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CELSION CORP
Form 10-K/A
January 28, 2003

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

AMENDMENT NO. 1
ON
FORM 10-K/A

(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, 2002

or

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

For the transition period from _____ to _____

Commission file number 000-14242

CELSION CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE

52-1256615

State or Other Jurisdiction
of Incorporation or Organization

(I.R.S. Employer
Identification No.)

10220-I OLD COLUMBIA ROAD
COLUMBIA, MARYLAND

21046-1705

(Address of Principal Executive Offices)

(Zip Code)

(410) 290-5390

Registrant's telephone number, including area code

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

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

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

Not Applicable

Indicate by check mark whether the Registrant (1) has filed all reports
required to be filed by Section 13 or 15(d) of the Securities Exchange Act of
1934 during the preceding 12 months (or for such shorter period that the
Registrant was required to file such reports), and (2) has been subject to such

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filing requirements for the past 90 days. Yes No

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

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

As of December 26, 2002, 96,492,556 shares of the Registrant's Common Stock were issued and outstanding. As of December 26, 2002, the aggregate market value of voting stock held by non-affiliates of the Registrant was approximately \$38,188,207, based on the closing price for the Registrant's Common Stock on that date as quoted on the American Stock Exchange.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement in connection with its Annual Meeting of Stockholders, scheduled for February 18, 2003, filed with the Securities and Exchange Commission on January 10, 2003, are incorporated by this reference into Part III hereof, as indicated herein.

PART I

ITEM 1. BUSINESS

GENERAL

We develop medical treatment systems primarily to treat breast cancer and a chronic prostate enlargement condition, common in older males, known as benign prostatic hyperplasia, or BPH, using minimally invasive focused heat technology. We also are working with Duke University on the development of heat-sensitive liposome compounds for use in the delivery of chemotherapy drugs to tumor sites, and with the Memorial Sloan-Kettering Cancer Center, or Sloan-Kettering, on the development of heat-activated gene therapy compounds.

BPH TREATMENT SYSTEM

Benign Prostatic Hyperplasia

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

As BPH is an age-related disorder, its incidence increases with maturation of the population. Industry estimates suggest that more than 9 million men in the United States experience BPH symptoms and that more than 26 million men are affected by BPH worldwide. As the population continues to age, the prevalence of BPH can be expected to continue to increase. It is generally

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estimated that approximately 50% of men over the age of 55 and 90% of men over 75 will have BPH symptoms at various times. Industry studies estimate the overall costs of BPH therapy for those patients currently seeking treatment to be approximately \$2.5 to \$3.0 billion annually in the United States and \$8.0 to \$10.0 billion worldwide.

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

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

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

Accordingly, neither the medicinal treatments nor the surgical alternatives presently available appear to provide fully satisfactory, cost-effective treatment solutions for BPH sufferers.

Celsion BPH Treatment System

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We have developed a BPH treatment system--"Microwave Uretheroplasty(TM)"--that combines our microwave thermotherapy capability with a proprietary balloon compression technology licensed from MMTC, Inc. The system consists of a microwave generator and conductors and a computer and computer software programs that control the focusing and application of heat, plus a specially designed balloon catheter. Treatment using this system consists of two fundamental elements:

- Celsion's proprietary catheter, incorporating a balloon enlargement device, delivers computer-controlled transurethral microwave heating directly to the prostate at temperatures greater than 44 degrees C (111 degrees F).
- Simultaneously, the balloon inflates the device and expands to press the walls of the urethra from the inside outward as the surrounding prostate tissue is heated.

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

Pre-clinical animal studies have demonstrated that a natural "stent," or reinforced opening, in the urethra forms after the combined heat plus compression treatment. Also, the BPH system's relatively low temperature (43 degrees C to 45 degrees C) (109 degrees F to 113 degrees F) 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.

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

Ultimate Food and Drug Administration, or FDA, approval for a device such as our equipment typically requires two phases of clinical testing. The purpose of Phase I testing is to show feasibility and safety and involves a small group of patients. Phase II testing is designed to show safety and efficacy. The FDA approved an Investigational Device Exemption, or IDE, to allow clinical testing of our BPH system in June 1998 and we completed initial Phase I clinical feasibility human trials of the BPH system at Montefiore Medical Center in May 1999. In the Phase I trials, the combination of computer-controlled microwave heat and balloon catheter expansion was able to increase peak flow rates and to provide immediate relief of symptoms caused by BPH. In addition, we undertook an expanded Phase I study to test an accelerated treatment protocol, which was completed in May 2000, at Montefiore Medical Center. In July 2000, the FDA approved the commencement of multiple-site Phase II studies to collect the safety and efficacy data necessary for FDA premarketing approval ("PMA") for commercialization. All 160 patients required to be treated under the Phase II trial had been treated as of November 29, 2001 and, as of that date, we submitted the first two of three required modules to the FDA in support of the PMA. We expect to submit the last module, consisting of clinical data, early in 2003. If Phase II testing produces anticipated results and if our BPH system meets all other requirements for FDA approval and receives such approval, we

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intend to begin marketing the BPH system during the second calendar quarter of 2003.

Based on the information we have collected to date, we believe that our BPH system has the potential to deliver a treatment that is performed in one hour or less on an outpatient basis, generally would not require post-treatment catheterization, and would deliver symptomatic relief and an increase in urinary flow rates promptly after the procedure is completed.

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BREAST CANCER TREATMENT SYSTEM

Prevalence of Breast Cancer

Breast cancer is one of the leading causes of death among women in the United States. 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 the United States in each of the years from 1995 through 1999.

Current Treatment for Breast Cancer

Breast cancer is presently generally 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. The more severe forms of surgical intervention can result in disfigurement and a need for extended prosthetic and rehabilitation therapy.

In addition, heat therapy (also known as hyperthermia or thermotherapy) is a 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, 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. The complete response rate for this purpose means the total absence of a treated tumor for a minimum of two years. Comparable increases in the complete response rate were reported with the use of 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.

Heat Therapy in Conjunction with Radiation; First Generation Celsion Equipment

In 1989, we obtained FDA premarketing approval for our microwave-based Microfocus 1000 heat therapy equipment for use on surface and subsurface tumors in conjunction with radiation therapy. Until 1995, we marketed our Microfocus equipment for this use in 23 countries, but microwave heat therapy was not widely accepted in the United States medical community as an effective cancer treatment. Moreover, due to the limitations of microwave technology available at the time, it was difficult to deliver a controlled amount of heat to subsurface tumors without overheating surrounding healthy tissue.

New Microwave Technology from MIT

In 1993, we began working with researchers at the Massachusetts Institute of Technology, or MIT, who had developed, originally for the United States Defense Department, the microwave control technology known as "Adaptive

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Phased Array", or APA. This technology permits properly designed microwave equipment to focus and concentrate energy targeted at diseased tissue areas deep within the body and to heat them selectively, without adverse impact on surrounding healthy tissue. In 1996, MIT granted us an exclusive worldwide license to use this technology for medical applications and, since that time, we have concentrated on developing a second generation of Microfocus equipment capable of focusing microwave energy on specific tissue areas. We have now incorporated the APA technology in our second-generation microwave therapy equipment.

Second Generation Celsion Breast Cancer Treatment System

Using the APA technology, we have 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 that control the focusing, application and duration of the thermotherapy, and a specially designed patient treatment table.

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In 1998, we completed pre-clinical animal testing of our 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, these studies demonstrated that our system is capable of selectively heating tumors at temperatures up to 46 degrees C (115 degrees F) without damage to surrounding healthy tissues. High temperatures maintained for eight to ten minutes can cause complete tumor necrosis (death), 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 our equipment to focus heat deep into animal tissue at precise locations and in small target areas. In our view, these animal tests demonstrate that it is possible to eliminate tumors by heat alone and without the use of radiation. Using the pre-clinical data from Massachusetts General, the FDA granted Celsion a supplemental premarketing approval to incorporate the APA technology with Celsion's already approved Microfocus 1000 system. The APA technology enhances the ability of the Microfocus 1000 system to focus energy.

In January 1999, we received an IDE from the FDA to permit clinical testing of our breast cancer treatment system, and also received FDA approval to proceed with Phase I human clinical studies. In August 2000, we completed the treatment of ten patients in the Phase I study using our breast cancer equipment at Columbia Hospital in West Palm Beach, Florida, and at Harbor UCLA Medical Center in Torrance, California. In the study, our equipment was clinically tested on female breast tumors on a minimally invasive basis through a single application of precisely controlled and targeted heat. In December 2000, we received approval from the FDA to commence Phase II trials for our breast cancer system.

The Phase II trials consist of two protocols--the first (IIA) is designed to ablate (kill) small breast tumors using heat alone and the second (IIB) is designed to downsize large breast cancer tumors using a combination of heat and chemotherapy, thus allowing a surgeon to perform a lumpectomy rather than a mastectomy, thereby preserving the affected breast. These trials are currently under way at The Center for Breast Surgery (Columbia/HCA) in Florida, Comprehensive Breast Center in Florida, Harbor UCLA in California, Mroz-Baier Breast Care Center in Memphis, Tennessee, Halle Martin Luther Breast Center in Halle, Germany, and with Dr. Lynne Clarke in Tacoma, Washington. We expect to add a total of four additional sites, in the United States and in Europe, early in 2003. In July 2002, we reached the endpoint for the IIB protocol by

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determining the maximum heat dosage required to optimize the treatment. We have learned from our current and potential clinical investigators that our breast cancer treatment system has the potential to meet a significant unmet need in the realm of breast cancer treatment. Currently 25% to 30% of all lumpectomy patients are recalled for a second surgery (commonly referred to as a second incision) when, through pathological examinations, the surgeon discovers that viable cancer cells remain in the margins surrounding the area from which the tumor has been removed. This additional procedure is costly for the surgeon and other medical providers and traumatic for the patient.

We believe that studies will demonstrate that our treatment system, in conjunction with lumpectomy, would lead to a reduction in the rate of second incisions. Based on our Phase II trial results to date and our new learning, we decided to revise our IIB protocol to provide a clinical endpoint demonstrating that the incidence of second incision could be significantly reduced if a patient underwent treatment with our system prior to lumpectomy. We submitted the revision of our IIB protocol to the FDA in July 2002 and, in August 2002, the FDA approved our revised protocol on condition that the IIB trials be expanded from 43 to 222 patients, with half the patients being treated with Celsion's system followed by lumpectomy and the remainder undergoing conventional lumpectomies alone. At the same time, we reviewed and revised our IIA protocol to clarify the clinical endpoints. As revised, the IIA trials will now be fully randomized against patients receiving preoperative chemotherapy alone and the study size has been increased from 130 to 312 patients. Treatments under both protocols were halted while the revisions were in process. We anticipate that both the IIA and IIB trials will be completed by the end of calendar year 2003 and, if successful, that we will file for the addition of new indications of use to the existing FDA premarketing approval for our Microfocus 1000 equipment early in 2004.

THERMO-LIPOSOMES--DUKE UNIVERSITY TECHNOLOGY

Background

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 avoid destruction by the body's immune system, and allowing them to accumulate in tumors. However, with presently available technology, it often takes two to four hours for commercial liposomes to release their drug contents to a tumor, severely limiting the clinical efficacy of liposome chemotherapy treatments.

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Development of Thermo-Sensitive Liposomes

A team of Duke University scientists has developed heat-sensitive liposomes comprised of materials that rapidly change porosity when heated to a specific point. As the heat-sensitive liposomes circulate within the small arteries, arterioles, and capillaries, the drug contents of the liposomes are released at significantly higher levels in those tissue areas 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 heat-sensitive liposomes deposited 50 times the amount of drugs at a specific heated tissue site, when compared to conventional liposomes. We have been a sponsor of this research, which is part of a larger Duke University project to develop new temperature-sensitive liposomes, temperature-sensitive gene promoters and related compounds, and we are the exclusive licensee of Duke University's heat-activated liposome technology.

Celsion's focused microwave equipment is used to provide minimally

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invasive heating of cancerous tumors to trigger heat-activated liposomes within the tumors. The heat-activated liposomes, which encapsulate chemotherapeutic agents, are injected into the bloodstream, where they remain encapsulated until they release their drug payload inside the heated tumor. In preliminary tumor growth delay studies conducted at Duke University, tumor-bearing mice received a single intravenous injection of the liposome with a 5mg per kilogram Doxorubicin concentration. This was immediately followed by heating of the tumor to 42 degrees C (108 degrees F) for one hour. The result of the study was a complete disappearance of the tumors in 11 out of 11 mice. These animals remained disease free through the 60 days of the study.

In November 2001, we completed large animal toxicity studies involving our Doxorubicin-laden thermo-liposome at the Roswell Park Cancer Institute, a cancer research organization in Buffalo, New York. In March 2002, we filed an Investigational New Drug, or IND, application with the FDA for the use of this liposome in the treatment of prostate cancer using our Microfocus equipment as the means of heat activation. In June 2002, the IND became effective, allowing us to proceed with human clinical trials. We expect to start the Phase I clinical trials at Roswell Park Cancer Institute early in 2003.

In addition, in January 2001, we entered into a Material Transfer Agreement, or MTA, with the National Cancer Institute, or NCI, under which we are supplying heat-activated liposomes to enable the NCI to conduct clinical trials on liver cancer. NCI will use an RF heating device to isolate the tumors and to heat the liver, activating Celsion's heat-activated liposomes to kill peripheral cancer cells. Liver cancer has yet to be successfully treated with existing treatment modalities. NCI expects to complete the animal toxicity studies and submit an IND application to the FDA for approval early in 2003.

Celsion and Duke University are pursuing further development work and pre-clinical studies aimed at using the new thermo-liposome technology in conjunction with our APA focused heat technology for a variety of applications, including cancer chemotherapy. We view 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 to fight cancer in chemotherapy regimens 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.

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

Production of Heat-Sensitive Liposomes

We have established a relationship with British Columbia Cancer Authority, or BCCA, of Vancouver, Canada to provide Quality System Regulation, or QSR (formerly Good Manufacturing Practices, or GMP), production of our heat-activated liposome for our large animal toxicity studies under our Material Transfer Agreement with the National Cancer Institute and for our planned Phase I clinical study in humans. BCCA is a leading drug formulation and discovery company that specializes in liposome drug development. Celsion will require a large-scale liposome manufacturer at such time, if any, as it reaches Phase II clinical trials and beyond. Toward that end, we are in the process of identifying a large-scale producer of the Doxorubicin-based heat-activated

liposome.

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HEAT-ACTIVATED GENE THERAPY COMPOUNDS--SLOAN-KETTERING TECHNOLOGY

Background

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

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

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

The Celsion Technology--CRI Plus Focused Heat

CRI can be activated in tumors by minimally invasive focused heat in the range of 41 degrees C (106 degrees F). This focused heat may be generated by Celsion's Adaptive Phased Array microwave technology, which provides deep heating without damage to surrounding healthy tissue. Having increased the susceptibility of cancer cells to DNA-damaging agents, radiation and chemotherapy treatment may then be administered with less frequency and/or at lower doses than currently is possible. CRI would then deactivate and the patient would resume normal post-treatment care.

In September 2001, scientists at Sloan-Kettering successfully completed pre-clinical laboratory feasibility demonstrations to assess the safety and biological activity of CRI. In December 2001, a small animal feasibility study was completed at Sloan-Kettering's Good Laboratory Practice facility to assist in drug formulation. Further studies with large animals to assess toxicity effects are being conducted and are expected to continue into 2003. Based on the current development timeline, we expect to file an IND application with the Food and Drug Administration by the end of calendar year 2003 and anticipate that we will be in a position to commence Phase I clinical (human) trials before the end of calendar year 2004. At such time as we determine safety and dosage in our preliminary studies, we expect to form partnership(s) with one or more drug companies to scale-up manufacturing and marketing for larger pivotal studies.

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In May 2000, we entered into an exclusive worldwide agreement for the commercial rights to the CRI, heat-activated gene therapy technology developed by Sloan-Kettering.

DEVELOPMENT, MARKETING AND SALES STRATEGY

OVERVIEW AND GOALS

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

- o Short-Term Goals: 12 to 24 Months
 - complete the clinical testing and commercialization of our BPH treatment system;
 - complete the development, clinical testing, and commercialization of our second generation technology for the eradication of cancerous breast tumors; and

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- pursue the development and testing of targeted drug delivery via heat-sensitive liposomes for the purpose of concentrating chemotherapeutic drugs at tumor sites.
- o Longer-Term Goals: 18 Months and Beyond
 - continue the development of gene therapy to significantly improve the effectiveness of radiation and chemotherapy on tumors; and
 - initiate, either alone or with partners, the development of cost-effective enhancements and variations of our technology, including a version of our 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.

We anticipate that, in the near term (up to 24 months), the source of our revenues will be from our proprietary technology for BPH and for treatment of breast cancer and deep-seated tumors through the use of focused microwave heat therapy equipment, if the necessary testing and regulatory approval processes are completed. We intend to generate initial sales through the development of marketing alliances.

In the longer term (from 18 months to 36 months and beyond), we will seek to develop new revenue streams from our current work with Duke University in targeted drug delivery systems and with Sloan-Kettering in gene therapy. We anticipate that revenues will come from the licensing of this 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, because this technology is designed to be used in conjunction with our APA-improved microwave equipment, we expect that the

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acceptance of the technology will generate demand for our equipment which, in turn, is expected to create equipment sales revenues. To prepare for future marketing of our heat-sensitive drug delivery systems, we intend to explore the possibilities of forming alliances with pharmaceutical companies, major hospitals and health maintenance organizations.

BPH TREATMENT SYSTEM

Our BPH treatment system is expected to be marketed to the constituencies critical to its success. Particularly, towards the approximately two million readily identified BPH sufferers currently employing drug therapies, as well as the estimated seven million United States men afflicted with BPH who are not currently being treated--the "watchful waiters"--with a focused message designed to encourage these BPH sufferers to take advantage of a solution that will relieve their symptoms and help to restore the quality of their lives. We expect that this marketing effort will include the following elements:

- o Reimbursement
 - We have established reimbursement under the TUMT reimbursement code for Medicare patients participating in our Phase II clinical trials. Based on this precedent, we expect that our BPH treatment will be covered in a like manner by private insurers.
 - o Targeting Key Constituencies:
 - Urology Practices. We expect first to target large urology practices, starting with the large practices participating in our Phase II trial. We expect that our Microwave Uretheroplasty(TM) equipment will be placed in urologists' offices with no up-front capital cost to the physicians. The urologists will purchase a unique disposable catheter from Celsion or its marketing partner for each treatment. We believe that urology practices have experienced a loss of revenue to primary care physicians as a result of new drug therapies introduced to treat BPH and other urological disorders and that urologists will be favorably disposed toward our Microwave Uretheroplasty(TM) system, which could offer them a significant new revenue source.
 - Consumers. We also expect BPH sufferers will be targeted through aggressive use of promotional and advertising media. Due to the specificity of our target patient audience (males 50 years and older) and the geographic concentration of retirees, we expect that specific media in well defined and discrete markets will generate a high level of awareness of the availability of, and interest in, our treatment system. We also expect that the Internet and other electronic methods will be utilized to direct prospective patients to urology offices equipped to perform our Microwave Uretheroplasty(TM) procedure.
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- Primary Care Physicians. The marketing approach has been designed to bypass primary care physicians, whom we believe to be the most significant barrier to the success of our BPH treatment system. Generally, under current managed care protocols, a patient must first visit his primary care physician who, after reviewing the patient's symptoms, may either treat him or refer him to a specialist. With increasing availability of drug therapies to treat urological disorders, the number of referrals to urologists has been declining. We intend to ensure that BPH sufferers are aware of our Microwave Uretheroplasty(TM) treatment system so that they are in a position to insist that they be referred to a urologist to obtain treatment.

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Celsion does not plan to develop an internal sales and marketing capability for its BPH business. Rather, Celsion intends to enter into a strategic alliance with a larger medical products company regarding the sales, supply and distribution of its Microwave Urethoplasty(TM) treatment system. Such a strategic relationship should allow Celsion to maintain its focus on its core development activities while leveraging its sales force infrastructure and marketing expertise. To this end, effective January 21, 2003, Celsion entered into a Distribution Agreement with Boston Scientific Corporation, pursuant to which Celsion has granted Boston Scientific exclusive rights to market and distribute the Microwave BPH 800 Urethroplasty(TM) System and its component parts for the treatment BPH in all territories other than China, Taiwan, Hong Kong, Macao, Mexico and Central and South America. Additional information relating to Celsion's strategic partnership with Boston Scientific appears in our Current Report on Form8-K filed with the Securities and Exchange Commission on January 22, 2003.

LICENSE AGREEMENTS AND PROPRIETARY RIGHTS

We do not own any patents, although we do have three United States patents pending, two of which have been filed internationally. Two of our pending United States patent applications are directed to our BPH treatment system, with the third directed to our breast cancer treatment. Through our license agreements with MIT, MMTC, Duke and Sloan-Kettering, we have exclusive rights, within defined fields of use, to nine United States patents. Three of these patents relate to the treatment of BPH, four relate to thermotherapy for cancer, including the APA technology, one relates to heat-sensitive liposomes and one relates to gene therapy.

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

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

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

On November 10, 1999, we entered into a license agreement with Duke University under which we received exclusive rights (subject to certain exceptions) to commercialize and use Duke's thermo-liposome technology. The license agreement contains annual royalty and minimum payment provisions and also requires us to make milestone-based royalty payments measured by various events, including product development stages, FDA applications and approvals,

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foreign marketing approvals and achievement of significant sales. However, in lieu of such milestone-based cash payments, Duke has agreed to accept shares of our Common Stock to be issued in installments at the time each milestone payment is due, with each installment of shares to be calculated at the average closing price of the Common Stock during the 20 trading days prior to issuance. The total number of shares issuable to Duke under these provisions is subject to adjustment in certain cases, and Duke has "piggyback" registration rights for public offerings taking place more than one year after the effective date of the license agreement. We are currently renegotiating certain terms of our contractual arrangements with Duke.

Our rights under our license agreement with Duke University extend for the longer of 20 years or the end of any term for which any relevant patents are issued by the United States Patent and Trademark Office. Currently, we have

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rights to Duke's patent for its thermo-liposome technology in the United States, which expires in 2018, and to future patents received by Duke in Canada, Europe, Japan and Australia, where it has patent applications pending. The European application can result in coverage in the United Kingdom, France and Germany. For this technology, our license rights are worldwide, with various patent rights covering the United States, Canada, the United Kingdom, France, Germany and Japan.

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

In addition to the rights available to us under completed or pending license agreements, we rely on our own proprietary know-how and experience in the development and use of microwave thermotherapy equipment, which we seek to protect, in part, through proprietary information agreements with employees, consultants and others. We cannot offer assurances that these information agreements will not be breached, that we will have adequate remedies for any breach or that these agreements, even if fully enforced, will be adequate to prevent third-party use of our proprietary technology. Similarly, we cannot guarantee that technology rights licensed to us by others will not be successfully challenged or circumvented by third parties, or that the rights granted will provide us with adequate protection. We are aware of published patent applications filed after November 29, 2001 and issued patents belonging to other companies, and it is uncertain whether any of those patent documents, or patent applications filed before November 29, 2001 of which we may not have any knowledge, will require us to alter our potential products or processes, pay licensing fees, or cease certain activities.

MANUFACTURING

Celsion presently manufactures its BPH equipment in-house and anticipates that it will continue to do so for the immediate future. However, as the market develops, we expect that we will outsource some or all of our BPH equipment manufacturing.

We believe we are best suited to conduct basic research and development activities, to pursue a prototype product through clinical testing and regulatory approval, to engage in initial manufacturing activities during

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product launch and to market the final product. Accordingly, we do not intend to engage in large-scale manufacturing with respect to our breast cancer treatment system or any other possible future products, but instead intend generally to outsource the manufacture of final commercial products, components and disposables. Based on past experience, we do not anticipate any significant obstacles in identifying and contracting with qualified suppliers and manufacturers.

THIRD-PARTY REIMBURSEMENT

Third-party reimbursement arrangements will likely be essential to commercial acceptance of our new devices, and overall cost-effectiveness and physician advocacy will be keys to obtaining such reimbursement. We believe that our equipment can be used to deliver treatment at substantially lower total cost than surgical treatments for BPH or cancer or than continuous drug therapy. Consequently, we believe that third-party payors seeking procedures that provide quality clinical outcomes at relatively lower cost will help drive acceptance of our products.

For BPH, our strategy is to use reimbursement codes currently approved for TUMT in the United States and which have been approved for Medicare patients in connection with BPH treatment in our Phase II clinical trials. For breast cancer, we expect that our strategy for obtaining new reimbursement authorizations in the United States will be to obtain appropriate reimbursement codes and to perform studies in conjunction with clinical trials to establish the efficacy and cost-effectiveness of the procedures as compared to surgical and drug treatments for BPH and cancerous breast tumors. We plan to use this information when approaching health care payors to obtain new reimbursement authorizations.

With the increasing use of managed care and capitation as means to control health care costs in the United States, we believe that physicians may view our products as a tool to treat BPH and breast 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-eligible population is moving into a managed care system.

Subject to regulatory approval for the use of our equipment to treat BPH and breast cancer, we anticipate that physicians will submit insurance claims for reimbursement for such procedures to third-party payors, such as Medicare carriers, Medicaid carriers, health maintenance organizations and

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private insurers. In the United States and in international markets, third-party reimbursement is generally available for existing therapies used to treat cancer and BPH. The availability and level of reimbursement from such payors for the use of our new products will be a significant factor in our ability to commercialize these systems.

We expect that new regulations regarding third-party reimbursement for certain investigational devices in the United States will allow us to pursue early reimbursement from Medicare with individual clinical sites prior to receiving FDA approval. However, FDA approval likely will be necessary to obtain a national coverage determination from Medicare. The national coverage determination for third-party reimbursement will depend on the determination of the Centers for Medicare and Medicaid Service, or CMS (formerly known as the United States Health Care Financing Administration, or HCFA), which establishes national coverage policies for Medicare carriers, including the amount to be

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reimbursed, for coverage of claims submitted for reimbursement related to specific procedures. Private insurance companies and health maintenance organizations make their own determinations regarding coverage and reimbursement based upon "usual and customary" fees. Reimbursement experience with a particular third-party payor does not reflect a formal reimbursement determination by the third-party payor. New outpatient procedure codes were instituted on August 1, 2000. Our ability to petition successfully for these new reimbursement codes will ultimately determine the degree of success we achieve in implementing our business model.

Internationally, we expect to seek reimbursement approvals for procedures utilizing our new products on an individual country basis. Some countries currently have established reimbursement authorizations for transurethral microwave therapy. We expect to use clinical studies and physician advocacy to support reimbursement requests in countries in which there is currently no reimbursement for such procedures.

REGULATION OF SALES IN THE UNITED STATES

FDA REGULATION--RESEARCH AND APPROVAL

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

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

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

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

Clinical trials are typically conducted in two or three sequential

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phases, but the phases may overlap. Phase I clinical trials involve the initial introduction of the therapy to a small number of subjects. Phase II trials are generally larger trials conducted in the target population. For devices such as our Microwave Urethreroplasty(TM) treatment system, Phase II studies may serve as the pivotal trials demonstrating safety and effectiveness required for approval. In the case of drugs and biological products, Phase II clinical trials generally are conducted in a target patient population to gather evidence about the pharmacokinetics, safety and biological or clinical efficacy of the drug for specific indications, to determine dosage tolerance and optimal dosage and to

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identify possible adverse effects and safety risks. When a drug or biological compound has shown evidence of efficacy and an acceptable safety profile in Phase II evaluations, Phase III clinical trials are undertaken to serve as the pivotal trials to demonstrate clinical efficacy and safety in an expanded patient population.

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

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

The FDA is authorized to require user fees for submission of NDAs and BLAs. The current user fee for such applications is \$267,606 and may increase from year to year.

The FDA is also authorized to require annual user fees for approved products and for companies with establishments at which finished products are manufactured, which fees may increase from year to year. The FDA may waive or reduce such user fees under special circumstances. We intend to seek waivers or reductions of user fees where possible, but we cannot be assured that we will be eligible for any such waiver or reduction.

FDA REGULATION--POST-APPROVAL REQUIREMENTS

Even if we receive necessary regulatory approvals for one or more of our product candidates, our manufacturing facilities and products are subject to

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ongoing review and periodic inspection. Each U.S. device, drug and biologic manufacturing establishment must be registered with the FDA. Manufacturing establishments in the U.S. and abroad are subject to inspections by the FDA and must comply with the FDA's QSR regulations. Medical devices also must comply with the FDA's QSR regulations. In order to ensure full technical compliance with such regulations, manufacturers must expend funds, time and effort in the areas of production and quality control.

FDA REGULATION--MANUFACTURING STANDARDS

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

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

Failure to comply with applicable regulatory requirements can result in, among other things, warning letters, fines, injunctions and other equitable remedies, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant approvals, pre-market clearance or pre-market approval, withdrawal of approvals and criminal prosecution.

OTHER FEDERAL REGULATION

The Federal Communications Commission (FCC) regulates the frequencies of microwave and radio-frequency emissions from medical and other types of equipment to prevent interference with commercial and governmental

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communications networks. The FCC has approved the frequency of 915 MHz for medical applications, and machines utilizing that frequency do not require shielding to prevent interference with communications. Our Microfocus and BPH treatment products utilize the 915 MHz frequency.

In December 1984, the Health Care Financing Administration (now known as the Centers for Medicare and Medicaid Service (CMS)) 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 U.S. have approved reimbursement for this type of thermotherapy treatment under their health policies. Thermotherapy treatment administered using equipment that has received a PMA is eligible for such reimbursement.

REGULATION OF FOREIGN SALES

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

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the European Free Trade Association, or in certain other countries specified in the Federal Food, Drug and Cosmetic Act.

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

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

Upon exportation, our products would be subject to regulation by national governments and supranational agencies as well as by local agencies affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. There can be no assurance that one or more countries or agencies will not impose regulations or requirements that could have a material adverse effect on our ability to sell our products. In the EU, the harmonization of standards has caused a shift from a country-by-country regulatory system towards an EU-wide single regulatory system. However, many members of the EU have imposed additional country-specific regulations/requirements. The approval procedure varies from member state to member state, and the time required may be longer or shorter than that required for FDA approval. There can be no assurance that the changes in the regulatory schemes imposed either by the EU, supranational agencies or individual countries affecting our products will not have a material adverse effect on the our ability to sell our products in countries other than the U.S.

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

We sold our original products in 23 countries in Asia, Europe and South America. Meeting the registration requirements within these countries was the responsibility of our 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. We expect to receive approvals for marketing in a number of countries outside the U.S. prior to the time that we will be able to market our products in the U.S. However, the timing for such approvals currently is not known.

COMPETITION

Many companies and institutions are engaged in research and development of thermotherapy technologies for both cancer and prostate disease products that seek treatment outcomes similar to those we are pursuing. In addition, a number of companies and institutions are pursuing alternative treatment strategies through the use of RF, laser and ultrasound energy sources, all of which appear to be in the early stages of development and testing. Potential competitors engaged in all areas of cancer and prostate treatment research in the U.S. and other countries include, among others, major pharmaceutical and chemical companies, specialized technology companies, universities and other research

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institutions. See "Risk Factors."

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There currently are three principal competitors in the MI market for BPH treatment systems: Medtronic (NYSE:MDT), Urologix (NASDAQ:ULGX) and TherMatrx (private). In addition to Celsion, one other company, ACMI (a privately held company selling Prostalund technology from Sweden), is in the process of FDA review of a minimally invasive BPH treatment system. These companies utilize one of two major approaches to BPH treatment:

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

Medtronic acquired its TUNA business as part of its acquisition of Vidamed, Inc. for \$329 million in April 2002. TUNA technology is labor intensive for the physician and requires a significant learning curve prior to perfecting the technique. Patients require post-treatment catheterization and significant pre-medication is common.

TUMT technology is currently the dominant MI alternative. Urologix is the market leader in TUMT systems. Its machines currently list for approximately \$90,000 and its single use catheters cost between \$1,000 and \$1,200. Urologix's technology uses a "water cooled" catheter, which is designed to use high microwave energy without damaging the urethral lining. TherMatrx takes a simpler approach, offering a low power machine that does not require cooling. The sales price of the TherMatrx equipment is approximately \$25,000, due to its relatively less complex design. The catheter used in conjunction with this equipment sells in the same range as the Urologix catheter. Both Urologix's and TherMatrx's products (and ACMI's Prostalund, which has not been approved) require pre-medication, are more difficult for the physician to administer than is the Celsion Microwave Urethroplasty(TM) system and require post-treatment catheterization of the patient.

We believe that our technology is a leap forward in the advancement of microwave therapy. Celsion relies on Microwave Urethroplasty(TM) in addition to traditional microwave energy. The addition of balloon compression within the prostatic portion of the urethra allows for immediate relief to the patient and in most cases can avoid post treatment catheterization. Thus, Celsion's technology allows for the type of rapid relief for the patient normally associated with drug therapies while avoiding the side effects and significant delays in patient symptomatic relief associated with other minimally invasive therapies.

PRODUCT LIABILITY AND INSURANCE

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic products. We presently have product liability insurance limited to \$5,000,000 per incident, and, if we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim out of our own limited resources.

EMPLOYEES

We presently employ 23 full-time employees and one part-time employee and also utilize the services of part-time consultants from time to time. In

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addition, our Scientific Advisory Board actively assists our management with advice on various projects. None of our employees are represented by a collective bargaining organization, and we consider our relations with our employees to be good.

ITEM 2. PROPERTIES

We lease premises consisting of approximately 22,451 square feet of administrative office, laboratory and workshop space at 10220-I Old Columbia Road, Columbia, Maryland 21046-1705 from an unaffiliated party under a five-year lease (7,056 square feet) that expires on June 30, 2005 and a sublease (15,395 square feet), which expires on October 31, 2005. Rent expense for the year ended September 30, 2002 was \$359,206. Future minimum lease obligations are as follows:

2003	\$ 302,779
2004	\$311,789
2005	\$239,018

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ITEM 3. LEGAL PROCEEDINGS

The following information was reported by Celsion under Item 5 in a Current Report on Form 8-K dated January 25, 2002 filed with the Securities and Exchange Commission (SEC) on January 29, 2002:

As previously reported, on April 27, 2000, Celsion commenced an action (the "Original Suit") in the United States District Court for the District of Maryland (the "Maryland Court") against Warren C. Stearns, a former director of the Company ("W.C. Stearns"), Mr. Stearns' management company and a number of his affiliates, family members and colleagues (collectively, the "Original Defendants"), who held warrants (the "Original Warrants") for the purchase of approximately 4.1 million shares of Celsion's Common Stock at \$0.41 per share. On January 18, 2001, the Maryland Court transferred the case to the United States District Court for the Northern District of Illinois, in Chicago (the "Chicago Court"). On July 17, 2001, Celsion filed a motion to amend its complaint to add a second count, alleging that Mr. Stearns, on behalf of himself and the other Original Defendants, had executed a Mutual Release which released any right the Original Defendants had to exercise the warrants ("Count II"). The motion was granted on July 19, 2001.

On August 9, 2001, the Original Defendants filed a counterclaim (the "Counterclaim") against the Celsion, certain of its officers and directors, and an attorney and law firm that previously had represented Celsion. On September 10, 2001, the Chicago Court dismissed, with prejudice, Count I of the Complaint. On November 23, 2001, Celsion and certain of its officers and directors filed a motion to dismiss the Counterclaim.

On January 25, 2002, Celsion and Augustine Y. Cheung, Spencer J. Volk, Walter B. Herbst, LaSalle D. Leffall, Claude Tihon, John Mon, Max E. Link (all of whom are present or former officers and/or directors of the Company), George Bresler, Bresler, Goodman & Unterman LLP and The George Bresler Trust on the one hand (collectively, the "Company

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Parties"), and Stearns Management Company, Anthony Riker, Ltd., John T. Horton, The George T. Horton Trust, Warren R. Stearns, Charles A. Stearns, and W.C. Stearns (collectively, the "Stearns Parties"), on the other hand, entered into a settlement agreement (the "Settlement Agreement"). Pursuant to the Settlement Agreement, Celsion, among other things, has agreed (a) to pay to W.C. Stearns the lesser of (i) the Stearns Parties' actual legal fees, costs and expenses incurred in connection with the Original Suit, the Counterclaim and the Settlement Agreement or (ii) \$265,000; (b) to issue to the Stearns Parties warrants (the "Settlement Warrants") to purchase a total of 6,325,821 shares of Celsion's Common Stock, at an exercise price of \$0.01 per share; and (c) to register for resale the shares underlying the Settlement Warrants. The Settlement Warrants are in replacement of the Original Warrants, the validity of which was at issue in the Original Suit. However, while the Original Warrants, among other things, contained antidilution provisions ensuring the Stearns Parties the right to purchase 4.6875% of Celsion's Common Stock, on a fully diluted basis, until completion of the Celsion's next public offering (as defined) and a renewal right at the election of the holder, the Settlement Warrants contain no such provisions. In addition, pursuant to the Settlement Agreement, the Company Parties, on the one hand, and the Stearns Parties, on the other, unconditionally released one another from any and all claims arising prior to the effective date of the Settlement Agreement and agreed to dismiss, with prejudice, the Original Suit, including the Counterclaim.

The Settlement Agreement has the effect of fully and finally resolving the matters in dispute in the Original Suit and the Counterclaim between the Company Parties, on the one hand, and the Stearns Parties, on the other hand.

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

Not applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

MARKET PRICE FOR OUR COMMON STOCK

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

	High	Low
FISCAL YEAR ENDED SEPTEMBER 30, 2001		
First Quarter (October 1 - December 31, 2000)	\$ 2.19	\$ 0.75
Second Quarter (January 1 - March 31, 2001)	\$ 3.75	\$ 0.94
Third Quarter (April 1 - June 30, 2001)	\$ 1.25	\$ 0.60

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Fourth Quarter (July 1 - September 30, 2001)	\$ 0.85	\$ 0.40
FISCAL YEAR ENDED SEPTEMBER 30, 2002		
First Quarter (October 1 - December 31, 2001)	\$ 0.68	\$ 0.40
Second Quarter (January 1 - March 31, 2002)	\$ 0.98	\$ 0.59
Third Quarter (April 1 - June 30, 2002)	\$ 0.80	\$ 0.40
Fourth Quarter (July 1 - September 30, 2002)	\$ 0.53	\$ 0.34

On December 23, 2002, the last reported sale price for our Common Stock on The American Stock Exchange was \$0.41. As of December 23, 2002, there were approximately 1,300 holders of record of our Common Stock.

DIVIDEND POLICY

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

ISSUANCE OF SHARES WITHOUT REGISTRATION

During the fiscal quarter ended September 30, 2002, we issued the following securities without registration under the Securities Act of 1933, as amended (the "Securities Act"):

- On August 1, 2002, Celsion issued a total of 200,000 shares of its Common Stock for cash consideration of \$2,000 upon exercise of stock purchase warrants. On September 4, 2002, Celsion issued a total of 150,000 shares of its Common Stock for cash consideration of \$1,500 upon exercise of stock purchase warrants. On September 12, 2002, Celsion issued a total of 200,000 shares of its Common Stock for cash consideration of \$2,000 upon exercise of stock purchase warrants. On September 24, 2002, Celsion issued a total of 250,000 shares of its Common Stock for cash consideration of \$2,500 upon exercise of stock purchase warrants. On September 26, 2002, Celsion issued a total of 200,000 shares of its Common Stock for cash consideration of \$2,000 upon exercise of stock purchase warrants. These shares are restricted stock, and the certificates representing such shares are endorsed with Celsion's standard restrictive legend, with a stop transfer instruction recorded by the transfer agent. Accordingly, Celsion views the shares issued as exempt from registration under Sections 4(2) and/or 4(6) of the Securities Act.
- On July 1, 2002, Celsion also issued 14,709 shares of its Common Stock to a consultant for services valued at \$7,500. These shares are restricted stock, and the certificates representing such shares are endorsed with the Celsion's standard restricted stock legend, with a stop transfer instruction recorded by the transfer agent. Accordingly, Celsion views the shares issued as exempt from registration under Sections 4(2) and/or 4(6) of the Securities Act.
- On September 4, 2002, Celsion issued 918,000 shares of its Common Stock upon conversion of 459 shares of its Series B 8% Convertible Preferred Stock. These shares are restricted stock, and the certificates representing such shares are endorsed with Celsion's standard restricted stock legend, with a stop transfer instruction recorded by the transfer agent. Accordingly, Celsion views the shares issued as exempt from registration under Sections 4(2) and/or 4(6) of the Securities Act.

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Celsion views these issuances as transactions by an issuer not involving any public offering and therefore as exempt from registration under Sections 4(2) and/or 4(6) of the Securities Act.

See also "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

ITEM 6. SELECTED FINANCIAL DATA

The following table contains certain financial data for Celsion for the five fiscal years ended September 30, 2002 is qualified in its entirety by, and should be read in conjunction with, the "Item 8. Financial Statements and Supplementary Data and Financial Disclosure" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations."

	1998	1999	YEAR ENDED SEPTEMBER 2000	2001
STATEMENT OF OPERATIONS DATA:				
Revenues:				
Product Sales (Net)	\$ 174,182	\$ --	\$ 3,420	\$ --
Research and development contracts	--	--	--	--
Total revenues	174,182	3,420	3,420	--
Cost of sales	136,500	--	246	--
Gross profit on product sales	37,682	--	3,174	--
Other costs and expenses:				
Selling, general and administrative	2,515,822	1,371,161	2,662,623	3,000,000
Research and development	1,534,872	1,019,941	2,238,292	4,000,000
Total operating expenses	4,050,694	2,391,102	4,900,915	7,000,000
(Loss) from operations	(4,013,012)	(2,391,102)	(4,897,741)	(7,000,000)
Other income (expense)	11,870	15,744	--	--
Interest income (expense)	(199,346)	(60,834)	350,526	--
Net (loss)	\$ (4,200,488)	\$ (2,436,192)	\$ (4,547,215)	\$ (6,999,999)

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Net loss per share	\$ (0.12)	\$ (0.05)	\$ (0.08)	\$
	=====	=====	=====	=====
Weighted average shares outstanding	34,867,001	45,900,424	59,406,921	72,

	1998	1999	AS OF SEPTEMBER 30, 2000	20
	-----	-----	-----	-----
BALANCE SHEET DATA:				
Cash and cash equivalents	\$ 54,920	\$ 1,357,464	\$ 8,820,196	\$ 2
Working Capital	(2,000,351)	906,926	8,509,173	2
Total Assets	330,738	1,558,684	9,117,821	2
Long-term debt, less current maturities	--	--	--	
Redeemable preferred stock:				
Series A 10% Convertible Preferred Stock	--	--	5,176,000	1
Series B 8% Convertible Preferred Stock	--	--	--	
Accumulated deficit	(19,464,010)	(21,900,202)	(26,770,917)	(33
Total stockholders' equity (deficit)	(1,851,067)	1,037,125	8,726,429	2

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

FORWARD-LOOKING STATEMENTS

Certain of the statements contained in this Annual Report on Form 10-K/A, including certain in this section, are forward-looking. In addition, from time to time we may publish forward-looking statements relating to such matters as anticipated financial performance, business prospects, technological developments, new products, research and development activities and similar matters. These statements involve known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among other things, unforeseen changes in the course of research and development activities and in clinical trials; possible changes in cost and timing of development and testing, capital structure, and other financial items; changes in approaches to medical treatment; introduction of new products by others; possible acquisitions of other technologies, assets or businesses; possible actions by customers, suppliers, strategic partners, potential strategic partners, competitors and regulatory authorities, as well as those listed under "Risk Factors" below and elsewhere in this Annual Report on Form 10-K/A. In some cases, you can identify

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forward-looking statements by terminology such as "may," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential" or "continue" or the negative of such terms or other comparable terminology. Forward-looking statements are only predictions. Actual events or results may differ materially. In evaluating these statements, you should specifically consider various factors, including the risks outlined under "Risk Factors." Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of such statements, or for updating such statements after the date hereof.

BASIS OF PRESENTATION

Since inception, the Company has incurred substantial operating losses, principally from expenses associated with our research and development programs, the clinical trials conducted in connection with our thermotherapy systems and applications for submission to the Food and Drug Administration. We believe these expenditures are essential for the commercialization of our technologies. As a result of these expenditures, as well as related general and administrative expenses Celsion had an accumulated deficit of \$43,820,081 as of September 30, 2002. We expect such operating losses to continue in the near term and for the foreseeable future as we continue our product development efforts, and undertake marketing and sales activities. Celsion'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. There can be no assurance that we will be able to commercialize our technology successfully or that we ever will achieve profitability. Our operating results have fluctuated significantly in the past and we expect that such results will fluctuate significantly from quarter to quarter in the future and will depend on a number of factors, many of which are outside Celsion's control.

We will need substantial additional funding in order to complete the development, testing and commercialization of our cancer treatment and BPH products and of potential new products. It is our current intention both to increase the pace of development work on our present products and to make a significant commitment to thermo-sensitive liposome and gene therapy research and development projects. The increase in the scope of present development work and such new projects will require additional funding, at least until we are able to begin marketing our products.

If adequate funding is not available in the future, Celsion 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 us to relinquish rights to certain of our technologies, products or potential markers. Furthermore, if we cannot fund its ongoing development and other operating requirements, and particularly those associated with our obligation to conduct clinical trials under our licensing agreements, Celsion will be in breach of its commitments under such licensing agreements and could therefore lose its license rights, with material adverse effects Celsion. Management is continuing its efforts to obtain additional funds so that Celsion can meet its obligations and sustain operations.

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RESULTS OF OPERATIONS

Comparison of Fiscal Year Ended September 30, 2002 and Fiscal Year Ended September 30, 2001

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We generated no revenues during the fiscal year ended September 30, 2002 or the fiscal year ended September 30, 2001.

Research and development expenditures in the year ended September 30, 2002 were \$5,004,687, an increase of \$929,438, or 23%, compared to the fiscal year ended September 30, 2001. The increase was attributable to costs incurred in undertaking pivotal Phase II clinical trials for both our BPH and breast cancer treatment systems. These costs included increased personnel costs as well as costs related to the acquisition of equipment and materials necessary to complete the trials. Additionally, during the year we completed the large animal toxicity studies using our heat-activated liposomes.

Selling, general and administrative expense increased by 52%, to \$4,833,005 for the fiscal year ended September 30, 2002 compared to \$3,211,625 for the fiscal year ended September 30, 2001. The increase was due primarily to increased staffing and legal costs associated with private placements and various SEC filings. Celsion also incurred costs associated with settlement of its ongoing lawsuit with Warren C. Stearns and his associates. Under the terms of the settlement, Celsion issued to the Stearns group certain Common Stock purchase warrants that were at issue in the litigation, together with additional warrants as compensation for relinquishment of certain anti-dilution rights under the disputed warrants and up to \$265,000 in cash to reimburse Stearns for costs incurred up to the settlement date. Celsion accrued the remaining amounts due to Spencer J. Volk, its former President and Chief Executive Officer, under the terms of the agreement governing his retirement. Finally, Celsion incurred consulting costs related to the exploration of the feasibility of setting up a business in China (including Hong Kong, Taiwan and Macao).

The increase in research and development, selling, general and administrative expenses described above, together with the absence of revenues during the relevant periods, resulted in a loss from operations of \$9,837,692 for the year ending September 30, 2002 compared to a loss \$7,286,874 for the year ended September 30, 2001, representing an increase of \$2,550,818.

Interest income net of interest expense decreased by \$269,717 to \$48,321 for the fiscal year ended September 30, 2002 compared to \$318,038 for the fiscal year ended September 30, 2001. This decrease is the result of a combination of lower average funds available for investment and lower interest rates in fiscal 2002.

Comparison of Fiscal Year Ended September 30, 2001 and Fiscal Year Ended September 30, 2000

We generated no revenues during the fiscal year ended September 30, 2001, compared to revenues on the sale of parts and equipment in the amount of \$3,240 during the fiscal year ended September 30, 2000.

Research and development expenditures in the year ended September 30, 2001 were \$4,075,249, an increase of \$1,836,957, or 82%, compared to the fiscal year ended September 30, 2000. The increase was attributable to costs incurred in undertaking pivotal Phase II clinical trials for both our BPH and breast cancer treatment systems. These costs included increased personnel costs as well as costs related to the acquisition of equipment and materials necessary to complete the trials. Additionally, during the year we initiated development of our heat-activated liposomes by formulating the drug and undertaking large animal toxicity studies.

Selling, general and administrative expense increased by 21%, to \$3,211,625 for the fiscal year ended September 30, 2001 compared to \$2,662,623 for the fiscal year ended September 30, 2000. The increase was due primarily to increased staffing, principally our newly retained Chief Financial Officer, and legal costs associated with the conversion of the Series A 10% Convertible

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Preferred Stock, various SEC filings and settlement of a long-standing trade dispute with a former distributor in Hong Kong.

The increase in research and development, selling, general and administrative expenses described above, together with the absence of revenues, resulted in a loss from operations of \$7,286,874 for the year ending September 30, 2001 compared to a loss \$4,897,741 for the year ended September 30, 2000, representing an increase of \$2,389,133.

Interest income net of interest expense decreased by \$32,488, to \$318,038 for the fiscal year ended September 30, 2001 compared to \$350,526 for the fiscal year ended September 30, 2000. This decrease reflects the fact that, as Celsion has no revenues, all expenditures are met from cash reserves. As cash reserves declined, interest income is likewise reduced.

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LIQUIDITY AND CAPITAL RESOURCES

Since inception, our expenses have significantly exceeded our revenues, resulting in an accumulated deficit of \$43,820,081 at September 30, 2002. We have incurred negative cash flows from operations since our inception and have funded our operations primarily through the sale of equity securities. As of September 30, 2002, we had cash of \$928,819 and total current assets of \$1,510,175, compared with current liabilities of \$774,959, resulting in a working capital surplus of \$735,216. As of September 30, 2001, we had \$2,510,136 in cash and total current assets of \$2,661,341, compared with current liabilities of \$272,441, which resulted in a working capital surplus of \$2,388,900 at fiscal year end. The decrease in working capital at September 30, 2002 as compared to September 30, 2001 was due to the fact that, during the past fiscal year, we drew on our cash reserves to pay for our ongoing operations.

We do not have any bank financing arrangements and have funded our operations primarily through private placement offerings of equity securities. On October 15, 2002, Celsion completed a private placement resulting in net proceeds of approximately \$748,000 and, on November 12, 2002, Celsion completed a private placement generating approximately \$300,000 in net proceeds.

For all of fiscal year 2003, we expect to expend a total of approximately \$8,500,000 for clinical testing of our breast cancer and BPH treatment systems, as well as corporate overhead, which we expect to fund from our current resources. The foregoing amounts are estimates based upon assumptions as to the availability of funding, the scheduling of institutional clinical research and testing 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. We expect to fund our operations through the 2003 fiscal year through a combination of private placements of equity and up-front and other funding contributed by one or more strategic partners for the BPH business. Additionally, if as currently anticipated our BPH system is approved for marketing during the course of fiscal 2003 funding could be generated from the sale of catheters.

Our available cash on hand is sufficient to fund our activities through December 31, 2002. Subsequent to December 30, 2002, we received further funding through a private placement of \$425,000 and issuance of a note in the amount of \$500,000 which funds will be sufficient to fund operations through February 2003. On January 21, 2003, Celsion reached an agreement with Boston Scientific Corporation under which Boston Scientific will market and distribute the Company's BPH treatment system. In connection with this agreement Boston Scientific purchased \$5 million of Celsion Common Stock and agreed to invest a further \$10 million in a combination equity and licensing fees upon Celsion

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meeting certain milestones. The initial investment will be sufficient to repay the \$500,000 note and to fund the Company's operations through the end of fiscal year 2003 and further investments will contribute to Celsion's funding requirements for the future. Our dependence on raising additional capital will continue at least until we are able to begin marketing our new technologies. Our future capital requirements and the adequacy of our financing depend upon numerous factors, including the successful commercialization of our Microwave Urethoplasty(TM) and breast cancer treatment systems, progress in product development efforts, progress with pre-clinical studies and clinical trials, the cost and timing of production arrangements, the development of effective sales and marketing activities, the cost of filing, prosecuting, defending and enforcing intellectual property rights, competing technological and market developments and the development of strategic alliances for the marketing of our products. We 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. We do not have any committed sources of financing, and cannot guarantee that additional funding will be available in a timely manner, on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, scale back or eliminate certain aspects of our operations or attempt to obtain funds through unfavorable arrangements with partners or others that may require us to relinquish rights to certain of our technologies, product candidates, products or potential markets or which otherwise may be materially unfavorable to us. Furthermore, if we cannot fund our ongoing development and other operating requirements, particularly those associated with our obligation to conduct clinical trials under our licensing agreements, we will be in breach of our commitments under these licensing agreements and could therefore lose our license rights, which could have material adverse effects on our business.

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RISK FACTORS

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

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

Since Celsion's inception in 1982, our expenses have substantially exceeded our revenues, resulting in continuing losses and an accumulated deficit of \$43,820,081 at September 30, 2002, including losses of \$6,923,227 for the fiscal year ended September 30, 2001 and \$9,751,082 for the fiscal year ended September 30, 2002. Because we presently have no revenues and are committed to continuing our product research, development and commercialization programs, we will continue to experience significant operating losses unless and until we complete the development of new products and these products have been clinically tested, approved by the FDA and successfully marketed. We have funded our operations primarily through the sale of Celsion's securities and have limited working capital for our product research, development, commercialization and other activities.

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

We marketed and sold our original microwave thermotherapy products, which produced modest revenues from 1990 to 1994, but ceased marketing these

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products in 1995. We have devoted our resources in ensuing years to developing a new generation of thermotherapy and other products, but cannot market these products unless and until we have completed clinical testing and obtained all necessary governmental approvals. Accordingly, we have no current source of revenues, much less profits, to sustain our present operations, and no revenues will be available unless and until our new products are clinically tested, approved by the FDA and successfully marketed. We cannot guarantee that any or all of our products will be successfully tested, approved by the FDA or marketed, successfully or otherwise, at any time in the foreseeable future or at all.

OUR MICROWAVE HEAT THERAPY TECHNOLOGY IS STILL UNDERGOING CLINICAL TESTING AND MAY NOT ACHIEVE SUFFICIENT ACCEPTANCE BY THE MEDICAL COMMUNITY TO SUSTAIN OUR BUSINESS.

To date, microwave heat therapy has not been widely accepted in the United States medical community as an effective treatment for BPH or for cancer treatment, with or without the concurrent use of radiation. We believe that this is primarily due to the inability of earlier technology adequately to focus and control heat directed at specific tissue locations and to conclusions that were drawn from a widely publicized study by the Radiation Oncology Therapy Group that purported to show that thermotherapy in conjunction with radiation was only marginally effective. Subsequent to the publication of that study, the Health Care Financing Administration, a HCFA (now known as the Centers for Medicare and Medicaid Services, or CMS) established a low medical reimbursement rate for all thermotherapy equipment designed to be used in conjunction with radiation. While management believes that our new technology is capable of overcoming the limitations of the earlier technology, the medical community may not embrace the perceived advantages of our "adaptive phased array," or APA, focused heat therapy without more extensive testing and clinical experience than we will be able to provide. To date, we have completed and submitted to the FDA only Phase I clinical trials of our Microwave Urethoplasty(TM) treatment system, although we have completed patient treatments in our Phase II trials. Our PMA application is being submitted on a modular basis, consisting of three separate filings: a manufacturing module, a pre-clinical module and a module consisting of 12-month patient follow-up data. The first two out of three modules were submitted in November 2001 and we expect to submit the remaining module after the 12-month patient follow-up data has been collected and the first two modules have been cleared by the FDA. The manufacturing module has been cleared, we anticipate that the FDA will clear the pre-clinical module in the near future and we have completed collection of the 12-month patient follow-up data. Therefore, we presently anticipate that we will submit the third module early in 2003. Our new breast cancer treatment technology is currently in Phase II trials. Our technology may not prove as effective in practice as we anticipate based on testing to date. If further testing and clinical practice do not confirm the safety and efficacy of our technology or, even if further testing and practice produce positive results but the medical community does not view this new form of heat therapy as effective and desirable, our efforts to market our new products may fail, with material adverse consequences to our business. We intend to petition CMS for a new reimbursement code for our breast cancer treatment. The success of our business model depends significantly upon our ability to petition successfully for favorable reimbursement codes. However, we cannot offer any assurances as to when, if ever, CMS may act on our request to establish a reimbursement code for our breast cancer treatment system. In addition, there can be no assurance that the reimbursement level established for our breast cancer treatment system, if established, will be sufficient for us to carry out our business plan effectively.

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

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We will need substantial additional funding in order to complete the development, testing and commercialization of our BPH and breast cancer treatment systems and heat-activated liposome and cancer repair inhibitor products, as well as other potential new products. We expended approximately \$9,359,311 in the 12 months ending September 30, 2002. As of that date, we had

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available a total of approximately \$928,900 to fund additional expenditures. On October 15, 2002, Celsion completed a private placement resulting in net proceeds of approximately \$748,000 and, on November 12, 2002, Celsion completed a private placement generating approximately \$300,000 in net proceeds. Our available cash on hand is sufficient to fund our activities through December 31, 2002, although since December 30, 2002 we received further funding through a private placement of \$425,000 and issuance of a note in the amount of \$500,000, which funds will be sufficient to fund operations through February 2003. On January 21, 2003, Celsion reached an agreement with Boston Scientific Corporation under which Boston Scientific will market and distribute the Company's BPH treatment system. In connection with this agreement Boston Scientific purchased \$5 million of Celsion Common Stock and agreed to invest a further \$10 million in a combination of equity and licensing fees upon Celsion meeting certain milestones. The initial investment will be sufficient to repay the \$500,000 note and fund operations through the end of fiscal year 2003 and further investments will contribute to Celsion's funding requirements for the future. In addition, it is our current intention both to increase the pace of development work on our present products and to make a significant commitment to our heat-activated liposome and cancer repair inhibitor research and development projects. The increase in the scope of present development work and the commitment to these new projects, as well as our ongoing activities, will require additional external funding, at least until we are able to begin marketing our products and to generate sufficient cash flow from the sale of those products to support our continued operations.

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

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

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

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Delays or rejections in obtaining regulatory approvals would adversely affect our ability to commercialize any product candidates and our ability to generate product revenues or royalties.

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

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

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

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

In many of the foreign countries in which we may do business or in which our products may be sold, we will be subject to regulation by national governments and supranational agencies as well as by local agencies affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax

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requirements. There can be no assurance that one or more countries or agencies will not impose regulations or requirements that could have a material adverse effect on our ability to sell our products.

The European Union, or EU, has a registration process that includes registration of manufacturing facilities (known as "ISO certification") and product certification (known as a "CE Mark"). We have obtained ISO certification for our existing facilities. However, there is no guarantee that we will be successful in obtaining EU certifications for any new facilities or for our products, or that we will be able to maintain our existing certifications in the future.

Foreign government regulation may delay marketing of our new products for a considerable period of time, impose costly procedures upon our activities or provide an advantage to larger companies that compete with us. There can be no assurance that we will be able to obtain necessary regulatory approvals, on a timely basis or at all, for any products that we develop. Any delay in obtaining, or failure to obtain, necessary approvals would materially and adversely affect the marketing of our contemplated products subject to such approvals and, therefore, our ability to generate revenue from such products.

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

Failure to comply with applicable domestic and foreign regulatory requirements, can result in, among other things, warning letters, fines, injunctions and other equitable remedies, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant approvals, pre-market clearance or pre-market approval, withdrawal of approvals and criminal prosecution of Celsion and its employees, all of which would have a material adverse effect on our business.

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

Currently, we have nine utility patents pending in the United States Patent & Trademark Office. One application directed to our breast cancer treatment and another application directed to our Microwave Urethreroplasty(TM) treatment for BPH have been allowed and should issue as United States patents within the next few months. We have filed international applications with respect to the above technologies in various countries including Japan, China, Europe, and Canada. Three additional U.S. utility applications are on file directed to various features of our breast cancer treatment and three additional applications are on file directed to different features of our thermotherapy treatment of BPH. The ninth application on file is directed to our deep tumor therapy treatment. However, even when our pending applications mature into United States patents, our business will still depend on license agreements that we have entered into with third parties until the third parties' patents expire. We intend to file applications for international patent protections for inventions covered by our U.S. applications. However, there can be no assurance when, if ever, we will receive such international patent protection.

Our success will depend, in substantial part, on our ability to maintain our rights under license agreements granting us rights to use patented technologies. We have entered into exclusive license agreements with MIT, for APA technology, and with MMTC, a privately owned developer of medical devices, for microwave balloon catheter technology. We have also entered into a license agreement with Duke University, under which we have exclusive rights to commercialize medical treatment products and procedures based on Duke University's thermo-liposome technology and a license agreement with Memorial Sloan-Kettering Cancer Center under which we have rights to commercialize certain cancer repair inhibitor products. The MIT, MMTC, Duke University and Sloan-Kettering agreements each contain license fee, royalty and/or research support provisions, testing and regulatory milestones, and other performance requirements that we must meet by certain deadlines. If we were to breach these or other provisions of the license and research agreements, we could lose our ability to use the subject technology, as well as compensation for our efforts in developing or exploiting the technology. Also, loss of our rights under the MIT license agreement would prevent us from proceeding with our most current product development efforts, which are dependent on licensed APA technology. Any such loss of rights and access to technology would have a material adverse effect on our business.

Further, we cannot guarantee that any patent or other technology rights licensed to us by others will not be challenged or circumvented successfully by third parties, or that the rights granted will provide adequate protection. We

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are aware of published patent applications and issued patents belonging to others, and it is not clear whether any of these patents or applications, or

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

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

Various methods for treating cancer currently are, and in the future may be expected to be, the subject of extensive research and development. Many possible treatments that are being researched, if successfully developed, may not require, or may supplant, the use of our thermotherapy technology. These alternate treatment strategies include the use of radio frequency (RF), laser and ultrasound energy sources. The successful development and acceptance of any one or more of these alternative forms of treatment could render our technology obsolete as a cancer treatment method.

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

Our success depends significantly on the continued contributions of our executive officers, scientific and technical personnel and consultants, and on our ability to attract additional personnel as we seek to implement our business strategy and develop our products and businesses. During our operating history, we have assigned many essential responsibilities to a relatively small number of individuals. However, as our business and the demands on our key employees expand, we have been, and will continue to be, required to recruit additional qualified employees. The competition for such qualified personnel is intense, and the loss of services of certain key personnel or our inability to attract additional personnel to fill critical positions as we implement our business strategy could adversely affect our business.

Effective October 4, 2001, Spencer J. Volk, formerly the President, Chief Executive Officer and a director of Celsion, resigned from all of these positions. Our Board has appointed Dr. Augustine Y. Cheung, formerly the Chairman and Chief Scientific Officer, to serve as Celsion's President and Chief Executive Officer and Dr. Max Link, a director since 1997, has assumed the position of Chairman of the Board. Effective September 20, 2002, Dr. LaSalle Leffall resigned as a member of our Board of Directors. At its meeting on December 27, 2002, the Board appointed Dr. Gary Pace to fill the remainder of Dr. Leffall's term and to reduce the number of directors constituting the whole Board from seven to six.

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

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

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

Our ability to commercialize our 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. The reimbursement status of newly approved medical products is subject to significant uncertainty. We cannot guarantee that adequate third-party insurance coverage will be available for us to establish and maintain price levels sufficient for us to realize an appropriate return on our investment in developing new therapies. Government, private health insurers and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the l