

Celsion CORP
Form 10-K
March 17, 2010

Use these links to rapidly review the document

[CELSION CORPORATION FORM 10-K TABLE OF CONTENTS](#)
[FINANCIAL STATEMENTS](#)

[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, 2009

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 Each Class	Name of Each Exchange on Which Registered
COMMON STOCK, PAR VALUE \$.01 PER SHARE	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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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 definition of "accelerated filer" "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one)

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 16, 2010, 12,209,810 shares of the Registrant's Common Stock were issued and outstanding.

As of June 30, 2009, the aggregate market value of voting common stock held by non-affiliates of the Registrant was approximately \$47,616,505, 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 2010 Annual Meeting of Stockholders, which is scheduled to be held on June 25, 2010, 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>3</u>
<u>Celsion's Approach</u>	<u>4</u>
<u>Phase I Clinical Trial Primary Liver Cancer</u>	<u>4</u>
<u>Phase III Global 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>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>PART II</u>	<u>17</u>
<u>ITEM 4. 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 5. SELECTED FINANCIAL DATA</u>	<u>17</u>
<u>ITEM 6. 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>

Edgar Filing: Celsion CORP - Form 10-K

Table of Contents

<u>COMPARISON OF FISCAL YEAR ENDED DECEMBER 31, 2009 AND FISCAL YEAR ENDED DECEMBER 31, 2008</u>	<u>19</u>
<u>Financial Condition, Liquidity and Capital Resources</u>	<u>20</u>
<u>Off-Balance Sheet Arrangements</u>	<u>21</u>
<u>ITEM 6A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	<u>21</u>
<u>ITEM 7. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	<u>21</u>
<u>ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	<u>21</u>
<u>ITEM 8A. CONTROLS AND PROCEDURES</u>	<u>21</u>
<u>ITEM 8B. OTHER INFORMATION</u>	<u>21</u>
<u>PART III</u>	<u>22</u>
<u>ITEM 9. DIRECTORS AND EXECUTIVE OFFICERS</u>	<u>22</u>
<u>ITEM 10. EXECUTIVE COMPENSATION</u>	<u>22</u>
<u>ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	<u>22</u>
<u>ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS</u>	<u>23</u>
<u>ITEM 13. PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	<u>23</u>
<u>ITEM 14. 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 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. 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 pivotal 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 (39.5-42 degrees Celsius) releases the entrapped doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

Table of Contents

Celsion has also demonstrated feasibility for a product pipeline of cancer drugs that employ its heat activated liposomal technology in combination with known chemotherapeutics including docetaxel and carboplatin. We believe that our technology can improve efficacy and safety of anticancer agents whose mechanism of action and safety profile are well understood by the medical and regulatory communities. Additionally, we have formed a joint research agreement with Royal Phillips Electronics to evaluate the combination of Phillips' high intensity focused ultrasound with Celsion's ThermoDox® to determine the potential of this combination to treat a broad range of cancers.

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 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 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") in 2007 for net aggregate payments of \$43 million, receiving \$13 million in 2007 and \$15 million in each of 2008 and 2009.

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 submicroscopic 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 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

Table of Contents

temperature of 39° 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.

Heat adds permeability
39 T 42°C

Mechanical release
at 39°-42°C

Leaky tumor vessels
37°C

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. We are currently in a Phase III clinical trial for primary liver cancer and a Phase II study for recurrent chest wall breast cancer. Celsion completed animal studies which demonstrated that 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.

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

Table of Contents

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 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 (greater than 80° C.) to ablate the tumor, it may fail to treat micrometastases in the outer margins of the ablation zone 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 in over 70 clinical sites in North America, Italy, China, Taiwan, Hong Kong, Korea, Japan, Thailand, Malaysia and the Philippines, with nearly 50% of the planned 600 patients now enrolled in the study. The primary endpoint for the study is progression free survival and we expect to complete patient enrollment in this clinical trial by the middle of 2010.

Table of Contents

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 39.5° 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.

Breast Cancer Clinical Phase I/II Clinical Trial

In 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 109 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 enroll the Phase I portion of the study in the first half 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 has developed a third stable heat activated liposomal formulation. This drug encapsulates carboplatin and in early studies has shown favorable release characteristics and formulation stability.

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 \$13.7 million and \$12.0 million for the years ended December 31, 2009 and 2008, 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 \$1.4 million). The FDA may waive or reduce such user fees under certain circumstances, such as Orphan Drug Status. 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

Currently, we employ 19 full-time employees and also utilize 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

Table of Contents

licensed from Duke, the Company has licensed from Valentis, CA certain global rights covering the use of pegylation for temperature sensitive liposomes.

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 2009, the FDA granted orphan drug designation for ThermoDox®. Orphan drug designation entitles the Company to seven years of market exclusivity following FDA approval, FDA assistance in clinical trial design, a reduction in FDA user fees, U.S. tax credits related to development expenses as well as the opportunity to apply for funding from the U.S. government to defray the costs of clinical trial expenses.

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.

ThermoDox® is a registered trademark in the United States, Australia, the European Communities (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Korea, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, UK), Honk Kong, Japan, New Zealand, Peru, Singapore and Taiwan. The Company has registered transliterations of ThermoDox® in Japan, Singapore and Taiwan. In addition, the Company has filed for trademark protection for ThermoDox® in over twenty five additional countries world-wide.

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.

Table of Contents

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 \$82.1 million at December 31, 2009. For the year ended December 31, 2009 we incurred a net loss of \$15.2 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.

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 RAISE ADDITIONAL CAPITAL, WE MAY NOT BE ABLE TO COMPLETE THE DEVELOPMENT, TESTING AND COMMERCIALIZATION OF OUR TREATMENT SYSTEMS.

As of December 31, 2009, we had approximately \$14.1 million in cash, short term investments and other receivables and current assets. To complete the development and commercialization of our product, we will need to raise substantial amounts of additional capital. 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 we can not raise additional capital, 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 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-

Table of Contents

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 19 full-time employees. We rely, and expect to continue to rely, on third-party Clinical Research Organizations to conduct 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 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

Table of Contents

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, are all 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 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.

Table of Contents

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.

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

Table of Contents

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.

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

Table of Contents

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 \$5.18 and a low price of \$2.05 in the 52-week period ending December 31, 2009. 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 to our stockholders one right per share of our Common Stock. When these rights become exercisable, each right entitles their holders to purchase one ten-thousandth (1/10,000) of a share of our Series C Junior Participating Preferred Stock (the "Preferred Stock") at a price of \$66.90 per one ten-thousandth (1/10,000) share. 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 receive, upon the exercise of their rights and in lieu of the Preferred Stock, the number of shares of our Common Stock (or the number of shares of stock of any company into which we are merged) having a value equal to twice the exercise price of their rights in exchange for the \$66.90 exercise price. 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

Table of Contents

Bylaws and of Delaware law may also discourage, delay or prevent a third party from acquiring or merging with us, even if such action were beneficial to some, or even a majority, of our stockholders.

ITEM 1B. UNRESOLVED STAFF COMMENTS

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, 2009 was \$0.2 million. The future minimum lease obligation for 2010 is \$180,000. The Company is currently investigating its options to either renew its current lease or find other office facilities.

ITEM 3. LEGAL PROCEEDINGS

None.

Table of Contents**PART II****ITEM 4. 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, 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
YEAR ENDED DECEMBER 31, 2009		
First Quarter (January 1 - March 31, 2009)	\$ 3.60	\$ 2.05
Second Quarter (April 1 - June 30, 2009)	\$ 4.85	\$ 3.00
Third Quarter (July 1 - September 30, 2009)	\$ 5.18	\$ 3.25
Fourth Quarter (October 1 - December 31, 2009)	\$ 3.54	\$ 2.74

On March 16, 2010, the last reported sale price for our Common Stock on The NASDAQ Stock Market was \$3.82. As of March 16, 2010, there were approximately 800 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 11. 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 11,000 shares of Common Stock in 2007 and 4,600 shares of Common Stock in 2009 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.

ITEM 5. SELECTED FINANCIAL DATA

Not required.

Table of Contents

ITEM 6. 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 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

On September 30, 2009, the Company completed a registered direct offering with a select group of institutional investors that raised gross proceeds of \$7.1 million and net proceeds of \$6.3 million. The Company sold 2,018,153 units at a price of \$3.50 per unit. Each unit consisted of one share of common stock and a warrant to purchase 0.5 shares of common stock. The Company issued 2,018,153 shares of its common stock and warrants to purchase 1,009,076 shares of common stock. The warrants have an exercise price of \$5.24 per share and are exercisable at any time on or after the six month anniversary of the date of issuance and on or prior to 66 months after the date of issuance. Under the terms of the warrants, upon certain transactions, including a merger, tender offer or sale of all or substantially all of the assets of the Company, each warrant holder may elect to receive a cash payment in exchange for the warrant, in an amount determined by application of the Black-Scholes option valuation model.

Critical Accounting Policies and Estimates

Our financial statements, which appear at Item 7 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 Accounting Standards Codification ("ASC") 718, *Compensation Stock Compensation*, 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

Table of Contents

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, 2009
Risk-free interest rate	1.21 to 2.82%	1.76 to 3.54%
Expected volatility	71.28% - 77.17%	69% - 71.33%
Expected life (in years)	2.7 - 6.3	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 2009 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, 2009 and 2008.

Licensing Revenue

Licensing revenue in 2008 was \$2.5 million as a result of the up-front non refundable licensing payment received from Yakult Honsha for the commercial rights to market ThermoDox® in Japan. The Company had no licensing revenue in 2009.

Research and Development Expenses

Research and development expenses increased by \$1.7 million, from \$12.0 million in 2008 to \$13.7 million in 2009. 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 increased by \$1.3 million, from 2.0 million in 2008 to \$3.3 million in 2009. The increase is attributable to the expiration of the indemnity reserve recorded by the Company prior to 2008 and amortized as a reduction of general and administrative expenses through mid 2009. The amortization of the indemnity reserve was \$1.1 million in 2009 compared to \$2.4 million in 2008.

Table of Contents

Other income (expense)

We had other income of \$0.3 million in 2009 compared to other expense of \$0.3 million in 2008. In 2008, the Company wrote down the carrying value of a note receivable by \$0.9 million. In 2009, the Company wrote off the note receivable and retained the collateral for this note. At the time of the retention of the collateral, its value increased by \$0.2 million which was recorded in other income.

Change in warrant liability

The warrant liability incurred on September 30, 2009 was recorded at fair value. The decrease in the fair value of the warrant liability in 2009 for the period since inception was \$0.7 million.

Interest income

Interest income was \$0.05 million in 2009 compared to \$0.22 million in 2008. The decrease was insignificant.

Interest expense

Interest expense was \$0.09 million in 2009 compared to \$0.14 million in 2008. The decrease was insignificant.

Tax benefit

The Company reported an income tax expense of \$0.8 million in 2007 representing the alternative minimum tax due as a result of the gain on the sale of the medical device assets. In December 2009, the Company filed for, and has received, a refund of that tax pursuant to Revenue Procedure 2009-52 and recorded a tax benefit in that amount.

Financial Condition, Liquidity and Capital Resources

Since inception, excluding the two payments totaling \$30 million from Boston Scientific received in 2008 and 2009, 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 \$82.1 million at December 31, 2009.

At December 31, 2009, we had total current assets of \$14.1 million (including cash and short term investments of \$12.6 million) and current liabilities of \$3.8 million, resulting in a working capital surplus of \$10.3 million. 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.

Net cash used in operating activities for the year ended December 31, 2009 was \$0.9 million. Exclusive of the \$15.0 million payment received from Boston Scientific the net cash used in operations was \$15.9 million. The \$15.9 million net cash requirement was funded from cash on hand at the beginning of the year, the \$15.0 million account payment collected from Boston Scientific and the \$6.3 million net proceeds from an equity offering. Net cash used for investing activities was \$1.7 million in 2009, primarily for purchases of short-term investments. Exclusive of the net proceeds from the equity offering in 2009, net cash used in financing activities was \$0.2 million for the year ended December 31, 2009 which represents the payments made on notes payable.

At December 31, 2009 the Company had cash, cash equivalents and short term investments of \$12.6 million. The \$12.6 million of cash resources is expected to be adequate to fund operations into

Table of Contents

the first quarter of 2011. 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 6A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Required.

ITEM 7. 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-20.

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 8A(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, 2009, 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, 2009 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, 2009, which appears in Item 14 of this Report.

ITEM 8B. OTHER INFORMATION

None.

Table of Contents**PART III****ITEM 9. DIRECTORS AND EXECUTIVE OFFICERS**

The information required by this Item 9 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 10. EXECUTIVE COMPENSATION

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

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.

Equity Compensation Plan Information as of December 31, 2009

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	1,720,580(1) \$	3.92	882,284
Equity compensation plans not approved by security holders	(2)	0.00	(2)
Total	1,720,580 \$	3.92	882,284

-
- (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 Plan in connection with employment agreements.
- (2) As discussed further in Notes 12 and 13 to the Company's financial statements, the Company has warrants outstanding at December 31, 2009 enabling the holders thereof to purchase 1,032,410 shares of the Company's Common Stock at a weighted-average exercise price of \$5.34. 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 13 of the Company's financial statements for descriptions of the plans under which equity securities of the Company are authorized for issuance.

Table of Contents**ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

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.

ITEM 13. PRINCIPAL ACCOUNTANT FEES AND SERVICES

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. 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 reports of our independent registered public accountants and Management's Report on Internal Control over Financial Reporting.

	Page
REPORTS	
<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>
FINANCIAL STATEMENTS	
<u>Balance Sheets</u>	<u>F-3</u>
<u>Statements of Operations</u>	<u>F-4</u>
<u>Statements of Cash Flows</u>	<u>F-5</u>
<u>Statements of Changes in Stockholders' Equity</u>	<u>F-6</u>
<u>NOTES TO FINANCIAL STATEMENTS</u>	<u>F-7</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.

Edgar Filing: Celsion CORP - Form 10-K

Table of Contents

EXHIBIT NO.	DESCRIPTION
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.
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.
10.2.7	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.

Edgar Filing: Celsion CORP - Form 10-K

Table of Contents

EXHIBIT NO.	DESCRIPTION
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.
10.4.3	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, 2008.
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.

Edgar Filing: Celsion CORP - Form 10-K

Table of Contents

EXHIBIT NO.	DESCRIPTION
10.8	License Agreement dated July 18, 2003, between the Company and Duke University. (Confidential treatment requested.), incorporated herein by reference to Exhibit 4.3 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	Asset Purchase Agreement, dated as of April 17, 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 April 18, 2007
10.13.1	First Amendment to the Asset Purchase Agreement, dated June 5, 2008, by and between Celsion Corporation and Boston Scientific Corporation, incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2009.
10.13.2	Second Amendment to the Asset Purchase Agreement, dated June 2, 2009, 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 June 2, 2009.
10.14	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.
10.15	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.

Edgar Filing: Celsion CORP - Form 10-K

Table of Contents

EXHIBIT NO.	DESCRIPTION
10.16	Development, Product Supply and Commercialization Agreement, effective December 5, 2008, by and between the Company and Yakult Honsha Co., Ltd., herein by reference to Exhibit 10.15 to the Annual Report on Form 10-K of the Company for the Year Ended December 31, 2008. (Confidential treatment requested.)
10.17	Placement Agency Agreement dated September 25, 2009 among Celsion Corporation and Needham & Company, LLC., incorporated herein by reference to Exhibit 1.1 to the Current Report on Form 8-K of the Company, filed September 28, 2009.
10.17.1	Form of Common Stock Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company, filed September 28, 2009.
10.17.2	Form of Subscription Agreement, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed September 28, 2009.
10.17.3	Escrow Agreement by and between JPMorgan Chase Bank, N.A., Celsion Corporation, and Needham & Company, LLC., incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of the Company, filed September 28, 2009.
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 15(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 16, 2010

By: /s/ Michael H. Tardugno

Michael H. Tardugno
President and Chief Executive Officer

March 16, 2010

By: /s/ Timothy J. Tumminello

Timothy J. Tumminello
Controller & Interim Chief Accounting 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:

SIGNATURE	TITLE	DATE
/s/ Michael H. Tardugno _____ Michael H. Tardugno	President and Chief Executive Officer (Principal Executive Officer)	March 16, 2010
/s/ Timothy J. Tumminello _____ Timothy J. Tumminello	Controller & Interim Chief Accounting Officer (Principal Financial and Accounting Officer)	March 16, 2010
/s/ Max E. Link _____ Max E. Link	Chairman of the Board	March 16, 2010
/s/ Gary W. Pace _____ Gary W. Pace	Director	March 16, 2010
/s/ Gregory Weaver _____ Gregory Weaver	Director	March 16, 2010
/s/ Augustine Chow _____ Augustine Chow	Director	March 16, 2010

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, 2009. 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.

SIGNATURE	TITLE	DATE
<u>/s/ Michael H. Tardugno</u> Michael H. Tardugno	President and Chief Executive Officer (Principal Executive Officer)	March 16, 2010
<u>/s/ Timothy J. Tumminello</u> Timothy J. Tumminello	Controller & Interim Chief Accounting Officer (Principal Financial and Accounting Officer)	March 16, 2010

F-1

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Celsion Corporation
Columbia, Maryland

We have audited the accompanying balance sheets of Celsion Corporation (the "Company") as of December 31, 2009 and 2008, and the related statements of operations, changes in stockholders' equity, and cash flows for the years then ended. The Company'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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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, 2009 and 2008, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Stegman & Company
Baltimore, Maryland
March 16, 2010

Table of Contents**CELSION CORPORATION****BALANCE SHEETS**

	December 31,	
	2009	2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,923,476	\$ 3,456,225
Short-term investments, available for sale, at fair value	5,695,466	4,061,320
Refundable income taxes	806,255	
Due from Boston Scientific Corporation		15,000,000
Prepaid expenses and other receivables	695,021	305,888
Total current assets	14,120,218	22,823,433
Property and equipment (at cost less accumulated depreciation of \$881,278 and \$771,624, respectively)	537,407	222,638
Other assets:		
Deposits and other assets	97,082	362,651
Note receivable (net of allowance and discount of \$1,128,821 at December 31, 2008)		221,179
Patent license fees, net	50,625	58,125
Total other assets	147,707	641,955
Total assets	\$ 14,805,332	\$ 23,688,026
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable trade	\$ 2,190,957	\$ 1,186,511
Other accrued liabilities	1,451,542	1,459,391
Note payable current portion	108,332	234,735
Indemnity reserve		1,053,357
Total current liabilities	3,750,831	3,933,994
Common stock warrant liability	821,891	
Note payable non-current portion	179,868	
Other liabilities noncurrent	16,948	27,643
Total liabilities	4,769,538	3,961,637
Stockholders' equity:		
Common stock \$0.01 par value (75,000,000 and 250,000,000 shares authorized; 12,895,174 and 10,816,088 shares issued and 12,134,900 and 10,156,350 shares outstanding at	128,952	108,161

Edgar Filing: Celsion CORP - Form 10-K

December 31, 2009 and 2008,
respectively)

Additional paid-in capital	95,035,165	89,183,549
Accumulated other comprehensive income	68,173	
Accumulated deficit	(82,119,826)	(66,923,972)
Subtotal	13,112,464	22,367,738
Less: Treasury stock, at cost (760,274 and 659,738 shares at December 31 2009 and 2008, respectively)	(3,076,670)	(2,641,349)
Total stockholders' equity	10,035,794	19,726,389
Total liabilities and stockholders' equity	\$ 14,805,332	\$ 23,688,026

See accompanying notes to the financial statements.

F-3

Table of Contents

CELSION CORPORATION
STATEMENTS OF OPERATIONS

	Year ended December 31,	
	2009	2008
Licensing revenue	\$	\$ 2,500,000
Operating expenses:		
Research and development	13,680,939	12,006,218
General and administrative	3,326,610	2,043,193
Total operating expenses	17,007,549	14,049,411
Loss from operations	(17,007,549)	(11,549,411)
Other income (expense):		
Other income (expense)	322,414	(316,899)
Gain from valuation of common stock warrant liability	731,785	
Interest income	46,161	221,707
Interest expense	(94,920)	(141,612)
Total other income (expense)	1,005,440	(236,804)
Loss before income taxes	(16,002,109)	(11,786,215)
Income tax benefit	806,255	
Net loss	\$ (15,195,854)	\$ (11,786,215)
Basic and diluted net loss per common share	\$ (1.43)	\$ (1.16)
Basic and diluted weighted average shares outstanding	10,655,200	10,148,958

See accompanying notes to the financial statements.

Table of Contents

CELSION CORPORATION
STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2009	2008
Cash flows from operating activities:		
Net loss	\$ (15,195,854)	\$ (11,786,215)
Non-cash items included in net loss:		
Depreciation and amortization	109,654	69,468
Amortization of indemnity reserve	(1,053,357)	(2,431,715)
Gain on valuation of common stock warrant liability issued in connection with equity financing	(731,785)	
Stock based compensation options	894,277	750,822
Stock based compensation restricted stock	182,593	110,667
Amortization of deferred license fee	7,500	7,500
Shares issued in exchange for services	14,700	
Recovery of bad debt on note receivable	(214,142)	
Bad debt Celsion Canada note receivable		1,160,348
Net changes in:		
Due from Boston Scientific Corporation	15,000,000	15,000,000
Refundable income taxes	(806,255)	
Prepaid expenses and other receivables	(389,133)	181,139
Deposits and other assets	265,569	536,617
Accounts payable trade	1,004,446	(643,946)
Income taxes payable		(546,000)
Other accrued liabilities	(18,544)	(127,422)
Net cash (used in) provided by operating activities	(930,331)	2,281,263
Cash flows from investing activities:		
Purchases of short-term investments available for sale	(8,498,217)	(3,113,820)
Sales of short-term investments available for sale	6,932,244	2,052,500
Purchases of property and equipment	(136,223)	(24,225)
Net cash used in investing activities	(1,702,196)	(1,085,545)
Cash flows from financing activities:		
Net proceeds from direct offering	6,334,513	
Payments on note payable	(234,735)	(676,866)
Net cash provided by (used in) financing activities	6,099,778	(676,866)
Net increase in cash and cash equivalents	3,467,251	518,852
Cash and cash equivalents at beginning of period	3,456,225	2,937,373
Cash and cash equivalents at end of period	\$ 6,923,476	\$ 3,456,225
Cash paid for:		
Interest	\$ 91,120	\$ 141,612
Income taxes	\$	\$ 546,000

See accompanying notes to the financial statements.

Table of Contents

CELSION CORPORATION
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2009 AND 2008

	Common Stock Outstanding		Additional Paid-in Capital	Treasury Stock		Accumulated Other Comp. Income	Accumulated	Total
	Shares	Amount		Shares	Amount			
Balance at January 1, 2008	10,124,184	\$ 107,839	\$ 88,319,985	659,738	\$ (2,638,952)	\$	\$ (55,137,757)	\$ 30,651,115
Stock-based compensation expense related to employee stock options			750,822					750,822
Stock-based compensation expense related to restricted stock			110,667					110,667
Shares issued in exchange for services	2,500	25	(25)					
Issuance of restricted stock upon vesting	29,666	297	(297)					
Treasury stock acquired			2,397		(2,397)			
Net loss							(11,786,215)	(11,786,215)
Balance at December 31, 2008	10,156,350	108,161	89,183,549	659,738	(2,641,349)		(66,923,972)	19,726,389
Shares issued under direct offering	2,018,153	20,182	4,760,655					4,780,837
Stock-based compensation expense related to employee stock options			894,277					894,277
Stock-based compensation expense related to restricted stock			182,593					182,593
Shares issued in exchange for services	4,600	46	14,654					14,700

Edgar Filing: Celsion CORP - Form 10-K

Issuance of restricted stock upon vesting	56,333	563	(563)						
Treasury stock acquired	(100,536)			100,536	(435,321)				(435,321)
Unrealized gain (loss) on investments						68,173			68,173
Net loss							(15,195,854)		(15,195,854)
Balance at December 31, 2009	12,134,900	\$ 128,952	\$ 95,035,165	760,274	\$ (3,076,670)	\$ 68,173	\$ (82,119,826)	\$ 10,035,794	

See accompanying notes to the financial statements.

F-6

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS

YEARS ENDED DECEMBER 31, 2009 AND 2008

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 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. Events and conditions arising subsequent to the most recent balance sheet date have been evaluated for their possible impact on the financial statements. These events and conditions did not give rise to any information that required accounting recognition or disclosure in the financial statements other than those arising in the ordinary course of business.

Revenue Recognition

At the inception of each collaborative agreement that includes milestone payments, the Company evaluates whether each milestone is substantive on the basis of the contingent nature of the milestone, specifically reviewing factors such as the scientific and other risks that must be overcome to achieve the milestone, as well as the level of effort and investment required. Milestones that are not considered substantive and that do not meet the separation criteria are accounted for as license payments and recognized on a straight-line basis over the remaining period of performance. Payments received or reasonably assured after performance obligations are met completely are recognized as earned.

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 Accounting Standards Codification (ASC) 320, *Investments 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 other comprehensive gain or

Table of Contents

CELSION CORPORATION
NOTES TO FINANCIAL STATEMENTS (Continued)
YEARS ENDED DECEMBER 31, 2009 AND 2008

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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.

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 approximately \$110,000 and \$69,000 for years ended December 31, 2009 and 2008, 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 of \$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, 2009 the total accumulated amortization expense is \$22,500. The weighed-average amortization period for these assets is 10 years.

Indemnity Reserve

Upon the sale of its 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 evaluated the indemnity reserve on a quarterly basis, reducing it as the risk of the indemnity decreased and amortized it over the period of the indemnification. As of December 31, 2009 and 2008, the indemnity reserve was \$-0- and \$1,053,357, respectively. For the year ended December 31, 2009 and 2008, the Company recorded a non-cash benefit of \$1,053,357 and \$2,432,000, respectively, as a result of the amortization of this indemnity reserve.

Comprehensive Income

ASC 220, *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 ASC 220 is to report a measure (comprehensive income (loss)) of all changes in equity of

Table of Contents

CELSION CORPORATION
NOTES TO FINANCIAL STATEMENTS (Continued)
YEARS ENDED DECEMBER 31, 2009 AND 2008

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

an enterprise that result from transactions and other economic events in a period other than transactions with owners.

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.

Since the Company incurred a loss from operations for 2009 and 2008, the outstanding options for 1,641,979 and 1,255,880 shares, respectively, and the warrants outstanding to purchase 1,032,410 and 96,789 shares, respectively, 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 ASC 845, *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.

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. In accordance with ASC 740, *Income Taxes*, 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 Company recognizes interest and/or penalties related to income tax matters in the income tax expense category.

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 ASC 718, *Compensation Stock Compensation*, 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 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 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 13, 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").

Recent Accounting Pronouncements.

In January 2010, the Financial Accounting Standards Board ("FASB") issued updated guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. This update requires new disclosures on significant transfers of assets and liabilities between Level 1 and Level 2 of the fair value hierarchy (including the reasons for these transfers) and the reasons for any transfers in or out of Level 3. This update also requires a reconciliation of recurring Level 3 measurements about purchases, sales, issuances and settlements on a gross basis. In addition to these new disclosure requirements, this update clarifies certain existing disclosure requirements. For example, this update clarifies that reporting entities are required to provide fair value measurement disclosures for each class of assets and liabilities rather than each major category of assets and liabilities. This update also clarifies the requirement for entities to disclose information about both the valuation

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. This update will become effective for the Company with the interim and annual reporting period beginning January 1, 2010, except for the requirement to provide the Level 3 activity of purchases, sales, issuances, and settlements on a gross basis, which will become effective for the Company with the interim and annual reporting period beginning January 1, 2011. The Company will not be required to provide the amended disclosures for any previous periods presented for comparative purposes. Other than requiring additional disclosures, adoption of this update will not have a material effect on the Company's consolidated financial statements.

In September 2009, the FASB provided updated guidance (1) on whether multiple deliverables exist, how the deliverables in a revenue arrangement should be separated, and how the consideration should be allocated; (2) requiring an entity to allocate revenue in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price; and (3) eliminating the use of the residual method and requiring an entity to allocate revenue using the relative selling price method. The update is effective for fiscal years beginning on or after June 15, 2010, with early adoption permitted. Adoption may either be on a prospective basis or by retrospective application. The Company is currently evaluating the effect of this update to its accounting and reporting systems and processes; however, at this time the Company is unable to quantify the impact on its consolidated financial statements of its adoption or determine the timing and method of its adoption.

2. FINANCIAL CONDITION

Since inception, the Company has incurred substantial operating losses, principally from expenses associated with the Company's research and development programs, clinical trials conducted in connection with the Company's treatment systems, and applications and submissions to the Food and Drug Administration. The Company believes these expenditures are essential for the commercialization of its technologies. As a result of these expenditures, as well as general and administrative expenses, the Company has an accumulated deficit of \$82.1 million as of December 31, 2009.

The Company expects its operating losses to continue for the foreseeable future as it continues its product development efforts, and when it undertakes marketing and sales activities. The Company's ability to achieve profitability is dependent upon its ability to obtain governmental approvals, produce, and market and sell its new products. There can be no assurance that the Company will be able to commercialize its technology successfully or that profitability will ever be achieved. The operating results of the Company have fluctuated significantly in the past. The Company expects that its operating results will fluctuate significantly in the future and will depend on a number of factors, many of which are outside the Company's control.

The Company will need substantial additional funding in order to complete the development, testing and commercialization of its cancer treatment products. Celsion has made a significant commitment to heat-activated liposome research and development projects and it is the Company's intention at least to maintain, and possibly increase, the pace and scope of these activities. The commitment to these new projects will require additional external funding, at least until the Company is able to generate sufficient cash flow from sale of one or more of its products to support its

Table of Contents**CELSION CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)****YEARS ENDED DECEMBER 31, 2009 AND 2008****2. FINANCIAL CONDITION (Continued)**

continued operations. Management believes that adequate funding is available from cash resources on hand at December 31, 2009 to fund operations as least through the end of 2010.

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

3. COMPREHENSIVE LOSS

Comprehensive loss is comprised of net loss adjusted for changes in market values of securities available for sale. Below is a reconciliation of net loss to comprehensive loss for the years ended December 31, 2009 and 2008:

	Year ended December 31, 2009
Net loss	\$ (15,195,854)
Unrealized gain (loss) on securities available for sale	68,173
Comprehensive loss	\$ (15,127,681)

4. SHORT TERM INVESTMENTS AVAILABLE FOR SALE

Short term investments available for sale of \$5,695,466 and \$4,061,320 as of December 31, 2009 and 2008, respectively, 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 Income.

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 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

Table of Contents

CELSION CORPORATION
NOTES TO FINANCIAL STATEMENTS (Continued)
YEARS ENDED DECEMBER 31, 2009 AND 2008

4. SHORT TERM INVESTMENTS AVAILABLE FOR SALE (Continued)

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.

	December 31,	
	2009	2008
Short-term investments available for sale, at fair value		
Bonds corporate issuances	\$ 5,528,164	\$ 2,661,219
Bonds government agencies		1,400,101
Equity securities (see Note 7)	167,302	
Total	\$ 5,695,466	\$ 4,061,320

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

	December 31, 2009		December 31, 2008	
	Cost	Fair Value	Cost	Fair Value
Short-term investments				
Bonds corporate issuances	\$ 5,528,164	\$ 5,528,164	\$ 2,661,219	\$ 2,661,219
Bonds government agencies			1,400,101	1,400,101
Equity securities (see Note 7)	108,373	167,302		
Total	\$ 5,636,537	\$ 5,695,466	\$ 4,061,320	\$ 4,061,320
Bond maturities				
Within 3 months	\$ 1,894,022	\$ 1,894,022	\$ 2,962,978	\$ 2,962,978
Between 3-12 months	3,321,320	3,321,320	1,098,342	1,098,342
Between 1-2 years	312,822	312,822		
Total	\$ 5,528,164	\$ 5,528,164	\$ 4,061,320	\$ 4,061,320

5. FAIR VALUES OF FINANCIAL INSTRUMENTS

ASC 820, *Fair Value Measurements and Disclosures*, 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:

Edgar Filing: Celsion CORP - Form 10-K

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.

F-13

Table of Contents**CELSION CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)****YEARS ENDED DECEMBER 31, 2009 AND 2008****5. FAIR VALUES OF FINANCIAL INSTRUMENTS (Continued)**

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 and liabilities measured at fair value on a recurring basis are summarized below:

	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Short-term investments available for sale, December 31, 2009	\$ 5,695,466	\$ 5,528,164	\$	\$ 167,302
Short-term investments available for sale, December 31, 2008	\$ 4,061,320	\$ 4,061,320	\$	\$
Liabilities:				
Common stock warrants, December 31, 2009	\$ 821,891	\$	\$	\$ 821,891
Common stock warrants, December 31, 2008	\$	\$	\$	\$

The following is a summary the changes in the common stock warrant liability for the year ended December 31, 2009:

Beginning balance, January 1, 2009	\$
Issuances	1,553,676
Realized gain included in net loss	(731,785)
Ending balance, December 31, 2009	\$ 821,891

6. PREPAID EXPENSES

Under its ThermoDox® licensing agreement for the Japanese territory with Yakult Honsha ("Yakult") (see Note 16), Yakult is obligated to fund all the development and clinical trial costs necessary to obtain regulatory approval in Japan. Accordingly, Celsion will be reimbursed for Research and Development costs it incurs in connection with Japanese patients treated in the global Phase III clinical trial. For the year ended December 31, 2009, Celsion has recorded an expense reimbursement of \$655,912 on the Research and Development expense line of the Statement of Operations and of this amount, Celsion has invoiced and collected \$384,174 from Yakult, with the balance of \$271,738 recorded as a prepaid expense to be invoiced to Yakult.

7. NOTE RECEIVABLE

In January, 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") microwave

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

7. NOTE RECEIVABLE (Continued)

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 for \$20,000,000 as discussed below. 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 restricted shares of Celsion common stock owned by Dr. Cheung and his wife and the commitment of Canada, including its successors, to pay a 5% royalty on the net sales of Canada up to \$18,500,000. On November 25, 2008, Medifocus, Inc. ("Medifocus"), a company listed on the Toronto Exchange Company (TSXV-MFS), announced that it completed a transaction with Canada to purchase 100% of the issued and outstanding shares of Canada.

The terms of the note receivable from Dr. Cheung 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 was recorded for the year ended December 31, 2008. No interest income was recognized during 2009.

The Company previously 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 of December 31, 2008 and March 31, 2009, the Company reduced the carrying value of the note to \$221,179. In June 2009, the Company's management determined the note was uncollectable, wrote off the balance of \$221,179 and retained the 100,536 restricted shares of Celsion common stock that was pledged as collateral. The 100,536 shares of common stock were valued at \$435,321, or \$4.33 per share, and were transferred to treasury stock at cost. The treasury stock's cost value of \$435,321 exceeded the net carrying value of the \$221,179 note receivable and in June 2009 the Company recorded the difference of \$214,142 as other income.

8. OTHER ASSETS

In June 2009, the Company recorded in other assets and other income an amount due of \$108,373 from Medifocus as a result of a March 2006 amendment to the Transition Services Agreement between Celsion Canada and Celsion. The \$108,273 asset value reflected the estimated net realizable value of 903,112 equity units due from Medifocus (each equity unit represents one common share of stock and one warrant to purchase one common share of stock). In the third quarter of 2009, Medifocus delivered 903,112 shares of common stock to Celsion and the value of this investment was reclassified from other assets to short investments. See Notes 3 and 4 above.

9. NOTE PAYABLE

In July 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. The note was repaid in 2009.

In October 2009, the Company financed \$288,200 of lab equipment through a capital lease, with thirty monthly payments of \$11,654 through April 2012.

Table of Contents**CELSION CORPORATION****NOTES TO FINANCIAL STATEMENTS (Continued)****YEARS ENDED DECEMBER 31, 2009 AND 2008****10. OTHER ACCRUED LIABILITIES**

Other accrued liabilities at December 31, 2009 and 2008 include the following:

	December 31,	
	2009	2008
Amounts due to Contract Research Organizations and under other contractual agreements	\$ 1,122,370	\$ 513,961
Accrued payroll and related	262,396	358,790
Accrued professional fees	47,000	362,500
Other	19,776	224,140
Total	\$ 1,451,542	\$ 1,459,391

11. INCOME TAXES

A reconciliation of the Company's statutory tax rate to the effective rate for the years ended December 31, 2009 and 2008 is as follows:

	2009	2008
Federal statutory rate	34.0%	34.0%
State taxes, net of federal tax benefit	5.4	4.6
Recapture of alternative minimum tax	(5.0)	0.0
Valuation allowance	(39.4)	(38.6)
Effective tax rate	(5.0)%	0.0%

As of December 31, 2009, the Company had net operating loss carryforwards of approximately \$61.9 million for Federal income tax purposes that are available to offset future taxable income through the year 2029.

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
10,716	12/31/2028
14,300	12/31/2029
\$ 63,506	

Table of Contents

CELSION CORPORATION
NOTES TO FINANCIAL STATEMENTS (Continued)
YEARS ENDED DECEMBER 31, 2009 AND 2008

11. INCOME TAXES (Continued)

The components of the Company's deferred tax asset as of December 31, 2009 and 2008 are as follows:

In thousands	December 31,	
	2009	2008
Net operating loss carryforwards	\$ 24,526	\$ 19,004
Compensation expense related to employee stock options	412	413
Subtotal	24,938	19,417
Valuation allowance	(24,938)	(19,417)
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.

The Company reported income tax expense of \$0.8 million for the year ended December 31, 2007 representing the alternative minimum tax due as a result of the gain on the sale of the medical device assets. In December 2009, the Company filed for a refund of that tax pursuant to Revenue Procedure 2009-52, requesting a refund of \$806,255. This amount was received by the Company in February 2010.

12. STOCKHOLDERS' EQUITY*Common Stock*

On September 30, 2009, the Company closed a registered direct offering with a select group of institutional investors that raised gross proceeds of \$7.1 million and net proceeds of \$6.3 million. The Company sold 2,018,153 units at a price of \$3.50 per unit. Each unit consisted of one share of common stock and a warrant to purchase 0.5 shares of common stock. The Company issued 2,018,153 shares of its common stock and warrants to purchase 1,009,076 shares of common stock. The warrants have an exercise price of \$5.24 per share and are exercisable at any time on or after the six month anniversary of the date of issuance and on or prior to 66 months after the date of issuance. Under the terms of the warrants, upon certain transactions, including a merger, tender offer or sale of all or substantially all of the assets of the Company, each warrant holder may elect to receive a cash payment in exchange for the warrant, in an amount determined by application of the Black-Scholes option valuation model. Accordingly, pursuant to ASC 815.40, *Derivative Instruments and Hedging - Contracts in Entity's Own Equity*, the warrants are recorded as a liability and then marked to market each period through the Statement of Operations in other income or expense. As of September 30, 2009, the Company recorded a warrant liability of \$1.6 million based on the fair value offset by a reduction in additional-paid in-capital. At the end of each subsequent quarter, the Company will revalue the fair value of the warrants and the change in fair value will be recorded as a change to the warrant liability and the difference will be recorded through the Statement of Operations in other income or expense. The fair

Table of Contents

CELSION CORPORATION
NOTES TO FINANCIAL STATEMENTS (Continued)
YEARS ENDED DECEMBER 31, 2009 AND 2008

12. STOCKHOLDERS' EQUITY (Continued)

value of the warrants at December 31, 2009 was \$0.8 million, calculated using the Black-Scholes option-pricing model with the following assumptions:

	December 31, 2009
Risk-free interest rate	2.69%
Expected volatility	58.9%
Expected life (in years)	2.6
Expected forfeiture rate	0%
Expected dividend yield	0.00%

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. During the second quarter of 2009, the Company retained collateral pursuant to an uncollectible notes receivable (see Note 7) of 100,536 shares of common stock that were transferred to treasury stock at a cost of \$435,321, or \$4.33 per share.

13. STOCK BASED COMPENSATION*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 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

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

13. STOCK BASED COMPENSATION (Continued)

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, 2009 and 2008, options to purchase 16,567 and 265,844 shares, respectively, 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, 2009 and 2008, options for 667 and 395,283 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, 2009 and 2008, 450,000 and 465,500 options, respectively, were issued under the 2007 Plan. During 2009 and 2008, a total of 46,667 and 47,333 options were canceled or expired under the 2007 Plan.

As of December 31, 2009, for all stock options plans there were a total of 2,762,668 shares reserved and there were a total of 1,120,689 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, 2009 AND 2008

13. STOCK BASED COMPENSATION (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 ASC 718, *Compensation Stock Compensation*, 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. There were 4,600 options issued to consultants during the year ended December 31, 2009 and none in 2008.

Warrants

In addition to the warrants discussed above in Note 12, the Company has warrants outstanding at December 31, 2009 enabling the holders thereof to purchase up to 23,334 shares of the Company's Common Stock at a weighted average exercise price of \$9.86. 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, 2009 or 2008 related to warrants outstanding.

The following is a summary of stock option and warrant activity for the two years ended December 31, 2009:

Stock Options	Number Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2008	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		
Granted	450,000	2.90		
Exercised				
Canceled or expired	(63,901)	4.77		
Outstanding at December 31, 2009	1,641,979	\$ 3.96	7.66	\$ 591,355
Exercisable at December 31, 2009	695,523	\$ 4.64	6.93	\$ 202,339

Table of Contents

CELSION CORPORATION
NOTES TO FINANCIAL STATEMENTS (Continued)
YEARS ENDED DECEMBER 31, 2009 AND 2008

13. STOCK BASED COMPENSATION (Continued)

A summary of stock options outstanding at December 31, 2009 by price range is as follows:

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number Outstanding	Weighted Average Contractual Term (in years)	Weighted Average Exercise Price	Number Outstanding	Weighted Average Contractual Term (in years)	Weighted Average Exercise Price
\$2.00 - \$3.00	900,500	8.06	\$ 2.61	286,792	7.49	\$ 2.56
\$3.01 - \$5.00	275,698	7.22	4.01	176,698	7.02	4.21
\$5.01 - \$7.00	418,405	7.54	5.73	184,823	6.83	5.94
\$7.01 - \$10.00	23,835	3.41	8.28	23,669	3.38	8.28
\$10.01 - \$30.00	23,333	3.75	18.11	23,333	3.75	18.11
\$150.75	208	4.44	150.75	208	4.44	150.75

A summary of warrants outstanding as of December 31, 2009 is as follows:

Warrants	Number Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2008	566,793	\$ 15.61		
Granted				
Exercised				
Canceled or expired	(470,004)	15.04		
Outstanding at December 31, 2008	96,789	18.28		
Granted	1,009,076	5.24		
Exercised				
Canceled or expired	(73,455)	20.96		
Outstanding at December 31, 2009	1,032,410	\$ 5.34	5.13	\$
Exercisable at December 31, 2009	23,334	\$ 9.86	0.16	\$

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

13. STOCK BASED COMPENSATION (Continued)

Restricted Stock

A summary of the status of the Company's non-vested restricted stock awards as of December 31, 2009 and changes during the two years ended December 31, 2009, is presented below:

Restricted Stock	Number Outstanding	Weighted Average Exercise Price
Non-vested stock awards outstanding at January 1, 2008	50,000	\$ 2.42
Granted	52,500	3.39
Vested	(29,667)	3.10
Forfeited		
Non-vested stock awards outstanding at December 31, 2008	72,839	2.84
Granted	67,100	3.09
Vested	(56,333)	2.78
Forfeited	(5,000)	3.39
Non-vested stock awards outstanding at December 31, 2009	78,599	3.06

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, 2009
Risk-free interest rate	1.21 to 2.82%	1.76 to 3.54%
Expected volatility	71.28%-77.17%	69%-71.33%
Expected life (in years)	2.7-6.3	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 2009 and 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 and non-vested restricted stock awards amounted to \$1.1 million and \$0.8 million for the years ended December 31, 2009 and 2008, respectively. No compensation cost related to share-based payments arrangements was capitalized as part of the cost of any asset at December 31, 2009 and 2008.

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

13. STOCK BASED COMPENSATION (Continued)

As of December 31, 2009, there was \$1.6 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. The weighted average grant-date fair values of the options granted during the years ended December 31, 2009 and 2008 were \$1.85 and \$4.80, 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, each right entitles their holders to purchase one ten-thousandth (1/10,000) of a share of our Series C Junior Participating Preferred Stock (the "Preferred Stock") at a price of \$66.90 per one ten-thousandth (1/10,000) share. 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 receive, upon the exercise of their rights and in lieu of the Preferred Stock, the number of shares of our Common Stock (or the number of shares of stock of any company into which we are merged) having a value equal to twice the exercise price of their rights in exchange for the \$66.90 exercise price. 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.

14. 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 in for the year ended December 31, 2009 and 2008 was \$83,742 and \$14,180, respectively and was made in Company stock.

15. LICENSES OF INTELLECTUAL PROPERTY AND PATENTS

On November 10, 1999, the Company entered into a license agreement with Duke University under which the Company received worldwide exclusive rights (subject to certain exceptions) to commercialize and use Duke's thermally sensitive liposome technology. The license agreement contains annual royalty and minimum payment provisions due on net sales. The agreement also required 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

Table of Contents

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2009 AND 2008

15. LICENSES OF INTELLECTUAL PROPERTY AND PATENTS (Continued)

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 for milestone based royalties under this license agreement. An amendment to the Duke license agreement contains certain development and regulatory milestones, and other performance requirements that the Company has met with respect to the use of the licensed technologies. The Company will be obligated to make royalty payments based on sales to Duke upon commercialization, until the last of the Duke patents expire. For the years ended December 31, 2009 and 2008, the Company has not incurred any expense under this agreement and will not incur any future liabilities until commercial sales commence.

Under the November 1999 license agreement with Duke, the Company has rights to the thermally sensitive liposome technology, including Duke's US patents covering the technology as well as all foreign counter parts and related pending applications. Foreign counterpart applications have been issued in Europe, Hong Kong and Australia, have been allowed in Canada and remain pending in Japan. The European patent has been validated in Austria, Belgium, France, Germany, Great Britain, Italy, Luxembourg, Monaco, Spain and Switzerland. In addition, the Duke license agreement provides the Company with rights to multiple issued and pending US patents related to the formulation and use of heat sensitive liposomes. The Company's rights under the license agreement with Duke University extend for the life of the last-to-expire of the licensed patents.

The Company has licensed from Valentis, CA certain global rights covering the use of pegylation for temperature sensitive liposomes.

In addition to the rights available to the Company under completed or pending license agreements, the Company is actively pursuing patent protection for technologies developed by the Company. Among these patents is a family of pending US and international patent applications which seek to protect the Company's proprietary method of storing ThermoDox® which is critical for world wide distribution channels.

ThermoDox® is a registered trademark in the United States, Australia, the European Communities: (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Korea, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, UK), Hong Kong, Japan, New Zealand, Peru, Singapore and Taiwan. The Company has registered transliterations of ThermoDox® in Japan, Singapore and Taiwan. In addition, the Company has filed for trademark protection for ThermoDox® in over twenty five additional countries world-wide.

Finally, through proprietary information agreements with employees, consultants and others, the Company seeks to protect its own proprietary know-how and trade secrets. The Company cannot offer assurances that these confidentiality 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

Table of Contents

CELSION CORPORATION
NOTES TO FINANCIAL STATEMENTS (Continued)
YEARS ENDED DECEMBER 31, 2009 AND 2008

15. LICENSES OF INTELLECTUAL PROPERTY AND PATENTS (Continued)

circumvented by third parties, or that the rights granted will provide the Company with adequate protection.

16. LICENSING AGREEMENT

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.

17. CONTINGENT LIABILITIES AND COMMITMENTS*Lease commitments*

Following is a summary of the future minimum payments required under leases that have initial or remaining lease terms of one year or more as of December 31, 2009:

	Capital Leases	Operating Leases
For the year ending December 31:		
2010	\$ 139,848	\$ 180,000
2011	139,848	
2012	58,270	
2013		
2014 and beyond		
Total minimum lease payments	337,996	\$ 180,000
Less amounts of lease payments that represent interest	49,766	
Present value of future minimum capital lease payments	288,200	
Less current obligations under capital leases	108,332	
Long-term capital lease obligations	\$ 179,868	

F-25
