

Celsion CORP
Form 10-K
March 27, 2009

Use these links to rapidly review the document

[CELSION CORPORATION FORM 10-K TABLE OF CONTENTS](#)
[ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES](#)

[Table of Contents](#)

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:

Edgar Filing: Celsion CORP - Form 10-K

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.

Table of Contents**CELSION CORPORATION****FORM 10-K****TABLE OF CONTENTS**

<u>PART I</u>	<u>1</u>
<u>ITEM 1. BUSINESS</u>	<u>1</u>
<u>FORWARD-LOOKING STATEMENTS</u>	<u>1</u>
<u>General</u>	<u>1</u>
<u>THERMODOX® (DOXORUBICIN ENCAPSULATED IN HEAT-ACTIVATED LIPOSOME)</u>	<u>2</u>
<u>Liver Cancer Overview</u>	<u>4</u>
<u>Celsion's Approach</u>	<u>4</u>
<u>Phase I Clinical Trial Primary Liver Cancer</u>	<u>4</u>
<u>Phase III Clinical Trial Primary Liver Cancer</u>	<u>4</u>
<u>THERMODOX® FOR RECURRENT CHEST WALL BREAST CANCER</u>	<u>5</u>
<u>Recurrent Chest Wall Breast Cancer Overview</u>	<u>5</u>
<u>Celsion's Approach</u>	<u>5</u>
<u>RCW Breast Cancer Clinical Phase I/II Trial</u>	<u>5</u>
<u>PRODUCT FEASIBILITY</u>	<u>6</u>
<u>RESEARCH AND DEVELOPMENT</u>	<u>6</u>
<u>FDA REGULATION</u>	<u>6</u>
<u>Research and Development</u>	<u>6</u>
<u>Post Approval Requirements</u>	<u>7</u>
<u>Inspections</u>	<u>8</u>
<u>Recalls</u>	<u>8</u>
<u>Other FDA Regulations</u>	<u>8</u>
<u>PRODUCT LIABILITY AND INSURANCE</u>	<u>8</u>
<u>EMPLOYEES</u>	<u>8</u>
<u>COMPETITION</u>	<u>8</u>
<u>LICENCES, PATENTS AND TRADEMARKS</u>	<u>8</u>
<u>ITEM 1A. RISK FACTORS</u>	<u>9</u>
<u>ITEM 1B. UNRESOLVED STAFF COMMENTS</u>	<u>16</u>
<u>ITEM 2. PROPERTIES</u>	<u>16</u>
<u>ITEM 3. LEGAL PROCEEDINGS</u>	<u>16</u>
<u>ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	<u>16</u>
<u>PART II</u>	<u>17</u>
<u>ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	<u>17</u>
<u>MARKET PRICE FOR OUR COMMON STOCK</u>	<u>17</u>
<u>DIVIDEND POLICY</u>	<u>17</u>
<u>SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS</u>	<u>17</u>
<u>ISSUANCE OF SHARES WITHOUT REGISTRATION</u>	<u>17</u>
<u>ISSUER PURCHASES OF EQUITY SECURITIES</u>	<u>17</u>
<u>ITEM 6. SELECTED FINANCIAL DATA</u>	<u>18</u>
<u>ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	<u>18</u>
<u>Overview</u>	<u>18</u>
<u>Significant Events</u>	<u>18</u>
<u>CRITICAL ACCOUNTING POLICIES AND ESTIMATES</u>	<u>18</u>
<u>Results of Operations</u>	<u>19</u>
<u>COMPARISON OF FISCAL YEAR ENDED DECEMBER 31, 2008 AND FISCAL YEAR ENDED DECEMBER 31, 2007</u>	<u>19</u>
<u>Financial Condition, Liquidity and Capital Resources</u>	<u>20</u>

Table of Contents

<u>ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	<u>20</u>
<u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	<u>20</u>
<u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	<u>20</u>
<u>ITEM 9A. CONTROLS AND PROCEDURES</u>	<u>21</u>
<u>ITEM 9B. OTHER INFORMATION</u>	<u>21</u>
<u>PART III</u>	<u>21</u>
<u>ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS</u>	<u>21</u>
<u>ITEM 11. EXECUTIVE COMPENSATION</u>	<u>21</u>
<u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	<u>21</u>
<u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS</u>	<u>22</u>
<u>ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	<u>22</u>
<u>ITEM 15. EXHIBITS and FINANCIAL STATEMENT SCHEDULES</u>	<u>23</u>
<u>1 FINANCIAL STATEMENTS</u>	<u>23</u>
<u>2 FINANCIAL STATEMENT SCHEDULES</u>	<u>23</u>
<u>3 EXHIBITS</u>	<u>23</u>

Table of Contents

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

Table of Contents

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

Table of Contents

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.

Table of Contents

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

ITEM 1B. UNRESOLVED STAFF COMMENTS

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.

Table of Contents**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****MARKET PRICE FOR OUR COMMON STOCK**

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.

Table of Contents

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Edgar Filing: Celsion CORP - Form 10-K

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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

F-1

Table of Contents

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

Table of Contents

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	222,638	267,881
Other assets		
Advances under Celsion (Canada), Ltd.		
Transition Services Agreement (net of allowance of \$649,891 and \$442,225, respectively)		200,000
Note receivable (net of allowance and discount of \$1,128,820 and \$168,473, respectively)	221,179	1,181,527
Due from Boston Scientific Corporation Non Current		15,000,000
Deposits and other assets	362,651	899,268
Patent licensing fees (net of accumulated amortization of \$15,000 and \$7,500, respectively)	58,125	65,625
Total other assets	641,955	17,346,420
Total assets	\$23,688,026	\$39,038,701

Table of Contents

CELSION CORPORATION
BALANCE SHEETS (Continued)
DECEMBER 31, 2008 AND 2007

	December 31,	
	2008	2007
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable trade	\$ 1,186,511	\$ 1,830,457
Indemnity reserve	1,053,357	3,485,072
Other accrued liabilities	1,459,391	1,571,308
Income taxes payable		546,000
Accrued non-cash compensation		8,910
Note payable current portion	234,735	676,859
Total current liabilities	3,933,994	8,118,606
Long-term liabilities		
Note payable		234,742
Other liabilities	27,643	34,238
Total long-term liabilities	27,643	268,980
Total liabilities	3,961,637	8,387,586
Stockholders' equity		
Common stock \$0.01 par value (250,000,000 shares authorized; 10,816,088 and 10,783,922 shares outstanding at December 31, 2008 and December 31, 2007, respectively.)	108,161	107,839
Additional paid-in capital	89,183,549	88,319,985
Accumulated deficit	(66,923,972)	(55,137,757)
	22,367,738	33,290,067
Less: Treasury stock at cost	(2,641,349)	(2,638,952)
Total stockholders' equity	19,726,389	30,651,115
Total liabilities and stockholders' equity	\$ 23,688,026	\$ 39,038,701

See accompanying notes.

CELSION CORPORATION
STATEMENTS OF OPERATIONS

FOR THE YEARS ENDED DECEMBER 31, 2008 AND 2007

	Years Ended December 31,	
	2008	2007
Licensing revenue	\$ 2,500,000	\$
Operating expenses:		
Research and development	12,006,218	8,230,888
General and administrative	2,043,193	5,354,504
Total operating expenses	14,049,411	13,585,392
Loss from operations	(11,549,411)	(13,585,392)
Other income (expense):		
Other (expense) / income, net	(316,899)	(457,370)
Interest income	221,707	668,846
Interest expense	(141,612)	(694,709)
Total other income (expense)	(236,804)	(483,233)
Loss from continuing operations before income taxes	(11,786,215)	(14,068,625)
Income taxes		
Loss from continuing operations	(11,786,215)	(14,068,625)
Discontinued Operations (Note 13)		
Income from discontinued operations (including gain on sale of \$48,029,445 in 2007)		50,236,777
Income tax expense		(819,095)
Income from discontinued operations		49,417,682
Net income / (loss)	\$ (11,786,215)	\$ 35,349,057
Net loss from continuing operations per common share basic	\$ (1.16)	\$ (1.31)
Net loss from continuing operations per common share diluted	\$ (1.16)	\$ (1.31)
Net income from discontinued operations per common share basic	\$	\$ 4.60
Net income from discontinued operations per common share diluted	\$	\$ 4.29
Net income / (loss) per common share basic	\$ (1.16)	\$ 3.29
Net income / (loss) per common share diluted	\$ (1.16)	\$ 3.07
Weighted average shares outstanding basic	10,148,958	10,732,478
Weighted average shares outstanding diluted	10,148,958	11,514,032

See accompanying notes.

CELSION CORPORATION
STATEMENTS OF CASH FLOWS

YEARS ENDED DECEMBER 31, 2008 AND 2007

	Year Ended December 31,	
	2008	2007
Cash flows from operating activities		
Net (loss)/income for the year	\$(11,786,215)	\$ 35,349,057
Non-cash items included in net income/loss:		
Depreciation and amortization	69,468	169,129
Accretion of discount on note receivable		(99,921)
Gain on sale of medical device business		(48,029,445)
Amortization of indemnity reserve	(2,431,715)	
Stock based compensation Options	750,822	999,883
Stock based compensation Restricted Stock	110,667	70,678
Amortization of deferred license fee	7,500	(269,840)
Shares issued in exchange for services		68,555
Amortization of patent license		61,606
Loss from disposal of property and equipment		15,145
Allowance for bad debt Celsion Canada	1,160,348	442,225
Net changes in:		
Accounts receivable-trade	183,043	1,699,330
Other receivables	8,783	(25,435)
Due from Boston Scientific	15,000,000	
Inventories		5,792
Prepaid expenses	(10,687)	173,620
Escrow account-license fee		1,824,740
Deposits and other assets	536,617	(245,337)
Accounts payable trade and accrued interest	(643,946)	358,539
Income taxes payable	(546,000)	546,000
Other accrued liabilities	(127,422)	(2,697,106)
Net cash provided by/ (used in) operating activities	2,281,263	(9,582,785)
Cash flows from investing activities		
Purchases of short term investments, available for sale	(6,369,394)	(5,000,000)
Sale of short-term investments, available for sale	2,052,500	10,000,000
Proceeds from sale of medical device business assets		9,958,615
Advances under Celsion Canada transition services agreement		(55,403)
Loss on investment in Celsion China, Ltd.		
Payment of licensing fee		(1,600,000)
Proceeds from sale of property and equipment		100
Purchase of property and equipment	(24,225)	(91,195)
Net cash (used in)/ provided by investing activities	(4,341,119)	13,212,117
Cash flows from financing activities		
Proceeds from note payable		1,181,925
Payments on note payable	(676,866)	(270,324)
Proceeds from loan payable		
Exercise of common stock options		2,718
Purchase of treasury stock		(2,638,952)
Net cash used in financing activities	(676,866)	(1,724,633)
Net (decrease)/ increase in cash and cash equivalents	(2,736,722)	1,904,699
Cash and cash equivalents at beginning of period	2,937,373	1,032,674

Edgar Filing: Celsion CORP - Form 10-K

Cash and cash equivalents at end of period \$ 200,651 \$ 2,937,373

Cash paid for:

Interest	\$ 141,612	\$ 31,022
Income taxes	\$ 546,000	\$ 273,095

See accompanying notes.

F-6

Table of Contents

CELSION CORPORATION
STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2007
Schedule of non-cash investing and financing activities:	
Sales price of Prolieve assets	\$ 60,000,000
Repayment of principal and interest on loan from Boston Scientific Corporation	(16,941,385)
Amounts due from Boston Scientific Corporation	(30,000,000)
Payment of licensing fee	(3,100,000)
 Net cash received from sale of the Prolieve assets	 \$ 9,958,615

See accompanying notes.

F-7

Table of Contents

CELSION CORPORATION
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY/(DEFICIT)
YEARS ENDED DECEMBER 31, 2008 AND 2007

	Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
	Shares	Amount				
Balance at January 1, 2007	10,739,208	\$ 107,392	\$ 87,178,598	\$	\$ (90,486,814)	\$ (3,200,824)
Stock-based compensation expense related to employee stock options			999,883			999,883
Shares issued in exchange for services	16,896	169	68,386			68,555
Stock based compensation restricted stock			70,678			70,678
Issuance of restricted stock upon vesting	26,044	260	(260)			
Exercise of common stock warrants and options	1,774	18	2,700			2,718
Treasury stock acquired(1)				(2,638,952)		(2,638,952)
Net income					35,349,057	35,349,057
Balance at December 31, 2007	10,783,922	107,839	88,319,985	(2,638,952)	(55,137,757)	30,651,115
Stock-based compensation expense related to employee stock options			750,822			750,822
Shares issued in exchange for services	2,500	25	(25)			
Stock based compensation restricted stock			110,667			110,667
Issuance of restricted stock upon vesting	29,666	297	(297)			
Treasury stock acquired(1)			2,397	(2,397)		
Net loss					(11,786,215)	(11,786,215)
Balance at December 31, 2008	10,816,088	\$ 108,161	\$ 89,183,549	\$ (2,641,349)	\$ (66,923,972)	\$ 19,726,389

- (1) On December 7, 2007, the Company repurchased 659,738 shares of its Common Stock that was held by Boston Scientific Corporation. The purchase price was \$4.00 per share.

See accompanying notes.

Table of Contents

CELSION CORPORATION
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2008 AND 2007

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Celsion Corporation, referred to herein as "Celsion", "We", or "the Company," a Delaware corporation based in Columbia, Maryland, 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.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles and include the accounts of the Company.

Revenue Recognition

For 2008, we recognized as revenue a non-refundable \$2.5 licensing payment from Yakult since there were no future performance obligations associated with this payment.

Prior to 2008, when the Company operated a medical device business, revenue was recognized on medical device control units as they were sold to ultimate customers by Boston Scientific. Medical device control units shipped to Boston Scientific but not yet sold to ultimate customers were reflected in finished goods inventory. Revenue on the sale of catheter kits was recognized upon shipment to Boston Scientific. All of Company's revenues from the medical device business are included in Discontinued Operations, for the year ended December 31, 2007. As more fully described in Note 13 to the financial statements, the Company sold the assets of the medical device business to Boston Scientific on June 21, 2007.

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand and investments purchased with an original maturity of three months or less. A portion of these funds are not covered by FDIC insurance.

Fair Value of Financial Instruments

The carrying values of financial instruments approximate their respective fair values.

Short Term Investments

The Company classifies its investments in marketable securities with readily determinable fair values as investments available-for-sale in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, "Accounting for Certain Investments in Debt and Equity Securities". Available-for-sale securities consist of debt and equity securities not classified as trading securities or as securities to be held to maturity. The Company has classified all of its investments as available-for-sale. Unrealized holding gains and losses on available-for-sale securities are reported as a net amount in accumulated

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

other comprehensive gain or loss in stockholders' equity until realized. Gains and losses on the sale of available-for-sale securities are determined using the specific identification method.

The Company's short term investments consist of corporate bonds and government agency bonds.

Accounts Receivable Trade

Accounts receivable trade consist of amounts due to Celsion from Boston Scientific for the sale of medical device control units and catheter kits and amounts due for services. The assets of the medical device business were sold to Boston Scientific on June 21, 2007 see Note 13 for discontinued operations.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation. Depreciation is provided over the estimated useful lives of the related assets, ranging from three to seven years, using the straight-line method. Major renewals and improvements are capitalized at cost and ordinary repairs and maintenance are charged against operations as incurred. Depreciation expense was \$69,000 and \$169,000 for years ended December 31, 2008 and 2007, respectively.

The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An asset is considered impaired if its carrying amount exceeds the future net undiscounted cash flows that the asset is expected to generate. If such asset is considered to be impaired, the impairment recognized is the amount by which the carrying amount of the asset, if any, exceeds its fair value determined using a discounted cash flow model.

Deposits

Deposits include real property security deposits and other deposits which are contractually required and of a long-term nature.

Patent Licenses

The Company has purchased several licenses for rights to patented technologies. Patent license costs for \$73,125 have been capitalized and are amortized on a straight-line basis over the estimated life of the related patent. For the five year period ending December 31, 2008 the total accumulated amortization expense is \$15,000. The weighed-average amortization period for these assets is 10 years.

Indemnity Reserve

When the Company sold the medical device business in 2007, an indemnity reserve was established to cover the potential costs of the indemnity guarantee made to Boston Scientific as part of the sale of the business. The Company evaluates the likelihood of a potential claim under the indemnity guarantee and has been amortizing the indemnity reserve. The Company will continue to evaluate the indemnity reserve on a quarterly basis and reduce it as the risk of the indemnity decreases. As of December 31, 2008 and 2007, the indemnity reserve was \$1,053,000 and \$3,485,000, respectively. For the year ended

Table of Contents**CELSION CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)****YEARS ENDED DECEMBER 31, 2008 AND 2007****1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

December 31, 2008, the Company recorded a non-cash benefit of \$2,432,000 as a result of writing down the value of the indemnity reserve.

Comprehensive Income

SFAS No. 130, *Reporting Comprehensive Income*, establishes standards for the reporting and display of comprehensive income and its components in the Company's consolidated financial statements. The objective of SFAS No. 130 is to report a measure (comprehensive income (loss)) of all changes in equity of an enterprise that result from transactions and other economic events in a period other than transactions with owners. The Company had an unrealized gain of \$379 for the year ended December 31, 2008 and no unrealized gains or losses on short-term investments available-for-sale for the year ended December 31, 2007.

Research and Development

Research and development costs are expensed as incurred. Equipment and facilities acquired for research and development activities that have alternative future uses are capitalized and charged to expense over their estimated useful lives.

Net Income/(Loss) Per Common Share

Basic and diluted net income/(loss) per common share was computed by dividing net income/(loss) for the year by the weighted average number of shares of Common Stock outstanding, both basic and diluted, during each period. The impact of Common Stock equivalents has been excluded from the computation of diluted weighted average common shares outstanding in periods where there is a net loss, as their effect is anti-dilutive.

Income/(loss) per common share have been computed using the following:

	Years Ended December 31,	
	2008	2007
Weighted average common shares outstanding	10,148,958	10,732,478
Dilutive effect of outstanding options and warrants		781,554
Weighted average common shares outstanding diluted	10,148,958	11,514,032

Since the Company incurred a loss from continuing operations for 2008, the outstanding options for 1,255,880 shares and the warrants outstanding to purchase 96,789 shares were considered anti-dilutive and therefore were not included in the calculation of diluted shares.

Nonmonetary Transactions

Nonmonetary transactions are accounted for in accordance with Accounting Principles Board (APB) Opinion No. 29, Accounting for Nonmonetary Transactions, which provides that the transfer or distribution of a nonmonetary asset or liability generally is based on the fair value of the asset or liability that is received or surrendered, whichever is more clearly evident.

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Income Taxes

Income taxes are accounted for under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax asset and liabilities of a change in tax rates is recognized in results of operations in the period that the tax rate change occurs. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

The Company adopted the Financial Accounting Standards Board ("FASB") issued Interpretation 48 "Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109" ("Interpretation 48") as of January 1, 2007. Interpretation 48 states that a tax position is recognized as a benefit only if it is "more likely than not" that the tax position taken would be sustained in a tax examination, presuming that a tax examination will occur. The adoption of Interpretation 48 had no effect on the Company's financial statements.

The Company recognizes interest and/or penalties related to income tax matters in the income tax expense category.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Stock-Based Compensation

Stock options are generally granted with an exercise price at market value at the date of 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 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.

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

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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.

As more fully described in Note 10, the Company has three stock option plans that provide for non-qualified and incentive stock options to be issued to directors, officers, employees and consultants: the 2007 Employee Stock Incentive Plan ("the 2007 Plan"), the 2004 Employee Stock Incentive Plan (the "2004 Plan") and the 2001 Stock Option Plan (the "2001 Plan").

Significant New Accounting Pronouncements

Recent Accounting Pronouncements issued but not yet effective

In June 2008, the FASB ratified Emerging Issue Task Force ("EITF") Issue No. 07-5, "*Determining Whether an Instrument (or an Embedded Feature) is Indexed to an Entity's Own Stock*" (EITF 07-5). This issue provides guidance for determining whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock. EITF 07-5 applies to any freestanding financial instrument or embedded feature that has all the characteristics of a derivative under paragraphs 6-9 of Statement of Financial Accounting Standards No. 133, "*Accounting for Derivative Instruments and Hedging Activities*," (SFAS 133) for purposes of determining whether that instrument or embedded feature qualifies for the first part of the scope exception under paragraph 11(a) of SFAS 133. EITF 07-5 also applies to any freestanding financial instrument that is potentially settled in an entity's own stock, regardless of whether the instrument has all the characteristics of a derivative under paragraphs 6-9 of SFAS 133, for purposes of determining whether the instrument is within the scope of EITF Issue 00-19, "*Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*," (Issue 00-19) which provides accounting guidance for instruments that are indexed to, and potentially settled in, the issuer's own stock. EITF 07-5 is effective for fiscal years beginning after December 15, 2008. Early application is not permitted by entities that have previously adopted an alternative accounting policy. We are currently evaluating the requirements of EITF 07-5, but do not expect our adoption of this issue to have a material impact on our financial statements.

In May 2008, the FASB issued FASB Staff Position No. APB 14-1, "*Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)*" ("FSP APB 14-1"). Under the new rules for convertible debt instruments that may be settled entirely or partially in cash upon conversion, an entity should separately account for the liability and equity components of the instrument in a manner that reflects the issuer's economic interest cost. Previous guidance provided for accounting of this type of convertible debt instruments entirely as debt. For instruments subject to the scope of FSP APB 14-1, higher interest expense may result through the accretion of the discounted carrying value of the convertible debt instruments to their face amount over their term. FSP APB 14-1 will be effective for fiscal years beginning after December 15, 2008, and for interim periods within those fiscal years, with retrospective application required. Early adoption is not permitted. As of December 31, 2008, we do not have any instruments outstanding that would be subject to FSP APB 14-1, but any instruments that we may issue in the future will be subject to this pronouncement.

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

In December 2007, the FASB issued FASB Statement No. 141 (Revised 2007) ("SFAS 141R"), *Business Combinations*. SFAS 141R will significantly change the accounting for business combinations. Under SFAS 141R, an acquiring entity will be required to recognize all the assets acquired and liabilities assumed in a transaction at the acquisition date at fair value with limited exceptions. SFAS 141R will change the accounting treatment for certain specific items, including: acquisition costs will be generally expensed as incurred, minority interests will be valued at fair value at the acquisition date, acquired contingent liabilities will be recorded at fair value at the acquisition date and subsequently measured at either the higher of such amount or the amount determined under existing guidance for non-acquired contingencies, in-process research and development will be recorded at fair value as an indefinite-lived intangible asset at the acquisition date, restructuring costs associated with a business combination will be generally expensed subsequent to the acquisition date, and changes in deferred tax asset valuation allowances and income tax uncertainties after the acquisition date generally will affect income tax expense. SFAS 141R also includes a substantial number of new disclosure requirements. SFAS 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Earlier adoption is prohibited. We are required to record and disclose business combinations following existing GAAP until January 1, 2009.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"). SFAS 157 establishes a common definition for fair value to be applied to GAAP guidance requiring use of fair value, establishes a framework for measuring fair value, and expands disclosure about such fair value measurements. SFAS 157 applies to fair value measurements that are already required or permitted by other accounting standards, except for measurements of share-based payments and measurements that are similar to, but not intended to be, fair value. The FASB has previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. SFAS 157 was effective for fiscal years beginning after November 15, 2007. The effective date of SFAS 157 with regard to non-financial assets and liabilities is January 1, 2009. Our adoption of SFAS 157 with respect to financial assets and liabilities as of January 1, 2008 did not have a material impact on our financial statements.

Recent Accounting Pronouncements issued and adopted

In December 2007, the Financial Accounting Standards Board ratified Emerging Issue Task Force Issue No. 07-1 ("EITF 07-1"), *Accounting for Collaborative Arrangements*. The key elements of EITF 07-1 relate to: (a) the scope of the issue; (b) the income statement presentation of transactions with third parties; (c) the income statement presentation of payments between parties to the collaborative arrangement; (d) the disclosures about collaborative arrangements that should be required in the financial statements of the parties to the collaborative arrangements; and (e) the transition method. A contractual arrangement falls within the scope of EITF 07-1 if the arrangement requires the parties to be active participants and the arrangement exposes the parties to significant risks and rewards that are tied to the commercial success of the endeavor. Costs incurred and revenue generated on sales to third parties should be reported in the statement of operations based on the guidance in EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. The equity method of accounting should not be applied to a collaborative arrangement within the scope of this

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

issue without the creation of a separate legal entity for the arrangement. Payments between parties to the collaborative arrangement should be presented in the statement of operations based on the nature of the arrangement and each entity's business operations, the contractual terms of the arrangement as well as if existing GAAP is applicable. EITF 07-1 requires companies to disclose the nature and purpose of the arrangement, its rights and obligations under the arrangement, the accounting policy applied to the arrangement, and the amounts attributable to transactions between other participants to the collaborative arrangement and where in the statement of operations these amounts have been classified. EITF 07-1 requires that companies comply in its first fiscal year beginning after December 15, 2008 and transition to the guidance in this issue by retrospectively applying the guidance to all periods presented for all arrangements existing at the effective date, unless it is impracticable to do so. The impracticability assessment should be made on an arrangement-by-arrangement basis and certain disclosures would be required if a company utilized the impracticability exception. Our adoption of the provisions of EITF 07-1, did not have a material impact on our financial statements.

In June 2007, the FASB ratified Emerging Issue Task Force Issue No. 07-3 ("EITF 07-3"), *Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, which requires nonrefundable advance payments for goods and services that will be used or rendered for future research and development activities to be deferred and capitalized. These amounts will be recognized as an expense in the period that the related goods are delivered or the related services are performed or when an entity does not expect the goods to be delivered or services to be rendered. EITF 07-3 is effective for the fiscal years beginning after December 31, 2007, including interim periods within those fiscal years. Our adoption of the provisions of EITF 07-3, beginning January 1, 2008 did not have a material impact on our financial statements.

In February 2007, the FASB issued SFAS No. 159 *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* ("SFAS 159"), which became effective for fiscal periods beginning after November 15, 2007. Under SFAS 159, companies may elect to measure specified financial assets and liabilities at fair value that are not otherwise measured at fair value, with changes in fair value recognized in earnings each subsequent reporting period. This election, called the "fair value option," will enable some companies to reduce volatility in reported earnings caused by measuring related assets and liabilities differently. SFAS 159 also establishes presentation and disclosure requirements designed to draw a comparison between the different measurement attributes a company elects for similar types of assets and liabilities. We did not elect the "fair value option" for any financial assets or liabilities and, therefore, the adoption of SFAS 159 did not have an impact on our financial statements.

2. SHORT TERM INVESTMENTS AVAILABLE FOR SALE

Short term investments available for sale of \$7,316,894 as of December 31, 2008 and \$3,000,000 as of December 31, 2007 consist of money market funds, commercial paper, corporate debt securities, and government agency debt securities. They are valued at estimated fair value, with unrealized gains and losses reported as a separate component of stockholders' equity in Accumulated Other Comprehensive Loss.

Securities available for sale are evaluated periodically to determine whether a decline in their value is other than temporary. The term "other than temporary" is not intended to indicate a permanent

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

2. SHORT TERM INVESTMENTS AVAILABLE FOR SALE (Continued)

decline in value. Rather, it means that the prospects for near term recovery of value are not necessarily favorable, or that there is a lack of evidence to support fair values equal to, or greater than, the carrying value of the security. Management reviews criteria such as the magnitude and duration of the decline, as well as the reasons for the decline, to predict whether the loss in value is other than temporary. Once a decline in value is determined to be other than temporary, the value of the security is reduced and a corresponding charge to earnings is recognized.

Short term investments at fair value	December 31 2008	December 31, 2007
Money market funds and commercial paper	\$ 3,255,574	\$ 3,000,000
Bonds government agencies	1,400,101	
Bonds corporate issuances	2,661,219	
Total short-term investments, available for sale	\$ 7,316,894	\$ 3,000,000

3. FAIR VALUES OF FINANCIAL INSTRUMENTS

FASB Statement No. 157 establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1: Quoted prices (unadjusted) or identical assets or liabilities in active markets that the entity has the ability to access as of the measurement date.

Level 2: Significant other observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

Level 3: Significant unobservable inputs that reflect a reporting entity's own assumptions that market participants would use in pricing an asset or liability.

The fair values of securities available for sale are determined by obtaining quoted prices on nationally recognized exchanges (Level 1 inputs) or matrix pricing, which is a mathematical technique widely used in the industry to value debt securities without relying exclusively on quoted prices for the specific securities but rather by relying on the securities' relationship to other benchmark quoted securities (Level 2 inputs). Assets measured at fair value on a recurring basis are summarized below:

	Total Short-term Investments	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Short term investments available for sale at December 31, 2008	\$ 7,316,894	\$ 7,316,894	\$	\$
Short term investments available for sale at December 31, 2007	3,000,000	3,000,000		

F-16

Table of Contents

CELSION CORPORATION
NOTES TO FINANCIAL STATEMENTS (Continued)
YEARS ENDED DECEMBER 31, 2008 AND 2007

3. FAIR VALUES OF FINANCIAL INSTRUMENTS (Continued)

A summary of the cost of fair value of the Company's short term investments is as follows:

	2008		2007	
	Cost	Fair Value	Cost	Fair Value
Cash equivalents:				
Money market funds	3,255,574	3,255,574	3,000,000	3,000,000
Short term investments:				
Corporate notes and bonds	2,661,219	2,661,219		
U.S government agencies	1,400,101	1,400,101		
	4,061,320	4,061,320		
Total investments available for sale	7,316,894	7,316,894	3,000,000	3,000,000
Maturities				
Within 3 months	6,218,552	6,218,552	3,000,000	3,000,000
Between 3-12 months	1,098,342	1,098,342		
Between 1-2 years				
Total investmens available for sale	7,316,894	7,316,894	3,000,000	3,000,000

4. NOTE RECEIVABLE

On January 16, 2006, Celsion contributed to its wholly-owned subsidiary, Celsion (Canada) Limited ("Canada"), all of the Company's assets relating to its Adaptive Phased Array ("APA") technology for the treatment of breast cancer. Also on that date, the Company entered into a Stock Purchase Agreement with the Company's founder and former officer and director, Dr. Augustine Y. Cheung, whereby the Company sold to Dr. Cheung all of the issued and outstanding shares of capital stock of Canada. The Company also agreed to provide certain services to Canada pursuant to a Transition Services Agreement between the Company and Canada.

Under the Stock Purchase Agreement, all of the capital stock of Canada was transferred to Dr. Cheung in exchange for a promissory note made by Dr. Cheung in favor of the Company in the principal amount of \$1,500,000 to be paid over a period of up to 78 months and secured by a pledge of 100,536 shares of Celsion common stock owned by Dr. Cheung and his wife and the commitment of Canada to pay a 5% royalty on the net sales of certain products sold by, and patent royalties received by, Canada and its successors and assigns, of up to \$18,500,000.

The terms of the note receivable only specify an interest charge in the event that scheduled payments are in arrears. The \$1,500,000 note was therefore discounted at the prime rate in effect January 16, 2006 (7.25%) plus 1.0%, or 8.25%, and the balance, net of discount, of \$1,146,428 was recorded in the financial statements above. Interest income based on this receivable of \$21,319 and \$81,847 was recorded for the twelve- months ended December 31, 2008 and 2007, respectively.

The Company evaluated the likelihood that the receivable would be fully collected and as a result, an allowance was placed against the note to reduce the balance to the estimated net realizable value of the collateral underlying the note. As noted above, 100,536 shares of Celsion common stock are

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

4. NOTE RECEIVABLE (Continued)

pledged as collateral to the note. The closing price of Celsion's common stock on December 31, 2008 was \$2.20, which results in a total collateral value of \$221,179. Therefore, the carrying value of the note was reduced to \$221,179 as of December 31, 2008.

5. ADVANCES UNDER CELSION (CANADA), LIMITED TRANSITION SERVICES AGREEMENT

In conjunction with the sale of Canada, a Transition Services Agreement was entered into whereby (i) Celsion sublet space in the Company's offices for use by Canada to carry on its business, for a period of up to six (6) months from the date of the agreement; (ii) Celsion provided administrative support services as needed in the operation of Canada's business for the period of the sublease; and (iii) Celsion advanced funds to pay salary and health and dental insurance of each of certain employees of Canada and the expenses reasonably incurred in connection with the operation of Canada's business up to \$100,000 for the shorter of the period ending June 30, 2006 or the date of closing by Canada of a transaction involving the merger of Canada into a newly created Canadian Capital Pool Company and a simultaneous funding through a private placement of shares under terms approved by the Toronto Stock Exchange (the "Canada Transaction"). Within ten days after the closing of the Canada Transaction, Canada is obligated to pay the Company all amounts due under the Transition Services Agreement.

The Transition Services Agreement was amended on March 28, 2006 to advance Canada an additional \$200,000 to fund reasonable operating expenses. This additional advance is repayable under the same terms as the Transition Services Agreement. The cumulative balance advanced under the Transition Services Agreement, as amended, at December 31, 2008 was \$649,891.

When the Canada Transaction did not close by December 31, 2006, Celsion management established, based on discussions with Canada management, that diligent efforts were being made by Canada management to close the Canada Transaction on a timely basis and agreed to extend the due date for repayment of the loan to the earlier of the closing of the Canada Transaction or June 30, 2007. Canada did not close the transaction nor had it paid the amounts due as of the June 30, 2007 due date. Accordingly, during the quarter ended June 30, 2007, the Company placed an allowance against this receivable and recorded the estimated net realizable value of the receivable as \$200,000, which was guaranteed by Canada's majority holder. Given the collectability concern of this note receivable, the Company has increased its allowance to \$649,891 as of December 31, 2008 and recorded the estimated net realizable value of the receivable as zero.

6. NOTE PAYABLE

On July 23, 2007, the Company entered into a Premium Finance Agreement with Flatiron Capital Corporation ("Flatiron") whereby Flatiron funded certain insurance premiums in the amount of \$1,313,250 on behalf of the Company. Monthly payments are \$59,418 and interest accrues at a rate of 5.98% on outstanding balances. At December 31, 2008 and 2007, the balance outstanding was \$234,735 and \$911,601, respectively. The full \$234,735 due at December 31, 2008 will be repaid in 2009.

[Table of Contents](#)**CELSION CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)****YEARS ENDED DECEMBER 31, 2008 AND 2007****7. INCOME TAXES**

A reconciliation of the Company's statutory tax rate to the effective rate for the years ended December 31, 2008 and 2007 is as follows:

	2008	2007
Federal statutory rate	34.0%	34.0%
State taxes, net of federal tax benefit	4.6	4.6
Valuation allowance	(38.6)	(38.6)
	0.0%	0.0%

As of December 31, 2008, the Company had net operating loss carry forwards of approximately \$49.2 million for federal income tax purposes that are available to offset future taxable income through the year 2027.

Approximate Amount Of Unused Operating Loss Carryforwards (\$000s)	Expiration During Year Ended
\$ 5,002	12/31/2022
2,292	12/31/2023
15,655	12/31/2024
8,174	12/31/2025
7,367	12/31/2026
<u>10,716</u>	12/31/2028
<u>\$49,206</u>	

The components of the Company's deferred tax asset as of December 31, 2008 and 2007 are as follows:

	As of December 31,	
	2008	2007
	(\$000s)	(\$000s)
Net operating loss carry forwards	\$ 19,004	\$ 16,118
Compensation expense related to employee stock options	413	353
	19,417	30,448
Valuation allowance	(19,417)	(30,448)
Total deferred tax asset	\$	\$

The evaluation of the realizability of such deferred tax assets in future periods is made based upon a variety of factors that affect the Company's ability to generate future taxable income, such as intent and ability to sell assets and historical and projected operating performance. At this time, the Company has established a valuation reserve for all of its deferred tax assets. Such tax assets are available to be recognized and benefit future periods.

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

7. INCOME TAXES (Continued)

The income tax expense of \$0.8 million recorded on the year ended December 31, 2007 represents the alternative minimum tax that are due as a result of the gain on the sale of the medical device assets.

8. CELSION EMPLOYEE BENEFIT PLANS

Celsion maintains a defined-contribution plan under Section 401(k) of the Internal Revenue Code. The plan covers substantially all employees over the age of 21. Participating employees may defer a portion of their pretax earnings, up to the Internal Revenue Service annual contribution limit. Commencing in the fourth quarter for 2008, the Company began making a matching contribution up to a maximum of 3% of an employee's annual salary and the Company's total contribution for 2008 was \$14,180. For 2007 no employer contribution was made.

9. LICENSING AGREEMENTS

In December 2008, the Company entered into a licensing agreement with Yakult Honsha ("Yakult") 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, non refundable licensing fee which was recorded as licensing revenue in the fourth quarter of 2008. Celsion has the potential to receive an additional \$18 million upon receipt of marketing approval by the Japanese Ministry of Health, Labor and Welfare and has the potential to receive additional milestone payments tied to the achievement of certain levels of sales and approval for new indications. If marketing approval is obtained in Japan, Celsion will receive double digit escalating royalties on the sale ThermoDox® in Japan. Celsion also will be the exclusive supplier of ThermoDox® to Yakult.

On November 10, 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. The license agreement contains annual royalty and minimum payment provisions and also requires milestone-based royalty payments measured by various events, including product development stages, FDA applications and approvals, foreign marketing approvals and achievement of significant sales. However, in lieu of such milestone-based cash payments, Duke agreed to accept shares of the Company's Common Stock to be issued in installments at the time each milestone payment is due, with each installment of shares to be calculated at the average closing price of the Common Stock during the 20 trading days prior to issuance. The total number of shares issuable to Duke under these provisions is subject to adjustment in certain cases, and Duke has piggyback registration rights for public offerings taking place more than one year after the effective date of the license agreement. On January 31, 2003, the Company issued 253,691 shares of Common Stock to Duke University valued at \$2.2 million as payment under this licensing agreement.

With regard to Liposome patents licensed from Duke University, the Company has filed two additional patents related to the formulation and use of liposomes. Further, in relation to the patents licensed from Duke, the Company has licensed from Valentis, CA certain global rights covering the use of pegylation for temperature sensitive liposomes.

The Duke license agreement contains a license fee, royalty and/or research support provisions, testing and regulatory milestones, and other performance requirements that the Company must meet by

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

9. LICENSING AGREEMENTS (Continued)

certain deadlines with respect to the use of the licensed technologies. In conjunction with the patent holders, the Company intends to file international applications for certain of the United States patents. For the years ended December 31, 2008 and 2007 the Company did not incur any expense under this agreement but upon commercialization will be obligated to make royalty payments until the Duke patents expire.

The Company's rights under our license agreement with Duke University extend for the longer of 20 years or the 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 expire in 2018, and to future patents received by Duke in Canada, Europe, Japan and Australia, where it has patent applications pending. The European application can result in coverage in the United Kingdom, France and Germany. For this technology, license rights are worldwide, with various patent rights covering the United States, Canada, the United Kingdom, France, Germany and Japan.

10. STOCKHOLDERS' EQUITY

Treasury Stock

On December 7, 2007, the Company purchased 659,738 shares of its Common Stock that was held by Boston Scientific Corporation. The purchase price was \$2.64 million, which is \$4.00 per share. The Treasury Stock was accounted for under the cost method and is shown as a reduction of stockholders' equity.

Employee Stock Options

The Company has long-term compensation plans that permit the granting of incentive awards in the form of stock options. Generally, the terms of these plans require that the exercise price of the options may not be less than the fair market value of Celsion's Common Stock on the date the options are granted. Options generally vest over various time frames or upon milestone accomplishments. Some vest immediately. Others vest over a period between one and five years. The options generally expire ten years from the date of the grant.

2001 Stock Option Plan

In 2001, the Board of Directors adopted a stock plan for directors, officers and employees (the "2001 Plan") under which 666,667 shares were reserved for future issuance. The purpose of the 2001 Plan was to promote long-term growth and profitability of Celsion by providing key people with incentives to improve stockholder value and contribute to the growth and financial success of Celsion, and to enable the company to attract, retain and reward the best available persons for positions of substantial responsibility.

2004 Stock Incentive Plan

In 2004, the Board of Directors adopted a stock plan for directors, officers and employees (the "2004 Plan") under which 666,667 shares were reserved for future issuance. The plan provides for stock instruments to be issued enabling the holder thereof to acquire Common stock of the Company at

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

10. STOCKHOLDERS' EQUITY (Continued)

prices determined by the Company's Board of Directors. The purpose of the 2004 Plan was to promote the long-term growth and financial success of the Company and enable the Company to attract, retain and reward the best available persons for positions of substantial responsibility. The 2004 Plan permitted the granting of awards in the form of incentive stock options, restricted stock, restricted stock units, stock appreciation rights, phantom stock, and performance awards, or in any combination of the foregoing. The 2004 Plan terminates in 2014, 10 years from the date of the Plan's adoption by the Company's stockholders.

During the year ended December 31, 2008 and 2007, options to purchase 265,844 and 88,379 shares became available under the 2004 Plan and were rolled into the 2007 Stock Incentive Plan. The 2001 Plan permitted the granting of stock options (including nonqualified stock options and incentive stock options qualifying under Section 422 of the Code) and stock appreciation rights or any combination of the foregoing. During the year ended December 31, 2008 and 2007, options for 395,283 and 195,043 shares, respectively became available under the 2001 Plan and were rolled into the 2007 Stock Incentive Plan.

2007 Stock Incentive Plan

On June 13, 2007, the Company adopted the Celsion Corporation 2007 Stock Incentive Plan (the "2007 Plan") under which there were 1,000,000 shares available for issuance. The purpose of the 2007 Plan is to promote the long-term growth and profitability of the Company by providing incentives to improve stockholder value and enable the Company to attract, retain and reward the best available persons for positions of substantial responsibility. The 2007 Plan permits the granting of awards in the form of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights, phantom stock, and performance awards, or in any combination of the foregoing. During the year ended December 31, 2008, 465,500 options were issued. 2007 Plan. During 2008, a total of 47,333 options were canceled or expired under the 2007 Plan.

On December 31, 2008, for all stock options plans there were a total of 2,763,334 shares reserved and there were a total of 1,380,743 shares available for future issuance.

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

Incentive stock options may be granted to purchase shares of Common Stock at a price not less than 100% of the fair market value of the underlying shares on the date of grant, provided that the exercise price of any incentive option granted to an eligible employee owning more than 10% of the outstanding stock must be at least 110% of the such fair market value on the date of grant. Only officers and key employees may receive incentive stock options; all other qualified participants may receive non-qualified stock options.

Option awards vest upon terms determined by the Board of Directors. Restricted stock awards, performance stock awards and stock options are subject to accelerated vesting in the event of a change of control. The Company issues new shares to satisfy its obligations from the exercise of options.

Table of Contents

CELSION CORPORATION
NOTES TO FINANCIAL STATEMENTS (Continued)
YEARS ENDED DECEMBER 31, 2008 AND 2007

10. STOCKHOLDERS' EQUITY (Continued)Options Issued to Consultants for Services

The Company periodically issues options to consultants in exchange for services provided. The fair value of options 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. Generally, the terms of these plans require that the exercise price of such options may not be less than the fair market value of the Company's Common Stock on the date the options are granted. Consultant options generally vest over various time frames or upon milestone accomplishments. Some vest immediately upon issuance. The options generally expire 10 years from the date of grant. During the year ended December 31, 2007, options to purchase 10,000 shares at a strike price of \$5.84 were issued pursuant to a consulting agreement. There were no options issued to consultants in the years ended December 31, 2008 and 2007.

Warrants

Celsion has warrants outstanding at December 31, 2008 enabling the holders thereof to purchase up to 96,789 shares of the Company's Common Stock at a weighted average exercise price of \$18.28. The warrants were issued in exchange for consulting and financing services provided in prior years, including prior private placements of equity securities. There was no compensation or other expense recorded for the years ended December 31, 2008 or 2007 related to warrants outstanding.

The following is a summary of stock option and warrant activity for the two years ended December 31, 2008:

Stock Options	Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2007	858,527	\$ 8.58		
Granted	817,500	3.52		
Exercised	(666)	4.08		
Canceled or expired	(176,520)	5.76		
Outstanding at December 31, 2007	1,498,841	6.17		
Granted	465,500	4.80		
Exercised				
Canceled or expired	(708,461)	8.43		
Outstanding at December 31, 2008	1,255,880	4.38	8.3	1,243,512
Exercisable at December 31, 2008	396,315	\$ 5.34	7.2	\$2,743,369

Table of Contents

CELSION CORPORATION
NOTES TO FINANCIAL STATEMENTS (Continued)
YEARS ENDED DECEMBER 31, 2008 AND 2007

10. STOCKHOLDERS' EQUITY (Continued)

A summary of stock options outstanding at December 31, 2008 by price range is as follows:

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
\$2.0 to \$3.00	550,500	8.43	\$ 2.55	107,500	8.01	\$ 2.42
\$3.01 to \$5.00	212,031	7.97	\$ 4.18	158,465	7.88	\$ 4.20
\$5.01 to \$7.00	445,305	8.54	\$ 5.73	82,639	6.1	\$ 6.34
\$7.01 to \$10.00	23,835	4.41	\$ 8.28	23,502	4.35	\$ 8.29
\$10.01 to \$30.00	24,000	4.76	\$ 18.23	24,000	4.76	\$ 18.22
\$150.75 to \$150.75	208	5.44	\$ 150.75	208	5.44	\$ 150.75
	1,255,880	8.25	\$ 4.38	396,315	7.15	\$ 5.34

A summary of warrants outstanding as of December 31, 2008 is as follows:

Warrants	Warrants Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2007	702,401	\$ 14.83		
Granted				
Exercised	(1,108)	3.75		
Canceled or expired	(134,500)	8.50		
Outstanding December 31, 2007	566,793	15.61		
Exercised				
Canceled or expired	(470,004)	15.04		
Outstanding December 31, 2008	96,789	\$ 18.28	0.3	1,556,347
Exercisable at December 31, 2008	96,789	\$ 18.28	0.3	\$ 1,556,347

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

10. STOCKHOLDERS' EQUITY (Continued)

Restricted Stock

A summary of the status of the Company's non-vested restricted stock awards as of December 31, 2008 and changes during the years ended December 31, 2008 and 2007, is presented below:

Restricted Stock	Outstanding	Weighted Average Exercise Price
Non vested stock awards outstanding at January 1, 2007	26,444	\$ 3.76
Granted	53,000	2.53
Vested	(26,044)	4.12
Forfeited	(3,400)	2.44
Non vested stock awards outstanding at December 31, 2007		
Granted	50,000	2.40
Vested	50,000	2.52
Vested	(38,129)	2.75
Forfeited		
Non vested stock awards outstanding at December 31, 2008		
	61,871	\$ 2.40

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 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.

Total compensation cost charged related to employee stock options amounted to \$750,822 for the year ended December 31, 2008. Total compensation cost for share-based payment arrangements for the year ended December 31, 2007, representing employee compensation expense related to stock options and non-vested restricted stock awards, amounted to \$999,883. No compensation cost related to share-

Table of Contents

CELSION CORPORATION
NOTES TO FINANCIAL STATEMENTS (Continued)
YEARS ENDED DECEMBER 31, 2008 AND 2007

10. STOCKHOLDERS' EQUITY (Continued)

based payments arrangements was capitalized as part of the cost of any asset at December 31, 2008 and 2007.

As of December 31, 2008, there was \$1.2 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 1.8 years. At December 31, 2008, there were 1,255,880 options outstanding which were vested or expected to vest at a weighted average exercise price of \$4.38. The weighted average remaining contractual term of these options were 8.3 years.

The weighted average grant-date fair values of the options granted during the years ended December 31, 2008 and 2007 were \$4.80 and \$3.52 respectively.

Preferred Stock and Stockholder Rights Plan

The Company's Certificate of Incorporation and Bylaws authorizes the issuance of "blank check" preferred stock by the Board of Directors, on such terms as it determines and without further stockholder approval. The Company has also 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.

11. CONTINGENT LIABILITIES AND COMMITMENTS*Operating lease commitments*

The Company leases office space in Columbia, MD. Following is a summary of the future minimum rental payments required under leases that have initial or remaining lease terms of one year or more as of December 31, 2008:

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

Rent expense was \$0.2 million for the years ended December 31, 2008 and 2007, respectively.

The Company believes it has sufficient office space and facilities for the foreseeable future.

Table of Contents**CELSION CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)****YEARS ENDED DECEMBER 31, 2008 AND 2007****12. RELATED PARTY TRANSACTIONS**

In October 2007, the Company entered into an advisory agreement with a related party to provide consulting services to the Company. This agreement terminated effective March 2, 2008. Pursuant to the consulting agreement, the Company paid the related party \$4,583 and \$59,167 for the years ended December 31, 2008 and 2007.

The consulting agreement also granted the related party an option, not subject to performance conditions, for the purchase of 10,000 shares of Common Stock at a price of \$5.84 per share, which expired on March 3, 2008.

13. DISCONTINUED OPERATIONS

On April 17, 2007, the Company and Boston Scientific entered into an asset purchase agreement to reflect the exercise by Boston Scientific of its option to purchase all of the Prolieve assets of the Company (the "Asset Purchase Agreement"). The Board of Directors of the Company approved the Asset Purchase Agreement and the transactions contemplated thereby, and the Company's stockholders ratified the sale at the annual meeting on June 13, 2007. Pursuant to the Asset Purchase Agreement, Boston Scientific purchased the Prolieve assets for an aggregate purchase price of \$60 million, subject to reduction in accordance with the terms and conditions of the Asset Purchase Agreement. The transaction closed on June 21, 2007, and the Company recorded a gain on the sale in the amount of \$48 million.

The gain on the sale of Prolieve was calculated as follows:

Sales Price	\$ 60,000,000
Transaction fees and legal costs	(1,460,165)
Indemnity guarantee costs	(5,000,000)
Licensing fee	(3,100,000)
Adjusted Sales Price	50,439,835
Net assets sold	
Inventories	(2,824,757)
Laboratory and shop equipment	(150,503)
AMS License Fee	(1,545,893)
Liabilities Transferred	
Amortization of License Fee	2,111,111
Gain on Sale	\$ 48,029,793

As previously disclosed, the Company and Boston Scientific entered into a Transaction Agreement effective January 20, 2003 (the "Transaction Agreement"). As part of the consideration in the Transaction Agreement, the Company granted Boston Scientific an exclusive option to purchase the Prolieve assets for a price equal to the greater of \$60 million or a multiple of sales, exercisable for a period of five years and expiring in February 2009. As previously disclosed, on August 8, 2005, the Company and Boston Scientific entered into the First Amendment pursuant to which Boston Scientific agreed to lend the Company up to \$15 million to be evidenced by one or more convertible secured

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

13. DISCONTINUED OPERATIONS (Continued)

promissory notes (the "Notes"). The first installment of \$6 million was disbursed on August 17, 2005, the second and third installments, each of \$4.5 million, were disbursed on February 2, 2006, and July 28, 2006, respectively. The First Amendment also fixed the purchase option price at \$60 million (eliminating the multiple of sales).

The Asset Purchase Agreement reflects the agreement by the Company and Boston Scientific to further modify the terms of the purchase option granted to Boston Scientific on January 20, 2003 and amended on August 8, 2005. The revised terms provided for the aggregate purchase price of \$60 million to be paid in three installments consisting of \$30 million at closing on June 20, 2007 and \$15 million on each of the first and second anniversaries of the closing. The revised terms also provided that the \$30 million first installment was reduced at closing by approximately \$17 million, representing the principal and accrued interest due on the Notes.

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 has agreed to indemnify Boston Scientific for a period of two years from the closing, in an amount up to \$15 million of incurred costs, in the event of unforeseen intellectual property claims related to the Prolieve assets. In accordance with FASB interpretation No. 45 ("FIN 45"), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others an interpretation of FASB Statements No. 5, 57, and 107 and rescission of FASB interpretation No. 34*, the Company recorded an estimate for the fair value of standing ready to perform under the indemnification guarantee of \$5,000,000. This estimate was consistent with the fair value of insurance premiums to cover the entire \$15 million indemnity. On July 23, 2007, the Company purchased an insurance policy to cover \$10 million of the indemnity guarantee. The premium for this policy was \$1,313,250 and was recorded as a reduction of the accrued liability. The Company will continue to evaluate the accrued liability on a quarterly basis and reduce it as the risk of the indemnity decreases. As of December 31, 2008 and 2007 the indemnity reserve was \$1,053,000 and \$3,485,000, respectively. For the year ended December 31, 2008 the Company recorded a non-cash benefit of \$2,432,000 as a result of writing down the value of the indemnity reserve.