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

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**FORM 10-K**

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(Mark One)

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

**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2008**

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-15911

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**CELSION CORPORATION**

(Exact Name of Registrant as Specified in Its Charter)

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**DELAWARE**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**52-1256615**  
(I.R.S. Employer Identification No.)

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

**21046-2364**  
(Zip Code)

**(410) 290-5390**

Registrant's telephone number, including area code

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

Title of Class	Name of Each Exchange on Which Registered
COMMON STOCK, PAR VALUE \$.01 PER SHARE	THE NASDAQ STOCK MARKET, LLC

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

**Not Applicable**

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

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

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing

requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

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

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

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's Definitive Proxy Statement in connection with its 2009 Annual Meeting of Stockholders, which is scheduled to be held on May 15, 2009, are incorporated by reference into Part III hereof, as indicated herein.

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**CELSION CORPORATION**

**FORM 10-K**

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## PART I

### ITEM 1. BUSINESS

#### FORWARD-LOOKING STATEMENTS

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

#### General

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

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

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

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

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

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

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

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

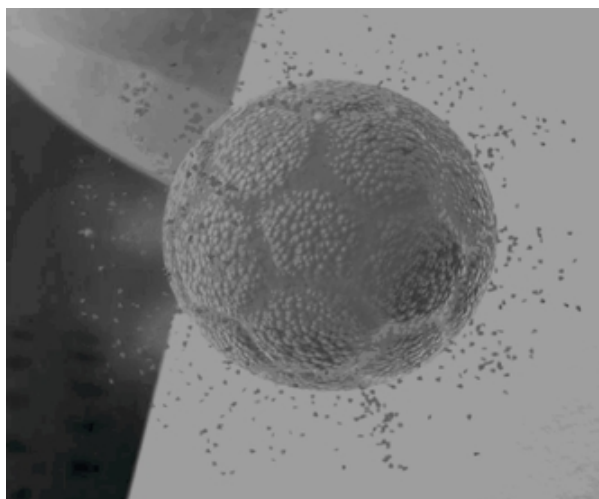
The Company makes available free of charge through its website, [www.celsion.com](http://www.celsion.com), its annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically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

#### **THERMODOX® (DOXORUBICIN ENCAPSULATED IN HEAT-ACTIVATED LIPOSOME)**

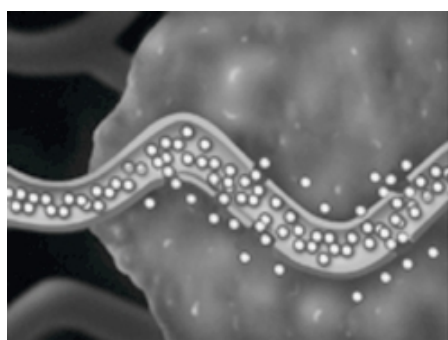
Liposomes are manufactured microscopic vesicles consisting of a discrete aqueous central compartment surrounded by a membrane bilayer composed of naturally occurring fats. Conventional liposomes have been designed and manufactured to carry drugs and increase residence time, thus allowing the drugs to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

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

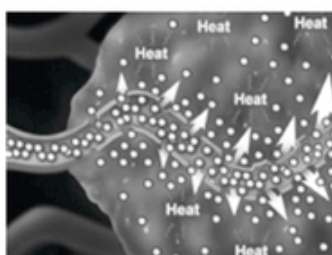
Celsion intends to use various available focused-heat technologies, such as radio frequency ablation ("RFA"), microwave energy and high intensity focused ultrasound, to activate the release of drugs from its novel heat sensitive liposomes. The illustration below depicts a drug being released from a heat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



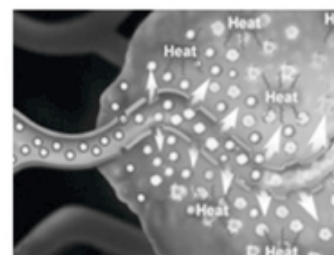
As is illustrated in the pictures below, our heat activated liposomes circulate within the tumor tissue and leaky tumor vessels vasculature, and when heat is added locally, it causes the rapid release of cancer drugs directly within the targeted tumor.



Leaky tumor vessels  
37°C



Heat adds permeability  
39 < T < 42°C



Mechanical release  
at 39°-42°C

This technology enables delivery of significantly higher concentrations of proven chemotherapy drugs directly to the tumor, stopping the progression of cancer and minimizing systemic toxicity. 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 is estimated that up to 90% of liver cancer patients will die within five years of diagnosis. There are approximately 20,000 new cases per year of HCC in the U.S. Worldwide, an estimated one million new cases of HCC are diagnosed each year, which ranks it as the fifth most commonly occurring solid tumor. HCC has the fastest rate of growth of all cancers and is projected to be the most prevalent form of cancer by 2020. HCC is commonly diagnosed in patients with longstanding hepatic disease and cirrhosis (primarily due to hepatitis C in the U.S. and Europe and hepatitis B in Asia).

Although the standard treatment for liver cancer is surgical excision of the tumor, up to 80% of patients are ineligible for surgery at the time of diagnosis as early stage liver cancer generally has few symptoms and when finally detected the tumor frequently is too large for surgery. There are few alternative treatments, since radiation therapy and chemotherapy are largely ineffective. For tumors generally up to 5 centimeters in diameter, RFA is emerging as the standard of care treatment approach which directly destroys the tumor tissue through the application of high temperatures by a probe inserted into the core of the tumor. Local recurrence rates after RFA are directly correlated to the size of the tumor. For tumors 3 cm or smaller in diameter the recurrence rate has been reported to be 10 - 20%; however, for tumors greater than 3 cm, local recurrence rates of 40% or higher have been observed.

## **Celsion's Approach**

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

## **Phase I Clinical Trial—Primary Liver Cancer**

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

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

## **Phase III Global Clinical Trial—Primary Liver Cancer**

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



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

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

### **Recurrent Chest Wall Breast Cancer Overview**

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

### **Celsion's Approach**

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

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

### **RCW Breast Cancer Clinical Phase I/II Clinical Trial**

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

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

## **PRODUCT FEASIBILITY**

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

## **RESEARCH AND DEVELOPMENT**

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

## **FDA REGULATION**

### **Research and Development**

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

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

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

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

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

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

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

The FDA is authorized to require various user fees, including NDA fees (currently up to \$1.18 million). The FDA may waive or reduce such user fees under special circumstances. We will seek waivers or reductions of user fees where possible, but we cannot be assured that we will be eligible for any such waiver or reduction.

### **Post-Approval Requirements**

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

## **Inspections**

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

## **Recalls**

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

## **Other FDA Regulations**

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

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

## **PRODUCT LIABILITY AND INSURANCE**

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic products. We presently have product liability insurance limited to \$10 million per incident, and if we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim out of our own limited resources.

## **EMPLOYEES**

As of December 31, 2008, we employed 17 full-time employees and also utilized the services of part-time consultants from time to time. None of our employees are covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

## **COMPETITION**

### **ThermoDox®**

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

## **LICENSES, PATENTS AND TRADEMARKS**

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

In 1999, the Company entered into a license agreement with Duke University under which the Company received exclusive rights (subject to certain exceptions) to commercialize and use Duke's thermo-liposome technology.

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

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

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

#### **ITEM 1A. RISK FACTORS**

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

#### **WE HAVE A HISTORY OF SIGNIFICANT LOSSES FROM CONTINUING OPERATIONS AND EXPECT TO CONTINUE SUCH LOSSES FOR THE FORESEEABLE FUTURE.**

Since Celsion's inception, our expenses have substantially exceeded our revenues, resulting in continuing losses and an accumulated deficit of \$66.9 million at December 31, 2008. For the year ended December 31, 2008, we incurred a loss from continuing operations of \$11.8 million. Because we presently have no product revenues and we are committed to continuing our product research, development and commercialization programs, we will continue to experience significant operating losses unless and until we complete the development of ThermoDox® and other new products and these products have been clinically tested, approved by the FDA and successfully marketed.

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

We have devoted our resources to developing a new generation of products but will not be able to market these products until we have completed clinical testing and obtain all necessary governmental approvals. In addition, our products are still in various stages of development and testing and cannot be marketed until we have completed clinical testing and obtained necessary governmental approval. Accordingly, our revenue sources are, and will remain, extremely limited until our products are clinically tested, approved by the FDA and successfully marketed. We cannot guarantee that any or all of our products will be successfully tested, approved by the FDA or marketed, successfully or otherwise, at any time in the foreseeable future or at all.

**IF WE DO NOT COLLECT THE RECEIVABLES FROM BOSTON SCIENTIFIC CORPORATION, WE MAY NOT BE ABLE TO COMPLETE THE DEVELOPMENT, TESTING AND COMMERCIALIZATION OF OUR TREATMENT SYSTEMS.**

As of December 31, 2008, we had approximately \$7.5 million in cash, cash equivalents, and short term investments. We also had \$15.0 million in receivables due to us from Boston Scientific in June 2009. Should Boston Scientific default on its obligations, we would need substantial additional funding in order to complete the development, testing and commercialization of our liver cancer and recurrent chest wall breast cancer treatment systems, as well as other potential new products. Other than the \$15.0 million due from Boston Scientific, we do not have any committed sources of financing and cannot offer any assurances that alternate funding will be available in a timely manner, on acceptable terms or at all.

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

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

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

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

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

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

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

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

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

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

accurately the timing of such trials, the costs associated with such trials or the procedures that are followed for such trials. We do not anticipate significantly increasing our personnel in the foreseeable future and therefore, expect to continue to rely on third parties to conduct all of our future clinical trials. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they do not carry out the trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become prohibitively expensive, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

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

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

The FDA and foreign regulatory agencies require that the safety and efficacy of product candidates be supported through adequate and well-controlled clinical trials. If the results of pivotal clinical trials do not establish the safety and efficacy of our product candidates to the satisfaction of the FDA and other foreign regulatory agencies, we will not receive the approvals necessary to market such product candidates. Even if regulatory approval of a product candidate is granted, the approval may include significant limitations on the indicated uses for which the product may be marketed.

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

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

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

Labeling and promotional activities also are regulated by the FDA. We must also comply with record keeping requirements as well as requirements to report certain adverse events involving our



products. The FDA can impose other post-marketing controls on us as well as our products including, but not limited to, restrictions on sale and use, through the approval process, regulations and otherwise.

Many states in which we do, or in the future, may do business, or in which our products may be sold, impose licensing, labeling or certification requirements that are in addition to those imposed by the FDA. There can be no assurance that one or more states will not impose regulations or requirements that have a material adverse effect on our ability to sell our products.

In many of the foreign countries in which we may do business or in which our products may be sold, we will be subject to regulation by national governments and supranational agencies as well as by local agencies affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. There can be no assurance that one or more countries or agencies will not impose regulations or requirements that could have a material adverse effect on our ability to sell our products.

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

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

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

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

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

Our cancer treatment development projects using ThermoDox® plus RFA or microwave heating, are currently in clinical trials. Any or all of these projects may prove not to be effective in practice. If testing and clinical practice do not confirm the safety and efficacy of our systems or, even if further testing and practice produce positive results but the medical community does not view these new forms of treatment as effective and desirable, our efforts to market our new products may fail, with material adverse consequences to our business.

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

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

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

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

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

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

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

There are many companies and other institutions engaged in research and development of various technologies for cancer treatment products that seek treatment outcomes similar to those that we are pursuing. We believe that the level of interest by others in investigating the potential of possible competitive treatments and alternative technologies will continue and may increase. Potential competitors engaged in all areas of cancer treatment research in the United States and other countries include, among others, major pharmaceutical, specialized technology companies, and universities and other research institutions. Most of our current and potential competitors have substantially greater financial, technical, human and other resources, and may also have far greater experience than do we, both in pre-clinical testing and human clinical trials of new products and in obtaining FDA and other regulatory approvals. One or more of these companies or institutions could succeed in developing products or other technologies that are more effective than the products and technologies that we have been or are developing, or which would render our technology and products obsolete and non-competitive. Furthermore, if we are permitted to commence commercial sales of any of our products, we will also be competing, with respect to manufacturing efficiency and marketing, with companies having substantially greater resources and experience in these areas.

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

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human therapeutic products. We presently have product liability insurance limited to \$10.0 million per incident and \$10.0 million annually. If we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim with our own limited resources, which could have a material adverse effect on our business. In addition, liability or alleged liability could harm the business by diverting the attention and resources of our management and by damaging our reputation.

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

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

**OUR STOCK PRICE HAS BEEN, AND COULD BE, VOLATILE.**

Market prices for our Common Stock and the securities of other medical, high technology companies have been volatile. Our Common Stock had a high price of \$6.68 and a low price of \$1.65 in the 52-week period ending December 31, 2008. Factors such as announcements of technological innovations or new products by us or by our competitors, government regulatory action, litigation, patent or proprietary rights developments and market conditions for medical and high technology stocks in general can have a significant impact on the market for our Common Stock.

**OUR STOCK HISTORICALLY HAS BEEN THINLY TRADED. THEREFORE, STOCKHOLDERS MAY NOT BE ABLE TO SELL THEIR SHARES FREELY.**

While our Common Stock is listed on The NASDAQ Stock Market, LLC (and previously on the American Stock Exchange), the volume of trading historically has been relatively light. There can be no assurance that our historically light trading volume, or any trading volume whatsoever, will be sustained in the future. Therefore, there can be no assurance that our stockholders will be able to sell their shares of our Common Stock at the time or at the price that they desire, or at all.

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

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

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**ITEM 2. PROPERTIES**

We lease premises consisting of approximately 13,891 square feet of administrative office, laboratory and workshop space at 10220-L Old Columbia Road, Columbia, Maryland 21046-2391 from an unaffiliated party under a seven-year lease that expires on October 31, 2010. Rent expense for the year ended December 31, 2008 was \$0.2 million. Future minimum lease obligations are as follows:

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

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

**ITEM 3. LEGAL PROCEEDINGS**

None.

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

None.

## PART II

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

#### MARKET PRICE FOR OUR COMMON STOCK

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

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

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

#### DIVIDEND POLICY

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

#### SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

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

#### ISSUANCE OF SHARES WITHOUT REGISTRATION

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

#### ISSUER PURCHASES OF EQUITY SECURITIES

None.

## ITEM 6. SELECTED FINANCIAL DATA

Not required.

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

### Overview

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

### Significant events

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

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

### *Stock-Based Compensation*

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

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

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

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

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

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

## Results of Operations

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

#### *Licensing Revenue*

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

#### *Research and Development Expenses*

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

#### *General and Administrative Expenses*

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

*Interest income*

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

*Interest expense*

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

**Financial Condition, Liquidity and Capital Resources**

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

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

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

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

**Off-Balance Sheet Arrangements**

None.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not Required.

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

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

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

None.



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

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

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

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

**ITEM 9B. OTHER INFORMATION**

None.

**PART III**

**ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS**

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

**ITEM 11. EXECUTIVE COMPENSATION**

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

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

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

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

<u>Plan category</u>	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,255,880(1)	\$ 4.38	1,380,743
Equity compensation plans not approved by security holders	—(2)	0.00	—(2)
<b>Total</b>	<b>1,255,880</b>	<b>\$ 4.38</b>	<b>1,380,743</b>

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

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

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

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

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

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

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES****1. FINANCIAL STATEMENTS**

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

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

**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:

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

<u>EXHIBIT NO.</u>	<u>DESCRIPTION</u>
4.2.1	Celsion Corporation and American Stock Transfer & Trust Company Rights Agreement dated as of August 15, 2002, incorporated herein by reference to Exhibit 99.1 to the Current Report on Form 8-K of the Company, filed August 21, 2002.
4.2.2	Amendment adopted January 16, 2003 to Rights Agreement between Celsion Corporation and American Stock Transfer & Trust Company, incorporated herein by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2004.
10.1.1	Celsion Corporation 2004 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2004.
10.1.2	Celsion Corporation 2007 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed June 15, 2007.
10.1.3	Form of Restricted Stock Agreement for Celsion Corporation 2004 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2006.
10.1.4	Form of Stock Option Agreement for Celsion Corporation 2004 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2006.
10.1.5	Form of Restricted Stock Agreement for Celsion Corporation 2007 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1.5 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2007.
10.1.6	Form of Stock Option Agreement for Celsion Corporation 2007 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1.6 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2007.
10.2.1	Stock Option Grant Agreement effective July 29, 2005 between Celsion Corporation and Lawrence S. Olanoff, incorporated herein by reference to Exhibit 99.1 to the Current Report on Form 8-K of the Company, filed July 29, 2005.
10.2.2	Letter dated March 16, 2006 from the Company to Lawrence S. Olanoff (awarding restricted stock pursuant to the Company's 2004 Stock Option Plan), incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed March 22, 2006.
10.2.3	Letter dated March 16, 2006 from the Company to Anthony P. Deasey (awarding restricted stock pursuant to the Company's 2004 Stock Option Plan) incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of the Company, filed March 22, 2006.
10.2.4	Letter dated March 16, 2006 from the Company to Carolyn Finkle (awarding restricted stock pursuant to the Company's 2004 Stock Option Plan) incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K of the Company, filed March 22, 2006.
10.2.5	Letter dated March 16, 2006 from the Company to Michael Oleck (awarding restricted stock pursuant to the Company's 2004 Stock Option Plan) incorporated herein by reference to Exhibit 10.4 to the Current Report on Form 8-K of the Company, filed March 22, 2006.

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

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

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

<u>EXHIBIT NO.</u>	<u>DESCRIPTION</u>
10.14	Stock Purchase Agreement, dated December 7, 2007, by and between Celsion Corporation and Boston Scientific Corporation, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed December 13, 2007.
10.15+	Development, Product Supply and Commercialization Agreement, executed on December 9, 2008, by and between the Company and Yakult Honsha Co., Ltd., filed herewith. (Confidential treatment requested.)
14.1	Code of Ethics and Business Conduct, incorporated herein by reference to Exhibit 14.1 to the Annual Report on Form 10-K of the Company for the Year Ended September 30, 2003.
23.1+	Consent of Stegman & Company, independent registered public accounting firm for the Company.
31.1+	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1^	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2^	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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+ Filed herewith.

^ Furnished herewith.



**SIGNATURES**

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

## CELSION CORPORATION

March 27, 2009	By: <u>/s/ MICHAEL H. TARDUGNO</u> Michael H. Tardugno <i>President and Chief Executive Officer</i>
March 27, 2009	By: <u>/s/ SEAN MORAN</u> Sean Moran <i>Senior Vice President &amp; Chief Financial Officer</i>

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:

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

## MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

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

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

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

Date: March 27, 2009

/s/ MICHAEL H. TARDUGNO

\_\_\_\_\_  
Michael H. Tardugno  
*Chief Executive Officer*

/s/ SEAN MORAN

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Sean Moran  
*Senior Vice President and Chief Financial Officer*

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
Celsion Corporation

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

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

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

/s/ Stegman & Company

Baltimore, Maryland  
March 25, 2009

## CELSION CORPORATION

## BALANCE SHEETS

DECEMBER 31, 2008 AND 2007

	December 31,	
	2008	2007
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 200,651	\$ 2,937,373
Short term investments available for sale, at fair value	7,316,894	3,000,000
Accounts receivable—trade	—	183,043
Other receivables	38,327	47,110
Due from Boston Scientific Corporation	15,000,000	15,000,000
Prepaid expenses	267,561	256,874
<b>Total current assets</b>	<u>22,823,433</u>	<u>21,424,400</u>
<b>Property and equipment—at cost</b>		
Furniture and office equipment	198,434	194,200
Computer hardware and software	318,122	338,349
Laboratory and shop equipment	345,558	305,340
Leasehold improvements	132,148	132,148
	<u>994,262</u>	<u>970,037</u>
Less: Accumulated depreciation	771,624	702,156
<b>Property and equipment—net</b>	<u>222,638</u>	<u>267,881</u>
<b>Other assets</b>		
Advances under Celsion (Canada), Ltd.		
Transition Services Agreement (net of allowance of \$649,891 and \$442,225, respectively)	—	200,000
Note receivable (net of allowance and discount of \$1,128,820 and \$168,473, respectively)	221,179	1,181,527
Due from Boston Scientific Corporation—Non Current	—	15,000,000
Deposits and other assets	362,651	899,268
Patent licensing fees (net of accumulated amortization of \$15,000 and \$7,500, respectively)	58,125	65,625
<b>Total other assets</b>	<u>641,955</u>	<u>17,346,420</u>
<b>Total assets</b>	<u>\$23,688,026</u>	<u>\$39,038,701</u>

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

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

See accompanying notes.

**CELSION CORPORATION**  
**STATEMENTS OF OPERATIONS**

**FOR THE YEARS ENDED DECEMBER 31, 2008 AND 2007**

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

See accompanying notes.

**CELSION CORPORATION**  
**STATEMENTS OF CASH FLOWS**  
**YEARS ENDED DECEMBER 31, 2008 AND 2007**

	<b>Year Ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Cash flows from operating activities</b>		
Net (loss)/income for the year	\$(11,786,215)	\$ 35,349,057
Non-cash items included in net income/loss:		
Depreciation and amortization	69,468	169,129
Accretion of discount on note receivable	—	(99,921)
Gain on sale of medical device business	—	(48,029,445)
Amortization of indemnity reserve	(2,431,715)	—
Stock based compensation—Options	750,822	999,883
Stock based compensation—Restricted Stock	110,667	70,678
Amortization of deferred license fee	7,500	(269,840)
Shares issued in exchange for services	—	68,555
Amortization of patent license	—	61,606
Loss from disposal of property and equipment	—	15,145
Allowance for bad debt—Celsion Canada	1,160,348	442,225
Net changes in:		
Accounts receivable-trade	183,043	1,699,330
Other receivables	8,783	(25,435)
Due from Boston Scientific	15,000,000	—
Inventories	—	5,792
Prepaid expenses	(10,687)	173,620
Escrow account-license fee	—	1,824,740
Deposits and other assets	536,617	(245,337)
Accounts payable—trade and accrued interest	(643,946)	358,539
Income taxes payable	(546,000)	546,000
Other accrued liabilities	(127,422)	(2,697,106)
<b>Net cash provided by/ (used in) operating activities</b>	<b>2,281,263</b>	<b>(9,582,785)</b>
<b>Cash flows from investing activities</b>		
Purchases of short term investments, available for sale	(6,369,394)	(5,000,000)
Sale of short-term investments, available for sale	2,052,500	10,000,000
Proceeds from sale of medical device business assets	—	9,958,615
Advances under Celsion Canada transition services agreement	—	(55,403)
Loss on investment in Celsion China, Ltd.	—	—
Payment of licensing fee	—	(1,600,000)
Proceeds from sale of property and equipment	—	100
Purchase of property and equipment	(24,225)	(91,195)
<b>Net cash (used in)/ provided by investing activities</b>	<b>(4,341,119)</b>	<b>13,212,117</b>
<b>Cash flows from financing activities</b>		
Proceeds from note payable	—	1,181,925
Payments on note payable	(676,866)	(270,324)
Proceeds from loan payable	—	—
Exercise of common stock options	—	2,718
Purchase of treasury stock	—	(2,638,952)
<b>Net cash used in financing activities</b>	<b>(676,866)</b>	<b>(1,724,633)</b>
<b>Net (decrease)/ increase in cash and cash equivalents</b>	<b>(2,736,722)</b>	<b>1,904,699</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>2,937,373</b>	<b>1,032,674</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 200,651</b>	<b>\$ 2,937,373</b>
<b>Cash paid for:</b>		
Interest	\$ 141,612	\$ 31,022
Income taxes	\$ 546,000	\$ 273,095

See accompanying notes.

**CELSION CORPORATION**  
**STATEMENTS OF CASH FLOWS**

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

See accompanying notes.



**CELSION CORPORATION**

**STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY/(DEFICIT)**

**YEARS ENDED DECEMBER 31, 2008 AND 2007**

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

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

See accompanying notes.

**CELSION CORPORATION**

**NOTES TO FINANCIAL STATEMENTS**

**YEARS ENDED DECEMBER 31, 2008 AND 2007**

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Description of Business*

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

*Basis of Presentation*

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

*Revenue Recognition*

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

Prior to 2008, when the Company operated a medical device business, revenue was recognized on medical device control units as they were sold to ultimate customers by Boston Scientific. Medical device control units shipped to Boston Scientific but not yet sold to ultimate customers were reflected in finished goods inventory. Revenue on the sale of catheter kits was recognized upon shipment to Boston Scientific. All of Company's revenues from the medical device business are included in Discontinued Operations, for the year ended December 31, 200. As more fully described in Note 13 to the financial statements, the Company sold the assets of the medical device business to Boston Scientific on June 21, 2007.

*Cash and Cash Equivalents*

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

*Fair Value of Financial Instruments*

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

*Short Term Investments*

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

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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

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

*Accounts Receivable—Trade*

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

*Property and Equipment*

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

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

*Deposits*

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

*Patent Licenses*

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

*Indemnity Reserve*

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

## CELSION CORPORATION

## NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

## 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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

*Comprehensive Income*

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

*Research and Development*

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

*Net Income/(Loss) Per Common Share*

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

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

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

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

*Nonmonetary Transactions*

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

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

*Income Taxes*

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

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

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

*Use of Estimates*

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

*Stock-Based Compensation*

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

The fair value of options, warrants and restricted stock granted is measured in accordance with SFAS 123(R) using the Black-Scholes option pricing model and recorded as an expense in the period in which such services are received. The fair values of stock options granted were estimated at the date of grant using the Black-Scholes option pricing model. The Black-Scholes model was originally developed for use in estimating the fair value of traded options, which have different characteristics from Celsion's nonqualified stock options. The model is also sensitive to changes in assumptions, which can materially affect the fair value estimate.

Expected volatilities utilized in the model are based on historical volatility of the Company's stock price. The risk free interest rate is derived from values assigned to U.S. Treasury strips as published in

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

the Wall Street Journal in effect at the time of grant. The model incorporates exercise, pre-vesting and post-vesting forfeiture assumptions based on analysis of historical data. The expected life of the fiscal 2008 grants was generated using the simplified method as allowed under Securities and Exchange Commission Staff Accounting Bulletin No. 107.

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

*Significant New Accounting Pronouncements*

*Recent Accounting Pronouncements issued but not yet effective*

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

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

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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

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

*Recent Accounting Pronouncements issued and adopted*

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

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

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

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

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

**2. SHORT TERM INVESTMENTS AVAILABLE FOR SALE**

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

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



**CELSION CORPORATION**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**YEARS ENDED DECEMBER 31, 2008 AND 2007**

**2. SHORT TERM INVESTMENTS AVAILABLE FOR SALE (Continued)**

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

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

**3. FAIR VALUES OF FINANCIAL INSTRUMENTS**

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

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

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

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

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

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

**CELSION CORPORATION**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**YEARS ENDED DECEMBER 31, 2008 AND 2007**

**3. FAIR VALUES OF FINANCIAL INSTRUMENTS (Continued)**

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

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

**4. NOTE RECEIVABLE**

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

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

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

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

**CELSION CORPORATION**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**YEARS ENDED DECEMBER 31, 2008 AND 2007**

**4. NOTE RECEIVABLE (Continued)**

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

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

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

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

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

**6. NOTE PAYABLE**

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

**CELSION CORPORATION**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**YEARS ENDED DECEMBER 31, 2008 AND 2007**

**7. INCOME TAXES**

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

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

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

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

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

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

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

**CELSION CORPORATION**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**YEARS ENDED DECEMBER 31, 2008 AND 2007**

**7. INCOME TAXES (Continued)**

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

**8. CELSION EMPLOYEE BENEFIT PLANS**

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

**9. LICENSING AGREEMENTS**

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

On November 10, 1999, the Company entered into a license agreement with Duke University under which the Company received exclusive rights (subject to certain exceptions) to commercialize and use Duke's thermo-liposome technology. The license agreement contains annual royalty and minimum payment provisions and also requires milestone-based royalty payments measured by various events, including product development stages, FDA applications and approvals, foreign marketing approvals and achievement of significant sales. However, in lieu of such milestone-based cash payments, Duke agreed to accept shares of the Company's Common Stock to be issued in installments at the time each milestone payment is due, with each installment of shares to be calculated at the average closing price of the Common Stock during the 20 trading days prior to issuance. The total number of shares issuable to Duke under these provisions is subject to adjustment in certain cases, and Duke has piggyback registration rights for public offerings taking place more than one year after the effective date of the license agreement. On January 31, 2003, the Company issued 253,691 shares of Common Stock to Duke University valued at \$2.2 million as payment under this licensing agreement.

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

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

**CELSION CORPORATION**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**YEARS ENDED DECEMBER 31, 2008 AND 2007**

**9. LICENSING AGREEMENTS (Continued)**

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

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

**10. STOCKHOLDERS' EQUITY**

Treasury Stock

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

Employee Stock Options

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

*2001 Stock Option Plan*

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

*2004 Stock Incentive Plan*

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

**CELSION CORPORATION**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**YEARS ENDED DECEMBER 31, 2008 AND 2007**

**10. STOCKHOLDERS' EQUITY (Continued)**

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

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

*2007 Stock Incentive Plan*

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

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

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

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

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

**CELSION CORPORATION**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**YEARS ENDED DECEMBER 31, 2008 AND 2007**

**10. STOCKHOLDERS' EQUITY (Continued)**

Options Issued to Consultants for Services

The Company periodically issues options to consultants in exchange for services provided. The fair value of options granted is measured in accordance with SFAS 123(R) using the Black-Scholes option pricing model and recorded as an expense in the period in which such services are received. Generally, the terms of these plans require that the exercise price of such options may not be less than the fair market value of the Company's Common Stock on the date the options are granted. Consultant options generally vest over various time frames or upon milestone accomplishments. Some vest immediately upon issuance. The options generally expire 10 years from the date of grant. During the year ended December 31, 2007, options to purchase 10,000 shares at a strike price of \$5.84 were issued pursuant to a consulting agreement. There were no options issued to consultants in the years ended December 31, 2008 and 2007.

Warrants

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

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

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



CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

10. STOCKHOLDERS' EQUITY (Continued)

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

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

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

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

**CELSION CORPORATION**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**YEARS ENDED DECEMBER 31, 2008 AND 2007**

**10. STOCKHOLDERS' EQUITY (Continued)**

Restricted Stock

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

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

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:

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

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

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

## CELSION CORPORATION

## NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

## 10. STOCKHOLDERS' EQUITY (Continued)

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

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

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

*Preferred Stock and Stockholder Rights Plan*

The Company's Certificate of Incorporation and Bylaws authorizes the issuance of "blank check" preferred stock by the Board of Directors, on such terms as it determines and without further stockholder approval. The Company has also implemented a stockholder rights plan and distributed rights to our stockholders. When these rights become exercisable, these rights entitle their holders to purchase one share of our Series C Junior Participating Preferred Stock at a price of \$66.90 per one ten-thousandth of a share of Series C Preferred Stock. If any person or group acquires more than 15% of our Common Stock, the holders of rights (other than the person or group crossing the 15% threshold) will be able to purchase, in exchange for the \$66.90 exercise price, \$133.80 of our Common Stock or the stock of any company into which we are merged.

## 11. CONTINGENT LIABILITIES AND COMMITMENTS

*Operating lease commitments*

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

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

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

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

## CELSION CORPORATION

## NOTES TO FINANCIAL STATEMENTS (Continued)

## YEARS ENDED DECEMBER 31, 2008 AND 2007

**12. RELATED PARTY TRANSACTIONS**

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

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

**13. DISCONTINUED OPERATIONS**

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

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

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

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

CELSION CORPORATION

NOTES TO FINANCIAL STATEMENTS (Continued)

YEARS ENDED DECEMBER 31, 2008 AND 2007

13. DISCONTINUED OPERATIONS (Continued)

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

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

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



## DEVELOPMENT, PRODUCT SUPPLY AND COMMERCIALIZATION AGREEMENT

FOR THERMODOX®

by and between

CELSION CORPORATION

and

YAKULT HONSHA CO., LTD.

Dated: December 1, 2008

Material in this Agreement has been omitted and filed separately with the Commission.

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**DEVELOPMENT, PRODUCT SUPPLY AND COMMERCIALIZATION AGREEMENT**

THIS DEVELOPMENT, PRODUCT SUPPLY AND COMMERCIALIZATION AGREEMENT (the "Agreement"), is executed and effective on December 5, 2008 (the "Effective Date"), by and between Celsion Corporation, a corporation organized and existing under the laws of the State of Delaware and having its principal office at 10220 Old Columbia Road, Suite L, Columbia, Maryland 21046 ("Celsion"), and Yakult Honsha Co., Ltd., a corporation

organized and existing under the laws of Japan and having its principal office at 1-19 Higashi Shinbashi 1-chome, Minato-ku, Tokyo, Japan (“Yakult”). Celsion and Yakult are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”

## INTRODUCTION

WHEREAS, Duke University granted rights with respect to ThermoDox Product to Celsion Corporation under the License Agreement dated on November 10, 1999, as amended by Amendment to License Agreement on January 15, 2003, and Amendment 2 to License Agreement on June 20, 2007. (“Duke Agreement”);

WHEREAS, Yakult has extensive experience and expertise in the development and commercialization of pharmaceutical products in Japan;

WHEREAS, Celsion has an ongoing research and development program in the field of ThermoDox Products and holds certain intellectual property in this field; and

WHEREAS, Celsion and Yakult and its Affiliates desire to collaborate on the research, development and commercialization of the ThermoDox Products in Japan upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual representations, covenants and agreements contained herein, Celsion and Yakult, intending to be legally bound, agree as follows:

## ARTICLE 1 DEFINITIONS

For purposes of this Agreement, the following initially capitalized terms, whether used in the singular or plural, shall have the following meanings:

**1.1** “Adverse Event” means any unfavorable and unintended sign, including an abnormal laboratory finding, symptom, or disease temporally associated with the use of ThermoDox Products, whether or not related to ThermoDox Products.

**1.2** “Affiliate” of a Party means any Person which directly or indirectly controls, is controlled by, or is under common control with such Party for so long as such control exists. For purposes of this definition, “control” of a Person means (including, with correlative meanings, “controlled by,” “controlling” and “under common control with”) the possession of

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(a) the power to direct or cause the direction of the management and policies of such Person, or (b) ownership of at least fifty percent (50%) of the securities or comparable equity interest (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) having the power to vote on or direct the affairs of the Person.

**1.3** “Bundled Product” means a product containing a ThermoDox Product and other products sold by Yakult, when sold together by Yakult have the intent of providing an aggregate price lower or higher than the price of each product sold separately.

**1.4** “Business Day” means any day that is not a Saturday, a Sunday or a national holiday in Japan or an official holiday in the state of New York as identified annually by the Parties.

**1.5** “Calendar Quarter” means for each Calendar Year, each of the three (3) month periods ending March 31, June 30, September 30 and December 31; provided, however, that the first Calendar Quarter for the first Calendar Year shall extend from the Effective Date to the end of the first complete calendar quarter thereafter.

**1.6** “Calendar Year” means, for the first calendar year, the period commencing on the Effective Date and ending on December 31 of the calendar year during which the Effective Date occurs, and each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31.

**1.7** “Celsion Confidential Information” means Confidential Information for which Celsion is the Disclosing Party.

**1.8** “Celsion Improvements” means any Improvements that are conceived, first made or invented during the Term solely by Celsion, or its Affiliates, agents, or sublicensees or by Third Parties acting on its behalf.

**1.9** “Celsion IND” means [ \* ] for a use of ThermoDox Product as filed with the US Food and Drug Administration.

**1.10** “Celsion Know-How” means Know-How that is either Controlled by Celsion on the Effective Date or comes within Celsion’s Control during the Term (other than Yakult Know-How pursuant to the licenses granted hereunder) and is necessary or useful for the Development, manufacture, use or Commercialization of any ThermoDox Product, provided that Celsion Know-How shall not include Celsion Improvements.

**1.11** “Celsion Patent Costs” means all Patent Costs incurred in the preparing, filing, prosecuting and maintaining Celsion Patent Rights.

**1.12** “Celsion Patent Rights” means any Patent Rights containing one or more claims that cover (i) the composition of matter of a ThermoDox Product or portion thereof, (ii) the manufacture or formulation of the foregoing, (iii) use of a ThermoDox Product for a Named Indication, or (iv) any Patent Rights otherwise necessary or useful for the Development,

\* Material has been omitted and filed separately with the Commission.

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manufacture, use or Commercialization of any ThermoDox Product for a Named Indication, which are Controlled by Celsion as of the Effective Date or come within Celsion's Control during the Term (other than (x) Yakult Patent Rights pursuant to the licenses granted hereunder and (y) Celsion Improvements), including any Patent Rights claiming Joint Improvements. As of the Effective Date, Celsion Patent Rights are [ \* ].

**1.13** "Celsion Technology," means Celsion Patent Rights and Celsion Know-How.

**1.14** "Change of Control" means with respect to a Party (1) the sale of all or substantially all of such Party's assets or business relating to this Agreement; (2) a merger, reorganization or consolidation involving such Party in which the voting securities of such Party outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (3) a person or entity, or group of persons or entities, acting in concert acquire more than fifty percent (50%) of the voting equity securities or management control of such Party.

**1.15** "Claims" means all charges, complaints, actions, suits, proceedings, hearings, investigations, claims and demands.

**1.16** "Clinical Study" is a scientific study of how a treatment works in humans. A Clinical Study is deemed to "commence" upon the first patient signing an informed consent in such Clinical Study. A Clinical Study can be a Phase I, Phase II or Phase III study. Clinical Studies shall have a corresponding meaning. A Phase IV study is not a Clinical Study.

**1.17** "CMC" means "Chemistry Manufacturing and Controls" and refers to the FDA and/or Japanese regulatory term used in drug manufacturing and development.

**1.18** "Collaboration" means the joint efforts of Celsion and Yakult to Develop and Commercialize ThermoDox Product for Named Indications pursuant to this Agreement.

**1.19** "Collateral Materials" means, with respect to a ThermoDox Product, information, data, or images reduced to a tangible form (which, for the avoidance of doubt, shall include electronic form) to the extent relating exclusively to such ThermoDox Product. By way of example and not limitation, Development Plans, NDAs, Regulatory Materials, Commercialization Plans, ThermoDox Product training program and Promotional Materials are all considered "Collateral Materials."

**1.20** "Commercialization" means any and all activities directed to marketing, promoting, distributing, offering for sale and selling a ThermoDox Product, importing a ThermoDox Product (to the extent applicable) and conducting Phase IV Studies. When used as a verb, "Commercialize" means to engage in Commercialization.

**1.21** "Commercialization Costs" of a ThermoDox Product means all Out-of-Pocket Costs and Expenses, incurred by Yakult or its Affiliates, to the extent provided for in an approved Commercialization Plan or otherwise approved in advance by the Committee, and

\* Material has been omitted and filed separately with the Commission.

solely to the extent related to marketing and sale of such ThermoDox Product in the Territory, consisting of:

**1.21.1** [ \* ];

**1.21.2** [ \* ];

**1.21.3** [ \* ];

**1.21.4** [ \* ];

**1.21.5** [ \* ];

**1.21.6** [ \* ];

**1.21.7** [ \* ].

**1.21.8** [ \* ];

**1.21.9** [ \* ];

**1.21.10** [ \* ]; and

**1.21.11** [ \* ].

**1.22** "Commercially Reasonable Efforts" means the efforts, activities and resources, which a diligent Third Party company active in the same Field as the respective Party would use (including, without limitation, the promptness with which such efforts and resources would be applied) in Developing, manufacturing, promoting or Commercializing its own pharmaceutical products that are of comparable market potential to the ThermoDox Product, taking into account all relevant factors including product labeling or anticipated labeling, present and future market potential, past performance of the ThermoDox Product and such Party's own pharmaceutical products that are of similar market potential, financial return, medical and clinical considerations, present and future regulatory environment and competitive market conditions, and the nature and extent of market exclusivity (including patent coverage and regulatory exclusivity), all as measured by the facts and circumstances at the time such efforts are due. Commercially Reasonable Efforts require that a Party, at a minimum, assign responsibility for such obligations to qualified employees, set annual goals and objectives for carrying out such obligations, and allocate appropriate resources designed to meet such goals and objectives.

1.23 “Committee” means the joint steering Committee.

1.24 “Confidential Information” means all secret, confidential or proprietary information or data, whether provided in written, oral, graphic, video, electronic or other form, provided by one Party (the “Disclosing Party”) to the other Party (the “Receiving Party”) pursuant to the terms of binding agreement between Yakult and Celsion for Development and

\* Material has been omitted and filed separately with the Commission.

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marketing of ThermoDox Product in Japan, dated August 13, 2008, this Agreement or generated pursuant to this Agreement, including without limitation, non-public information relating to the Disclosing Party’s existing or proposed research, development efforts, new inventions (whether or not patentable), patent applications, Know-How, Improvements by either or both Parties, sources of materials used, customers, financial information, personnel, business, products, and the terms of this Agreement. Notwithstanding the foregoing sentence, Confidential Information shall not include any information or materials that:

1.24.1 were already known by the Receiving Party or any of its Affiliates (other than under an obligation of confidentiality to the Disclosing Party) at the time of disclosure by the Disclosing Party, to the extent such Receiving Party has documentary evidence of independent discovery or development by or on behalf of the Receiving Party or any of its Affiliates, without the use of the Confidential Information belonging to the Disclosing Party;

1.24.2 were generally available to the public at the time of its disclosure to the Receiving Party;

1.24.3 became generally available to the public after its disclosure or development by either or both Parties, as the case may be, and other than through any act or omission of the Receiving Party in breach of the Receiving Party’s confidentiality obligations under this Agreement; or

1.24.4 were disclosed to the Receiving Party or any of its Affiliates, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others;

1.25 “Control” or “Controlled” means, with respect to any: (a) material, item of information, method, data or other Know-How, or (b) intellectual property right, the possession (whether by ownership or license, other than a license pursuant to this Agreement) by a Party or its Affiliates of the ability to grant to the other Party access and/or a license as provided herein under such item or right without violating the terms of any agreement or other arrangement with any Third Party existing at the applicable time.

1.26 “Country” means any generally recognized sovereign entity.

1.27 “Development” or “Develop” means preclinical and clinical drug development activities, including, among other things, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, manufacturing for Clinical Studies, preclinical studies, Clinical Studies, regulatory filing submission and approval, and regulatory affairs related to the foregoing. When used as a verb, “Develop” means to engage in Development. For clarity, Development does not include Phase IV Studies.

1.28 “Development Costs” of a ThermoDox Product means all Out-of-Pocket Costs and Expenses for work required for Development of such ThermoDox Product (including preclinical and clinical activities and CMC studies, regulatory activities and approvals, the recruiting and enrolling of patients in the Clinical Studies), and the cost to purchase the

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ThermoDox Product, in each case only to the extent provided for in an approved Development Plan or otherwise approved in writing and in advance by the Committee. Development Costs shall consist of:

1.28.1 [ \* ];

1.28.2 [ \* ]; and

1.28.3 [ \* ].

1.29 “Development Plan” for a ThermoDox Product means the written comprehensive plan for the Development of such ThermoDox Product through filing for Marketing Authorization, including activities designed to generate the preclinical, process development/manufacturing scale-up, clinical and regulatory information required for filing Marketing Authorization Applications and managing any contracted Third Party resources engaged to carry out any of the foregoing activities. The initial Development Plans for ThermoDox Products in the Territory shall be developed by Yakult and approved by the Committee within [ \* ] of the Effective Date, and may be amended and updated in accordance with Section 2.3 of this Agreement.

1.30 *(Intentionally Deleted)*

1.31 *(Intentionally Deleted)*

1.32 “FDA” means the U.S. Food and Drug Administration and any successor agency thereto.

1.33 “FD&C Act” means the U.S. Federal Food, Drug, and Cosmetic Act, as amended from time to time (21 U.S.C. §§ 301 et seq.), together with any rules and regulations promulgated thereunder.

1.34 “Field” means all therapeutic, prognostic and diagnostic applications for ThermoDox Product for human and non-human purposes for Named Indications.

**1.35** “First Commercial Sale” of a ThermoDox Product means the first shipment of such ThermoDox Product in quantities customarily required for a pharmaceutical product launch sold to a Third Party by Yakult, Yakult’s Affiliates, or Yakult’s sublicensees in the Territory after receipt of Marketing Authorization (and, where applicable, Price Approval) for such ThermoDox Product in the Territory.

**1.36** “Generic Product” means, on a Country-by-Country basis and ThermoDox Product-by- ThermoDox Product basis, a drug product independently developed by a Third Party that: (a) contains the same active pharmaceutical ingredient(s) as the ThermoDox Product, (b) can reasonably be or is reasonably used for the same indication or indications for which such ThermoDox Product is approved, (c) is approved for use and sale in the Territory in reliance on the prior approval of a ThermoDox Product as determined by the applicable Regulatory

\* Material has been omitted and filed separately with the Commission.

Authority, and (d) whose manufacture, importation, sale, offer for sale and/or use is not challenged under any Laws by Celsion or a Celsion Affiliate.

**1.37** “GCPs” means the then-current standards, practices and procedures promulgated or endorsed by the FDA for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials as set forth in the guidelines titled “Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance,” including related regulatory requirements imposed by the MHLW and comparable regulatory standards, practices and procedures imposed by any Regulatory Authority in the Territory, as well as guidelines promulgated by the ICH, as the foregoing may be updated from time to time, that provide assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

**1.38** “GLPs” means the then-current good laboratory practice standards promulgated or endorsed by the MHLW and comparable regulatory standards imposed by any Regulatory Authority in the Territory, as well as guidelines promulgated by the ICH, as the foregoing may be updated from time to time.

**1.39** “GMPs” means the then-current good manufacturing practices required by the MHLW for the manufacture and testing of pharmaceutical materials, and comparable Laws or regulations applicable to the manufacture and testing of pharmaceutical materials imposed by any Regulatory Authority in the Territory, as well as guidelines promulgated by the ICH, as the foregoing may be updated from time to time.

**1.40** “Governmental Authority” means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

**1.41** “ICH” means International Conference for Harmonization of Technical Requirements for Registration for Pharmaceuticals for Human Use.

**1.42** “Improvement” means any invention, discovery, modification or improvement (whether patentable or not) conceived, first made or invented by or on behalf of a Party during the Term related to ThermoDox Product and / or any other of its underlying LTSL technology which may be used in other Celsion products, including, without limitation, all new or improved ingredients, compositions, methods of synthesis, use, manufacture, preparation, presentation, means of delivery, dosage, formulation or analysis. For clarity, Improvement includes all Joint Improvements.

**1.43** “IND” means an Investigational New Drug Application, as defined in the FD&C Act, that is required to be filed with the FDA, or similar application or submission that is required to be filed with any Regulatory Authority in the Territory, before beginning clinical testing of a ThermoDox Product in human subjects. IND means the Celsion IND or the Yakult IND as the context requires.

**1.44** “Joint Improvement” means an Improvement that is conceived, first made or invented jointly by employees and/or agents of both Celsion and Yakult or their Affiliates.

**1.45** “Know-How” means any technology, technical information, know-how and materials, including, without limitation, all biological, chemical, pharmacological, toxicological, clinical, assay and other information, data, discoveries, inventions, improvements, processes, techniques, formulae and trade secrets, patentable or otherwise.

**1.46** “Laws” means laws, rules and regulations (including any rules, regulations, guidelines or other requirements of the Regulatory Authorities applicable to the Development, manufacturing, storage, distribution and Commercialization of ThermoDox Products) that may be in effect from time to time.

**1.47** “Losses” means any and all damages, awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses, lost profits and expenses (including, without limitation, court costs, interest and reasonable fees of attorneys, accountants and other experts) incurred by or awarded to Third Parties and required to be paid to Third Parties with respect to a Claim by reason of any judgment, order, decree, stipulation or injunction, or any settlement entered into in accordance with the provisions of this Agreement, together with all documented Out-of-Pocket Costs and Expenses incurred in complying with any judgments, orders, decrees, stipulations and injunctions that arise from or relate to a Claim of a Third Party.

**1.48** “LTSL” means any and all Lysolipid Thermally Sensitive Liposomes including, without limitation, ThermoDox Products and other heat activated encapsulated chemotherapeutic agents.

**1.49** “Marketing Authorization” means the approval by a Regulatory Authority for the sale of a ThermoDox Product within the Territory for which the Regulatory Authority has jurisdiction.

**1.50** “Marketing Authorization Application” or “MAA” means, with respect to a Country, the regulatory authorization application required to market and sell a ThermoDox Product in such Country as granted by the relevant Regulatory Authority, including any NDA or any marketing authorization application filed with the MHLW.

**1.51** “Material Breach” means any breach by any Party hereto of its representations, warranties, covenants, agreements or other performance obligations under this Agreement (other than a payment obligation) that (a) is material to this Agreement, taken as a whole, and (b) shall have continued for [ \* ] after notice thereof was provided to the alleged breaching Party by the non-breaching Party, with the exception of actions or omissions resulting from mutual agreement in writing by the Parties or required for compliance with any applicable Law.

**1.52** “MHLW” means Japan’s Ministry of Health, Labour and Welfare and any of its subsidiary agencies or local governments responsible for pharmaceutical matters, or any successor agency having substantially the same function.

\* Material has been omitted and filed separately with the Commission.

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**1.53** “Named Indications” means indications set forth on Schedule 1.53, as amended from time to time pursuant to the terms of this Agreement, including without limitation, any amendments necessary to include all indications involving the ThermoDox Products for which either Celsion (outside of the Territory) or Yakult (within the Territory) has received Marketing Authorization from the FDA or MHLW, respectively, or any other mutually agreed indication. As of the Effective Date, the Named Indication is Hepatocellular Carcinoma (“HCC”). As set forth in Sections 2.1 and 4.2, this Agreement requires Yakult to study and submit for approval all indications that have been approved by the FDA or other international Regulatory Authority (i.e. major market countries that participate in ICH such as UK, France, Germany and Canada).

**1.54** “NDA” means a new drug application or supplemental new drug application or any amendments thereto, submitted to the FDA in the United States, or the MHLW in the Territory, as the case may be.

**1.55** (*Intentionally Deleted*)

**1.56** “Net Sales” of a ThermoDox Product means, as determined in accordance with GAAP, the aggregate gross amount invoiced on account of sales of such ThermoDox Product by Yakult or any of its Affiliates or their sublicensees to a Third Party, less the amount of the following relating to such sale to the extent actually paid, granted or accrued:

**1.56.1** [ \* ];

**1.56.2** [ \* ];

**1.56.3** [ \* ];

**1.56.4** [ \* ]; and

**1.56.5** [ \* ].

For clarity, any tax, tariff, customs duty, excise or other duty or other governmental charge levied on the sale, transportation or delivery of a ThermoDox Product and borne by the seller thereof will not reduce Net Sales for Royalty Payments calculation. Net Sales shall be determined from books and records maintained by Yakult in accordance with GAAP, as consistently applied with respect to sales of all of its prescription pharmaceutical products. For clarity, ThermoDox Product professional samples or similar use of products shall be considered marketing expenses, and shall not be considered a discount or otherwise be used to offset Net Sales.

In the case of any sale for value, such as barter or counter-trade, of a ThermoDox Product, or part thereof, other than in an arm’s-length transaction exclusively for cash, Net Sales shall be deemed to be the Net Sales at which substantially similar quantities of such ThermoDox Product are sold for cash in an arm’s-length transaction.

\* Material has been omitted and filed separately with the Commission.

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Notwithstanding the foregoing, Net Sales shall not be reduced by customs or excise taxes, import duties, sales taxes and other taxes or duties related to the active ingredient in a ThermoDox Product or sales of a ThermoDox Product other than in finished form, all of which shall be deemed expenses incurred in connection with the manufacture of a ThermoDox Product.

In the event a ThermoDox Product is sold as a Bundled Product, Net Sales shall be calculated by multiplying the Net Sales of the Bundled Product by the fraction  $A/(A+B)$ , where A is the weighted (by sales volume) average sale price in the Territory of the ThermoDox Product in such Bundled Product when sold separately in finished form and B is the weighted (by sales volume) average sale price in the Territory of the other product(s) sold separately in finished form. In the event no such separate sales are made by Yakult or its Affiliates or sublicensees, Net Sales of the Bundled Product shall be calculated in a manner to be negotiated and agreed upon by the Parties, reasonably and in good faith, prior to any sale of such Bundled Product, which shall be based upon the relative value contributed to the Bundled Product of each of the active components of such Bundled Product.

**1.57** “Out-of-Pocket Costs and Expenses” means costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP), other than Affiliates or employees, by either Party.

**1.58** “Patent Costs” means all Out-of-Pocket Costs and Expenses incurred in preparation, filing, prosecuting and maintaining Patent Rights.

**1.59** “Patent Rights” means all patents and patent applications filed anywhere in the world including any continuations, continuations-in-part, divisions, provisionals or any substitute applications, any patent issued with respect to any such patent applications, any reissue, reexamination, renewal or extension (including any supplemental protection certificate) of any such patent, and any confirmation patent, registration patent or patent of addition based

on any such patent, and all foreign counterparts of any of the foregoing, and all patents and patent applications claiming priority to and from which others claim priority, or, as applicable, portions thereof or individual claims therein.

**1.60** “Patent Term Extension” means any term extensions, supplementary protection certificates, and equivalents thereof, offering patent protection beyond the initial term with respect to any issued Patent Rights.

**1.61** “Person” means any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship or other business organization.

**1.62** “Phase I Study” means, with respect to a ThermoDox Product, a clinical study identified as a Phase I Study in the Development Plan and conducted in humans on a pharmaceutical product with the primary purpose of determining safety, metabolism and pharmacokinetic properties, dosing and clinical pharmacology of such pharmaceutical product, and that is consistent with 21 C.F.R. § 312.21(a). Phase I Study also means the equivalent study in Japan.

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**1.63** “Phase II Study” means, with respect to a ThermoDox Product, a clinical study identified as a Phase II Study in the Development Plan and conducted in human patients designed to evaluate initial clinical efficacy and safety for such product for one or more indications, as well as to obtain further understanding of the dosage regimen before embarking on Phase III Studies, and that is consistent with 21 C.F.R. § 312.21(b). Phase II Study also means the equivalent study in Japan.

**1.64** “Phase III Study” means, with respect to a ThermoDox Product, a clinical study identified as a Phase III Study in the Development Plan and conducted as a pivotal trial for purposes of filing a Marketing Approval Application for a ThermoDox Product that provides for the clinical study of such ThermoDox Product on sufficient numbers of patients to confirm with statistical significance the efficacy, and confirm the safety of such ThermoDox Product sufficient to support such Marketing Approval Application for such ThermoDox Product, and is consistent with 21 C.F.R. § 312.21(c). Phase III Study also means the equivalent study in Japan.

**1.65** “Phase IV Study” means a study required by a Regulatory Authority that is a Phase IV post-marketing and safety study, clinical experience study, and all other similar types of studies or investigations for a ThermoDox Product that is initiated in the Territory after receipt of a Marketing Authorization for such ThermoDox Product in the Territory and is principally intended to support the marketing and Commercialization of such ThermoDox Product, including, without limitation, clinical experience investigations and studies conducted to fulfill local commitments made as a condition of any Marketing Authorization. For clarity, no Phase III Studies are included in this definition of Phase IV Studies. Phase IV Study also means the equivalent study in Japan.

**1.66** “Preclinical Development Plan” means a Development Plan directly relating to a Preclinical Study.

**1.67** “Preclinical Study” means, with respect to a ThermoDox Product, the testing of experimental drugs and chemical compounds in the laboratory (*in vitro*) or in animals. Preclinical Study shall not include testing, experimentation of other use in human patients.

**1.68** “Price Approval” means, in the Territory where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be).

**1.69** “Product Recall” means any recall or market withdrawal of a ThermoDox Product from or in the Territory.

**1.70** “Promotional Materials” means all written, printed, video or graphic advertising, promotional, educational and communication materials (other than the ThermoDox Product package insert), including all written, graphic, electronic, audio and video pieces and including

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journal advertisements, direct mail, direct-to-consumer advertising, internet postings, broadcast advertisements and sales aids, relating to the ThermoDox Products in the Territory.

**1.71** “Quality Agreement” means the agreement that will be executed between the Parties which will be an essential set of quality related requirements and responsibilities affecting manufacturing and testing of ThermoDox Product.

**1.72** “Regulatory Approvals” means all approvals (including, without limitation, INDs, Marketing Authorizations and supplements and amendments thereto), licenses, registrations or authorizations of any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity necessary for the Development or Commercialization of the ThermoDox Product, including clinical testing, importation, manufacture, distribution, use or sale of the ThermoDox Product in a given regulatory jurisdiction.

**1.73** “Regulatory Authority” means any applicable Governmental Authority responsible for the granting of Marketing Authorizations for a ThermoDox Product in a given regulatory jurisdiction, including, without limitation, the FDA and the MHLW.

**1.74** “Regulatory Materials” means any regulatory submissions, notifications, registrations, approvals and/or other filings and correspondence made to or with a Regulatory Authority, and any other records required to be maintained for possible audit by a Regulatory Authority, that are necessary or reasonably desirable to Develop, manufacture, store, promote, market, sell, Commercialize or otherwise distribute ThermoDox Products in the Territory.

**1.75** “Royalty Term” means on a ThermoDox Product-by- ThermoDox Product basis, the period beginning on the date of the First Commercial Sale of a ThermoDox Product in the Territory and ending on the last day on which Royalty Payments are payable by Yakult to Celsion pursuant to Section 5.5.

1.76 “Samples of Product Package” means product packages sample with no active ThermoDox Product, which will be used as Promotional Materials and distributed to members of the target audience of prescribers to market the potential use with patients in the Territory, or other similar type of activity and in accordance with all Laws.

1.77 “Territory” means Japan.

1.78 “ThermoDox Product” means any heat or radiation sensitive product containing a any molecule, compound structure or formulation of doxorubicin encapsulated in heat or radiation sensitive liposomes, as further described in [ \* ], and that may be covered by the Celsion Patent Rights. ThermoDox Product shall also include the combination of the foregoing with (a) one or more therapeutically active ingredients and/or (b) equipment for use with one or more of the foregoing. ThermoDox Products has a corresponding meaning.

1.79 “Third Party” means a Person who is not a Party or an Affiliate of a Party.

\* Material has been omitted and filed separately with the Commission.

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1.80 “United States” or “U.S.” means the United States of America, and its territories and possessions.

1.81 “Valid Claim” means any claim of (a) an issued and unexpired patent included in the Celsion Patent Rights that has not been revoked or held unenforceable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, and which has not been disclaimed, denied or admitted by Celsion to be invalid or unenforceable through reissue or disclaimer or otherwise, or (b) a pending patent application within the Celsion Patent Rights that has not been cancelled, withdrawn or abandoned; provided, however, when such patent issues based on such patent application, any claim contained therein shall be deemed a Valid Claim. If, in the Territory, there should be two (2) or more such decisions conflicting with respect to the validity of the same claim, the decision of the higher or highest tribunal shall thereafter control; however, should the tribunals be of equal rank, then the decision or decisions upholding the claim shall prevail when the conflicting decisions are equal in number, and the majority of the decisions shall prevail when the conflicting decisions are unequal in number.

1.82 “Yakult Confidential Information” means Confidential Information for which Yakult is the Disclosing Party.

1.83 “Yakult Improvements” means any Improvements that are (i) conceived, first made or invented during the Term solely by Yakult, or its Affiliates, agents, or sublicensees or by Third Parties acting on its behalf and (ii) is necessary or useful for the Development, manufacture, use or Commercialization of any ThermoDox Product.

1.84 “Yakult IND” means an IND that will be filed with Japan MHLW for Marketing Approval of a ThermoDox Product.

1.85 “Yakult Know-How” means Know-How that is either Controlled by Yakult on the Effective Date or comes within Yakult’s Control during the Term (other than Celsion Know-How pursuant to the licenses granted hereunder) and is necessary or useful for the Development, manufacture, use or Commercialization of any ThermoDox Product, provided that Yakult Know-How shall not include Yakult Improvements.

1.86 *(Intentionally Deleted)*

1.87 “Yakult Patent Rights” means any Patent Rights containing one or more claims that cover (i) the composition of matter of a ThermoDox Product or portion thereof, (ii) the manufacture or formulation of the foregoing, (iii) use of a ThermoDox Product for a Named Indication, or (iv) any Patent Rights otherwise necessary or useful for the Development, manufacture, use or Commercialization of any ThermoDox Product for a Named Indication, which are Controlled by Yakult as of the Effective Date or come within Yakult’s Control during the Term [ \* ].

1.88 “Yakult Technology” means Yakult Patent Rights and Yakult Know-How.

\* Material has been omitted and filed separately with the Commission.

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1.89 Construction. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement:

(a) “include,” “includes” and “including” are not limiting and mean include, includes and including, without limitation;

(b) definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms; (c) references to an agreement, statute, Law or instrument defined or referred to herein mean such agreement, statute, Law or instrument as from time to time amended, modified or supplemented, including (in the case of agreements and instruments) by waiver or consent and (in the case of statutes and Laws) by succession of comparable successor statutes or Laws and all attachments thereto and instruments incorporated therein; (d) references to a person are also to its successors and permitted assigns; (e) references to an “Article,” “Section,” “Exhibit” or “Schedule” refer to an Article or Section of, or any Exhibit or Schedule to, this Agreement unless otherwise indicated; (f) the word “will” shall be construed to have the same meaning and effect as the word “shall”; and (g) the word “any” shall mean “any and all” unless otherwise indicated by context.

#### Other Defined Terms

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Celsion	5.13
Celsion Indemnitees	Preamble
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**ARTICLE 2 DEVELOPMENT OF PRODUCTS; JOINT STEERING COMMITTEE**

[Yakult will provide (1) an English language translation of the summary of each study report and (2) a full and complete Japanese language version of each study report for Celsion regulatory purposes]

**2.1 Development.** Yakult shall, in accordance with the Development Plan set forth on Schedule 2.3.1, including the timing and costs set forth therein, and this Agreement, use Commercially Reasonable Efforts to Develop ThermoDox Products for the Named Indications. Yakult also shall use Commercially Reasonable Efforts to file Marketing Authorization Applications for ThermoDox Products in the Territory and to obtain Market Authorizations in the Territory. For clarity, Yakult shall be obligated to use Commercially Reasonable Efforts to obtain Marketing Authorization for all indications for which a ThermoDox Product has been approved by any Regulatory Authority outside of the Territory.

**2.2 Development and Discontinuation of Development.**

**2.2.1 Development of ThermoDox Products.**

(a) Yakult shall use Commercially Reasonable Efforts to Develop each ThermoDox Product in accordance with the applicable Development Plan.

(b) Yakult shall be responsible for

(i) conducting and completing Preclinical Studies, Phase I, Phase II and Phase III Studies, as required by MHLW, for each ThermoDox Product, [ \* ], and

(ii) preparing and submitting all Regulatory Materials to the appropriate Regulatory Authorities in the Territory necessary or desirable in order to obtain all requisite Marketing Authorizations for the ThermoDox Products in the Territory.

(c) Yakult may conduct Clinical Studies outside of the Territory in order to meet the standards for Regulatory Approval of ThermoDox Products in the Territory, provided that Yakult obtains preapproval from the Committee of any and all such activities.

(d) Within [ \* ] after its completion of each Phase I, Phase II and Phase III Study for a ThermoDox Product (“completion” meaning a final study report has been delivered to either Party), each Party shall submit to the Committee a report of the results of such study, together with all supporting

data. Based on the results obtained from each such Phase I, Phase II or Phase III Study, the Committee shall review and may amend the Development Plan for the ThermoDox Product. If the Committee determines that the results of such studies warrant further Development of the applicable ThermoDox Product, the amended Development Plan shall set forth the additional studies to be conducted for such ThermoDox Product and the timetable for initiating such studies. Yakult shall be responsible for conducting all subsequent Development activities for each ThermoDox Product in accordance with the revised Development Plan.

(e) Upon request by either Party, the other Party shall promptly, but in no event later than [ \* ] after such request (provided that such information is reasonably and readily available and has not already been provided) provide the Committee with

- (i) a summary in reasonable detail of all data generated or obtained from each discrete Development activity performed by such Party under a Development Plan for ThermoDox Products, such as any toxicology study, pharmacokinetics study, stability study and other discrete Clinical Study, and
- (ii) a final report of the results of each such Development activity, together with all material supporting data.

**2.2.2 Discontinuation of Development.** If the Committee decides to discontinue Developing a ThermoDox Product, the Development Plan for such ThermoDox Product shall immediately terminate upon such decision. Upon such determination by the Committee, the Committee shall remove such Named Indication(s) from Schedule 1.53 unless otherwise agreed to by the Parties.

### **2.3 Development Plans.**

**2.3.1 Initial Development Plan for ThermoDox Products.** The initial Development Plan for the ThermoDox Products in the Territory shall be completed and submitted to the Committee for review and approval within [ \* ] of the Effective Date. The initial Development Plan, and any proposed updates or amendments thereto proposed by Yakult pursuant to Section 2.3.4 hereof, shall be submitted to the Committee for review and approval,

\* Material has been omitted and filed separately with the Commission.

which approval shall occur (a) no later than [ \* ] after submission to the Committee for review and (b) not more than [ \* ] from the Effective Date. The approved Development Plan, as amended from time to time, shall be attached hereto as Schedule 2.3.1.

**2.3.2 Development Plans for Additional Indications.** When an additional indication is added to the Collaboration pursuant to Section 2.14.2, the applicable proposed Development Plan shall be adopted as the initial Development Plan for the Development of a ThermoDox Product for the additional indication through filing of an NDA for such ThermoDox Product.

**2.3.3 Scope of Development Plan.** The Development Plan for each ThermoDox Product shall specify the composition details of such ThermoDox Product and the Named Indication of such ThermoDox Product and shall, at minimum, set forth the specific Development activities for which Yakult will be responsible, relevant timelines, and the estimated number of patients to be enrolled in each Clinical Study and the estimated duration of each Clinical Study. An English language summary of all preclinical and clinical protocols must be submitted to the Committee for review and comment, with approval required within [ \* ].

**2.3.4 Updates to the Development Plan.** Beginning with the first full Calendar Year after the Effective Date, on an as-needed basis but not more frequently than once-per Calendar Year, Yakult shall prepare and submit for review and approval by the Committee, proposed updates and amendments to the then-existing Development Plan and prepare the Development Plan for each ThermoDox Product for the immediately subsequent Calendar Year.

**2.4 Implementation of Development Plan.** In implementing a Development Plan, Yakult shall make available such key personnel as may be necessary or appropriate to liaise on a regular basis with the Committee to resolve any questions regarding Yakult's implementation of the Development Plan and to communicate to the Committee timely suggestions for improving the Development Plan. In connection with the preparation and implementation of the Development Plan, Celsion and Yakult shall make available to each other any material data and information then in their possession pertaining to ThermoDox Product useful for such Development activities, and hereby grants to the other the right to use all such data and information for purposes of performing its obligations hereunder.

### **2.5 Development Costs and Funding.**

**2.5.1 Development Costs.** [ \* ] is obligated to [ \* ] fund all Clinical Studies, Preclinical Studies, all research and development costs (including Chemistry, Manufacturing and Controls ("CMC") studies) for MHLW approval of ThermoDox Products, provided however, that if Celsion's Phase III HCC Study does not lead to FDA Regulatory Approval, the Parties will fund a Follow-Up Phase III Study as set forth in Section 12.1.1.

**2.6 Access to Records and Facilities.** Each Party shall maintain scientific records, in sufficient detail and good scientific manner appropriate for obtaining Patent Rights and for regulatory purposes relating to the Development of ThermoDox Products. The records shall

\* Material has been omitted and filed separately with the Commission.

reflect all work done and results achieved in the performance of Development by such Party. For the purpose of ensuring compliance with all applicable Laws and other applicable regulatory requirements, a Party shall be entitled to access the other Party's and its Affiliates' records and facilities relating to the Development. Access is limited to: no more than [ \* ] occasions in each Calendar Year; on each occasion to no more than [ \* ] consecutive Business Days; during regular business hours; upon reasonable advance notice, at the requesting Party's own expense; with minimal disruption to the other Party's business. In all Third Party agreements the Third Parties shall be contractually required to provide each Party with access. If a Party requires additional access in order to comply with applicable regulatory requirements and submissions, the other Party will grant access and be flexible, as the situation will require, in accommodating the needs of the first Party.

**2.7 Commercialization.** Yakult shall be solely responsible for all Commercialization activities relating to the ThermoDox Products in the Territory, and for recommending pricing and other terms of sale for the ThermoDox Product in the Territory to the Committee for review and comment. Yakult shall use Commercially Reasonable Efforts in accordance with the applicable Commercialization Plan, including the timelines set forth therein, to (a) achieve First Commercial Sale of a ThermoDox Product as soon as practicable following issuance of a Marketing Authorization (and Price Approval where applicable) of such ThermoDox Product in the Territory, and (b) Commercialize such ThermoDox Product in the Territory once a Marketing Authorization (and Price Approval where applicable) for such ThermoDox Product is obtained, with the objective of maximizing the sales potential of the ThermoDox Products and promoting the therapeutic profile and benefits of the ThermoDox Products in the most commercially beneficial manner.

**2.8 Commercialization Plan.**

**2.8.1 Preparation and Updating of Commercialization Plans.** Commencing at least [ \* ] prior to the projected First Commercial Sale of a ThermoDox Product in the Territory, Yakult shall commence preparing an Initial Commercialization plan for such ThermoDox Product (the "Initial Commercialization Plan"). Thereafter, Yakult shall update the Commercialization plan for the Territory for such ThermoDox Product (the "Commercialization Plan") at least [ \* ]. The initial Commercialization Plans as so updated from time to time, shall be attached hereto as Schedule 2.8.1. Any subsequent Commercialization Plan, and any proposed updates or amendments to either of the foregoing, shall be submitted to the Committee for review and comment, which comment shall occur no later than [ \* ] after submission to the Committee for review.

**2.8.2 Contents of Commercialization Plan.** The Parties shall agree to annual minimum sales based on an independent formal market study. This market study shall be designed, managed and funded jointly by the Parties. Sales targets will be adjusted for additional approved indications beyond the Named Indications. Yakult shall select an independent marketing company that has previous experience with multinational pharmaceutical or biotechnology companies regarding drug pricing and marketing for the Territory. The direction and reporting responsibility will be the function of the Committee. Each

\* Material has been omitted and filed separately with the Commission.

Commercialization Plan shall encompass at least [ \* ] and shall contain at a minimum, in each case with respect to the Territory:

- (a) [ \* ];
- (b) [ \* ];
- (c) [ \* ];
- (d) [ \* ];
- (e) [ \* ];
- (f) [ \* ];
- (g) [ \* ]; and
- (h) [ \* ].

**2.8.3 Estimate of Commercialization Costs.** In addition to the items enumerated in Section 2.8.2, each Commercialization Plan shall set forth (a) the total budget on an annual basis for Commercialization activities set forth in the Commercialization Plan; and (b) pricing strategies specifically relating to the ThermoDox Product.

**2.9 Trademarks.** Yakult shall have the perpetual, exclusive for the Royalty Term and non-exclusive thereafter, [ \* ] right in the Territory to brand the ThermoDox Product using Celsion's trademarks, trade names and any other trademarks and trade names the Parties mutually agree are appropriate for the ThermoDox Product ("Product Marks"). Celsion shall own all rights in the Product Marks in the Territory and may register and maintain the Product Marks in the Territory and regions it determines reasonably necessary.

**2.10 Use of Promotional Materials.** The Yakult sales force will utilize only Promotional Materials to conduct promotional activities for the ThermoDox Product. All promotional activities and materials will be in accordance and compliance with Japanese regulatory requirements, as well as Celsion global promotional strategies, however, Japanese regulatory requirements prevails over any Celsion global promotional strategies. Celsion shall have rights to use all Promotional Materials.

**2.11 Contract Sales Forces.** Yakult may use any contract sales force to market a ThermoDox Product in the Territory without the prior written consent of Celsion.

**2.12 Conduct of Commercialization Activities.** Yakult shall use its Commercially Reasonable Efforts in Commercializing ThermoDox Products in the Territory, and shall conduct all Commercialization activities in the Territory in accordance with the applicable

\* Material has been omitted and filed separately with the Commission.

Commercialization Plan and this Agreement and in compliance with all applicable Laws and industry codes and standards. In addition, and without limiting the foregoing, Yakult shall:

**2.12.1 Statements About the ThermoDox Products.** Train and instruct its sales representatives (a) to make only those statements and claims regarding the ThermoDox Products, including as to efficacy and safety, that are consistent with the ThermoDox Product labeling and accompanying inserts and the Promotional Materials, and (b) not to make any untrue or misleading statements or comments about the ThermoDox Products, competitors or other products.

**2.12.2 Maintenance of Records.** Maintain records and otherwise establish procedures to ensure compliance with all applicable Laws and professional requirements that apply to the promotion and marketing of the ThermoDox Products.

**2.12.3 Medical and Scientific Affairs.** Be solely responsible for the execution of medical and scientific affairs and programs, including professional symposia and other educational activities, and medical affairs studies. Yakult shall have the right to respond to all questions or requests for information about the ThermoDox Products made by any medical professionals or any other Person, provided however, that this shall not be interpreted to limit Celsion's right to respond.

**2.13 Discontinuation of Commercialization.** If the Committee determines to discontinue Commercializing a ThermoDox Product, the Development Plan and the Commercialization Plan for such ThermoDox Product shall terminate immediately upon such decision. Upon such determination by the Committee, the Committee shall remove the relevant Named Indication(s) from Schedule 1.53, as applicable, unless otherwise agreed to by the Parties.

**2.14 Joint Steering Committee.** The Development and Commercialization of ThermoDox Products under this Agreement shall be conducted under the direction of a joint steering committee (the "Committee") as follows:

**2.14.1 Members; Officers.** Within [ \* ] after the Effective Date, the Parties shall establish the Committee, which shall consist of [ \* ], [ \* ] of whom shall be designated by [ \* ], each with the requisite experience and seniority to enable them to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the Committee. A Party may designate a substitute to temporarily attend and perform the functions of such Party's designee at any meeting of the Committee. From time to time, each Party may substitute one or more of its representatives of the Committee by providing written notice to the other Party. Celsion and Yakult each may, on advance notice to and the consent of the other Party, invite non-member employees of such Party to attend meetings of the Committee. Yakult shall designate one of its representatives to serve as chairperson of the Committee, which designation Yakult may change from time to time by written notice to Celsion. One member of Celsion shall serve as secretary of the Committee at each Committee meeting, and shall prepare minutes for all meetings.

\* Material has been omitted and filed separately with the Commission.

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**2.14.2 Responsibilities.** The Committee shall perform the following functions:

- (a) Determine the direction and objectives of the Collaboration;
- (b) Oversee all aspects of Yakult's development, implementation and management of the day-to-day activities of the Collaboration pursuant to the terms of this Agreement;
- (c) Review and approve the Development Plans, and review and comment on Commercialization Plans for ThermoDox Products and any material amendments thereto;
- (d) Review and approve the Development strategy, regulatory strategy, formulation and manufacturing process development strategy, and protocols and milestones for Clinical Studies (with such approval occurring within [ \* ]), as such strategies and protocols are proposed to the Committee by Yakult;
- (e) Review data and reports arising from and generated in connection with the Development and Commercialization of the ThermoDox Products;
- (f) Review and coordinate regulatory activities to be undertaken by Yakult in accordance with ARTICLE 8;
- (g) Review and have final approval authority with respect to "go/no-go" decisions for the Development of the ThermoDox Products recommended by Yakult;
- (h) Review activities conducted, if any, by a Party with respect to additional indications for ThermoDox Product;
- (i) Oversee the integration of new indications to be added to the Named Indications listed on Schedule 1.53;
- (j) Review and update Schedule 1.53;
- (k) Review and provide guidance for all pricing decisions (for purposes of coordinating pricing strategies outside of the Territory, only) and managed care contracting strategies to ensure consistency with the Commercialization Plan;
- (l) Resolve disputes and other matters concerning the Collaboration contemplated by this Agreement;

\* Material has been omitted and filed separately with the Commission.

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- (m) Estimate sales amounts, [ \* ]; and

- (n) Have such other responsibilities as may be assigned to the Committee pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

**2.14.3 Meetings.** The Committee shall meet in person ([ \* ] of which may be by videoconference) at least once every [ \* ] during the first [ \* ] Calendar Years of the Term of this Agreement and [ \* ] per Calendar Year thereafter, or more or less frequently as Celsion and Yakult mutually agree upon from time to time, or as reasonably requested by either such Party, on such dates, and at such places and times as the Parties shall mutually agree, provided that the Parties shall endeavor to have the first meeting of the Committee within [ \* ] after the Effective Date. Meetings of the Committee that are held in person shall alternate between offices of Yakult and Celsion, or such other place as the Parties may mutually agree. Each Party shall receive at least [ \* ] written notice of any meeting. The members of the Committee also may convene or be polled or consulted from time to time by means of telecommunications, video conferences, electronic mail or correspondence.

**2.14.4 Decision-Making.** The Committee may make decisions with respect to any subject matter that is subject to the Committee's decision-making authority and functions as set forth in Section 2.14.2. All decisions of the Committee shall be made by unanimous vote (by Persons present in Person or by telephone at any meeting) or written consent, with Yakult and Celsion each having, collectively, among its respective members, one (1) vote in all decisions. The Committee shall use Commercially Reasonable Efforts to resolve the matters within its roles and functions or otherwise referred to it. If the Committee cannot reach consensus on a matter within [ \* ] after such matter has been brought to the Committee's attention, then such matter shall be handled in the manner set forth below:

- (a) Dispute Resolution. [ \* ]

**2.15 Minutes of Committee Meetings.** Definitive minutes of all Committee meetings shall be finalized no later than [ \* ] after the meeting to which the minutes pertain as follows:

**2.15.1 Distribution of Minutes.** [ \* ] after a Committee meeting, the secretary of such Committee shall prepare and distribute to all members of such committee draft minutes of the meeting. Such minutes shall provide a list of any issues yet to be resolved, either within such Committee or through the relevant resolution process.

**2.15.2 Review of Minutes.** The members of each Committee shall then have [ \* ] after receiving such draft minutes to review the minutes and provide comments to the secretary of such Committee.

**2.15.3 Discussion of Comments.** Upon the expiration of such [ \* ] period, the Parties shall have an additional [ \* ] to discuss each other's comments and finalize the minutes. The secretary and chairperson(s) of such Committee shall each sign and date the final

\* Material has been omitted and filed separately with the Commission.

minutes. The signature of such chairperson(s) and secretary upon the final minutes shall indicate each Party's assent to the minutes.

**2.16 Expenses.** Each Party shall be responsible for all travel and related costs and expenses, including all Out-of-Pocket Costs and Expenses, for its members and other employee representatives to attend Committee meetings, and otherwise participate on the Committee.

### **ARTICLE 3 LICENSE GRANTS**

#### **3.1 License Grant to Yakult.**

**3.1.1** Subject to the terms and conditions of this Agreement, Celsion hereby grants to Yakult, during the Term of this Agreement, an exclusive license (even as to Celsion) in only the Territory, under the Celsion Technology, Celsion Improvements, Joint Improvements and Yakult Improvements, with the right to sublicense as provided in Section 3.4, to make, have made, sell, offer to sell, import and use ThermoDox Products in the Field.

**3.1.2** Except for the rights granted to Yakult under Section 3.1.1 of this Agreement, all right, title and interest in and to the Celsion Technology, Celsion Improvements, Joint Improvements and Yakult Improvements shall at all times remain with and be vested in Celsion. All rights with respect to any Celsion Technology, Celsion Improvements, Joint Improvements or Yakult Improvements that are not granted under 3.1.1 of this Agreement shall remain with Celsion and subject to Section 4.2, Celsion shall have the right to grant licenses to any Third Party under the Celsion Technology, Celsion Improvements, Joint Improvements and Yakult Improvements to make, have made, sell, offer to sell, import and use the ThermoDox Products outside the Territory. For clarity, the licenses and rights granted in Section 3.1.1 of this Agreement shall not be construed to convey any licenses or rights under the Celsion Patent Rights with respect to any active pharmaceutical ingredients other than doxorubicin.

**3.2 License Grants to Celsion.** Subject to the terms and conditions of this Agreement, Yakult hereby grants Celsion a perpetual, worldwide, non-exclusive royalty-free license, with the right to sublicense as provided in Section 3.4, for the purposes of (i) under Yakult's Technology, solely to the extent necessary for Celsion to exercise its rights and perform its obligations pursuant to this Agreement, (ii) utilizing any preclinical or clinical data or information, and any INDs, and NDAs developed in connection therewith, in connection with Yakult's performance of its obligations hereunder, for Celsion to make, have made, sell, offer to sell, import and use, Develop or Commercialize the ThermoDox Products in any Country outside the Territory.

**3.3** *(Intentionally Deleted)*

**3.4 Sublicensing and Subcontracting.**

### 3.4.1 Right to Sublicense or Subcontract.

(a) Neither Party may sublicense any of the rights granted under this Agreement, nor subcontract any of its obligations hereunder, without the prior written consent of the other Party, such consent not to be unreasonably delayed, withheld, refused or conditioned, except to its Affiliates, which right shall automatically terminate if and when such Affiliate ceases to be an Affiliate of such Party. Notwithstanding the foregoing, Yakult may subcontract its obligation for the Development of the ThermoDox Products without the consent of Celsion.

(b) Each sublicense or subcontract granted by a Party to a permitted sublicensee or subcontractor pursuant to Section 3.4.1(a) shall be subject and subordinate to the terms and conditions of this Agreement and shall contain terms and conditions consistent with those in this Agreement and shall not in any way diminish, reduce or eliminate a Party's obligations under this Agreement. Each Party shall provide the other Party with a copy of each such sublicense or subcontractor agreement within [ \* ] after the execution thereof. As set forth in the terms of the binding agreement dated August 13, 2008, between Yakult and Celsion for development and marketing of ThermoDox Products in Japan, Yakult does not have the right hereunder to grant to any sublicensee a manufacturing license to manufacture any ThermoDox Product.

**3.4.2 Liability for Affiliates, Sublicensees and Subcontractors.** Each Party shall ensure that each of its Affiliates and permitted sublicensees or subcontractors accepts and complies with all of the applicable terms and conditions of this Agreement as if such Affiliates or permitted sublicensees or subcontractors were a party to this Agreement and each Party shall remain fully responsible for its Affiliates' and permitted sublicensees' or subcontractors' performance under this Agreement.

## **ARTICLE 4 NON-COMPETE AND ADDITIONAL INDICATIONS**

**4.1 Non-Compete.** During the Term of this Agreement, neither Yakult nor any of its Affiliates shall, directly or indirectly, by itself or through any Third Party, Commercialize a competing heat activated liposomal drug other than ThermoDox Products (collectively, the "Competing Products").

**4.2 Additional Indications.** Yakult is required to research and submit a Marketing Authorization Application for Marketing Authorization in the Territory for all indications for which a ThermoDox Product has been approved by any Regulatory Authority outside of the Territory.

**4.2.1 Additional Proposal.** Each Party may propose to Develop jointly as part of the Collaboration a ThermoDox Product for an indication other than a Named Indication by submitting to the Committee at any time during the Term, a written proposal describing the proposed indication, as applicable, which shall include a proposed Development Plan for Developing a product containing such ThermoDox Product for such proposed indication (an "Additional Proposal"). The non-proposing Party on the Committee shall have sole discretion as to whether to accept such proposed indication as a Named Indication.

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**4.2.2 Acceptance of Proposed Indication.** If the non-proposing Party elects to accept the proposed indication as a Named Indication, it shall give the proposing Party a notice of acceptance in writing within [ \* ] after the Additional Proposal is submitted by the proposing Party, which acceptance shall become effective upon receipt. In and after such acceptance, such proposed indication shall be deemed a Named Indication and Schedule 1.53 shall be revised accordingly. The proposed development plan shall be adopted by the Parties as the initial Development Plan for developing a ThermoDox Product for the proposed indication.

**4.2.3 Rejection of Proposed Indication.** If the non-proposing Party fails to accept the proposed indication for a ThermoDox Product as a Named Indication, within [ \* ] after the proposing Party's submission of the Additional Proposal, then the provisions of Section 4.1 shall apply and, neither Party may, directly or indirectly, itself or through any Affiliate or Third Party, Develop or Commercialize the foregoing in the Territory.

## **ARTICLE 5 FINANCIAL PROVISIONS**

**5.1 Upfront Payment.** In consideration of Celsion's research and development costs incurred in the past and the licenses granted by Celsion to Yakult under the Celsion Patent Rights and the Celsion Know-How pursuant to this Agreement, simultaneously with the execution of this Agreement, Yakult shall make a non-creditable, non-refundable payment to Celsion in the amount of Two Million Five Hundred Thousand United States Dollars (\$2,500,000 (US)) by wire transfer within one (1) month of the Effective Date.

**5.2 Payment of Development Costs.** [ \* ]

**5.3 Milestone Payments.**

**5.3.1** In further consideration of the licenses granted by Celsion to Yakult under the Celsion Patent Rights and the Celsion Know-How pursuant to this Agreement, and in consideration of the ongoing research and development activities to be undertaken by Celsion, Yakult also shall pay to Celsion upon achievement of each such milestone, the amounts set forth below in Section 5.3.2 (each, a "Development Milestone"); provided that the payment for each Development Milestone ("Milestone Payment") shall be made only once for each applicable ThermoDox Product to reach such Development Milestone, and no payment shall be owed for a Development Milestone that is not reached. As set forth in the table in Section 5.3.2, a Development Milestone shall be deemed to have been achieved if a subsequent Development Milestone has been achieved.

**5.3.2** Upon achievement of a Development Milestone, Yakult shall promptly, but in no event more than [ \* ] after the achievement of each such Development Milestone, notify Celsion in writing of such achievement. For each Development Milestone achieved, Yakult shall promptly, but in no event more than [ \* ] after the achievement of such Development Milestone, remit payment to Celsion for such Development Milestone. For the avoidance of doubt, each Milestone Payment described below shall be paid only once during the Term, regardless of the number of ThermoDox Products that achieve the corresponding Development Milestone.

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Development Milestone	Milestone Payment Payment for ThermoDox Product
(a) MHLW Marketing Authorization of a ThermoDox Product for HCC	Eighteen Million United States Dollars (\$18,000,000 (US)) [ * ]
(b) Annual Sales [ * ]	[ * ]
(c) Annual Sales [ * ]	[ * ]
(d) MHLW Approval of Any New Indications [ * ].	[ * ]

Any dispute under this Section 5.3 that relates to whether a milestone event has occurred shall first be referred to the Committee for resolution, and if not successfully resolved as set forth in Section 2.14.4, it shall be subject to arbitration under Section 14.5.

**5.3.3 First Milestone Payment.** Upon MHLW Marketing Authorization of a ThermoDox Product for HCC in the Territory, Yakult shall pay Celsion Eighteen Million United States Dollars (\$18,000,000 (US)); the “First Milestone Payment”. [ \* ].

**5.4 Sale of ThermoDox Products in the Territory.**

**5.4.1 Royalty.** For each sale of a ThermoDox Product, Yakult shall make the following payments as royalties to Celsion (“Royalty Payments”):

Net Sales of All Applicable ThermoDox Products in the Territory in a Calendar Year	“Royalty Rate”
[ * ]	[ * ]
[ * ]	[ * ]
[ * ]	[ * ]

Royalty Payments will be made to Celsion on a [ \* ] basis upon completion of reporting process set forth in Section 5.7.2. When calculating the Royalty Payment for each [ \* ], Yakult shall (i) determine the correct Royalty Rate for [ \* ] and (ii) if necessary, increase or decrease the Royalty Payment for that [ \* ] to ensure that the proper Royalty Rate was paid for that [ \* ]. Any dispute under this Section 5.4 that relates to whether a sales target has been achieved shall first be referred to the Committee for resolution, and if not successfully resolved as set forth in Section 2.14.4, it shall be subject to arbitration under Section 14.5.

**5.5 Royalty Term.** Yakult’s obligation to pay royalties to Celsion on Net Sales of the ThermoDox Products pursuant to Section 5.4.1 shall commence upon the First Commercial Sale of such ThermoDox Product and shall expire upon [ \* ]. For clarity, the Royalty Term may be extended if there is [ \* ]. For avoidance of conflict of interest, Yakult shall continue

\* Material has been omitted and filed separately with the Commission.

to make all Milestone Payments and Royalty Payments for the full Royalty Term consistent with this Article 5 unless (i) Duke University terminates the Duke Agreement and (ii) [ \* ].

**5.6 Notices of Termination.** In the event that a Party has given the other Party any notice of termination of this Agreement under ARTICLE 12, no payments under this Section 5.7 shall become due with respect to the time period after the effective date of such termination, provided that any amounts payable by Yakult that are accrued and are due and owing with respect to the time period occurring prior to the effective date of termination shall remain due and payable hereunder.

**5.7 Reports and Payments.** With respect to a ThermoDox Product, the following provisions shall apply:

**5.7.1 Intercompany Sales.** [ \* ]

**5.7.2 Yakult Report.** Within [ \* ] after the end of [ \* ], Yakult shall submit to Celsion a written report (the “Yakult Report”) setting forth in reasonable detail the following revenue costs and expense information with respect to [ \* ]:

- (a) Net Sales;
- (b) [ \* ]; and
- (c) [ \* ].

**5.8 GAAP.** All financial terms and standards defined or used in this Agreement for sales or activities occurring pursuant to the terms of this Agreement shall be governed by and determined in accordance with Japanese generally accepted accounting principles, consistently applied (“GAAP”).

**5.9 (Intentionally Deleted)**

**5.10 Manner of Payments.** All sums due to Celsion under this Agreement shall be payable in United States Dollars from a banking institution in the United States or Japan by bank wire transfer in immediately available funds to such bank account(s) that Celsion shall designate at least [ \* ] prior to such transfer with all necessary information for such transfer, including account number and swift code. All sums due to Yakult under this Agreement shall be payable in United States Dollars to such bank account that Yakult may from time to time designate by notice to Celsion at least [ \* ] prior to such transfer

with all necessary information for such transfer, including account number and swift code. Any remittance transaction fees shall be borne by the paying Party. For any payments made in a Calendar Quarter, the exchange rate shall equal the arithmetic average of the daily exchange rates (obtained as described below) during such Calendar Quarter; each daily exchange rate shall be obtained from www.oanda.com. For Royalty Payments, the exchange rate is a daily average for the Calendar Quarter.

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**5.11 Interest on Late Payments.** If either Celsion or Yakult shall fail to make a timely payment pursuant to this Agreement, any such payment that is not paid on or before the date such payment is due under this Agreement (“Due Date”) shall bear interest, at a rate of [ \* ] percent [ \* ] per annum from the Due Date until paid in full, or if less, the maximum interest rate permitted by applicable Law. Any subsequent payment made by the defaulting party shall be credited first to all interest so accrued. Such interest shall be computed on the basis of a year of three hundred sixty (360) days for the actual number of days payment is delinquent.

**5.12 Default in Payments.** Any default by any Party hereto of its payment obligations hereunder that shall have continued for [ \* ] after notice thereof was provided to the alleged defaulting Party by the non-defaulting Party; provided that, in the event of a good faith payment dispute, such [ \* ] cure period shall be extended for an additional [ \* ] to resolve such dispute if the alleged defaulting Party has paid all undisputed amounts when due and provided the non-defaulting Party with a reasonably detailed written explanation of the alleged defaulting Party’s basis for disputing the payment obligation within the [ \* ] period following the notice of the default by the non-defaulting Party. The alleged defaulting Party shall pay interest on the final adjudicated amount due pursuant to Section 5.11 from the date that such payment was originally due.

**5.13 Tax Withholding; Value Added Tax.**

**5.13.1 Withholding.** Except as specifically provided herein, in the event such withholding is required under the appropriate local tax Laws by one (1) of the Parties (the “Withholding Party”) on account of monies payable to the other Party under this Agreement, such amounts shall be deducted from the amount of monies otherwise payable to the other Party under this Agreement, and any such withholding taxes required under applicable Law to be paid or withheld shall be an expense of, and borne solely by, such other Party. The Withholding Party shall use its best efforts to notify the other Party in advance of the withholding and shall secure and send to the other Party within a reasonable period of time proof of any such taxes paid or required to be withheld by the Withholding Party for the benefit of the other Party. The Parties shall reasonably cooperate with each other to ensure that any amounts required to be withheld by either Party are reduced in amount to the fullest extent permitted by Law. No deduction shall be made, or a reduced amount shall be deducted, if the other Party furnishes a document from the appropriate tax Regulatory Authorities to the Withholding Party certifying that the payments are exempt from income taxes or subject to reduced tax rates, according to the applicable convention for the avoidance of double taxation. Each Party agrees to assist the other Party, as may reasonably be necessary, in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force, and in minimizing the amount required to be so withheld or deducted, and provided further, that the paying Party shall provide such additional documentation from time to time as needed for the other party to confirm the payment of tax. In the event that withholding is required on a payment to a Party or its Affiliate under this Agreement that would not have been required but for an assignment or sublicense by the other Party or such other Party’s Affiliate, such payment will be grossed-up by the amount of the withholding if the non-assigning/non-sublicensing Party can demonstrate that the withholding will increase its overall current tax liability for the year at issue (after considering the application of any available foreign tax credit).

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**5.13.2 Value-Added Tax.** The Parties do not anticipate that payments under this Agreement will be subject to a value added tax or similar tax (“VAT”) and the Parties agree to cooperate with one another and use best efforts to ensure that the VAT does not represent an unnecessary cost in respect of payments made under this Agreement. Except as specifically provided, it is understood and agreed between the Parties that (a) all amounts payable under this Agreement are exclusive of any VAT, which shall be added thereon as applicable and (b) where VAT is properly added to a payment made under this Agreement, the Party making the payment will pay the amount of VAT only on receipt of a valid tax invoice issued in accordance with the Laws and regulations of the Country in which the VAT is chargeable. However, in the event that an assignment or sublicense or the choice of jurisdiction for performing any of its obligations hereunder by a Party (the “Responsible Party”) causes a VAT that would not otherwise be applicable to apply to a payment under this Agreement, then the Parties agree that the Responsible Party shall bear the burden of the VAT. In such event, the payment with respect to which such VAT is owing shall be made in such a manner as to ensure that the Party other than the Responsible Party receives (or pays) a sum equal to the sum which it would have received (or paid) had such VAT not been due.

**5.14 Financial Records; Audits.** Each Party shall keep, and shall cause its Affiliates and sublicensees to keep, such accurate and complete records of Net Sales and its Third Party royalty payments, Patent Costs, Development Costs and Commercialization Costs as are necessary to determine the amounts due to Yakult and Celsion under this Agreement. Such records shall be retained by each Party and all of its Affiliates and sublicensees (in such capacity, the “Recording Party”) for a period of no less than five (5) Calendar Years after the Calendar Year to which such records relate. During normal business hours and with reasonable advance notice to the Recording Party, such records shall be made available for inspection, review and audit, at the request and expense of the other Party (the “Auditing Party”), by an independent certified public accountant, or the local equivalent, appointed by such Auditing Party and reasonably acceptable to the Recording Party for the sole purpose of verifying the accuracy of the Recording Party’s accounting reports and payments made or to be made pursuant to this Agreement; provided, however, that such audits may not be performed more than [ \* ] after the payment or report to be audited has been issued or more than [ \* ] per Calendar Year and such Auditing Party shall not be permitted to audit the same period of time more than once. Such accountants shall be instructed not to reveal to the Auditing Party the details of its review, except for: (a) such information as is required to be disclosed under this Agreement, and (b) such information presented in a summary fashion as is necessary to report the accountants’ conclusions to the Auditing Party, and all such information shall be deemed Confidential Information of the Recording Party; provided, however, that in any event such information may be presented to the Auditing Party in a summary fashion as is necessary to report the accountants’ conclusions. All costs and expenses incurred in connection with performing any such audit shall be paid by the Auditing Party unless the audit discloses at least a [ \* ] percent ([ \* ]) shortfall, in which case the Recording Party will bear the [ \* ] of the audit for such Calendar Year. The Auditing Party will be entitled to recover any shortfall in



payments due to it as determined by such audit, plus interest thereon calculated in accordance with Section 5.11, or alternatively shall have the right to offset and deduct any such shortfall in payments due to it against payments the Auditing Party is otherwise required to make to the Recording Party under

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this Agreement. The Recording Party will be entitled to receive any overpayment made by it as determined by such audit by offsetting and deducting any such overpayment against payments the Recording Party is otherwise required to make to the Auditing Party under this Agreement. The documents from which the sums due under this ARTICLE 5 were calculated shall be retained by the relevant Party.

**5.15 Right of Offset.** Each Party hereby acknowledges and agrees that the other Party shall be entitled to offset, in part or in full, from time to time, any and all amounts owed to such Party under this Agreement, against any and all amounts due and unpaid by the other Party under this Agreement, unless such amounts are subject to an unresolved good faith payment dispute.

**5.16 Generic Entry.** If any Generic Product enters the market in the Territory or is expected to enter based on credible information, the Parties shall meet to discuss the anticipated decrease in annual sales of the corresponding ThermoDox Product in the Territory and corresponding effect on Royalty Payments, and possible methods to protect the market for the corresponding ThermoDox Product. However, if for any reason Marketing Authorization of any Generic Product introduction is withdrawn from the Territory, then the terms of this agreement shall apply, and if appropriate, Celsion and Yakult will renegotiate the ThermoDox royalty as affected by the Generic Product introduction and subsequent withdrawal with good faith efforts.

## **ARTICLE 6 PRODUCT SUPPLY AND DISTRIBUTION**

**6.1 Exclusive Supply of ThermoDox Products by Celsion.** Celsion shall, or shall cause its Third Party manufacturer to, manufacture and supply to Yakult, and Yakult shall order exclusively from Celsion, all of its requirements for ThermoDox Products for use in Clinical Studies to be performed in accordance with the Development Plan, and for the commercial sale of ThermoDox Products upon receipt of Marketing Authorization from MHLW. Notwithstanding this Article 6, the terms and conditions of the ThermoDox Product supply agreement between the Parties shall be addressed more specifically in a separate supply agreement to be negotiated and executed by the Parties within [ \* ] of the Effective Date of this Agreement.

**6.2 Pricing.** Both Parties agree to work cooperatively and in good faith to endeavor to achieve the lowest possible manufacturing cost per vial. The purchase price for all ThermoDox Products supplied by Celsion to Yakult hereunder shall be as follows:

(a) All ThermoDox Products supplied for use in the Clinical Studies and otherwise in the Development of the ThermoDox Products shall be sold by Celsion to Yakult at Celsion's [ \* ] ("Cost of Goods").

(b) All ThermoDox Products supplied for sale to end-users upon receipt of Marketing Authorization from MHLW shall be sold by Celsion to Yakult at [ \* ]. The price per vial charged by Celsion to Yakult shall not exceed [ \* ] United States Dollars ([ \* ] (US)) per vial during the [ \* ] of ThermoDox Product launch. Celsion shall use all Commercially Reasonable Efforts to reduce the cost per vial during the Term of the Agreement, and Yakult may, at its

\* Material has been omitted and filed separately with the Commission.

discretion, participate with Celsion in the development of appropriate cost reduction strategies. The price then shall be reduced to \$[ \* ] (estimate) in the [ \* ], \$[ \* ] (estimate) in the [ \* ], \$[ \* ] (estimate) in the [ \* ], and \$[ \* ] (estimate) from [ \* ] onwards as a function of these efforts.

## **ARTICLE 7 INTELLECTUAL PROPERTY**

**7.1 Ownership of Intellectual Property.**

**7.1.1 Yakult Technology.** As between the Parties, Yakult is and shall remain the sole owner of the Yakult Technology.

**7.1.2 Celsion Technology.** As between the Parties, Celsion is and shall remain the sole owner of the Celsion Technology.

**7.1.3 Joint Improvements and Yakult Improvements.** The Parties recognize that, as a result of the collaboration, certain Improvements may be deemed to be Joint Improvements or Yakult Improvements. Celsion shall solely own all Joint Improvements and Yakult Improvements. Yakult hereby irrevocably transfers and assigns, and shall cause each of its employees and personnel to irrevocably transfer and assign, its and their entire right, title and interest in any Joint Improvement and Yakult Improvement to Celsion. Yakult shall promptly take all necessary actions, and shall cause each of its employees, agents, representatives and personnel to promptly take all necessary actions, including executing documents of assignment, to vest all right, title and interest in any Joint Improvement and Yakult Improvement to Celsion.

**7.1.4 Inventorship.** For purposes of determining whether an Improvement is solely invented by Yakult or solely invented by Celsion, or a Joint Improvement, questions of inventorship shall be resolved in accordance with the U.S. patent Laws, but for any Improvement submitted for a patent application in Japan, in accordance with the Japanese patent Laws.

**7.2 Prosecution and Maintenance of Patents.**

**7.2.1 Prosecution and Maintenance of Celsion Patent Rights.** Celsion shall have the first right to prepare, file, prosecute, and maintain all Patent Rights to Celsion Technology, Joint Improvements and Yakult Improvements (the "Patent Portfolio Rights") throughout the world (including in the Territory); provided that all Patent Costs incurred by Celsion in prosecuting and maintaining Patent Portfolio Rights throughout the world will be borne by

solely by Celsion. Upon Yakult's written request, and provided Yakult provides such written request reasonably in advance of any relevant filing deadline or intended filing date, Celsion may file patent applications in good faith (including continuations, divisionals and continuations-in-part) or add new claims to existing patent applications directed to the ThermoDox Product.

**7.2.2 Right to Comment.** Celsion will keep Yakult fully informed of the status of the Patent Portfolio Rights in the Territory that could reasonably affect a ThermoDox Product, and will provide Yakult with copies of all substantive documentation submitted to, or

\* Material has been omitted and filed separately with the Commission.

received from, any patent offices in the Territory in connection therewith immediately after such submission or receipt. With respect to any substantive submissions that Celsion is required to or otherwise intends to submit to a patent office in the Territory and that could reasonably affect a ThermoDox Product, Celsion shall, if reasonably practical, provide a draft of such submission to Yakult at least [ \* ] prior to the deadline or intended filing date, whichever is earlier, for submission of such documentation. Yakult shall have the right to review and comment upon any such submission by Celsion to a patent office, if any, no later than [ \* ] prior to the applicable deadline or intended filing date. Celsion shall consider in good faith all comments provided by Yakult with respect to a Patent Portfolio Rights, to the extent that it could reasonably relate to a ThermoDox Product, and incorporate all such comments that Celsion deems reasonable and appropriate.

**7.2.3 Yakult Step-In Rights.** Celsion will notify Yakult in writing of any decision (a) not to file applications for, or (b) to cease prosecution and/or maintenance of, any Patent Portfolio Rights in the Territory that could reasonably affect a ThermoDox Product (herein any such Patent Portfolio Rights will be "Abandoned Patent Portfolio Rights"). Celsion will provide such written notice to Yakult upon the earlier of (i) its decision with respect to any of the foregoing, or (ii) [ \* ] prior to any filing or payment due date, or any other due date that requires action, in connection with such Abandoned Patent Portfolio Rights. In such event, Yakult shall have the right to make the filing, or to continue the prosecution or maintenance of such Abandoned Patent Portfolio Rights in Celsion's name, if necessary, and at Yakult's expense.

**7.2.4 Execution of Documents by Agents.** Each Party shall promptly execute or have executed by its appropriate agents such documents as may be necessary to obtain, perfect or maintain any Patent Rights filed or to be filed pursuant to this Agreement, including any assignments required to enable Yakult to file, prosecute or maintain Patent Rights in its own name pursuant to Section 7.2.3, and shall cooperate with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession reasonably necessary to obtain or maintain such Patent Rights.

### **7.3 Patent Infringement.**

**7.3.1 Third Party Patent Invalidity Claims.** Each Party shall promptly notify the other in the event of any legal or administrative action by any Third Party involving a Celsion Patent Right of which it becomes aware, including any nullity, challenge to the validity, revocation, reexamination or compulsory license proceeding. Celsion shall defend against any such action involving a Celsion Patent Right using counsel of its choice, in its own name, and any such defense shall be at Celsion's sole expense. Yakult, upon the request of Celsion, shall reasonably cooperate with Celsion in any such action at Celsion's expense. If Celsion fails to defend against any such action involving a Celsion Patent Right in the Territory, then Yakult shall have the right to defend such action, in its own name, and any such defense shall be at Celsion's expense.

**7.3.2 Infringement of Celsion Patent Rights.** In the event that Celsion or Yakult becomes aware of actual or threatened infringement of a Celsion Patent Right that

\* Material has been omitted and filed separately with the Commission.

directly affects ThermoDox Product Patents Rights during the Term, that Party will promptly notify the other Party in writing. Celsion shall in Celsion's or the relevant Celsion Affiliate's name and on Celsion's or the relevant Celsion Affiliate's behalf, bring an infringement action against the infringing Third Party by counsel of its choice, and any such action shall be at Celsion's expense. Upon request of Celsion, Yakult agrees to timely join as party-plaintiff in any such litigation, and in any event to cooperate with Celsion in connection with such infringement action including timely filing such action in Celsion's name if required. Yakult may elect to participate in such action with counsel of its own choosing at its sole cost and expense. If Celsion fails to pursue any actual infringement action where the Third Party is actually infringing Celsion Patent Rights in the Territory and where the infringement directly affects ThermoDox Products, then Yakult shall have the right to pursue such action, and any such action shall be at Yakult's expense in which case Celsion shall use its best efforts to work with Duke University to assign Celsion Patent Rights in the Territory to Yakult. If Celsion fails to bring an infringement action against the infringing Third Party where the Third Party is actually infringing and the infringement directly affects ThermoDox Products within [ \* ] after it becomes aware of such infringement, Yakult shall have the right to bring such infringement action in which case Celsion shall use its best efforts to work with Duke University to assign Celsion Patent Rights in the Territory to Yakult. Upon request of Yakult, Celsion agrees to timely join as party-plaintiff in any such litigation (i) at Yakult's expense if such Celsion Patent Rights successfully assigned to Yakult, or (ii) at Celsion's expense if such Celsion Patent Rights cannot be assigned to Yakult, and in any event to cooperate with Yakult in connection with such infringement action. Celsion shall have the right to retain any and all amounts received by Celsion as a result of Celsion's enforcement of the Celsion Patents Rights hereunder. For clarity, if any Celsion Patent Right is assigned to Yakult, such Celsion Patent Right becomes Yakult Patent Right and should no longer be subject to Royalty Term calculation.

**7.4 Notice of Generic Product Introduction in the Territory.** Notwithstanding the obligations in Section 7.3.2, if either Party learns of a Third Party introducing or planning to introduce a Generic Product in the Territory, that Party shall immediately notify the other Party.

**7.5 Patent Term Extension.** Celsion shall seek, in Celsion's name if so required, Patent Term Extensions of Celsion Patent Rights, supplemental patent protection certificates and the like, in the Territory. Celsion and Yakult shall cooperate with each other in connection with all such activities at Celsion's expense, and Celsion and its agents and attorneys will give due consideration to all suggestions and comments of Yakult regarding any such activities.

**7.6 Patent Challenge.** Yakult and its Affiliates hereby covenant and agree not to, directly or indirectly, commence or maintain any opposition proceeding, challenge the validity or enforceability of, or, without limiting Yakult's rights under Section 7.5, oppose any extension of or the grant of a supplementary protection certificate, with respect to any Celsion Patent Rights, actively participate in any interference proceeding (each such action, a "Patent Challenge"). To the extent the foregoing is unenforceable under the Law of a particular Country where a patent application within the Celsion Patent Rights is pending or a patent within the Celsion Patent Rights is issued, (a) Yakult and its Affiliates shall provide at least [ \* ] notice to Celsion before challenging the validity of any Celsion Patent Right and (b) Celsion shall be permitted to terminate this Agreement by written notice effective upon receipt if Yakult or its Affiliates

\* Material has been omitted and filed separately with the Commission.

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directly, or indirectly through a Third Party, commence or maintain any Patent Challenge. Yakult shall include provisions in all agreements granting sublicenses of Yakult's rights hereunder providing that if the sublicensee or its Affiliates undertake a Patent Challenge with respect to any Celsion Patent Right under which the sublicensee is sublicensed, Yakult shall be permitted to terminate such sublicense agreement in its entirety. If a sublicensee of Yakult (or an Affiliate of such sublicensee) undertakes a Patent Challenge of any such Celsion Patent Right under which such sublicensee is sublicensed, then Yakult upon receipt of notice from Celsion of such Patent Challenge may terminate the applicable sublicense agreement in its entirety. If Yakult fails to so terminate such sublicense agreement, Celsion shall terminate all licensed rights granted to Yakult covered by such sublicense agreement and any sublicenses previously granted in such Country(ies) shall automatically terminate. Yakult shall cooperate with Celsion's reasonable requests to cause such terminated sublicensee to discontinue all activities under such sublicense agreement.

## **ARTICLE 8 REGULATORY MATTERS**

**8.1 General.** Yakult shall own, control and be solely responsible for filing of all Regulatory Materials in relation to the Development and Commercialization of the ThermoDox Products in the Territory, and for obtaining all necessary Regulatory Approvals in the Territory with respect to the ThermoDox Products purchased, and for all ongoing communications with the Regulatory Authorities from the Effective Date, subject to Celsion's right to use the INDs and NDAs and all data generated in connection therewith for commercialization of ThermoDox Products outside the Territory, pursuant to the license granted by Yakult to Celsion set forth in ARTICLE 3 hereof. Yakult's responsibilities shall include without limitation, responsibility for: (i) filing, maintaining and updating any INDs and NDAs for ThermoDox Product(s); (ii) reporting all Adverse Events to the appropriate Regulatory Authorities; (iii) submitting Regulatory Materials to the appropriate Regulatory Authorities for Marketing Authorization; (iv) handling medical and technical complaints and disputes with the appropriate Regulatory Authorities, patients or physicians, and (v) dealing with Product Recalls. All Regulatory Materials (including Marketing Authorization) shall be owned solely by Yakult, including any data package related to such Marketing Authorizations, subject to the license granted to Celsion pursuant to ARTICLE 3 hereof.

### **8.2 Communications with Regulatory Authorities.**

**8.2.1** Yakult shall keep Celsion generally apprised of the status of all ongoing discussions with Regulatory Authorities. Yakult also shall provide Celsion with notice of all meetings, conferences, and discussions (including without limitation any meetings or any other meeting of experts convened by the MHLW concerning any topic relevant to the ThermoDox Products) scheduled with the MHLW concerning any regulatory matters relating to the ThermoDox Products promptly after the scheduling of such meeting, conference, or discussion. Celsion shall be entitled to have one or more representatives, as appropriate under the circumstance, present at all such meetings. Celsion and Yakult, through the Committee, shall use all reasonable efforts to agree in advance on the scheduling of such meetings, conferences and discussions and on the objectives to be accomplished at such meetings, conferences and discussions and the agenda for the meetings, conferences and discussions with the MHLW.

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**8.2.2** Each Party shall provide to the other Party, as soon as reasonably practicable but in no event more than [ \* ] after its receipt, copies of any material documents or other material correspondence received from the Regulatory Authorities pertaining to a ThermoDox Product. Yakult shall forward to Celsion English translations of all meeting minutes with the MHLW.

**8.3 Drug Safety.** The Parties shall separately execute a pharmacovigilance agreement ("Pharmacovigilance Agreement") for exchanging Adverse Event and other safety information relating to ThermoDox Products prior to Yakult's initiation of any clinical activity for the ThermoDox Product in the Territory. Such Pharmacovigilance Agreement shall ensure that Adverse Event and other safety information is exchanged according to a schedule that will permit each Party to comply with local regulatory requirements and all Laws.

**8.4 Regulatory Information.** Each Party agrees to provide the other with all reasonable assistance and take all actions reasonably requested by the other Party that are necessary or desirable to enable the other Party to comply with any Law applicable to the ThermoDox Products, including, but not limited to, Yakult's meeting its reporting and other obligations to maintain and update any Marketing Authorizations for the ThermoDox Products.

**8.5 Suspension of Clinical Development Activities.** Either Celsion or Yakult shall have the right to immediately suspend clinical development activities with respect to a ThermoDox Product for a particular indication, formulation or dosage form if such Party, in good faith, determines that there exists significant and urgent concerns relating to patient safety with respect to such clinical activities. The Party making the determination to suspend such clinical activities shall notify the other party in writing immediately of any such suspension and the reasons therefor. The Committee then shall promptly determine what actions should be taken with respect to such clinical activities. Once a determination is made by the Committee with respect to the appropriate actions to be taken, the Committee shall review and re-evaluate the Development Plan and make any changes necessary to implement such actions.

**8.6 Recalls or Other Corrective Action.** Yakult shall promptly notify Celsion of any material actions to be taken by Yakult with respect to any Product Recall prior to such action, if reasonably practicable under the circumstances, to permit Celsion a reasonable opportunity to consult with Yakult with respect thereto. Additional rights and obligations relating to a Product Recall may be further set forth in the Quality Agreement. [ \* ] ("Recall Costs"). Recall Costs means all [ \* ] (i) [ \* ], (ii) [ \* ], (iii) [ \* ], and (iv) [ \* ].

## **ARTICLE 9 CONFIDENTIAL INFORMATION; PUBLICATIONS AND PUBLICITY**

## 9.1 Confidential Information.

**9.1.1** Yakult and Celsion each agree that during the Term and thereafter for so long as such Confidential Information remains confidential and proprietary to the Disclosing Party, it will keep confidential and will cause each of its Affiliates to keep confidential, all Celsion Confidential Information or Yakult Confidential Information, as the case may be, that is

\* Material has been omitted and filed separately with the Commission.

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disclosed to it or to any of its Affiliates, pursuant to this Agreement, and not to use any Confidential Information except as expressly permitted hereunder. Notwithstanding the foregoing, in the case of Confidential Information identified in writing by one Party to the other, the obligations of confidentiality shall continue until such information is no longer considered a trade secret. When Confidential Information is disclosed other than in writing (in which case the Disclosing Party shall mark the document Confidential), the Disclosing Party shall make a reasonable effort to summarize such Confidential Information in writing and submit it to the Receiving Party within [ \* ] of initial disclosure. Unmarked or non-written information shall be treated as Confidential Information if it can be reasonably determined given the nature of the information and disclosure that such information should be treated as such. Yakult and Celsion each agree to take such action, and to cause its Affiliates to take such action, to preserve the confidentiality of Celsion Confidential Information and/or Yakult Confidential Information, as the case may be, as it would customarily take to preserve the confidentiality of its own confidential information, which in any event shall be no less than reasonable actions.

**9.1.2** Neither Yakult nor Celsion, nor any of their respective Affiliates, shall use the other Party's Confidential Information, except as expressly permitted in this Agreement.

**9.1.3** Yakult and Celsion each agree that any disclosure (a) by Yakult or any of its Affiliates of Celsion Confidential Information, or (b) by Celsion or any of its Affiliates of Yakult Confidential Information, shall be made subject to obligations of confidentiality at least as stringent as confidentiality obligations hereunder and only if and to the extent necessary to carry out its responsibilities or exercise its rights under this Agreement or as otherwise required by Law. Except as permitted by this ARTICLE 9, Yakult agrees not to disclose any Celsion Confidential Information and Celsion agrees not to disclose any Yakult Confidential Information, to any Third Parties, other than its directors, subcontractors, consultants, licensees and agents as permitted under this Section 9.1.3, under any circumstance, without the prior written consent of the other Party. Except as otherwise contemplated or required by this Agreement, Yakult and Celsion each agree, upon the other's request, to return all Celsion Confidential Information or Yakult Confidential Information, as the case may be, disclosed to the other Party pursuant to this Agreement, including all copies and extracts of documents, as promptly as practicable following such request upon the termination of this Agreement, except for one (1) copy which may be kept and used for the sole purpose of complying with any continuing obligations under this Agreement.

**9.1.4** Celsion and Yakult each represent, warrant and covenant that all of its directors, officers, employees, and any subcontractors, consultants, investigators, sublicensees or agents of such Party, who shall have access to Yakult Confidential Information or Celsion Confidential Information, as the case may be, are or shall be bound by written agreement to maintain such information in confidence consistent with the provisions hereof. Each Party agrees to use, and agrees to cause its Affiliates to use, reasonable efforts to enforce such obligations and to prohibit its employees and consultants from using such Confidential Information except as expressly permitted hereunder. Each Party shall be responsible for any breach of its obligations under this Article 9 in the event of a disclosure by its Affiliates, directors, officers, employees consultants, and advisors.

\* Material has been omitted and filed separately with the Commission.

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**9.1.5** Notwithstanding anything to the contrary in this ARTICLE 9, Yakult may disclose Celsion Confidential Information and Celsion may disclose Yakult Confidential Information (a) to Governmental Authorities (i) to the extent reasonably necessary to obtain or maintain INDs or Regulatory Approvals for any ThermoDox Product, and (ii) in order to respond to inquiries, requests or investigations relating to this Agreement; (b) to outside consultants and contractors, advisory boards, managed care organizations, and non-clinical and clinical investigators, in each case to the extent reasonably necessary to Develop, register or Commercialize any ThermoDox Product; provided that Yakult or Celsion, as the case may be, shall obtain the same confidentiality obligations from such Third Parties as it obtains with respect to its own similar types of confidential information; (c) in connection with filing or prosecuting Patent Rights as permitted by this Agreement; (d) in connection with prosecuting or defending litigation as permitted by this Agreement; (e) in connection with or included in scientific presentations and publications relating to ThermoDox Products, including abstracts, posters, journal articles and the like, which presentations and publications are authorized pursuant to Section 9.2; and (f) to the extent reasonably necessary in order to exercise or enforce its rights under this Agreement. In addition, either Party may disclose any Confidential Information of the other Party as may be otherwise required or requested to be disclosed in compliance with applicable Laws or regulations or order by a court or other Governmental Authority having competent jurisdiction; provided, that if either Celsion or Yakult is required to make any such disclosure of the Yakult Confidential Information or the Celsion Confidential Information, respectively, such Party shall give reasonable advance notice (to the extent possible) to the other Party of such disclosure requirement and the original Disclosing Party may in its discretion seek to secure confidential treatment of the Celsion Confidential Information or the Yakult Confidential Information, as the case may be, requested or required to be disclosed.

**9.2 Publications.** The Parties acknowledge that scientific and medical publications and presentations will be made in a manner consistent with industry standards for the development and commercialization of drugs in the Field, but must be strictly monitored to prevent any adverse effect from premature publication or dissemination of the results of the activities hereunder. Neither Party, nor any of its employees or contractors shall publish or present any information, including the results of any preclinical or clinical studies with respect to any ThermoDox Product without prior written approval of the Committee or the other Party. In the event either Party reviews a proposed Third Party academic, scientific, medical or other publication or presentation with respect to any ThermoDox Product, such Party shall submit a copy of such publication or presentation to the other Party's representatives on the Committee at least [ \* ] in advance (or, if such Party has fewer than [ \* ] to review a proposed Third Party publication or presentation, as soon as reasonably practicable) of such proposed publication or presentation being submitted to a publisher or other Third Party. In the event a Party or a Party's employee proposes to publish or make a publication or presentation with respect to any ThermoDox Product, such Party shall submit a copy of such publication or presentation to the other Party at least [ \* ] in advance of such proposed publication or presentation being submitted to a publisher or other Third Party. Nothing in this ARTICLE 9 shall be construed to (a) limit the right of Celsion's or Yakult's clinical investigators to publish the results of their

studies; or (b) prevent either Party from complying with applicable Law with respect to the disclosure of Clinical Study data and results. In any permitted publication or

\* Material has been omitted and filed separately with the Commission.

presentation by a Party, the other Party's contribution shall be duly recognized, and co-ownership shall be determined in accordance with customary standards.

**9.3 Registration and Filing of This Agreement.** If a Party determines that it is required by Law to publicly file, register or notify this Agreement with a Governmental Authority, such Party shall (a) initially file a redacted copy of this Agreement approved by both Parties (the "Redacted Agreement"), (b) request, and use commercially reasonable efforts to obtain, confidential treatment of all terms redacted from this Agreement, as reflected in the Redacted Agreement, for a reasonable period, (c) permit the other Party to review and approve such request for confidential treatment and any subsequent correspondence with respect thereto at least [ \* ] prior to its submission to such Governmental Authority, (d) promptly deliver to the other Party any written correspondence received by it or its representatives from such Governmental Authority with respect to such confidential treatment request and promptly advise the other Party of any other communications between it or its representatives with such Governmental Authority with respect to such confidential treatment request, (e) upon the written request of the other Party, request an appropriate extension of the term of the confidential treatment period, and (f) if such Governmental Authority requests any changes to the redactions set forth in the Redacted Agreement, discuss such changes with the other Party and take the other Party's comments into consideration when deciding whether to agree to such changes. Notwithstanding the foregoing, the Party who determines that it is required by Law to publicly file, register or notify this Agreement with a Governmental Authority shall have the final determination with respect to the redactions. Each Party shall be responsible for its own Out-of-Pocket Costs and Expenses in connection with any such filings, registrations or notifications.

**9.4 Publicity.** The public announcement of the execution of this Agreement is set forth on Schedule 9.4 attached hereto and shall be promptly disseminated following the execution of this Agreement by the Parties. In addition, the Parties may make public statements, including in analyst meetings, concerning the progress of the ThermoDox Products consistent with the disclosures that the Parties make for their other pharmaceutical products under development; provided that each Party shall obtain the other Party's prior written consent before making such public statements, such consent not to be unreasonably delayed, withheld or conditioned. Each Party shall cooperate with the other Party

\* Material has been omitted and filed separately with the Commission.

with respect to review and comment on such public statements. Without limiting the immediately preceding sentence, each Party shall not, without the other Party's prior written consent, such consent not to be unreasonably delayed, withheld or conditioned, make any public statement (written or oral) concerning the terms of this Agreement or concerning any ThermoDox Product, except where such statement: (a) is required by Law, (b) is required to be contained in financial statements of the Parties prepared in accordance with GAAP, or (c) has been announced previously in accordance with Section 9.1.5 or this Section 9.4. In the case of any public statement (written or oral) pursuant to (a) or (b) above, the Parties shall give the other Party sufficient advance notice of the text of such statement so that the other Party will have the opportunity to comment upon the statement, and the Party issuing such statement shall give due consideration to any such comments in the final statement.

**9.5 Prohibition on Solicitation.** Without the prior written consent of the other Party, neither Party nor its Affiliates shall during the Term of this Agreement or for a one-year period after the termination of this Agreement, solicit to hire (directly or indirectly), or hire any employee of the other Party.

## **ARTICLE 10 REPRESENTATIONS AND WARRANTIES; COVENANTS**

**10.1 Mutual Representations and Warranties.** Celsion and Yakult each represents and warrants to the other as of the Effective Date that:

**10.1.1** It has all requisite corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement by such Party have been duly and validly authorized and approved by proper corporate action on the part of such Party, and it has taken all other action required by Law, its certificate of incorporation or by-Laws, or any agreement to which it is a party or to which it may be subject, required to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of the other Party, this Agreement constitutes a legal, valid and binding obligation of such Party, enforceable against it in accordance with its terms, except as such enforceability may be limited by applicable insolvency and other Laws affecting creditors' rights generally, or by the availability of equitable remedies.

**10.1.2** The execution and delivery of this Agreement by such Party and the performance by such Party contemplated hereunder does not and will not violate any Laws or any order of any court or Governmental Authority to which it is subject, except for such violations that would not have a material adverse effect on the ability of such Party to perform its obligations under this Agreement.

**10.1.3** Neither the execution and delivery of this Agreement nor the performance hereof by such Party requires it to obtain any permits, authorizations or consents from any Governmental Authority (other than any Regulatory Approvals relating to the manufacture, use, importation or sale of any ThermoDox Product), or from any other person, firm or corporation, and such execution, delivery and performance will not result in the Material Breach of or give rise to any right of termination under any agreement or contract to which it is a

party or to which it may be subject, except for those breaches or rights that would not adversely affect its ability to perform its obligations under this Agreement.

**10.1.4** There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the knowledge of such Party, threatened against it or any of its Affiliates relating to the transactions contemplated by this Agreement.

**10.1.5** Its employees have executed agreements or have existing obligations under Law requiring assignment to such Party of all Improvements made by such individuals during the course of and as a result of their employment with such Party, and obligating such employees to maintain as confidential such Party's Confidential Information.

**10.2** Additional Yakult Representations and Warranties. Yakult further represents and warrants to Celsion as of the Effective Date that:

**10.2.1** Neither it nor any of its Affiliates currently has in clinical development, or has, prior to the Effective Date, adopted a plan to initiate Clinical Studies, for a Competing Product; and

**10.2.2** It has utilized its own scientific, marketing and distribution expertise and experience to analyze and evaluate both the scientific and commercial value of the Celsion ThermoDox Products and has relied on such analysis and evaluations in deciding to enter into this Agreement.

**10.3** Additional Celsion Representations and Warranties. Celsion further represents and warrants to Yakult as of the Effective Date that:

**10.3.1** No Third Party has challenged or has threatened in writing to challenge the extent, validity or enforceability of the patents encompassed within the Celsion Patent Rights relating to the ThermoDox Products (including by way of example through the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign entity), and to the knowledge of Celsion, all application, registration, maintenance and renewal fees in respect of the Celsion Patent Rights have been paid and all documents and certificates required to be filed with the relevant agencies for the purpose of maintaining such Celsion Patent Rights have been filed;

**10.3.2** To the knowledge of Celsion, none of the research, development, making, having made, use, sale, offering for sale or importation of any ThermoDox Product by or on behalf of Celsion has infringed or is infringing the claims of any patents of a Third Party. Neither Celsion nor any of its Affiliates have received any written notice or claim that the research, development, making, having made, use, sale, offering for sale or importation of any ThermoDox Product has infringed or is infringing the claims of any patents of a Third Party;

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**10.3.3** A complete and correct list of the Celsion Patent Rights is set forth in Section 1.12;

**10.3.4** Celsion Controls the Celsion Patent Rights, free of any lien, encumbrance, charge, security interest, mortgage or other similar restriction, and neither Celsion nor any of its Affiliates has entered into any agreement (other than fee for services agreements or material transfer agreements entered into in the ordinary course of business to develop the ThermoDox Products or any research agreements for non-commercial purposes) granting any right, interest or claim in or to any Celsion Patent Rights to any Third Party (including any academic organization or agency) with respect to the Territory;

**10.3.5** Except as disclosed in Section 1.12, none of the Celsion Patent Rights have been acquired by in-license, or otherwise made available (including pursuant to any immunity from suit arrangement) to Celsion or any of its Affiliates from a Third Party;

**10.3.6** Celsion has obtained assignment of the Celsion Patent Rights listed in Section 1.12, other than those acquired by in-license, from the inventors named therein, and all such assignments of inventorship rights are valid and enforceable;

**10.3.7** None of the rights of Celsion or its Affiliates under the Celsion Patent Rights were developed with federal funding from the United States government or any other Governmental Authority such that the United States government or other Governmental Authority has any march-in rights in or to any Celsion Patent Rights or such that Celsion or its Affiliates would be subject to any compulsory licensing requirements or any rights under 35 U.S.C. §§201-212;

**10.3.8** In the course of the Development of the ThermoDox Products, Celsion has not used any employee or consultant that is debarred by any Regulatory Authority, or who is or was to the knowledge of Celsion the subject of debarment proceedings by any Regulatory Authority; and

**10.3.9** All Development activities relating to the ThermoDox Products performed by Celsion, and to the knowledge of Celsion performed on its behalf, have been conducted in material compliance with applicable Law, except where failure to so comply would not be reasonably expected to have a material adverse effect on Yakult's rights hereunder.

**10.4** Covenants. Each Party hereby covenants and agrees during the Term that:

**10.4.1** It shall carry out the Development and Commercialization of the ThermoDox Products and its other obligations or activities hereunder in accordance with: (a) the

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terms of this Agreement, the Development Plan, and the Commercialization Plan, and (b) GCPs, GLPs and GMPs and all other applicable Laws and Marketing Authorizations;

**10.4.2** It will not enter into any agreement with a Third Party or undertake other activities or commitments which would have a material adverse effect on: (a) its ability to perform all of the obligations required of it hereunder, or (b) any of the rights granted to the other Party hereunder; and

**10.4.3** In the course of the Development or Commercialization of ThermoDox Products, it will not use any employee or consultant who has been debarred by any Regulatory Authority, or, to the best of such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

**10.5** Representations and Warranties of Celsion Concerning the Duke Agreement Celsion represents and warrants to Yakult that, as of the Effective Date:

**10.5.1** The Duke Agreement, is in full force and effect and has not been modified or amended (other than the amendments effective January 15, 2003 and June 20, 2007), except that no representation or warranty relating to the Duke Agreement is made with respect to Duke University or matters solely within the control or direction of Duke University that are not known to Celsion;

**10.5.2** To the best of Celsion's knowledge, Celsion is not in breach with respect to a material obligation under the Duke Agreement;

**10.5.3** Section 2.02 of the Duke Agreement requires that upon any termination of the Duke Agreement, all sublicenses granted by Celsion, which would include this Agreement with Yakult, shall be automatically assigned to Duke University, which shall thereafter receive all benefits and have all obligations under the sublicenses as in the place and stead of Celsion; and

**10.5.4** Celsion has not waived or allowed to lapse any of its rights under the Duke Agreement, and no such rights have lapsed or otherwise expired or been terminated.

**10.6** Celsion's Obligations Concerning the Duke Agreement Celsion agrees that during the term of this Agreement:

**10.6.1** [ \* ];

**10.6.2** [ \* ].

**10.6.3** [ \* ];

**10.6.4** [ \* ];

**10.6.5** [ \* ];

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**10.6.6** [ \* ]; and

**10.6.7** [ \* ].

**10.7** Additional Covenants of Celsion. Celsion covenants and agrees during the Term, except as required pursuant to any consent decree or agreement with any Governmental Authority or by Law and except as otherwise provided for in this Agreement, neither Celsion nor its Affiliates shall enter into any agreement with any Third Party, whether written or oral, with respect to, or otherwise assign, transfer, license, or convey its right, title or interest in or to, the Celsion Patent Rights, Celsion Know-How, any ThermoDox Product, in each case, that is in conflict with the rights granted by Celsion to Yakult under this Agreement.

**10.8** Disclaimer of Warranty. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS, WAIVES, AND RENOUNCES ANY WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF VALIDITY, NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

## **ARTICLE 11 INDEMNIFICATION**

**11.1** Indemnification by Yakult. Subject to the provisions of Section 11.3, Yakult shall defend, indemnify and hold harmless Celsion and its Affiliates and each of their respective officers, directors, shareholders, employees, successors and permitted assigns ("Celsion Indemnitees") from and against all Third Party Claims, and all associated Losses, to the extent arising out of: (a) Yakult's negligence or willful misconduct in performing any of its obligations under this Agreement, (b) a breach by Yakult of any of its representations, warranties, covenants or obligations under this Agreement, (c) subject to Section 11.3, the development, use, promotion, marketing, distribution, storage or sale of ThermoDox Products in the Territory by Yakult or any of its Affiliates, sublicensees, subcontractors, distributors or agents or on behalf of Yakult by a Third Party, or any warranty claims, Product Recalls, or any claims of personal injury or property damage occurring in the Territory, or (d) the manufacture, use, marketing, distribution, storage or sale of any product containing a ThermoDox Product developed or commercialized by or on behalf of Yakult outside of this Agreement; provided, however, that in all cases referred to in this Section 11.1, Yakult shall not be liable to indemnify Celsion for any Losses of Celsion to the extent that such Losses of Celsion arise from any action or non-action of Celsion for which Celsion is obligated to indemnify Yakult pursuant to Section 11.2.

**11.2** Indemnification by Celsion. Subject to the provisions of Section 11.3, Celsion shall defend, indemnify and hold harmless Yakult and its Affiliates and each of their officers, directors, shareholders, employees, successors and permitted assigns ("Yakult Indemnitees") from and against all Third Party Claims, and all associated Losses, to the extent arising out of: (a) Celsion's negligence or willful misconduct in performing any of its obligations under this Agreement, (b) a breach by Celsion of any of its representations, warranties, covenants or obligations under this Agreement, (c) subject to Section 11.3, the Development, use, promotion, marketing, distribution, storage or sale of ThermoDox Products outside of the Territory by

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Celsion or any of its Affiliates, subcontractors, distributors or agents or on behalf of Celsion by a Third Party, or any warranty claims, Product Recalls, or any claims of personal injury or property damage occurring outside of the Territory, (d) the manufacture of ThermoDox Products by Celsion or on behalf of Celsion by a Third Party, which indemnification will be more specifically set forth in the supply agreement referenced in Section 6.1, or (e) the manufacture, use, marketing, distribution, storage or sale of any product containing a ThermoDox Product to which Yakult's rights have been terminated and have reverted to Celsion, but only to the extent such Claims arise out of Celsion's activities after such reversion, developed or commercialized by or on behalf of Celsion outside of this Agreement; provided, however, that in all cases referred to in this Section 11.2, Celsion shall not be liable to indemnify Yakult to the extent that such Losses of Yakult arise from any action or non-action of Yakult for which Yakult is obligated to indemnify Celsion pursuant to Section 11.1.

### **11.3 Procedure for Indemnification.**

**11.3.1 Notice.** Each Party (the "Indemnified Party") will notify promptly the other Party (the "Indemnifying Party") if it becomes aware of a Claim (actual or potential) by any Third Party (a "Third Party Claim") for which indemnification may be sought by the Indemnified Party, and will give such information with respect thereto as the Indemnifying Party shall reasonably request. If any proceeding (including any governmental investigation) is instituted involving the Indemnified Party, the Indemnified Party shall not make any admission or statement concerning a Third Party Claim, but shall promptly notify the Indemnifying Party in writing and the Indemnifying Party and Indemnified Party shall meet to discuss how to respond to such Third Party Claim. The Indemnifying Party shall not be obligated to indemnify the Indemnified Party to the extent any admission or statement made by the Indemnified Party, or any failure by the Indemnified Party to notify the Indemnifying Party of the Claim, materially prejudices the defense of the Third Party Claim.

**11.3.2 Defense of Claim.** The Indemnifying Party shall defend the Indemnified Party against the Third Party Claim; provided, that the Indemnifying Party has the financial resources to satisfy, and expressly agrees that it shall be responsible for satisfying and discharging, any judgment or award made to the Third Party as a result of such proceedings or settlement amount agreed to with the Third Party in respect of the Third Party Claim, without prejudice to any provision in this Agreement or right under applicable Law that allows the Indemnifying Party subsequently to recover any amount from the Indemnified Party. The Indemnifying Party shall retain counsel reasonably acceptable to the Indemnified Party (such acceptance not to be unreasonably withheld, refused, conditioned or delayed) to represent the Indemnified Party and shall pay the fees and expenses of such counsel related to such proceeding. In any such proceeding, the Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of the Indemnified Party unless: (a) the Indemnifying Party and the Indemnified Party shall have mutually agreed to the retention of such counsel, or (b) the named parties to any such proceeding (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party and representation of both Parties by the same counsel would be inappropriate due to actual or potential differing interests between them. In the circumstance described in the preceding sentence, all reasonable attorneys' fees and expenses of the Indemnified Party shall be

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reimbursed as they are incurred. The Indemnified Party shall have the right to control the defense of the Third Party Claim only if the Indemnifying Party fails to defend the Third Party Claim, and if the Indemnified Party controls the defense of such Third Party Claim, the Indemnifying Party shall have the right to participate in such defense at the Indemnifying Party's own expense. The Indemnified Party shall not settle any claim for which it is seeking indemnification without the prior consent of the Indemnifying Party, which consent shall not be unreasonably withheld, refused, conditioned or delayed. The Indemnified Party shall, at the Indemnifying Party's expense and request, cooperate in all reasonable respects in the defense of the Third Party Claim.

**11.3.3 Settlement of Claim.** The Indemnifying Party shall not, without the written consent of the Indemnified Party (which consent shall not be unreasonably withheld), effect any settlement of any pending or threatened proceeding in which the Indemnified Party has sought indemnification hereunder from the Indemnifying Party, unless such settlement involves solely monetary damages and includes an unconditional release of the Indemnified Party from all liability on claims that are the subject matter of such proceeding.

**11.4 Insurance.** Each Party shall, upon the Effective Date and for a period of [ \* ] after the completion of its Development and Commercialization activities hereunder, obtain and/or maintain, at its sole cost and expense, product liability insurance (including any self-insured arrangements) against all liabilities arising out of activities that such Party performs under or in connection with this Agreement in such amounts and for such coverage that are reasonable and customary in the Japanese pharmaceutical industry for companies of comparable size and activities.

**11.5 Limitation of Liability.** NOTWITHSTANDING ANY OTHER LANGUAGE TO THE CONTRARY CONTAINED HEREIN, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST REVENUES OR PROFITS, BUSINESS OR GOODWILL, OR THE COST OF PROCUREMENT OF SUBSTITUTE GOODS, TECHNOLOGY OR SERVICES) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH A BREACH OR ALLEGED BREACH OF THIS AGREEMENT. THE FOREGOING SENTENCE SHALL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER THIS ARTICLE OR LIABILITIES RESULTING FROM A BREACH OF THE CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 9 ABOVE.

## **ARTICLE 12 TERM AND TERMINATION**

### **12.1 Term.**

**12.1.1 Expiration.** This Agreement shall commence as of the Effective Date and, unless sooner terminated as provided herein, shall expire upon [ \* ] (the "Term"). Notwithstanding the foregoing, If Celsion's Phase III HCC Study does not lead to approval by

\* Material has been omitted and filed separately with the Commission.

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the FDA, then (a) the Parties may mutually elect to extend the Term as will be reasonably necessary to conduct a Phase III HCC Study (the "Follow-Up HCC Study") to lead to approval in the Territory, (b) [ \* ] and (c) either party shall have the right to terminate the Agreement.

### **12.2 Termination for Cause.**



**12.2.1 Termination for Material Breach.** Celsion shall have the right to terminate this Agreement pursuant to the provisions of

Sections 12.2.1(a) and 12.2.1(b) below by provision of written notice to Yakult, and Yakult shall have the right to terminate this Agreement pursuant to the provisions of Sections 12.2.1(c) and 12.2.1(d) below by provision of written notice to Celsion:

(a) Upon Celsion's notice to Yakult that a Material Breach by Yakult has occurred, the Parties will meet to discuss in good faith whether a plan to remedy the Material Breach can be mutually agreed upon. If the Parties fail to so agree within [ \* ] after the date of such notice, Section 12.2.1(b) below shall apply.

(b) Subject to the terms hereof, upon the occurrence of any Material Breach by Yakult after compliance with the provisions of Section 12.2.1(a), Celsion may terminate this Agreement upon [ \* ] prior written notice to Yakult, with such termination to be effective upon the expiration of such [ \* ] period; provided, however, that in case of a default of a payment obligation, such notice will lapse without effect if Yakult cures such default within such time.

(c) Upon Yakult's notice to Celsion that a Material Breach by Celsion has occurred, the Parties will meet to discuss in good faith whether a plan to remedy the Material Breach can be mutually agreed upon. If the Parties fail to so agree within [ \* ] after the date of such notice, Section 12.2.1(d) below shall apply.

(d) Subject to the terms hereof, upon the occurrence of any Material Breach by Celsion after compliance with the provisions of Section 12.2.1(c), Yakult may terminate this Agreement upon [ \* ] prior written notice, with such termination to be effective upon the expiration of such [ \* ] period; provided, however, that in case of a default of a payment obligation, such notice will lapse without effect if Celsion cures such default within such time.

(e) The provisions of Section 12.2.1(b) and 12.2.1(d) shall be stayed during the pendency of the matters (including, without limitation, the notice and meeting processes) contemplated by this Section 12.2.1.

**12.2.2 Termination as a Result of Insolvency.** This Agreement may be terminated in its entirety at any time during the Term by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the event of any involuntary bankruptcy or receivership proceeding, such right to terminate shall

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only become effective if the Party consents to the involuntary bankruptcy or receivership or such proceeding is not dismissed within [ \* ] after the filing thereof.

**12.2.3 Termination by Yakult.** [ \* ]

**12.2.4 Termination for Failure to Achieve Minimum Sales Targets.** Celsion shall have the right to terminate this Agreement, if Yakult fails to reach, for [ \* ], any of the sales milestones set forth in the Commercialization Plan for ThermoDox Products as determined by an independent expert that has substantial experience developing sales forecasts (including drug pricing and marketing policies) for multi-national pharmaceutical and/or biotechnology companies in the market of the Territory, as selected by Yakult.

**12.3 Change of Control.** This Agreement shall survive and remain in full force and effect after the consummation of a Change of Control transaction involving either Celsion or Yakult.

**12.4 Termination of Duke Agreement** Upon any termination of the Duke Agreement with respect to the Territory or in its entirety, the sublicense granted by Celsion to Yakult under this Agreement shall be, as provided in Article 2.02 of the Duke Agreement regarding survival of sublicenses, automatically assigned to Duke University. Duke University shall thereafter receive all benefits of Celsion and be obligated to perform all covenants of Celsion under this Agreement in the place and stead of Celsion, and Celsion shall not retain any such rights and duties. Yakult shall thereafter receive all of its benefits and be obligated to perform all of its covenants under this Agreement for the benefit of Duke University, and shall in no event incur, merely as the result of the assignment of this Agreement to Duke University, any obligation for any additional payments or royalties or any other financial obligation not already provided for in this Agreement.

**ARTICLE 13 EFFECTS OF TERMINATION**

**13.1 Effect of Termination by Celsion for Cause or by Yakult Voluntarily.** Without limiting any other legal or equitable remedies that Celsion may have and in addition to each Party's rights and obligations under Section 13.5, if Celsion terminates this Agreement in accordance with Section 12.2, or if Yakult terminates this Agreement for convenience pursuant to Section 12.2.3, then with respect to each applicable ThermoDox Product that was contributed to the Collaboration by Celsion:

**13.1.1** The licenses granted by Celsion to Yakult under this Agreement shall immediately terminate;

**13.1.2** Yakult shall, within [ \* ] after the termination, pay Celsion all amounts due pursuant to this Agreement that accrued prior to the effective date of termination;

**13.1.3** Celsion may elect to have any Third Party agreements to which Yakult is a party providing for Development, Commercialization or manufacturing services assigned to Celsion, to the extent assignment is permitted by such agreements and provided that Yakult is

\* Material has been omitted and filed separately with the Commission.

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not required to pay any consideration or commence litigation in order to effect an assignment of any such agreement to Celsion; and

**13.1.4** Unless Celsion agrees otherwise, after the notice of termination is given, Yakult shall continue its Development and/or Commercialization activities in accordance with the applicable Development Plan or Commercialization Plan until the effective date of such termination; provided, however, that during such period the Parties will develop a transition plan in order to facilitate the transfer of Development and Commercialization activities from Yakult to Celsion thereafter. The Parties shall carry out the transition in accordance with Section 13.5.

**13.2** Effect of Termination by Yakult for Cause. Without limiting any other legal or equitable remedies that Yakult may have, and in addition to each Party's rights and obligations under Section 13.5, if Yakult has the right to terminate this Agreement under Section 12.2.1 then Yakult may elect to (a) terminate this Agreement pursuant to Section 12.2.1, as applicable, or (b) continue this Agreement by notice to Celsion; provided, however, that if Yakult opts to continue this Agreement pursuant to subparagraph (b), then (i) all documents and other materials that support all INDs and NDAs in the Territory (if any) owned by Celsion for ThermoDox Products shall be immediately transferred to Yakult and Yakult shall assume responsibility for all Clinical Studies for the ThermoDox Products then under Development in the Territory, (ii) Celsion's rights and Yakult's obligations under ARTICLE 3 shall terminate, and (iii) the Committee established pursuant to ARTICLE 2 shall be permanently disbanded.

**13.3** Effect of Termination for Insolvency. If either Party terminates the Agreement pursuant to Section 12.2.2, then (a) the Parties shall carry out the transition in accordance with Section 13.5, (b) the terminating Party's rights and the non-terminating Party's obligations under ARTICLE 3 shall terminate, and (c) the Committee established pursuant to ARTICLE 2 shall be permanently disbanded.

**13.4** Effect of Termination for Failure to Meet Minimum Sales Targets. Upon termination pursuant to Section 12.2.4:

- (a) [ \* ], and
- (b) [ \* ].

**13.5** Termination Assistance and Technology Transfer. Prior to the effective date of termination of this Agreement pursuant to Section 12.2.2, 12.2.3 and 12.2.4, the Parties shall agree upon a transition plan to minimize any disruption to the Development or Commercialization of the ThermoDox Products. The transition plan shall include a mutually agreed-upon schedule for transition activities. The Discontinuing Party, which shall be Yakult if terminated under Sections 12.1.2, 12.2.3 or 12.2.4, and the insolvent party if terminated subject to 12.2.2 (the "Discontinuing Party"), and the other Party (the "Non-Discontinuing Party") shall conduct transition activities pursuant to the transition plan and Sections 13.5.1 through 13.5.4 below:

\* Material has been omitted and filed separately with the Commission.

**13.5.1** Technology Transfer. Consistent with the principle of avoiding supply disruption and in accordance with the transition plan established pursuant to Section 13.3, the Discontinuing Party shall promptly provide the Non-Discontinuing Party with any then-existing documentation, technical information and other Know-How, in the form and format in which such materials are maintained by the Discontinuing Party in the ordinary course of its business (provided that the Discontinuing Party shall use Commercially Reasonable Efforts to provide such materials in a form and format useable by the Non-Discontinuing Party), that are necessary for the manufacture and sale of ThermoDox Products. Such documentation, technical information and other Know-How shall include without limitation: (a) [ \* ], (b) [ \* ], (c) [ \* ], (d) [ \* ], (e) [ \* ], and (f) [ \* ]. In addition, prior to the effective date of termination, and for up to [ \* ] thereafter, the Discontinuing Party shall make available to the Non-Discontinuing Party, the reasonable assistance of the Discontinuing Party's employees, and shall request that any external Third Party manufacturers be available, to support the transfer of the manufacturing technology to the Non-Discontinuing Party. The Discontinuing Party shall use commercially reasonable efforts to ensure that these personnel will cooperate with the Non-Discontinuing Party in the implementation of the manufacturing technology until such implementation has been completed successfully.

\* Material has been omitted and filed separately with the Commission.

**13.5.2** Delivery of Collateral Materials. As soon as reasonably practicable after the effective date of termination of this Agreement for each applicable ThermoDox Product, the Discontinuing Party shall provide to the Non-Discontinuing Party or its designee the following materials, provided that such materials shall be provided in the form and format in which such materials are maintained by the Discontinuing Party in the ordinary course of business (provided that the Discontinuing Party shall use commercially reasonable efforts to provide such materials in a form and format useable by the Non-Discontinuing Party), and such materials to the extent that they are related to such ThermoDox Products as to which such termination relates, shall be provided to the Non-Discontinuing Party such that the Non-Discontinuing Party will be in a position to continue to research, Develop and Commercialize ThermoDox Products anywhere in the world:

(a) all data, information and materials (including source data and source documents) that (i) was used for the preparation and/or filing of, or otherwise supports, any NDA, IND or Phase IV Study, (ii) obtained during Development, or (iii) is related to the applicable ThermoDox Products, including, without limitation, all Regulatory Approvals and clinical trial agreements (to the extent such agreements have not been cancelled, and are assignable without the Discontinuing Party being required to pay any consideration or commence litigation in order to effect an assignment of any such agreement to the Non-Discontinuing Party);

(b) all final pre-clinical and clinical study reports and clinical study protocols in the Discontinuing Party's possession or in the possession of its Affiliates and permitted sublicensees;

(c) all products and materials with trademarks and product logos, if any, prepared for or actually used in commerce by the Discontinuing Party or its Affiliates for the applicable ThermoDox Product; and

(d) Commercialization Plans, to the extent relating to ThermoDox Products (with information relating to other Yakult products redacted) and Promotional Materials.

**13.5.3 Assignment of Rights and Grant of Licenses.** Effective upon termination of this Agreement:

(a) the Discontinuing Party shall promptly assign to the Non-Discontinuing Party, or a Non-Discontinuing Party Affiliate identified by the Non-Discontinuing Party, all of Discontinuing Party's right, title and interest in and to the materials transferred by the Discontinuing Party pursuant to Section 13.5.2, including the goodwill attendant to any trademarks or logos relating to any ThermoDox Product, if the Discontinuing Party is Celsion, all of Celsion's right, title and interest in and to the material that are necessary for the Development and Commercialization of any ThermoDox Product hereunder, including without limitation the rights granted by Duke University to Celsion under the License Agreement entered into on November 20, 1999 and amended effective January 15,

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2003 and further amended effective June 20, 2007, to the extent the Discontinuing Party Controls such materials;

(b) If First Commercial Sale of a ThermoDox Product has occurred prior to the effective date of such termination and such ThermoDox Product is being Commercialized at the time of such termination and any of the Discontinuing Party housemarks are being used on packaging or advertising and Promotional Materials for such ThermoDox Product, Yakult and Celsion shall enter into a customary transitional trademark license agreement in order to permit the Non-Discontinuing Party to continue to use, ThermoDox Product packaging and advertising and promotional materials bearing such Discontinuing Party housemark; and

(c) the Discontinuing Party grants to the Non-Discontinuing Party a non-exclusive, irrevocable, perpetual, fully paid up, royalty free, sublicenseable, transferable license under all Patent Rights and Know-How Controlled by the Discontinuing Party and actually being used by the Discontinuing Party at the time of termination in connection with the Development or Commercialization of the ThermoDox Products that are subject to termination, to make, have made, sell, offer to sell, import and use such ThermoDox Products containing such ThermoDox Products in the Field in the Territory and any other Collateral Materials relating to the ThermoDox Products to which such termination relates, to the extent such Collateral Materials cannot be assigned pursuant to Section 13.5.3(a). The foregoing license shall include the right to copy, create derivative works of, perform, publicly display, use, and modify, Collateral Materials relating to such ThermoDox Products. For clarity, the foregoing license may not be exercised until the applicable effective termination date of this Agreement. the Non-Discontinuing Party shall be liable for any royalties or other payments due and owing by the Discontinuing Party to a Third Party as a result of the Non-Discontinuing Party's exercise of the license granted in this Section 13.5.3(c).

**13.5.4 Inventory.** Upon the applicable effective termination date, the Discontinuing Party shall transfer to the Non-Discontinuing Party, [ \* ]. The Non-Discontinuing Party shall have the right [ \* ]. For clarity, the Non-Discontinuing Party shall have the right [ \* ].

**13.6 Termination Due To Serious Safety Concern** . In the event either Party has notified the other Party in writing that it has determined in good faith that it is not advisable to continue Development or Commercialization of a ThermoDox Products as a result of a serious safety issue regarding the use of such ThermoDox Products pursuant to Section 8.5, then the Parties will promptly wind-down and terminate all Development and Commercialization of the applicable ThermoDox Products and all costs of such wind-down and termination will be Development Costs or marketing expenses, as the case may be, to be borne as otherwise set forth in this Agreement depending on the activity involved. However, before deciding to wind down and terminate, if Yakult has a reasonable belief of a sound scientific and medical basis as to the safety of the approved dosage form and formulation of the ThermoDox Product in the Territory, then the Parties shall enter into discussions about the advisability and terms of continuing to market the ThermoDox Product in the Territory.

\* Material has been omitted and filed separately with the Commission.

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**13.7 Survival.** Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve any Party from obligations which are expressly or by implication intended to survive termination, relinquishment or expiration of this Agreement and shall not affect or prejudice any provision of this Agreement which is expressly or by implication provided to come into effect on, or continue in effect after, such termination, relinquishment or expiration.

**ARTICLE 14 MISCELLANEOUS**

**14.1 Relationship of the Parties.** Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, each Party's legal relationship under this Agreement to the other Party shall be that of independent contractor. This Agreement is not a partnership agreement and nothing in this Agreement shall be construed to establish a relationship of co-partners or joint venturers between the Parties.

**14.2 Further Assurances.** Each Party hereby agrees to execute, acknowledge and/or deliver such further instruments, and to do all other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**14.3 Force Majeure.** Neither Party shall be liable to the other Party for any direct, indirect, consequential, incidental, special, punitive, exemplary or other damages arising out of or relating to the suspension or termination of any of its obligations or duties under this Agreement by reason of the occurrence of a Force Majeure Event (a "Force Majeure Event"), provided such Party complies with its obligations under this Section 14.3.

(a) A Force Majeure Event is an event that is unforeseen and beyond the reasonable control of a Party or its Affiliates, and not due to the malfeasance of the Party or its Affiliates, that could not reasonably have been avoided by the exercise of due care and prevents the Party from performing its obligations under this Agreement, including, but not limited to, injunction, fire, accident, labor difficulty, strike, riot, civil commotion, act of God, inability to obtain raw materials, or delay or errors by shipping companies (not occasioned by negligence of the Party).

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(b) A Force Majeure Event that materially interferes with the ability of a Party to perform its obligations or duties under this Agreement shall not excuse such Party from the performance of its obligations or duties, but shall merely suspend such performance during the continuation of the event. The affected Party shall promptly notify the other Party of the occurrence and particulars, and shall provide the other Party with its best estimate of the duration of the Force Majeure Event. The Party so affected shall use Commercially Reasonable Efforts to avoid or remove such causes of nonperformance as soon as is reasonably practicable. Upon termination of the Force Majeure Event, the performance of any suspended obligation or duty shall promptly recommence.

**14.4 Governing Law.** This Agreement shall be construed, and the respective rights of the Parties determined, according to the substantive law of the State of New York, notwithstanding the provisions governing conflict of laws under New York law to the contrary, except matters of intellectual property law which shall be determined in accordance with the intellectual property laws applicable to the intellectual property in question.

**14.5 Arbitration.**

(a) With the exception of those matters referred for decision making under Section 2.14.4 and under Section 5.14 for resolution by independent accountants, in the event of any dispute arising out of or relating to this Agreement, the Parties shall first attempt to resolve such dispute through good-faith negotiations. Such negotiations shall not extend for a period of more than [ \* ] following notification of such dispute to the other Party.

(b) Either Party may refer any such dispute to the Parties' respective Chief Executive Officers or Managing Director, who shall confer on the resolution of the issue. Any final decision mutually agreed to by such officers shall be conclusive and binding on the Parties. If such officers are not able to agree on a resolution within [ \* ] after such issue was first referred to them, either Party may, by written notice to the other Party, elect to initiate arbitration pursuant to Section 14.5 (c).

(c) Any arbitration under this Section 14.5 shall be administered by the American Arbitration Association under its Commercial Arbitration Rules then in effect (the "Arbitration Rules") and as otherwise described in this Section 14.5(c). The arbitration shall take place at a location to be agreed by the Parties; provided, however, that in the event that the Parties are unable to agree on a location for an arbitration under this Agreement within [ \* ] of the demand therefore, such arbitration shall be held in New York, New York.

(i) Full Arbitration. Unless Section 14.5(c)(ii) is invoked for an expedited arbitration, the following procedures apply:

(1) The Parties shall appoint an arbitrator by mutual agreement. If the Parties cannot agree on the appointment of an arbitrator within [ \* ] of the demand for arbitration, an arbitrator shall be appointed in accordance with the Arbitration Rules.

\* Material has been omitted and filed separately with the Commission.

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(2) Either Party may apply to the arbitrator for interim injunctive relief until the arbitration decision is rendered or the matter is otherwise resolved. Either Party also may, without waiving any right or remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending resolution of the arbitration matter pursuant to this Section 14.5(c)(i). The arbitrator shall have the authority to grant any equitable and legal remedies that would be available in any judicial proceeding instituted to resolve the dispute submitted to arbitration; provided, however, that the arbitrator shall not have the power to alter, amend, or otherwise affect the terms or provisions of this Agreement. Judgment upon any award rendered pursuant to this Section may be entered by any court having jurisdiction over the Parties' other assets.

(3) Each Party shall bear its own costs and expenses and attorneys' fees, and the Party that does not prevail in the arbitration proceeding shall pay the arbitrator's fees and any administrative fees of arbitration.

(4) Except to the extent necessary to confirm an award or decision or as may be required by applicable Law, neither Party may, and the Parties shall instruct the arbitrator not to, disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the arbitration matter would be barred by the applicable New York statute of limitations.

(5) The Parties hereby agree that any payment to be made by a Party pursuant to a decision of the arbitrator shall be made in United States Dollars, free of any tax or other deduction. The Parties further agree that the decision of the arbitrator shall be the sole, exclusive and binding remedy between them regarding determination of the arbitration matters presented and the Parties hereby waive the right to contest the award in any court or other forum.

(ii) Expedited Arbitration. Any dispute may be referred by either Party for expedited arbitration, in which case the procedures set forth in Section 14.5(a) shall apply, except as follows:

(1) A single, independent, conflict-free arbitrator shall be appointed, who shall have sufficient background, expertise, and experience to resolve the dispute ("the Expert");

(2) Each Party shall submit a written summary of such Party's position to the Expert within [ \* ] of the selection of the Expert. Within [ \* ] after receipt of such summaries by the Expert, the Expert shall make a determination that the Expert considers the most fair and reasonable to the Parties, and shall provide the Parties with a written statement setting forth the basis of the determination.

(iii) Binding Arbitration. All arbitration decisions and outcomes to resolve disputes are binding to both Parties and will serve as the final decision.

**14.6** *(Intentionally Deleted)*

\* Material has been omitted and filed separately with the Commission.

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**14.7** Assignment. This Agreement, and any rights or obligations of either Party hereunder, may not be assigned by either Party without the prior consent of the other Party; provided, however, that either Party may assign this Agreement, in whole or in part, to any of its Affiliates if such Party remains secondarily liable for performance of this Agreement; and provided further that either Party may assign this Agreement to a successor to all or substantially all of the assets of such Party whether by merger, sale of stock, sale of assets or other similar transaction. This Agreement shall be binding upon and, subject to the terms of the foregoing sentence, inure to the benefit of the Parties hereto, and their permitted successors, legal representatives and assigns, including without limitation, any successor of a Party as a result of a Change of Control transaction involving such Party.

**14.8** Notices. All demands, notices, consents, approvals, reports, requests and other communications hereunder must be in writing and will be deemed to have been duly given only if mailed by express delivery service (which notice shall be effective five (5) Business Days after such mailing) to the Parties at the following addresses:

Celsion Corporation:

Celsion Corporation  
10220 Old Columbia Road  
Suite L  
Columbia, MD 21046  
Attn: Michael H. Tardugno, President

With a copy to:

Venable LLP  
750 E. Pratt Street  
Suite 900  
Baltimore, Maryland 21202  
Attn: Michael J. Baader, Esquire

Yakult:

Yakult Honsha Co., Ltd.  
6 F Ginza-Kobiki Bldg., 16-21,  
Ginza 7-Chome, Chuo-ku, Tokyo, Japan  
Attn: [ \* ], Head of the Pharmaceutical Division

With a copy to:

Yakult Honsha Co., Ltd.  
6 F Ginza-Kobiki Bldg., 16-21,  
Ginza 7-Chome, Chuo-ku, Tokyo, Japan  
Attn: General Manager, Pharmaceutical Department

\* Material has been omitted and filed separately with the Commission.

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or to such other address as the addressee shall have last furnished in writing in accordance with this provision to the addressor.

**14.9** Severability. In the event of the invalidity of any provisions of this Agreement, the Parties agree that such invalidity shall not affect the validity of the remaining provisions of this Agreement. The Parties will replace an invalid provision with valid provisions which most closely approximate the purpose and economic effect of the invalid provision. In the event that the terms and conditions of this Agreement are materially altered as a result of the preceding sentences, the Parties shall renegotiate the terms and conditions of this Agreement in order to resolve any inequities. Nothing in this Agreement shall be interpreted so as to require either Party to violate any applicable Laws, rules or regulations.

**14.10** Headings. The headings used in this Agreement have been inserted for convenience of reference only and do not define or limit the provisions hereof.

**14.11** Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by Law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

**14.12** Entire Agreement. This Agreement (including the exhibits and schedules hereto) constitutes the entire agreement between the Parties hereto with respect to the within subject matter and supersedes all previous agreements and understandings between the Parties, whether written or oral, including

the terms of binding agreement between Yakult and Celsion for Development and marketing of ThermoDox Product in Japan, dated August 13, 2008. This Agreement may be altered, amended or changed only by a writing making specific reference to this Agreement and signed by duly authorized representatives of Celsion and Yakult.

**14.13 No License.** Nothing in this Agreement shall be deemed to constitute the grant of any license or other right to either Party, to or in respect of any ThermoDox Product, patent, trademark, Confidential Information, trade secret or other data or any other intellectual property of the other Party, except as expressly set forth herein.

**14.14 No Third Party Beneficiaries.** None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including without limitation any creditor of either Party hereto. No such Third Party shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any Claim in respect of any debt, liability or obligation (or otherwise) against either Party hereto.

**14.15 Counterparts.** This Agreement may be executed in two or more counterparts or facsimile versions (to be promptly followed by original signatures), each of which, when

executed, shall be deemed to be an original and all of which together shall constitute one and the same document.

IN WITNESS WHEREOF, Celsion and Yakult, by their duly authorized officers, have executed this Agreement as of the Effective Date.

**Celsion Corporation**

**Yakult Honsha Co., Ltd.**

By: /s/ Michael H. Tardugno  
Name: Michael H. Tardugno  
Title: President & CEO

By: /s/ Sumiya Hori  
Name: Sumiya Hori  
Title: President

**SCHEDULE 1.53**

Hepatocellular Carcinoma

SCHEDULE 2.3.1

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SCHEDULE 2.8.1

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SCHEDULE 9.4





**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
Celsion Corporation  
Columbia, Maryland

We consent to the incorporation by reference in the Registration Statements on Forms S-8 (File Nos. 333-145680, 333-139784, 333-127045, 333-116435 and 333-67508) and on Form S-3 (File Nos. 333-115890, 333-108318, 333-100638, 333-82450 and 333-64710) of Celsion Corporation of our report dated March 25, 2009, with respect to the financial statements of Celsion Corporation, included in the annual report (Form 10-K) for the year ended December 31, 2008.

/s/ Stegman & Company

Baltimore, Maryland  
March 25, 2009

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## QuickLinks

[Exhibit 23.1](#)

**CELSION CORPORATION**

**CERTIFICATION**

I, Michael H. Tardugno, certify that:

1. I have reviewed this Annual Report on Form 10-K of Celsion Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2009

/s/ MICHAEL H. TARDUGNO

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Michael H. Tardugno  
Chief Executive Officer  
Celsion Corporation

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## QuickLinks

[Exhibit 31.1](#)

**CELSION CORPORATION**

**CERTIFICATION**

I, Sean Moran, certify that:

1. I have reviewed this Annual Report on Form 10-K of Celsion Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal controls over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2009

/s/ SEAN MORAN

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Sean Moran  
Senior Vice President and Chief Financial Officer  
Celsion Corporation

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## QuickLinks

[Exhibit 31.2](#)

**CELSION CORPORATION  
CERTIFICATION  
PURSUANT TO 18 UNITED STATES CODE §1350  
AS ADOPTED PURSUANT TO  
§906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Celsion Corporation (the "Company") on Form 10-K for the period ended December 31, 2008, as filed with the Securities and Exchange Commission on or about March 27, 2009 (the "Report"), I, Michael H. Tardugno, Chief Executive Officer of the Company, certify, pursuant to 10 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 27, 2009

/s/ MICHAEL H. TARDUGNO

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Michael H. Tardugno  
Chief Executive Officer

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## QuickLinks

[Exhibit 32.1](#)



**CELSION CORPORATION  
CERTIFICATION  
PURSUANT TO 18 UNITED STATES CODE §1350  
AS ADOPTED PURSUANT TO  
§906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Celsion Corporation (the "Company") on Form 10-K for the period ended December 31, 2008, as filed with the Securities and Exchange Commission on or about March 27, 2009 (the "Report"), I, Sean Moran, Principal Accounting Officer of the Company, certify, pursuant to 10 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 27 , 2009

/s/ SEAN MORAN

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Sean Moran  
Senior Vice President and Chief Financial Officer

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## QuickLinks

[Exhibit 32.2](#)