

CELSION CORP
Form 424B3
June 23, 2004

Filed Pursuant to Rule 424(b)(3)

Registration No. 333-115890

PROSPECTUS

CELSION CORPORATION
13,376,139 SHARES
COMMON STOCK

This Prospectus of Celsion Corporation, or the Company, a Delaware corporation, relates to the offer and sale from time to time by certain selling stockholders (the "Selling Stockholders") of up to 8,652,441 shares of the Company's common stock, par value \$0.01 per share (the "Common Stock") that are presently outstanding, and up 4,723,698 shares of Common Stock issuable upon the exercise of certain Common Stock purchase warrants (the "Warrants"). The shares of Common Stock offered hereby are referred to collectively as the "Shares." See "Selling Stockholders" and "Plan of Distribution."

The Company will not receive any proceeds from sales of Shares by the Selling Stockholders. However, the Company will receive proceeds upon exercise of the Warrants, up to a maximum of \$4,604,032, if all of the Warrants are exercised for cash.

The Selling Stockholders or pledgees, donees, transferees or other successors in interest that receive Shares by way of gift, partnership distribution or other non-sale transfer, may offer and sell some, all or none of the Shares under this Prospectus. The Selling Stockholders or their successors may determine the prices at which they will sell their Shares, which may be the then-prevailing market price or some other price. In connection with such sales, the Selling Stockholders or their successors may use brokers or dealers, who may receive compensation or commissions for such sales. The Company has agreed to bear all expenses in connection with the registration of the Shares. However, the Selling Stockholders will pay any brokerage commissions, discounts and fees in connection with the sale of their Shares. A Selling Stockholder's net proceeds from the sale of Shares will be the sales price of the Shares sold for the account of such Selling Stockholder, less applicable commissions, discounts and fees.

The Common Stock is traded on The American Stock Exchange under the symbol "CLN." On June 9, the closing price of the Common Stock on The American Stock Exchange was \$0.67.

INVESTMENT IN THE COMPANY'S COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. YOU SHOULD CAREFULLY CONSIDER THE RISK FACTORS BEGINNING ON PAGE 9 OF THIS PROSPECTUS BEFORE PURCHASING ANY OF THE SHARES FROM THE SELLING STOCKHOLDERS.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this Prospectus is June 16, 2004

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We have informed the Selling Stockholders that the anti-manipulative rules under the Securities Exchange Act of 1934, including Regulation M, may apply to their sales of Shares in the market. We have furnished the Selling Stockholders with a copy of these rules. We have also informed the Selling Stockholders that they must deliver a copy of this Prospectus with any sale of their Shares.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports and other information with the U.S. Securities and Exchange Commission, or the SEC. You may read and copy any document that we have filed at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information about the operation of its public reference facilities. Our SEC filings are also available to you free of charge at the SEC's web site at <http://www.sec.gov>. The file number of the reports that we file under the Securities Exchange Act of 1934 is 000-14242.

We have filed a registration statement on Form S-3 with the SEC (File No. 333-115890) that covers the resale of the Shares offered hereby. This Prospectus is a part of that registration statement, but does not include all of the information included in the registration statement. You should refer to the registration statement for additional information about us and the Shares. Statements that we make in this Prospectus relating to any document filed as an exhibit to or incorporated by reference into the registration statement may not be complete. You should review the referenced document itself for a complete understanding of its terms.

The SEC allows us to "incorporate by reference" certain information we file with them, which means that we can disclose important information to you in this Prospectus by referring you to those documents. The documents that have been incorporated by reference are an important part of the Prospectus, and you should be sure to review that information in order to understand the nature of any investment by you in the Shares. In addition to previously filed documents that are incorporated by reference, documents that we file with the SEC after the date of this Prospectus will automatically update the registration statement. The documents that we have previously filed and that are incorporated by reference into this Prospectus include the following:

- o Our Annual Report on Form 10-K for the fiscal year ended September

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30, 2003;

- o Our Transition Report on Form 10-Q for the three-month period ended December 31, 2003;
- o Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2004;
- o Our Current Report on Form 8-K filed on May 25, 2004;
- o Our Current Report on Form 8-K filed on June 2, 2004;
- o Our Proxy Statement relating to our 2004 Annual Meeting of Stockholders; and
- o The description of our Common Stock included in our registration statement on Form 8-A filed on May 26, 2000 (File No. 001-15911).

All documents and reports filed by us pursuant to Sections 13 (a), 13 (c), 14 or 15 (d) of the Securities Exchange Act of 1934 after the date of this Prospectus and prior to the date that the offering of Shares made hereby is terminated automatically will be incorporated by reference into this Prospectus. Any statement contained in a document incorporated or deemed to be incorporated by reference into this Prospectus shall be modified or superseded for the purposes of this Prospectus to the extent that a statement contained in this Prospectus, or in any other subsequently filed document which also is, or is deemed to be, incorporated by reference, modifies or supersedes that statement. Any statement modified or superseded shall not be deemed, except as modified or superseded, to constitute a part of this Prospectus.

We will provide you with copies of any of the documents incorporated by reference at no charge to you. However, we will not deliver copies of any exhibits to those documents unless the exhibit itself is specifically incorporated by reference. If you would like a copy of any document, please write or call us at:

Celsion Corporation
10220-L Old Columbia Road
Columbia, MD 21046-2364
Attention: Corporate Secretary
(410) 290-5390

You should only rely upon the information included in or incorporated by reference into this Prospectus or in any Prospectus supplement that is delivered to you. We have not authorized anyone to provide you with additional or different information. You should not assume that the information included in or incorporated by reference into this Prospectus or any Prospectus Supplement is accurate as of any date later than the date on the front of the Prospectus or Prospectus Supplement.

CAUTIONARY STATEMENT ABOUT FORWARD-LOOKING STATEMENTS

Throughout this Prospectus and the other documents incorporated by reference into this Prospectus, we make certain "forward-looking" statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance or achievements predicted, implicitly or explicitly, by such forward-looking statements. Such factors include, among other things, those listed under "Risk Factors" as well as those discussed

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elsewhere in this Prospectus and the documents incorporated by reference into this Prospectus. In some cases, you can identify 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 and involve various risks and uncertainties including:

- o unforeseen changes in the course of research and development activities and in clinical trials;
- o possible changes in cost and timing of development and testing, capital structure and other financial matters;
- o changes in approaches to medical treatment;
- o introduction of new products by others;
- o possible acquisitions of other technologies, assets or businesses;
- o possible actions by customers, suppliers, competitors, regulatory authorities and others; and
- o other risks detailed from time to time in the Company's reports filed with the SEC.

Actual events or results may differ materially from those contemplated by this Prospectus and the other documents incorporated by reference into this Prospectus. In evaluating these statements, you should specifically consider various factors, including those listed above and outlined under "Risk Factors." Although we believe that our 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. We are under no duty to update any forward-looking statements after the date of this Prospectus to conform such statements to actual results or circumstances.

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SUMMARY INFORMATION ABOUT THE COMPANY

This summary highlights selected information contained elsewhere in this Prospectus and incorporated into this Prospectus by reference. This summary may not contain all of the information that may be important to you in considering an investment in our Common Stock. You should read the entire Prospectus, including "Risk Factors" carefully before making an investment decision.

GENERAL

Celsion Corporation, based in Columbia, Maryland, is a biotechnology company dedicated to the development and commercialization of treatment systems for cancer and other diseases using focused heat energy, either administered alone or in combination with other therapeutic devices, heat-activated genes and heat-activated drugs. In February 2004 we received premarketing approval (PMA) from the Food and Drug Administration, or FDA for our Prolieve(TM) Thermodilatation system for the treatment of Benign Prostatic Hyperplasia, or BPH, a chronic condition of enlargement of the prostate common in older men, and

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have begun to market. We also are currently in active clinical development and testing of (i) systems using our Adaptive Phased Array (APA) focused microwave technology, licensed from the Massachusetts Institute of Technology (MIT), to treat both early stage cancer and locally advanced breast cancer, and (ii) heat-activated liposome technology, licensed from Duke University, to deliver chemotherapeutic drugs for the treatment of prostate and liver cancer. In addition, our gene-based Cancer Repair Inhibitor (CRI), licensed from Memorial Sloan-Kettering Cancer Center (Sloan-Kettering), is in late-stage animal testing

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

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" (MI) therapies, are available as alternatives to the TURP procedure. The primary MI treatments use microwave heating (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 (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.

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

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

CELSION BPH TREATMENT SYSTEM

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

- o Celsion's proprietary catheter, incorporating a balloon enlargement device, delivers computer-controlled transurethral microwave heating directly to the prostate at temperatures greater than 44(degree) C (111(degree) F).
- o 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 serves effectively to kill off prostate cells outside the wall of the urethra, thereby creating sufficient space for the enlarged natural opening.

Pre-clinical animal studies have demonstrated that a natural "stent," or reinforced opening, in the urethra forms after the combined heat plus compression treatment. Also, the Prolieve system's relatively low temperature (43(degree) C to 45(degree) C) appears to be sufficient to kill prostatic cells surrounding the urethra wall, thereby creating space for the enlargement of the urethra opening. However, the temperature is not high enough to cause swelling in the urethra.

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Celsion's Prolieve Thermodilatation system 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 Prolieve system include walk-in, outpatient treatment that can be completed in less than an hour; no required sedation; generally no post-operative catheterization; and rapid symptomatic relief from BPH.

We recently completed the FDA approval process and received a PMA, which permitted us to begin to market the Prolieve system, on February 19, 2004. Since that time we have begun to market the Prolieve system through Boston Scientific Corporation, with which we entered into a strategic relationship in January 2003.

We have received a warning letter from the FDA regarding the Phase I and Phase II clinical trials of the Prolieve system. The warning letter reflects matters that arose during the course of an inspection conducted by the FDA's Baltimore regional office from December 9 through December 18, 2003 under a program designed to ensure that data and information contained in certain submissions to the FDA, including PMA applications, are scientifically valid and accurate and to ensure that human subjects are protected from undue hazard or risk during scientific investigations.

The warning letter addressed four general areas--monitoring, investigational agreements, provision of information to certain investigators, and FDA reporting--in connection with the Prolieve studies, both of which were completed by January 2002. Subsequent to the inspection, we took certain actions to address the observations of the FDA inspector and on December 23, 2003, made a written submission to the agency regarding those corrective and compliance actions. In addition, since receipt of the warning letter, the Company has spoken with representatives of the FDA regarding compliance matters and has initiated short- and long-term corrective and compliance measures to address fully the issues raised by the FDA.

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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 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

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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 that 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 who had developed, originally for the United States Defense Department, the microwave control technology known as "Adaptive Phased Array" (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 equipment capable of focusing microwave energy on specific tissue areas. We have 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.

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(degree) C (115(degree) 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

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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 is designed to ablate (kill) small breast tumors including microscopic lesions in the margin of the tumor, leaving the margins clear of viable cancer cells using heat alone and the second 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 St. Joseph's Hospital Breast Center in Orange, California, Harbor-UCLA Medical Center in Torrance, California, the University of Oklahoma at Oklahoma City, Comprehensive Breast Center of Coral Springs in Coral Springs, Florida, Mroz-Baier Breast Care Center in Memphis, Tennessee, Lynne Clark, M.D. in Tacoma, Washington, Breast Care Specialists in Norfolk, Virginia, and Bolton Breast Unit.

Effective May 25, 2004, we suspended both branches of our pivotal Phase II trials using the Company's advanced phase array microwave technology in the treatment of small and late stage breast cancer tumors. The decision to suspend was taken after preliminary evaluation of interim (midpoint) data from the trials. In the small tumor study, the Company determined that it was achieving the primary endpoint of reducing second incisions, but that it was not consistently meeting its secondary endpoint of reducing tumor burden as measured by tumor necrosis. The Company believes that these inconsistent results may be due to inconsistent delivery of an adequate thermal dose. In the late-stage study, the Company was encountering difficulties in enrolling sufficient patients in part due to a change in the prevailing standard of care specified in the study protocol and in part due to a shortage of late-stage tumor patients, due to earlier detection of breast cancer.

THERMODOX (TM) (DOXORUBICIN ENCAPSULATED IN HEAT-ACTIVATED LIPOSOME); DUKE UNIVERSITY

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 the tumors, severely limiting the clinical efficacy of liposome chemotherapy treatments.

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 that have been

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heated for 30 to 60 minutes than in areas that do not receive heat. In animal trials it has been determined that 50 times the amount of drugs carried by heat-sensitive liposomes was deposited 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 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 5 mg per kilogram Doxorubicin concentration. This was immediately followed by heating of the tumor to 42(degree) C (108(degree) F) for one hour. The result of the study was a complete regression of the tumors in 11 out of 11 mice. These animals remained disease free through 60 days of the study.

In November 2001, we completed large animal toxicity studies involving ThermoDox(TM), our Doxorubicin-laden thermo-liposome, at the Roswell Park Cancer Institute, a cancer research organization in Buffalo, New York, and at Dartmouth Hitchcock Medical Center, a teaching hospital associated with Dartmouth Medical College. In March 2002, we filed an Investigational New Drug, or IND, application with the FDA for the use of ThermoDox in the treatment of prostate cancer using our Prolieve equipment as the means of heat-activation. The IND became effective in June 2002 and we have had a Phase I clinical trial underway at Roswell Park and Regional Urology in Shreveport, Louisiana.

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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 ThermoDox to enable the NCI to conduct clinical trials on liver cancer. NCI is using an RF heating device to ablate the tumors and to heat the liver, activating ThermoDox to kill peripheral cancer cells. Liver cancer has yet to be successfully treated with existing treatment modalities. NCI is currently completing pre-clinical studies and we filed an IND for the treatment of liver cancer on December 22, 2003.

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In addition, in January 2001, we entered into a Material Transfer Agreement (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 is using 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 is currently completing preclinical studies and we hope to file an IND for the treatment of liver cancer early in 2004.

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.

ALLIED TECHNOLOGY

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

This heating system is currently being clinically evaluated at Duke. A Phase I trial has been completed and a Phase II trial is underway. The combination of trials was designed to demonstrate the system's ability to enhance the combined therapeutic effect of liposomal encapsulations of Doxorubicin(R) plus traditional paclitaxel (Taxol(R)) in the management of locally advanced breast cancer. Results of the Phase I study, which included 21 women, indicated that tumor growth was halted in all of the women participating in the trial and that 50% of the treated tumors were reduced in size. Eleven percent of the trial participants had complete pathologic

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responses, meaning no cancer was found in the breast tissue upon analyzing its surgical remains, and 33% of patients had complete clinical responses, meaning visible signs of the tumor could no longer be detected. An additional 17% of trial participants were converted from mastectomy candidates to lumpectomy candidates. Celsion intends to work with Duke University staff to explore the potential for using this heating system in combination with ThermoDox to treat breast cancer.

PRODUCTION OF HEAT-SENSITIVE LIPOSOMES

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

SLOAN-KETTERING / CELSION HEAT-ACTIVATED GENE THERAPY COMPOUNDS

BACKGROUND

Cancer cells have the ability to repair themselves after radiation or chemotherapy. Thus, patients require repeated treatments to destroy substantially all of the cancer cells. Celsion has licensed from Sloan-Kettering Cancer Center, a biomedical innovation that promises significant improvements in cancer therapy. Sloan-Kettering has developed biological modifiers that inhibit 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 looking for ways to mitigate these side effects. In radiation therapy, these 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(degree) C (106(degree) F). This focused heat may be generated by Celsion's Adaptive Phased Array microwave technology or other heating systems. Having increased the susceptibility of cancer cells to DNA-damaging agents, radiation and chemotherapy treatment may then be administered with less frequency and/or at lower doses than currently is possible. CRI would then

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deactivate and the patient would resume normal post-treatment care.

In September 2001, scientists at Sloan-Kettering successfully completed pre-clinical laboratory feasibility demonstrations to assess safety and biological activity of CRI. In December 2001, a small animal feasibility study was completed at Sloan-Kettering's Good Laboratory Practice (GLP) facility to assist in drug formulation. Further studies with large animals to assess toxicity effects are expected to be conducted. Following completion of these toxicity studies, the Company expects to file an IND.

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

In addition, in the July 1, 2000 issue of *Cancer Research*, a Duke University research scientist reported on his initial use of heat to activate gene therapy and to increase the production in animals of Interleukin-12, a genetic protein, in order to delay tumor

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growth. On August 8, 2000, we entered into an agreement with Duke University, subsequently renewed for consecutive six-month periods, under which Celsion has the right, for a period of six months thereafter, to negotiate an exclusive license for this technology.

RISK FACTORS

You should carefully consider the risks described below before making a decision to invest in our Common Stock. You should also refer to the other information in this Prospectus, as well as the information incorporated by reference into this Prospectus, including our financial statements and the related notes. The risks and uncertainties described below are not the only ones that could affect our Company. Additional risks and uncertainties of which we are unaware or that we currently believe are immaterial also may become important factors affecting our business. If any one or more of the following risks occur, our business, results of operations and financial condition could be materially harmed. As a result, the trading price of our Common Stock could decline, and you could lose all or part of your investment. The terms the "Company," "we," "us" and "our" used throughout this Prospectus all refer to Celsion Corporation.

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 \$66,297,896 at March 31, 2004, including losses of \$14,293,081 for the 12 months ended December 31, 2003 and \$6,065,680 for the quarter ended March 31, 2004. Because we presently have only limited 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. In addition, we have

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funded our operations for many years primarily through the sale of the Company'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.

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

SOME OF OUR TECHNOLOGY IS STILL UNDERGOING CLINICAL TESTING; OUR TECHNOLOGIES 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 this study, the HealthCare Financing Administration, or 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 received a PMA from the FDA for our Prolieve system for the treatment of BPH, but we can offer no assurance that the Prolieve system will be accepted by the medical community widely or at all. Our new cancer treatment technology is currently in Phase II trials. This technology may not prove as effective in practice as we on anticipate. 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

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our ability to petition successfully for 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.

We will need substantial additional funding in order to complete the development, testing and commercialization of our breast cancer treatment system and heat-activated liposome and cancer repair inhibitor products, as well as other potential new products. We expended approximately \$14,333,740 in the 12-month period ended December 31, 2003 and an additional \$6,155,472 in the three months ended March 31, 2004. As of that date, we had available a total of approximately \$19,426,771 to fund our operations. We have both increased the pace of development work on our present products and made a significant commitment to our heat-activated liposome and cancer repair inhibitor research and development projects and it is our intention to at least maintain, or increase the pace and scope of these activities. The increase in the scope of present development work and the commitment to these new projects will require additional external funding, at least until we are able to generate sufficient cash flow from sale of one or more of our products to support our continued operations. We do not have any committed sources of financing and cannot offer any assurances that additional funding will be available in a timely manner, on acceptable terms or at all.

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

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

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

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

Even if regulatory approval of a product candidate is granted, the

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approval may include significant limitations on the indicated uses for which the product may be marketed. In addition, 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.

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

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

The EU has a registration process that includes registration of manufacturing facilities (known as "ISO certification") and product certification (known as a "CE Mark"). We have obtained ISO certification for our existing facilities. However, there is no guarantee that we will be successful in obtaining European certifications for new facilities or for our products, or that we will be able to maintain its 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 its activities and provide an advantage to larger companies that compete with it. 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 it develops. Any delay in obtaining, or failure to obtain, necessary approvals would materially and adversely affect the marketing of our contemplated products subject to such approvals and, therefore, our ability to generate revenue from such products.

Even if regulatory authorities approve our product candidates, such products and our facilities, including facilities located outside the EU, may be subject to ongoing testing, review and inspections by the European health regulatory authorities. After receiving premarketing approval, in order to manufacture and market any of 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

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approvals and criminal prosecution of the Company 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 three utility patents pending in the United States Patent & Trademark Office. Two are directed to our Prolieve system for the treatment of BPH and the other is directed to our breast cancer treatment system. However, even when our pending applications mature into United States patents, our business will still depend on license agreements that it has entered into with third parties until the third parties' patents expire.

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, an advanced phased array radio frequency (RF) heating system designed specifically for use with chemotherapeutic drugs for the treatment of locally advanced breast cancer 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. Further, loss of our rights under the MIT license agreement would prevent us from proceeding with most our 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 are aware of published

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

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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 ITS BUSINESS STRATEGY AND DEVELOP ITS 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. Further, we do not carry "key man" insurance on any of our personnel. Therefore, loss of the services of key personnel would not be ameliorated by the receipt of the proceeds from such insurance.

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

Our business strategy contemplates growth and diversification. As manufacturing, marketing, sales, and other personnel, and expand our manufacturing and research and development capabilities we add, 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 businesses effectively if we are unable to alleviate the strain on resources caused by growth in a timely and successful manner. There can be no assurance that we will be able to manage our growth and a failure to do so could have a material adverse effect on our business.

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 level of reimbursement for new therapeutic

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products approved for marketing by the FDA. Accordingly, even if coverage and reimbursement are provided by government, private health insurers and third-party payors for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for health care providers.

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

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

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

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

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

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

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WE PRESENTLY HAVE LIMITED MARKETING AND SALES CAPABILITY AND WILL BE REQUIRED TO DEVELOP SUCH CAPABILITIES AND TO ENTER INTO ALLIANCES WITH OTHERS POSSESSING SUCH CAPABILITIES IN ORDER TO COMMERCIALIZE OUR PRODUCTS SUCCESSFULLY.

We have begun to commercialize and market our Prolieve Thermodilatation system through Boston Scientific. Consequently, we are dependent upon Boston Scientific for the successful introduction and marketing of our Prolieve system. There can be no assurance that Boston Scientific will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for Prolieve system. We intend to market our other products, if and when such products are approved for commercialization by the FDA, through other strategic alliances and distribution arrangements with third parties. There can be no assurance that we will be able to establish such sales and marketing capabilities successfully or successfully enter into third-party marketing or distribution arrangements and, to the extent that we do enter into such arrangements, we will be dependent, to some degree, on our marketing and distribution partners. We have limited experience and capabilities in marketing, distribution and direct sales, although we expect to attempt to recruit experienced marketing and sales personnel as we pursue commercialization. In attracting, establishing and maintaining a marketing and sales force or entering into third-party marketing or distribution arrangements with other companies, we expect to incur significant additional expense. There can be no assurance that, to the extent we enter into any commercialization arrangements with third parties as and when our other products or services receive FDA approval, such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for our products and services. There also can be no assurance that our direct sales, marketing, licensing and distribution efforts would be successful or that revenue from such efforts would exceed expenses.

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WE DEPEND ON THIRD-PARTY SUPPLIERS TO PROVIDE US WITH COMPONENTS REQUIRED FOR OUR PRODUCTS AND MAY NOT BE ABLE TO OBTAIN THESE COMPONENTS ON FAVORABLE TERMS OR AT ALL.

We are not currently manufacturing any products, but are using our facilities to assemble prototypes of the equipment for research and development purposes. We currently purchase certain specialized microwave and thermometry components and applicator materials and the catheter unit used for our clinical trial products from single or limited source suppliers because of the small quantities involved. While we have not experienced any significant difficulties in obtaining these components, the loss of an important current supplier could require that we obtain a replacement supplier, which could result in delays and additional expense in being able to make prototype equipment available for clinical trials and other research purposes. For our Prolieve equipment, we use outside contractors to manufacture finished equipment and the disposable catheter kit used in conjunction with the equipment. In turn, these suppliers are dependent on single source and other components suppliers. Although we believe that alternative sources of supply would be available if the need arose, the loss of one or more of these suppliers would require that we obtain a replacement source, which could result in delays and additional expense to redesign the product to accept the replacement vendor.

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

We have never paid cash dividends and do not anticipate paying cash

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dividends on our common or preferred stock in the foreseeable future. Therefore, our stockholders cannot achieve any degree of liquidity with respect to their shares of Common Stock except by selling such shares.

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

As of April 30, 2004, we had outstanding and exercisable warrants and options to purchase a total of 23,724,677 shares of our Common Stock at exercise prices ranging from \$0.25 to \$5.00 per share (with a weighted average exercise price of approximately \$0.89 per share). In addition, we had outstanding but unexercisable and unvested warrants and options to purchase a total of 1,965,000 shares of our Common Stock at exercise prices ranging from \$0.40 to \$1.50 per share (with a weighted average exercise price of approximately \$0.85 per share). Some of the prices are below the current market price of our Common Stock, which has ranged from a low of \$1.04 to a high of \$1.26 over the 20 trading days ending April 30, 2004. If holders choose to exercise such warrants and options at prices below the prevailing market price for the Common Stock, the resulting purchase of a substantial number of shares of our Common would have a dilutive effect on our stockholders and could adversely affect the market price of our issued and outstanding Common Stock and convertible securities. In addition, holders of these options and warrants who have the right to require registration of the Common Stock under certain circumstances and who elect to require such registration, or who exercise their options or warrants and then satisfy the one-year holding period and other requirements of Rule 144 of the Securities Act, will be able to sell in the public market shares of Common Stock purchased upon such exercise.

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

Our Common Stock currently trades on The American Stock Exchange (the Amex). The Amex, as a matter of policy, will consider the suspension of trading in, or removal from listing of, any stock when, in the opinion of the Amex, (i) the financial condition and/or operating results of an issuer appear to be unsatisfactory; (ii) it appears that the extent of public distribution or the aggregate market value of the stock has become so reduced as to make further dealings on the Amex inadvisable; (iii) the issuer has sold or otherwise disposed of its principal operating assets; or (iv) the issuer has sustained losses which are so substantial in relation to its overall operations or its existing financial condition has become so impaired that it appears questionable, in the opinion of the Amex, whether the issuer will be able to continue operations and/or meet its obligations as they mature. For example, the Amex will consider suspending dealings in or delisting the stock of an issuer if the issuer has sustained losses from continuing operations and/or net losses in its five most recent fiscal years. Another instance where the Amex would consider suspension or delisting of a stock is if the stock has been selling for a substantial period of time at a low price per share and the issuer fails to effect a reverse split of such stock within a reasonable time after being notified that the Amex deems such action to be appropriate. We have sustained net losses for our last five fiscal years (and beyond) and our Common Stock has been trading at relatively low prices. Therefore, our Common Stock may be at risk for delisting by the Amex.

Upon any such delisting, the Common Stock would become subject to the penny stock rules of the SEC, which generally are applicable to equity securities with a price of less than \$5.00 per share (other than securities registered on certain national securities

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

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

Market prices for our Common Stock and the securities of other medical, high technology companies have been volatile. Our Common Stock has had a high price of \$0.40 and a low price of \$2.10 in the 52-week period ending April 30, 2004. Factors such as announcements of technological innovations or new products by us or by our competitors, government regulatory action, litigation, patent or proprietary rights developments and market conditions for medical and high technology stocks in general can have a significant impact on the market for our Common Stock.

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

While our Common Stock is listed on the Amex, the volume of trading historically has been relatively light. Although trading volume has increased recently, there can be no assurance that this increased trading volume, our historically light trading volume, or any trading volume whatsoever will be sustained in the future. Therefore, there can be no assurance that our stockholders will be able to sell their shares of our Common Stock at the time or at the price that they desire, or at all.

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

Our Certificate of Incorporation and Bylaws may discourage, delay or prevent a merger or acquisition that a stockholder may consider favorable by authorizing the issuance of "blank check" preferred stock. The Board of Directors may issue this preferred stock, on such terms as it determines, without further stockholder approval. Therefore, the Board may issue such preferred stock on terms unfavorable to a potential bidder in the event that it opposes a merger or acquisition. In addition, our classified Board of Directors may discourage such transactions by increasing the amount of time necessary to obtain majority representation on the Board. We also have implemented a stockholder rights plan and distributed rights to our stockholders. When these rights become exercisable, these rights entitle their holders to purchase one share of our Series C Junior Participating Preferred Stock at a price of \$4.46 per one ten-thousandth of a share of Series C Preferred Stock. If any person or

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group acquires more than 15% of our Common Stock, the holders of rights (other than the person or group crossing the 15% threshold) will be able to purchase, in exchange for the \$4.46 exercise price, \$8.92 of our Common Stock or the stock of any company into which we are merged. Because these rights may substantially dilute stock ownership by a person or group seeking to take us over without the approval of our Board of Directors, our rights plan could make it more difficult for a person or group to take us over (or acquire significant ownership interest in us) without negotiating with our Board regarding such a transaction. Certain other provisions of our Bylaws and of Delaware law may also discourage, delay or prevent a third party from acquiring or merging with us, even if such action were beneficial to some, or even a majority, of our stockholders.

USE OF PROCEEDS

The Selling Stockholders will receive all of the net proceeds from the sale of their respective Shares; we will not receive any proceeds from these sales. The holders of the Warrants are under no obligation to exercise them at any time or at all.

The exercise price for the Warrants is payable in cash (except that Warrants to purchase 121,680 shares at \$0.77 per share are subject to "cashless" or "net" exercise provisions). If all of the Warrants (including those subject to "cashless" exercise) are

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exercised for cash, we will receive aggregate consideration of \$4,504,032. We intend to use any proceeds from exercise of the Warrants for working capital and general corporate purposes.

RESALES BY SELLING STOCKHOLDERS

This Prospectus relates to the proposed resale by the Selling Stockholders of the Shares, consisting of up to 8,652,441 shares of Common Stock, and up to 4,723,698 shares of Common Stock issuable upon the exercise of the Warrants. The following table sets forth, as of May 21, 2004, certain information with respect to the persons for whom the Company is registering the Shares for resale to the public. Except as indicated by footnote below, no such person has had a material relationship or has held any position or office, with the Company within the last three years and, to our knowledge, based on information provided by the Selling Stockholders, no such person is a broker-dealer or an affiliate of a broker-dealer. The Company will not receive any of the proceeds from the sale of the Shares, but may receive up to \$4,604,032 upon the cash exercise of the Warrants.

NAME OF SELLING STOCKHOLDER	SECURITIES BENEFICIALLY OWNED PRIOR TO OFFERING (1)		SECURITIES OFFERED HEREBY (2)	SECURITIES BENEFICIALLY OWNED AFTER OFFERING (3)
	COMMON STOCK	WARRANTS	COMMON STOCK	AMOUNT
Silver Lake Investment Partners Ltd.	2,727,273	818,182	3,545,455	0
Gwynneth Gold Ltd.	550,000	165,000	715,000	0
Goldpac Investment Partners Ltd.	0	878,516	878,516	0

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Zhitao He	2,750,000	825,000	3,575,000	0
Chan Wai	1,100,000	330,000	1,430,000	120,000
Sun Yiu Kwong	600,000	150,000	650,000	100,000
Liu Chi Kong	390,000	117,000	507,000	0
Ying Rong Shi	200,000	60,000	260,000	0
Tan Hong Jiu	100,000	30,000	130,000	0
Jacob L. Jacobson	194,076	0	194,074	0
Gloria Li	116,145	19,000	78,772	56,373
Alan J. Fenn	50,000	0	50,000	0
Kaijun Wu	12,320	0	12,320	0
John Mon (4)	348,288	1,160,000	600,000	908,288
Augustine Y. Cheung (5)	3,537,176	1,750,000	400,000	4,887,176
Ira M. Weingarten	0	75,000	50,000	25,000
Steve Chizzik	0	50,000	50,000	0
Strategic Growth International, Inc.	0	450,000	250,000	200,000

- (1) We have computed "beneficial ownership" in accordance Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1934 for purposes of this table. Therefore, the table reflects a person as having "beneficial ownership" of shares of Common Stock if such person has the right to acquire such shares within 60 days of May 21, 2004. For purposes of computing the percentage of outstanding shares of Common Stock held by each person or group of persons named above, we have assumed to be outstanding any security which such person or persons has or have the right to acquire within that 60-day period. All of the Warrants are currently exercisable and, therefore, the Selling Stockholders may be deemed to be the beneficial owner of the shares of Common Stock underlying such Warrants pursuant to Rule 13d-3(d). However, securities that may be acquired within that 60-day period are not deemed to be outstanding for purposes of computing the percentage ownership of any other person. Notwithstanding the foregoing, for purposes of this table, we have not, however, included the Shares underlying warrants and registered hereby under the column "Securities Beneficially Owned Prior to Offering--Common Stock." Instead, the Shares are reflected under the column "Securities Offered Hereby." Except as indicated in the footnotes to this table and pursuant to applicable community property laws, the Company believes, based on information supplied by such persons, that the persons named in this table have sole voting and investment power with respect to all shares of Common Stock which they beneficially own.
- (2) Represents the maximum number of shares of Common Stock issuable to each Selling Stockholder upon exercise in full of Warrants issued or issuable thereto.
- (3) Assumes the eventual sale of all Shares by each Selling Stockholder. There can be no assurance that any Selling Stockholder will sell any or all of the Shares owned thereby or issuable thereto.
- (4) Until February 2004, Mr. Mon was a director of the Company and, until May 2004, he served as corporate secretary. Mr. Mon has been, and continues to be, a vice president of the Company.
- (5) Dr. Cheung is a director and serves as president, chief executive officer and chief scientific officer of the Company.

* Less than 1%.

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PLAN OF DISTRIBUTION

The Selling Stockholders may, in their discretion, offer and sell Shares from time to time on The American Stock Exchange or otherwise at prices and on terms then prevailing at prices related to the then-current market price, or at negotiated prices. The distribution of the Shares may be effected from time to time in one or more transactions including, without limitation:

- o ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- o transactions involving block trades;
- o purchases by a broker, dealer or underwriter as principal and resale by that person for its own account under this Prospectus;
- o put or call option transactions;
- o privately negotiated transactions; or
- o by any other legally available means.

In effecting sales, broker-dealers or agents engaged by the Selling Stockholders may arrange for other broker-dealers or agents to participate. From time to time, one or more of the Selling Stockholders may pledge, hypothecate or grant a security interest in some or all of the Shares owned thereby, and the pledgees, secured parties or persons to whom such securities have been hypothecated shall, upon foreclosure in the event of default, be deemed to be Selling Stockholders under this Prospectus. In addition, the Selling Stockholders may from time to time sell short the Common Stock of the Company and, in such instances, this Prospectus may be delivered in connection with such short sale and the Shares offered hereby may be used to cover such short sale.

Sales of Selling Stockholders' Shares may also be made pursuant to Rule 144 under the Securities Act of 1933, where applicable. The Selling Stockholders' Shares may also be offered in one or more underwritten offerings, on a firm commitment or best efforts basis. The Company will receive no proceeds from the sale of Shares by the Selling Stockholders, although it will receive the exercise price upon any exercise of Warrants.

To the extent required under the Securities Act of 1933, the aggregate amount of Selling Stockholders' Common Stock being offered and the terms of the offering, the names of any such agents, brokers, dealers or underwriters and any applicable commission with respect to a particular offer will be set forth in an accompanying Prospectus supplement. Any underwriters, dealers, brokers or agents participating in the distribution of the Shares may receive compensation in the form of underwriting discounts, concessions, commissions or fees from a Selling Stockholder and/or purchasers of Selling Stockholders' Shares, for whom they may act. In addition, Selling Stockholders may be deemed to be underwriters under the Securities Act and any profits on the sale of Shares by them may be deemed to be discounts or commissions under the Securities Act. Selling Stockholders may have other business relationships with the Company or its affiliates in the ordinary course of business.

From time to time, each of the Selling Stockholders may transfer, pledge, donate or assign their Shares to lenders, family members and others and each of such persons will be deemed to be a Selling Stockholder for purposes of this Prospectus. The number of Shares beneficially owned by those Selling Stockholders who transfer, pledge, donate or assign Shares will decrease as and when they take such actions. The plan of distribution for the Shares sold

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hereunder will otherwise remain unchanged, except that the transferees, pledgees, donees or other successors will be Selling Stockholders hereunder.

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Without limiting the foregoing, in connection with distributions of the Shares, a Selling Stockholder may enter into hedging transactions with broker-dealers and the broker-dealers may engage in short sales of the Common Stock in the course of hedging the positions they assume with such Selling Stockholder. A Selling Stockholder may also enter into option or other transactions with broker-dealers that involve the delivery of Shares to the broker-dealers, who may then resell or otherwise transfer such Shares. A Selling Stockholder may also lend or pledge Shares to a broker-dealer and the broker-dealer may sell the Shares so borrowed or, upon default, may sell or otherwise transfer the pledged Shares.

Under applicable rules and regulations under the Securities Exchange Act, any person engaged in the distribution of the Common Stock may not bid for or purchase shares of Common Stock during a period which commences one business day (five business days, if the Company's public float is less than \$25 million or its average daily trading volume is less than \$100,000) prior to such person's participation in the distribution, subject to exceptions for certain passive market making activities. In addition and without limiting the foregoing, each Selling Stockholder will be subject to applicable provisions of the Securities Exchange Act and the rules and regulations thereunder, including, without limitation, Regulation M, which provisions may limit the timing of purchases and sales of shares of the Company's Common Stock by such Selling Stockholder.

The Company is bearing all costs relating to the registration of the Shares (other than fees and expenses, if any, of counsel or other advisors to the Selling Stockholders). Any commissions, discounts or other fees payable to broker-dealers in connection with any sale of the Shares will be borne by the Selling Stockholders selling such Shares.

The Company may indemnify the Selling Stockholders in certain circumstances, against certain liabilities, including liabilities arising under the Securities Act of 1933.

LEGAL MATTERS

The legality of the securities in this offering is being passed upon for us by Anita J. Finkelstein, Esquire, our Vice President and General Counsel.

EXPERTS

Our financial statements at September 30, 2001, 2002 and 2003 and for the years ended September 30, 2001, 2002 and 2003 are incorporated by referenced into this Prospectus from our Annual Report on Form 10-K for the year ended September 30, 2003 have been audited by Stegman & Co., independent accountants, and are so incorporated by reference in reliance upon such report given upon the authority of such firm as experts in accounting and auditing.

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13,376,139 SHARES

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COMMON STOCK

CELSION CORPORATION

PROSPECTUS

NO DEALER, SALES REPRESENTATIVE OR ANY OTHER PERSON HAS BEEN AUTHORIZED TO GIVE ANY INFORMATION OR MAKE ANY REPRESENTATION OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS AND, IF GIVEN OR MADE, YOU MUST NOT RELY UPON SUCH INFORMATION OR REPRESENTATION AS HAVING BEEN AUTHORIZED BY CELSION CORPORATION. THIS PROSPECTUS DOES NOT CONSTITUTE AN OFFER OF ANY SECURITIES OTHER THAN THOSE TO WHICH IT RELATES OR AN OFFER TO SELL, OR A SOLICITATION OF AN OFFER TO BUY, TO ANY PERSON OR IN ANY JURISDICTION WHERE AN OFFER OR SOLICITATION WOULD BE UNLAWFUL. NEITHER THE DELIVERY OF THIS PROSPECTUS NOR ANY SALE MADE HEREUNDER, SHALL, UNDER ANY CIRCUMSTANCES, CREATE AN IMPLICATION THAT THE INFORMATION CONTAINED HEREIN IS CORRECT AS OF ANY DATE SUBSEQUENT TO, OR THAT THERE HAS BEEN NO CHANGE IN THE AFFAIRS OF CELSION CORPORATION SINCE, THE DATE OF THIS PROSPECTUS.

THE DATE OF THIS PROSPECTUS IS JUNE 16, 2004