

Celsion CORP
Form 10-K
March 15, 2012

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2011

OR

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

For the transition period from _____ to _____

Commission file number 001-15911

CELSION CORPORATION
(Exact Name of Registrant as Specified in Its Charter)

DELAWARE
(State or Other Jurisdiction of Incorporation or
Organization)

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

997 LENOX DRIVE, SUITE 100
LAWRENCEVILLE, NJ
(Address of Principal Executive Offices)

08648
(Zip Code)

(609) 896-9100

Registrant's Telephone Number, Including Area Code

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

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

Name of Each Exchange on Which Registered
NASDAQ CAPITAL MARKET

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

None

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

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

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

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes No

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

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

Large Accelerated Filer	<input type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-accelerated Filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller Reporting Company	<input type="checkbox"/>

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

As of June 30, 2011, the aggregate market value of the common stock held by non-affiliates of the Registrant was approximately \$39,649,964, based on the closing sale price for the Registrant's common stock on that date as reported by the NASDAQ Capital Market. For purposes of this calculation, shares of common stock held by directors and officers of the Registrant at June 30, 2011 were excluded.

As of March 14, 2012, 33,217,366 shares of the Registrant's common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement to be filed for its 2012 Annual Meeting of Stockholders are incorporated by reference into Part III hereof. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

CELSION CORPORATION
FORM 10-K
TABLE OF CONTENTS

PART I		
ITEM 1.	<u>BUSINESS</u>	1
	<u>FORWARD-LOOKING STATEMENTS</u>	1
	<u>OVERVIEW</u>	1
	<u>THERMODOX® (DOXORUBICIN ENCAPSULATED IN HEAT-ACTIVATED LIPOSOME)</u>	
	<u>Liver Cancer Overview</u>	4
	<u>Celsion's Approach</u>	4
	<u>Phase I Clinical Trial – Primary Liver Cancer</u>	5
	<u>Phase III Clinical Trial – Primary Liver Cancer (The HEAT Study)</u>	5
	<u>THERMODOX® FOR RECURRENT CHEST WALL BREAST CANCER</u>	
	<u>Recurrent Chest Wall Breast Cancer Overview</u>	6
	<u>Celsion's Approach</u>	6
	<u>Breast Cancer Clinical Phase I/II Trial</u>	6
	<u>THERMODOX® FOR COLORECTAL LIVER METASTASES</u>	7
	<u>Colorectal Liver Metastases Overview</u>	7
	<u>Celsion's Approach</u>	7
	<u>Phase II Clinical Trial – (The ABLATE Study)</u>	7
	<u>PRODUCT FEASIBILITY</u>	7
	<u>BUSINESS STRATEGY</u>	8
	<u>RESEARCH AND DEVELOPMENT EXPENDITURES</u>	9
	<u>FDA REGULATION</u>	9
	<u>Research and Development</u>	9
	<u>Post-Approval Requirements</u>	10
	<u>Inspections</u>	10
	<u>Recalls</u>	10
	<u>Other FDA Regulations</u>	10
	<u>PRODUCT LIABILITY AND INSURANCE</u>	11
	<u>COMPETITION</u>	11
	<u>LICENSES, PATENTS, TRADEMARKS AND REGULATORY EXCLUSIVITY</u>	
	<u>EMPLOYEES</u>	11
	<u>COMPANY INFORMATION</u>	12
	<u>AVAILABLE INFORMATION</u>	12
	<u>LIQUIDITY AND CAPITAL REASOURCES</u>	12
	<u>RECENT EVENTS</u>	13
	<u>EXECUTIVE OFFICERS OF THE REGISTRANT</u>	13
ITEM 1A.	<u>RISK FACTORS</u>	15
ITEM 1B.	<u>UNRESOLVED STAFF COMMENTS</u>	23
ITEM 2.	<u>PROPERTIES</u>	23
ITEM 3.	<u>LEGAL PROCEEDINGS</u>	23
ITEM 4.	<u>MINE SAFETY DISCLOSURES</u>	23

Table of Contents

CELSION CORPORATION
FORM 10-K
TABLE OF CONTENTS (continued)

PART II	
ITEM 5.	<u>MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u> 24
	<u>Market Price for Our Common Stock</u> 24
	<u>Dividend Policy</u> 24
	<u>Securities Authorized for Issuance Under Equity Compensation Plans</u> 24
	<u>Unregistered Shares of Equity Securities</u> 24
	<u>Issuer Purchases of Equity Securities</u> 24
ITEM 6.	<u>SELECTED FINANCIAL DATA</u> 24
ITEM 7.	<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u> 25
	<u>Overview</u> 25
	<u>Significant Events</u> 25
	<u>Critical Accounting Policies and Estimates</u> 26
	<u>Results Of Operations</u> 27
	<u>Comparison of Fiscal Year Ended December 31, 2011 And Fiscal Year Ended December 31, 2010</u> 27
	<u>Financial Condition, Liquidity and Capital Resources</u> 28
	<u>Contractual Obligations</u> 32
	<u>Off-Balance Sheet Arrangements and Contractual Obligations</u> 32
ITEM 7A.	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u> 32
ITEM 8.	<u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u> 32
ITEM 9.	<u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u> 32
ITEM 9A.	<u>CONTROLS AND PROCEDURES</u> 33
ITEM 9B.	<u>OTHER INFORMATION</u> 34
PART III	
ITEM 10.	<u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u> 35
ITEM 11.	<u>EXECUTIVE COMPENSATION</u> 35
ITEM 12.	<u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u> 35
	<u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u> 36
ITEM 13.	<u>AND DIRECTOR INDEPENDENCE</u> 36
ITEM 14.	<u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u> 36
PART IV	
ITEM 15.	<u>EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u> 37
1.	<u>FINANCIAL STATEMENTS</u> 37
2.	<u>FINANCIAL STATEMENT SCHEDULES</u> 37
3.	<u>EXHIBITS</u> 37

SIGNATURES

43

4

Table of Contents

PART I

ITEM 1. BUSINESS

FORWARD-LOOKING STATEMENTS

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

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

Trademarks

The Celsion brand and product names, including but not limited to Celsion®, contained in this document are trademarks, registered trademarks or service marks of Celsion Corporation in the United States (U.S.) and certain other countries. This document also contains references to trademarks and service marks of other companies that are the property of their respective owners.

OVERVIEW

Celsion Corporation is an innovative oncology drug development company focused on the development of treatments for those suffering with difficult to treat forms of cancer. We are working to develop and commercialize more

efficient, effective, targeted chemotherapeutic oncology drugs based on our proprietary heat-activated liposomal technology. The promise of this drug technology is to maximize efficacy while minimizing side-effects common to cancer treatments.

Our lead product ThermoDox® is being evaluated in a Phase III clinical trial for primary liver cancer (the HEAT study), a Phase II clinical trial for colorectal liver metastasis (CRLM) and a Phase II clinical trial 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 heat at mild hyperthermia temperatures (greater than 40 degrees Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in and around the targeted tumor.

Table of Contents

The U.S. Food and Drug Administration (FDA) has granted our pivotal Phase III HEAT study for ThermoDox®, in combination with radiofrequency ablation a Special Protocol Assessment and has designated it as a Fast Track Development Program. We have received written guidance from the FDA stating that, assuming the results of our ongoing studies are adequate, we may submit our New Drug Application (NDA) for ThermoDox® pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act. A 505(b)(2) NDA provides that some of the information from the reports required for marketing approval may come from studies that the applicant does not own or for which the applicant does not have a legal right of reference and permits a manufacturer to obtain marketing approval for a drug without needing to conduct or obtain a right of reference for all of the required studies. The availability of Section 505(b)(2) and the designation of ThermoDox® as a Fast Track Development Program may provide us with an expedited pathway to approval. There can be no assurance, however, that the results of our ongoing studies will be adequate to obtain approval of ThermoDox® under Section 505(b)(2). Drug research and development is an inherently uncertain process and there is a high risk of failure at every stage prior to approval and the timing and the outcome of clinical results is extremely difficult to predict. Clinical development successes and failures can have a disproportionate positive or negative impact on our scientific and medical prospects, financial prospects, financial condition, and market value.

In December 2011, the European Medicines Agency (EMA) provided written, scientific advice confirming that the HEAT Study is acceptable as a basis for submission of a marketing authorization application (MAA). Based on feedback and guidance received from the EMA, we expect that future results demonstrating a convincing magnitude of improvement in progression-free survival, the study's primary endpoint, along with a favorable benefit-risk ratio in the HEAT Study, would be sufficient as the primary basis for registration of ThermoDox® in Europe. The EMA also supported our manufacturing strategy and technology transfer protocols, which will allow us to establish multiple manufacturing sites to support commercialization of ThermoDox® outside the United States. In March of 2011, we announced that the European Commission granted orphan drug designation for ThermoDox® in primary liver cancer, which provides assistance and incentives, including 10 years of marketing exclusivity subsequent to product approval, in support of product candidates intended for the treatment of a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union. ThermoDox® also holds orphan drug designation in the U.S.

We have also demonstrated the feasibility for a product pipeline of cancer drugs that employ our heat activated liposomal technology in combination with known chemotherapeutics including docetaxel and carboplatin. We believe that our technology can improve efficacy and safety of anticancer agents whose mechanism of action and safety profile are well understood by the medical and regulatory communities. Our approach provides a comparatively cost effective, low risk approval pathway. An element of our business strategy is to pursue, as resources permit, the research and development of a range of product candidates for a variety of indications. This is intended to allow us to diversify the risks associated with our research and development expenditures. To the extent we are unable to maintain a broad range of product candidates, our dependence on the success of one or a few product candidates would increase. Additionally, we had formed a joint research agreement with Philips Healthcare, a division of Royal Philips Electronics to evaluate the combination of Philips' high intensity focused ultrasound (HIFU) with ThermoDox® to determine the potential of this combination to treat a broad range of cancers. For certain markets, we may seek licensing partners to share in the development and commercialization costs. We will also evaluate licensing cancer products from third parties for cancer treatments to expand our product pipeline.

In 2005, the Company made a strategic decision to divest its medical device business. The Company sold this medical device business to Boston Scientific Corporation (Boston Scientific) in 2007 for net aggregate payments of \$43 million, receiving \$13 million in 2007 and \$15 million in each of 2008 and 2009. Since this divestiture, we have dedicated our efforts and resources to the development and commercialization of innovative cancer drugs including tumor-targeting treatments using focused heat energy in combination with heat-activated drug delivery systems. To support our research and development, we have raised gross proceeds of approximately \$67.6 million in equity

financings in the years 2009 through 2011.

On December 5, 2008, we entered into a development, product supply and commercialization agreement with Yakult Honsha Co. (the Yakult Agreement) under which Yakult was granted the exclusive right to commercialize and market ThermoDox® for the Japanese market. We were paid a \$2.5 million up-front licensing fee and may receive additional payments from Yakult upon receipt of marketing approval by the Japanese Ministry of Health, Labor and Welfare as well as upon the achievement of certain levels of sales and approval for new indications. Under the Yakult Agreement, we will receive double digit escalating royalties on the sale of ThermoDox® in Japan, when and if any such sales occur and we also will be the exclusive supplier of ThermoDox® to Yakult. Concurrent with a convertible preferred stock equity financing in January 2011, we amended the Yakult Agreement to provide for up to \$4.0 million in an accelerated partial payment to us of a future drug approval milestone. The terms of the Yakult Agreement provided for the payment to us of \$2.0 million upon the closing of the preferred equity financing and an additional \$2.0 million conditioned upon the resumption of enrollment of Japanese patients in the Japan cohort of the HEAT Study. In consideration of these accelerated milestone payments from Yakult, we have agreed to reduce future drug approval milestone payments by approximately forty percent (40%). All other milestone payments are unaffected.

Table of Contents

On July 11, 2011, after reviewing data from 535 randomized patients enrolled in our pivotal Phase III HEAT study, the Data Monitoring Committee (DMC) for this trial unanimously recommended that the trial continue to enroll patients at all clinical sites except those in Japan with the goal of reaching enrollment of 600 patients, as required by the study protocol. The DMC maintained its recommendation to continue withholding enrollment of additional patients in Japan pending certain guidance from the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan. The recommendation followed a review of safety data from 18 Japanese patients enrolled in the study, when compared to patient data from the rest of the Phase III trial. As a part of its commitment to the PMDA, the DMC independently assesses patients randomized at Japanese sites. The DMC continues to review safety and efficacy data in accordance with the PMDA in Japan and the DMC's charter, however there can be no assurance that the DMC will permit resumption of patient enrollment in Japan or at all nor can there be any assurance that we will receive the second \$2 million payment from Yakult pursuant to the amended Yakult Agreement.

On August 3, 2011, we announced that we had reached our preplanned enrollment objective of 600 patients in the pivotal Phase III HEAT study. The target enrollment figure is designed to ensure that the study's primary end point, progression-free survival, can be achieved with adequate statistical power, and is one of two triggers for an interim efficacy analysis by the study's DMC. The second trigger was the occurrence of 190 progression-free survival (PFS) events in the study population. We met the second trigger of 190 PFS events in the third quarter of 2011 which allowed us to conduct a planned interim analysis in the fourth quarter of 2011. On November 28, 2011, we announced that the independent DMC for the HEAT Study completed a pre-planned interim analysis for safety, efficacy and futility and unanimously recommended that the study continue to its final analysis as planned. The DMC evaluated data from 613 patients in its review, which was conducted following realization of 219 PFS events within the study population. A total of 380 events of progression are required to reach the planned final analysis of the study which we reconfirmed was projected to occur in late 2012.

Consistent with our global regulatory strategy, we are continuing to enroll patients in the HEAT Study in order to randomize at least 200 patients in the People's Republic of China (PRC), a requirement for registrational filing in the PRC. The HEAT study has already enrolled a sufficient number to support registrational filings in South Korea and Taiwan, two important markets for ThermoDox®. Continued enrollment also has the potential to reduce the timeline of the final data read out, though we cannot guarantee such a result.

In December 2011, Celsion completed the consultative review process with the European Medicines Agency (EMA) for the HEAT Study and received written scientific advice from the EMA confirming that the Company's HEAT Study is acceptable as a basis for submission of a marketing authorization application. Other important feedback received from this review process were:

Future results demonstrating a convincing magnitude of improvement in PFS along with a favorable benefit-risk ratio would be sufficient as a primary basis for registration of ThermoDox® in Europe and
The EMA also supported the Company's manufacturing strategy and technology transfer protocols which will allow the Company to establish multiple manufacturing sites to support commercialization of ThermoDox® outside the United States

In January 2012, we announced the enrollment of our first patient in the randomized Phase II study of ThermoDox® in combination with radiofrequency ablation for the treatment of colorectal liver metastases (the ABLATE Study). The ABLATE Study is expected to enroll up to 88 patients with colorectal cancer metastasized to the liver. Patients will be randomized to receive either RFA plus ThermoDox® or RFA alone for the treatment of their liver tumors. The primary study endpoint is based on one year local tumor recurrence, with secondary endpoints of time to progression and overall survival.

Table of Contents

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

THERMODOX® (DOXORUBICIN ENCAPSULATED IN HEAT-ACTIVATED LIPOSOME)

Liposomes are manufactured submicroscopic vesicles consisting of a discrete aqueous central compartment surrounded by a membrane bilayer composed of naturally occurring lipids. 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. A team of research scientists at Duke University developed a heat-sensitive liposome which rapidly changes its structure when heated to a threshold minimum temperature of 40° to 42° Celsius. Heating creates channels in the liposome bilayer that allow an encapsulated drug to rapidly disperse into the surrounding tissue. 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.

We intend to use several available focused-heat technologies, such as radio frequency ablation (RFA), microwave energy and high intensity focused ultrasound (HIFU), to activate the release of drugs from our novel heat-sensitive liposomes.

Our heat-activated liposomes circulate within the tumor tissue and leaky tumor vessels vasculature. When heat is added locally, it causes the rapid release of the encapsulated chemotherapeutic agent directly within the targeted tumor. Our proprietary heat-activated liposome technology enables delivery of significantly higher concentrations of proven chemotherapy drugs directly to the tumor, stopping the progression of cancer and minimizing systemic toxicities. Currently in a Phase III clinical trial for primary liver cancer and in two Phase II studies for recurrent chest wall breast cancer and CRLM, Celsion has completed animal studies that demonstrate 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 approved liposomal formulations of doxorubicin on the market today.

Liver Cancer Overview

Primary liver cancer (hepatocellular carcinoma or “HCC”) is one of the most common and deadliest forms of cancer worldwide. It ranks as the fifth most common solid tumor cancer. It is estimated that up to 90% of liver cancer patients will die within five years of diagnosis. The incidence of primary liver cancer is approximately 28,000 cases per year in the United States, approximately 40,000 cases per year in Europe and is rapidly growing worldwide at approximately 750,000 cases per year. HCC has the fastest rate of growth of all cancers and is projected to be the most prevalent form of cancer by 2020. HCC is commonly diagnosed in patients with longstanding hepatic disease and cirrhosis (primarily due to hepatitis C in the U.S. and Europe and hepatitis B in Asia).

At an early stage, the standard first line treatment for liver cancer is surgical resection of the tumor, up to 80% of patients are ineligible for surgery or transplantation at time of diagnosis as early stage liver cancer generally has few

symptoms and when finally detected the tumor frequently is too large for surgery. There are few alternative treatments, since radiation therapy and chemotherapy are largely ineffective. For tumors generally up to 5 centimeters in diameter, RFA has emerged as the standard of care treatment 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 directly correlates 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.

Table of Contents

Celsion's Approach

While RFA uses extremely high temperatures (greater than 80° Celsius) to ablate the tumor, it may fail to treat micro-metastases in the outer margins of the ablation zone because temperatures in the periphery may not be high enough to destroy the cancer cells. Local recurrence can be a problem especially for tumors greater than 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 novel treatment approach is intended to deliver the drug directly to those cancer cells that survive RFA. This approach will also increase the delivery of the doxorubicin at the desired tumor site while potentially reducing drug exposure distant to the tumor site.

Phase I Clinical Trial - Primary Liver Cancer

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

In 2007 we initiated a second Phase I dose escalation study designed to investigate simplification of the current RFA/ThermoDox® treatment regimen including a single vial formulation of ThermoDox® designed for commercial distribution. The study also permitted multiple dosing in liver cancer patients. This clinical trial was completed in 2008.

Phase III Global Clinical Trial - Primary Liver Cancer (The HEAT Study)

For primary liver cancer, our HEAT study to evaluate ThermoDox® is a pivotal 600 patient double-blinded, placebo-controlled, global Phase III study conducted at 79 clinical sites under a Special Protocol Assessment (SPA) agreement with the FDA. The HEAT study is designed to evaluate the efficacy of ThermoDox® in combination with RFA when compared to patients who receive RFA alone as the control. The study is being conducted in 79 clinical sites in the United States, Canada, Italy, China, Taiwan, Hong Kong, Korea, Thailand, Malaysia and the Philippines, and we reached our preplanned enrollment objective of 600 patients in August 2011. The primary endpoint for the study is PFS with a secondary confirmatory endpoint of Overall Survival (OS). In the third quarter of 2011, we reached 190 PFS events in the study population, which allowed us to conduct the planned interim efficacy analysis. With agreement of the FDA, enrollment of the HEAT Study was increased to 700 in 2011. No other element of the SPA were affected by this change.

In August 2010, the FDA designated the HEAT study for ThermoDox®, in combination with RFA, as a Fast Track Development Program. The Fast Track Development Program provides for expedited regulatory review for new drugs that treat serious or life threatening diseases which are not satisfactorily treated by existing therapies, or for drugs that provide a significant advantage over existing therapies for serious diseases. Under the Fast Track designation, we are eligible to submit an NDA on a rolling basis. This permits the FDA to review sections of the NDA in advance of receiving the complete submission.

We have received written guidance from the FDA stating that, assuming the results of our ongoing studies are adequate, we may submit our NDA for ThermoDox® pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act. A 505(b)(2) NDA provides that some of the information from the reports required for marketing approval may come from studies that the applicant does not own or for which the applicant does not have a legal right of reference and permits a manufacturer to obtain marketing approval for a drug without needing to conduct or obtain

a right of reference for all of the required studies. The availability of Section 505(b)(2) and the designation of ThermoDox® as a Fast Track Development Program will provide us with an expedited pathway to approval. There can be no assurance, however, that the results of our ongoing studies will be adequate to obtain approval of ThermoDox® under Section 505(b)(2).

The DMC, comprised of an independent group of medical and scientific experts, reviews study data at regular intervals to ensure the safety of all patients enrolled in the trial, the quality of the data collected, and the continued scientific validity of the trial design. In November, 2011, the DMC completed a planned interim analysis for safety, efficacy and futility and unanimously recommended that the study continue to its final analysis as planned. The DMC evaluated data from 613 patients in its review, which was conducted following the realization of 219 progression-free survival (PFS) events within the study population. A total of 380 events of progression are required to reach the planned final analysis of the study.

Table of Contents

In 2009, the FDA granted orphan drug designation to ThermoDox® for the treatment of HCC. The Orphan Drug Act provides economic incentives to companies to develop drugs that demonstrate promise for the treatment of life-threatening or very serious conditions that are rare and affect less than 200,000 individuals in the U.S. Orphan drug designation entitles us to seven years of market exclusivity following FDA approval, if any, FDA assistance in clinical trial design, reduction in FDA user fees, U.S tax credits related to development expenses as well as the opportunity to apply for funding from the U.S. government to defray costs of clinical trial expenses. In 2011, the European Commission granted orphan drug designation for ThermoDox® for the treatment of HCC in Europe. As established by the European Medicine Agency (EMA), orphan drug designation provides for scientific advice and regulatory assistance from the EMA, direct access to centralized marketing authorization and certain financial incentives, such as reduction of fees associated with pre-authorization inspections and marketing authorization application fees. The orphan drug designation in Europe also provides 10 years of market exclusivity subsequent to product approval, if any.

In December 2011, the European Medicines Agency (EMA) provided written, scientific advice confirming that the HEAT Study, a multinational, double-blind, placebo controlled pivotal study of ThermoDox® in combination with radio frequency ablation (RFA) for the treatment of hepatocellular carcinoma (HCC), or primary liver cancer, is acceptable as a basis for submission of a marketing authorization application (MAA). Based on feedback and guidance received from the EMA, we expect that future results demonstrating a convincing magnitude of improvement in progression-free survival, the study's primary endpoint, along with a favorable benefit-risk ratio in the HEAT Study, would be sufficient as the primary basis for registration of ThermoDox® in Europe. The EMA also supported our manufacturing strategy and technology transfer protocols, which will allow us to establish multiple manufacturing sites to support commercialization of ThermoDox® outside the United States. In March of 2011, we announced that the European Commission granted orphan drug designation for ThermoDox® in primary liver cancer, which provides assistance and incentives, including 10 years of marketing exclusivity subsequent to product approval, in support of product candidates intended for the treatment of a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union. ThermoDox® also holds orphan drug designation in the U.S.

THERMODOX® FOR RECURRENT CHEST WALL BREAST CANCER

Recurrent Chest Wall (RCW) Breast Cancer Overview

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

Celsion's Approach

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

and activate ThermoDox® at the desired target site.

Microwave hyperthermia as a separate standalone 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 heating cancer cells with a microwave device for sixty minutes at 43°C has been found to be tumoricidal. We expect that the combination of microwave hyperthermia and ThermoDox® will be more efficacious than microwave hyperthermia alone or treatment with existing non-heat activated liposomal formulations.

Table of Contents

Breast Cancer Clinical Phase I/II Clinical Trial - The DIGNITY Study

In 2009, the Company commenced a pivotal open label, dose-escalating ThermoDox® Phase I/Phase II clinical trial for patients with RCW breast cancer – (the DIGNITY Study). The Dignity Study is designed to establish a safe therapeutic dose in Phase I, and in Phase II to demonstrate local control, including complete and partial responses, and stable disease as its primary endpoint. The Dignity Study is also planned to evaluate kinetics in ThermoDox® produced from more than one manufacturing site.

The Company completed enrollment of the Phase I portion of the study in 2010 and an independent Data Safety Monitoring Board declared 50mg/m² to be the phase II dose. The Phase II portion of the DIGNITY Study protocol has been reviewed by the FDA and is planned to commence in 2012 at four to five investigation sites.

Duke University has completed a Phase I dose escalating ThermoDox® study in patients with RCW breast cancer and has presented preliminary results from the 16 enrolled patients that characterize the safety of the drug in RCW patients and the feasibility of ThermoDox® administration in these patients. Furthermore, data presented by Duke suggested a beneficial clinical effect of ThermoDox®. Duke reported that the combination of ThermoDox with HEAT in all the patients showed evidence of clinical activity and two of the six patients who were treated with the 50mg/m² dosage had a complete local response.

THERMODOX® FOR COLORECTAL LIVER METASTASES

The American Cancer Society estimates that there were over 141,000 new cases of colorectal cancer and about 51,000 colorectal cancer deaths in 2010. Up to 25% of patients with colorectal cancer present with liver metastases and another 50% develop liver metastases within 5 years. Median survival of patients with colorectal liver metastases (CRLM) is 6-12 months if untreated. While hepatic resection is potentially curative, most CRLM patients are inoperable and therefore radiofrequency ablation (RFA) is a commonly used local treatment modality. Because RFA is both efficacious and widely accepted, a rational strategy is to attempt to increase its efficacy for medium (3.1-5.0 cm) and large (> 5.0 cm) CRLM tumors with an adjuvant such as ThermoDox®.

Celsion's Approach

The liver is a common site of metastases for cancers of the colon and rectum, as it provides a favorable environment for their growth and proliferation. Addressing these metastases allows us to improve three- and five-year survival rates among patients with this aggressive disease. While RFA can be effective in treating these tumors, it is often limited to smaller metastases within the liver. Adding ThermoDox® to RFA as adjuvant therapy is a combination which has demonstrated early clinical promise in treating larger tumors and multifocal disease.

Phase II Clinical Trial – The ABLATE Study

In 2011, we initiated a Phase II study of ThermoDox® in combination with RFA for the treatment of colorectal liver metastases. The ABLATE Study is expected to enroll up to 88 patients with colorectal cancer metastasized to the liver. Patients will be randomized to receive either RFA plus ThermoDox® or RFA alone for the treatment of their liver tumors. The primary study endpoint is based on one year local tumor recurrence, with secondary endpoints of time to progression and overall survival. On February 13, 2012, we announced that the first patient had been enrolled in the Phase II ABLATE study.

PRODUCT FEASIBILITY

We developed a stable heat activated liposomal formulation of docetaxel which we have 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. We continue to evaluate its formulation. In addition, the Company has developed a third stable heat activated liposomal formulation. This drug encapsulates carboplatin and in early studies has shown favorable release characteristics and formulation stability.

In September 2010, we announced the award of a competitive Phase I Small Business Innovation and Research (SBIR) grant from the National Institutes of Health (NIH), to support the proposal, "New Thermal Sensitive Carboplatin Liposomes for Cancer". This funding supports our efforts to develop a proprietary heat-activated liposomal technology in combination with carboplatin, an approved and frequently used oncology drug for treatment of a wide range of cancers. We received approximately \$153,000 from this grant in 2011 to support formulation development and preclinical efficacy studies in collaboration with Duke University.

Table of Contents

BUSINESS STRATEGY

Clinical outcomes in the treatment of primary liver cancer remain poor worldwide, with the 5-year survival rate at less than 10% and median survival from time of diagnosis at approximately 30 months. Cure, usually through surgery, is possible in fewer than 20% of patients. The World Health Organization estimates that primary liver cancer may become the number one cancer worldwide, surpassing lung cancer, by 2020.

With primary liver cancer representing a major global challenge, we have implemented a streamlined, global regulatory strategy aimed at addressing as many markets as possible, as rapidly as possible, with our HEAT study. We have focused in particular on the Asia Pacific region where the incidence of hepatitis B, a leading cause of liver cancer, is widespread. The HEAT Study has already reached sufficient local enrollment to support registration filings in two important markets in the Asia-Pacific region, South Korea and Taiwan. Enrollment in China is quickly approaching the minimum 200 patient requirement necessary to support local registrational filing in this important market, where over 50% of the incidences of primary liver cancer exist. In Japan, our partner Yakult, remains enthusiastic about ThermoDox® and has indicated its plans to continue evaluation of ThermoDox® separately from the HEAT study, due to the different standard of care in Japan.

In the United States, we have secured several designations which will support our clinical, regulatory and commercial strategies. In addition to the Special Protocol Assessment (SPA) with the FDA, we have received Fast Track designation from the FDA, providing for a rolling NDA submission, a 6 month regulatory review and a simplified review process. Additionally, FDA has provided support for a 505(b) 2 NDA submission. We have a comprehensive program to address the chemistry, manufacturing and controls portion of the application by working to complete three registration batches of ThermoDox®, the foundation for an uninterrupted, global commercial supply at launch. Adding to a successful commercial strategy, we have also secured Orphan Drug Designation for ThermoDox® in primary liver cancer in both Europe and the United States, providing for ten and seven years of market exclusivity, respectively, following approval. Together, these strategies are expected to provide for a more streamlined and straightforward review process as well as a successful product launch.

If the HEAT Study proves successful, it would add not only one of the most important new chemotherapeutic treatments to the oncologists' arsenal, but validate a novel, highly-versatile technology with the potential to affect many cancers. While the significant majority of our capital resources are focused on the HEAT study, we recognize that the unique properties of ThermoDox® support its potential well beyond this study's indication, and are taking steps to explore its utility in other areas. We continue to move forward with planning and execution of additional studies where ThermoDox® has demonstrated potential for significant benefit, including:

- Recurrent chest wall breast cancer, which is the subject of the Company's ongoing Phase II potentially registrational DIGNITY study,
- Metastatic liver cancers or cancers of various primary origin metastasized to the liver, through initiation of the ABLATE study, a randomized Phase II study, and
 - Bone cancers, the subject of a planned Phase II study with joint research partner Philips Healthcare.

Our clinical development team has taken great care to ensure that these studies are supportive of potential Compendia listing of ThermoDox® in their respective indications. Compendia listing in the US supports adoption from the medical community as well as reimbursement from private and public payors. We view this as a critical means of multiplying the clinical and commercial value of ThermoDox® as rapidly as possible following its validation in the HEAT Study. Furthermore, as ThermoDox® represents an attractive, late-stage asset, we continue to explore partnering opportunities which would complement and advance our global commercialization strategy.

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

Table of Contents

RESEARCH AND DEVELOPMENT EXPENDITURES

We are engaged in a limited amount of research and development in our own facilities and also sponsor research programs in partnership with various research institutions, including the National Cancer Institute and Duke University. The majority of the spending in research and development is for the funding of ThermoDox® clinical trials. Research and development expenses were approximately \$19.9 million and \$14.7 million for the years ended December 31, 2011 and 2010, respectively. See Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operation for additional information regarding expenditures related to our research and development programs.

FDA REGULATION

Research and Development

Our research and development activities, pre-clinical tests and clinical trials are subject to extensive regulation by the FDA as would the manufacturing, marketing and labeling of our products, if any. 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 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 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 (IRB), and with patient informed consent. An IRB will consider, among other things, ethical factors and the safety of human subjects and the possible liability of the institution conducting the clinical trials.

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

profile in Phase II evaluations, Phase III clinical trials are undertaken to serve as the pivotal trials to demonstrate clinical efficacy and safety in an expanded patient population. In 2008, we, in collaboration with the FDA, received a Special Protocol Assessment for our Phase III HEAT study, having proceeded to this phase directly from Phase I assessment.

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

Table of Contents

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

The FDA is authorized to require various user fees, including NDA fees (currently up to \$1.4 million). The FDA may waive or reduce such user fees under certain circumstances, such as orphan drug designation for a product candidate. We will seek waivers or reductions of user fees where possible, but we cannot be assured that we will be eligible for any such waiver or reduction.

Post-Approval Requirements

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

Inspections

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

Recalls

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

Other FDA Regulations

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

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

Table of Contents

PRODUCT LIABILITY AND INSURANCE

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

COMPETITION

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

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

ThermoDox®

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

LICENSES, PATENTS, TRADEMARKS AND REGULATORY EXCLUSIVITY

In 1999, the Company entered into a license agreement with Duke University under which we received exclusive rights (subject to certain exceptions) to commercialize and use Duke's thermo-liposome technology. In relation to these liposome patents licensed from Duke University, we have filed two additional patents related to the formulation and use of liposomes. We have also licensed from Valentis, CA certain global rights covering the use of pegylation for temperature sensitive liposomes.

In 2003, our obligations under the license agreement with Duke University with respect to the testing and regulatory milestones and other licensed technology performance deadlines were eliminated in exchange for a payment of shares of our 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, we have filed international applications for a certain number of the United States patents.

Our 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 have been granted. The European grant provides coverage in the European Community. For this technology, the Company's license rights are worldwide, including the United States, Canada, certain European countries, Australia, Hong Kong, and Japan.

Table of Contents

In 2009, the FDA granted orphan drug designation for ThermoDox®. Orphan drug designation entitles the Company to seven years of market exclusivity following FDA approval, if any, FDA assistance in clinical trial design, a reduction in FDA user fees, U.S. tax credits related to development expenses as well as the opportunity to apply for funding from the U.S. government to defray the costs of clinical trial expenses. In 2011, the European Commission granted orphan drug designation for ThermoDox® for the treatment of HCC in Europe. As established by the European Medicine Agency (“EMA”), orphan drug designation provides for scientific advice and regulatory assistance from the EMA, direct access to centralized marketing authorization and certain financial incentives, such as reduction of fees associated with pre-authorization inspections and marketing authorization application fees. The orphan drug designation in Europe also provides 10 years of market exclusivity subsequent to product approval.

In addition to the rights available to us under completed or pending license agreements, we rely on our proprietary know-how and experience in the development and use of heat for medical therapies, which we seek to protect, in part, through proprietary information agreements with employees, consultants and others. We cannot offer assurances that these information agreements will not be breached, that we 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. Please refer to Item 1A, Risk Factors, including, but not limited to, “We rely on trade secret protection and other unpatented proprietary rights for important proprietary technologies, and any loss of such rights could harm our business, results of operations and financial condition.” Similarly, we cannot guarantee that technology rights licensed to us by others will not be successfully challenged or circumvented by third parties, or that the rights granted will provide us with adequate protection. Please refer to Item 1A, Risk Factors, including, but not limited to, “Our business depends on licensing 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.”

EMPLOYEES

As of March 14, 2012, we employed 19 full-time employees. We also maintain active independent contractor relationships with various individuals, most of whom have month-to-month or annual consulting agreements. None of our employees are covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

COMPANY INFORMATION

Celsion was founded in 1982 and is a Delaware corporation. Our principal executive offices are located at 997 Lenox Drive, Suite 100, Lawrenceville, NJ 08648. Our telephone number is (609) 896-9100. The Company’s website is www.celsion.com. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated in, this Annual Report.

AVAILABLE INFORMATION

We make available free of charge through our website, www.celsion.com, its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission (the “SEC”). In addition, our website includes other items related to corporate governance matters, including, among other things, our corporate governance principles, charters of various committees of the Board of Directors, and our code of business conduct and ethics applicable to all employees, officers and directors. We intend to disclose on our internet website any amendments to or waivers from our code of business conduct and ethics as well as any amendments to its corporate governance principles or the charters of various committees of the Board of Directors. Copies of these documents may be obtained, free of charge, from our website. In addition, copies of these documents will be made available free of charge upon written request. The SEC also maintains an internet site that contains

reports, proxy and information statements and other information regarding issuers that file periodic and other reports electronically with the Securities and Exchange Commission. The address of that site is www.sec.gov. The information available on or through our website is not a part of this Annual Report on Form 10-K and should not be relied upon.

Table of Contents

LIQUIDITY AND CAPITAL RESOURCES

During 2011, we completed the following equity transactions:

- We raised gross proceeds of approximately \$5.1 million in a registered direct offering on January 18, 2011, in which we issued 5,000 shares of 8% redeemable convertible preferred stock (which were all converted into shares of common stock in connection with the Company's registered direct offering on July 25, 2011), and warrants to purchase up to 2,083,333 shares of common stock.
- We raised gross proceeds of approximately \$8.6 million in a private placement offering on June 2, 2011, in which we issued 3,218,612 shares of common stock and warrants to purchase up to 3,218,612 shares of common stock.
- We raised gross proceeds of approximately \$6.6 million in a registered direct offering on July 6, 2011, in which we issued 2,095,560 shares of common stock and warrants to purchase up to 628,668 shares of common stock.
- We raised gross proceeds of approximately \$13.0 million in a registered direct offering on July 25, 2011, in which we issued 3,047,682 shares of common stock and warrants to purchase up to 914,305 shares of common stock.
- We raised gross proceeds of approximately \$5.4 million in a private placement offering on July 25, 2011, in which we issued 1,281,031 shares of common stock and warrants to purchase up to 512,412 shares of common stock.
- We raised gross proceeds of approximately \$15.0 million in a private placement offering on December 6, 2011, in which we issued 6,486,488 shares of common stock and warrants to purchase up to 3,243,244 shares of common stock.
- We raised gross proceeds of approximately \$3.2 million by selling 1,340,514 shares of common stock under our committed equity financing facility with Small Cap Biotech Value Ltd. during 2011.

As a result of these equity transactions, the Company collectively raised \$58.0 million in gross proceeds by issuing approximately 19.7 million shares of our common stock and warrants to purchase approximately 10.6 million shares of our common stock. This includes approximately \$433,000 of gross proceeds received from the exercise of certain warrants issued by the Company to certain holders thereof into approximately 157,000 shares of common stock.

We believe that our cash and investment resources of \$30.5 million on hand at December 31, 2011 are sufficient to fund operations into the second half of 2013.

RECENT EVENTS

Director and Officer Equity Compensation Awards

In February 2012, the Company's board of directors approved the recommendations and ratified the determinations of its compensation committee and granted stock options to all of the Company's executive officers and directors. Collectively, directors and executive officers were granted options to purchase 135,000 and 77,000 options respectively to purchase our common stock, respectively.

EXECUTIVE OFFICERS OF THE REGISTRANT

The following table sets forth the names, ages and positions of our executive officers as of March 14, 2012:

Name	Age	Position
------	-----	----------

Edgar Filing: Celsion CORP - Form 10-K

Michael H. Tardugno	61	Director, President and Chief Executive Officer
Nicholas Borys, M.D.	53	Vice President and Chief Medical Officer
Gregory Weaver	55	Senior Vice President and Chief Financial Officer
Jeffrey W. Church	55	Senior Vice President, , Corporate Strategy and Investor Relations
Robert A. Reed, Ph.D.	51	Vice President, Executive Director, CMC and Technical Operations
Timothy J. Tumminello	54	Controller and Chief Accounting Officer

Table of Contents

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

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

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

Mr. Gregory Weaver. Mr. Weaver joined the Celsion management team as Senior Vice President and Chief Financial Officer effective July 8, 2011. Mr. Weaver had been a director of the Company since June 2005. Mr. Weaver served as Poniard Pharmaceuticals' Chief Financial Officer and Senior Vice President from August 2009 to August 2010. Prior to joining Poniard, a public oncology drug development company, Mr. Weaver served as Chief Financial Officer of Talyst, Inc., a privately-held pharmacy information product company, from 2007 to 2008. Prior to that, he served as Senior Vice President and Chief Financial Officer of Sirna Therapeutics, a public RNAI therapeutics company until the sale of the company to Merck, Inc. in 2006. From 2002 to 2005, Mr. Weaver was Chief Financial Officer of Nastech Pharmaceuticals, a public drug delivery company. From 1999 to 2002, Mr. Weaver was Chief Financial Officer of Ilex Oncology Inc., a public cancer drug development company, and from 1996 to 1998, he was Chief Financial Officer of Prism Technologies, a privately-held medical device manufacturer. In addition, Mr. Weaver held increasingly senior positions with Fidelity Capital in Boston and Arthur Andersen LLP. Mr. Weaver has also served as a Director and Chairman of the Audit Committee of SCOLR Pharmaceuticals, a public drug delivery company from 2007 to 2009. Mr. Weaver is a certified public accountant and received his MBA from Boston College and his B.S. in accounting from Trinity University.

Mr. Jeffrey W. Church. Mr. Church was appointed by the board of directors of the Company as Senior Vice President, Corporate Strategy and Investor Relations effective July 8, 2011. Mr. Church joined Celsion on July 6, 2010 as Vice President and Chief Financial Officer until he was appointed as Senior Vice President, Corporate Strategy and Investor Relations in July 2011. Immediately prior to joining Celsion, Mr. Church served as Chief Financial Officer and Corporate Secretary of Alba Therapeutics Corporation, a privately held life science company from 2007 until 2010. From 2006 until 2007, he served as Vice President, CFO and Corporate Secretary for Novavax, Inc., a publicly traded vaccine development company. From 1998 until 2006, he served as Vice President, CFO and Corporate Secretary for GenVec, Inc., a publicly traded life science and biotechnology company. Prior to that, he held senior financial positions at BioSpherics Corporation and Meridian Medical Technologies, both publicly traded companies. He started his career in the Baltimore office of Price Waterhouse from 1979 until 1986. Mr. Church holds a B.S. degree in accounting from the University of Maryland and is a certified public accountant.

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

Table of Contents

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

ITEM 1A. RISK FACTORS

The following is a summary of the risk factors, uncertainties and assumptions 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 and our forward-looking statements. 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. Moreover, we operate in a competitive and rapidly changing environment. New factors emerge from time to time and it is not possible to predict the impact of all of these factors on our business, financial condition or results of operations. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events, or otherwise. You are advised, however, to consult any further disclosure we make on related subjects in our reports on forms 10-Q and 8-K filed with the SEC.

RISKS RELATING TO OUR BUSINESS

We have a history of significant losses from continuing operations and expect to continue such losses for the foreseeable future.

Since Celsion's inception, our expenses have substantially exceeded our revenues, resulting in continuing losses and an accumulated deficit of \$124 million at December 31, 2011. For the year ended December 31, 2011, we incurred a net loss of \$23.2 million. Because we presently have no product revenues and we are committed to continuing our product research, development and commercialization programs, we will continue to experience significant operating losses unless and until we complete the development of ThermoDox® and other new products and these products have been clinically tested, approved by the FDA and successfully marketed.

Drug development is an inherent uncertain process with a high risk of failure at every stage of development.

We have a number of drug candidates in research and development ranging from the early discovery research phase through preclinical testing and clinical trials. Preclinical testing and clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development. It will take us several years to complete clinical studies. The start or end of a clinical study is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator drug or required prior therapy, clinical outcomes or our own financial constraints. The failure of one or more of our drug candidates could have a material adverse effect on our business, financial condition and results of operations.

If we do not obtain or maintain FDA and international regulatory approvals for our drug candidates on a timely basis, or at all, or if the terms of any approval impose significant restrictions or limitations on use, we will be unable to sell those products and our business, results of operations and financial condition will be negatively affected.

To obtain regulatory approvals from the FDA and international regulatory agencies, we must conduct clinical trials demonstrating that our products are safe and effective. We may need to amend ongoing trials or the FDA and/or international regulatory agencies may require us to perform additional trials beyond those we planned. This process generally takes a number of years and requires the expenditure of substantial resources. The time required for completing testing and obtaining approvals is uncertain, and the FDA and foreign regulatory agencies have substantial discretion, at any phase of development, to terminate clinical studies, require additional clinical development or other testing, delay or withhold registration and marketing approval and mandate product withdrawals, including recalls. In addition, undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities. Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

Table of Contents

We do not expect to generate significant revenue for the foreseeable future.

We have devoted our resources to developing a new generation of products and 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 currently only have one collaboration partner, Yakult, under a development, product supply and commercialization agreement, as amended, under which we may receive royalties on the sale of ThermoDox® in Japan, when and if any such sales occur. We cannot guarantee that any 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.

We will need to raise substantial additional capital to fund our planned future operations, and we may be unable to secure such capital without dilutive financing transactions. If we are not able to raise additional capital, we may not be able to complete the development, testing and commercialization of our product candidates.

As of December 31, 2011, we had approximately \$30.5 million in cash, cash equivalents and short-term investments. To complete the development and commercialization of our product, we will need to raise substantial amounts of additional capital to fund our operations. We do not have any committed sources of financing and cannot assure you that alternate funding will be available in a timely manner, on acceptable terms or at all. We may need to pursue dilutive equity financings, such as the issuance of shares of common stock, convertible debt or other convertible or exercisable securities. Such dilutive equity financings would dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock. In addition, a financing could result in the issuance of new securities that may have rights, preferences or privileges senior to those of our existing stockholders.

If we cannot raise additional capital, we may be required to delay, reduce or eliminate certain aspects of our operations or attempt to obtain funds through unfavorable arrangements with partners or others that may force us to relinquish rights to certain of our technologies, products or potential markets or that could impose onerous financial or other terms. Furthermore, if we cannot fund our ongoing development and other operating requirements, particularly those associated with our obligations to conduct clinical trials under our licensing agreements, we will be in breach of these licensing agreements and could therefore lose our license rights, which could have material adverse effects on our business.

We have no internal sales or marketing capability. If we are unable to create sales, marketing and distribution capabilities or enter into alliances with others possessing such capabilities to perform these functions, we will not be able to commercialize our products successfully.

We currently have no sales, marketing or distribution capabilities. 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. If we decide to market our products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market our products, we will need to establish and maintain partnership arrangements, and there can be no assurance that we will be able to enter into third-party marketing or distribution arrangements on acceptable 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 and there can be no assurance that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for our products and services.

Table of Contents

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 a 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 breach these or other provisions of the license and research agreements, we will 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 may be required to alter any of our potential products or processes, or enter into a license and pay licensing fees to a third party or cease certain activities. There can be no assurance that we can obtain a license to any technology that we determine we need on reasonable terms, if at all, or that we could develop or otherwise obtain alternate technology. If a license is not available on commercially reasonable terms or at all, our business, results of operations, and financial condition could be significantly harmed and we may be prevented from developing and commercializing the product. 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 rely on trade secret protection and other unpatented proprietary rights for important proprietary technologies, and any loss of such rights could harm our business, results of operations and financial condition.

We 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 assure you that these agreements are adequate to protect our trade secrets and confidential information or will not be breached or, if breached, we will have adequate remedies. Furthermore, others may independently develop substantially equivalent confidential and proprietary information or otherwise gain access to our trade secrets or disclose such technology.

Our products may infringe patent rights of others, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages or limit our ability to commercialize our products.

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

and require revalidation, which could delay our ability to commercialize our products. Any infringement action asserted against us, even if we are ultimately successful in defending against such action, would likely delay the regulatory approval process of our products, harm our competitive position, be expensive and require the time and attention of our key management and technical personnel.

Table of Contents

We rely on third parties to conduct all of our clinical trials. If these third parties are unable to carry out their contractual duties in a manner that is consistent with our expectations, comply with budgets and other financial obligations or meet expected deadlines, we may not receive certain development milestone payments or be able to obtain regulatory approval for or commercialize our product candidates in a timely or cost-effective manner.

We rely, and expect to continue to rely, on third-party clinical research organizations to conduct our clinical trials. Because we do not conduct our own clinical trials, we must rely on the efforts of others and cannot always control or predict accurately the timing of such trials, the costs associated with such trials or the procedures that are followed for such trials. We do not expect to significantly increase our personnel in the foreseeable future and may continue to rely on third parties to conduct all of our future clinical trials. If these third parties are unable to carry out their contractual duties or obligations in a manner that is consistent with our expectations or meet expected deadlines, if they do not carry out the trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become significantly expensive, we may not receive development milestone payments when expected or at all, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Our business is subject to numerous and evolving state, federal and foreign regulations and we may not be able to secure the government approvals needed to develop and market our products.

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

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

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

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

deemed deficient in any significant way, it could have a material adverse effect on the Company.

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

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

Table of Contents

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 healthcare industry could adversely affect our business.

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations. There have been a number of government and private sector initiatives during the last few years to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements. It is uncertain whether or when any legislative proposals will be adopted or what actions federal, state, or private payers for health care treatment and services may take in response to any healthcare reform proposals or legislation. We cannot predict the effect healthcare reforms may have on our business and we can offer no assurances that any of these reforms will not have a material adverse effect on our business. These actual and potential changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. In addition, uncertainty remains regarding proposed significant reforms to the U.S. healthcare system.

The success of our products may be harmed if the government, private health insurers and other third-party payors do not provide sufficient coverage or reimbursement.

Our ability to commercialize our new cancer treatment systems successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payers. 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 payers are increasingly attempting to contain healthcare 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 payers for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for health care providers.

Our products may not achieve sufficient acceptance by the medical community to sustain our business.

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

The commercial potential of a drug candidate in development is difficult to predict. If the market size for a new drug is significantly smaller than we anticipate, it could significantly and negatively impact our revenue, results of

operations and financial condition.

It is very difficult to estimate the commercial potential of product candidates due to important factors such as safety and efficacy compared to other available treatments, including potential generic drug alternatives with similar efficacy profiles, changing standards of care, third party payer reimbursement standards, patient and physician preferences, the availability of competitive alternatives that may emerge either during the long drug development process or after commercial introduction, and the availability of generic versions of our successful product candidates following approval by government health authorities based on the expiration of regulatory exclusivity or our inability to prevent generic versions from coming to market by asserting our patents. If due to one or more of these risks the market potential for a drug candidate is lower than we anticipated, it could significantly and negatively impact the revenue potential for such drug candidate and would adversely affect our business, financial condition and results of operations.

Table of Contents

Technologies for the treatment of cancer are subject to rapid change, and the development of treatment strategies that are more effective than our technologies could render our technologies obsolete.

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

We may not be able to hire or retain key officers or employees that we need to implement our business strategy and develop our products and business.

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

Our success will depend in part on our ability to grow and diversify, which in turn will require that we manage and control our growth effectively.

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

We face intense competition and the failure to compete effectively could adversely affect our ability to develop and market our products.

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

We may be subject to significant product liability claims and litigation.

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human therapeutic products. We presently have product liability insurance limited to \$10 million per incident and \$10 million annually. If we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim with our own limited resources, which could have a severe adverse effect on our business. Whether or not we are ultimately successful in any product liability litigation, such litigation would harm the business by diverting the attention and resources of our management, consuming substantial amounts of our financial resources and by damaging our reputation. Additionally, we may not be able to maintain our product liability insurance at an acceptable cost, if at all.

Table of Contents

RISKS RELATED TO OUR COMMON STOCK

The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors and subject us to securities class action litigation.

The trading price for our common stock has been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospect. Our common stock had a high price of \$4.23 and a low price of \$1.69 in the 52-week period ended December 31, 2011. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this “Risk Factors” section and other factors, including:

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

variance in our financial performance from the expectations of investors;

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

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

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

conditions and trends in the markets we serve;

changes in general economic, industry and market conditions;

success of competitive products and services;

changes in market valuations or earnings of our competitors;

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

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

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

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

recruitment or departure of key personnel;

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

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

the trading volume of our common stock.

Table of Contents

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

We may be unable to maintain compliance with NASDAQ Marketplace Rules which could cause our common stock to be delisted from The NASDAQ Capital Market. This could result in the lack of a market for our common stock, cause a decrease in the value of an investment in us, and adversely affect our business, financial condition and results of operations.

On April 6, 2011, we received notice from The NASDAQ Listing Qualifications Department that we were not in compliance with the minimum Market Value of Listed Securities (MVLS) requirement for continued listing on The NASDAQ Capital Market, as set forth in NASDAQ Listing Rule 5550(b)(2) (the Rule), which requires a listed company to maintain a minimum MVLS of \$35 million. On May 10, 2011, we received a letter from NASDAQ stating that our MVLS had been \$35 million or greater for the previous ten consecutive business days (from April 26, 2011 to May 9, 2011) and that we had regained compliance with the Rule.

We cannot guarantee that our MVLS will remain at or above \$35 million and if our MVLS again drops below \$35 million, the stock could become subject to delisting again. If our common stock is delisted, trading of the stock will most likely take place on an over-the-counter market established for unlisted securities, such as the Pink Sheets or the OTC Bulletin Board. An investor is likely to find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors may not buy or sell our common stock due to difficulty in accessing over-the-counter markets, or due to policies preventing them from trading in securities not listed on a national exchange or other reasons. In addition, as a delisted security, our common stock would be subject to SEC rules regarding "penny stock," which impose additional disclosure requirements on broker-dealers. The regulations relating to penny stocks, coupled with the typically higher cost per trade to investors in penny stocks due to factors such as broker commissions generally representing a higher percentage of the price of a penny stock than of a higher priced stock, would further limit the ability and willingness of investors to trade in our common stock. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified executives and employees and to raise capital.

The adverse capital and credit market conditions could affect our liquidity.

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

Our stock historically has been thinly traded. Therefore, stockholders may not be able to sell their shares freely.

While our common stock is listed on The NASDAQ Capital Market, the volume of trading historically has been relatively light. There can be no assurance that our historically light trading volume, or any trading volume

whatsoever, will be sustained in the future. Therefore, there can be no assurance that our stockholders will be able to sell their shares of our common stock at the time or at the price that they desire, or at all.

Table of Contents

We have not paid dividends on our common stock in the past and do not intend to do so for the foreseeable future.

We have never paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future for holders of our common stock

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 our board of directors on such terms as it determines, without further stockholder approval. Therefore, our board of directors may issue such preferred stock on terms unfavorable to a potential bidder in the event that our board of directors opposes a merger or acquisition. In addition, our classified board of directors may discourage such transactions by increasing the amount of time necessary to obtain majority representation on our board of directors. We also have implemented a stockholder rights plan and distributed to our stockholders one right per share of our common stock. When these rights become exercisable, each right entitles their holders to purchase one ten-thousandth (1/10,000) of a share of our Series C Junior Participating Preferred Stock at a price of \$66.90 per one ten-thousandth (1/10,000) share. If any person or group acquires more than 15% of our common stock, the holders of rights (other than the person or group crossing the 15% threshold) will be able to receive, upon the exercise of their rights and in lieu of the Series C Junior Participating Preferred Stock, the number of shares of our common stock (or the number of shares of stock of any company into which we are merged) having a value equal to twice the exercise price of their rights in exchange for the \$66.90 exercise price. Because these rights may substantially dilute stock ownership by a person or group seeking to take us over without the approval of our board of directors, 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 of directors regarding such a transaction. Certain other provisions of our Bylaws and of Delaware law may also discourage, delay or prevent a third party from acquiring or merging with us, even if such action were beneficial to some, or even a majority, of our stockholders.

ITEM 1B.UNRESOLVED STAFF COMMENTS

None.

ITEM 2.PROPERTIES

On July 21, 2011, the Company executed a lease with Brandywine Operating Partnership, L.P. (Brandywine), a Delaware limited partnership for a 10,870 square foot premises located in Lawrenceville, New Jersey. On October 3, 2011, the Company relocated its offices to Lawrenceville, New Jersey from Columbia, Maryland. The lease has a term of 66 months and provides for 6 months rent free, with the first monthly rent payment of approximately \$23,000 due in April 2012. Also, as required by the lease, the Company provided Brandywine with an irrevocable and unconditional standby letter of credit for \$250,000, which the Company secured with an escrow deposit at its banking institution of this same amount. The standby letter of credit will be reduced by \$50,000 on each of the 19th, 31st and 43rd months from the initial term, with the remaining \$100,000 amount remaining until the Lease Term has expired.

We believe our existing facility is suitable and adequate to conduct our business.

ITEM 3.LEGAL PROCEEDINGS

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

ITEM 4.MINE SAFETY DISCLOSURES

Not Applicable.

23

Table of Contents

PART II

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

Market Price for Our Common Stock

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

	High	Low
YEAR ENDED DECEMBER 31, 2010		
First Quarter (January 1 – March 31, 2010)	\$ 4.69	\$ 2.76
Second Quarter (April 1 – June 30, 2010)	\$ 5.44	\$ 3.13
Third Quarter (July 1 – September 30, 2010)	\$ 3.42	\$ 2.97
Fourth Quarter (October 1 – December 31, 2010)	\$ 3.63	\$ 2.01
YEAR ENDED DECEMBER 31, 2011		
First Quarter (January 1 – March 31, 2011)	\$ 2.97	\$ 2.18
Second Quarter (April 1 – June 30, 2011)	\$ 3.37	\$ 2.16
Third Quarter (July 1 – September 30, 2011)	\$ 4.23	\$ 2.50
Fourth Quarter (October 1 – December 31, 2011)	\$ 3.67	\$ 1.69

On March 14, 2012, the last reported sale price for our Common Stock on the NASDAQ Capital Market was \$1.70. As of March 14, 2012, there were approximately 11,000 stockholders of record of our Common Stock.

Dividend Policy

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

Securities Authorized For Issuance Under Equity Compensation Plans

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

Unregistered Shares Of Equity Securities

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

Issuer Purchases Of Equity Securities

None.

ITEM 6.SELECTED FINANCIAL DATA

Not required.

Table of Contents

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

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

Overview

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

Our lead product ThermoDox® is being evaluated in a Phase III clinical trial, which we refer to as the HEAT study, for primary liver cancer and two Phase II studies for recurrent chest wall breast cancer and CRLM. ThermoDox® is a liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. Localized mild hyperthermia (greater than 40 degrees Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

Significant Events

In August 2011, we announced that we had reached our preplanned enrollment objective of 600 patients in the pivotal Phase III HEAT study. The target enrollment figure is designed to ensure that the study's primary end point, progression-free survival, can be achieved with adequate statistical power, and is one of two triggers for an interim efficacy analysis by the study's DMC. The second trigger was the occurrence of 190 progression-free survival (PFS) events in the study population. We met the second trigger of 190 PFS events in the third quarter of 2011, which allowed us to conduct the planned interim analysis in the fourth quarter of 2011.

Consistent with our global regulatory strategy, we are continuing to enroll patients in the HEAT study in order to randomize at least 200 patients in the Peoples Republic of China (PRC), a requirement for registrational filing in the PRC. The HEAT study has enrolled a sufficient number to support registrational filings in South Korea and Taiwan, two important markets for ThermoDox®. Continued enrollment will not affect the timing of the planned interim analysis, and has the potential to reduce the timeline of the final data read out, though we can not guarantee such a result.

In November 2011, we announced that the independent Data Monitoring Committee (DMC) for our Phase III HEAT Study, had completed a planned interim analysis for safety, efficacy and futility and unanimously recommended that the study continue to its final analysis as planned. The DMC evaluated data from 613 patients in its review, which was conducted following the realization of 219 progression-free survival (PFS) events within the study population. A total

of 380 events of progression are required to reach the planned final analysis of the study.

Consistent with our global regulatory strategy, we are continuing to enroll patients in the HEAT study in order to randomize at least 200 patients in the Peoples Republic of China (PRC), a requirement for registrational filing in the PRC. The HEAT study has enrolled a sufficient number to support registrational filings in South Korea and Taiwan, two important markets for ThermoDox®. Continued enrollment will not affect the timing of the planned interim analysis, and has the potential to reduce the timeline of the final data read out, though we can not guarantee such a result.

Table of Contents

During 2011, we completed the following equity transactions:

- We raised gross proceeds of approximately \$5.1 million in a registered direct offering on January 18, 2011, in which we issued 5,000 shares of 8% redeemable convertible preferred stock (which were all converted into shares of common stock in connection with the Company's registered direct offering on July 25, 2011), and warrants to purchase up to 2,083,333 shares of common stock.
- We raised gross proceeds of approximately \$8.6 million in a private placement offering on June 2, 2011, in which we issued 3,218,612 shares of common stock and warrants to purchase up to 3,218,612 shares of common stock.
- We raised gross proceeds of approximately \$6.6 million in a registered direct offering on July 6, 2011, in which we issued 2,095,560 shares of common stock and warrants to purchase up to 628,668 shares of common stock.
- We raised gross proceeds of approximately \$13.0 million in a registered direct offering on July 25, 2011, in which we issued 3,047,682 shares of common stock and warrants to purchase up to 914,305 shares of common stock.
- We raised gross proceeds of approximately \$5.4 million in a private placement offering on July 25, 2011, in which we issued 1,281,031 shares of common stock and warrants to purchase up to 512,412 shares of common stock.
- We raised gross proceeds of approximately \$15.0 million in a private placement offering on December 6, 2011, in which we issued 6,486,488 shares of common stock and warrants to purchase up to 3,243,244 shares of common stock.
- We raised gross proceeds of approximately \$3.2 million by selling 1,340,514 shares of common stock under our committed equity financing facility with Small Cap Biotech Value Ltd. during 2011.

As a result of these equity transactions, the Company collectively raised \$58.0 million in gross proceeds by issuing approximately 19.7 million shares of our common stock and warrants to purchase approximately 10.6 million shares of our common stock. This includes approximately \$433,000 of gross proceeds received from the exercise of certain warrants issued by the Company to certain holders thereof into approximately 157,000 shares of common stock.

We believe that our cash and investment resources of \$30.5 million on hand at December 31, 2011 are sufficient to fund operations into the second half of 2013.

Critical Accounting Policies and Estimates

Our financial statements, which appear at Item 7 to this Annual Report on Form 10-K, have been prepared in accordance with accounting principles generally accepted in the United States, which require that we 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

We follow the provisions of ASC topic 718 "Compensation" which requires the expense recognition over a service period for the fair value of share based compensation awards, such as stock options, restricted stock and performance based shares. This standard allows us to establish modeling assumptions as to expected stock price volatility, option terms, forfeiture and dividend rates, which directly impact estimated fair value as determined. Our practice is to

utilize reasonable and supportable assumptions which are reviewed with the board and its appropriate committee.

Table of Contents

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

Results of Operations

Comparison of Fiscal Year Ended December 31, 2011 and Fiscal Year Ended December 31, 2010.

Licensing Revenue

In the first quarter of 2011, we recognized \$2 million in licensing revenue after amending our development, product supply and commercialization agreement for ThermoDox® with Yakult Honsha Co. to provide for accelerated payments of up to \$4 million in future milestone payments, including \$2 million that was paid to us on January 12, 2011, in exchange for a reduction in product approval milestones that we may receive in the future under the Yakult Agreement. We had no licensing revenue for the year ended December 31, 2010.

Research and Development Expenses

Research and Development (R&D) expenses increased to \$19.9 million in 2011 compared to \$14.7 million in 2010. Costs associated with our Phase III HEAT study increased to \$12.1 million in 2011 compared to \$8.2 million in 2010. This increase is primarily the result of costs for investigator grants, monitoring costs and milestone payments associated with higher patient enrollment levels for the Phase III HEAT study. Costs associated with our recurrent chest wall breast cancer clinical trial (RCW) decreased to \$0.4 million in 2011 compared to \$0.6 million in 2010. We completed the Phase I portion of this trial in the first half of 2011. In 2011, we initiated a Phase II study of ThermoDox® in combination with radiofrequency ablation (RFA) for the treatment of colorectal liver metastases (CRLM). Costs associated with the Company's CRLM trial were \$0.3 million in 2011. Costs associated with the production of ThermoDox® trials increased to \$4.3 million in 2011 compared to \$2.9 million in the same period of 2010 primarily due to ongoing progress towards developing our commercial manufacturing capabilities for ThermoDox®. Other preclinical, regulatory, personnel and other costs remained relatively unchanged at \$2.8 million in 2011 from 2010.

General and Administrative Expenses

General and administrative expenses increased slightly to \$5.2 million in 2011 compared to \$4.9 million in 2010. We continue to carefully monitor operating costs and focus our efforts and financial resources on completing enrollment and patient follow-up in the Phase III HEAT study.

Other income (expense)

Other income for 2011 was not significant compared to \$0.2 million in 2010. In November 2010, we were awarded a \$244,000 grant under the Qualifying Therapeutic Discovery Project (QTDP) program under The Patient Protection and Affordable Care Act of 2010 (PPACA). This maximum grant amount for a single program was awarded to us for the ThermoDox® clinical development program, which is currently conducting clinical trials for primary liver cancer

and recurrent chest wall breast cancer.

Change in common stock warrant liability

A common stock warrant liability was incurred as a result of warrants issued in a public offering in September 2009. This liability is calculated at its fair market value using the Black-Scholes option-pricing model and is adjusted at the end of each quarter. During 2011 and 2010, we recorded a non-cash benefit of \$0.1 million and \$0.6 million respectively based on the change in this fair value during the respective years.

Table of Contents

Interest income and expense

Interest income was \$0.2 million in 2011 as a result of the financing activities we completed during 2011. In connection with the shares of preferred stock we issued in our January 2011 preferred stock offering, we incurred dividend charges of approximately \$0.5 million in 2011. In connection with our July 2011 financings, all outstanding shares of preferred stock mandatorily converted into common stock in August 2011. See the section titled “Financial Condition, Liquidity and Capital Resources” below for additional information regarding the July 2011 financings and the conversion of preferred stock.

Interest income and interest expense were not significant in 2010.

Financial Condition, Liquidity and Capital Resources

Since our inception, we have incurred significant losses and negative cash flows from operations. We have financed our operations primarily through the net aggregate proceeds of \$43 million we received from the divestiture of our medical device business to Boston Scientific in 2007 (paid to us in installments of \$13 million in 2007 and \$15 million in each of 2008 and 2009), amounts received under our product licensing agreement with Yakult and a series of equity financings. The process of developing and commercializing ThermoDox® requires significant research and development work and clinical trial studies, as well as significant manufacturing and process development efforts. We expect these activities, together with our general and administrative expenses to result in significant operating losses for the foreseeable future. Our expenses have significantly and regularly exceeded our revenues, and we had an accumulated deficit of \$124 million at December 31, 2011.

At December 31, 2011 we had total current assets of \$31.5 million (including cash, cash equivalents and short term investments of \$30.5 million) and current liabilities of \$6.2 million, resulting in a net working capital of \$25.3 million. At December 31, 2010, we had total current assets of \$2.0 million (including cash, cash equivalents and short term investments of \$1.5 million) and current liabilities of \$6.8 million, resulting in a working capital deficit of \$4.8 million. The equity financing transactions in 2011 raised approximately \$58 million in gross proceeds, significantly strengthening our financial condition.

We believe that our cash and investment resources of \$30.5 million on hand at December 31, 2011 are sufficient to fund operations into the second half of 2013.

Net cash used in operating activities for the 2011 was \$22.8 million. Our 2011 net loss included \$1.3 million in non-cash stock-based compensation expense.

We will require additional capital to develop our product candidates through clinical development, manufacturing, and commercialization. We may seek additional capital through further public or private equity offerings, debt financing, additional strategic alliance and licensing arrangements, collaborative arrangements or some combination of these alternatives. If we raise additional funds through the issuance of equity securities, stockholders will likely experience dilution and the equity securities may have rights, preferences, or privileges senior to those of the holders of our common stock. If we raise funds through the issuance of debt securities, those securities would have rights, preferences, and privileges senior to those of our common stock. If we seek strategic alliances, licenses, or other alternative arrangements, such as arrangements with collaborative partners or others, we may need to relinquish rights to certain of our existing or future technologies, product candidates, or products which we would otherwise seek to develop or commercialize on our own, or to license the rights to our technologies, product candidates, or products on terms that are not favorable to us. The overall status of the economic climate could also result in the terms of any equity offering, debt financing, or alliance, license, or other arrangement being even less favorable to us and our stockholders than if the overall economic climate were stronger. In addition, we may continue to seek government sponsored research collaborations and grants.

If adequate funds are not available through either the capital markets, strategic alliances, or collaborators, we may be required to delay, reduce the scope of or eliminate our research, development or clinical programs or our manufacturing or commercialization efforts, effect additional changes to our facilities or personnel or obtain funds through other arrangements that may require us to relinquish some of our assets or rights to certain of our existing or future technologies, product candidates or products on terms not favorable to us. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, may have a negative effect on our business, results of operations and financial condition.

Table of Contents

Net cash provided by financing activities was \$52.8 million during 2011 which consisted of \$4.3 million from the January 2011 preferred stock offering described below under the heading “January 2011 Preferred Stock Offering”, \$7.8 million from the private placement offering we completed under the heading “June 2, 2011 Private Placement Offering”, \$6.0 million from the registered direct offering we completed under the heading “July 6, 2011 Registered Direct Offering”, \$17.0 million from the registered direct and private placement offerings we completed under the heading “July 25, 2011 Registered Direct and Private Placement Offerings”, \$13.9 million from the private placement offering we completed under the heading “December 6, 2011 Private Placement Offering”, \$0.4 million from the exercise of preferred stock and common stock warrants and \$3.4 million of gross proceeds from the committed equity financing facility described below under Part II, Item 2 “Unregistered Sales of Equity Securities and Use of Proceeds”.

The \$22.8 million net cash requirement was mostly funded from cash and short term investments. At December 31, 2011, we had cash, cash equivalents and short term investments of \$30.5 million. We will need substantial additional capital to complete our clinical trials, obtain marketing approvals and to commercialize our products.

January 2011 Preferred Stock Offering

On January 14, 2011, we completed the issuance and sale of 5,000 shares of our 8% redeemable convertible preferred stock and warrants to purchase up to 2,083,333 shares of common stock to institutional investors as well as certain officers and directors of the Company in a registered direct offering. The convertible preferred stock and warrants were sold in units, with each unit consisting of one share of convertible preferred stock and a warrant to purchase up to 416.6666 shares of common stock at an exercise price of \$3.25 per whole share of common stock. The units were offered and sold to unaffiliated third party investors at a negotiated purchase price of \$1,000 per unit and to officers and directors at an at-the-market price of \$1,197.92 per unit in accordance with the NASDAQ Stock Market Rules. Concurrent with the issuance and sale of the units, the Company issued warrants to purchase up to 350 shares of the convertible preferred stock at an exercise price of \$1,000 per whole share of preferred stock to certain affiliates of Dominick & Dominick LLC, as placement agent for the offering. The Company received gross proceeds from the offering of approximately \$5.1 million, before deducting placement agent fees and offering expenses.

Each share of preferred stock was convertible into shares of common stock at an initial conversion price of \$2.40 per share, subject to adjustment in the event of stock splits, recapitalizations or reorganizations affecting all holders of common stock equally. The mandatory conversion provisions of the convertible preferred stock were triggered by the July 25, 2011 registered direct and private placement offerings described below under the heading “July 25, 2011 Registered Direct and Private Placement Offerings”, since the sale of our common stock in those offerings was for not less than \$4.00 per share and we received aggregate gross proceeds of at least \$10 million in those offerings. As a result, 839 shares of convertible preferred stock which were outstanding at the time, were converted into 349,582 shares of our common stock.

Until the shares of convertible preferred stock were converted on or about August 5, 2011, issued and outstanding shares accrued dividends at a rate of 8% per annum. Dividends on the shares of convertible preferred stock were payable on a quarterly basis from the original issue date, commencing on April 15, 2011 and were payable only in cash. During the first nine months of 2011, the Company accrued dividends of approximately \$0.5 million on the outstanding shares of preferred stock. These amounts were paid within 15 days of the end of each fiscal quarter and upon conversion of the shares of convertible preferred stock.

During the third quarter of 2011, warrants issued in this offering were exercised, resulting in receipt by the holders of such warrants of 71,666 shares of common stock collectively. The Company received gross proceeds of \$172,000 from the exercise of these warrants.

Table of Contents

June 2, 2011 Private Placement Offering

On June 2, 2011, we completed the issuance and sale of 3,218,612 shares of our common stock and warrants to purchase up to 3,218,612 shares of common stock to institutional investors as well as certain officers and directors of the Company in a private placement transaction. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a warrant to purchase one share of common stock. Units sold to unaffiliated institutional investors were sold at a negotiated purchase price of \$2.65 per unit and to officers and directors at \$2.895 per unit, the latter representing the consolidated closing bid price per share of common stock plus a warrant premium of \$0.125 per unit. The warrants are exercisable on or after December 2, 2011 at an exercise price of \$2.77 and expire 78 months after the date of issuance. The Company received gross proceeds from the offering of approximately \$8.6 million, before deducting placement agent fees and offering expenses. Concurrent with the issuance and sale of the units, the Company entered into a registration rights agreement with the investors that required the Company to file a registration statement with the Securities and Exchange Commission covering the resale by the investors of the common stock and the shares of common stock issuable upon exercise of the warrants, which registration statement became effective on June 24, 2011.

July 6, 2011 Registered Direct Offering

On July 6, 2011, we completed the issuance and sale in a registered direct offering of 2,095,560 shares of our common stock and warrants to purchase up to 628,668 shares of common stock to institutional investors. The common stock and warrants were sold in units at a price of \$3.1675 per unit, with each unit consisting of one share of common stock and a warrant to purchase 0.3 shares of common stock. The warrants were exercisable immediately at an exercise price of \$3.13 and expire five years from the date of issuance. The Company received gross proceeds from the offering of approximately \$6.6 million, before deducting placement agent fees and offering expenses.

During the third quarter of 2011, warrants issued in this offering were exercised for 71,034 shares of common stock. The Company received gross proceeds of \$222,336 from the exercise of these warrants.

July 25, 2011 Registered Direct and Private Placement Offerings

On July 25, 2011, we completed the issuance and sale in a registered direct offering of 3,047,682 shares of our common stock and warrants to purchase up to 914,305 shares of common stock to institutional investors. The common stock and warrants were sold in units at a price of \$4.2575 per unit, with each unit consisting of one share of common stock and a warrant to purchase 0.3 shares of common stock. The warrants were exercisable immediately at an exercise price of \$4.22 and expire five years from the date of issuance. The Company received gross proceeds from the offering of approximately \$13.0 million, before deducting placement agent fees and offering expenses.

On July 25, 2011, we also completed the issuance and sale of 1,281,031 shares of our common stock and warrants to purchase up to 512,412 shares of common stock to institutional investors as well as a director of the Company and an investor affiliated with another director of the Company in a private placement transaction. The common stock and warrants were sold in units at a price of \$4.27 per unit, with each unit consisting of one share of common stock and a warrant to purchase 0.4 shares of common stock. The warrants were exercisable immediately at an exercise price of \$4.22 and expire five years from the date of issuance. The Company received gross proceeds from the offering of approximately \$5.5 million, before deducting placement agent fees and offering expenses. Concurrent with the issuance and sale of the units, the Company entered into a registration rights agreement with the investors that required the Company to file a registration statement with the Securities and Exchange Commission covering the resale by the investors of the common stock and the shares of common stock issuable upon exercise of the warrants, which registration statement became effective on September 22, 2011.

Table of Contents

December 6, 2011 Private Placement Offering

On December 6, 2011, the Company completed the issuance and sale of 6,486,488 shares of common stock and warrants to purchase up to 3,243,244 shares of common stock in a private placement transaction to certain institutional investors as well as two members of our board of directors. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a half of a warrant to purchase one share of common stock. Units sold to unaffiliated institutional investors were sold at a negotiated purchase price of \$2.3125 per unit representing the consolidated closing bid price per share of common stock plus a warrant premium of \$0.125 per unit. The Company received gross proceeds from the offering of approximately \$15.0 million before deducting estimated offering expenses. Each warrant to purchase shares of the Company's common stock has an exercise price of \$2.36 per share, for total potential additional proceeds to the Company of up to approximately \$7.5 million upon exercise of the warrants. The warrants are immediately exercisable for cash or, solely in the absence of an effective registration statement, by net exercise and will expire five years from the date of issuance. Concurrent with the issuance and sale of the units, the Company entered into a registration rights agreement with the investors that required the Company to file a registration statement with the Securities and Exchange Commission covering the resale by the investors of the common stock and the shares of common stock issuable upon exercise of the warrants, which registration statement became effective on February 8, 2011.

Committed Equity Financing Facility

On June 17, 2010, we entered into a common stock purchase agreement with Small Cap Biotech Value Ltd. (SCBV), providing for a financing arrangement that is referred to as a committed equity line financing facility (CEFF). The CEFF provided that, upon the terms and subject to the conditions set forth therein, SCBV would purchase shares of common stock valued at up to \$15.0 million over the 24-month term of the CEFF under certain specified conditions and limitations, including that in no event would we sell under the CEFF more than 2,404,434 shares of common stock (i.e., one share less than 20% of our outstanding shares of common stock on June 17, 2010, the closing date of the CEFF) less the number of shares of common stock we issued to SCBV on the closing date as commitment shares. SCBV also agreed that in no event would SCBV purchase any shares of our common stock which, when aggregated with all other shares of our common stock then beneficially owned by SCBV, would result in the beneficial ownership by SCBV of more than 9.9% of the then outstanding shares of our common stock. These maximum share and beneficial ownership limitations were not able to be waived by the parties.

During 2011, we completed three draws and sales to SCBV under the CEFF as follows:

Date	Shares Issued	Gross Proceeds	Per Share	Broker Fees and Expenses
March 16, 2011	275,855	\$ 608,347	\$ 2.21	\$ 19,489
April 25, 2011	407,703	867,680	\$ 2.13	27,872
May 6, 2011	656,956	1,949,117	\$ 2.97	280,891
Total	1,340,514	\$ 3,425,144	\$ 2.56	\$ 328,252

The proceeds of the draws were used for general corporate purposes, including the funding of the Company's clinical development pipeline of cancer drugs. SCBV is an accredited investor as such term is defined in Rule 501 of Regulation D of the Securities, and all sales of our common stock to SCBV pursuant to the CEFF were exempt from registration pursuant to Section 4(2) of the Securities Act and Rule 506 of Regulation D of the Securities Act. We registered the resale of the shares of common stock issued to SCBV pursuant to the CEFF under the Securities Act on a registration statement on Form S-1.

Availability under the CEFF was exhausted during the second quarter of 2011. The CEFF terminated automatically on the date on which SCVB purchased the entire commitment amount under the CEFF.

Table of Contents

We currently estimate we will use approximately \$19 - \$21 million of cash in 2012 to fund operations. Significant additional capital will be required after 2012 to develop our product candidates through clinical development, manufacturing, and commercialization. We may seek additional capital through further public or private equity offerings, debt financing, additional strategic alliance and licensing arrangements, collaborative arrangements, or some combination of these financing alternatives. If we raise additional funds through the issuance of equity securities, the percentage ownership of our stockholders could be significantly diluted and the newly issued equity securities may have rights, preferences, or privileges senior to those of the holders of our common stock. If we raise funds through the issuance of debt securities, those securities may have rights, preferences, and privileges senior to those of our common stock. If we seek strategic alliances, licenses, or other alternative arrangements, such as arrangements with collaborative partners or others, we may need to relinquish rights to certain of our existing or future technologies, product candidates, or products we would otherwise seek to develop or commercialize on our own, or to license the rights to our technologies, product candidates, or products on terms that are not favorable to us. The overall status of the economic climate could also result in the terms of any equity offering, debt financing, or alliance, license, or other arrangement being even less favorable to us and our stockholders than if the overall economic climate were stronger. We also will continue to look for government sponsored research collaborations and grants to help offset future anticipated losses from operations and, to a lesser extent, interest income.

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

Contractual Obligations

On July 21, 2011, the Company executed a lease with Brandywine Operating Partnership, L.P. (Brandywine), a Delaware limited partnership for a 10,870 square foot premises located in Lawrenceville, New Jersey. On October 3, 2011, the Company relocated its offices to Lawrenceville, New Jersey from Columbia, Maryland. The lease has a term of 66 months and provides for 6 months rent free, with the first monthly rent payment of approximately \$23,000 due in April 2012. Also, as required by the lease, the Company provided Brandywine with an irrevocable and unconditional standby letter of credit for \$250,000, which the Company secured with an escrow deposit at its banking institution of this same amount. The standby letter of credit will be reduced by \$50,000 on each of the 19th, 31st and 43rd months from the initial term, with the remaining \$100,000 amount remaining until the lease term has expired.

Off-Balance Sheet Arrangements

We do not utilize off-balance sheet financing arrangements as a source of liquidity or financing.

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 and incorporated herein by reference.

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

None.

32

Table of Contents

ITEM 9A.CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

We have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) under the supervision, and with the participation, of our management, including our principal executive officer and principal financial officer. Based on that evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2011, which is the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures are effective.

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

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

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2011. 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 (COSO Framework). Based on its evaluation, management has concluded that the Company's internal control over financial reporting is effective as of December 31, 2011.

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

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

(c) Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting in the fiscal quarter ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial

reporting.

(d) Inherent Limitations on the Effectiveness of Controls

Our management, including the chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures and our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Table of Contents

ITEM 9B.OTHER INFORMATION

None.

34

Table of Contents

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information relating to our executive officers required by this Item is set forth in Part I — Item 1 of this report under the caption “Executive Officers of the Registrant” and is incorporated herein by reference. The other information required by this Item 10 is herein incorporated 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 herein incorporated 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 herein incorporated 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, 2011

The following table discloses information about the options issued and available for issuance under all outstanding Company option plans as of December 31, 2011.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	3,168,011 (1)	\$ 3.73	274,877
Equity compensation plans not approved by security holders	— (2)	—	— (2)
Total	2,245,046	\$ 3.73	274,877

-
- (1) Includes both vested and unvested options to purchase common stock issued to employees, officers, and directors and outside consultants under the Company’s 2001 Stock Option Plan, the 2004 Stock Incentive Plan, and the 2007 Stock Incentive Plan, (the “Plans”). Certain of these options to purchase common stock were issued under the Plan in connection with employment agreements.
- (2) As discussed further in Notes 10 and 12 to the Company’s financial statements in this Annual Report, the Company has warrants outstanding at December 31, 2011 enabling the holders

thereof to purchase 11,598,617 shares of the Company's common stock at a weighted-average exercise price of \$3.15. 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 we issue additional stock, options, warrants or other convertible securities below the exercise price of the subject securities.

Please also refer to Note 11 of the Company's financial statements in this Annual Report for descriptions of the plans under which equity securities of the Company are authorized for issuance.

Table of Contents

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

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

Table of Contents

PART IV.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. FINANCIAL STATEMENTS

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

	Page
REPORTS	
Report of Independent Registered Public Accounting Firm	F-1
FINANCIAL STATEMENTS	
Balance Sheets	F-2
Statements of Operations	F-3
Statements of Cash Flows	F-4
Statements of Changes in Stockholders' Equity	F-5
NOTES TO FINANCIAL STATEMENTS	F-7

2. FINANCIAL STATEMENT SCHEDULES

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

3. EXHIBITS

The following documents are included as exhibits to this report:

EXHIBIT NO.	DESCRIPTION
3.1	Certificate of Incorporation of Celsion (the "Company"), as amended, incorporated herein by reference to Exhibit 3.1.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2004.
3.2	Certificate of Ownership and Merger of Celsion Corporation (a Maryland Corporation) into Celsion (Delaware) Corporation (inter alia, changing the Company's name to "Celsion Corporation" from "Celsion (Delaware) Corporation), incorporated herein by reference to Exhibit 3.1.3 to the Annual Report on Form 10-K of the Company for the year ended September 30, 2000.
3.3	Certificate of Designations of Series C Junior Participating Preferred Stock of Celsion Corporation, incorporated herein by reference to Exhibit 4.4 to the Form S-3 Registration Statement (File No. 333-100638), filed October 18, 2002.
3.4	Certificate of Amendment of the Certificate of Incorporation effective and filed on February 27, 2006, incorporated therein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company filed on March 1, 2006.
3.5	

Certificate of Designation for 8% Series A Redeemable Convertible Preferred Stock of Celsion Corporation, incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K as filed with the SEC on January 18, 2011.

Table of Contents

EXHIBIT NO. DESCRIPTION

3.6	By-laws of the Company, as amended and restated, incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company, filed December 1, 2011.
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, 2000.
4.2	Celsion Corporation and American Stock Transfer & Trust Company Rights Agreement dated as of August 15, 2002, incorporated herein by reference to Exhibit 99.1 to the Current Report on Form 8-K of the Company, filed August 21, 2002.
4.3	Amendment No. 1, adopted January 16, 2003, to Rights Agreement between Celsion Corporation and American Stock Transfer & Trust Company, incorporated herein by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2004.
4.4	Form of Common Stock Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company, filed with the SEC on September 28, 2009.
4.5	Registration Rights Agreement, dated June 17, 2010, by and between Celsion Corporation and Small Cap Biotech Value, Ltd., incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company, filed with the SEC on June 18, 2010.
4.6	Form of Common Stock Warrant, incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the SEC on January 18, 2011.
4.7	Form of Common Stock Warrant incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on June 2, 2011.
4.8	Registration Rights Agreement, dated May 26, 2011, by and among Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on June 2, 2011.
4.9	Form of Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on July 6, 2011.
4.10	Registration Rights Agreement, dated July 25, 2011, by and between Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the SEC on July 25, 2011.
4.11	Form of Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on July 25, 2011.
4.12	Form of Warrant to Purchase Common Stock, incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the SEC on July 25, 2011.
4.13	Form Warrant to Purchase Common Stock Purchase, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on December 6, 2011.
4.14	

Registration Rights Agreement, dated December 1, 2011, by and between Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the SEC on December 6, 2011.

10.1 Celsion Corporation 2004 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2004.

Table of Contents

EXHIBIT NO. DESCRIPTION

10.2	Celsion Corporation 2007 Stock Incentive Plan, as amended, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on June 29, 2010.
10.3	Form of Restricted Stock Agreement for Celsion Corporation 2004 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2006.
10.4	Form of Stock Option Grant Agreement for Celsion Corporation 2004 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2006.
10.5	Form of Restricted Stock Agreement for Celsion Corporation 2007 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1.5 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2007.
10.6	Form of Stock Option Grant Agreement for Celsion Corporation 2007 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1.6 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2007.
10.7	Restricted Stock Agreement, dated October 3, 2006, between Celsion Corporation and William Hahne, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on October 10, 2006.
10.8	Stock Option Grant Agreement dated October 3, 2006, between Celsion Corporation and William Hahne, incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of the Company, filed on October 10, 2006.
10.9	Stock Option Agreement effective January 3, 2007, between Celsion Corporation and Michael H. Tardugno, incorporated herein by reference Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on January 3, 2007.
10.10	Employment Agreement, effective January 3, 2007, between Celsion Corporation and Mr. Michael H. Tardugno, incorporated herein by reference to Exhibit 99.1 to the Current Report on Form 8-K of the Company, filed on December 21, 2006.
10.11	Employment Agreement, effective March 1, 2009, between the Company and Michael H. Tardugno, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on February 19, 2008.
10.12	Separation Agreement and General Release, dated January 6, 2010, between Celsion Corporation and Sean Moran, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on January 8, 2010.
10.13	Employment Offer Letter, entered into on June 15, 2010, between the Company and Jeffrey W. Church, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on June 18, 2010.
10.14*	

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.

10.15* License Agreement dated July 18, 2003, between the Company and Duke University, incorporated herein by reference to Exhibit 10.1 to the Registration Statement of the Company (File No. 333-108318) filed on August 28, 2003.

Table of Contents

EXHIBIT NO. DESCRIPTION

10.16	Distribution Agreement effective as of January 20, 2003, by and between Celsion Corporation and Boston Scientific Corporation, incorporated herein by reference to Exhibit 99.1 the Current Report on Form 8-K filed on January 22, 2003.
10.17*	Transaction Agreement effective as of January 20, 2003, by and between Celsion Corporation and Boston Scientific Corporation, incorporated herein by reference to Exhibit 99.2 to the Current Report on Form 8-K filed on January 22, 2003.
10.18	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 on August 9, 2005.
10.19*	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.
10.20	Asset Purchase Agreement, dated as of April 17, 2007, by and between Celsion Corporation and Boston Scientific Corporation, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on April 18, 2007
10.21	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 on December 13, 2007.
10.22	First Amendment to the Asset Purchase Agreement, dated June 5, 2008, by and between Celsion Corporation and Boston Scientific Corporation, incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2009.
10.23	Second Amendment to the Asset Purchase Agreement, dated June 2, 2009, by and between Celsion Corporation and Boston Scientific Corporation incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on June 2, 2009.
10.24	Loan and Security Agreement, dated as of November 9, 2007, by and between Celsion Corporation and Manufacturers and Traders Trust, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on November 14, 2007.
10.25*	Development, Product Supply and Commercialization Agreement, effective December 5, 2008, by and between the Company and Yakult Honsha Co., Ltd., herein by reference to Exhibit 10.15 to the Annual Report on Form 10-K of the Company for the Year Ended December 31, 2008.
10.26*	The 2nd Amendment To The Development, Product Supply And Commercialization Agreement, effective January 7, 2011, by and between the Company and Yakult Honsha Co., Ltd. incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed with the SEC on January 18, 2011.
10.27	Placement Agency Agreement dated September 25, 2009 among Celsion Corporation and Needham & Company, LLC., incorporated herein by reference to Exhibit 1.1 to the Current Report on Form 8-K of

the Company, filed on September 28, 2009.

10.28 Form of Subscription Agreement, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on September 28, 2009.

10.29 Escrow Agreement, dated September 25, 2009, by and between JPMorgan Chase Bank, N.A., Celsion Corporation, and Needham & Company, LLC., incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of the Company, filed on September 28, 2009.

Table of Contents

EXHIBIT NO. DESCRIPTION

10.30	Common Stock Purchase Agreement, dated June 17, 2010, by and between Celsion Corporation and Small Cap Biotech Value, Ltd., incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on June 18, 2010.
10.31	Securities Purchase Agreement dated January 12, 2011 by and among Celsion Corporation and the Investors named therein, incorporated herein by reference to Exhibit 10.2 on Form 8-K of the Company filed on January 18, 2011.
10.32	Form of Purchase Agreement, dated May 26, 2011, by and among Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on June 2, 2011.
10.33	Form of Securities Purchase Agreement, dated June 30, 2011, by and among Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on July 6, 2011.
10.34	Form of Securities Purchase Agreement, dated July 20, 2011, by and among Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on July 25, 2011
10.35	Form of Purchase Agreement, dated July 20, 2011, by and among Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on July 25, 2011.
10.36	Lease Agreement, executed July 21, 2011, by and between Celsion Corporation and Brandywine Operating Partnership, L.P., incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on July 25, 2011.
<u>10.37+</u>	Offer letter, dated July 8, 2011, by and between Celsion Corporation and Gregory Weaver.
<u>10.38+</u>	Change in control severance agreement, dated November 29, 2011, by and between Celsion Corporation and Michael H. Tardugno.
<u>10.39+</u>	Change in control severance agreement, dated November 29, 2011, by and between Celsion Corporation and Gregory Weaver.
<u>10.40+</u>	Change in control severance agreement, dated November 29, 2011, by and between Celsion Corporation and Nicholas Borys, M.D.
<u>10.41+</u>	Change in control severance agreement, dated November 29, 2011, by and between Celsion Corporation and Jeffrey W. Church.
<u>10.42+</u>	Change in control severance agreement, dated November 29, 2011, by and between Celsion Corporation and Robert A. Reed.
10.43	Form of Purchase Agreement, dated December 1, 2011, by and among Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on December 6, 2011.

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.

41

Table of Contents

EXHIBIT NO.	DESCRIPTION
<u>32.1</u> [^]	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.
<u>32.2</u> [^]	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.
101 ^{**}	The following materials from the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Condensed Consolidated Balance Sheets, (ii) the unaudited Condensed Consolidated Statements of Operations, (iii) the unaudited Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements.

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

+ Filed herewith.

[^] Furnished herewith.

** Exhibit 101 is being furnished and, in accordance with Rule 406T of Regulation S-T, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Securities Exchange Act.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused its annual report on Form 10-K to be signed on its behalf by the undersigned thereunto duly authorized.

CELSION CORPORATION
Registrant

March 15, 2012 By: /s/ Michael H. Tardugno
Michael H. Tardugno
President and Chief Executive Officer

March 15, 2012 By: /s/ Gregory Weaver
Gregory Weaver
Senior Vice President and
Chief Financial Officer

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

Name	Position	Date
/s/ MICHAEL H. TARDUGNO (Michael H. Tardugno)	President and Chief Executive Officer (Principal Executive Officer) and Director	March 15, 2012
/s/ GREGORY WEAVER (Gregory Weaver)	Senior Vice President and Chief Financial Officer (Principal Financial Officer)	March 15, 2012
/s/ TIMOTHY J. TUMMINELLO (Timothy J. Tumminello)	Controller and Chief Accounting Officer	March 15, 2012
/s/ MAX E. LINK (Max E. Link, PhD.)	Chairman of the Board, Director	March 15, 2012
/s/ AUGUSTINE CHOW (Augustine Chow, PhD.)	Director	March 15, 2012
/s/ FREDERICK J. FRITZ (Frederick J. Fritz)	Director	March 15, 2012
/s/ ROBERT W. HOOPER (Robert W. Hooper)	Director	March 15, 2012
/s/ ALBERTO MARTINEZ (Alberto Martinez)	Director	March 15, 2012

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

Celsion Corporation

Columbia, Maryland

We have audited the accompanying balance sheets of Celsion Corporation (the "Company") as of December 31, 2011 and 2010, and the related statements of operations, changes in stockholders' (deficit) equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Celsion Corporation as of December 31, 2011 and 2010, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Stegman & Company

Baltimore, Maryland

March 15, 2012

Table of Contents

CELSION CORPORATION
BALANCE SHEETS

	December 31,	
	2011	2010
ASSETS		
Current assets:		
Cash and cash equivalents	\$20,145,854	\$1,138,916
Short-term investments	10,400,905	395,556
Refundable income taxes	-	-
Prepaid expenses and other current assets	961,726	492,184
Total current assets	31,508,485	2,026,656
Property and equipment (at cost, less accumulated depreciation of \$643,472 and \$1,046,758, respectively)	782,720	378,672
Other assets:		
Security deposit on letter of credit	250,000	-
Deposits and other assets	72,629	76,796
Patent license fees, net	35,625	43,125
Total other assets	358,254	119,921
Total assets	\$32,649,459	\$2,525,249
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable - trade	\$4,010,203	\$4,548,586
Other accrued liabilities	2,031,934	2,124,189
Note payable - current portion	110,287	123,465
Total current liabilities	6,152,424	6,796,240
Common stock warrant liability	166,398	248,131
Note payable – non-current portion	71,602	56,403
Other liabilities - noncurrent	65,467	-
Total liabilities	6,455,891	7,100,774
Stockholders' (deficit) equity:		
Common stock - \$0.01 par value (75,000,000 shares authorized; 33,899,057 and 14,091,370 shares issued and 33,186,325 and 13,331,096 shares outstanding at December 31, 2011 and 2010, respectively)	338,991	140,914
Additional paid-in capital	153,237,225	99,316,859
Accumulated other comprehensive loss	(276,700)	(18,367)
Accumulated deficit	(124,221,823)	(100,938,261)
Subtotal	29,077,693	(1,498,855)
Treasury stock, at cost (712,732 and 760,274 shares at December 31 2011 and 2010, respectively)	(2,884,125)	(3,076,670)
Total stockholders' equity (deficit)	26,193,568	(4,575,525)
Total liabilities and stockholders' equity (deficit)	\$32,649,459	\$2,525,249

See accompanying notes to the financial statements.

Table of Contents

CELSION CORPORATION
STATEMENTS OF OPERATIONS

	Year ended December 31,	
	2011	2010
Licensing revenue	\$ 2,000,000	\$ —
Operating expenses:		
Research and development	\$ 19,863,836	\$ 14,714,460
General and administrative	5,154,933	4,922,967
Total operating expenses	25,018,769	19,637,427
Loss from operations	(23,018,769)	(19,637,427)
Other income (expense):		
Other income	42,149	244,460
Change in valuation of common stock warrant liability	81,733	573,760
Interest income	174,064	32,289
Interest expense	(501,855)	(31,517)
Total other (expense) income	(203,909)	818,992
Loss before income taxes	(23,222,678)	(18,818,435)
Income tax benefit	-	-
Net loss	\$ (23,222,678)	\$ (18,818,435)
Net loss per common share – basic and diluted	\$ (1.11)	\$ (1.52)
Weighted average common shares outstanding – basic and diluted	20,917,678	12,375,402

See accompanying notes to the financial statements.

Table of Contents

CELSION CORPORATION
STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2010	2010
Cash flows from operating activities:		
Net loss	\$ (23,222,678)	\$ (18,818,435)
Non-cash items included in net loss:		
Depreciation and amortization	169,358	165,480
Change in fair value of common stock warrant liability	(81,733)	(573,760)
Stock based compensation - options	1,036,337	1,295,382
Stock based compensation – restricted stock	171,549	357,678
Shares issued out of treasury	60,360	–
Amortization of patent license fee	7,500	7,500
Shares issued in exchange for services	71,550	18,060
Change in deferred rent liability	65,467	–
Net changes in:		
Refundable income taxes	–	806,255
Prepaid expenses and other	(393,676)	340,837
Deposits and other assets	4,167	20,286
Accounts payable	(538,383)	2,357,629
Other accrued liabilities	(92,255)	655,699
Net cash used in operating activities	(22,742,437)	(13,367,389)
Cash flows from investing activities:		
Purchases of investment securities	(10,659,238)	(11,844,356)
Proceeds from sale and maturity of investment securities	395,556	17,057,726
Security deposit on letter of credit	(250,000)	–
Purchases of property and equipment	(573,406)	(6,745)
Net cash (used in) provided by investing activities	(11,087,088)	5,206,625
Cash flows from financing activities:		
Proceeds from sale of 8% Series A Redeemable, Convertible Preferred Stock, net of issuance costs	4,324,080	–
Proceeds from sale of equity, net of issuance costs	48,082,025	2,484,536
Proceeds from exercise of common stock warrants	428,337	–
Proceeds from note payable	144,448	–
Principal payments on note payable	(142,427)	(108,332)
Net cash provided by financing activities	52,836,463	2,376,204
Increase in cash and cash equivalents	19,006,938	(5,784,560)
Cash and cash equivalents at beginning of period	1,138,916	6,923,476
Cash and cash equivalents at end of period	\$ 20,145,854	\$ 1,138,916
Cash paid for:		
Interest	\$ 501,855	\$ 31,517
Income taxes	\$ –	\$ –

See accompanying notes to the financial statements.

F-4

Table of Contents

CELSION CORPORATION
STATEMENTS OF CHANGES IN STOCKHOLDERS' (DEFICIT) EQUITY
YEARS ENDED DECEMBER 31, 2011 AND 2010

	Common Stock Outstanding		Additional Paid in Capital	Treasury Stock		Accumulated Other Compr. Income	Accumulated Deficit	Total
	Shares	Amount		Shares	Amount			
Balance at December 31, 2009	12,134,900	\$128,952	\$95,035,165	760,274	\$(3,076,670)	\$68,173	\$(82,119,826)	\$10,035,794
Comprehensive loss:								
Net loss	-	-	-	-	-	-	(18,818,435)	(18,818,435)
Unrealized loss on investments available for sale	-	-	-	-	-	(86,540)	-	(86,540)
Total comprehensive loss								(18,904,975)
Shares issued under CEFF, net of issuance costs	1,103,919	11,039	2,611,497	-	-	-	-	2,622,536
Stock-based compensation expense	-	-	1,653,060	-	-	-	-	1,653,060
Issuance of restricted stock upon vesting	86,277	863	(863)	-	-	-	-	-
Shares issued in exchange for services	6,000	60	18,000					18,060
Balance at December 31, 2010	13,331,096	\$140,914	\$99,316,859	760,274	\$(3,076,670)	\$(18,367)	\$(100,938,261)	\$(4,575,525)

Table of Contents

CELSION CORPORATION
 STATEMENTS OF CHANGES IN STOCKHOLDERS' (DEFICIT) EQUITY (continued)
 YEARS ENDED DECEMBER 31, 2011 AND 2010

	Common Stock Outstanding		Additional Paid in Capital	Treasury Stock		Accumulated Other Compr. Income	Accumulated Deficit	Total
	Shares	Amount		Shares	Amount			
Comprehensive loss:								
Net loss	-	-	-	-	-	-	(23,222,678)	(23,222,678)
Unrealized loss on investments available for sale	-	-	-	-	-	(258,333)	-	(258,333)
Total comprehensive loss								(23,481,011)
Valuation of common stock warrants in connection with issuance of 8% Series A Redeemable, Convertible Preferred Stock	-	-	2,030,000	-	-	-	-	2,030,000
Conversion of 8% Series A Redeemable, Convertible Preferred Stock	2,083,322	20,833	2,610,514	-	-	-	-	2,631,347
Shares issued under CEFF, net of issuance costs	1,340,514	13,405	3,102,682	-	-	-	-	3,116,087
Registered Direct and Private Placement								
Private Placement common stock offerings	16,129,373	161,294	44,543,243	-	-	-	-	44,704,537
Conversion of common stock warrants	156,866	1,569	426,768	-	-	-	-	428,337

Edgar Filing: Celsion CORP - Form 10-K

Stock-based compensation expense	-	-	1,207,886	-	-	-	-	1,207,886
Issuance of restricted stock upon vesting	97,612	976	(976))	-	-	-	-
Issuance of common stock out of treasury	47,542	-	249	(47,542)	192,545	-	(60,884)) 131,910
Balance at December 31, 2011	33,186,325	\$338,991	\$153,237,225	712,732	\$(2,884,125)	\$(276,700)	\$(124,221,823)	\$26,193,568

See accompanying notes to the financial statements.

Table of Contents

CELSION CORPORATION
NOTES TO FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2011 AND 2010

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

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

Basis of Presentation

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

Events and conditions arising subsequent to the most recent balance sheet date have been evaluated for their possible impact on the financial statements and accompanying notes. No events and conditions would give rise to any information that required accounting recognition or disclosure in the financial statements other than those arising in the ordinary course of business.

Revenue Recognition

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

Cash and Cash Equivalents

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

Fair Value of Financial Instruments

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

Short Term Investments

The Company classifies its investments in marketable securities with readily determinable fair values as investments available-for-sale in accordance with Accounting Standards Codification (ASC) 320, Investments - Debt and Equity Securities. Available-for-sale securities consist of debt and equity securities not classified as trading securities or as securities to be held to maturity. The Company has classified all of its investments as available-for-sale. Unrealized holding gains and losses on available-for-sale securities are reported as a net amount in accumulated other comprehensive gain or loss in stockholders' equity until realized. Gains and losses on the sale of available-for-sale securities are determined using the specific identification method. The Company's short term investments consist of corporate bonds and government agency bonds.

F-7

Table of Contents

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation. Depreciation is provided over the estimated useful lives of the related assets, ranging from three to seven years, using the straight-line method. Major renewals and improvements are capitalized at cost and ordinary repairs and maintenance are charged against operating expenses as incurred. Depreciation expense was approximately \$169,000 and \$165,000 for years ended December 31, 2011 and 2010, respectively.

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

Deposits

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

Patent Licenses

The Company has purchased several licenses for rights to patented technologies. Patent license costs of \$73,125 have been capitalized and are amortized on a straight-line basis over the estimated life of the related patent. As of December 31, 2011, the total accumulated amortization expense is \$37,500. The weighed-average amortization period for these assets is 10 years.

Comprehensive Income (Loss)

ASC 220, Comprehensive Income, establishes standards for the reporting and display of comprehensive income and its components in the Company's consolidated financial statements. The objective of ASC 220 is to report a measure (comprehensive income (loss)) of all changes in equity of an enterprise that result from transactions and other economic events in a period other than transactions with owners.

Research and Development

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

Net Loss Per Common Share

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

The outstanding equity awards for 3,168,511 and 2,245,046 shares, respectively, and the warrants outstanding to purchase 11,598,617 and 1,009,076 shares, respectively, were considered anti-dilutive and therefore were not included in the calculation of diluted shares.

F-8

Table of Contents

Income Taxes

Income taxes are accounted for under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax asset and liabilities of a change in tax rates is recognized in results of operations in the period that the tax rate change occurs. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. In accordance with ASC 740, Income Taxes, a tax position is recognized as a benefit only if it is “more likely than not” that the tax position taken would be sustained in a tax examination, presuming that a tax examination will occur. The Company recognizes interest and/or penalties related to income tax matters in the income tax expense category. The Company remains subject to examination for income tax returns for the years ending after 2008.

Stock-Based Compensation

Compensation costs for all stock-based awards is measured at fair value on the date of the grant and recognized over the service period for awards expected to vest. Such value is recognized as expense over the service period. The estimation of stock-based awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from the current estimates, such amounts will be recorded as cumulative adjustment in the period estimates are revised. We consider many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience.

Recent Accounting Pronouncements.

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

In May 2011, the FASB issued ASU 2011-04 on fair value disclosures. This guidance amends certain accounting and disclosure requirements related to fair value measurements. It is effective on a prospective basis for interim and annual reports beginning after December 15, 2011. Early application is not permitted. The Company is currently ASU 2011-04 but we do not expect the impact of adoption to be material.

In June 2011, the FASB issued ASU 2011-05 on the presentation of comprehensive income, which amends current comprehensive guidance. This accounting update eliminates the option to present the components of other comprehensive income as part of stockholders’ equity. Instead, the Company must report Comprehensive income in either a single continuous statement of comprehensive income which contains two sections, net income and other comprehensive income, or in two separate but consecutive statements.

ASU 2011-05 was initially to be effective for public companies during the interim and annual periods beginning after December 15, 2011 with early adoption permitted. However, changes in ASU 2011-05 that related to the presentation of reclassification adjustments to other comprehensive income were deferred in December 2011 upon the FASB’s issuance of ASU 2011-12, which allows the FASB time to redeliberate whether to present the effects of reclassifications out of accumulated other comprehensive income on the components of net other income on the face of the financial statements for all periods presented. While the FASB is considering the operational concerns about the presentation requirements for reclassification adjustments and the needs of financial statement users for additional information about reclassification adjustments, the Company is required to continue reporting reclassifications out of

accumulated other comprehensive income consistent with the presentation requirements in effect before ASU 2011-05. All other requirements in ASU 2011-05 are not effected by ASU 2011-12 including the requirement to report comprehensive income either in a single continuous financial statement or in two separate but consecutive financial statements. Public entities should apply these requirements for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of ASU 2011-0 and ASU 2011-12 will not have an impact on the Company's consolidated financial position, results of operations or cash flows as it only requires a change in the format of the current presentation.

F-9

Table of Contents

2. FINANCIAL CONDITION

Since inception, the Company has incurred substantial operating losses, principally from expenses associated with the Company's research and development programs, clinical trials conducted in connection with the Company's product candidates, and applications and submissions to the Food and Drug Administration. The Company believes these expenditures are essential for the commercialization of its technologies. As a result of these expenditures, as well as general and administrative expenses, the Company has an accumulated deficit of \$124.2 million as of December 31, 2011.

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

The Company will need substantial additional funding in order to complete the development, testing and commercialization of its oncology product candidates and we have made a significant commitment to heat-activated liposome research and development projects and it is our intention at least to maintain, and possibly increase, the pace and scope of these activities. The commitment to these new projects will require additional external funding, at least until the Company is able to generate sufficient cash flow from sale of one or more of its products to support its continued operations. We believe cash and investment resources on hand at December 31, 2011 are sufficient to fund operations into the second half of 2013.

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

3. COMPREHENSIVE LOSS

Comprehensive loss is comprised of net loss adjusted for changes in fair values of securities available for sale. Below is a reconciliation of net loss to comprehensive loss for the years ended December 31, 2011 and 2010:

	Year ended December 31,	
	2011	2010
Net loss	\$ (23,222,678)	\$ (18,818,435)
Unrealized loss on securities available for sale	(258,333)	(86,540)
Comprehensive loss	\$ (23,481,011)	\$ (18,904,975)

4. SHORT TERM INVESTMENTS AVAILABLE FOR SALE

Short term investments available for sale of \$10,400,905 and \$395,556 as of December 31, 2011 and 2010, respectively, consist of money market funds, commercial paper, corporate debt securities, and government agency

debt securities. They are valued at estimated fair value, with unrealized gains and losses reported as a separate component of stockholders' equity in Accumulated Other Comprehensive Income.

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

Table of Contents

Short-term investments available for sale, at fair value	December 31,	
	2011	2010
Bonds – corporate issuances	\$ 10,400,905	\$ 301,632
Equity securities	–	93,924
Total	\$ 10,400,905	\$ 395,556

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

	December 31, 2011		December 31, 2010	
	Cost	Fair Value	Cost	Fair Value
Short-term investments				
Bonds- corporate issuances	\$ 10,565,315	\$ 10,400,905	\$ 301,632	\$ 301,632
Equity securities	108,373	–	108,373	93,924
Total	\$ 10,673,688	\$ 10,400,905	\$ 410,005	\$ 395,556
Bond maturities				
Within 3 months	\$ 5,128,560	\$ 5,036,920	\$ 301,632	\$ 301,632
Between 3-12 months	5,436,755	5,363,985	–	–
Between 1-2 years	–	–	–	–
Total	\$ 10,565,315	\$ 10,400,905	\$ 301,632	\$ 301,632

5. FAIR VALUES OF FINANCIAL INSTRUMENTS

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

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

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

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

Table of Contents

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

	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
December 31, 2011				
Bonds- corporate issuances	\$ 10,400,905	\$ 10,400,905	\$ -	\$ -
Equity securities	-	-	-	-
Short-term investments available for sale, December 31, 2011	\$ 10,400,905	\$ 10,400,905	\$ -	\$ -
December 31, 2010				
Bonds- corporate issuances	\$ 301,632	\$ 301,632	\$ -	\$ -
Equity securities	93,924	-	-	93,924
Short-term investments available for sale, December 31, 2010	\$ 395,556	\$ 301,632	\$ -	\$ 93,924
Liabilities:				
Common stock warrants, December 31, 2011	\$ 166,398	\$ -	\$ -	\$ 166,398
Common stock warrants, December 31, 2010	\$ 248,131	\$ -	\$ -	\$ 248,131

The following is a summary the changes in the common stock equity securities and warrant liability for the years ended December 31, 2011 and 2010:

	Equity Securities	Warrant Liability
Beginning balance, January 1, 2010	\$ 167,302	\$ 821,891
Unrealized gain included in other comprehensive (loss) income	(73,378)	-
Realized gain included in net loss	-	(573,760)
Ending balance, December 31, 2010	93,924	248,131
Unrealized gain (loss) included in other comprehensive (loss) income	(93,924)	-
Realized gain included in net loss	-	(81,733)
Ending balance, December 31, 2011	\$ -	\$ 166,398

The following table shows the Company's investment securities gross unrealized losses and fair value by investment category and length of time that individual securities have been in a continuous unrealized loss position at December 31, 2011 and 2010. The Company has reviewed individual securities to determine whether a decline in fair value below the amortizable cost basis is other than temporary.

	December 31, 2011		Total
	Less than 12 months	12 months or Longer	

Edgar Filing: Celsion CORP - Form 10-K

Description of Securities	Fair Value	Gross Unrealized Holding Losses	Fair Value	Gross Unrealized Holding Losses	Fair Value	Gross Unrealized Holding Losses
Available for Sale						
Bonds	\$10,400,905	\$(168,327)	\$-	\$-	\$10,400,905	\$(168,327)
Equity securities	-	(93,924)	-	(14,449)	-	(108,373)
	\$10,400,905	\$(262,251)	\$-	\$(14,449)	\$10,400,905	\$(276,700)

F-12

Table of Contents

	Less than 12 months		December 31, 2010 12 months or Longer		Total	
	Fair Value	Gross Unrealized Holding Losses	Fair Value	Gross Unrealized Holding Losses	Fair Value	Gross Unrealized Holding Losses
Available for Sale						
Bonds	\$301,632	\$-	\$-	\$-	\$301,632	\$-
Equity securities	93,924	(14,449)	-	-	93,924	(14,449)
	\$395,556	\$(14,449)	\$-	\$-	\$395,556	\$(14,449)

6. OTHER CURRENT ASSETS

Other current assets at December 31, 2011 and 2010 include the following:

	December 31,	
	2011	2010
Advances to investigator sites	758,296	-
Franchise taxes receivable	39,104	41,364
Raw materials for ThermoDox® registration batches	163,561	132,451
Prepaid professional fees	-	37,500
Amortizable expenses associated with Committed Equity Financing Facility	-	274,806
Other	765	6,063
Total	\$ 961,726	\$ 492,184

7. OTHER ACCRUED LIABILITIES

Other accrued liabilities at December 31, 2011 and 2010 include the following:

	December 31,	
	2011	2010
Amounts due to Contract Research Organizations and other contractual agreements	\$ 1,234,875	\$ 1,497,441
Accrued payroll and related benefits	632,425	460,614
Accrued professional fees	137,400	138,900
Other	27,234	27,234
Total	\$ 2,031,934	\$ 2,124,189

8. NOTE PAYABLE

In October 2009, the Company financed \$288,200 of lab equipment through a capital lease. This lease obligation has thirty monthly payments of \$11,654 through April 2012. During 2011, the Company made principal and interest payments totaling \$139,848. The outstanding lease obligation is \$56,403 as of December 31, 2011.

In November 2011, the Company financed \$144,448 of lab equipment through a capital lease. This lease obligation has thirty monthly payments of \$5,651 through February 2014. During 2011, the Company made principal and interest payments totaling \$23,450. The outstanding lease obligation is \$125,485 as of December 31, 2011. See Note 17 to the financial statements.

Table of Contents

9. INCOME TAXES

A reconciliation of the Company's statutory tax rate to the effective rate for the years ended December 31, 2011 and 2010 is as follows:

	2011	2010
Federal statutory rate	34.0%	34.0%
State taxes, net of federal tax benefit	4.6	5.4
Recapture of alternative minimum tax	—	—
Valuation allowance	(38.6)	(39.4)
Effective tax rate	—%	—%

The components of the Company's deferred tax asset as of December 31, 2011 and 2010 are as follows:

In thousands	December 31,	
	2011	2010
Net operating loss carry forwards	\$ 40,104	\$ 31,341
Compensation expense related to employee stock options	2,285	1,917
Subtotal	42,389	33,258
Valuation allowance	(42,389)	(33,258)
Total deferred tax asset	\$ -	\$ -

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

During 2011 the Company performed analyses to determine if there were changes in ownership, as defined by Section 382 of the Internal Revenue Code that would limit its ability to utilize certain net operating loss and tax credit carryforwards. The Company determined that it experienced an ownership change, as defined by Section 382, in connection with its registered direct and private placement offerings on July 25, 2011. As a result, the utilization of the Company's federal tax net operating loss carryforwards generated prior to the ownership change is limited. As of December 31, 2011, the Company has net operating loss carryforwards for U.S. federal and state tax purposes of approximately \$103.8 million, before excluding net operating losses that have been limited as a result of Section 382 limitations. The annual limitation due to Section 382 for net operating loss carry forward utilization is approximately \$4.9 million. The utilization of these net operating loss carryforwards may be further limited if the Company experiences future ownership changes as defined in Section 382 of the Internal Revenue Code.

Approximate Amount Of Unused Operating Loss Carry Forwards (\$000s)	Expiration During Year Ended
\$ 5,003	2022
2,292	2023
15,655	2024
8,174	2025

Edgar Filing: Celsion CORP - Form 10-K

7,367	2026
10,716	2028
14,300	2029
18,045	2030
22,292	2031
\$ 103,844	

F-14

Table of Contents

10. STOCKHOLDERS' EQUITY

The Company filed with the Securities and Exchange Commission a \$50 million shelf registration statement on Form S-3 that allowed the Company to issue any combination of common stock, preferred stock or warrants to purchase common stock or preferred stock. This shelf registration was declared effective on April 17, 2009. As of July 25, 2011, this shelf registration statement had been fully utilized.

January 2011 Preferred Stock Offering

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

The Company received gross proceeds from the offering of approximately \$5.1 million, before deducting placement agents' fees and offering expenses. The preferred shares are convertible into shares of common stock by the holders thereof at any time and have a mandatory redemption date of January 14, 2013 at a stated redemption value of \$1,000 per preferred share. The convertible preferred shares are also subject to mandatory conversion upon the occurrence of certain events, including the sale of Common Stock in one or more offerings for not less than \$4.00 per share and aggregate gross proceeds of \$10 million, the achievement of a twenty day trading average of our Common Stock above \$6.00 per share, or the receipt of an aggregate at least \$4,000,000 as actual, or advanced payment of future, license, milestone or royalty payments from a strategic, licensing or development partner.

Until such time as the preferred shares are redeemed, issued and outstanding shares accrue dividends at a rate of 8% per annum. Dividends on the convertible preferred shares are payable on a quarterly basis from the original issue date commencing on April 15, 2011 and are payable only in cash.

The Units were sold pursuant to the Company's shelf registration statement on Form S-3 (Registration No. 333-158402), which was declared effective by the SEC on April 17, 2009, as supplemented by prospectus supplements dated January 12, 2011 and January 13, 2011 filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act of 1933, as amended. In connection with the offering, placement agent fees and other offering expenses totaling \$675,918 were capitalized as deferred financing fees and were amortized as interest costs over the period from inception until the January 14, 2013 mandatory redemption date. When the preferred shares are converted, the unamortized portion related to such shares are recorded as a cost of capital. Deferred financing fees of \$77,853 were amortized during the nine months ended September 30, 2011. During the period from the date of the offering and through September 30, 2011, all 5,000 preferred shares were converted into 2,083,322 shares of the Company's common stock. In connection with these conversions, deferred financing fees of \$598,065 were reclassified as a cost of capital.

During the third quarter of 2011, one holder of 25 shares of preferred stock voluntarily converted their preferred shares into 10,416 shares of the Company's common stock. As a result of the Securities Purchase Agreement between the Company and certain institutional investors entered into on July 20, 2011 and closed on July 25, 2011, the mandatory conversion of all outstanding preferred stock was triggered. During the third quarter of 2011, 839 shares of 8% Series A Redeemable Convertible Preferred Stock were outstanding, which are convertible into 349,582 shares of our common stock. The mandatory conversions occurred in August 2011. No other shares of preferred stock were outstanding after this conversion.

F-15

Table of Contents

During the third and fourth quarters of 2011, Placement Agent Warrants were exercised resulting in receipt by holders of 71,666 and 14,166 shares of common stock respectively. The Company received gross proceeds collectively of \$206,000 from the exercise of these warrants.

June 2, 2011 Private Placement Offering

On June 2, 2011, the Company completed the issuance and sale in a private placement transaction with institutional investors, as well as certain officers and directors of the Company, of 3,218,612 shares of common stock (the “Common Stock”) and warrants (the “Warrants”) to purchase up to 3,218,612 shares of common stock. The Common Stock and Warrants were sold in units (the “Units”), with each Unit consisting of one share of Common Stock and a Warrant to purchase one share of common stock. Units sold to unaffiliated institutional investors were sold at a negotiated purchase price of \$2.65 per Unit and to officers and directors at \$2.895 per Unit, the latter representing the consolidated closing bid price per share of Common Stock plus a warrant premium of \$0.125 per Unit. The Warrants are immediately exercisable and have a term of exercise of seventy-eight months from the date of issuance and an exercise price of \$2.77 per share. The Company received gross proceeds from the offering of approximately \$8.6 million before deducting estimated offering expenses.

Concurrent with the issuance and sale of the Units, Common Stock and Warrants pursuant to the Purchase Agreement, the Company also entered into a Registration Rights Agreement with the Investors (the “Registration Rights Agreement”) that required the Company to file a resale registration statement with the Securities and Exchange Commission covering the resale by the Investors of the Common Stock and the shares of common stock issuable upon exercise of the Warrants. These Units were filed pursuant to Rule 424(b)(3) under the Securities Act of 1933 on the Prospectus for Registration Statement No. 333-174960 and was declared effective on June 24, 2011.

July 6, 2011 Registered Direct Offering

On July 6, 2011, the Company completed the issuance and sale in a registered offering of 2,095,560 shares of our common stock and warrants to purchase up to 628,668 shares of our common stock to institutional investors. The securities were sold in units at a price of \$3.1675 per unit, with each unit consisting of one share of common stock and a warrant to purchase 0.3 shares of common stock, for an aggregate offering price of \$6,637,688 (the “Offering”). Net proceeds from the offering were approximately \$6 million.

Each Warrant to purchase shares of Common Stock will have an exercise price of \$3.13 per share, for total potential additional proceeds to the Company of up to approximately \$2 million upon exercise of the Warrants. The Warrants are immediately exercisable for cash or, solely in the absence of an effective registration statement, by net exercise and will expire five years from the date of issuance.

The offer and sale of the Common Stock and Warrants (and the shares of Common Stock issuable upon exercise of the warrants) are registered under the Securities Act of 1933 (the “Securities Act”), as amended, on a registration statement on Form S-3 (File No. 333-158402).

During the third quarter of 2011, one holder exercised Warrants for 71,034 shares of common stock. The Company received gross proceeds of \$222,336 from the exercise of these warrants.

July 25, 2011 Registered Direct and Private Placement Offerings

On July 25, 2011, the Company completed a registered offering of 3,047,682 shares of its common stock and warrants (the “RD Warrants”) to purchase up to 914,305 shares of its common stock. The common stock and the warrants were sold in units at a price of \$4.2575 per unit, with each unit consisting of one share of the Company’s common stock and

a warrant to purchase 0.30 shares of the Company's common stock, for an aggregate registered offering price of \$12,975,506 (the "Registered Offering").

The offer and sale of the Company's common stock issued in the Registered Offering and the shares of common stock issuable upon exercise of the warrants issued in the Registered Offering are registered under the Securities Act of 1933, as amended (the "Securities Act"), on a registration statement on Form S-3 (File No. 333-158402), as supplemented and amended by the prospectus supplement filed with the Securities and Exchange Commission on July 25, 2011.

Table of Contents

On July 20, 2011, the Company entered into a Purchase Agreement (the “Private Placement Purchase Agreement” and, together with the Registered Direct Purchase Agreement, the “Agreements”) under which the Company agreed to enter into a private placement with other accredited institutional investors, a member of the Company’s Board of Directors, and an accredited institutional investor affiliated another member of the Company’s Board of Directors (collectively, the “Private Offering Purchasers”). Pursuant to the Private Placement Purchase Agreement, the Company issued 1,281,031 shares of its common stock and warrants (the “Private Placement Warrants”) to purchase up to 512,412 shares of its common stock. The Private Placement Purchase Agreement provided that the securities will be sold in units at a price of \$4.27 per unit, with each unit consisting of one share of the Company’s common stock and a warrant to purchase 0.40 shares of the Company’s common stock, for an aggregate private offering price of \$5,469,998 (the “Private Offering,” collectively with the Registered Offering, the “Offerings”).

In the Offerings, each warrant to purchase shares of the Company’s common stock will have an exercise price of \$4.22 per share, for total potential additional proceeds to the Company of up to approximately \$6 million upon exercise of the warrants. The warrants in the Offerings are immediately exercisable for cash or, solely in the absence of an effective registration statement, by net exercise and will expire five years from the date of issuance.

Concurrent with the issuance and sale of the Private Offering common stock and warrants, the Company also entered into a Registration Rights Agreement with the Private Offering Purchasers (the “Registration Rights Agreement”) that requires the Company to file a registration statement within 30 days of the closing date on July 25, 2011 with the Securities and Exchange Commission covering the resale by the Private Offering Purchasers of the common stock issued in the Private Offering and the shares of common stock issuable upon exercise of the warrants issued in the Private Offering. These Units were filed pursuant to Rule 424(b)(3) under the Securities Act of 1933 on the Prospectus for Registration Statement No. 333-176486 and was declared effective on September 22, 2011.

The purchase and issuance of securities in the Offerings were completed on July 25, 2011. Net proceeds from the Registered Offering and the Private Placement Offering aggregated approximately \$17 million.

December 6, 2011 Private Placement Offering

On December 6, 2011, the Company completed the issuance and sale in a private placement transaction with institutional investors, as well as certain directors of the Company, of 6,486,488 shares of common stock and warrants to purchase up to 3,243,244 shares of common stock. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a half of a warrant to purchase one share of common stock. Units sold to unaffiliated institutional investors were sold at a negotiated purchase price of \$2.3125 per unit representing the consolidated closing bid price per share of common stock plus a warrant premium of \$0.125 per unit. The Company received gross proceeds from the offering of approximately \$15.0 million before deducting estimated offering expenses.

In this offering, each warrant to purchase shares of the Company’s common stock will have an exercise price of \$2.36 per share, for total potential additional proceeds to the Company of up to approximately \$7.5 million upon exercise of the warrants. The warrants in the Offering are immediately exercisable for cash or, solely in the absence of an effective registration statement, by net exercise and will expire five years from the date of issuance.

Concurrent with the issuance and sale of the Offering common stock and warrants, the Company also entered into a Registration Rights Agreement with the Purchasers (the “Registration Rights Agreement”) that requires the Company to file a registration statement with the Securities and Exchange Commission covering the resale by the Purchasers of the common stock issued in the Offering and the shares of common stock issuable upon exercise of the warrants issued in the Offering. These units were filed pursuant to Rule 424(b)(3) under the Securities Act of 1933 on the Prospectus for Registration Statement No. 333- 178679 and was declared effective on February 8, 2012.

Table of Contents

Committed Equity Financing Facility (CEFF)

On June 17, 2010, we entered into a Committed Equity Financing Facility (CEFF) with Small Cap Biotech Value Ltd. (SCBV). The CEFF provides that, upon the terms and subject to the conditions set forth therein, SCBV is committed to purchase up to \$15.0 million worth of our shares of common stock over the 24-month term of the CEFF under certain specified conditions and limitations, provided that in no event may we sell under the CEFF more than 2,404,434 shares of common stock, which is equal to one share less than 20% of our outstanding shares of common stock on June 17, 2010, the closing date of the CEFF, less the number of shares of common stock we issued to SCBV on the closing date as Commitment Shares (described below). Furthermore, in no event shall SCBV purchase any shares of our common stock which, when aggregated with all other shares of our common stock then beneficially owned by SCBV, would result in the beneficial ownership by SCBV of more than 9.9% of the then outstanding shares of our common stock. These maximum share and beneficial ownership limitations may not be waived by the parties.

In partial consideration for SCBV's execution and delivery of the CEFF, we issued to SCBV 40,000 shares of our common stock (the "Commitment Shares"). The issuance of the Commitment Shares, together with all other shares of common stock issuable to SCBV pursuant to the terms of the CEFF, is exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(2) and Regulation D under the Securities Act.

In the second half of 2010, the Company completed three draws and sales to SCBV under the CEFF collectively totaling 1,063,919 shares of common stock for gross proceeds of \$2,577,061. Broker fees and other expenses associated with the 2010 draws totaled \$84,722.

During 2011, the Company completed the following draws and sales to SCBV under the CEFF as follows:

Date	Shares Issued	Gross Proceeds	Per Share	Broker Fees and Expenses
March 16, 2011	275,855	\$ 608,347	\$ 2.21	\$ 19,489
April 25, 2011	407,703	867,680	\$ 2.13	27,872
May 6, 2011	656,956	1,949,117	\$ 2.97	280,891
Total	1,340,514	\$ 3,425,144	\$ 2.56	\$ 328,252

In connection with the CEFF, the Company capitalized and deferred approximately \$332,000 of fees and expenses. A portion of these amounts were amortized each time the Company completed a draw under the CEFF. During 2011, \$274,806 of these expenses was amortized in connection with the three draws in 2011.

The proceeds from the CEFF draws were used for general corporate purposes, including the funding of the Company's clinical development pipeline of cancer drugs. SCBV is an accredited investor as such term is defined in Rule 501 of Regulation D of the Securities Act of 1933, as amended (the "Securities Act"), and all sales of the Company's common stock to SCBV pursuant to the CEFF were exempt from registration pursuant to Section 4(2) of the Securities Act and Rule 506 of Regulation D of the Securities Act. The Company has registered the resale of the shares of common stock issued to SCBV pursuant to the CEFF under the Securities Act on a registration statement on Form S-1.

Availability under the CEFF was exhausted during the second quarter of 2011. Also, in connection with recent equity offerings in the second quarter of 2011, the Company agreed to suspend the use of the CEFF and expensed the unamortized deferred financing fees of \$274,806 in the second quarter of 2011.

Table of Contents

11. STOCK BASED COMPENSATION

Employee Stock Options

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

2001 Stock Option Plan

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

2004 Stock Incentive Plan

In 2004, the Board of Directors adopted a stock plan for directors, officers and employees (the "2004 Plan") under which 666,667 shares were reserved for future issuance. The plan provides for stock instruments to be issued enabling the holder thereof to acquire Common stock of the Company at prices determined by the Company's Board of Directors. The purpose of the 2004 Plan was to promote the long-term growth and financial success of the Company and enable the Company to attract, retain 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.

Any options forfeited or terminated under the 2001 Plan and 2004 Plan are rolled into the 2007 Stock Incentive Plan for future issuance. At December 31, 2010, 590,994 and 455,195 of available options from these two plans respectively are available for future issuance under 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 1,000,000 were 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. At the Celsion Corporation 2010 Annual Meeting of Stockholders, the 2007 Plan was amended to increase the number of shares available from 1,000,000 to 2,000,000.

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

During the year ended December 31, 2011 and 2010, 1,246,667 and 769,743 equity awards, respectively, were issued under the 2007 Plan. During 2011 and 2010, a total of 256,002 and 92,276 options were canceled or expired under the plans collectively.

Table of Contents

As of December 31, 2011, for all stock options plans there were a total of 3,443,388 shares reserved and there were a total of 274,877 shares available for future issuance.

In February 2012, the Company's board of directors approved the recommendations and ratified the determinations of its compensation committee and granted stock options to all of the Company's executive officers and directors. Collectively, directors and executive officers were granted options to purchase 135,000 and 77,000 options respectively to purchase our common stock, respectively.

Total compensation cost charged related to employee stock options and non-vested restricted stock awards amounted to \$1.2 million and \$1.7 million for the years ended December 31, 2011 and 2010, respectively. No compensation cost related to share-based payments arrangements was capitalized as part of the cost of any asset at December 31, 2011 and 2010.

As of December 31, 2011, there was \$1.1 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 2.0 years. The weighted average grant-date fair values of the equity awards granted during the years ended December 31, 2011 and 2010 were \$1.81 and \$2.19, respectively.

Equity Awards Issued to Consultants for Services

The Company periodically issues equity awards to consultants in exchange for services provided. The fair value of options granted is measured in accordance with ASC 718, Compensation – Stock Compensation, using the Black-Scholes option pricing model and recorded as an expense in the period in which such services are received. Generally, the terms of these plans require that the exercise price of such awards may not be less than the fair market value of the Company's Common Stock on the date the equity awards are granted. Consultant equity awards generally vest over various time frames or upon milestone accomplishments. Some vest immediately upon issuance. The equity awards generally expire 10 years from the date of grant. There were 22,500 and 176,000 awards issued to consultants during the year ended December 31, 2011 and 2010, respectively.

The following is a summary of stock option activity for the two years ended December 31, 2011:

	Number Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Stock Options				
Outstanding at January 1, 2010	1,641,979	\$ 3.96		
Granted	656,500	3.04		
Exercised	-	-		
Canceled or expired	(130,833)	3.03		
Outstanding at December 31, 2010	2,167,646	3.96		
Granted	1,195,667	3.67		
Exercised	-	-		
Canceled or expired	(250,169)	3.23		
Outstanding at December 31, 2011	3,113,144	\$ 3.75	6.68	\$ -
Exercisable at December 31, 2011	1,755,606	\$ 4.45	5.16	\$ -

Table of Contents

A summary of stock options outstanding at December 31, 2011 by price range is as follows:

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number Outstanding	Weighted Average Remaining Contractual Term (in years)	Weighted Average Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Term (in years)	Weighted Average Exercise Price
2.00 - \$3.00	1,923,168	7.51	\$2.61	846,878	6.03	\$2.61
3.01 - \$5.00	470,864	7.42	3.72	230,364	5.81	4.04
5.01 - \$7.00	401,905	5.37	5.74	361,155	5.32	5.76
7.01 - \$10.00	293,666	1.46	7.21	293,666	1.46	7.21
10.01 - \$30.00	23,333	1.75	18.10	23,333	1.75	8.29
30.01 - \$150.75	208	2.44	150.75	208	2.44	150.75
	3,113,144			1,755,606		

Restricted Stock

A summary of the status of the Company's non-vested restricted stock awards as of December 31, 2011 and changes during the two years ended December 31, 2011, is presented below:

	Number Outstanding	Weighted Average Exercise Price
Restricted Stock		
Non-vested stock awards outstanding at January 1, 2010	78,599	\$ 3.06
Granted	113,243	3.16
Vested and issued	(92,276)	2.84
Forfeited	(22,166)	3.06
Non-vested stock awards outstanding at December 31, 2010	77,400	\$ 3.47
Granted	51,000	2.73
Vested and issued	(67,200)	3.12
Forfeited	(6,333)	3.96
Non-vested stock awards outstanding at December 31, 2011	54,867	\$ 3.16

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,

Edgar Filing: Celsion CORP - Form 10-K

	2011	2010
Risk-free interest rate	2.29 to 2.97%	0.80 to 3.24%
Expected volatility	72.15% - 81.06%	71.52% - 85.75%
Expected life (in years)	6.25	2.9 - 6.5
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 2011 and 2010 grants was generated using the simplified method as allowed under Securities and Exchange Commission Staff Accounting Bulletin No. 107.

F-21

Table of Contents

12. WARRANTS

As more fully described in Note 10, the Company completed a series of equity financing transactions in 2011.

In connection with the January 2011 Preferred Stock Offering, the Company issued warrants to purchase up to 2,083,333 shares of common stock with an exercise price of \$3.25 per whole share of common stock and Placement Agent Warrants to purchase up to 350 shares of the convertible preferred stock. These Placement Agent Warrants are equivalent to 145,833 shares of common stock at an exercise price of \$2.40 per whole share.

In connection with the June 2, 2011 Private Placement Offering, the Company issued warrants to purchase up to 3,218,612 shares of common stock with an exercise price of \$2.77 per whole share of common stock.

In connection with the July 6, 2011 Registered Direct Offering, the Company issued warrants to purchase up to 628,668 shares of common stock with an exercise price of \$3.13 per whole share of common stock.

In connection with the July 25, 2011 Registered Direct Offering, the Company issued warrants to purchase up to 914,305 shares of common stock with an exercise price of \$4.22 per whole share of common stock.

In connection with the July 25, 2011 Private Placement Offering, the Company issued warrants to purchase up to 512,412 shares of common stock with an exercise price of \$4.22 per whole share of common stock.

In connection with the December 6, 2011 Private Placement Offering, the Company issued warrants to purchase up to 3,243,244 shares of common stock with an exercise price of \$2.36 per whole share of common stock.

The following is a summary of all warrant activity for 2011:

Warrants	Number Issued	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2010	1,009,076	\$5.24	3.25	\$ —
Common stock warrants granted in connection with the January 2011 Preferred Stock Offering	2,083,333	3.25	4.54	—
Placement Agent Warrants granted (as if exercised and converted to common stock)	145,833	2.40	4.54	—
Common stock warrants granted in connection with the June 2, 2011 Private Placement Offering	3,218,612	2.77	5.91	—
Common stock warrants granted in connection with the July 6, 2011 Registered Direct Offering	628,668	3.13	4.52	—
Common stock warrants granted in connection with the July 25, 2011 Registered Direct Offering	914,305	4.22	4.57	—
Common stock warrants granted in connection with the July 25, 2011 Private Placement Offering	512,412	4.22	4.57	—
Common stock warrants granted in connection with the December 6, 2011 Private Placement Offering	3,243,244	2.36	4.94	—
Exercise of common stock warrants	(156,866)	2.73	4.53	—
Outstanding and exercisable at December 31, 2011	11,598,617	\$3.15	4.92	\$ —

Table of Contents

Common Stock Warrant Liability

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

As of December 31, 2011 and 2010, the Company recorded a common stock warrant liability of \$0.2 million. The fair value of the warrants at December 31, 2011 was calculated using the Black-Scholes option-pricing model with the following assumptions:

	December 31, 2011
Risk-free interest rate	0.83%
Expected volatility	75.2%
Expected life (in years)	1.6
Expected forfeiture rate	0%
Expected dividend yield	0.00%

13. 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 IRS annual contribution limit. Commencing in the fourth quarter for 2008, the Company began making a matching contribution up to a maximum of 3% of an employee's annual salary and the Company's total contribution in for the year ended December 31, 2011 and 2010 was \$60,630 and \$60,949 respectively. The Company's contribution was made in the form of our common stock.

14. LICENSES OF INTELLECTUAL PROPERTY AND PATENTS

On November 10, 1999, the Company entered into a license agreement with Duke University under which the Company received worldwide exclusive rights (subject to certain exceptions) to commercialize and use Duke's thermally sensitive liposome technology. The license agreement contains annual royalty and minimum payment provisions due on net sales. The agreement also required milestone-based royalty payments measured by various events, including product development stages, FDA applications and approvals, foreign marketing approvals and achievement of significant sales. However, in lieu of such milestone-based cash payments, Duke agreed to accept shares of the Company's Common Stock to be issued in installments at the time each milestone payment is due, with each installment of shares to be calculated at the average closing price of the Common Stock during the 20 trading days prior to issuance.

The total number of shares issuable to Duke under these provisions is subject to adjustment in certain cases, and Duke has piggyback registration rights for public offerings taking place more than one year after the effective date of the license agreement. On January 31, 2003, the Company issued 253,691 shares of Common Stock to Duke University valued at \$2.2 million as payment for milestone based royalties under this license agreement. An amendment to the Duke license agreement contains certain development and regulatory milestones, and other performance requirements that the Company has met with respect to the use of the licensed technologies. The Company will be obligated to make royalty payments based on sales to Duke upon commercialization, until the last of the Duke patents expire.

For the years ended December 31, 2011 and 2010, the Company has not incurred any expense under this agreement and will not incur any future liabilities until commercial sales commence.

F-23

Table of Contents

Under the November 1999 license agreement with Duke, the Company has rights to the thermally sensitive liposome technology, including Duke's US patents covering the technology as well as all foreign counterpart applications and related pending applications. Foreign counterpart applications have been issued in Europe, Hong Kong, Australia and Canada and has been allowed in Japan. The Japanese allowed application is expected to issue without hindrance in March of 2011. The European patent has been validated in Austria, Belgium, France, Germany, Great Britain, Italy, Luxembourg, Monaco, Spain and Switzerland. In addition, the Duke license agreement provides the Company with rights to multiple issued and pending US patents related to the formulation, method of making and use of heat sensitive liposomes. The Company's rights under the license agreement with Duke University extend for the life of the last-to-expire of the licensed patents.

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

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

ThermoDox® is a registered trademark in the United States, Argentina, Australia, Canada, China, Columbia, the European Communities: (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Korea, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, UK), Hong Kong, Israel, Japan, New Zealand, Peru, Philippines, Russia, Singapore, South Korea and Taiwan. The Company has registered transliterations of ThermoDox® in China, Hong Kong, Japan, Singapore, South Korea and Taiwan. The Company has an additional 14 trademark protection applications pending for ThermoDox® in countries world-wide.

Finally, through proprietary information agreements with employees, consultants and others, the Company seeks to protect its own proprietary know-how and trade secrets. The Company cannot offer assurances that these confidentiality agreements will not be breached, that the Company will have adequate remedies for any breach, or that these agreements, even if fully enforced, will be adequate to prevent third-party use of the Company's proprietary technology. Similarly, the Company cannot guarantee that technology rights licensed to it by others will not be successfully challenged or circumvented by third parties, or that the rights granted will provide the Company with adequate protection.

15. LICENSING AGREEMENT

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

Concurrent with the January 2011 Preferred Equity Financing as discussed in Note 10 to the Financial Statements, the Company amended its Development, Product Supply and Commercialization Agreement with Yakult to provide for up to \$4.0 million in an accelerated partial payment to the Company of a future drug approval milestone. The terms of the agreement with Yakult provide for the payment to the Company of \$2.0 million upon the closing of the preferred equity financing and an additional \$2.0 million conditioned upon the resumption of enrollment of Japanese patients in

the Japan cohort of the HEAT study. In consideration of these accelerated milestone payments from Yakult, the Company has agreed to reduce future drug approval milestone payments by approximately forty percent (40%).

F-24

Table of Contents

On August 3, 2011, we announced that we had reached our preplanned enrollment objective of 600 patients in the pivotal Phase III HEAT study. The target enrollment figure is designed to ensure that the study's primary end point, progression-free survival, can be achieved with adequate statistical power, and is one of two triggers for an interim efficacy analysis by the study's DMC. The second trigger was the occurrence of 190 progression-free survival (PFS) events in the study population. We met the second trigger of 190 PFS events in the third quarter of 2011 which allowed us to conduct a planned interim analysis in the fourth quarter of 2011. On November 28, 2011, we announced that the independent Data Monitoring Committee for the HEAT Study completed a pre-planned interim analysis for safety, efficacy and futility and unanimously recommended that the study continue to its final analysis as planned. The DMC evaluated data from 613 patients in its review, which was conducted following realization of 219 progression-free survival (PFS) events within the study population. A total of 380 events of progression are required to reach the planned final analysis of the study which we reconfirmed was projected to occur in late 2012.

16. OTHER INCOME

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

17. CONTINGENT LIABILITIES AND COMMITMENTS

In July 2011, the Company executed a lease (the "Lease") with Brandywine Operating Partnership, L.P. (Brandywine), a Delaware limited partnership for a 10,870 square foot premises located in Lawrenceville, New Jersey. In October 2011, the Company relocated its offices to Lawrenceville, New Jersey from Columbia, Maryland. The lease has a term of 66 months and provides for 6 months rent free, with the first monthly rent payment of approximately \$23,000 due in April 2012. Also, as required by the Lease, the Company provided Brandywine with an irrevocable and unconditional standby letter of credit for \$250,000, which the Company secured with an escrow deposit at its banking institution of this same amount. The standby letter of credit will be reduced by \$50,000 on each of the 19th, 31st and 43rd months from the initial term, with the remaining \$100,000 amount remaining until the Lease Term has expired.

Following is a summary of the future minimum payments required under leases that have initial or remaining lease terms of one year or more as of December 31, 2011:

	Capital Leases	Operating Leases
For the year ending December 31:		
2012	\$ 126,087	\$ 207,889
2013	67,817	281,261
2014	11,303	286,696
2015	—	292,131
2016 and beyond	—	372,298
Total minimum lease payments	205,207	\$ 1,440,275
Less amounts of lease payments that represent interest	23,318	
Present value of future minimum capital lease payments	181,889	
Less current obligations under capital leases	110,287	
	\$ 71,602	

