENSEE shall, within ten (10) days after the date of such filing, send written notice of such filing, together with a copy of the preliminary prospectus included in such registration statement, to LICENSOR. Upon the written request of LICENSOR to be included in such registration statement as a selling stockholder, given not later than twenty (20) days after receipt of such notice, LICENSEE shall include in such registration statement all or any portion of the shares of Common Stock previously issued by LICENSEE to LICENSOR hereunder, as LICENSOR shall so request. However, if the managing underwriter of such public offering shall express objection to the inclusion of all or part of such shares of Common Stock of LICENSOR in such public offering because of prevailing market conditions or other factors, the amount of such shares of Common Stock of LICENSOR to be so registered in such offering shall be reduced to the level which such managing underwriter deems appropriate in relation to the size of the underwritten offering and the ability of the market to accommodate the sale of such shares of Common Stock of LICENSOR, provided, however, that if any shares of Common Stock are being included in such offering on behalf of any selling stockholders other than LICENSOR, any reduction of offered securities imposed on LICENSOR shall be proportional to any reduction imposed on such other selling stockholders; and further provided that, at the request of the managing underwriter of such public offering, LICENSOR may be required to refrain from selling its shares of Common Stock pursuant to such registration statement for a "lock-up" period of up to nine (9) months after the completion of the public sale of securities offered by LICENSEE in such public offering, on terms no less favorable than those applicable to other selling stockholders.

Whenever required under this Section 4.02(h) to effect the registration of any securities, LICENSEE shall, as expeditiously as reasonably possible:

(i) Prepare and file with the SEC a registration statement with respect to such securities and use its best efforts to cause such registration statement to become effective, and, upon the request of LICENSOR, keep such registration statement effective for at least nine (9) months.

(ii) Prepare and file with the SEC such amendments and supplements to such registration statement and the prospectus used in connection with such registration statement as may be necessary to comply with the provisions of the SECURITIES ACT with respect to the disposition of all securities covered by such registration statement.

(iii) Furnish to LICENSOR such numbers of copies of a prospectus, including a preliminary prospectus, in conformity with the requirements of the SECURITIES ACT, and such other documents as they may reasonably request in order to facilitate the disposition of securities owned by them.

(iv) Use its best efforts to register and qualify the securities covered by such registration statement under the securities laws of such jurisdictions as shall be reasonably requested by LICENSOR for the distribution of the securities covered by the registration statement, provided that LICENSEE shall not be required in connection therewith or as a condition thereto to qualify to do business or to file a general consent to service of process in any such jurisdiction.

(v) In the event of an underwritten public offering, enter into and perform its obligations under an underwriting agreement with terms generally satisfactory to LICENSEE and the managing underwriter of such offering.

(vi) Notify LICENSOR promptly after LICENSEE shall have received notice thereof, of the time when the registration statement becomes effective or any supplement to any prospectus forming a part of the registration statement has been filed.

(vii) Notify LICENSOR of any stop order suspending the effectiveness of the registration statement and use its reasonable best efforts to remove such stop order.

It shall be a condition precedent to the obligations of LICENSEE to take any action pursuant to the provisions of this Section 4.02(h) that LICENSOR shall furnish to LICENSEE such information in writing regarding itself, the securities held by it, and the intended method of disposition of such securities, as LICENSEE shall reasonably request and as shall be required to effect the registration of such securities. In that connection, LICENSOR shall be required to represent to LICENSEE that all such information which is given is both complete and accurate in all material respects. LICENSOR shall also deliver to LICENSEE a statement in writing that it has a bona fide intention to sell, transfer or otherwise dispose of such securities.

"Registration Expenses" shall mean all expenses incurred by LICENSEE in complying with the provisions of this Section 4.02(h), including, without limitation, all registration and filing fees, printing expenses, fees and disbursements of counsel for LICENSEE, blue sky fees and expenses, and the expense of any special audits incident to or required by any such registration. "Selling Expenses" shall mean all underwriting discounts, selling commissions and underwriters' expense allowances applicable to the sale of the securities of LICENSOR, and all fees and disbursements of any special counsel or accountant or

other expert for LICENSOR. All Registration Expenses incurred in connection with any registration, qualification or compliance pursuant to this Section 4.02(h) shall be borne by LICENSEE, and all Selling Expenses shall be borne by LICENSOR.

If LICENSOR proposes to distribute its securities through an underwriter, LICENSEE shall enter into an underwriting agreement in customary form with the underwriter or underwriters, provided that the terms thereof shall not be materially less favorable to LICENSEE than those customarily arranged in comparable underwritten offerings.

LICENSOR shall have no right to obtain or seek an injunction restraining or otherwise delaying any such registration as the result of any controversy that might arise with respect to the interpretation or implementation of this Section 4.02(h).

Nothing contained herein shall be deemed to limit the rights of LICENSOR to offer or make a public sale of any portion of such securities under Rule 144 of the SEC or any other applicable provisions of federal and state securities laws. Furthermore, if, in the opinion of counsel for LICENSEE, the offering or transfer by LICENSOR in the manner proposed (including, without limitation, the number of shares proposed to be offered or transferred and the method of offering or transfer) is exempt from the registration requirements of the Securities Act under Rule 144 or otherwise, LICENSEE shall not be required to effect any registration of such securities under the Securities Act.

If, instead of a public offering of securities, LICENSOR shall, at any time, offer or propose to offer all or any part of the securities of LICENSEE which it holds, for sale in an arms-length private transaction, it shall, before completing such transaction, notify LICENSEE of the specific terms and conditions of the intended sale, including the identity of the proposed buyer, and LICENSEE shall have then have the prior right, during a period of thirty (30) days from receipt of such notification, to elect to purchase such securities on the same terms and conditions, such election to be made by notice to LICENSOR within such thirty (30) day period and to be consummated as set forth in such notices.

#### **ARTICLE 5- SHARING OF ALLIANCE FEES**

5.01 - Upon execution of a DEVELOPMENT ALLIANCE by LICENSEE with a third party, LICENSEE will pay LICENSOR the greater of [Confidential Treatment Requested]United States Dollars (\$[Confidential Treatment Requested]) or [Confidential Treatment Requested] percent ([Confidential Treatment Requested]%) of the total value of any ALLIANCE FEE received by LICENSEE. Such total value of the ALLIANCE FEE shall mean the value of any cash received by LICENSEE as part of the ALLIANCE FEE added to the cash value of any non-cash consideration received by the LICENSEE as part of the ALLIANCE FEE. If LICENSEE receives non-cash consideration as part of an ALLIANCE FEE, LICENSEE and LICENSOR will negotiate in good faith to determine the cash value of such non-cash consideration.

5.02 - In the event that LICENSOR becomes a holder of equity in SUBSIDIARY under Article 4.02(e) hereof, the parties will renegotiate the provisions of this Article 5.

## ARTICLE 6 - DUE DILIGENCE REQUIREMENTS

6.01 - LICENSEE shall use commercially reasonable efforts to bring LICENSED PRODUCTS to market through a diligent program for exploitation of the PATENT RIGHTS, to develop manufacturing capabilities, and to continue active, diligent marketing efforts for LICENSED PRODUCTS throughout the term of this AGREEMENT.

6.02 - Within six months of the EFFECTIVE DATE, LICENSEE shall submit to LICENSOR a plan (the "PLAN") for development of LICENSED PRODUCTS. LICENSOR will have the right to review and approve this PLAN so that the PLAN is reasonably acceptable to LICENSOR. Once approved, this PLAN will be used to determine if LICENSEE is making acceptable progress to commercialize LICENSED PRODUCTS. Any proposed changes in the PLAN will be discussed by LICENSOR and LICENSEE and must be reasonably acceptable to both parties.

6.03 - Within six-months of the time that LICENSEE or LICENSOR demonstrates in an animal model reasonably acceptably to both parties that a candidate LICENSED PRODUCT has efficacy in treating a disease or altering a physiological process in a useful way, LICENSEE shall present to LICENSOR a development plan outlining how the LICENSEE intends to develop the LICENSED PRODUCT from the candidate. Said development plan shall include evidence that LICENSEE has made arrangements for production of GMP grade material for use in clinical trials and for studies of toxicity that will be carried out under protocols that meet all standards for approval by the FDA or a comparable regulatory agency in a foreign country.

6.04 - LICENSEE agrees to use commercially reasonable efforts to develop a sublicensing program to effect commercialization of LICENSED PRODUCTS that the LICENSEE decides not to exploit on its own.

6.05 - During the term of this AGREEMENT, LICENSEE will submit annual progress reports to LICENSOR with the royalty report due pursuant to Article 3 hereof by February 28 of each year which discuss the progress and results, as well as ongoing plans, with respect to the HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS.

6.06 - LICENSEE shall support pre-clinical and clinical research at Duke University to develop LICENSED PRODUCTS. The nature and scope of these research projects shall be determined in good faith between the parties. Such research support shall begin no later than November 20, 1999 and shall continue for no less than sixteen (16) months from such date. LICENSEE agrees to commit no less than an aggregate of [Confidential Treatment Requested]United States Dollars (\$[Confidential Treatment Requested]) to total direct and indirect costs of such preclinical and clinical studies within said sixteen month period. The details of the research projects and the timing of such funding by LICENSEE will be embodied in appropriate non-clinical and clinical research agreements between LICENSEE and LICENSOR.

6.07 - LICENSOR may terminate this AGREEMENT or convert this AGREEMENT to a non-exclusive AGREEMENT if LICENSEE fails to meet any of the commercialization milestones in this Article 6 after notice and opportunity to cure as specified under Section 10.03 hereof.

## ARTICLE 7 - PATENT PROSECUTION, EXPENSES, DEFENSE, AND INFRINGEMENT

7.01 - Subsequent to the EFFECTIVE DATE of this AGREEMENT, LICENSOR shall continue to have sole responsibility for filing, prosecuting and maintaining appropriate patent protection in the United States and in those MAJOR MARKET COUNTRIES where patent protection is available for the PATENT RIGHTS, and all of the expenses of such protection shall be paid by LICENSOR. LICENSOR shall keep LICENSEE advised as to the prosecution of such applications by forwarding to LICENSEE copies of all official correspondence relating thereto. LICENSEE agrees to cooperate with LICENSOR in the prosecution of the U.S. Patent Applications to insure that the application reflects, to the best of LICENSEE'S knowledge, all items of commercial and technical interest and importance. All final decisions with respect to the prosecution of said application are reserved to LICENSOR.

7.02 - Subsequent to the EFFECTIVE DATE of this AGREEMENT, LICENSEE shall designate the foreign countries ("DESIGNATED COUNTRIES") other than MAJOR MARKET COUNTRIES, if any, in which LICENSEE desires patent protection, and LICENSOR agrees to proceed to seek patent protection in such DESIGNATED COUNTRIES. LICENSEE shall be responsible for reimbursing LICENSOR for foreign patent expenses incurred in perfecting patent protection in DESIGNATED COUNTRIES. LICENSOR may elect to seek patent protection in countries not so designated by LICENSEE, in which case LICENSOR shall be solely responsible for all expenses attendant thereto; however, in such instances LICENSEE shall forfeit its rights under this AGREEMENT as to those countries.

7.03 - Section 7.01 of this AGREEMENT notwithstanding, LICENSEE shall reimburse LICENSOR for all out-of-pocket legal expenses incurred in the prosecution and maintenance of PATENT RIGHTS in the United States of America, in MAJOR MARKET COUNTRIES, and in DESIGNATED COUNTRIES, according to the following schedule:

a. Within thirty (30) days after the EFFECTIVE DATE of this AGREEMENT, a sum equal to the amount of all unreimbursed expenses incurred by LICENSOR in the prosecution of PATENT RIGHTS; and

b. Subsequent to the EFFECTIVE DATE of this Agreement, LICENSOR shall invoice LICENSEE for additional patent expenses as they are incurred, and LICENSEE shall reimburse LICENSEE within thirty (30) days of being invoiced.

7.04 - LICENSEE and LICENSOR shall give prompt notice to each other of each claim or allegation received by it that the manufacture, use or sale of LICENCED PRODUCTS constitutes a significant infringement of a third party patent or patents. LICENSEE shall have the primary right and responsibility at its own expense to defend and control the defense of any such claim against LICENSEE, by counsel of its choosing. The settlement of any such actions must be approved by

LICENSOR, which approval may not be unreasonably withheld. LICENSOR agrees to cooperate with LICENSEE in any reasonable manner deemed by LICENSEE to be necessary in defending or prosecuting such action. Notwithstanding the foregoing, LICENSOR shall in its sole discretion and at its sole cost, be entitled to participate through counsel of its own choosing in any such action.

7.05 - Upon learning of the infringement of HEAT TRIGGERED DELIVERY TECHNOLOGY or PATENT RIGHTS by a third party, the party learning of such infringement shall promptly inform the other party in writing of that fact along with any evidence available pertaining to the infringement. LICENSEE may at its own expense take whatever steps are necessary to stop the infringement and recover damages. In such case, LICENSEE will keep LICENSOR informed of the steps taken and the progress of any legal actions taken. Any award granted to LICENSEE by a court or in settlement for lost sales, less any reasonable attorney's fees, shall be considered as NET SALES by the LICENSEE, and LICENSEE shall pay royalties on such an awards as specified under Section 3.01 hereof. LICENSEE will pay to LICENSOR [Confidential Treatment Requested] percent ([Confidential Treatment Requested]%) of any punitive damages awarded during an infringement action or settlement that are in excess of legal expenses incurred by LICENSEE in enforcing its rights to the HEAT TRIGGERED DELIVERY TECHNOLOGY or the PATENT RIGHTS. If LICENSEE does not undertake, within sixty (60) days of notice, to enforce its rights to the HEAT TRIGGERED DELIVERY TECHNOLOGY or the PATENT RIGHTS against the infringing party, the LICENSOR shall have the right, at its own expense to take whatever steps are necessary to stop the infringement and recover damages, and shall be entitled to retain damages so recovered.

#### **ARTICLE 8 - GOVERNMENT CLEARANCE AND EXPORT**

8.01 - LICENSEE agrees to use its best efforts to have LICENSED PRODUCTS cleared for marketing in those countries in which LICENSEE intends to sell LICENSED PRODUCTS by the responsible government agencies requiring such clearance. To accomplish said clearances at the earliest possible date, LICENSEE agrees to file, according to the usual practice of LICENSEE, any necessary data with said government agencies. Should LICENSEE terminate this AGREEMENT, LICENSEE agrees to assign its full interest and title in such market clearance application, including all data relating thereto, to LICENSOR at no cost to LICENSOR.

8.02 - This agreement is subject to all of the United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities and technology.

#### **ARTICLE 9 - PUBLICATION AND CONFIDENTIALITY**

9.01 - LICENSEE agrees that the right of publication of the invention and said HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS shall reside in the inventor and other staff of LICENSOR. The LICENSOR shall use its best efforts to provide a copy of such publication forty-five (45) days in advance of such submission for review by LICENSEE so that LICENSEE can advise LICENSOR on issues relating to patent protection, but such review will be in no way construed as a right to restrict such publication. LICENSEE shall also have the right to publish and/or co-author any publication on the HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS based upon data developed by LICENSEE according to usual academic procedures.

9.02 - Each party shall keep confidential and not disclose, directly or indirectly, for a period of [Confidential Treatment Requested] ([Confidential Treatment Requested]) years from the date of disclosure, and shall not use for the benefit of itself or any other individual or entity any CONFIDENTIAL INFORMATION of the other, except with the prior written approval of the disclosing party (the "DISCLOSING PARTY"). "CONFIDENTIAL INFORMATION" means any trade secrets or confidential, proprietary information, whether written, oral, digital or other form, which is unique, confidential or proprietary to the DISCLOSING PARTY, including but not limited to, the applicable HEAT TRIGGERED DELIVERY TECHNOLOGY, PATENT RIGHTS, LICENSED PRODUCTS and any other materials or information related to the business or activity of the DISCLOSING PARTY which is not generally known to others engaged in similar businesses or activities. Information disclosed in written media shall be clearly marked "CONFIDENTIAL" in order to be entitled to protection as CONFIDENTIAL INFORMATION. Information disclosed orally or in other media shall be considered CONFIDENTIAL INFORMATION only if the information is reduced to a written summary by the DISCLOSING PARTY, and if said written summary is marked "CONFIDENTIAL" and sent to the party receiving the disclosure within thirty (30) days of the date of disclosure. The recipient of such CONFIDENTIAL INFORMATION has no confidentiality obligation hereunder with respect to CONFIDENTIAL INFORMATION that (a) was in the possession of, or was rightfully known, by such recipient without a confidentiality obligation prior to receipt of such CONFIDENTIAL INFORMATION from the DISCLOSING PARTY; (b) is, or becomes, generally known to the public without violation of this AGREEMENT; (c) is retained by such recipient in good faith from a third party having the right to disclose such CONFIDENTIAL INFORMATION without a confidentiality obligation; (d) is independently developed by such recipient without the participation of individuals who have had access to the CONFIDENTIAL INFORMATION; or (e) is required to be disclosed by law or government authority, provided such recipient provides the DISCLOSING PARTY with reasonable advance written notice.

#### **ARTICLE 10 - DURATION AND TERMINATION**

10.01 - This AGREEMENT shall become effective upon the EFFECTIVE DATE, and unless sooner terminated in accordance with any of the provisions herein, shall remain in full force and effect for the life of the last-to-expire of the patents and patent applications included in the PATENT RIGHTS.

10.02 - LICENSEE may terminate this AGREEMENT at any time by giving LICENSOR written notice at least three (3) months prior to such termination, and thereupon terminate the manufacture, use or sale of LICENSED PRODUCTS.

10.03 - Except as provided above, if either party fails to fulfill any of its obligations under this AGREEMENT, the non-breaching party may terminate this AGREEMENT, upon written notice to the breaching party, as provided below. Such notice must contain a full description of the event or occurrence constituting a breach of this AGREEMENT. The party receiving notice of the breach will have the opportunity to cure that breach within ninety (90) days of receipt of notice. If the breach is not cured within that time, the termination will be effective as of the ninetieth (90th) day after receipt of notice. A party's ability to cure a breach will apply only to the first two breaches properly noticed under the terms of this AGREEMENT, regardless of the nature of those breaches. Any subsequent breach by that party will entitle the other party to terminate this AGREEMENT upon proper notice.

10.04 - Either party may immediately terminate this AGREEMENT for fraud, willful misconduct, or illegal conduct of the other party upon written notice of same to that other party.

10.05 - Upon the termination of this AGREEMENT, LICENSEE may notify LICENSOR of the amount of LICENSED PRODUCT LICENSEE then has on hand and LICENSEE shall then have a license to sell that amount of LICENSED PRODUCT, but no more, provided LICENSEE shall pay the royalty thereon at the rate and at the time provided for.

10.06 - If during the term of this AGREEMENT, LICENSEE shall become bankrupt or insolvent or if the business of LICENSEE shall be placed in the hands of a receiver or trustee, whether by the voluntary act of LICENSEE or otherwise, or if LICENSEE shall cease to exist as an active business, this AGREEMENT shall immediately terminate.

#### **ARTICLE 11 - LAW TO GOVERN**

11.01 - This AGREEMENT shall be construed and enforced in accordance with the laws of the State of North Carolina.

#### **ARTICLE 12 - NOTICES**

12.01 - Notice hereunder shall be deemed sufficient if given by registered mail, postage prepaid, and addressed to the party to receive such notice at the address given below, or such other address as may hereafter be designated by notice in writing.

##### **LICENSOR**

Office of Science and Technology  
Duke University  
Room 230, North Building  
Box 90083  
Durham, NC 27708

cc:

Office of the University Counsel  
Duke University  
2400 Pratt Street, Suite 4000  
Durham, NC 27710

##### **LICENSEE**

Celsion Corporation  
10220-1 Old Columbia Road  
Columbia, MD 21046-1705

cc:

Bresler Goodman & Unterman, LLP  
521 Fifth Avenue  
New York, NY 10175  
Attention: Kevin J. Lake, Esq.

#### **ARTICLE 13 - ASSIGNMENT**

13.01 - This AGREEMENT shall be binding upon and inure to the benefit of the respective successors and assigns of the parties hereto. However,

LICENSEE may not assign its rights in this AGREEMENT without approval by LICENSOR, such approval not to be unreasonably withheld. Notwithstanding the foregoing, the LICENSEE may assign its rights under this AGREEMENT, without the consent of the LICENSOR, to (i) the SUBSIDIARY referred to in Section 4.02 hereof and (ii) a third party which acquires all or substantially all of its assets.

#### **ARTICLE 14 - INDEMNITY, INSURANCE, REPRESENTATIONS, STATUS**

14.01 - Except for intellectual property infringement, LICENSEE agrees to indemnify, hold harmless and defend LICENSOR, its officers, and directors, employees, and agents, against any and all claims, suits, losses, damages, costs, fees, and expenses asserted by third parties, both government and non-government, resulting from or arising out of the exercise of the license granted hereunder; provided, however, that LICENSEE shall not be responsible for the negligence or intentional wrong doing of LICENSOR.

14.02 - LICENSEE shall maintain in force at its sole cost and expense, with reputable insurance companies, general liability insurance and products liability insurance coverage in an amount reasonably sufficient to protect against liability under paragraph 14.01 above. LICENSOR shall have the right to ascertain from time to time that such coverage exists, such right to be exercised in a reasonable manner.

14.03 -NOTHING IN THIS AGREEMENT SHALL BE DEEMED TO BE A REPRESENTATION OR WARRANTY BY LICENSOR OF THE VALIDITY OF ANY OF THE PATENTS OR THE ACCURACY, SAFETY, EFFICACY, OR USEFULNESS, FOR ANY PURPOSE, OF THE HEAT TRIGGERED DELIVERY TECHNOLOGY AND PATENT RIGHTS. LICENSOR SHALL HAVE NO OBLIGATION, EXPRESS OR IMPLIED, TO SUPERVISE, MONITOR, REVIEW OR OTHERWISE ASSUME RESPONSIBILITY FOR THE PRODUCTION, MANUFACTURE, TESTING, MARKETING OR SALE OF ANY LICENSED PRODUCT, AND LICENSOR SHALL HAVE NO LIABILITY WHATSOEVER TO LICENSEE OR ANY THIRD PARTIES FOR OR ON ACCOUNT OF ANY INJURY, LOSS, OR DAMAGE, OF ANY KIND OR NATURE, SUSTAINED BY, OR ANY DAMAGE ASSESSED OR ASSERTED AGAINST, OR ANY OTHER LIABILITY INCURRED BY OR IMPOSED UPON LICENSEE OR ANY OTHER PERSON OR ENTITY, ARISING OUT OF OR IN CONNECTION WITH OR RESULTING FROM:

- a. the production, use, or sale of any LICENSED PRODUCT;
- b. the use of any HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS; or
- c. any advertising or other promotional activities with respect to any of the foregoing.

14.04 - Notwithstanding the foregoing, LICENSOR hereby represents as follows: (i) to the best of its knowledge, LICENSOR has the legal power and authority to extend the rights granted to LICENSEE in this AGREEMENT and that it has not made any commitments to others inconsistent with or in degradation of such rights; and (ii) LICENSOR is not aware of any pending or threatened litigation involving any of the HEAT TRIGGERED DELIVERY TECHNOLOGY or PATENT RIGHTS licensed hereunder, and that, to its best knowledge, neither the HEAT TRIGGERED DELIVERY TECHNOLOGY nor PATENT RIGHTS are subject to any third party infringement claims.

14.05 - Neither party hereto is an agent of the other party for any purpose whatsoever.

14.06 - LICENSOR represents that to the best of its knowledge the HEAT TRIGGERED TECHNOLOGY releases agents under the conditions specified in PATENT RIGHTS.

14.07 - LICENSOR agrees that, with respect to the HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS, it will not assert against LICENSEE, or its vendees, mediate or immediate, any claim for infringement based on the manufacture, use or sale of any apparatus or product made or sold by LICENSEE under the license granted in this AGREEMENT upon which royalty has been paid in accordance with the provisions of this AGREEMENT.

#### **ARTICLE 15 - USE OF A PARTY'S NAME**

15.01 - Neither party will, without the prior written consent of the other party:

a. use in advertising, publicity or otherwise, any trade-name, personal name, trademark, trade device, service mark, symbol, or any abbreviation, contraction or simulation thereof owned by the other party; or

b. represent, either directly or indirectly, that any product or service of the other party is a product or service of the representing party or that it is made in accordance with or utilizes the information or documents of the other party.

#### **ARTICLE 16 - SEVERANCE, WAIVER AND ALTERATION**

16.01 - Each clause of this AGREEMENT is a distinct and severable clause and if any clause is deemed illegal, void or unenforceable, the validity, legality or enforceability of any other clause or portion of this AGREEMENT will not be affected thereby.

16.02 - The failure of a party in any instance to insist upon the strict performance of the terms of this AGREEMENT will not be construed to be a waiver or relinquishment of any of the terms of this AGREEMENT, either at the time of the party's failure to insist upon strict performance or at any time in the future, and such terms will continue in full force and effect.

16.03 - Any alteration, modification, or amendment to this AGREEMENT must be in writing and signed by both parties.

**ARTICLE 17 - TITLES**

17.01 - All titles and article headings contained in this AGREEMENT are inserted only as a matter of convenience and reference. They do not define, limit, extend or describe the scope of this AGREEMENT or the intent of any of its provisions.

**ARTICLE 18 - ENTIRE UNDERSTANDING**

18.01 - This AGREEMENT represents the entire understanding between the parties, and supersedes all other agreements, express or implied, between the parties concerning the FIELD, including the HEAT TRIGGERED DELIVERY TECHNOLOGY and PATENT RIGHTS.

IN WITNESS WHEREOF, the parties have caused these presents to be executed in duplicate as of the date and year first above written.

*SEAL*

*DUKE UNIVERSITY*

*By: /s/Gordan O. Williams  
-----  
Gordon O. Williams  
Vice Dean, Finance & Administration*

*SEAL*

*CELSION CORPORATION*

*By: /s/Augustine Y. Cheung  
-----  
Augustine Y. Cheung  
Chairman of the Board*

EXHIBIT 10.10

Celsion Corporation

March 23, 1999

To: Dr. Fred Sterzer  
President, President of MMTC  
12 Rozel Road  
Suite A203  
Princeton, NJ 08540

RE Amendment for the Use and Treatment of Prostate Cancer to the August 23, 1996 License Agreement and November 25, 1997 Amendment

Dear Fred:

This amendment as agreed is to be added to the existing agreement dated August 23, 1996 and amendment dated November 25, 1997 between MMTC and Celsion Corporation. The following agreed terms and conditions are for the expanded "Field of Use" for prostatic diseases in humans, "including the treatment of cancer and its symptoms of the prostate, except for the use with PULSED microwave".

The new terms and conditions of this amendment are listed in the following comparison table under the heading "New Amendment".

Comparison Table of MMTC Sterzer Agreements Dated August 23, 1996f and Proposed Amendment to Include Usage For Prostate Cancer

	Original	New Amendment
Date of Agreement	August 23, 1996 Amendment to License November 25, 1997	Amendment to the original agreement and Nov. 25, 1997 amendment as related to the use and treatment of Prostate Cancer. Unless stated otherwise, the terms and conditions of the original and prior amendment remains in force.
Field of Use	Treatment of prostatic diseases in humans, excepting the treatment of cancer of the prostate	Treatment of prostatic diseases in humans, including the treatment of cancer of the prostate, except for the use with Pulsed microwave
Rights	Perpetual, exclusive and worldwide license	Same

Comparison Table of MMTC Sterzer Agreements Dated August 23, 1996f and Proposed Amendment to Include Usage For Prostate Cancer

Up-front License fee	\$[Confidential Treatment Requested] April 1, 1999 for 12 months ending March 31, 2000 for a total of \$[Confidential Treatment Requested]	\$[Confidential Treatment Requested] /month beginning
Additional Fees for failure to meet development milestones	\$[Confidential Treatment Requested] for each failure 1. File IDE within 2 months after completion of necessary animal safety data (Montefiore Medical Ctr) 2. Commence clinical safety trial within 60 days of IDE and IRB approval 3. Commence clinical efficacy trial within 60 of IDE and IRB approval	\$[Confidential Treatment Requested] for each failure 1. File IDE within 2 months after completion of necessary animal safety data (UCSF) 2. Same 3. Same
Royalties payments	([Confidential Treatment Requested]%) annual Net Sales as defined in 3.3	Same
Minimum	Royalties \$[Confidential Treatment Requested]/yr for a period of 7 years beginning the earlier of first full year of commercialization or the fiscal year beginning after December 31, 1999	\$[Confidential Treatment Requested]/yr for a period of 7 years beginning the earlier of the first full year of commercialization or the fiscal year beginning after December 31, 2001

Unless otherwise mentioned in the New Amendment all terms and conditions remain in force as worded in the Original Agreement dated August 23, 1996 and the Amendment dated November 25, 1997. The effective date of this amendment is April 1, 1999 upon payment by Celsion of the first Up-Front license fee of \$[Confidential Treatment Requested]/month, thereafter monthly for an additional 11 months for a total payment of \$[Confidential Treatment Requested] (12X\$[Confidential Treatment Requested]). It is agreed, a portion of this license fee (amount used at the discretion of MMTC) will be used to further development of the MMTC radiometry technology of which Celsion will pay MMTC royalties for its use as under the royalty structure of the initial agreement.

In addition, Celsion will give MMTC access to any materials from the proposed sponsored research agreement between Celsion and UCSF to be used by MMTC for any grants MMTC desires to make application for. This represents the entirety of this new amendment and is initiated by the two parties with the following authorized signatures.

By /s/John Mon  
 -----  
 John Mon  
 General Manager, Celsion Corporation

By /s/Dr. Fred Sterzer  
 -----  
 Dr. Fred Sterzer  
 President, MMTC

**EXHIBIT 10.11**

**OPTION AGREEMENT  
(SK#3898)**

Effective on February 26,1999 (hereinafter the "Effective Date")

SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, a not-for-profit corporation organized and existing under the laws of the State of New York, and having a place of business located at 1275 York Avenue, New York, New York 10021 (hereinafter "SKI") and

CELSION CORPORATION, a corporation organized under the laws of the State of Maryland, and having a place of business located at 10220-1 Old Columbia Road, Columbia, Maryland 21046-1705 ("CELSION"). .

WHEREAS, SKI possesses certain PATENT RIGHTS (defined herein below), relating to heat sensitive gene therapy, uses of DNA-PK to enhance sensitization of tumors to conventional treatments;

WHEREAS, SKI wishes to have the PATENT RIGHTS evaluated and applied to commercial purposes as quickly as possible in order that products resulting therefrom may be available for public use and benefit;

WHEREAS, CELSION is focused on hyperthermic treatment of cancer and would like to have an option to obtain an exclusive license to use said PATENT RIGHTS for such use in the treatment of cancer; and

WHEREAS, SKI is willing to grant an OPTION to CELSION for a license to use the PATENT RIGHTS on the terms and conditions hereinafter set forth.

NOW, THEREFORE, in view of these premises and in consideration of the mutual covenants herein contained, the Parties hereto agree as follows;

**ARTICLE 1  
DEFINITIONS**

**ARTICLE I - DEFINITIONS**

For the purpose of this Agreement, the following words and phrases shall have the following meanings:

1.1 "CELSION" shall include its Affiliates, that is, any person, firm, corporation or other entity controlling, controlled by, or under common control with a party hereto. The term "control" wherever used throughout this Agreement shall mean ownership, directly or indirectly, of more than 50% of the equity capital. With regard to SKI, "Affiliate" shall mean the Memorial Sloan-Kettering Cancer Center and the Memorial Hospital for Cancer and Allied Diseases.

1.2 "Patent Rights" shall mean all of the following SKI intellectual property:

- (a) The United States patent application entitled, "Uses of DNA-PK", filed on July 1, 1998;
- (b) United States and foreign patents issued from such application, and from divisionals and continuations of this application;
- (c) claims of U.S. and foreign continuation-in-part applications, and of the resulting patents, which are directed to subject matter specifically described in such United States patent application;
- (d) any reissues or re-examinations of patents described in (a), (b), or (c), above.

1.3 "Field of Use" shall mean the use of the PATENT RIGHTS in the field of cancer therapy.

## **ARTICLE 2**

### **OPTION**

2.1 SKI hereby grants to CELSION for six (6) months from the Effective Date an exclusive option to an exclusive, world-wide license, with the right to sublicense for the PATENT RIGHTS in the FIELD, to be negotiated in good faith on reasonable terms and conditions, including license issue fee, milestone payments, and royalties. If CELSION decides to exercise this option, it shall so notify SKI in writing within the term of this agreement. In the event the parties, acting in good faith, fail to reach a mutually acceptable agreement within three (3) months after commencing negotiations, SKI shall be entitled to negotiate a license with a third party for PATENT RIGHTS.

2.2 Notwithstanding any other provisions of this Agreement, it is agreed that SKI and its Affiliates shall retain the right to practice the licensed PATENT RIGHTS for its own teaching, research and patient care activities. All rights reserved to the United States Government and others under 35 USC ss.ss.200-212, as amended, shall remain and shall in no way be affected by this Agreement.

**ARTICLE 3**  
**CONSIDERATION**

3.1 Upon signing this Agreement, CELSION shall pay to SKI (\$ Confidential Treatment Requested) U.S. dollars (Confidential Treatment Requested), Such payment will not be credited against fees, advances or royalties under any license agreement later negotiated.

**ARTICLE 4**  
**PATENT PROSECUTION**

4.1 Upon signing this Agreement, CELSION shall pay to SKI (\$ Confidential Treatment Requested) as reimbursement for past patent expenses.

4.2 CELSION shall be responsible for and pay all reasonable patent costs and expenses incurred by SKI for the preparation, filing, prosecution, issuance, and maintenance of the PATENT RIGHTS during the term of this Agreement. CELSION shall pay to SKI all such costs and expenses within thirty (30) days of receipt of an invoice of such costs and expenses.

4.3 SKI shall diligently prosecute and maintain the PATENT RIGHTS in the United States and in such countries as are determined by SKI and agreed to by CELSION, using counsel of its choice. If CELSION does not agree to bear the expense of filing patent applications in any foreign countries in which SKI wishes to obtain patent protection, then SKI may file and prosecute such applications at its own expense and any rights granted hereunder shall exclude such countries.

4.4 SKI shall provide CELSION with copies of all relevant documentation so that CELSION may be informed and to give CELSION reasonable opportunity to advise SKI of the continuing prosecution, and CELSION agrees to keep this documentation confidential.

**ARTICLE 5**  
**NOTICES**

5.1 Any payment, notice or other communication pursuant to this Agreement shall be sufficiently made or given when delivered by courier or other means providing proof of delivery to such party at its address below or as it shall designate by written notice given to the other party:

In the case of SKI:

Sloan-Kettering Institute for Cancer Research 1275 York Avenue  
New York, New York 10021  
Attention: James S. Quirk  
Senior Vice President  
Research Resources Management

In the case of LICENSEE:

Celsion Corporation  
10220-1 Old Columbia Road  
Columbia, MD 21046-1705  
Attention: Augustine Y. Cheung, Ph.D.  
Chairman

**ARTICLE 6**  
**NON-USE OF NAMES**

6.1 CELSION shall not use the names of SKI or its Affiliates, nor any of their employees, nor any adaptation thereof, in any advertising, promotional or sales literature without prior written consent obtained from SKI in each case.

**ARTICLE 7**  
**TERM**

7.1 This Agreement shall terminate six (6) months after the Effective Date or three (3) months after CELSION exercises its option granted under Article 2, whichever is longer, unless terminated sooner as provided in this Article 7.

7.2 CELSION shall be entitled to terminate this Agreement for any reason upon thirty (30) days advance written notice to SKI.

7.3 Upon any material breach of this Agreement by CELSION, SKI shall have the right to terminate this Agreement and the rights, privileges and license granted hereunder by thirty (30) days' notice to CELSION. Such termination shall become effective unless CELSION shall have cured any such breach prior to the expiration of the thirty (30) day period.

7.4 SKI may terminate this Agreement if CELSION becomes insolvent or, a petition in bankruptcy is filed against CELSION and is consented to, acquiesced in or remains undismissed for thirty (30) days; or makes a general assignment for the benefit of creditors, or a receiver is appointed for CELSION, and CELSION does not return to solvency before the expiration of a thirty (30) day period.

7.5 Upon termination of this Agreement, for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination,

**ARTICLE 8**  
**MISCELLANEOUS PROVISIONS**

8.1 This Agreement shall be governed by and construed in accordance with the laws of the State of New York.

8.2 This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective legal representatives, successors and permitted assigns.

8.3 Except as otherwise expressly set forth in this Agreement, SKI MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND VALIDITY OF PATENT RIGHTS CLAIMS, ISSUED OR PENDING.

8.4 Paragraph headings are inserted herein for convenience of reference only and do not form a part of this Agreement, and no construction or inference shall be derived therefrom.

8.5 This Agreement and the instruments, documents and other agreements referred to herein or signed concurrently set forth the entire agreement and understanding of the parties regarding the subject matter.

8.6 This Agreement may be executed in any number of counterparts and each of such counterparts shall for all purposes be an original and all such counterparts shall together constitute but one and the same agreement.

8.7 This Agreement may be amended, modified, superseded or canceled, and any of the terms hereof may be waived, only by a written instrument executed by each party hereto or, in the case of waiver, by the party waiving compliance. The delay or failure of any party at any time or times to require performance of any provision hereof shall in no manner affect the rights at a later time to enforce the same. No waiver by any party of any condition or of the breach of

any term contained in this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

8.8 No person not a party to this Agreement, including any employee of any party to this Agreement, shall have or acquire any rights by reason of this Agreement, nor shall any party hereto have any obligations or liabilities to such other Person by reason of this Agreement. Nothing contained in this Agreement shall be deemed to constitute the parties partners with each other or any Person.

8.9 This Agreement may not be assigned by CELSION without prior written consent from SKI, except that CELSION may, without SKI's consent, assign this Agreement to any entity that it may merge into, consolidate with, or transfer substantially all of its assets ("substantially" being EIGHTY PERCENT (80%) or more thereof) as an entirety, so long as the successor surviving corporation in any such merger, consolidation, transfer or reorganization assumes in writing the obligations of this Agreement.

8.10 The provisions of this Agreement are severable, and in the event that any provisions of this Agreement shall be determined to be invalid or unenforceable under any controlling body of the law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions hereof.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date first written above,

*Signed by /s/G.J.Bernhardt*  
-----  
*James S. Quirk*  
*Senior Vice President*  
*Research Resouces Management*

*Signed by /s/Augustine Y. Cheung*  
-----  
*Augustine Y. Cheung, Ph.D.*  
*Chairman*

*Date": 3/16/99*  
-----

*Date: 3/11/99*  
-----

(Logo)

Senior Vice President  
Research Resources Management

March 16, 1999

**TO WHOM IT MAY CONCERN:**

In my absence, Mr. Gustave J. Bernhardt, Director, Research Resources Management, will sign as an institutional official for the Sloan-Kettering Institute for Cancer Research.

*/s/ James S. Quirk*  
-----  
*James S. Quirk*  
*Senior Vice President*

JSQ:meb

Memorial Sloan-Kettering Cancer Center 1275 York Avenue, New York, New York 10021 NCI-designated Comprehensive Cancer Center

**EXHIBIT 10.12**

(Logo)

**Office of Industrial Affairs**

August 31, 1999

John Mon  
General Manager  
Celsion Corporation  
10220-1 Old Columbia Road  
Columbia, MD 21046-1705

Dear John:

It was a pleasure speaking with you last week. This letter will confirm that April 9, 1999 is the accurate effective date of the Option Agreement between Sloan-Kettering Institute for Cancer Research and Celsion Corporation signed on February 26, 1999. The revised effective date was agreed to during a conversation between you and Steve Bertha in March but has not been made a formal amendment to the agreement. If Celsion would like a formal amendment to the option agreement, then we will prepare one. The option period will expire on November 9, 1999.

Please do not hesitate to contact me if you have any questions. I look forward to our upcoming meeting.

Sincerely,

*/s/Jennifer A. Brooks*

-----  
*Jennifer A. Brooks*  
*Licensing Associate*

Memorial Sloan-Kettering Cancer Center 1275 York Avenue, New York, New York 10021 NCI-designated Comprehensive Cancer Center

**EXHIBIT 10.25**

**Form of Warrant**

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED OR ANY STATE SECURITIES LAWS AND NEITHER THE SECURITIES NOR ANY INTEREST THEREIN MAY BE OFFERED, SOLD, TRANSFERRED, PLEDGED OR OTHERWISE DISPOSED OF EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER SUCH ACT OR SUCH LAWS OR AN EXEMPTION FROM REGISTRATION UNDER SUCH ACT AND SUCH LAWS WHICH, IN THE OPINION OF COUNSEL FOR THE HOLDER, WHICH COUNSEL AND OPINION ARE REASONABLY SATISFACTORY TO COUNSEL FOR THIS CORPORATION, IS AVAILABLE.

Warrant Certificate No.: \_\_\_\_\_

Date of Issue: \_\_\_\_\_

Void after 5:00 p.m. New York time on \_\_\_\_\_.

**CELSION CORPORATION**

This certifies that \_\_\_\_\_ (the "Holder"), for a value received, is entitled, subject to the adjustment and to the other terms set forth below, to purchase from Celsion Corporation, a Maryland corporation (the "Company"), \_\_\_\_\_ fully paid and non-assessable shares of the Common Stock, par value \$0.01 per share, of the Company (the "Common Stock") at the Exercise Price of \$0.90 per share. The Warrant shall be exercisable at any time on and after the date hereof but not later than 5:00 P.M. (New York time) on the third anniversary of the date hereof (the "Expiration Date"), upon surrender to the Company at its principle office at 10220-I Old Columbia Road, Columbia, MD 21046-1705, Attention: Dr. Augustine Cheung, Chairman of the Board and Chief Executive Officer (or at such other location as the Company may advise the Holder in writing) of this Warrant properly endorsed with the Purchase Form attached hereto duly filled in and signed and upon payment in cash or cashier's check of the aggregate Exercise Price for the number of shares for which this Warrant is being exercised determined in accordance with the provisions hereof. From and after April 1, 1999, the Company, at its option, may redeem in whole or in part this Warrant for an amount equal to \$0.01 per share if the current market value of the Common Stock, as determined in accordance with paragraph (c) hereof, rises to more than \$1.80 per share at any time from and after April 1, 1999. The Company must give at least thirty (30) days notice of such redemption, during which period the holders of the Warrants may exercise their Warrants in accordance with the terms thereof. The Exercise Price and, in some cases, the number of shares purchasable hereunder are subject to adjustment as provided in Section (g) of this Warrant. This Warrant and all rights hereunder, to the extent not exercised in the manner set forth herein shall terminate and become null and void on the Expiration Date. In the event that the Holder does not exercise this Warrant pursuant to the terms of this Warrant, then this Warrant shall expire, be canceled, and be null and void.

(a) Exercise of Warrant. This Warrant may be exercised in whole or in part at any time or from time to time on or after the date hereof, but not later than 5:00 p.m. New York time, on the Expiration Date. If such date is a day on which banking institutions are authorized by law to close, then the expiration date shall be on the next succeeding day which shall not be such a day. This Warrant may be exercised by presentation and surrender hereof to the Company or at the office of its stock transfer agent, if any, with written notice duly executed and accompanied by payment in cash or cash equivalent of the Exercise Price for the number of shares specified in such notice, together with all federal and state taxes applicable upon such exercise. If this Warrant should be exercised in part only, the Company shall, upon surrender of this Warrant for cancellation, execute and deliver a new Warrant evidencing the right of the holder to purchase the balance of the shares purchasable hereunder. Upon receipt by the Company of this Warrant at the office or agency of the Company, in proper form for exercise, the Holder shall be deemed to be the holder of record of the shares of Common Stock issuable upon such exercise, notwithstanding that the stock transfer books of the Company shall then be closed or that certificates representing such shares of Common Stock shall not then be actually delivered to the Holder.

(b) Reservation of Shares. The Company hereby agrees that at all times there shall be reserved for issuance and/or delivery upon exercise of this Warrant such number of shares of its Common Stock as shall be required for issuance or delivery upon exercise of this Warrant.

(c) Fractional Shares. No fractional shares or script representing fractional shares shall be issued upon the exercise of this Warrant. With respect to any fraction of a share called for upon any exercise hereof, the Company shall pay to the Holder an amount in cash equal to such fraction multiplied by the current market value of such fractional share, determined as follows:

(1) If the Common Stock is listed on a national securities exchange, admitted to unlisted trading privileges on such exchange or quoted on the Nasdaq National Market System or other interdealer trading systems providing last sale information, the current value shall be the last reported sale price of the Common Stock on such exchange, Nasdaq/NMS or trading system on the last business day prior to the date of exercise of this Warrant or if no such sale is made on such day, the average closing bid and asked prices for such day on such exchange, Nasdaq/NMS or trading system; or

(2) If the Common Stock is not so listed or admitted to unlisted trading privileges, the current value shall be the mean of the last reported bid and asked prices reported by an interdealer quotation system deemed reliable by the Company on the last business day prior to the date of the exercise of this Warrant; provided that if the Common Stock is quoted on more than one such system, the Company shall utilize, in order of priority, Nasdaq, the NASD OTC Bulletin Board or the National Quotation Bureau, Inc.; or

(3) If the Common Stock is not so listed or admitted to unlisted trading privileges and bid and asked prices are not so reported, the current value shall be an amount, not less than book value, determined in such reasonable manner as may be prescribed by the Board of Directors of the Company, such determination to be final and binding on the Holder.

(d) Restrictions on Transfer. The securities represented hereby and the shares to be issued on exercise have not been registered under federal or state securities laws. They may not be sold or offered for sale in the absence of effective registration under such securities laws, or an opinion of counsel satisfactory to the Company that such registration is not required.

(e) Exchange, Assignment or Loss of Warrant. This Warrant is exchangeable, without expense, at the option of the Holder, upon presentation and surrender hereof to the Company or at the office of its stock transfer agent, if any, for other Warrants of different denominations entitling the holder thereof to purchase in the aggregate the same number of shares of Common Stock purchasable hereunder. Subject to compliance with Section (d) hereof, this Warrant is assignable. Any such assignment shall be made by surrender of this Warrant to the Company or at the office of its stock transfer agent, if any, with written notice of assignment duly executed and funds sufficient to pay any transfer tax; whereupon the Company shall, without charge, execute and deliver a new Warrant in the name of the assignee named in such instrument of assignment and this Warrant shall promptly be canceled. This Warrant may be divided or combined with other Warrants which carry the same rights upon presentation hereof at the office of the Company or at the office of its stock transfer agent, if any, together with a written notice specifying the names and denominations in which new Warrants are to be issued and signed by the Holder hereof. The term "Warrant" as used herein includes any Warrant issued in substitution for or replacement of this Warrant, or into which this Warrant may be divided or exchanged and the term "original issue date hereof" shall refer to the date that the Company first issued a Warrant which was subsequently transferred or exchanged for another. Upon receipt by the Company of evidence satisfactory to it of the loss, theft, destruction or mutilation of this Warrant, and (in the case of loss, theft or destruction) of reasonably satisfactory indemnification, and upon surrender and cancellation of this Warrant, if mutilated, the Company will execute and deliver a new Warrant of like tenor and date. Any such new Warrant executed and delivered shall constitute an additional contractual obligation on the part of the Company whether or not this Warrant so lost, stolen, destroyed, or mutilated shall be at any time enforceable by anyone.

(f) Rights of the Holder. The Holder shall not, by virtue hereof, be entitled to any rights of a shareholder in the Company either at law or in equity, and the rights of the Holder are limited to those expressed in this Warrant and are not enforceable against the Company except to the extent set forth herein.

(g) Anti-Dilution Provisions.

(1) Adjustment of Number of Shares. Anything in this Section

(g) to the contrary notwithstanding, in case the Company shall at any time issue Common Stock by way of dividend or other distribution on any stock of the Company or subdivide or combine the outstanding shares of Common Stock, the Exercise Price shall be proportionately decreased in the case of such issuance (on the day following the date fixed for determining shareholders entitled to receive such dividend or other distribution) or decreased in the case of such subdivision or increased in the case of such combination (on the date that such subdivision or combination shall become effective).

(2) No Adjustment for Small Amounts. Anything in this Section

(g) to the contrary notwithstanding, the Company shall not be required to give effect to any adjustment in the Exercise Price unless and until the net effect of one or more adjustments, determined as above provided, shall have required a change of the Exercise Price by at least one cent, but when the cumulative net effect of more than one adjustment so determined shall be to change the actual Exercise Price by at least one cent, such change in the Exercise Price shall thereupon be given effect.

(3) Number of Shares Adjusted. Upon any adjustment of the Exercise Price other than pursuant to Section (g)(1) hereof, the holder of this Warrant shall thereafter (until another such adjustment) be entitled to purchase, at the new Exercise Price, the number of shares, calculated to the nearest full share, obtained by multiplying the number of shares of Common Stock initially issuable upon exercise of this Warrant by the Exercise Price in effect on the date hereof and dividing the product so obtained by the new Exercise Price.

(4) Common Stock Defined. Whenever reference is made in this Section (g) to the issue or sale of shares of Common Stock, the term "Common Stock" shall mean the common shares of the Company of the class authorized as of the date hereof and any other class of stock ranking on a parity with such Common Stock. However, subject to the provisions of Section (j) hereof, shares issuable upon exercise hereof shall include only shares of the class designated as Common Stock of the Company as of the date hereof.

(h) Officer's Certificate. Whenever the Exercise Price shall be adjusted as required by the provisions of Section (g) hereof, the Company shall forthwith file in the custody of its Secretary or an Assistant Secretary at its principal office, and with its stock transfer agent, if any, an officer's certificate showing the adjusted Exercise Price determined as herein provided and setting forth in reasonable detail the facts requiring such adjustment. Each such officer's certificate shall be made available at all reasonable times for inspection by the Holder and the Company shall, forthwith after each such adjustment, deliver a copy of such certificate to the Holder. Such certificate shall be conclusive as to the correctness of such adjustment.

(i) Notice to Warrant Holders. So long as this Warrant shall be outstanding and unexercised (i) if the Company shall pay any dividend or make any distribution upon the Common Stock, or (ii) if the Company shall offer to the holders of Common Stock for subscription or purchase by them any shares of stock of any class or any other rights or (iii) if any capital reorganization of the Company, reclassification of the capital stock of the Company, consolidation or merger of the Company with or into another corporation, sale, lease or transfer of all or substantially all of the property and assets of the Company to another corporation, or voluntary or involuntary dissolution, liquidation or winding up of the Company shall be effected, then, in any such case, the Company shall cause to be delivered to the Holder, at least ten (10) days prior to the date specified in (x) or (y) below, as the case may be, a notice containing a brief description of the proposed action and stating the date on which (x) a record is to be taken for the purpose of such dividend, distribution or rights, or (y) such reclassification, reorganization, consolidation, merger, conveyance, lease, dissolution, liquidation or winding up is to take place and the date, if any, is to be fixed, as of which the holders of Common Stock of record shall be entitled to exchange their shares of Common Stock for securities or other property deliverable upon such reclassification, reorganization, consolidation, merger, conveyance, dissolution, liquidation or winding up.

(j) Reclassification, Reorganization or Merger. In case of any reclassification, capital reorganization or other change of outstanding shares of Common Stock of the Company (other than a change in par value, or from par value to no par value or from no par value to par value, or as a result of an issuance of Common Stock by way of dividend or other distribution or of a subdivision or combination), or in case of any consolidation or merger of the Company with or into another corporation (other than a merger in which the Company is the continuing corporation and which does not result in any reclassification, capital reorganization or other change of outstanding shares of Common Stock of the class issuable upon exercise of this Warrant) or in case of any sale or conveyance to another corporation of the property of the Company as an entirety or substantially as an entirety, the Company shall cause

effective provision to be made so that the Holder shall have the right thereafter, by exercising this Warrant, to purchase the kind and amount of shares of stock and other securities and property receivable upon such reclassification, capital reorganization or other change, consolidation, merger, sale or conveyance. Any such provision shall include provisions for adjustments which shall be as nearly equivalent as may be practicable to the adjustments provided for in this Warrant. The foregoing provisions of this Section (j) shall similarly apply to successive reclassifications, capital reorganizations and changes of shares of Common Stock and to successive consolidations, mergers, sale or conveyances. In the event that in any such capital reorganization or reclassification, consolidation, merger, sale or conveyance, additional shares of Common Stock shall be issued in exchange, conversion, substitution or payment, in whole or in part, for or of a security of the Company other than Common Stock, any such issue shall be treated as an issue of Common Stock covered by the provisions of Subsection (g) (1) hereof with the amount of the consideration received upon the issue thereof being determined by the Board of Directors of the Company, such determination to be final and binding on the holder.

(k) **Applicable Law.** This Warrant shall be governed by, and construed in accordance with, the laws of the State of Maryland.

(l) **Optional Waiver.** Holder may waive by signed writing any rights of Holder contained herein.

(m) IN ADDITION TO THE RESTRICTIONS ON TRANSFERABILITY DESCRIBED HEREIN, THE SECURITIES ISSUABLE ON EXERCISE OF THIS WARRANT SHALL NOT BE SOLD, PLEDGED, TRANSFERRED, HYPOTHECATED OR ASSIGNED WITHIN 7 DAYS BEFORE OR 180 DAYS AFTER THE DATE OF EFFECTIVENESS OF A REGISTRATION STATEMENT FILED BY THE COMPANY WITH THE SECURITIES AND EXCHANGE COMMISSION IN CONNECTION WITH A PUBLIC OFFERING OF THE COMPANY'S SECURITIES. THIS RESTRICTION IS IN ADDITION TO AND NOT IN LIEU OF THE RESTRICTIONS CONTAINED HEREIN AND AS SUCH, THIS 180 DAY PERIOD MAY EXPIRE PRIOR TO OR BEYOND THE RESTRICTIONS IMPOSED HEREIN. THIS RESTRICTION SHALL OBLIGATE ALL SUCCESSORS IN INTEREST TO THE SHARES ISSUED ON EXERCISE. CERTIFICATES REPRESENTING THE WARRANT STOCK SHALL BEAR A LEGEND EVIDENCING THIS RESTRICTION.

THIS WARRANT CERTIFICATE is granted and sold as of the date first above written.

**CELSION CORPORATION**

By: \_\_\_\_\_

Name:

Title:

**Attest:**

\_\_\_\_\_

Name:

Title:

**PURCHASE FORM**

Dated: \_\_\_\_\_

Celsion Corporation  
10220-I Old Columbia Road  
Columbia, MD 21046-1705  
Attention: Mr. John Mon, Secretary

Dear Mr. Mon:

Attached hereto is Celsion Corporation's Warrant Certificate No. \_\_\_\_\_, giving the Holder thereof the right to purchase \_\_\_\_\_ shares of the Common Stock, par value \$0.01 per share, of the Company (the "Common Stock") at the Exercise Price of \$0.90 per share.

I/We hereby notify you that I/we are exercising my/our right to purchase \_\_\_\_\_ shares of the Common Stock at the Exercise Price of \$0.90 per share (the "Shares") and have enclosed herewith my/our check in the amount of \$\_\_\_\_\_, representing the aggregate exercise price of the Shares. If transfer taxes (federal or state) are applicable to this transaction, I/we understand that you will be billing me/us for said taxes, which I/we agree will be promptly remitted to you within ten (10) days of my/our receipt of notification.

I/We hereby state that the Shares being purchased are to be held by me/us for investment purposes and not with a view to sale, except pursuant to an effective registration statement or an exemption therefrom.

Please cancel the enclosed Warrant Certificate and, if applicable, send me/us a Warrant Certificate, in partial substitution on identical terms, for the remaining shares not being purchased pursuant to this notification.

Yours very truly,

\_\_\_\_\_

Please type or print:

\_\_\_\_\_

**Name**  
**Address**  
**City State Zip Code**

**Exhibit 23.1**

**CONSENT OF INDEPENDENT AUDITORS**

We hereby consent to the inclusion in Form 10-K for the fiscal year ended September 30, 1999 of our report dated November 1, 1999 relating to the financial statements of Celsion Corporation.

*/s/ Stegman & Co.*

-----  
*Stegman & Co.*

*Baltimore, Maryland  
December 30, 1999*

## ARTICLE 5

PERIOD TYPE	12 MOS
FISCAL YEAR END	SEP 30 1999
PERIOD START	OCT 01 1998
PERIOD END	SEP 30 1999
CASH	1357464
SECURITIES	0
RECEIVABLES	1812
ALLOWANCES	0
INVENTORY	22059
CURRENT ASSETS	1424058
PP&E	251139
DEPRECIATION	224874
TOTAL ASSETS	1558684
CURRENT LIABILITIES	517132
BONDS	0
PREFERRED MANDATORY	0
PREFERRED	0
COMMON	533705
OTHER SE	503420
TOTAL LIABILITY AND EQUITY	1558684
SALES	0
TOTAL REVENUES	0
CGS	0
TOTAL COSTS	0
OTHER EXPENSES	2391102
LOSS PROVISION	(2391102)
INTEREST EXPENSE	(60834)
INCOME PRETAX	(2436192)
INCOME TAX	0
INCOME CONTINUING	(2436192)
DISCONTINUED	0
EXTRAORDINARY	0
CHANGES	0
NET INCOME	(2436192)
EPS BASIC	(.05)
EPS DILUTED	(.05)

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