

Celsion CORP
Form 10-K
March 27, 2009

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

FORM 10-K

(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2008

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 001-15911

CELSION CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE

(State or Other Jurisdiction of
Incorporation or Organization)

52-1256615

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

10220-L OLD COLUMBIA ROAD
COLUMBIA, MARYLAND
(Address of Principal Executive Offices)

21046-2364
(Zip Code)

(410) 290-5390

Registrant's telephone number, including area code

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

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Title of Class
COMMON STOCK, PAR VALUE \$.01 PER SHARE

Name of Each Exchange on Which Registered
THE NASDAQ STOCK MARKET, LLC

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) 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, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

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

As of March 19, 2009, 10,816,088 shares of the Registrant's Common Stock were issued and outstanding.

As of June 30, 2008, the aggregate market value of voting common stock held by non-affiliates of the Registrant was approximately \$39,799,040, based on the closing price for the Registrant's Common Stock on that date as quoted on The NASDAQ Stock Market.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement in connection with its 2009 Annual Meeting of Stockholders, which is scheduled to be held on May 15, 2009, 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 similar import regarding the Company's expectations. Forward-looking statements are only predictions. Actual events or results may differ materially. Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our industry, business and operations, we cannot guarantee that actual results will not differ materially from our expectations. In evaluating such forward-looking statements, you should specifically consider various factors, including the risks outlined under "Risk Factors." The discussion of risks and uncertainties set forth in this Annual Report on Form 10-K is not necessarily a complete or exhaustive list of all risks facing the Company at any particular point in time. We operate in a highly competitive, highly regulated and rapidly changing environment, and our business is in a state of evolution. Therefore, it is likely that new risks will emerge, and that the nature and elements of existing risks will change, over time. It is not possible for management to predict all such risk factors or changes therein, or to assess either the impact of all such risk factors on our business or the extent to which any individual risk factor, combination of factors, or new or altered factors may cause results to differ materially from those contained in any forward-looking statement. We disclaim any obligation to revise or update any forward-looking statement that may be made from time to time by us or on our behalf.

General

Celsion Corporation ("Celsion" or the "Company" or "we") is an innovative oncology drug development company focused on improving treatment for those suffering with highly aggressive and difficult to treat forms of cancer. We are working to develop and commercialize more efficient, effective and targeted chemotherapeutic oncology drugs based on our proprietary heat-activated liposomal technology. The promise of this drug technology is to maximize efficacy while minimizing side-effects common to cancer treatments.

Our lead product ThermoDox® is being evaluated in a Phase III clinical trial for primary liver cancer and a Phase II study for recurrent chest wall breast cancer. ThermoDox® is a liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. Localized mild hyperthermia (40-42 degrees Celsius) releases the entrapped

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doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

Celsion is also developing a product pipeline of cancer drugs that employ its heat activated liposomal technology. We are developing a liposomal formulation of docetaxel and plan to develop a number of other liposomal formulations for existing chemotherapeutic cancer drugs where we believe that our technology can improve efficacy and safety. We have formed a joint research agreement with Royal Phillips Electronics that is evaluating the combination of Phillips' high intensity focused ultrasound with Celsion's heat activated liposomal technology to develop new cancer drugs.

For certain indications, the Company may seek licensing partners to share in the development and commercialization costs. The Company will also evaluate licensing cancer products from third parties for cancer treatments to expand its development pipeline.

In December 2008, the Company entered into a licensing agreement with Yakult Honsha under which Yakult was granted the exclusive right to commercialize and market ThermoDox® for the Japanese market. Celsion was paid a \$2.5 million up-front licensing fee and Celsion has the potential to receive an additional \$18 million upon receipt of marketing approval by the Japanese Ministry of Health, Labor and Welfare. Celsion also has the potential to receive additional milestone payments tied to the achievement of certain levels of sales and approval for new indications. Celsion will receive double digit escalating royalties on the sale of ThermoDox® in Japan, when and if any such sales occur. Celsion also will be the exclusive supplier of ThermoDox® to Yakult.

In 2005, the Company made a strategic decision to divest its medical device business. The Company sold this business to Boston Scientific Corporation ("Boston Scientific") for \$60 million. In 2008, the Company collected a \$15 million installment payment from the sale of these assets and is due to receive the final \$15 million installment payment in June 2009. The results of operations for the medical device business for the year ended December 31, 2007 has been reclassified as a discontinued operation.

Celsion was founded in 1982 and is a Delaware corporation. 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 is 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 (the "SEC"). 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)

Liposomes are manufactured microscopic vesicles consisting of a discrete aqueous central compartment surrounded by a membrane bilayer composed of naturally occurring fats. Conventional liposomes have been designed and manufactured to carry drugs and increase residence time, thus allowing the drugs to remain in the bloodstream for extended periods of time before they are removed from the body. However, the current existing liposomal formulations of cancer drugs and liposomal cancer drugs under development do not provide for the immediate release of the drug and the direct targeting of organ specific tumors, two important characteristics that are required for improving the efficacy of cancer drugs such as doxorubicin. Through a perpetual, world-wide, exclusive development

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and commercialization license from Duke University, Celsion has licensed novel, heat activated liposomal technology that is differentiated from other liposomes through its unique low heat-activated release of encapsulated chemotherapeutic agents. A team of research scientists at Duke developed a heat-sensitive liposome which rapidly changes its structure when heated to a threshold minimum temperature of 40° to 42° C. Heating creates channels in the liposome bilayer that allow an encapsulated drug to rapidly disperse into the surrounding tissue.

Celsion intends to use various available focused-heat technologies, such as radio frequency ablation ("RFA"), microwave energy and high intensity focused ultrasound, to activate the release of drugs from its novel heat sensitive liposomes. The illustration below depicts a drug being released from a heat activated liposome.

As is illustrated in the pictures below, our heat activated liposomes circulate within the tumor tissue and leaky tumor vessels vasculature, and when heat is added locally, it causes the rapid release of cancer drugs directly within the targeted tumor.

This technology enables delivery of significantly higher concentrations of proven chemotherapy drugs directly to the tumor, stopping the progression of cancer and minimizing systemic toxicity. Celsion has completed animal studies that demonstrated intravenous administration of ThermoDox®, in combination with targeted heat to the tumor, can produce doxorubicin drug concentrations in tumor tissue that are much greater than existing approved liposomal formulations of doxorubicin on the market today.

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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. Worldwide, an estimated one million new cases of HCC are diagnosed each year, which ranks it as the fifth most commonly occurring solid tumor. HCC has the fastest rate of growth of all cancers and is projected to be the most prevalent form of cancer by 2020. HCC is commonly diagnosed in patients with longstanding hepatic disease and cirrhosis (primarily due to hepatitis C in the U.S. and Europe and hepatitis B in Asia).

Although the standard treatment for liver cancer is surgical excision of the tumor, up to 80% of patients are ineligible for surgery at the 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 5 centimeters in diameter, RFA is emerging as the standard of care treatment approach which directly destroys the tumor tissue through the application of high temperatures by a probe inserted into the core of the tumor. Local recurrence rates after RFA are directly correlated to the size of the tumor. For tumors 3 cm or smaller in diameter the recurrence rate has been reported to be 10 - 20%; however, for tumors greater than 3 cm, local recurrence rates of 40% or higher have been observed.

Celsion's Approach

While RFA uses extremely high temperatures (80° - 100° C.) to ablate the tumor, it may fail to treat micrometastases 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 three centimeters 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 doxorubicin at the desired tumor site while potentially reducing drug exposure distant to the tumor site.

Phase I Clinical Trial Primary Liver Cancer

In the second quarter of 2007, the Company completed the first Phase I single dose escalation clinical trial that investigated ThermoDox® in combination with RFA for the treatment of primary and metastatic liver cancer. The study was carried out at the National Cancer Institute ("NCI"), which is part of the National Institutes of Health ("NIH") and Queen Mary Hospital in Hong Kong.

In 2007, the Company initiated a second Phase I dose escalation study designed to investigate simplification of the current RFA/ThermoDox® treatment regimen including a single vial formulation of ThermoDox® and a reduction of the pre-treatment prophylactic dosing. The study also permitted multiple dosing in liver cancer patients. This clinical trial was completed in 2008.

Phase III Global Clinical Trial Primary Liver Cancer

We are conducting a ThermoDox® double-blinded, placebo-controlled, global Phase III clinical study with ThermoDox® in primary liver cancer study under a Special Protocol Assessment agreement with the FDA. The study is designed to evaluate the efficacy of ThermoDox® in combination with RFA when compared to patients who receive RFA alone as the control. The study is being conducted at approximately 40 clinical sites in North America, Italy, China, Taiwan, Hong Kong, and Korea and is

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planned to enroll a total of 600 patients. The primary endpoint for the study is progression free survival, and we expect to complete patient enrollment in this clinical trial by the end of the first quarter of 2010.

THERMODOX® FOR RECURRENT CHEST WALL BREAST CANCER

Recurrent Chest Wall Breast Cancer Overview

Breast cancer is the most common malignancy in women in both the United States and the world. Despite a variety of therapeutic approaches, up to 40% of the estimated 95,000 patients in the United States undergoing a mastectomy as their primary treatment will develop locally recurrent RCW breast cancer. There is currently no effective chemotherapeutic standard of care for RCW breast cancer and as a result, many of these patients will die within two years of the recurrence. Patients with RCW breast cancer suffer from disfiguring tumors and other symptoms including pain, foul-smelling wounds, and a very visual reminder of tumor progression.

Celsion's Approach

Since its inception, Celsion has been actively seeking a targeted localized treatment for breast cancer. ThermoDox® in conjunction with localized microwave hyperthermia is being developed to treat RCW breast cancer. 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's liposomal encapsulated doxorubicin is released by heat generated from an external microwave tissue hyperthermia device that is placed on a woman's chest. The microwave hyperthermia heats the target to a temperature adequate to activate ThermoDox® but not to ablate the tissue like RFA. Upon heating to 40° to 42° C, a significant concentration of doxorubicin is released directly to the tumor. As in the liver cancer program, the Company uses a commercially available thermotherapy device to heat the target tissue and activate ThermoDox® at the desired target site.

Microwave hyperthermia as a separate stand alone treatment has been found to have the ability to kill breast cancer cells. Because breast cancer cells have higher water content than surrounding normal cells, the tumor is heated to a greater extent than normal breast tissue and is selectively destroyed. Thus, just heating cancer cells with a microwave device for sixty minutes at 43°C has been found to be tumoricidal. Celsion expects that the combination of microwave hyperthermia and ThermoDox® will be more efficacious than microwave hyperthermia alone or treatment with existing non-heat activated liposomal formulations.

RCW Breast Cancer Clinical Phase I/II Clinical Trial

In February 2009, the Company commenced a pivotal open label, dose escalating ThermoDox® Phase I/Phase II clinical trial for patients with RCW breast cancer. The study will evaluate 100 patients at ten clinical sites in the United States, and the primary endpoint is durable complete local response, which means that the detectable chest wall tumors have disappeared for at least three months. The Company expects to complete enrollment by the middle of 2010.

Duke University is also conducting a Phase I dose escalating ThermoDox® study in patients with RCW breast cancer. Duke has presented preliminary results from the first twelve patients that demonstrate ThermoDox® had a beneficial clinical effect, even at lower than optimal dosages. The first eight patients all showed evidence of clinical activity and two out of six patients that were treated at the 30mg dosage had a complete local response.

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PRODUCT FEASIBILITY

The Company has developed a stable heat activated liposomal formulation of docetaxel. The Company has evaluated the liposomal docetaxel formulation in animal studies that demonstrated a statistically significant tumor inhibition effect when compared both to free Docetaxel and a non-heat sensitive formulation. The Company is continuing to evaluate its formulation and is seeking a licensing partner to assist in the funding of this product. In addition, the Company is evaluating in animal studies its heat activated liposomal technology in combination with a peptide ligand that has an affinity for EGF receptors to be able to provide targeted cancer treatments.

RESEARCH AND DEVELOPMENT

Celsion engages in a limited amount of research and development in its own facilities and also sponsors research programs in partnership with various research institutions, including the National Cancer Institute and Duke University. The majority of the spending in research and development is for the funding of ThermoDox® clinical trials. Our expenditures for research and development were approximately \$12 million and \$8.2 million for the years ended December 31, 2008 and 2007, respectively.

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 Food and Drug Administration (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 heat-activated liposomes will 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, 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 a New Drug Application ("NDA"); and (e) FDA approval of the application, including approval of all product labeling.

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

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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. Phase II studies may serve as the pivotal trials, providing the demonstration of safety and effectiveness required for approval. However, the FDA may require additional, post-market trials as a condition of approval. In the case of drugs and biological products, Phase II clinical trials generally are conducted in a target patient population to gather evidence about the pharmacokinetics, safety and biological or clinical efficacy of the drug for specific indications, to determine dosage tolerance and optimal dosage and to identify possible adverse effects and safety risks. When a drug or biological compound has shown evidence of efficacy and an acceptable safety profile in Phase II evaluations, Phase III clinical trials are undertaken to serve as the pivotal trials to demonstrate clinical efficacy and safety in an expanded patient population.

There can be no assurance that any of our clinical trials will be completed successfully within any specified time period or at all. Either the FDA or we may suspend clinical trials at any time, if the FDA, our Data Monitoring Committee, 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 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 \$1.18 million). The FDA may waive or reduce such user fees under special circumstances. We will 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.

Post-Approval Requirements

After receipt of necessary regulatory approvals for initial manufacturing and sale of our product candidates, our contract manufacturing facilities and products are subject to ongoing review and periodic inspection. Each U.S. drug 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 current Good Manufacturing Practices. In order to ensure full technical compliance with such practices, 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.

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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 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, instability of product or defects in labeling.

Other FDA Regulations

We are also subject to recordkeeping and reporting 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. 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.

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 \$10 million per incident, and if we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim out of our own limited resources.

EMPLOYEES

As of December 31, 2008, we employed 17 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.

COMPETITION

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 in human clinical development.

LICENSES, PATENTS AND TRADEMARKS

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.

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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 2003, Celsion's obligations under the license agreement with respect to the testing and regulatory milestones and other licensed technology performance deadlines were eliminated in exchange for a payment from Celsion in shares of its Common Stock. The license agreement continues to be subject to agreements to pay a royalty based upon future sales. In conjunction with the patent holder, the Company intends to file international applications for certain of the United States patents.

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 European Community. For this technology, the Company's license rights are worldwide, including the United States, Canada, the European Community, Australia, Hong Kong, 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 FROM CONTINUING OPERATIONS AND EXPECT TO CONTINUE SUCH LOSSES FOR THE FORESEEABLE FUTURE.

Since Celsion's inception, our expenses have substantially exceeded our revenues, resulting in continuing losses and an accumulated deficit of \$66.9 million at December 31, 2008. For the year ended December 31, 2008, we incurred a loss from continuing operations of \$11.8 million. Because we presently have no product revenues 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 development of ThermoDox® and 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.

We have devoted our resources to developing a new generation of products but will not be able to market these products until we have completed clinical testing and obtain all necessary governmental approvals. In addition, our 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 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 DO NOT COLLECT THE RECEIVABLES FROM BOSTON SCIENTIFIC CORPORATION, WE MAY NOT BE ABLE TO COMPLETE THE DEVELOPMENT, TESTING AND COMMERCIALIZATION OF OUR TREATMENT SYSTEMS.

As of December 31, 2008, we had approximately \$7.5 million in cash, cash equivalents, and short term investments. We also had \$15.0 million in receivables due to us from Boston Scientific in June 2009. Should Boston Scientific default on its obligations, we would 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. Other than the \$15.0 million due from Boston Scientific, we do not have any committed sources of financing and cannot offer any assurances that alternate funding will be available in a timely manner, on acceptable terms or at all.

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

WE RELY ON A SOLE SOURCE FOR THE MANUFACTURING OF THERMODOX®. THE FAILURE OF THIS MANUFACTURER TO PROPERLY PERFORM ITS OBLIGATIONS TO SUPPLY THERMODOX® COULD HALT OR DELAY OUR CLINICAL TRIALS.

We are dependent on a single contract manufacturer to produce ThermoDox® for clinical trials. This contract manufacturer is subject to ongoing periodic inspection by the FDA and corresponding foreign agencies to ensure strict compliance with current good manufacturing practices and other governmental regulations and standards. We have limited control over our contract manufacturer and its ability to maintain adequate quality control, quality assurance and qualified personnel. We are in the process of establishing a second source manufacturer as a back up facility; however, we will need to obtain FDA clearance prior to being able to utilize ThermoDox® manufactured by the second source in clinical trials. Failure by our sole source contract manufacturer to produce ThermoDox® batches that meet specifications or failure to comply with or maintain any of the required international quality standards could adversely affect our ability to complete clinical trials and obtain regulatory approval for ThermoDox® and would adversely impact 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.

We intend to market our 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.

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 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 Duke University license agreement contains a license fee, royalty and/or research support provisions, testing and regulatory milestones, and other performance requirements that we must meet by certain deadlines. If we were to breach these or other provisions of the license and research agreements, we could lose our ability to use the subject technology, as well as compensation for our efforts in developing or exploiting the technology. Any such loss of rights and access to technology could have a material adverse effect on our business.

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

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 17 full-time employees. We rely, and expect to continue to rely, on third-party Clinical Research Organizations to conduct all of our clinical trials. Because we do not conduct our own clinical trials, we must rely on the efforts of others and cannot always control or predict

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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.

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 recordkeeping and reporting 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. We must also comply with record keeping requirements as well as requirements to report certain adverse events involving our

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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.

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.

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

Our cancer treatment development projects using ThermoDox® plus RFA or microwave heating, are currently in 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.

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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 TECHNOLOGIES COULD RENDER OUR TECHNOLOGIES OBSOLETE.

Various methods for treating cancer currently are, and in the future are 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 for 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 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 current 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.

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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 \$10.0 million per incident and \$10.0 million annually. If we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim with our own limited resources, which could have a material adverse effect on our business. In addition, liability or alleged liability could harm the business by diverting the attention and resources of our management and by damaging our reputation.

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

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

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 \$6.68 and a low price of \$1.65 in the 52-week period ending December 31, 2008. 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 NASDAQ Stock Market, LLC (and previously on the American Stock Exchange), 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.

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 (the "Board"), 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 the Board opposes a merger or acquisition. In addition, our classified Board 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, 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.

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Not applicable.

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 21046-2391 from an unaffiliated party under a seven-year lease that expires on October 31, 2010. Rent expense for the year ended December 31, 2008 was \$0.2 million. Future minimum lease obligations are as follows:

For the year ending December 31:	(\$000s)
2009	212
2010	180
2011	
2012 and beyond	
	\$ 392

Celsion has adequate office and laboratory space for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

None.

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

None.

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On February 8, 2008, our Common Stock began to trade on The NASDAQ Stock Market. Previously, our Common Stock traded on the American Stock Exchange. The following table sets forth the high and low sales prices for our Common Stock reported by The American Stock Exchange and the NASDAQ Stock Market. The quotations set forth below do not include retail markups, markdowns or commissions.

	High	Low
YEAR ENDED DECEMBER 31, 2007		
First Quarter (January 1 - March 31, 2007)	\$5.40	\$1.93
Second Quarter (April 1 - June 30, 2007)	\$7.67	\$3.55
Third Quarter (July 1 - September 30, 2007)	\$6.68	\$5.10
Fourth Quarter (October 1 - December 31, 2007)	\$6.05	\$2.85
YEAR ENDED DECEMBER 31, 2008		
First Quarter (January 1 - March 31, 2008)	\$6.68	\$2.80
Second Quarter (April 1 - June 30, 2008)	\$6.00	\$3.38
Third Quarter (July 1 - September 30, 2008)	\$4.48	\$1.72
Fourth Quarter (October 1 - December 31, 2008)	\$3.40	\$1.65

On March 19, 2009, the last reported sale price for our Common Stock on The NASDAQ Stock Market was \$2.60. As of March 19, 2009, there were approximately 388 holders of record of our Common Stock.

DIVIDEND POLICY

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

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

See "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters - Equity Compensation Plan Information."

ISSUANCE OF SHARES WITHOUT REGISTRATION

On March 19, 2007, we issued 5,896 shares of Common Stock, valued at \$25,000, to Dr. Max Link as a retainer for his services as Chairman of the Board of Directors. Additionally, the Company issued a total of 11,000 shares of Common Stock in 2007 to a consultant as compensation for services. The total value of the shares was \$44,000. These shares are restricted stock, and the certificates representing such shares are endorsed with the Company's standard restricted stock legend, with a stop transfer instruction recorded by the transfer agent. Accordingly, Celsion views the shares issued as exempt from registration under Sections 4(2) and/or 4(6) of the Securities Act of 1933, as amended.

ISSUER PURCHASES OF EQUITY SECURITIES

None.

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ITEM 6. SELECTED FINANCIAL DATA

Not required.

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

Overview

Celsion is an innovative oncology drug development company focused on improving treatment for those suffering with highly aggressive and difficult to treat forms of cancer. We are working to develop and commercialize more efficient, effective, targeted chemotherapeutic oncology drugs based on our proprietary heat-activated liposomal technology. Our lead product ThermoDox® is being tested in human clinical trials for the treatment of primary liver cancer and recurrent chest wall breast cancer.

Significant events

In June 2007, the Company divested and sold its medical device business assets to Boston Scientific. The results from operations from the medical device business have been reclassified into discontinued operations for the years ended December 31, 2008 and 2007. The medical device assets were sold to Boston Scientific for an aggregate purchase price of \$60.0 million payable in three installments consisting of \$30.0 million at closing and \$15.0 million on each of the first and second anniversaries of the closing. The Company received \$15 million in cash from Boston Scientific in 2008 and the final \$15,000,000 installment is due to the Company in June 2009. In addition to the other indemnification provisions, such as indemnification for breaches of representations, warranties and covenants contained in the Asset Purchase Agreement, the Company agreed to indemnify Boston Scientific for a period of two years from the closing, in an amount up to \$15.0 million of incurred costs, in the event of unforeseen intellectual property claims related to the medical device assets. The \$30.0 million paid at closing was reduced by approximately \$17.0 million, representing the principal and accrued interest due on promissory notes previously issued by the Company to Boston Scientific, and certain royalty payments to American Medical Systems under the Settlement and License Agreement dated as of February 7, 2007.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

Stock-Based Compensation

Stock options are generally granted with an exercise price at market value at the date of the grant. The stock options generally expire 10 years from the date of grant. Stock option awards vest upon terms determined by the Board of Directors. Restricted stock awards have been granted with a vesting schedule.

The fair value of options, warrants and restricted stock granted is measured in accordance with SFAS 123(R) using the Black-Scholes option pricing model and recorded as an expense in the period in which such services are received. The fair values of stock options granted were estimated at the date of grant using the Black-Scholes option pricing model. The Black-Scholes model was originally developed

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for use in estimating the fair value of traded options, which have different characteristics from Celsion's nonqualified stock options. The model is also sensitive to changes in assumptions, which can materially affect the fair value estimate. The Company used the following assumptions for determining the fair value of options granted under the Black-Scholes option pricing model:

	Year Ended December 31, 2008	Year Ended December 31, 2007
Risk-free interest rate	1.76% to 3.54%	4.14% to 5.24%
Expected volatility	69% 71.33%	65% 282%
Expected life (in years)	5 6	5 6
Expected dividend yield	0.00%	0.00%

Expected volatilities utilized in the model are based on historical volatility of the Company's stock price. The risk free interest rate is derived from values assigned to U.S. Treasury strips as published in the Wall Street Journal in effect at the time of grant. The model incorporates exercise, pre-vesting and post-vesting forfeiture assumptions based on analysis of historical data. The expected life of the fiscal 2008 grants was generated using the simplified method as allowed under Securities and Exchange Commission Staff Accounting Bulletin No. 107.

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

Results of Operations

Comparison of the years ended December 31, 2008 and 2007.

Licensing Revenue

Licensing revenue increased to \$2.5 million in 2008 as a result of the up-front non-refundable licensing payment received from Yakult Honsha for the rights to commercial and market ThermoDox® in Japan.

Research and Development Expenses

Research and development expenses increased by \$3.8 million, from \$8.2 million in 2007 to \$12 million in 2008. The increase is attributable to clinical trial costs for the primary liver cancer clinical trial and drug manufacturing costs to supply product for the clinical trial.

General and Administrative Expenses

General and administrative expenses decreased by \$3.4 million, from 5.4 million in 2007 to \$2 million in 2008. The decreases are attributable to a \$1.6 million larger write off to the indemnity reserve and a decrease in salaries due to severance payments made in 2007.

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Interest income

Interest income decreased by \$.5 million from \$.7 million in 2007 to \$.2 million in 2008. The decrease is attributable to lower interest rates and having less cash available to invest.

Interest expense

Interest expense decreased by \$.5 million from \$.7 million in 2007 to \$.2 million in 2008. The decrease is attributable to having less debt outstanding in 2008 as compared to 2007.

Financial Condition, Liquidity and Capital Resources

Since inception, excluding the \$15 million payment from Boston Scientific received in 2008, we have incurred negative cash flows from operations. We have financed our operations primarily through the sales of equity and through the divestiture of the medical device business. Our expenses have significantly and regularly exceeded our revenues, and we have an accumulated deficit of \$66.9 million at December 31, 2008.

At December 31, 2008, we had total current assets of \$22.8 million (including cash and short term investments of \$7.5 million) and current liabilities of \$3.9 million, resulting in a working capital surplus of \$18.9 million. At December 31, 2007, we had total current assets of \$21.4 million (including cash and short term investments of \$5.9 million) and current liabilities of \$8.1 million, resulting in a working capital surplus of \$13.3 million.

Net cash provided by operating activities for the year ended December 31, 2008 was \$2.3 million. Exclusive of the \$15 million payment received from Boston Scientific the net cash used in operations was \$12.7 million. The \$12.7 million net cash requirement was funded from cash on hand at the beginning of the year and the \$15 million account payment collected from Boston Scientific. Net cash used in financing activities was \$.7 million for the year ended December 31, 2008 which represents the payments made on notes payable.

At December 31, 2008, the Company had cash, cash equivalents and short term investments of 7.5 million and \$15 million due from Boston Scientific in June 2009. The \$22.5 million of cash resources is expected to be adequate to fund operations at least through the middle of 2010. The Company will need substantial additional capital to complete its clinical trials, obtain marketing approvals and to commercialize the products.

Off-Balance Sheet Arrangements

None.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Required.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements, supplementary data and report of independent registered public accounting firm are filed as part of this report on pages F-2 through F-25.

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

None.

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ITEM 9A(T). CONTROLS AND PROCEDURES

We have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act) under the supervision, and with the participation, of our management, including our principal executive officer and principal financial officer. Based on that evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2008, which is the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures are effective.

There have been no changes in our internal controls over financial reporting in the fiscal quarter ended December 31, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management has issued its Report on Internal Control over Financial Reporting as of December 31, 2008, which appears in Item 15 of this Report.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS

The information required by this Item 10 is incorporated herein by reference to the definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated herein by reference to the definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by this Item 12 is incorporated herein by reference to the definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Table of Contents**Equity Compensation Plan Information as of December 31, 2008**

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,255,880(1)	\$ 4.38	1,380,743
Equity compensation plans not approved by security holders		(2)	(2)
Total	1,255,880	\$ 4.38	1,380,743

- (1) Includes both vested and unvested options to purchase Common Stock issued to employees, officers, and directors and outside consultants under the Company's 2001 Stock Option Plan, the 2004 Stock Incentive Plan, and the 2007 Stock Incentive Plan (the "Plans"). Certain of these options to purchase Common Stock were issued under the Plans in connection with employment agreements.
- (2) As discussed further in Note 12 to the Company's financial statements, the Company has warrants outstanding at December 31, 2008 enabling the holders thereof to purchase 96,789 shares of the Company's Common Stock at a weighted-average exercise price of \$18.28. Certain of the warrants have price protection or anti-dilution rights that entitle the holders to reduce the exercise price of such securities if the Company issues additional stock, options, warrants or other convertible securities below the exercise price of the subject securities.

Please also refer to Note 10 of the Company's financial statements for descriptions of the plans under which equity securities of the Company are authorized for issuance.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this Item 13 is incorporated herein by reference to the definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 is incorporated herein by reference to the definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Table of Contents**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES****1. FINANCIAL STATEMENTS**

The following is a list of the financial statements of Celsion Corporation filed with this Annual Report on Form 10-K, together with the report of our independent registered public accountants and Management's Report on Internal Control over Financial Reporting.

	Page
<u>REPORTS</u>	
<u>Management's Report on Internal Control over Financial Reporting</u>	<u>F-1</u>
<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>
<u>FINANCIAL STATEMENTS</u>	
<u>Balance Sheets</u>	<u>F-3</u>
<u>Statements of Operations</u>	<u>F-5</u>
<u>Statements of Cash Flows</u>	<u>F-6</u>
<u>Statements of Changes in Stockholders' Equity</u>	<u>F-8</u>
<u>NOTES TO FINANCIAL STATEMENTS</u>	<u>F-9</u>

2. FINANCIAL STATEMENT SCHEDULES

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

3. EXHIBITS

The following documents are included as exhibits to this report:

EXHIBIT NO. DESCRIPTION

- 3.1.1 Certificate of Incorporation of Celsion (the "Company"), as amended, incorporated herein by reference to Exhibit 3.1.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2004.
- 3.1.2 Certificate of Ownership and Merger of Celsion Corporation (a Maryland Corporation) into Celsion (Delaware) Corporation (inter alia, changing the Company's name to "Celsion Corporation" from "Celsion (Delaware) Corporation), incorporated herein by reference to Exhibit 3.1.3 to the Annual Report on Form 10-K of the Company for the year ended September 30, 2000.
- 3.1.3 Certificate of Designations of Series C Junior Participating Preferred Stock of Celsion Corporation, incorporated herein by reference to Exhibit 4.4 to the Form S-3 Registration Statement (File No. 333-100638), filed October 18, 2002.
- 3.1.4 Certificate of Amendment of the Certificate of Incorporation effective and filed on February 27, 2006, incorporated therein by reference to Exhibit 3.3 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2006.
- 3.2 By-laws of the Company, as amended, incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company, filed December 14, 2007.
- 4.1 Form of Common Stock Certificate, par value \$0.01, incorporated herein by reference to Exhibit 4.1 to the Annual Report on Form 10-K of the Company for the year ended September 30, 2001.

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EXHIBIT NO. DESCRIPTION

- 4.2.1 Celsion Corporation and American Stock Transfer & Trust Company Rights Agreement dated as of August 15, 2002, incorporated herein by reference to Exhibit 99.1 to the Current Report on Form 8-K of the Company, filed August 21, 2002.
- 4.2.2 Amendment adopted January 16, 2003 to Rights Agreement between Celsion Corporation and American Stock Transfer & Trust Company, incorporated herein by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2004.
- 10.1.1 Celsion Corporation 2004 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2004.
- 10.1.2 Celsion Corporation 2007 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed June 15, 2007.
- 10.1.3 Form of Restricted Stock Agreement for Celsion Corporation 2004 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2006.
- 10.1.4 Form of Stock Option Agreement for Celsion Corporation 2004 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2006.
- 10.1.5 Form of Restricted Stock Agreement for Celsion Corporation 2007 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1.5 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2007.
- 10.1.6 Form of Stock Option Agreement for Celsion Corporation 2007 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1.6 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2007.
- 10.2.1 Stock Option Grant Agreement effective July 29, 2005 between Celsion Corporation and Lawrence S. Olanoff, incorporated herein by reference to Exhibit 99.1 to the Current Report on Form 8-K of the Company, filed July 29, 2005.
- 10.2.2 Letter dated March 16, 2006 from the Company to Lawrence S. Olanoff (awarding restricted stock pursuant to the Company's 2004 Stock Option Plan), incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed March 22, 2006.
- 10.2.3 Letter dated March 16, 2006 from the Company to Anthony P. Deasey (awarding restricted stock pursuant to the Company's 2004 Stock Option Plan) incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of the Company, filed March 22, 2006.
- 10.2.4 Letter dated March 16, 2006 from the Company to Carolyn Finkle (awarding restricted stock pursuant to the Company's 2004 Stock Option Plan) incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K of the Company, filed March 22, 2006.
- 10.2.5 Letter dated March 16, 2006 from the Company to Michael Oleck (awarding

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restricted stock pursuant to the Company's 2004 Stock Option Plan) incorporated herein by reference to Exhibit 10.4 to the Current Report on Form 8-K of the Company, filed March 22, 2006.

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EXHIBIT NO. DESCRIPTION

- 10.2.6 Restricted Stock Agreement dated October 3, 2006, incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K of the Company, filed October 10, 2006.
- 10.2.7 Stock Option Grant Agreement dated October 3, 2006, incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of the Company, filed October 10, 2006.
- 10.2.8 Stock Option Agreement effective January 3, 2007 between Celsion Corporation and Michael H. Tardugno, incorporated herein by reference Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed January 3, 2007.
- 10.3.1 Form of Series 600 Warrant issued to Certain Employees and Directors on May 16, 1996 to Purchase Common Stock of the Company, incorporated herein by reference to Exhibit 10.17 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1998.
- 10.3.2 Form of Series 500 Warrant to Purchase Common Stock of the Company pursuant to the Private Placement Memorandum dated January 6, 1997, as amended, incorporated herein by reference to Exhibit 10.15 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1998.
- 10.3.3 Form of Series 300 Warrant issued to Nace Resources, Inc. to purchase Common Stock of the Company, incorporated herein by reference to Exhibit 10.13 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1998.
- 10.3.4 Form of Series 250 Warrant issued to Dunn Hughes Holding, Inc. to Purchase Common Stock of the Company, incorporated herein by reference to Exhibit 10.12 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1998.
- 10.3.5 Form of Series 200 Warrant issued to certain employees, directors and consultants to Purchase Common Stock of the Company, incorporated herein by reference to Exhibit 10.11 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1998.
- 10.3.6 Form of Warrant to Purchase Common Stock of the Company pursuant to the Private Placement Memorandum dated October 11, 2001, incorporated herein by reference to Exhibit 10.23 to the Annual Report on Form 10-K of the Company for the year ended September 30, 2001.
- 10.3.7 Form of Warrant to Purchase Common Stock Units of the Company issued to Placement Agents pursuant to the Private Placement Memorandum dated October 18, 2001, incorporated herein by reference to Exhibit 4.4 to the Registration Statement on Form S-3 of the Company (File No. 333-82450), filed February 8, 2002.
- 10.3.8 Form of Warrant to Purchase Common Stock of the Company pursuant to a private placement by the Company which closed on June 3, 2002, incorporated herein by reference to Exhibit 4.6 to the Registration Statement on Form S-3 of the Company (File No. 333-100638), filed October 18, 2002.

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EXHIBIT NO. DESCRIPTION

- 10.3.9 Form of Warrant to Purchase Common Stock issued to the Placement Agents pursuant to the Private Placement Memorandum of the Company dated May 30, 2003, as supplemented, incorporated herein by reference to Exhibit 4.3 to the Registration Statement of the Company (File No. 333-108318) filed August 28, 2003.
- 10.4.1 Employment Agreement effective January 1, 2004, between the Company and Anthony P. Deasey, incorporated herein by reference to Exhibit 99.2 to the Current Report on Form 8-K of the Company, filed December 8, 2004.
- 10.4.2 Advisory Agreement between the Company and Dr. Kris Venkat dated August 1, 2001, incorporated herein by reference to Exhibit 10.24 to the Annual Report on Form 10-K of the Company for the year ended September 30, 2001.
- 10.4.3 Separation Agreement and General Release effective January 16, 2006, by and between Celsion Corporation and Dr. Augustine Y. Cheung, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K of the Company, filed January 18, 2006.
- 10.4.4 Stock Purchase Agreement made January 16, 2006, by and among Dr. Augustine Y. Cheung, the Company, and Celsion (Canada) Limited, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed January 18, 2006.
- 10.4.5 Consulting Agreement effective January 16, 2006, by and between Celsion Corporation and Dr. Augustine Y. Cheung, incorporated herein by reference to Exhibit 10.4 to the Current Report on Form 8-K of the Company, filed January 18, 2006.
- 10.4.6.1 Transition Services Agreement effective January 16, 2006, by and between the Company and Celsion (Canada) Limited, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K of the Company, filed January 18, 2006.
- 10.4.6.2 First amendment to Transition Services Agreement entered into as of March 28, 2006, by and between Celsion Corporation and Celsion (Canada) Limited, incorporated herein by reference to Exhibit 10.24 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2006.
- 10.4.7 Employment Agreement, effective January 3, 2007, between Celsion Corporation and Mr. Michael H. Tardugno, incorporated herein by reference to Exhibit 99.1 to the Current Report on Form 8-K of the Company, filed December 21, 2006.
- 10.4.8 Separation Agreement and General release effective September 24, 2007, by and between the Company and Anthony P. Deasey, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed September 27, 2007.
- 10.4.9 Employment Offer Letter, dated November 21, 2008, between the Company and Sean F. Moran, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed November 26, 2008.
- 10.4.10 Employment Agreement, effective March 1, 2009, between the Company and Michael H. Tardugno, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed February 19, 2009.

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EXHIBIT NO. DESCRIPTION

- 10.5 Patent License Agreement between the Company and Duke University dated November 10, 1999, incorporated herein by reference to Exhibit 10.9 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1999 (Confidential Treatment Requested).
- 10.6 Letter Agreement with Goldpac Investment Partners dated October 17, 2001, incorporated herein by reference to Exhibit 4.5 to the Form S-3 Registration Statement (File No. 333-82450), filed February 8, 2002.
- 10.7 Letter dated May 8, 2002, from Legg Mason Wood Walker, Incorporated ("Legg Mason") to the Company regarding retention of Legg Mason as financial advisor, incorporated herein by reference to Exhibit 10.30 to the Annual Report on Form 10-K of the Company for the year ended September 30, 2002.
- 10.8 License Agreement dated July 18, 2003, between the Company and Duke University (Confidential treatment requested.), incorporated herein by reference to Exhibit 10.1 to the Registration Statement of the Company (File No. 333-108318), filed August 28, 2003.
- 10.9 Distribution Agreement effective as of January 20, 2003, by and between Celsion Corporation and Boston Scientific Corporation, incorporated herein by reference to Exhibit 99.2 the Current Report on Form 8-K filed January 22, 2003.
- 10.10.1 Transaction Agreement effective as of January 20, 2003, by and between Celsion Corporation and Boston Scientific Corporation, incorporated herein by reference to Exhibit 99.1 to the Current Report on Form 8-K, filed January 22, 2003. (Confidential treatment requested.)
- 10.10.2 First Amendment to Transaction Agreement effective as of August 8, 2005, between Celsion Corporation and Boston Scientific Corporation, incorporated herein by reference to Exhibit 99.1 to the Current Report on Form 8-K, filed August 9, 2005.
- 10.11.1 Convertible Secured Promissory Note dated as of August 8, 2005, between Celsion Corporation and Boston Scientific Corporation, incorporated herein by reference to Exhibit 99.2 to the Current Report on Form 8-K of the Company, filed August 9, 2005.
- 10.11.2 Convertible Secured Promissory Note dated July 28, 2006, between Celsion Corporation and Boston Scientific Corporation incorporated herein by reference to Exhibit 99.2 to the Current Report on Form 8-K of the Company, filed August 6, 2006.
- 10.12 Settlement and License Agreement dated February 7, 2007, by and among Celsion Corporation, American Medical Systems and AMS Research Corporation, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2007.
- 10.13 Loan and Security Agreement, dated as of November 9, 2007, by and between Celsion Corporation and Manufacturers and Traders Trust, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on November 14, 2007.

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EXHIBIT NO. DESCRIPTION

- 10.14 Stock Purchase Agreement, dated December 7, 2007, by and between Celsion Corporation and Boston Scientific Corporation, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed December 13, 2007.
- 10.15+ Development, Product Supply and Commercialization Agreement, executed on December 9, 2008, by and between the Company and Yakult Honsha Co., Ltd., filed herewith. (Confidential treatment requested.)
- 14.1 Code of Ethics and Business Conduct, incorporated herein by reference to Exhibit 14.1 to the Annual Report on Form 10-K of the Company for the Year Ended September 30, 2003.
- 23.1+ Consent of Stegman & Company, independent registered public accounting firm for the Company.
- 31.1+ Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2+ Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1^ Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2^ Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
-

+ Filed herewith.

^ Furnished herewith.

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SIGNATURES

Pursuant to the requirement of Section 13 or 159(d) of the Securities Exchange Act of 1934, the Registrant has duly caused its annual report on Form 10-K to be signed on its behalf by the undersigned thereunto duly authorized.

CELSION CORPORATION

March 27, 2009

By: /s/ MICHAEL H. TARDUGNO

 Michael H. Tardugno
President and Chief Executive Officer

March 27, 2009

By: /s/ SEAN MORAN

 Sean Moran
Senior Vice President & Chief Financial Officer

Pursuant to the requirement of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

NAME	TITLE	DATE
<u>/s/ MICHAEL H. TARDUGNO</u> Michael H. Tardugno	President and Chief Executive Officer (Principal Executive Officer)	March 27, 2009
<u>/s/ SEAN MORAN</u> Sean Moran	Senior Vice President & Chief Financial Officer	March 27, 2009
<u>/s/ MAX E. LINK</u> Max E. Link	Chairman of the Board	March 27, 2009
<u>/s/ GARY W. PACE</u> Gary W. Pace	Director	March 27, 2009
<u>/s/ GREGORY WEAVER</u> Gregory Weaver	Director	March 27, 2009
<u>/s/ AUGUSTINE CHOW</u> Augustine Chow	Director	March 27, 2009

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MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The management of Celsion Corporation is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America (GAAP). The Company's internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and disposition of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP and that receipts and expenditures of the Company are being made only in accordance with authorization of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

This annual report on Form 10-K does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting because management's report was not subject to attestation pursuant to temporary rules of the SEC that permit the Company to provide only this management's report.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate. A control system, no matter how well designed and operated can provide only reasonable, but not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their cost.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2008. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (the "COSO Framework".) Based on its evaluation, management has concluded that the Company's internal control over financial reporting is effective.

Date: March 27, 2009

/s/ MICHAEL H. TARDUGNO

/s/ SEAN MORAN

Michael H. Tardugno
Chief Executive Officer

Sean Moran
Senior Vice President and Chief Financial Officer

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Celsion Corporation

We have audited the accompanying balance sheets of Celsion Corporation as of December 31, 2008 and 2007, and the related statements of operations, changes in stockholders' equity, and cash flows for each of the years in the two year period ended December 31, 2008. Celsion Corporation's management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Celsion Corporation as of December 31, 2008 and 2007, and the results of its operations and its cash flows for each of the years in the two year period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America.

/s/ Stegman & Company

Baltimore, Maryland
March 25, 2009

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CELSION CORPORATION
BALANCE SHEETS
DECEMBER 31, 2008 AND 2007

	December 31,	
	2008	2007
ASSETS		
Current assets		
Cash and cash equivalents	\$ 200,651	\$ 2,937,373
Short term investments available for sale, at fair value	7,316,894	3,000,000
Accounts receivable trade		183,043
Other receivables	38,327	47,110
Due from Boston Scientific Corporation	15,000,000	15,000,000
Prepaid expenses	267,561	256,874
Total current assets	22,823,433	21,424,400
Property and equipment at cost		
Furniture and office equipment	198,434	194,200
Computer hardware and software	318,122	338,349
Laboratory and shop equipment	345,558	305,340
Leasehold improvements	132,148	132,148
	994,262	970,037
Less: Accumulated depreciation	771,624	702,156
Property and equipment net		