CELSION CORP
Form 10-K
March 27, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2006

or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number 000-14242

CELSION CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE	**52-1256615**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
10220-L OLD COLUMBIA ROAD	**21046-2364**

COLUMBIA, MARYLAND
(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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act YES ¨ NO x

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

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

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

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

Large Accelerated Filer ¨ Accelerated Filer ¨ Non-accelerated Filer x

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

As of March 23, 2007, 10,827,643 shares of the Registrant s Common Stock were issued and outstanding.

As of June 30, 2006, the aggregate market value of voting common stock held by non-affiliates of the Registrant was approximately $26,837,000 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 2007 Annual Meeting of Stockholders, which is expected to be held on June 13, 2007, are incorporated by reference into Part III hereof, as indicated herein.

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PART I

ITEM 1. BUSINESS

FORWARD-LOOKING STATEMENTS

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

GENERAL

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

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

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The Prolieve Thermodilatation system for the treatment of BPH was approved by the Food and Drug Administration (FDA) in 2004 and is being marketed by Celsion s exclusive distributor Boston Scientific Corporation (Boston Scientific , BSC) Boston Scientific also has a five year (expiring in February 2009) option to purchase the Prolieve assets and technology for $60 million. The funds generated to date from sales of Prolieve have been used in the development of the Company s first drug, ThermoDox. Celsion is currently engaged in three Phase I, dose escalation studies, in the treatment of primary liver cancer and in the treatment of recurrent chest wall breast cancer.

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

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

Our principal offices are located at 10220-L Old Columbia Road, Columbia, Maryland and our telephone numbers are (410) 290-5490 and (800) 262-0394. The Company s website id www.celsion.com

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

THERMODOX (DOXORUBICIN ENCAPSULATED IN HEAT-ACTIVATED LIPOSOME)

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

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

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

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Animal studies have demonstrated that the intravenous administration of ThermoDox in combination with targeted heat to the tumor can produce tumor tissue concentrations higher than that achieved in the same experiments with traditional or non-heat sensitive liposomal doxorubicin formulations when given at the same dose as ThermoDox. Celsion is pursuing primary liver cancer as its lead indication for ThermoDox. The Company is also evaluating the possibility of using ThermoDox or other chemotherapeutic agents encapsulated in its heat activated liposome to treat other cancers.

Liver Cancer Overview

Primary liver cancer (hepatocellular carcinoma or HCC) is one of the most common and deadliest forms of cancer worldwide. It is estimated that up to 90% of liver cancer patients will die within five years of diagnosis. There are approximately 20,000 new cases per year of HCC in the U.S. With the inclusion of liver metastases from other cancers (e.g. colon, lung, breast, etc) the total number of cases of liver cancer in the U.S. increases significantly.

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

Celsion s Approach

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

Liver Cancer Phase I Trial

A Phase I single dose escalation study is underway which is investigating ThermoDox in combination with RFA for the treatment of liver cancer. The study is currently being performed at the National Cancer Institute (NCI), which is part of the National Institutes of Health (NIH) and Queen Mary s Hospital in Hong Kong. The Company treated its first patient on February 14, 2005, and expects to complete treatment of all patients in the Phase I study by the middle of 2007. The Company is currently working with the FDA to finalize plans for a Phase III study for the treatment of primary liver cancer which it hopes to initiate in late 2007.

In February 2007, the Company initiated a Phase I dose escalation study designed to investigate simplification of the current RFA/ThermoDox treatment regimen including a single vial formulation of ThermoDox and reducing the pre-treatment prophylactic dosing. The study also allows multiple dosing in liver cancer patients. The study is currently being performed at the Cleveland Clinic Foundation and at North Shore Long Island Jewish Health System. The first patient in this study was treated during February 2007. This study is not expected to impact the timing of the Phase III liver study discussed above[CC1].

Recurrent Chest Wall Breast Cancer Overview

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

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

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

Breast Cancer Phase I Trial

Celsion has provided a research grant to Duke University and will provide clinical supplies of ThermoDox to support a Phase I multiple dose, open label study of the safety and pharmacokinetics in RCW patients. Duke enrolled the first patient in May 2006 and expects to complete enrollment in the study by the third quarter of 2007.

PROLIEVE THERMODILATATION SYSTEM

Focused Heat Treatment

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

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

The procedure is eligible for Medicare/Medicaid and insurance reimbursement averaging $3,600. The market for minimally invasive procedures is currently approximately $75 million and growing rapidly. Management believes the potential for Prolieve could be greater than $125 million.

As mentioned above, Celsion has granted Boston Scientific exclusive marketing rights to the Prolieve Thermodilatation System. In addition, Celsion has also granted Boston Scientific the option to purchase the assets and technology relating to Prolieve for a period of five years from its launch (February 2004) for a price of $60 million. Boston Scientific has also loaned Celsion $15,000,000 ($16,277,698 including accrued interest at December 31, 2006), which can be applied against the option purchase price for the Prolieve Thermodilatation System.

Marketing, Distribution and Supply

Celsion markets the Prolieve system through an exclusive Distribution Agreement with Boston Scientific Corporation, pursuant to which Celsion granted Boston Scientific exclusive rights to market and distribute Prolieve and its component parts for the treatment of BPH. Under the terms of this agreement Boston Scientific markets and distributes Prolieve in the United States and has a license to market and distribute the product worldwide, with the exception of Greater China, Mexico and Central and South America. Boston Scientific, through its urology sales force, launched the product in the United States in February 2004 targeting urology practices throughout the country. Trial of the system is generated through the placement of control units in physician s offices for an evaluation period at the end of which the physician either acquires the machine or returns it to Boston Scientific. Since approval in February 2004, Prolieve has been sold exclusively in the United States generating revenues of approximately $11,251,000, $12,320,000 and $2,506,000 in the years ended December 31, 2006, 2005 and 2004, respectively.

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

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

RESEARCH AND DEVELOPMENT

Celsion engages in a limited amount of research and development in its own facilities, and instead sponsors the majority of its research programs in partnership with various research institutions, including Duke University. Our expenditures for research and development were approximately $9,345,000 $10,081,000 and $11,533,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

CONDUCT OF CLINICAL TRIALS

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

FDA REGULATION

Research and Development

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

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

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

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

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

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

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

The FDA is authorized to require various user fees including NDA fees (currently up to $896,200) and PMA application fees (currently ranging from $20,275 up to $281,600). The FDA is also authorized to require annual user fees for approved products and for companies with establishments at which finished products are manufactured, which fees may increase from year to year. The FDA may waive or reduce such user fees under special circumstances. We seek waivers or reductions of user fees where possible, but we cannot be assured that we will be eligible for any such waiver or reduction.

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Post-Approval Requirements

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

Inspections

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

Recalls

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

Other FDA Regulations

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

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

OTHER FEDERAL REGULATIONS

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

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.

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EMPLOYEES

As of December 31, 2006, we employed 29 full-time employees and also utilized the services of part-time consultants from time to time. None of our employees are covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

SEASONALITY

Customer purchasing patterns do not show significant predictable seasonal variation.

COMPETITION

Prolieve

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

ThermoDox

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

LICENSES, PATENTS AND TRADEMARKS

The Company owns three United States patents pertaining to the treatment of enlarged prostate or prostate cancer. These three patents are all being pursued internationally for patent right protection in a number of territories. Additionally, the Company has filed four other related patent applications in the U.S. and overseas. With regard to Liposome patents licensed from Duke University, the Company has filed two additional patents related to the formulation and use of liposomes. Further, in relation to the patents licensed from Duke, the Company has licensed from Valentis, CA certain global rights covering the use of pegylation for temperature sensitive liposomes

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

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

In 1999 the Company entered into a license agreement with Duke University under which the Company received exclusive rights (subject to certain exceptions) to commercialize and use Duke s thermo-liposome technology. In January 2003, Celsion purchased these rights from Duke in exchange for 253,691 shares of the Company s Common Stock with a value of $2,175,014, subject to any agreement to pay a royalty based upon future sales.

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The Company s rights under the license agreement with Duke University extend for the longer of 20 years or the end of any term for which any relevant patents are issued by the United States Patent and Trademark Office. Currently, the Company has rights to Duke s patent for its thermo-liposome technology in the United States, which expires in 2018, and to future patents received by Duke in Canada, Europe, Japan and Australia, where it has patent applications pending. The European application can result in coverage in the United Kingdom, France and Germany. For this technology, the Company s license rights are worldwide, with various patent rights covering the United States, Canada, the United Kingdom, France, Germany and Japan.

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

ITEM 1A. RISK FACTORS

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

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

Since Celsion s inception in 1982, our expenses have substantially exceeded our revenues, resulting in continuing losses and an accumulated deficit of $90,486,814 at December 31, 2006, including losses of $7,584,230 for the year then ended. Because we presently have only limited revenues from sales of our Prolieve system and related disposables and we are committed to continuing our product research, development and commercialization programs, we will continue to experience significant operating losses unless and until we complete the commercialization of Prolieve, as well as the development of other new products and these products have been clinically tested, approved by the FDA and successfully marketed.

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

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

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

We will need substantial additional funding in order to complete the development, testing and commercialization of our liver cancer and recurrent chest wall breast cancer treatment systems, as well as other potential new products. We expended approximately $9,345,400 on research and development activities in the 12-month period ended December 31, 2006. As of that date, we had approximately $9,032,700 in cash, cash equivalents and short term investments on hand to fund our operations. We have made a significant commitment to our heat-activated liposome research and development projects and it is our intention at least to maintain, or increase the pace and scope of these activities. The commitment to these new projects could require additional external funding, at least until we are able to generate sufficient cash flow from sale of one or more of our products to support our continued operations. We do not have any committed sources of financing and cannot offer any assurances that additional funding will be available in a timely manner, on acceptable terms or at all.

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

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

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

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

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

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

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

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

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

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

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

We currently have only 29 full-time employees. We rely, and expect to continue to rely, on third-party CROs to conduct all of our clinical trials. We have contracted with Theradex to conduct our Phase I liver cancer trial and with INC Research, Inc. to conduct our Prolieve post-market study. Because we do not conduct our own clinical trials, we must rely on the efforts of others and cannot always control or predict accurately the timing of such trials, the costs associated with such trials or the procedures that are followed for such trials. We do not anticipate significantly increasing our personnel in the foreseeable future and therefore, expect to continue to rely on third parties to conduct all of our future clinical trials. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they do not carry out the trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become prohibitively expensive, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

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

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

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

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

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

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

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

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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Furthermore, if we are permitted to commence commercial sales of any of our products, we will also be competing, with respect to manufacturing efficiency and marketing, with companies having substantially greater resources and experience in these areas.

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

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

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

As of December 31, 2006, we had exercisable warrants and options outstanding enabling the holders thereof to purchase a total of 1,346,089 shares of our Common Stock, including 670,898 shares issueable upon exercise of stock warrants. The exercise prices of these options and warrants range from $2.18 to $75.00 per share, with a weighted average exercise price of $11.96 per share.

We had additional unvested and unexercisable options outstanding to purchase a total of 196,688 shares of our Common Stock at exercise prices ranging from $2.18 to $22.50 per share. Some of the prices are below the current market price of our Common Stock, which has ranged from a low of $1.90 to a high of $2.31 over the 20 trading days ending December 31, 2006 and from a low of $3.58 to a high of $4.75 over the 20 trading days ending March 23, 2007.

If holders of our options and warrants choose to exercise such instruments at prices below the prevailing market price for our Common Stock, the resulting purchase of a substantial number of shares of our Common Stock would have a dilutive effect on our stockholders and could adversely affect the market price of our issued and outstanding Common Stock. 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 (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.

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On June 14, 2006 and subsequently and separately on September 6, 2006, Celsion received notice from the Amex that the Amex had determined that the Company was not in compliance with certain conditions of the continued listing standards of Section 1003 of the Amex Company Guide. Specifically, the Amex noted that the Company s shareholders equity continues to be less than $4,000,000 and losses from continuing operations and/or net losses were incurred in three of the last four fiscal years, and that shareholders equity was less than $6,000,000 and losses from continuing operations and/or net losses were incurred in each of the last five fiscal years. Additionally, the Company s shareholders equity was less than $2,000,000 and losses from continuing operations and/or net losses were incurred in two of its three most recent fiscal years.

Pursuant to the notice dated June 14, 2006, the Company was afforded the opportunity to submit a plan of compliance to the Amex and on July 14, 2006, it presented its plan to the Amex. On August 31, 2006, the Amex notified the Company that it had accepted the Company s plan of compliance and granted the Company an extension until December 14, 2007 to regain compliance with the continued listing standards. The Company will be subject to periodic review by the Amex staff during the extension period. Failure to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the extension period could result in the Company being delisted from the Amex.

If the Company were to be delisted from the Amex, the Common Stock would become subject to the penny stock rules of the SEC, which generally are applicable to equity securities with a price of less than $5.00 per share (other than securities registered on certain national securities exchanges or quoted on the Nasdaq system, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with bid and ask quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer s account. In addition, the penny stock rules require that, prior to a transaction in a penny stock that is not otherwise exempt from such rules; the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser s written agreement to the transaction. These disclosure requirements would be likely to have a material adverse effect on stock 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.

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

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

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 had a high price of $5.83 and a low price of $1.80 in the 52-week period ending December 31, 2006. 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. There can be no assurance that 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.

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

Our Certificate of Incorporation and Bylaws may discourage, delay or prevent a merger or acquisition that a stockholder may consider favorable by authorizing the issuance of blank check preferred stock. This preferred stock may be issued by the Board of Directors, on such terms as it determines, without further stockholder approval. Therefore, the Board may issue such preferred stock on terms unfavorable to a potential bidder in the event that is opposes a merger or acquisition. In addition, our classified Board of Directors may discourage such transactions by increasing the amount of time necessary to obtain majority representation on the Board. We also have implemented a stockholder rights plan and distributed rights to our stockholders. When these rights become exercisable, these rights entitle their holders to purchase one share of our Series C Junior Participating Preferred Stock at a price of $66.90 per one ten-thousandth of a share of Series C Preferred Stock. If any person or group acquires more than 15% of our Common Stock, the holders of rights (other than the person or group crossing the 15% threshold) will be able to purchase, in exchange for the $66.90 exercise price, $133.80 of our Common Stock or the stock of any company into which we are merged. Because these rights may substantially dilute stock ownership by a person or group seeking to take us over without the approval of our Board of Directors, our rights plan could make it more difficult for a person or group to take us over (or acquire significant ownership interest in us) without negotiating with our Board regarding such a transaction. Certain other provisions of our Bylaws and of Delaware law may also discourage, delay or prevent a third party from acquiring or merging with us, even if such action were beneficial to some, or even a majority, of our stockholders.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease premises consisting of approximately 13,891 square feet of administrative office, laboratory and workshop space at 10220-L Old Columbia Road, Columbia, Maryland 21046-2364 from an unaffiliated party under a seven-year lease that expires on October 31, 2010. Rent expense for the year ended December 31, 2006 was $283,870. Future minimum lease obligations are as follows: