Celsion CORP Form 10-K March 28, 2011

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2010

OR

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

For the transition period from

Commission file number 001-15911

#### **CELSION CORPORATION**

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE 52-1256615
(State or Other Jurisdiction of Incorporation or Organization) Identification No.)

10220-L OLD COLUMBIA ROAD
COLUMBIA, MARYLAND 21046
(Address of Principal Executive Offices)
21046-2364
(Zip Code)

to

(410) 290-5390 Registrant's Telephone Number, Including Area Code

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

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

Name of Each Exchange on Which Registered NASDAQ CAPITAL MARKET

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

None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes " No x

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

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

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate website, 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). (The Registrant is not yet required to submit Interactive Data) Yes "No"

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

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

Large Accelerated
Filer

Non-accelerated Filer

o (Do not check if a smaller reporting company)

Smaller Reporting Company x

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes "No x

As of June 30, 2010, the aggregate market value of the Common Stock held by non-affiliates of the Registrant was approximately \$39,649,964, based on the closing sale price for the Registrant's Common Stock on that date as reported by the NASDAQ Capital Market. For purposes of this calculation, shares of Common Stock held by directors and officers of the Registrant at June 30, 2010 were excluded.

As of March 25, 2011, 13,853,636 shares of the Registrant's Common Stock were issued and outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

None

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#### PART I

ITEM 1. BUSINESS

#### FORWARD-LOOKING STATEMENTS

Certain of the statements contained in this Annual Report on Form 10-K are forward-looking and constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, from time to time we may publish forward-looking statements relating to such matters as anticipated financial performance, business prospects, technological developments, new products, research and development activities and other aspects of our present and future business operations and similar matters that also constitute such forward-looking statements. These statements involve known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among other things, unforeseen changes in the course of research and development activities and in clinical trials; possible changes in cost and timing of development and testing, capital structure, and other financial items; changes in approaches to medical treatment; introduction of new products by others; possible acquisitions of other technologies, assets or businesses; possible actions by customers, suppliers, strategic partners, potential strategic partners, competitors and regulatory authorities, as well as those listed under "Risk Factors" below and elsewhere in this Annual Report on Form 10-K. In some cases, you can identify forward-looking statements by terminology such as "expect", "anticipate", "estimate", "plan", "believe" and words of similar import regarding 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.

Unless the context requires otherwise or unless otherwise noted, all references in this Annual Report on Form 10-K to "Celsion" and to the "Company". "we", "us", or "our" are to Celsion Corporation.

## **OVERVIEW**

Celsion Corporation is an innovative oncology drug development company focused on the development of therapeutics 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. The promise of this drug technology is to maximize efficacy while minimizing side effects common to cancer treatments.

Our lead product, ThermoDox®, is being evaluated in a Phase III clinical trial, which we refer to as the HEAT study, for primary liver cancer and a Phase I/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 (greater than 40 degrees Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in the region of the tumor target.

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. Our approach provides a comparatively cost effective, low risk approval pathway. Additionally, we have formed a joint research agreement with Phillips Healthcare to evaluate the combination of Phillips' high intensity focused ultrasound (HIFU) with ThermoDox® to determine the potential of this combination to treat a broad range of cancers.

For certain markets, we may seek licensing partners to share in the development and commercialization costs. We will also evaluate licensing cancer products from third parties for cancer treatments to expand our development pipeline.

In the fourth quarter of 2008, we entered into a Development, Product Supply and Commercialization Agreement with Yakult Honsha under which Yakult was granted the exclusive right to commercialize and market ThermoDox® for the Japanese market. We were paid a \$2.5 million up-front licensing fee and we have the potential to receive additional payments from Yakult upon receipt of marketing approval by the Japanese Ministry of Health, Labor and Welfare as well as upon the achievement of certain levels of sales and approval for new indications. We will receive double digit escalating royalties on the sale ThermoDox® in Japan, when and if any such sales occur. We also will be the exclusive supplier of ThermoDox® to Yakult.

Concurrent with a preferred equity financing in January 2011, the Company amended its Development, Product Supply and Commercialization Agreement with Yakult to provide for up to \$4.0 million in an accelerated partial payment to us of a future drug approval milestone. The terms of the agreement with Yakult provide for the payment to the Company of \$2.0 million upon the closing of the preferred equity financing and an additional \$2.0 million conditioned upon the resumption of enrollment of Japanese patients in the Japan cohort of the HEAT study. In consideration of these accelerated milestone payments from Yakult, we have agreed to reduce future drug approval milestone payments by approximately forty percent (40%). All other milestone payments are unaffected.

In 2005, the Company made a strategic decision to divest its medical device business. The Company sold this medical device 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. Since then, the Company has raised approximately \$15.4 million in equity financing providing a total of \$60 million to support its research and operations.

#### 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 University developed a heat-sensitive liposome which rapidly changes its structure when heated to a threshold minimum temperature of 40° to 42° Celsius. Heating creates channels in the liposome bilayer that allow an encapsulated drug to rapidly disperse into the surrounding tissue.

Celsion intends to use several 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.

Our heat-activated liposomes circulate within the tumor tissue and leaky tumor vessels vasculature. When heat is added locally, it causes the rapid release of the encapsulated chemotherapeutic agent directly within the targeted tumor.

Celsion's proprietary heat-activated liposome technology enables delivery of significantly higher concentrations of proven chemotherapy drugs directly to the tumor, stopping the progression of cancer and minimizing systemic toxicities. Currently in a Phase III clinical trial for primary liver cancer and a Phase I/II study for recurrent chest wall breast cancer, Celsion has completed animal studies that demonstrated intravenous administration of ThermoDox®, in combination with targeted heat to the tumor, can produce doxorubicin drug concentrations in tumor tissue that are much greater than existing approved liposomal formulations of doxorubicin on the market today.

#### Liver Cancer Overview

Primary liver cancer (hepatocellular carcinoma or "HCC") is one of the most common and deadliest forms of cancer worldwide. It ranks as the fifth most common solid tumor cancer. It is estimated that up to 90% of liver cancer patients will die within five years of diagnosis. The incidence of primary liver cancer is approximately 20,000 cases per year in the United States, approximately 40,000 cases per year in Europe and is rapidly growing worldwide at approximately 750,000 cases per year. 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).

At an early stage, the standard first line treatment for liver cancer is surgical resection 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, radio frequency ablation (RFA) has emerged 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 then 80° Celsius) to ablate the tumor, it may fail to treat micro-metastases in the outer margins of the ablation zone 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, we completed our 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, we 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 (The HEAT Study)

For primary liver cancer, ThermoDox® is being evaluated in a pivotal 600 patient double-blinded, placebo-controlled, global Phase III study (the "HEAT study") at 76 clinical sites under a Special Protocol Assessment ("SPA") agreement with the U.S. Food Drug Administration ("FDA"). The HEAT 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 76 clinical sites in the United States, Canada, Italy, China, Taiwan, Hong Kong, Korea, Japan, Thailand, Malaysia and the Philippines, with approximately 90% of the planned 600 patients now enrolled in the study. The primary endpoint for the study is progression free survival ("PFS") with a secondary confirmatory endpoint of overall survival. A pre-planned, unblinded interim efficacy analysis will be performed by an independent Data Monitoring Committee when enrollment in the HEAT study is complete and 190 PFS events are realized in the study population.

On October 1, 2010, we were advised that after reviewing data from 401 randomized patients enrolled in the HEAT study, the Data Monitoring Committee (the "DMC") for this trial unanimously recommended that the trial continue to enroll patients with the goal of reaching the 600 patients required to complete the study. The DMC, comprised of an independent group of medical and scientific experts, reviews study data at regular intervals to ensure the safety of all patients enrolled in the trial, the quality of the data collected, and the continued scientific validity of the trial design. In addition, the DMC has recommended, and confirmed such recommendation on November 24, 2010, a hold on enrollment of additional patients in this trial in Japan in accordance with the requirements of the DMC's charter pending review by the DMC of certain safety and efficacy data as required by the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan.

On February 9, 2011, after reviewing data from 482 randomized patients enrolled in our pivotal Phase III HEAT study, the DMC for this trial unanimously recommended that the trial continue to enroll patients at all clinical sites except for those in Japan with the goal of reaching the 600 patients required to complete the study. The DMC continues to review safety and efficacy data in accordance with the PMDA in Japan and the DMC's charter. We expect to complete patient enrollment in the HEAT study in mid-2011 with the interim analysis completed approximately 6 to 8 weeks later.

At this time, the Company is unable to determine what, if any, effects the catastrophic events resulting from the March 11, 2011 earthquake and Tsunami in Japan will have on the conduct or timeframe of the Phase III HEAT Trial or the DMC's review of safety and efficacy data. The HEAT study is designed, however, to be completed with or without Phase III data from Japan.

In August 2010, the FDA designated the HEAT Study of the Company's investigational drug, ThermoDox@, in combination with RFA, as a Fast Track Development Program. The FDA's Fast Track Development Program provides for expedited regulatory review for new drugs that treat serious or life threatening diseases which are not satisfactorily treated by existing therapies, or for drugs that provide a significant advantage over existing therapies for serious diseases. Under the Fast Track Designation, we are now eligible to submit a U.S. New Drug Application (NDA) on a rolling basis. This permits the FDA to review sections of the NDA in advance of receiving the complete submission.

We have received written guidance from the FDA stating that, assuming the results of our ongoing studies are adequate, we may submit our New Drug Application ("NDA") for ThermoDox® pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act. A 505(b)(2) NDA provides that some of the information from the reports required for marketing approval may come from studies that the applicant does not own or for which the applicant does not have a legal right of reference and permits a manufacturer to obtain marketing approval for a drug without needing to conduct or obtain a right of reference for all of the required studies. The availability of Section 505(b)(2) and the designation of ThermoDox® as a Fast Track Development Program will provide us with an expedited pathway to approval. There can be no assurance, however, that the results of our ongoing studies will be adequate to obtain approval of ThermoDox® under Section 505(b)(2).

In 2009, the FDA granted Orphan Drug Designation for ThermoDox® for the treatment of HCC. FDA's Orphan Drug Act provides economic incentives to encourage companies to develop drugs that demonstrate promise for the treatment of life-threatening or very serious conditions that are rare and affect less than 200,000 individuals in the U.S. Orphan drug designation entitles Celsion to seven years of market exclusivity following FDA approval, FDA assistance in clinical trial design, reduction in FDA user fees, U.S tax credits related to development expenses as well as the opportunity to apply funding from the U.S. government to defray costs of clinical trial expenses. In 2011, the European Commission granted Orphan Drug Designation for ThermoDox® for the treatment of HCC in Europe. As established by the European Medicine Agency ("EMA"), Orphan Drug Designation provides for scientific advice and regulatory assistance from the EMA, direct access to centralized marketing authorization and certain financial

incentives, such as reduction of fees associated with pre-authorization inspections and marketing authorization application fees. The Orphan Drug Designation in Europe also provides 10 years of market exclusivity subsequent to product approval.

#### THERMODOX® FOR RECURRENT CHEST WALL BREAST CANCER

Recurrent Chest Wall ("RCW") Breast Cancer Overview

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

#### Celsion's Approach

Since its inception, Celsion has been actively seeking a targeted localized treatment for breast cancer. ThermoDox® in conjunction with localized microwave hyperthermia is being developed to treat RCW breast cancer. Studies at Duke University and other centers have indicated that heat may improve the therapeutic action of non-temperature sensitive liposomal doxorubicin formulations in advanced loco-regional breast cancer. Celsion's liposomal encapsulated doxorubicin is released by heat generated from an external microwave tissue hyperthermia device that is placed on a woman's chest. The microwave hyperthermia heats the target to a temperature adequate to activate ThermoDox® but not to ablate the tissue like RFA. Upon heating to 40° to 42° C, a significant concentration of doxorubicin is released directly to the tumor. As in our 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. We expect 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 has completed enrollment of the Phase I portion (9 patients) of the study in 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.

#### PRODUCT FEASIBILITY

The Company has developed a stable heat activated liposomal formulation of docetaxel. The Company has also 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. In September 2010, we announced the award of a competitive Phase I Small Business Innovation and Research (SBIR) grant from the National Institutes of Health (NIH), to support the proposal, "New Thermal Sensitive Carboplatin Liposomes for Cancer". This funding will support the Company's efforts to develop its proprietary heat-activated liposomal technology in combination with carboplatin, an approved and frequently used oncology drug for treatment of a wide range of cancers. The grant is valued at approximately \$200,000 and will support formulation development and preclinical efficacy studies in collaboration with Duke University.

#### **BUSINESS STRATEGY**

An element of our business strategy is to pursue, as resources permit, the research and development of a range of product candidates for a variety of indications. This is intended to allow us to diversify the risks associated with our research and development expenditures. To the extent we are unable to maintain a broad range of product candidates, our dependence on the success of one or a few product candidates would increase.

Furthermore, our current business strategy includes the option of entering into collaborative arrangements with third parties to complete the development and commercialization of our product candidates. In the event that third parties take over the clinical trial process for one or more of our product candidates, the estimated completion date would largely be under the control of that third party rather than us. We cannot forecast with any degree of certainty which proprietary products or indications, if any, will be subject to future collaborative arrangements, in whole or in part, and how such arrangements would affect our development plan or capital requirements. Our programs may also benefit from subsidies, grants, or government or agency-sponsored studies that could reduce our development costs.

As a result of the uncertainties discussed above, among others, we are unable to estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our research and development projects in a timely manner or our failure to enter into collaborative agreements when appropriate could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our business strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

While our estimated future capital requirements are uncertain and could increase or decrease as a result of many factors, including the extent to which we choose to advance our research, development and clinical trials, or if we are in a position to pursue manufacturing, commercialization activities, it is clear we will need significant additional capital to develop our product candidates through clinical development, manufacturing, and commercialization. We do not know whether we will be able to access additional capital when needed or on terms favorable to us or our stockholders.

As a clinical stage biopharmaceutical company, our business and our ability to execute our strategy to achieve our corporate goals are subject to numerous risks and uncertainties. Material risks and uncertainties relating to our business and our industry are described under Part I, Item 1A – Risk Factors appearing in this Annual Report.

#### RESEARCH AND DEVELOPMENT EXPENDITURES

We are engaged in a limited amount of research and development in our own facilities and also sponsor 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. Research and development expenses were approximately \$14.7 million and \$13.7 million for the years ended December 31, 2010 and 2009, respectively. See Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operation for additional information regarding expenditures related to our research and development programs.

#### 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.

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. In 2007, the Company, with the support of the FDA, received a Special Protocol Assessment for its Phase III trial, having proceeded to this phase directly from Phase I assessment.

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 Designation for a product candidate. 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.

## 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 are also 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.

#### **COMPETITION**

Competition in the discovery and development of new methods for treating and preventing disease is intense. We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies both in the U.S. and abroad. We face significant competition from organizations pursuing the same or similar technologies used by us in our drug discovery efforts and from organizations developing pharmaceuticals that are competitive with our product candidates.

Most of our competitors, either alone or together with their collaborative partners, have substantially greater financial resources and larger research and development staffs than we do. In addition, most of these organizations, either alone or together with their collaborators, have significantly greater experience than we do in developing products, undertaking preclinical testing and clinical trials, obtaining FDA and other regulatory approvals of products, and manufacturing and marketing products. Mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated among our competitors. These companies, as well as academic institutions, governmental agencies, and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical and biotechnology field also depends on the status of our collaborations and on the continuing availability of capital to us.

#### 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, TRADEMARKS AND REGULATORY EXCLUSIVITY

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

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 2011, the European Commission granted Orphan Drug Designation for ThermoDox® for the treatment of HCC in Europe. As established by the European Medicine Agency ("EMA"), Orphan Drug Designation provides for scientific advice and regulatory assistance from the EMA, direct access to centralized marketing authorization and certain financial incentives, such as reduction of fees associated with pre-authorization inspections and marketing authorization application fees. The Orphan Drug Designation in Europe also provides 10 years of market exclusivity subsequent to product approval.

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.

#### **EMPLOYEES**

As of March 15, 2011, we employed 16 full-time employees. We also maintain active independent contractor relationships with various individuals, most of whom have month-to-month or annual consulting agreements. None of our employees are covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

#### **COMPANY INFORMATION**

Celsion was founded in 1982 and is a Delaware corporation. Our principal executive offices are located at 10220-L Old Columbia Road, Columbia, Maryland 21046. Our telephone numbers are (410) 290-5490 and (800) 262-0394. The Company's website is www.celsion.com.

#### **AVAILABLE INFORMATION**

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, the Company's website includes other items related to corporate governance matters, including, among other things, the Company's corporate governance principles, charters of various committees of the Board of Directors, and the Company's code of business conduct and ethics applicable to all employees, officers and directors. The Company intends to disclose on its internet website any amendments to or waivers from its code of business conduct and ethics as well as any amendments to its corporate governance principles or the charters of various committees of the Board of Directors. Copies of these documents may be obtained, free of charge, from the Company's website. In addition, copies of these documents 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 information available on or through our website is not a part of this Annual Report on Form 10-K and should not be relied upon.

#### RECENT EVENTS

#### Clinical Trials

On December 5, 2008, the Company entered into a Development, Product Supply and Commercialization Agreement for Thermodox® with Yakult Honsha Co. (the "Yakult Agreement") pursuant to which the Company granted to Yakult an exclusive license, solely in the Japanese market, to make, sell, import and use Thermodox® for the indications set forth in the Yakult Agreement in consideration of certain milestone and royalty payments, including an \$18 million milestone payment upon approval of Thermodox® by the Japanese Ministry of Health, Labor and Welfare for the treatment of primary liver cancer (the "Approval Milestone"). On January 11, 2011, the Company entered into an

amendment to the Yakult Agreement (the "Amendment") that provides for (i) a payment by Yakult to the Company of \$2 million that the Company received on January 12, 2011 in consideration of a partial reduction in the Approval Milestone, and (ii) if and when the DMC permits the resumption of patient enrollment in Japan for pivotal Phase III clinical study for ThermoDox®, a payment by Yakult to the Company of an additional \$2 million in consideration of an additional, partial reduction in the Approval Milestone. Assuming payment by Yakult of the \$4 million contemplated by the Amendment and the partial reductions in the Approval Milestone related thereto, the aggregate Approval Milestone that the Company may receive in the future will have been reduced by approximately forty percent (40%).

On February 9, 2011, after reviewing data from 482 randomized patients enrolled in our pivotal Phase III HEAT study, the DMC for this trial unanimously recommended that the trial continue to enroll patients at all clinical sites except for those in Japan with the goal of reaching the 600 patients required to complete the study. The DMC continues to review safety and efficacy data in accordance with the PMDA in Japan and the DMC's charter, however there can be no assurance that the DMC will permit resumption of patient enrollment in Japan or at all nor can there be any assurance that the Company will receive the second \$2 million payment from Yakult pursuant to the Amendment to the Yakult Agreement.

At this time, the Company is unable to determine what, if any, effect the catastrophic events resulting from the March 11, 2011 earthquake and Tsunami in Japan will have on the conduct or timeframe of the Phase III HEAT Trial or the DMC's review of safety and efficacy data.

### Liquidity and Capital Resources

On June 17, 2010, we entered into a financing arrangement, sometimes referred to as a committed equity line financing facility (the "CEFF"), with Small Cap Biotech Value, Ltd. (the "Purchaser") that provides that, upon the terms and subject to the conditions set forth therein, the Purchaser is committed to purchase up to \$15.0 million worth of our common stock over the 24-month term of the Purchase Agreement, up to a maximum of 2,404,434 shares, under certain specified conditions and limitations. As of March 22, 2011, we have sold 1,339,774 shares of our common stock to the Purchaser pursuant to the CEFF for aggregate net proceeds of \$3,073,328 including 583,132 shares that were sold on December 30, 2010 for aggregate net proceeds of \$1,125,670 and 275,855 shares that were sold on March 16, 2011 for aggregate net proceeds of \$588,793.

On January 12, 2011, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with a select group of institutional investors, including certain officers and directors of the Company, to sell up to 5,000 shares of 8% redeemable convertible preferred stock (the "Preferred Stock") with a stated value of \$1,000 and warrants (the "Included Warrants") to purchase up to 2,083,333 shares of common stock in a registered direct offering. The Preferred Stock and Included Warrants were sold in units (the "Units"), with each Unit consisting of one share of Preferred Stock and an Included Warrant to purchase up to 416.6666 shares of common stock at an exercise price of \$3.25 per whole share of common stock. The Units were sold to unaffiliated third party investors at a negotiated purchase price of \$1,000 per Unit and to officers and directors at an at-the-market price of \$1,197.92 per Unit in accordance with the NASDAQ Stock Market Rules. Each share of Preferred Stock is convertible into shares of common stock at an initial conversion price of \$2.40 per share, subject to adjustment in the event of stock splits, recapitalizations or reorganizations that affect all holders of common stock equally. The Company received gross proceeds from the offering of approximately \$5.1 million, before deducting placement agents' fees and estimated offering expenses. Concurrent with the issuance and sale of the Units, the Company issued a warrant (the "Placement Agent Warrant") to purchase up to 350 shares of Preferred Stock at an exercise price of \$1,000 per whole share of Preferred Stock to Dominick & Dominick LLC, as placement agent.

The Units were sold pursuant to the Company's shelf registration statement on Form S-3 (Registration No. 333-158402), which was declared effective by the SEC on April 17, 2009, as supplemented by prospectus supplements dated January 12, 2011 and January 13, 2011 filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

#### Director and Officer Equity Compensation Awards

On February 25, 2011, the Company's board of directors approved the recommendations and ratified the determinations of its compensation committee and granted stock options to all of the Company's executive officers and directors. Directors Dr. Max E. Link, Gregory Weaver, Dr. Augustine Chow, Robert W. Hooper and Dr. Alberto Martinez were awarded options to purchase 50,000, 50,000, 40,000, 40,000 and 15,000 shares of Common Stock respectively. Executive officers Michael H. Tardugno, Jeffrey W. Church, Dr. Nicholas Borys and Dr. Robert A. Reed were awarded options to purchase 180,000, 70,000, 70,000 and 70,000 shares of Common Stock respectively. All options granted have a 10 year term and vest equally over three years. Also, Jeffrey W. Church was granted 10,000 shares of Common Stock that vested immediately.

ITEM 1A. RISK FACTORS

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

#### RISKS RELATING TO OUR BUSINESS

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 \$100 million at December 31, 2010. For the year ended December 31, 2010 we incurred a net loss of \$18.4 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.

IF OUR PRODUCTS FAIL IN CLINICAL TRIALS, WE WILL BE UNABLE TO OBTAIN OR MAINTAIN FDA AND INTERNATIONAL REGULATORY APPROVALS AND WILL BE UNABLE TO SELL THOSE PRODUCTS.

To obtain regulatory approvals from the FDA and international regulatory agencies, we must conduct clinical trials demonstrating that our products are safe and effective. We may need to amend ongoing trials or the FDA and/or international regulatory agencies may require us to perform additional trials beyond those we planned. Such occurrences could result in significant delays and additional costs, and related clinical trials may be unsuccessful.

#### 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 PRODUCT CANDIDATES.

As of December 31, 2010, we had approximately \$1.5 million in cash and short term investments. 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-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.

OUR PRODUCTS COULD INFRINGE PATENT RIGHTS OF OTHERS, WHICH MAY REQUIRE COSTLY LITIGATION AND, IF WE ARE NOT SUCCESSFUL, COULD CAUSE US TO PAY SUBSTANTIAL DAMAGES OR LIMIT OUR ABILITY TO COMMERCIALIZE OUR PRODUCTS.

Our commercial success depends on our ability to operate without infringing the patents and other proprietary rights of third parties. There may be third party patents that relate to our products and technology. We may unintentionally infringe upon valid patent rights of third parties. Although we are currently not involved in any material litigation involving patents, a third party patent holder could assert a claim of patent infringement against us in the future. Alternatively, we may initiate litigation against the third party patent holder to request that a court declare that we are not infringing the third party's patent and/or that the third party's patent is invalid or unenforceable. If a claim of infringement is asserted against us and is successful, and therefore we are found to infringe, we could be required to pay damages for infringement, including treble damages if it is determined that we knew or became aware of such a patent and we failed to exercise due care in determining whether or not we infringed the patent. If we have supplied infringing products to third parties or have licensed third parties to manufacture, use or market infringing products, we may be obligated to indemnify these third parties for damages they may be required to pay to the patent holder and for any losses they may sustain. We can also be prevented from selling or commercializing any of our products that use the infringing technology in the future, unless we obtain a license from such third party. A license may not be available from such third party on commercially reasonable terms, or may not be available at all. Any modification to include a non-infringing technology may not be possible or if possible may be difficult or time-consuming to develop, and require revalidation, which could delay our ability to commercialize our products. Any infringement action asserted against us, even if we are ultimately successful in defending against such action, would likely delay the regulatory approval process of our products, harm our competitive position, be expensive and require the time and attention of our key management and technical personnel.

WE RELY ON THIRD PARTIES TO CONDUCT ALL OF OUR CLINICAL TRIALS. IF THESE THIRD PARTIES ARE UNABLE TO CARRY OUT THEIR CONTRACTUAL DUTIES IN A MANNER THAT IS CONSISTENT WITH OUR EXPECTATIONS, COMPLY WITH BUDGETS AND OTHER FINANCIAL OBLIGATIONS OR MEET EXPECTED DEADLINES, WE MAY NOT RECEIVE CERTAIN DEVELOPMENT MILESTONE PAYMENTS OR BE ABLE TO OBTAIN REGULATORY APPROVAL FOR OR COMMERCIALIZE OUR PRODUCT CANDIDATES IN A TIMELY OR COST-EFFECTIVE MANNER.

We currently have only 16 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 are unable to carry out their contractual duties or obligations in a manner that is

consistent with our expectations or meet expected deadlines, if they do not carry out the trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become prohibitively expensive, we may not receive development milestone payments when expected or at all, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. At this time, the Company is unable to determine what, if any, effect the catastrophic events resulting from the March 11, 2011 earthquake and Tsunami in Japan will have on the conduct or timeframe of clinical trials for our Phase III HEAT study at sites in Japan. In addition, enrollment of additional patients at clinical sites in Japan for our Phase III HEAT study is currently on hold pending the DMC's ongoing review of safety and efficacy data in accordance with the PMDA in Japan and the DMC's charter. A failure to resume patient enrollment at clinical trial sites in Japan could have a material adverse affect on our financial condition as the resumption of patient enrollment is a condition to our receipt of an accelerated \$2 million development milestone payment under our agreement with Yakult and is a mandatory conversion event of our 8% redeemable convertible preferred stock.

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.

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.

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations. There have been a number of government and private sector initiatives during the last few years to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements. 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. These actual and potential changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. In addition, uncertainty remains regarding proposed significant reforms to the U.S. healthcare system.

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 product candidates 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 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 business 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 million per incident and \$10 million annually. If we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim with our own limited resources, which could have a material adverse effect on our business. In addition, liability or alleged liability could harm the business by diverting the attention and resources of our management and by damaging our reputation.

#### RISKS RELATED TO OUR COMMON STOCK

THE MARKET PRICE OF OUR COMMON STOCK HAS BEEN, AND MAY CONTINUE TO BE VOLATILE AND FLUCTUATE SIGNIFICANTLY, WHICH COULD RESULT IN SUBSTANTIALLY LOSSES FOR INVESTORS AND SUBJECT US TO SECURITIES CLASS ACTION LITIGATION.

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 \$5.44 and a low price of \$2.01 in the 52-week period ending December 31, 2010. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this "Risk Factors" section and other factors, including:

fluctuations in our quarterly operating results or the operating results of our competitors;

variance in our financial performance from the expectations of investors;

changes in the estimation of the future size and growth rate of our markets;

changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results:

failure of our products to achieve or maintain market acceptance or commercial success;

conditions and trends in the markets we serve;

changes in general economic, industry and market conditions;

success of competitive products and services;

changes in market valuations or earnings of our competitors;

changes in our pricing policies or the pricing policies of our competitors;

announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;

changes in legislation or regulatory policies, practices, or actions;

the commencement or outcome of litigation involving our company, our general industry or both;

recruitment or departure of key personnel;

changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;

actual or expected sales of our common stock by our stockholders; and

the trading volume of our common stock.

In addition, the stock market in general, the NASDAQ Capital Market and the market for pharmaceutical companies in particular, may experience a loss of investor confidence. Such loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose us to securities class action litigation. Such litigation, even if unsuccessful, could be costly to defend and divert management's attention and resources, which could further materially harm our financial condition and results of operations.

#### THE ADVERSE CAPITAL AND CREDIT MARKET CONDITIONS COULD AFFECT OUR LIQUIDITY.

Adverse capital and credit market conditions could affect our ability to meet liquidity needs, as well as our access to capital and cost of capital. The capital and credit markets have been experiencing extreme volatility and disruption for more than 12 months. In recent months, the volatility and disruption have reached unprecedented levels and the markets have exerted downward pressure on availability of liquidity and credit capacity for certain issuers. For example, recently credit spreads have widened considerably. Our results of operations, financial condition, cash flows and capital position could be materially adversely affected by continued disruptions in the capital and credit markets.

# 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 Capital Market, 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.

# WE HAVE NOT PAID DIVIDENDS ON OUR COMMON STOCK IN THE PAST AND DO NOT INTEND TO DO SO FOR THE FORESEEABLE FUTURE.

We have never paid cash dividends on our Common Stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. As a result, the return on an investment in our Common Stock will depend entirely upon the future appreciation in the price of our Common Stock. Our stockholders cannot achieve any degree of liquidity with respect to their shares of Common Stock except by selling such shares.

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

## ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We currently lease 13,891 square feet for our corporate office, laboratory and workshop space located at 10220-L Old Columbia Road, Columbia, Maryland 21046-2391 from an unaffiliated party under a seven-year lease that expired on October 31, 2010. Rent expense for the year ended December 31, 2010 was \$0.3 million. The Company is currently renting this facility on a month-to-month basis as it investigates its options to either renew its current lease or relocate its operations to a new facility.

## ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

ITEM 4. (REMOVED AND RESERVED)

#### **PART II**

# ITEM MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND 5. ISSUER PURCHASES OF EQUITY SECURITIES

#### MARKET PRICE FOR OUR COMMON STOCK

Our Common Stock trades on the NASDAQ Capital Market under the symbol "CLSN". The following table sets forth the high and low closing sale prices for the periods indicated. The quotations set forth below do not include retail markups, markdowns or commissions.

	High	Low
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
YEAR ENDED DECEMBER 31, 2010		
First Quarter (January 1 – March 31, 2010)	\$4.69	\$2.76
Second Quarter (April 1 – June 30, 2010)	\$5.44	\$3.13
Third Quarter (July 1 – September 30, 2010)	\$3.42	\$2.97
Fourth Quarter (October 1 – December 31, 2010)	\$3.63	\$2.01

On March 24, 2011, the last reported sale price for our Common Stock on the NASDAQ Capital Market was \$2.38. As of March 24, 2011, there were approximately 10,900 stockholders of record of our Common Stock.

# **DIVIDEND POLICY**

We have never declared or paid and have no present intention to pay cash dividends on our Common Stock in the foreseeable future. We intend to retain any earnings for use in our business operations.

In January 2011, the Company entered into a definitive securities purchase agreement with a select group of institutional investors, including certain officers and directors of the Company, to sell 5,000 shares of 8% redeemable convertible preferred stock with a stated value of \$1,000 and warrants to purchase up to 2,083,333 shares of common stock in a registered direct offering. The convertible preferred stock and warrants were sold in units (the "Units"), with each Unit consisting of one share of convertible preferred stock and a warrant to purchase up to 416.6666 shares of common stock at an exercise price of \$3.25 per whole share of common stock. The Units were offered and sold to unaffiliated third party investors at a negotiated purchase price of \$1,000 per Unit and to officers and directors at an at-the-market price of \$1,197.92 per Unit in accordance with the NASDAQ Stock Market Rules. Each share of preferred stock is convertible into shares of common stock at an initial conversion price of \$2.40 per share, subject to adjustment in the event of stock splits, recapitalizations or reorganizations that affect all holders of common stock equally. The Company received gross proceeds from the offering of approximately \$5.1 million, before deducting placement agents' fees and estimated offering expenses.

The convertible preferred shares may be redeemed by the holders thereof at any time and have a mandatory redemption date of January 14, 2013. The convertible preferred shares are also subject to mandatory conversion upon the occurrence of certain events, including the sale of Common Stock in one or more offerings for not less than \$4.00 per share and aggregate gross proceeds of \$10 million, the achievement of a twenty day trading average of our

Common Stock above \$6.00 per share, or the receipt of an aggregate at least \$4,000,000 as actual, or advanced payment of future, license, milestone or royalty payments from a strategic, licensing or development partner. Until such time as preferred shares are redeemed, issued and outstanding shares shall accrued dividends at a rate of 8% per annum. Dividends on the convertible preferred shares are payable on a quarterly basis from the original issue date commencing on April 15, 2011 and are payable only in cash.

# SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

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

# UNREGISTERED SHARES OF EQUITY SECURITIES

All unregistered shares of equity securities have been previously reported by the Company in its Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

## ISSUER PURCHASES OF EQUITY SECURITIES

None.

ITEM 6. SELECTED FINANCIAL DATA

Not required.

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

The following discussions should be read in conjunction with our financial statements and related notes thereto included in this Annual Report on Form 10-K. The following discussion contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause actual results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those described under Part I, Item 1A – Risk Factors appearing in this Annual Report on Form 10-K and factors described in other cautionary statements, cautionary language and risk factors set forth in other documents that we file with the Securities and Exchange Commission. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

#### Overview

Celsion is an innovative oncology drug development company focused on the development of treatments 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. The promise of this drug technology is to maximize efficacy while minimizing side effects common to cancer treatments.

Our lead product ThermoDox® is being evaluated in a Phase III clinical trial, which we refer to as the HEAT study, for primary liver cancer and a Phase I/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 encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

# Significant Events

The Company entered into a Committed Equity Financing Facility ("CEFF") with Small Cap Biotech Value, Ltd "(SCBV") on June 17, 2010. The CEFF provides that, upon the terms and subject to the conditions set forth therein, SCBV is committed to purchase up to \$15.0 million worth of our shares of common stock over the 24-month term of the CEFF under certain specified conditions and limitations. For a more complete description of the CEFF, see Note 11 of the Financial Statements. As of March 22, 2011, we have sold 1,339,774 shares of our common stock to the Purchaser pursuant to the CEFF for aggregate net proceeds of \$3,073,328 including 583,132 shares that were sold on December 30, 2010 for aggregate net proceeds of \$1,125,670 and 275,855 shares that were sold on March 16, 2011 for aggregate net proceeds of \$588,793.

In November 2010, the Company was awarded a \$244,000 grant under the Qualifying Therapeutic Discovery Project (QTDP) program under The Patient Protection and Affordable Care Act of 2010 (PPACA). This maximum grant

amount for a single program was awarded to Celsion for its Thermodox® clinical development program, which is currently conducting clinical trials for primary liver cancer and recurrent chest wall breast cancer. The funds will be used for development expenses.

On January 12, 2011, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with a select group of institutional investors, including certain officers and directors of the Company, to sell up to 5,000 shares of 8% redeemable convertible preferred stock (the "Preferred Stock") with a stated value of \$1,000 and warrants (the "Included Warrants") to purchase up to 2,083,333 shares of common stock in a registered direct offering. The Preferred Stock and Included Warrants were sold in units (the "Units"), with each Unit consisting of one share of Preferred Stock and an Included Warrant to purchase up to 416.6666 shares of common stock at an exercise price of \$3.25 per whole share of common stock. The Units were sold to unaffiliated third party investors at a negotiated purchase price of \$1,000 per Unit and to officers and directors at an at-the-market price of \$1,197.92 per Unit in accordance with the NASDAQ Stock Market Rules. Each share of Preferred Stock is convertible into shares of common stock at an initial conversion price of \$2.40 per share, subject to adjustment in the event of stock splits, recapitalizations or reorganizations that affect all holders of common stock equally. The Company received gross proceeds from the offering of approximately \$5.1 million, before deducting placement agents' fees and estimated offering expenses. Concurrent with the issuance and sale of the Units, the Company issued a warrant (the "Placement Agent Warrant") to purchase up to 350 shares of Preferred Stock at an exercise price of \$1,000 per whole share of Preferred Stock to Dominick & Dominick LLC, as placement agent.

The Units were sold pursuant to the Company's shelf registration statement on Form S-3 (Registration No. 333-158402), which was declared effective by the Securities and Exchange Commission on April 17, 2009, as supplemented by prospectus supplements dated January 12, 2011 and January 13, 2011 filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

## 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 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,		
	2010	2009	
Risk-free interest rate	0.80 to 3.24%	1.21 to 2.82%	
Expected volatility	71.52% - 85.75%	71.28% - 77.17%	
Expected life (in years)	2.9-6.5	2.7-6.3	
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 2010 and 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 Fiscal Year Ended December 31, 2010 and Fiscal Year Ended December 31, 2009.

## Research and Development Expenses

Research and Development ("R&D") expenses increased to \$14.7 million in 2010 compared to \$13.7 million in 2009. Costs associated with the Company's Phase III liver cancer clinical trial increased to \$8.2 million in the 2010 compared to \$7.0 million in the same period of 2009. This increase is related to milestone payments, investigator grants and monitoring costs associated with the increase in patient enrollment in the HEAT study during 2010. Costs associated with the Company's recurrent chest wall breast cancer clinical trial (RCW) decreased to \$0.6 million in 2010 compared to \$1.2 million in 2009. During 2010, the Company managed the RCW trial utilizing internal resources compared to utilizing a contract resource organization in 2009. Costs associated with the production of Thermodox® trials increased slightly to \$2.9 million in 2010 compared to \$2.8 million in the same period of 2009 due to the replenishment of Thermodox® clinical supplies to all trial sites. Also included in these production costs are \$0.2 million associated with the acceleration of Company's commercial manufacturing strategy.

### General and Administrative Expenses

General and administrative expenses increased to \$4.9 million in 2010 compared to \$3.3 million in 2009. The increase is partially 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. The remaining difference is mostly attributable to non-cash stock option and stock award expense to employees, directors and consultants in 2010.

## Other income (expense)

The Company had other income of \$0.8 million in 2010 compared to \$1.8 million in 2009. In November 2010, the Company was awarded a \$244,000 grant under the Qualifying Therapeutic Discovery Project (QTDP) program under The Patient Protection and Affordable Care Act of 2010 (PPACA). This maximum grant amount for a single program was awarded to Celsion for its Thermodox® clinical development program, which is currently conducting clinical trials for primary liver cancer and recurrent chest wall breast cancer. In 2009, the Company wrote off a 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 common stock warrant liability

A common stock warrant liability was incurred as a result of warrants issued in a public offering in September 2009. This liability is calculated at its fair market value using the Black-Scholes option-pricing model and is adjusted at the end of each quarter. During 2010, the Company recorded a non-cash benefit of \$0.6 million based on the change in this fair value from the end of 2009. In 2009, the Company recorded a non-cash benefit of \$0.7 million based on the decrease in the fair value of the warrant liability from its inception in September 2009.

## Interest income and expense

Interest income and expense was not significant in 2010 and 2009.

#### 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 a refund of that tax pursuant to Revenue Procedure 2009-52 and recorded a tax benefit in that amount. This tax refund was received in 2010.

## Financial Condition, Liquidity and Capital Resources

Since inception, excluding the net aggregate payments from Boston Scientific of \$43 million (\$13 million in 2007 and \$15 million received in each of 2008 and 2009), we have incurred significant losses and negative cash flows from operations. We have financed our operations primarily through the sale of equity and through the divestiture of our medical device business in 2007. The process of developing and commercializing Thermodox® requires significant research and development work and clinical trial studies, as well as significant manufacturing and process development efforts. These activities, together with our general and administrative expenses are expected to result in significant operating losses for the foreseeable future. Our expenses have significantly and regularly exceeded our revenues, and we have an accumulated deficit of \$100 million at December 31, 2010.

At December 31, 2010 we had total current assets of \$2.0 million (including cash and short term investments of \$1.5 million) and current liabilities of \$6.8 million, resulting in a working capital shortage of \$4.8 million. 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.

Net cash used in operating activities for the 2010 was \$13.4 million. The Company's 2010 net loss included \$1.7 million in non-cash stock-based compensation expense and approximately \$2.5 million in accrued expenses associated with unbilled clinical trial costs and ThermoDox® manufacturing-related activities. The Company's 2010 cash flow was also favorably impacted by the receipt of an \$806,000 tax refund in the first quarter of 2010.

The \$13.4 million net cash requirement was mostly funded from cash and short term investments, refunds and other receivables totaling of \$14.0 million held at the beginning of the year and the receipt of a tax grant in the fourth quarter of 2010 totaling \$0.2 million. Net cash provided by financing activities was \$2.4 million for 2010 which related to proceeds provided by the utilization of the Committed Equity Financing Facility (as discussed in the next paragraph) partially offset by scheduled principal payments made on notes payable.

At December 31, 2010, the Company had cash, cash equivalents and short term investments of \$1.5 million. The Company will need substantial additional capital to complete its clinical trials, obtain marketing approvals and to commercialize its products. Since January 1, 2010, the Company completed the following transactions to address its future capital requirements:

Committed Equity Financing Facility - The Company entered into a Committed Equity Financing Facility ("CEFF") with Small Cap Biotech Value, Ltd "(SCBV") on June 17, 2010. The CEFF provides that, upon the terms and subject to the conditions set forth therein, SCBV is committed to purchase up to \$15.0 million worth of our shares of common stock over the 24-month term of the CEFF under certain specified conditions and limitations. For a more complete description of the CEFF, see Footnote 11 of the Financial Statements. As of March 22, 2011, we have sold 1,339,774 shares of our common stock to the Purchaser pursuant to the CEFF for aggregate net proceeds of \$3,073,328 including 583,132 shares that were sold on December 30, 2010 for aggregate net proceeds of \$1,125,670 and 275,855 shares that were sold on March 16, 2011 for aggregate net proceeds of \$588,793.

Qualifying Therapeutic Discovery Project - On November 1, 2010, the Company was awarded a \$244,000 grant under the Qualifying Therapeutic Discovery Project (QTDP) program under The Patient Protection and Affordable Care Act of 2010 (PPACA). This maximum grant amount for a single program was awarded to Celsion for its Thermodox® clinical development program, which is currently conducting clinical trials for primary liver cancer and recurrent chest wall breast cancer.

Equity Offering - In January 2011, the Company completed a registered offering of \$5.1 million of convertible preferred stock and common stock warrants. See Item 1. Business - "Recent Developments - Liquidity and Capital Resources."

Licensing Transaction - On January 11, 2011, the Company amended its Development, Product Supply and Commercialization Agreement for Thermodox® with Yakult Honsha Co. to provide for accelerated payment of up to \$4 million in future milestone payments, including \$2 million that was paid to the Company on January 12, 2011, in exchange for a 40% reduction in aggregate approval milestones that the Company may receive under the Yakult Agreement. See Item 1. Business - "Recent Developments - Clinical Trials."

We currently estimate we will use approximately \$15 to \$16 million of cash in 2011. Significant additional capital will be required in 2011 to develop our product candidates through clinical development, manufacturing, and commercialization. We may seek additional capital through further public or private equity offerings, debt financing, additional strategic alliance and licensing arrangements, collaborative arrangements, or some combination of these financing alternatives. If we are successful in raising additional funds through the issuance of equity securities, investors will likely experience dilution, or the equity securities may have rights, preferences, or privileges senior to those of the holders of our common stock. If we raise funds through the issuance of debt securities, those securities would have rights, preferences, and privileges senior to those of our common stock. If we seek strategic alliances, licenses, or other alternative arrangements, such as arrangements with collaborative partners or others, we may need to relinquish rights to certain of our existing or future technologies, product candidates, or products we would otherwise seek to develop or commercialize on our own, or to license the rights to our technologies, product candidates, or products on terms that are not favorable to us. The overall status of the economic climate could also result in the terms of any equity offering, debt financing, or alliance, license, or other arrangement being even less favorable to us and our stockholders than if the overall economic climate were stronger. We also will continue to look for

government sponsored research collaborations and grants to help offset future anticipated losses from operations and, to a lesser extent, interest income.

If adequate funds are not available through either the capital markets, strategic alliances, or collaborators, we may be required to delay or, reduce the scope of, or eliminate our research, development, clinical programs, manufacturing, or commercialization efforts, or effect additional changes to our facilities or personnel, or obtain funds through other arrangements that may require us to relinquish some of our assets or rights to certain of our existing or future technologies, product candidates, or products on terms not favorable to us.

Off-Balance Sheet Arrangements and Contractual Obligations

We have no off-balance sheet financing arrangements other than in connection with our operating leases, which are disclosed in the contractual commitments table in our Form 10-K for the year ended December 31, 2010.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Required.

#### ITEM 8.FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements, supplementary data and report of independent registered public accounting firm are filed as part of this report on pages F-2 through F-22 and incorporated herein by reference.

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

None.

#### ITEM 9A(T). CONTROLS AND PROCEDURES

#### (a) Disclosure 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, 2010, which is the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures are effective.

# (b) Management's Report on Internal Control Over Financial Reporting

The Company's management 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 a process designed by, or under the supervision of, the Company's chief executive officer and chief financial officer, or persons performing similar functions, and effected by the Company's board of directors, management and other personnel, 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.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2010. 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.

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

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 there cost.

# (c) Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting in the fiscal quarter ended December 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B.	OTHER INFORMATION
None.	
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#### **PART III**

# ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Set forth below is certain information regarding the Company's current directors and the Company's executive officers.

NAME	AGE	POSITION(S)
Max E. Link, Ph.D.	70	Chairman, Director
Michael H. Tardugno	60	President, Chief Executive Officer and Director
Gregory Weaver	54	Director
Augustine Chow, Ph.D.	58	Director
Robert W. Hooper	64	Director
Alberto R. Martinez, MD	61	Director
Jeffrey W. Church	54	Vice President and Chief Financial Officer
Nicholas Borys	51	Vice President and Chief Medical Officer
Robert A. Reed, Ph.D.	50	Vice President, CMC and Technological
		Operations
Timothy J. Tumminello	53	Controller & Chief Accounting Officer

Dr. Max E. Link. Dr. Link has served as a director of the Company since 1997 and has been the Chairman of the Board of Directors since October 2001. Dr. Link currently serves on the board of directors of a number of pharmaceutical and biotechnology companies. From 1993 to 1994, Dr. Link served as Chief Executive Officer of Corange, Ltd., a life science company that was subsequently acquired by Hoffman-LaRoche. From 1971 to 1993, Dr. Link served in numerous positions with Sandoz Pharma AG, culminating in his appointment as Chairman of their Board of Directors in 1992. From 2001 to 2003, Dr. Link served as Chairman and Chief Executive Officer of Centerpulse Ltd. Dr. Link currently serves on the Boards of Directors of Alexion Pharmaceuticals, Inc., Discovery Laboratories, Inc. and Cytrx Corporation. Dr. Link holds a Ph.D. in Economics from the University of St. Gallen (Switzerland).

Mr. Gregory Weaver. Mr. Weaver has been a director of the Company since 2005. Mr. Weaver served as Poniard Pharmaceuticals' Chief Financial Officer and Senior Vice President from August 2009 to August 2010. Prior to joining Poniard, a public oncology drug development company, Mr. Weaver served as Chief Financial Officer of Talyst, Inc., a privately-held pharmacy information product company, from 2007 to 2008. Prior to that, he served as Senior Vice President and Chief Financial Officer of Sirna Therapeutics, a public RNAI therapeutics company until the sale of the company to Merck, Inc. in 2006. From 2002 to 2005, Mr. Weaver was Chief Financial Officer and Corporate Secretary of Nastech Pharmaceuticals, a public drug delivery company. From 1999 to 2002, Mr. Weaver was Chief Financial Officer of Ilex Oncology Inc., a public cancer drug development company, and from 1996 to 1998, he was Chief Financial Officer of Prism Technologies, a privately-held medical device manufacturer. In addition, Mr. Weaver held increasingly senior positions with Fidelity Capital in Boston and Arthur Andersen LLP. Mr. Weaver has also served as a Director and Chairman of the Audit Committee of SCOLR Pharmaceuticals, a public drug delivery company from 2007 to 2009. Mr. Weaver is a certified public accountant and received his MBA from Boston College and his B.S. in accounting from Trinity University.

Dr. Augustine Chow. Dr. Augustine Chow was appointed to the Board of Directors in March 2007. Dr. Chow has served as the Chief Executive Officer of Harmony Asset Limited since 1996, a publicly listed investment company specializing in China and Hong Kong. From 1990 to 1998, Dr. Chow was the Chief Executive Officer of Allied Group of Companies based in Hong Kong. Prior to this, Dr. Chow held increasingly senior positions with Brunswick Corporation and Outboard Marine Corporation. Dr. Chow has held numerous directorships of listed and non-listed

companies, principally in Hong Kong, China and the United Kingdom. He has also participated and managed over fifty direct investments in China. Dr. Chow holds a M.Sc. from London Business School, a Ph.D. in Transfer of Technology from the University of South Australia, a DBA in Internet Research from Southern Cross University, and an Engineering Doctorate in Commercialization of Radical Innovation from the City University of Hong Kong.

Mr. Robert W. Hooper. Mr. Hooper has served as a director of the Company since July 2010. He is currently President of Crows Nest Ventures, Inc. a privately held company, and provides advisory and consulting services to the healthcare industry. From 1997 to 2001, Mr. Hooper served as President North America for IMS Health, a publicly traded healthcare information and market research company. From 1993 to 1997, he served as President of Abbott Laboratories Canada. From 1989 to 1993, he served as Managing Director, Australia/Asia for Abbott Laboratories. Prior to that, he held increasingly senior positions at E.R. Squibb and Sterling Winthrop Labs. Mr. Hooper holds a B.A degree in Biology from Wilkes University.

Dr. Alberto R. Martinez. Dr. Martinez joined Celsion's Board of Directors effective December 6, 2010. He is currently a consultant to the healthcare industry. From 2007 to 2008, Dr. Martinez served as the President and Chief Operating Officer of Talecris Biotherapeutics, Inc., a publicly traded life science company. Prior to that, Dr. Martinez served as Talecris' President and Chief Executive Officer from October 2005 until June 2007. Prior to that, he held increasingly senior positions as Executive Vice President of Worldwide Commercial Operations at ZLB Behring (subsequently renamed CSL Behring). Prior to his work with ZLB Behring, Dr. Martinez served in various international positions at Sandoz Pharmaceutical (today Novartis) in Brazil, Switzerland, Spain and the U.S. for eighteen years. Dr. Martinez completed his undergraduate and graduate studies at the University of Sao Paulo and received his medical degree from the University of Sao Paulo in 1973. After completing his residency in Pediatrics in 1975, he studied Business and Marketing Administration at the Foundation Getulio Vargaas of the University of Sao Paulo.

# **Executive Officers**

Following are the biographical summaries for each of the Company's executive officers. Each executive officer is elected by, and serves at the pleasure of the Board of Directors.

Mr. Michael H. Tardugno. Mr. Tardugno was appointed President and Chief Executive Officer of the Company on January 3, 2007 and was elected to the Board of Directors on January 22, 2007. Prior to joining the Company and for the period from February 2005 to December 2006, Mr. Tardugno served as Senior Vice President and General Manager of Mylan Technologies, Inc., a subsidiary of Mylan Laboratories. Before Mylan, from 1998 to 2005, Mr. Tardugno was Executive Vice President of Songbird Hearing, Inc. From 1996 to 1998, he was Senior Vice President of Technical Operations for Bristol-Myers Squibb, and from 1977 to 1995, he held increasingly senior executive positions with Bausch & Lomb and Abbott Laboratories. Mr. Tardugno holds a B.S. degree in Biology from St. Bonaventure University and completed the Harvard Business School, Program for Management Development.

Dr. Nicholas Borys. Dr. Borys joined Celsion on October 1, 2007 as Vice President and Chief Medical Officer of the Company. In this position, Dr. Borys manages the clinical development program for Celsion. Dr. Borys has accumulated extensive experience in all phases of pharmaceutical development with a focus in oncology. Immediately prior to joining Celsion, Dr. Borys served as Chief Medical Officer of Molecular Insight Pharmaceuticals, Inc., a molecular imaging and nuclear oncology pharmaceutical start-up company, from 2004 until 2007. From 2002 until 2004 he served as the Vice President and Chief Medical Officer of Taiho Pharma USA, a Japanese start-up oncology therapeutics company. Prior to that he held increasingly senior positions at Cytogen Corporation, Anthra Pharmaceuticals, Inc., Amersham Healthcare, Inc. and Hoffmann La-Roche Inc. Dr. Borys attended Rutgers University and holds an M.D. Degree from American University of the Caribbean.

Mr. Jeffrey W. Church. Mr. Church joined Celsion in July 2011 as Vice President, Chief Financial Officer and Corporate Secretary. In this position Mr. Church manages the financial, accounting and administrative operations for Celsion. Mr. Church has extensive experience in financial and accounting operations in both private and public life science and medical device companies. Immediately prior to joining Celsion, Mr. Church served as Chief Financial Officer and Corporate Secretary of Alba Therapeutics Corporation, a privately held life science company from 2007 until 2010. From 2006 until 2007, he served as Vice President, CFO and Corporate Secretary for Novavax, Inc., a publicly traded vaccine development company. From 1998 until 2006, he served as Vice President, CFO and Corporate Secretary for GenVec, Inc., a publicly traded life science and biotechnology company. Prior to that, he held senior financial positions at BioSpherics Corporation and Meridian Medical Technologies, both publicly traded companies. He started his career in the Baltimore office of Price Waterhouse from 1979 until 1986. Mr. Church holds a B.S. degree in accounting from the University of Maryland and is a certified public accountant.

Robert A. Reed, Ph.D. Dr. Reed joined Celsion on May 11, 2009 as Executive Director, CMC and Technological Operations. In this position Dr. Reed oversees the CMC, QA and Technological Operations functions for Celsion. On February 25, 2011, Dr. Reed was appointed as Vice President, CMC and Technological Operations. Prior to joining Celsion, Dr. Reed was Vice President, Pharmaceutical Operations at XenoPort, Inc., has 20+ years of experience & responsibility across XenoPort, Inc, 2006 to 2009, Merck & Company, Inc., 1993 to 2005, and The Liposome Company, Inc., 1990 to 1993, with extensive scientific and regulatory experience in the design and development of pharmaceutical products. He holds a Ph.D. in Analytical Chemistry from The University of North Carolina at Chapel Hill and was the recipient of a 3 year NIH Postdoctoral Individual Award at Princeton University.

Mr. Timothy J. Tumminello. Mr. Tumminello joined Celsion as Assistant Controller in April, 2009 and was appointed as the Company's Controller and Interim Chief Accounting Officer on January 6, 2010. At the time of Mr. Church's appointment as Chief Financial Officer in July 2010, Mr. Tumminello was named the Chief Accounting Officer. Prior to Celsion, Mr. Tumminello was employed by IC Isaacs & Company, Inc., a publicly traded company, from 1997 to 2009 and held various positions during his tenure that included serving as Vice President, Controller and Principal Financial Officer. Mr. Tumminello was employed in the Baltimore office of Deloitte & Touche LLP from 1991 until 1997.

#### **AUDIT COMMITTEE**

The Board of Directors has an Audit Committee consisting of Gregory Weaver, chairman, and Dr. Max Link and Dr. Augustine Chow. The Audit Committee operates under a written charter as amended and restated effective May 4, 2007. A copy of the charter is available on our web site, located at http://www.celsion.com. Additional copies of the charter are available upon written request to the Company. All members of the Audit Committee meet the independence standards established by the SEC and NASDAQ.

The Audit Committee assists the Board in fulfilling its responsibility to oversee management's implementation of the Company's financial reporting process. In discharging its oversight role, the Audit Committee reviewed and discussed the audited financial statements contained in the Company's 2010 Annual Report on Form 10-K with the Company's management and the Company's independent registered public accounting firm. Management is responsible for the financial statements and the reporting process, including the system of internal controls. The Company's independent registered public accounting firm is responsible for expressing an opinion on the conformity of those financial statements with accounting principles generally accepted in the United States.

The Board of Directors has determined that Mr. Gregory Weaver is qualified to serve as the "audit committee financial expert" as defined by Item 407(d)(5) of Regulation S-K and that Drs. Link and Chow meet the financial literacy requirements under applicable NASDAQ rules.

### STOCKHOLDER RECOMMENDATION PROCESS

The Nominating and Governance Committee will consider director candidates recommended by stockholders, provided that the stockholder making the recommendation follows the procedure set forth below. Stockholder recommendations should be submitted to the Company in writing, as follows:

Corporate Secretary Celsion Corporation 10220-L Old Columbia Road Columbia, Maryland 21046

Suggestions received by the Corporate Secretary before December 3, 2010 will be considered by the Nominating and Governance Committee for nomination and election at the 2011 annual meeting of stockholders.

A stockholder's notice to the Corporate Secretary must set forth:

- a) as to each stockholder-proposed nominee:
- i) the name, age, business address and residence address of the nominee;
  - ii) the principal occupation or employment of the nominee;
- iii) an undertaking to provide a completed director's and officer's questionnaire in the form required by the Company within two weeks of the submission:
  - iv) a statement as to the nominee's citizenship; and
- v) any other information relating to the nominee that is required to be disclosed in solicitations for proxies for election of directors pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated

thereunder; and

- b) as to the stockholder giving the notice:
- i) the name and record address of the stockholder; and
- ii) the number of shares of Common Stock that the stockholder beneficially owns.

The Company or the Nominating and Governance Committee may require a stockholder who proposes a nominee to furnish such other information as may reasonably be required by the Company to determine the eligibility or suitability of the proposed nominee to serve as director of the Company. Finally, among candidates who meet the foregoing criteria, the Nominating and Governance Committee also considers the Company's current and anticipated needs, including expertise, diversity and balance of inside, outside and independent directors.

#### **REVISIONS TO PROCESS**

The Nominating and Governance Committee and stockholder recommendation processes have been developed to provide a flexible framework to permit the director nomination process to move forward effectively. The Nominating and Governance Committee intends to review these processes from time to time in light of the Company's evolving needs and changing circumstances, as well as changes in legal requirements and stock exchange listing standards. The Nominating and Governance Committee may revise these processes or adopt new ones based on such periodic reviews.

#### STOCKHOLDER COMMUNICATIONS

The Board of Directors has adopted a process through which interested stockholders may communicate with the Board of Directors. Stockholders who wish to send communications to the Board of Directors, or any particular director, should address such communications to the Corporate Secretary, at the Company's headquarters in Columbia, Maryland. The envelope containing any such communication should be prominently marked "To the Attention of the Board of Directors" or to a particular committee or director, and the communication should include a representation from the stockholder indicating the stockholder's address and the number of shares of the Company's Common Stock beneficially owned by the stockholder. Our Corporate Secretary is primarily responsible for monitoring communications from stockholders. Depending upon the content of a particular communication, as he deems appropriate, our Corporate Secretary will: (i) forward the communication to the director, directors or committee to whom it is addressed; (ii) attempt to handle the inquiry directly, for example where it is a request for information about the Company or it is a stock-related matter; or (iii) not forward communications such as solicitations, junk mail and obviously frivolous or inappropriate communications. At each meeting of the Board of Directors, the Corporate Secretary will present a summary of all communications, whether or not forwarded, received since the last meeting and will make those communications available to the directors on request.

# SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires the Company's executive officers and directors and persons who own more than 10% of a registered class of our equity securities to file reports regarding ownership and changes in ownership of such equity securities with the SEC. Executive officers, directors and greater than 10% stockholders are required by SEC regulations to furnish to us copies of all reports that they file pursuant to Section 16(a). Subject to the following sentence, based solely on our review of the copies of such forms furnished between January 1, 2010 and December 31, 2010, or with respect to our fiscal year ended December 31, 2010, and on our discussions with directors and executive officers, we believe that, during the fiscal year ended December 31, 2010, all applicable Section 16(a) filing requirements were met.

# **CODE OF ETHICS**

The Company has adopted a Code of Ethics and Business Conduct applicable to its directors, officers (including its Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and other officers performing similar functions) and employees. This Code of Ethics constitutes a code of ethics applicable to senior financial officers within the meaning of the Sarbanes-Oxley Act of 2002 and SEC rules. A copy of the Code of Ethics and Business Conduct is available on the Company's website at http://www.celsion.com and any stockholder may obtain a copy by making a written request to the Company's Corporate Secretary, 10220-L Old Columbia Road, Columbia, MD 21046. In the event of any amendments to or waivers of the terms of the Code of Ethics, such matters will be posted promptly to the Company's website.

#### ITEM 11.

#### **EXECUTIVE COMPENSATION**

#### 2010 SUMMARY COMPENSATION TABLE

The following table sets forth the aggregate cash and other compensation paid, for the year ended December 31, 2010, to the Company's Chief Executive Officer and each of its other executive officers whose annual salary and non-equity incentive compensation for the fiscal year ended December 31, 2010 exceeded \$100,000 (the "Named Executive Officers").

Name and Principal Position	Year	Salary (\$)	Stock Awards (\$)	Option Awards (\$) (1)	Bonus (\$) (2)	401(k) Stock Match (3)	All Other Compensation	Total (\$)
Michael H. Tardugno (4) President and Chief	2010	\$ 360,500	\$51,191	\$ 265,436	\$121,405	\$ 9,775	\$45,000	\$853,307
Executive Officer	2009	359,693	72,000	131,840	51,191	11,281	<u>-</u>	626,005
Nicholas Borys(5) Vice President and Chief	2010	295,050	22,159	79,487	57,240	7,615	23,831	485,382
Medical Officer	2009	293,975	14,400	61,525	22,158	8,567	24738	425,363
Jeffrey W. Church(6) Vice President and Chief Financial Officer	2010	119,231	84,750	248,617	30,500	-	-	483,098
	2010	100.000	10.002	10.260	20 214	( 240	2.750	265 675
Robert A. Reed (7) Vice President, CMC and	2010	198,000	ŕ	19,369	38,314	6,240		265,675
Technological Operations	2009	125,654	30,373	53,634	10,000	860	2,702	223,225

<sup>(1)</sup> The value reported for Stock and Option Awards is the aggregate grant date fair value of restricted stock awards granted to the named executive officers in the years shown, determined in accordance with FASB ASC Topic 718, disregarding adjustments for forfeiture assumptions. The assumptions for making the valuation determinations are set forth in the Note 12 in the financial statements.

<sup>(2)</sup>Bonuses for 2010 were paid during the first quarter of 2011, in respect of 2010 performance and non-equity incentive compensation plan awards for 2009 were paid during the first quarter of 2010, in respect of 2009 performance.

<sup>(3)</sup> The Company has a 401(k) plan whereby it matches 50% up to 6% an employee contributes from their salary. The Company's matching contribution is made in Celsion common stock.

<sup>(4)</sup> Mr. Tardugno's other compensation for 2010 consists of a \$45,000 temporary living allowance.

<sup>(5)</sup> Dr. Borys' other compensation for 2010 and 2009 consists of a temporary living allowance of \$23,831 and \$24,738, respectfully.

- (6)Mr. Church joined Celsion in July 2010 as Vice President, Chief Financial Officer and Corporate Secretary. Mr. Church's base salary is \$250,000 per year.
- (7)Dr. Reed joined Celsion in May 2010 as Executive Director, CMC and Technological Operations. In February 2011, Dr. Reed was made Vice President, CMC and Technological Operations. Dr. Reed's base salary is \$198,000 per year. Dr. Reed's other compensation for 2010 and 2009 consists of a temporary living allowance of \$3,750 and \$2,702, respectfully.

## NARRATIVE DISCLOSURE TO SUMMARY COMPENSATION TABLE

## **Employment Agreements**

The Company and Mr. Tardugno entered into an employment agreement, effective March 1, 2009, which superseded the previous employment agreement with Mr. Tardugno and pursuant to which Mr. Tardugno continues to serve as our President and Chief Executive Officer. Subject to earlier termination pursuant to the terms of the agreement, the initial term of the agreement shall end on January 1, 2013, with automatic one (1) year renewals thereafter, unless either party provides a notice of non-renewal. Mr. Tardugno's employment agreement provides for an initial annual base salary of \$360,500, subject to annual adjustment by the Board of Directors of the Company or the Compensation Committee (the "Base Salary").

Mr. Tardugno is also eligible for an annual performance bonus from the Company, pursuant to the Company's management incentive bonus program, or policy or practice of the Board or its Compensation Committee, in effect from time to time. The amount of such bonus will be determined by the Board or its Compensation Committee in its sole and absolute discretion and will not exceed 70% of the then-current Base Salary except pursuant to a specific finding by the Board or its Compensation Committee that a higher percentage is appropriate. Under the Agreement, the Company agreed to grant to Mr. Tardugno, at the time of its usual annual grant to employees, annual stock options to purchase shares of the Company's common stock as the Board or its Compensation Committee shall determine.

In the event, (A) that the Company terminates the agreement other than for "cause" (as defined in the agreement) or (B) Mr. Tardugno terminates the agreement upon the occurrence of: (i) a material adverse change in his duties or authority; (ii) a situation in which he is no longer at least one of the President or the Chief Executive Officer of the Company; (iii) a bankruptcy filing or similar action by or against the Company; or (iv) another material breach of the Agreement by the Company (each, a "Triggering Event"), Mr. Tardugno will be entitled to receive a severance payment equal to his base annual salary at the time of termination (the "Reference Amount"), payable in accordance with the Company's normal payroll practices and may exercise any vested options within one (1) year of his termination date, after which time any unexercised options shall be forfeited.

In the event of termination of his employment upon a Triggering Event within two years following a "change in control" (as described below), or, if within such two-year period (i) there is a material adverse change in his compensation or benefits, or (ii) any successor to the Company does not assume the Company's obligation under the agreement, and he terminates his employment, Mr. Tardugno is entitled to a lump sum severance payment equal to the Reference Amount and any previously unvested options granted to Mr. Tardugno and covered by the employment agreement shall immediately vest and become and remain fully exercisable through their original terms and otherwise in accordance with their respective original terms. The agreement also provides that such severance is payable following a change in control if Mr. Tardugno elects to terminate his employment for any reason or no reason commencing with the sixth and ending with the twelfth month following the change in control. Under the agreement, a "change in control" is deemed to occur: (i) if any person becomes the direct or indirect beneficial owner of more than 50% of the combined voting power of the Company's then-outstanding securities; (ii) there is a change in a majority of the directors in office during any twenty-four (24) month period; (iii) the Company engages in a recapitalization, reorganization, merger, consolidation or similar transaction after which the holders of the Company's voting securities before the transaction do not continue to hold at least 50% of the voting securities of the Company or its successor after the transaction; or (iv) upon the complete liquidation or dissolution of the Company or the sale or other disposition of substantially all of its assets after which the holders of the Company's voting securities before such sale or disposition do not continue to hold at least 50% of the voting securities of the Company or its successor after such sale or disposition.

In the event that Mr. Tardugno is terminated for cause or is receiving severance payments contemplated under the employment agreement, Mr. Tardugno shall, among other things, not provide any services, directly or indirectly, to any other business or commercial entity in the Company's "Field of Interest" (as such term is defined in his employment agreement), solicit any customers or suppliers of the Company, directly or indirectly, or employ or seek to employ an employee of the Company for a period of two years following the date of termination. In addition, at no time during the term of the employment agreement or thereafter will Mr. Tardugno knowingly make any written or oral untrue statement that disparages the Company in communications with any customer, client or the public. Mr. Tardugno is also subject to confidentiality provisions in his employment agreement.

The Company and Dr. Borys entered into an employment offer letter on August 23, 2007, pursuant to which Dr. Borys agreed to serve as the Vice President and Chief Medical Officer of the Company. Under the terms of the offer letter, the Company agreed to pay Dr. Borys an annual starting salary of \$270,000, subject to annual review. Dr. Borys is also eligible for an annual bonus, with a target of 35% of his annual base salary, conditioned on his and the Company's

performance against key performance objectives, and annual discretionary stock option awards. The Company also agreed to provide Dr. Borys with a monthly housing allowance of \$2,000 (subject to actual housing costs) for the first 18 months of employment or a relocation allowance, if Dr. Borys chose to relocate to the Columbia, Maryland area. Dr. Borys' employment with the Company is "at-will".

In connection with Mr. Church's appointment as Vice President and CFO, the Company and Mr. Church entered into an employment offer letter signed by Mr. Church on June 15, 2010 (the "Offer Letter"). Pursuant to the Offer Letter, Mr. Church will receive a starting base salary of \$250,000 and will be eligible for an annual bonus, with a target of 35% of his annual base salary, conditioned on his and the Company's performance against key business objectives.

Mr. Church received a grant of options to purchase 100,000 shares of the Company's Common Stock (the "Option Grant") at a price equal to the closing price on NASDAQ on the day the Board approved the Option Grant, which will vest in quarters over four years on January 1, 2011 and annually thereafter. Mr. Church will also be considered for a discretionary stock option award in 2011 and annually thereafter. Mr. Church also received a grant of 25,000 shares of the Company's Common Stock, which will vest in thirds over 3 years with the first vesting date on July 1, 2010 and annually thereafter. Mr. Church's employment will be "at-will"; however, if the Company terminates Mr. Church for any reason other than just cause, the Company will pay Mr. Church a salary continuation and COBRA payment benefit for up to three months. The salary and benefit payments will cease at the end of the three month period or if he finds new employment prior to the three month period, the benefit will be reduced by the amount of compensation which he will receive from the new employer.

The Company and Dr. Reed entered into an employment offer letter on April 30, 2009, pursuant to which Dr. Reed agreed to serve as the Executive Director, CMC and Technological Operations of the Company. Under the terms of the offer letter, the Company agreed to pay Dr. Reed an annual starting salary of \$198,000, subject to annual review. Dr. Reed is also eligible for an annual bonus, with a target of 25% of his annual base salary, conditioned on his and the Company's performance against key performance objectives, and annual discretionary stock option awards. Dr. Reed's employment with the Company is "at-will". In February 2011, Dr Reed was appointed as Vice President, CMC and Technological Operations of the Company.

## Material Terms of Option Grants and Grants of Restricted Stock

Mr. Tardugno was issued an option to purchase 75,000 shares of Common Stock on February 19, 2010 at an exercise price of \$2.94 per share. This option vests over three years. Dr. Borys was issued an option to purchase 40,000 shares of Common Stock on February 19, 2010 at an exercise price of \$2.94 per share. This option vests over three years. Mr. Church was issued an option to purchase 100,000 shares of Common Stock on July 6, 2010 at an exercise price of \$3.39 per share. This option vests in quarters starting January 1, 2011 and three years annually thereafter. Dr. Reed was issued an option to purchase 25,000 shares of Common Stock on February 19, 2010 at an exercise price of \$2.94 per share. This option vests over three years.

Mr. Tardugno was issued a stock grant for 17,412 shares on February 19, 2010. Dr. Borys was issued a stock grant for 7,537 shares on February 19, 2010. Dr. Reed was issued a stock grant for 3,402 shares on February 19, 2010. Mr. Tadugno's and Dr. Borys' grants vested immediately. Mr. Church was issued a stock grant for 25,000 shares on July 6, 2010. Mr. Church's grants vested in thirds starting on the grant date and annually thereafter.

# Material Terms of Non-Equity Incentive Awards

The Company has an incentive compensation plan in which all members of senior management participate. The plan is performance driven based on objectives that are established annually by mutual agreement of management and the Compensation Committee. The objectives are operational in nature and include completion of development projects, fund raising, cost controls, business development and profit and loss goals. They may from time to time include share price objectives, however, as all of the operating objectives are ultimately directed at creating shareholder value. The objectives are designed to achieve timely and efficient product development including completion of clinical studies and regulatory approvals. Executives are individually evaluated for their contribution to the Company's achievement of these objectives. Payouts under this plan, which can be as high as 70% of the base salary for the C.E.O., can be in cash and/or equity awards with various vesting provisions. This component of compensation is provided, among other reasons, to create incentives for executives to meet short and medium term performance goals of the Company, without regard to the stock price. Objectives are weighted in terms of overall importance to meeting the Company's operating plan and the amount of the reward is determined on a sliding scale dependent on the achievement of objectives and the relative importance of the objectives achieved.

Pursuant to his employment agreement, Mr. Tardugno is eligible for annual non-equity incentive compensation targeted at 70% of his base salary amount. On March 4, 2011, Mr. Tardugno received an annual bonus payment \$103,000 representing 28.6% of his base salary, which was based on his and the Company's performance in 2010. For 2010, Mr. Tardugno's incentive compensation was based upon four major company objectives that were as follows: progress in patient enrollment for the primary liver clinical trial, commencement of a recurrent chest wall breast cancer clinical trial, ensure reliability and scalability of Thermodox manufacturing process, and various financial and management initiatives. Mr. Tardugno received \$18,405 under a one time incentive to broaden the Phase III Heat Study into certain target countries.

Dr. Borys is eligible for a non-equity incentive compensation targeted at 35% of his base salary. On March 4, 2011, Dr. Borys received an annual bonus of \$57,240, representing 19.4% of his base salary amount, which was based on his and the Company's performance for 2010. For 2010, Dr. Borys' incentive compensation was based upon four major company objectives that were as follows: progress in patient enrollment for the primary liver clinical trial, commencement of the recurrent chest wall breast cancer clinical trial, development of product pipeline, and various financial and management initiatives.

Mr. Church is eligible for a non-equity incentive compensation targeted at 35% of his base salary. On March 4, 2011, Mr. Church received an annual bonus of \$30,500, representing 12.2% of his base salary amount, which was based on his and the Company's performance for 2010. On February 25, Mr. Church was also issued a stock grant for 10,000 shares which vested immediately.

Dr. Reed is eligible for a non-equity incentive compensation targeted at 25% of his base salary. On March 4, 2011, Dr. Reed received an annual bonus of \$28,314, representing 14.3% of his base salary amount, which was based on his and the Company's performance for 2010.

### All Other Compensation

Mr. Tardugno was paid other compensation during 2010 of \$45,000 which represents a temporary living allowance. Mr. Tardugno also received a \$9,775 401(k) matching Celsion common stock contribution. Dr. Borys was paid \$23,831 of other compensation during 2010, which represents a temporary living allowance. Dr. Borys also received a \$7,615 401(k) matching Celsion common stock contribution. Dr. Reed was paid \$3,750 of other compensation during 2010, which represents a temporary living allowance. Dr. Reed also received a \$6,240 401(k) matching Celsion common stock contribution.

#### ADDITIONAL COMPENSATION DISCLOSURE NARRATIVE

#### **Retirement Benefits**

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. The match is paid for in Common Stock, which vests over a period of three years.

## **Executive Perquisites**

The Company may provide perquisites to its executive officers other than those that may be called for in employment contracts. For the year ended December 31, 2010, the Company did not pay any perquisites.

# Post-Employment Compensation

Mr. Tardugno's employment agreement provides for post-employment benefits. Please refer to the description of Mr. Tardugno's employment agreement, which contains a description of such benefits, under the heading "Employment Agreements" above.

# 2010 OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END TABLE

The following table summarizes the unexercised options, non-vested stock and equity incentive plan awards outstanding and held by each of the Named Executive Officers as of December 31, 2010.

		Option Awards			Stock Awards		
	N	No. of Securitie	No. of Securities	S		No. of Shares	Market Value
		Underlying	Underlying			or Units	of Shares or
		Unexercised	Unexercised	Option		of Stock	Units of Stock
		Options	Options	Exercise	Option	That Have	That Have Not
		(#)	(#)	Price	Expiration	Not Vested	Vested
Name	Grant Date	Exercisable	Unexercisable	(\$)	Date	(#)	(\$)
Michael H.							
Tardugno(1)	1/3/2007	322,500	215,000	\$ 2.42	1/3/2017		
	2/19/2008	37,500	56,250	\$ 5.50	2/19/2018		
	1/19/2009	25,000	50,000	\$ 2.72	2/19/2019		
	2/19/2010	-	- 85,000	\$ 2.94	2/19/2010	)	
Nicholas							
Borys(2)	9/24/2007	75,000	_	- \$ 6.10	9/24/2017		
	2/19/2008	17,500	17,500	\$ 5.50	2/19/2018		
	1/19/2009	11,667	23,333	\$ 2.72	2/19/2018		
	2/19/2010	-	_ 40,000	\$ 2.94	2/19/2020		
Jeffrey W.							
Church (3)	7/6/2010	-	_ 100,000	\$ 3.39	7/1/2020	16,667	\$ 34,167
Robert A.							
Reed (4)	5/15/2009	5,000	15,000	\$ 4.05	5/15/2019		
	2/19/2010	-	_ 25,000	\$ 2.94	2/19/2020	5,000	\$10,250

#### Notes:

- (1) Mr. Tardugno's stock options granted on January 3, 2007 and February 19, 2008 vest in four equal installments commencing on the first anniversary from the date of grant. The stock options granted on January 19, 2009 and February 19, 2010 vest in three equal installments commencing on the first anniversary from the date of grant.
- (2) Dr. Borys' stock options granted on September 24, 2007 and February 19, 2008 vest in four equal installments commencing on the first anniversary from the date of grant. The stock options granted on February 19, 2009 and February 19, 2010 vest in three equal installments commencing on the first anniversary from the date of grant.
- (3) Mr. Church's stock options granted on July 6, 2010 vest in quarters starting January 1, 2011 and three years annually thereafter. The stock grant for 25,000 shares on July 6, 2010 vested in thirds starting on the grant date and annually thereafter.
- (4) Dr. Reed's stock options granted on May 15, 2009 vest in four equal installments commencing on the first anniversary from the date of grant. The stock options granted on February 19, 2010 vest in three equal installments commencing on the first anniversary from the date of grant.

# DIRECTOR COMPENSATION

#### 2010 DIRECTOR COMPENSATION TABLE

The following table sets forth the cash and noncash compensation paid to the Company's directors for the year ended December 31, 2010:

	Fees Earned or			
	Paid in Cash	Stock Awards	Option Awards	
Name	(\$)	(\$)	(\$) (1)	Total (\$)
Max E. Link	53,600	_	67,795	121,395
Augustine Chow	36,600		48,425	85,025
Gregory Weaver	51,800	_	48,425	100,225
Robert W. Hooper	13,517 (5)		65,348	78,865
Alberto Martinez	<del>-(6</del> )	_	54,438	54,438
Gary W. Pace	20,383 (5)	_	48,425	68,808

(1) The value reported for Stock and Option Awards is the aggregate grant date fair value of restricted stock awards granted to the named executive officers in the years shown, determined in accordance with FASB ASC Topic 718, disregarding adjustments for forfeiture assumptions. The assumptions for making the valuation determinations are set forth in the Note 12 to the financial statements included in this Annual Report on Form 10-K. The grant date fair value of stock option awards to directors during the year ended December 31, 2010 were as follows:

	Number of	E '		C D
	Options	Exercise		Grant Date
Name	Granted	Price	Expires	Fair Value
Max E. Link	35,000 (2)	\$ 2.94	2/19/2020	67,797
Augustine Chow	25,000 (2)	\$ 2.94	2/19/2020	48,423
Gregory Weaver	25,000 (2)	\$ 2.94	2/19/2020	48,423
Robert W. Hooper	30,000 (3)	\$ 3.36	7/29/2020	65,348
Alberto Martinez	30,000 (4)	\$ 2.81	12/3/2020	54,438
Gary W. Pace	25,000 (2)	\$ 2.94	2/19/2020	48,423

- (2) These stock options were granted on February 19, 2010 and vest in three equal installments commencing on the first anniversary from the date of grant.
- (3) These stock options were granted on July 29, 2010 and vest in three equal installments commencing on the first anniversary from the date of grant.
- (4) These stock options were granted on December 3, 2010 and vest in three equal installments commencing on the first anniversary from the date of grant.
- (5) On July 29, 2010, Gary Pace tendered his resignation from the Board of Directors. Robert W. Hooper was appointed by the Board of Directors to take his place.
- (6) Dr Alberto Martinez was appointed to the Board of Directors on December 3, 2010.

During the year ended December 31, 2010, each non-employee of the Company received annual cash compensation in the amount of \$25,000 payable quarterly, and an additional \$1,000 for attendance at special meetings of the Board of Directors and each meeting of a committee of the Board of Directors that was not held in conjunction with a meeting of the Board of Directors. Each other non-employee director is reimbursed for his out-of-pocket costs of attending meetings of the Board of Directors and of committees of the Board of Directors. Additionally, the Chairman of the Audit Committee received an additional annual cash fee of \$8,000 and the Chairman of the Compensation Committee received an additional annual cash fee of \$5,000.

#### SECTION 162(M)

Section 162(m) of the Internal Revenue Code provides for non-deductibility, in certain cases, of compensation paid to certain executives in excess of \$1 million per year. The Company does not have a policy limiting compensation to amounts deductible under Section 162(m). The Company's compensation plans are designed so that qualified performance-based awards issued under the plans would not be subject to Section 162(m) limits. Section 162(m) limits would apply to salary, non-performance based bonuses, restricted stock awards that are not performance based and certain amounts included under "All Other Compensation" in the Summary Compensation Table.

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

The following table sets forth certain information known to the Company regarding the beneficial ownership of the Company's Common Stock as of March 24, 2011 by:

each person or group known by us to own beneficially more than 5% of the outstanding Common Stock;

each of our directors and the director nominees, as well as each executive officer named in the Summary Compensation Table appearing under the heading "Executive Compensation"; and

our directors and executive officers as a group.

We determine beneficial ownership in accordance with the rules of the SEC. Unless otherwise indicated, the persons included in the table have sole voting and investment power with respect to all shares beneficially owned thereby. Shares of Common Stock subject to options that are currently exercisable or that become exercisable within 60 days of March 24, 2011 are treated as outstanding and beneficially owned by the holder of such options. However, these shares are not treated as outstanding for purposes of computing the percentage ownership of any other person.

#### NUMBER OF SHARES OF COMMON STOCK BENEFICIALLY OWNED

NAME OF BENEFICIAL OWNER*	NUMBER OF SHARES OF COMMON STOCK BENEFICIALLY OWNED(1)	PERCENT OF SHARES OF COMMON STOCK OUTSTANDING(2)
Max E. Link(3)	331,639	2.41%
Augustine Chow(4)	80,000	**
Gregory Weaver(5)	65,000	**
Robert W. Hooper (6)	13,000	**
Alberto Martinez(7)	69,166	**
Michael H. Tardugno(8)	717,494	5.20 %
Nicholas Borys(9)	171,104	1.24 %
Jeffrey Church(10)	49,999	**
Robert A. Reed (11)	26,735	**
Directors and Executive Officers as a group		
(9 persons)(12)	1,524,137	11.05 %

- \* The address of each of the persons named is c/o Celsion Corporation, 10220-L Old Columbia Road, Columbia, MD 21046.
- \*\* Less than 1%.
  - (1) Beneficial Ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Except as indicated by footnote, and subject to community property laws where applicable, the persons named in the table above have sole voting and investment power with respect to all shares of Common Stock shown as beneficially owned by them.
  - (2) Based on 13,787,804 shares of Common Stock outstanding as of March 24, 2011.
  - (3) Includes 169,077 shares of Common Stock underlying options, warrants and convertible preferred stock currently exercisable or exercisable within 60 days of March 24, 2011.
  - (4) Includes 80,000 shares of Common Stock underlying options, warrants and convertible preferred stock currently exercisable or exercisable within 60 days of March 24, 2011.
  - (5) Includes 50,000 shares of Common Stock underlying options, warrants and convertible preferred stock currently exercisable or exercisable within 60 days of March 24, 2011.
  - (6) Includes 10,000 shares of Common Stock underlying options, warrants and convertible preferred stock currently exercisable or exercisable within 60 days of March 24, 2011.
  - (7) Includes 69,166 shares of Common Stock underlying options, warrants and convertible preferred stock currently exercisable or exercisable within 60 days of March 24, 2011.
  - (8) Includes 590,832 shares of Common Stock underlying options, warrants and convertible preferred stock currently exercisable or exercisable within 60 days of March 24, 2011.
  - (9) Includes 142,917 shares of Common Stock underlying options, warrants and convertible preferred stock currently exercisable or exercisable within 60 days of March 24, 2011.
  - (10) Includes 39,999 shares of Common Stock underlying options, warrants and convertible preferred stock currently exercisable or exercisable within 60 days of March 24, 2011.
  - (11) Includes 20,833 shares of Common Stock underlying options, warrants and convertible preferred stock currently exercisable or exercisable within 60 days of March 24, 2011.
  - (12) Includes 1,172,824 shares of Common Stock underlying options, warrants and convertible preferred stock currently exercisable or exercisable within 60 days of March 24, 2011.

Equity Compensation Plan Information as of December 31, 2010

The following table discloses information about the options issued and available for issuance under all outstanding Company option plans as of December 31, 2010.

	Number of securities to be issued upon exercise of outstanding options, warrants	Weighted-average exercise price of outstanding options, warrants and	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in
Plan category	and rights (a)	rights (b)	column (a)) (c)
Equity compensation plans			
approved by security holders	2,245,046 (1)(1)	\$ 3.73	1,265,542
Equity compensation plans not			
approved by security holders	<del></del>	_	— (2)
Total	2,245,046	\$ 3.73	1,265,542

<sup>(1)</sup> 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.

Please also refer to Note 12 of the Company's financial statements for descriptions of the plans under which equity securities of the Company are authorized for issuance.

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

#### DIRECTOR INDEPENDENCE

In accordance with NASDAQ rules, the Company requires that at least a majority of the directors serving at any time on the Board of Directors be independent, that all the members of the Audit Committee satisfy the NASDAQ financial literacy requirements and that at least one member of the Audit Committee qualify as an "audit committee financial expert" under the NASDAQ rules. The Board of Directors has determined that of the six currently serving directors, Dr. Max E. Link, Dr. Augustine Chow, Mr. Gregory Weaver, Mr. Robert W. Hooper and Dr. Alberto Martinez are independent under the NASDAQ rules. In addition, the Board of Directors has made the affirmative determination that none of the independent directors has a material relationship with the Company other than his service as a director.

#### RELATED PERSON TRANSACTIONS

<sup>(2)</sup> As discussed further in Notes 10 and 11 to the Company's financial statements, the Company has warrants outstanding at December 31, 2010 enabling the holders thereof to purchase 1,009,076 shares of the Company's Common Stock at a weighted-average exercise price of \$5.24. 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.

On January 12, 2011, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with a select group of institutional investors, including certain officers and directors of the Company, to sell up to 5,000 shares of 8% redeemable convertible preferred stock (the "Preferred Stock") with a stated value of \$1,000 and warrants (the "Included Warrants") to purchase up to 2,083,333 shares of common stock in a registered direct offering. The Preferred Stock and Included Warrants were sold in units (the "Units"), with each Unit consisting of one share of Preferred Stock and an Included Warrant to purchase up to 416.6666 shares of common stock at an exercise price of \$3.25 per whole share of common stock. The Units were sold to unaffiliated third party investors at a negotiated purchase price of \$1,000 per Unit and to officers and directors at an at-the-market price of \$1,197.92 per Unit in accordance with the NASDAQ Stock Market Rules. Each share of Preferred Stock is convertible into shares of common stock at an initial conversion price of \$2.40 per share, subject to adjustment in the event of stock splits, recapitalizations or reorganizations that affect all holders of common stock equally. The Company received gross proceeds from the offering of approximately \$5.1 million, before deducting placement agents' fees and estimated offering expenses. Concurrent with the issuance and sale of the Units, the Company issued a warrant (the "Placement Agent Warrant") to purchase up to 350 shares of Preferred Stock at an exercise price of \$1,000 per whole share of Preferred Stock to Dominick & Dominick LLC, as placement agent.

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The table below sets forth the related party participation in the offering:

			TOTAL
RELATED PARTY	POSITION(S)	UNITS	SUBSCRIPTION
Max E. Link	Chairman, Director	41	\$49,114.72
Michael H. Tardugno	President, Chief Executive Officer, and	41	\$49,114.72
	Director		
Robert W. Hooper	Director	12	\$14,375.04
Alberto R. Martinez	Director	83	\$99,427.36
Jeffrey W. Church	Vice President and Chief Financial Officer	8	\$9,583.36
Nicholas Borys	Vice President and Chief Medical Officer	6	\$7,187.52
Timothy J. Tumminello	Controller & Chief Accounting Officer	8	\$9,583.36

ITEM 14.

#### PRINCIPAL ACCOUNTANT FEES AND SERVICES

#### **FEES**

The following table presents fees for professional audit services rendered by Stegman and Company for the audit of the Company's annual financial statements and review of financial statements included in the Company's Forms 10-Q for the fiscal years ended December 31, 2010 and December 31, 2009, and fees for other services rendered by Stegman during those periods:

	FISCAL YEAR 2010		FISCAL YEAR 2009	
		% OF		% OF
FEE CATEGORY	AMOUNT	TOTAL	AMOUNT	TOTAL
Audit Fees	\$ 80,500	75	\$ 89,700	71
Audit Related Fees	18,650	17	19,300	15
Tax Fees	8,000	7	10,750	9
All Other Fees	935	1	6,610	5
Total Fees	\$ 108,085	100	\$ 126,360	100

Audit fees consist of fees for professional services rendered by Stegman and Company for the audit of the Company's annual financial statements and for reviews of the quarterly financial statements included in the Company's Forms 10-Q. Tax fees consist of fees for preparation of the Company's federal and state tax returns. Audit related fees pertain to the work performed during the Company's equity offerings in 2010. All other fees consist of fees for attendance at the Company's annual meetings, review of registration statements and similar matters. Stegman rendered no financial information systems design and implementation services to the Company during fiscal years 2010 and 2009 and, therefore, no fees were charged for such services during those periods.

#### SERVICES BY EMPLOYEES OF STEGMAN & COMPANY

No part of Stegman's engagement to audit the Company's financial statements for the fiscal year ended December 31, 2010 was attributable to work performed by persons other than Stegman's full-time, permanent employees.

#### AUDIT COMMITTEE POLICY ON APPROVAL OF AUDIT AND NON-AUDIT SERVICES

It is the policy of the Audit Committee to pre-approve all audit and permissible non-audit services provided by the Company's independent accountants, in accordance with rules prescribed by the SEC. These services may include audit services, audit-related services, tax services, and other services. Pre-approval is based on a written proposal, accompanied by a cost estimate and estimated budget. The Audit Committee has delegated to its Chairman the authority to pre-approve audit and non-audit services with an estimated cost of up to \$25,000, provided the exercise of such authority is reported to the Audit Committee at its next regular meeting. The Audit Committee reserves the right, from time to time, to delegate pre-approval authority to other of its members, so long as such members are independent directors.

All of the services of Stegman and Company during fiscal years 2010 and 2009 were approved by the Audit Committee in accordance with its pre-approval policy and the approval requirements of the SEC.

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#### PART IV.

#### ITEM 15. EXHIBITS AND 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.

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REPORTS	
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Statements of Operations	F-3
Statements of Cash Flows	F-4
Statements of Changes in Stockholders' Equity	F-5
NOTES TO FINANCIAL STATEMENTS	F-6

#### 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	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.
3.2	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.
3.3	Certificate of Designations of Series C Junior Participating Preferred Stock of Celsion Corporation, incorporated herein by reference to Exhibit 4.4 to the Form S-3 Registration Statement (File No. 333-100638), filed October 18, 2002.
3.4	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.

2	3.5	Certificate of Designation for 8% Series A Redeemable Convertible Preferred Stock of Celsion
		Corporation, incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K as
		filed with the SEC on January 18, 2011.
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EXHIBIT NO. 3.6	DESCRIPTION  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	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.
4.3	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.
4.4	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 with the SEC on September 28, 2009.
4.5	Registration Rights Agreement, dated June 17, 2010, by and between Celsion Corporation and Small Cap Biotech Value, Ltd., incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company, filed with the SEC on June 18, 2010.
4.6	Form of 8% Series A Redeemable Convertible Preferred Stock Certificate incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K as filed with the SEC on January 18, 2011.
4.7	Form of Common Stock Warrant incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K as filed with the SEC on January 18, 2011.
4.8	Form of 8% Series A Redeemable Convertible Preferred Stock Warrant incorporated herein by reference to Exhibit 4.3 to the Current Report on Form 8-K as filed with the SEC on January 18, 2011.
10.1	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.
10.2	Celsion Corporation 2007 Stock Incentive Plan, as amended, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed June 29, 2010.
10.3	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.
10.4	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.
10.5	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.
10.6	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.
10.7	Restricted Stock Agreement dated October 3, 2006, incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K of the Company, filed October 10, 2006.
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EXHIBIT NO.	DESCRIPTION
10.8	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.
10.9	Stock Option Agreement effective January 3, 2007 between Celsion Corporation and Michael H. Tardugno, incorporated herein by reference Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed January 3, 2007.
10.10	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.
10.11	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.
10.12	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.
10.13	Separation Agreement and General Release, dated January 6, 2010, between Celsion Corporation and Sean Moran, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed January 8, 2010.
10.14	Employment Offer Letter, entered into on June 15, 2010, between the Company and Jeffrey W. Church, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed June 18, 2010.
10.15	Separation Agreement and General Release, dated January 6, 2010, between Celsion Corporation and Sean Moran, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed January 8, 2010.
10.16	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).
10.17	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.
10.18	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.
10.19	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.)

10.20	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.
10.01	
10.21	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.
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EXHIBIT NO.	DESCRIPTION
10.22	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.
10.23	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.
10.24	A 4 Providence A
10.24	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
10.25	Stock Purchase Agreement, dated December 7, 2007, by and between Celsion Corporation and Boston Scientific Corporation, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed December 13, 2007.
10.26	First Amondment to the Accet Durchess Assessment dated Ives 5, 2000, by and hetween Calcier
10.26	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.
10.27	Second Amendment to the Asset Purchase Agreement, dated June 2, 2009, by and between Celsion
10.21	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.
10.28	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.
10.29*	Development, Product Supply and Commercialization Agreement, effective December 5, 2008, by
10.27	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.
10.30*	The 2nd Amendment To The Development, Product Supply And Commercialization Agreement,
	effective January 7, 2011, by and between the Company and Yakult Honsha Co., Ltd. incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed with the SEC on January 18, 2011.
10.31	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.
10.32	Form of Subscription Agreement, incorporated herein by reference to Exhibit 10.1 to the Current
10.52	Report on Form 8-K of the Company, filed September 28, 2009.
10.33	Escrow Agreement by and between JPMorgan Chase Bank, N.A., Celsion Corporation, and
-0.00	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.
10.34	Common Stock Purchase Agreement, dated June 17, 2010, by and between Celsion Corporation and Small Cap Biotech Value, Ltd., incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed June 18, 2010.
10.35	Registration Rights Agreement, dated June 17, 2010, by and between Celsion Corporation and Small Cap Biotech Value, Ltd, incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of the Company, filed June 18, 2010.
10.36	Securities Purchase Agreement dated January 12, 2011 by and among Celsion Corporation and the Investors named therein, incorporated herein by reference to Exhibit 10.2 on Form 8-K of the Company, filed January 18, 2011.

EXHIBIT NO.	DESCRIPTION
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.

<sup>\*</sup>Portions of this exhibit have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, amended, and the omitted material has been separately filed with the Securities and Exchange Commission.

+ Filed herewith.

^ Furnished herewith.

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#### **SIGNATURES**

Pursuant to the requirements 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

Registrant

March 28, 2011 By: /s/ Michael H. Tardugno

Michael H. Tardugno

President and Chief Executive Officer

March 28, 2011 By: /s/ Jeffrey W. Church

Jeffrey W. Church

Vice President and Chief Financial

Officer

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

SIGNATURE	TITLE	DATE
/s/ Michael H. Tardugno Michael H. Tardugno	President and Chief Executive Officer(Principal Executive Officer)	March 28, 2011
/s/ Jeffrey W. Church Jeffrey W. Church	Vice President and Chief Financial Officer (Principal Financial Officer)	March 28, 2011
/s/ Timothy J. Tumminello	Controller and Chief Accounting Officer	March 28, 2011
Timothy J. Tumminello	Officer	2011
/s/ Max E. Link		March 28,
Max E. Link	Chairman of the Board	2011
/s/ Augustine Chow	Director	March 28,
Augustine Chow		2011
/s/ Gregory Weaver	Director	March 28, 2011

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Gregory Weaver

/s/ Robert W. Hooper Director March 28,

2011

Robert W. Hooper

/s/ Alberto Martinez Director March 28,

2011

Alberto Martinez

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#### 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, 2010 and 2009, and the related statements of operations, changes in stockholders' (deficit) 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit 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, 2010 and 2009, 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 24, 2011

## CELSION CORPORATION BALANCE SHEETS

	December 31,		
	2010	2009	
Current assets:			
Cash and cash equivalents	\$1,138,916	\$6,923,476	
Short-term investments	395,556	5,695,466	
Refundable income taxes	-	806,255	
Prepaid expenses and other current assets	492,184	695,021	
Total current assets	2,026,656	14,120,218	
Property and equipment (at cost, less accumulated depreciation of			
\$1,046,758 and \$881,278, respectively)	378,672	537,407	
Other assets:			
Deposits and other assets	76,796	97,082	
Patent license fees, net	43,125	50,625	
Total other assets	119,921	147,707	
Total assets	\$2,525,249	\$14,805,332	
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY			
Current liabilities:			
Accounts payable - trade	\$4,548,586	\$2,190,957	
Other accrued liabilities	2,124,189	1,451,542	
Note payable - current portion	123,465	108,332	
Total current liabilities	6,796,240	3,750,831	
Common stock warrant liability	248,131	821,891	
Note payable – non-current portion	56,403	179,868	
Other liabilities - noncurrent	-	16,948	
Total liabilities	7,100,774	4,769,538	
Stockholders' (deficit) equity:			
Common stock - \$0.01 par value (75,000,000 shares authorized; 14,091,370			
and 12,895,174 shares issued and 13,331,096 and 12,134,900 shares			
outstanding at December 31, 2010 and 2009, respectively)	140,914	128,952	
Additional paid-in capital	99,316,859	95,035,165	
Accumulated other comprehensive (loss) income	(18,367)		
Accumulated deficit	(100,938,261)	(82,119,826)	
Subtotal	(1,498,855)	13,112,464	
Treasury stock, at cost (760,274 shares at December 31 2010 and 2009)	(3,076,670 )	(3,076,670)	
Total stockholders' (deficit) equity	(4,575,525)	10,035,794	
Total liabilities and stockholders' (deficit) equity	\$2,525,249	\$14,805,332	

See accompanying notes to the financial statements.

## CELSION CORPORATION STATEMENTS OF OPERATIONS

	Year ended December 31,		
	2010	2009	
Operating expenses:			
Research and development	\$14,714,460	\$13,680,939	
General and administrative	4,922,967	3,326,610	
Total operating expenses	19,637,427	17,007,549	
Loss from operations	(19,637,427)	(17,007,549)	
Other income (expense):			
Other income	244,460	322,414	
Gain from valuation of common stock warrant liability	573,760	731,785	
Interest income	32,289	46,161	
Interest expense	(31,517)	(94,920 )	
Total other income	818,992	1,005,440	
Loss before income taxes	(18,818,435)	(16,002,109)	
Income tax benefit	-	806,255	
Net loss	\$(18,818,435)	\$(15,195,854)	
Net loss per common share – basic and diluted	\$(1.52)	\$(1.43)	
Weighted average common shares outstanding – basic and diluted	12,375,402	10,655,200	

See accompanying notes to the financial statements.

## CELSION CORPORATION STATEMENTS OF CASH FLOWS

Cash flows from operating activities:  Net loss  Non-cash items included in net loss:  Depreciation and amortization  Amortization of indemnity reserve  Change in fair value of common stock warrant liability  2010  2009  \$(18,818,435) \$(15,195,854)  109,654  - (1,053,357)  (573,760) (731,785)
Net loss \$(18,818,435) \$(15,195,854)  Non-cash items included in net loss:  Depreciation and amortization 165,480 109,654  Amortization of indemnity reserve - (1,053,357)
Non-cash items included in net loss:  Depreciation and amortization  Amortization of indemnity reserve  165,480  - (1,053,357)
Depreciation and amortization 165,480 109,654 Amortization of indemnity reserve - (1,053,357)
Amortization of indemnity reserve - (1,053,357)
Change in fair value of common stock warrant liability (573.760 ) (731.785 )
Change in fair value of common stock warrant maching
Stock based compensation - options 1,295,382 894,277
Stock based compensation – restricted stock 357,678 182,593
Amortization of patent license fee 7,500 7,500
Shares issued in exchange for services 18,060 14,700
Recovery of bad debt on note receivable - (214,142)
Net changes in:
Due from Boston Scientific Corporation - 15,000,000
Refundable income taxes 806,255 (806,255)
Prepaid expenses and other 340,837 (389,133)
Deposits and other assets 20,286 265,569
Accounts payable 2,357,629 1,004,446
Other accrued liabilities 655,699 (18,544)
Net cash used in operating activities (13,367,389) (930,331)
Cash flows from investing activities:
Purchases of investment securities (11,844,356) (8,498,217)
Proceeds from sale and maturity of investment securities 17,057,726 6,932,244
Purchases of property and equipment (6,745 ) (136,223 )
Net cash provided by (used in) investing activities 5,206,625 (1,702,196)
Cash flows from financing activities:
Proceeds from sale of equity, net of issuance costs 2,484,536 6,334,513
Principal payments on note payable (108,332) (234,735)
Net cash provided by financing activities 2,376,204 6,099,778
(Decrease) increase in cash and cash equivalents (5,784,560) 3,467,251
Cash and cash equivalents at beginning of period 6,923,476 3,456,225
Cash and cash equivalents at end of period \$1,138,916 \$6,923,476
Cash paid for:
Interest \$ 31,517 \$ 91,120
Income taxes \$ -

See accompanying notes to the financial statements.

#### CELSION CORPORATION STATEMENTS OF CHANGES IN STOCKHOLDERS' (DEFICIT) EQUITY YEARS ENDED DECEMBER 31, 2010 AND 2009

	Common Outstar		Additional		ury Stock	Accumulate Other Comp. (Lo		Accumulated	
	Shares	Amount	Paid-in Capital	Shares	Amount	Income		Deficit	Total
Balance at December 31, 2008	10,156,3505	§ 108,161	\$ 89,183,549	659,738\$	(2,641,349)	) \$	-\$	5 (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			<i>5.</i> 7,2						,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
stock	_	_	182,593	_	-	-	_	_	182,593
Shares issued in exchange for services	4,600	46	14,654	_			_	į	14,700
Issuance of restricted stock upon									2.,,
vesting	56,333	563	(563)	-	-	-	-	-	-
Treasury stock acquired	(100,536)	-	-	100,536	(435,321)	)	-		(435,321)
Unrealized gain on						<b>6</b> 0 1	72		68,173
investments Net loss		_	_	_	-	- 68,1	-	(15,195,854)(	
Balance at December 31,	_	_	_	-		-	_	(13,193,634)(	13,193,034)
2009	12,134,900	128,952	95,035,165	760,274	(3,076,670)	68,1	73	(82,119,826)	10,035,794
Stock-based compensation expense related to employee									
stock options	-	-	1,295,382	_			-	-	1, 295,382

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Stock-based compensation expense related to restricted stock			357,678	_	_	_	_	357,678
Shares issued			227,070					227,373
in exchange								40.060
for services	6,000	60	18,000	-	-	-	-	18,060
Issuance of restricted stock upon								
vesting	86,277	863	(863)	-	-	-	-	-
Shares issued under CEFF, net of								
issuance costs	1,103,919	11,039	2,611,497	-	-	-		2,622,536
Unrealized (loss) on								
investments	-	-	-	-	-	(86,540)	-	(86,540)
Net loss	-	-	-	-	-	-	(18,818,435)(	18,818,435)
Balance at December 31, 2010	13,331,096 \$	140 914	\$ 99,316,8597	(60 274\$ (3	076.670) \$	(18 367)\$	(100,938,261)	\$ (4 575 525)
2010	15,551,070 ψ	, 1 10,71 <sup>-</sup> T	Ψ 77,510,0377	$00,27 \pm \psi$ (3,	στο,στο, ψ	(10,307)	(100,750,201)	(1,5/5,525)

See accompanying notes to the financial statements.

# CELSION CORPORATION NOTES TO FINANCIAL STATEMENTS YEARS ENDED DECEMBER 31, 2010 AND 2009

#### 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 of Celsion have been prepared in accordance with generally accepted accounting principles ("GAAP") in the United States and include the accounts of the Company. The preparation of financial statements in conformity with GAAP requires management to make judgments, estimates, and assumptions that affect the amount reported in the Company's financial statements and accompanying notes. Actual results could differ materially from these estimates.

Events and conditions arising subsequent to the most recent balance sheet date have been evaluated for their possible impact on the financial statements and accompanying notes. Other than the Preferred Stock Offering completed in January 2011 as discussed in Note 11, no events and conditions would 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 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 operating expenses as incurred. Depreciation expense was approximately \$165,000 and \$110,000 for years ended December 31, 2010 and 2009, 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, 2010 the total accumulated amortization expense is \$30,000. The weighed-average amortization period for these assets is 10 years.

#### **Indemnity Reserve**

Upon the sale of the Company's 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, 2010 and 2009, the indemnity reserve was \$-0-. For the year ended December 31, 2010 and 2009, the Company recorded a non-cash benefit of \$-0- and \$1,053,357, respectively, as a result of the amortization of this indemnity reserve.

#### Comprehensive Income (Loss)

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 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 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 2010 and 2009, the outstanding equity awards for 2,245,046 and 1,720,578 shares, respectively, and the warrants outstanding to purchase 1,009,076 and 1,032,410 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 carry forwards. 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.

#### **Stock-Based Compensation**

Stock options are generally granted with an exercise price at market value on 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 that ranges from immediate vesting to three years.

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 12, 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.

From time to time, new accounting pronouncements are issued by FASB and are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued accounting pronouncements will not have a material impact on the Company's consolidated financial position, results of operations, and cash flows, or do not apply to our operations.

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 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 March 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act were signed into law. We are currently in the process of determining the effects, if any, of these new laws on the Company.

#### 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 product candidates, 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 \$100.5 million as of December 31, 2010.

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 product candidates. 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 oncology product candidates and we have made a significant commitment to heat-activated liposome research and development projects and it is our 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 continued operations. Management believes that adequate funding is available from cash resources on hand at December 31, 2010 to fund operations as least through the end of 2011.

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, 2010 and 2009:

	Year ended D	ecember 31,
	2010	2009
Net loss	\$(18,818,435)	\$(15,195,854)
Unrealized (loss) gain on securities available for sale	(86,540)	68,173
Comprehensive loss	\$(18,904,975)	\$(15,127,681)

#### 4. SHORT TERM INVESTMENTS AVAILABLE FOR SALE

Short term investments available for sale of \$395,556 and \$5,695,466 as of December 31, 2010 and 2009, 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 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.

	Decei	mber 31,
Short-term investments available for sale, at fair value	2010	2009
Bonds – corporate issuances	\$301,632	\$5,528,164
Equity securities (see Note 16)	93,924	167,302
Total	\$395,556	\$5,695,466

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

	December 31, 2010		December	31, 2009	
	Cost	Fair Value	Cost	Fair Value	
Short-term investments					
Bonds- corporate issuances	\$301,632	\$301,632	\$5,528,164	\$5,528,164	
Equity securities (see Note 16)	108,373	93,924	108,373	167,302	
Total	\$410,005	\$395,556	\$5,636,537	\$5,695,466	
Bond maturities					
Within 3 months	\$301,632	\$301,632	\$1,894,022	\$1,894,022	
Between 3-12 months	-	-	3,321,320	3,321,320	
Between 1-2 years	-	-	312,822	312,822	
Total	\$301,632	\$301,632	\$5,528,164	\$5,528,164	

#### 5. FAIR VALUES OF FINANCIAL INSTRUMENTS

FASB Accounting Standards Codification (ASC) Section 820, Fair Value Measurements and Disclosures, establishes a three tier level hierarchy for fair value measurements which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

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

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

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

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

Assets: December 31, 2010	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Bonds- corporate issuances	\$301,632	\$301,632	\$-	\$ -
Equity securities (see Note 16)	93,924	-	Ψ	Ψ