Celsion CORP
Form 10-K
March 28, 2011

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

FORM 10-K

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

For the fiscal year ended December 31, 2010

OR

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

For the transition period from to

Commission file number 001-15911

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

DELAWARE	52-1256615
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
10220-L OLD COLUMBIA ROAD COLUMBIA, MARYLAND	21046-2364
(Address of Principal Executive Offices)	(Zip Code)

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

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

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

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

None

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

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

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

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). (The Registrant is not yet required to submit Interactive Data) Yes ¨ No ¨

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

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

Large Accelerated Filer	o	Accelerated Filer	o
Non-accelerated Filer	o (Do not check if a smaller reporting company)	Smaller Reporting Company	x

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

None

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PART I

ITEM 1. BUSINESS

FORWARD-LOOKING STATEMENTS

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

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

OVERVIEW

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

Our lead product, ThermoDox®, is being evaluated in a Phase III clinical trial, which we refer to as the HEAT study, for primary liver cancer and a Phase I/II study for recurrent chest wall breast cancer. ThermoDox® is a liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of

cancers. Localized mild hyperthermia (greater than 40 degrees Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in the region of the tumor target.

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

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

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

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

In 2005, the Company made a strategic decision to divest its medical device business. The Company sold this medical device business to Boston Scientific Corporation ("Boston Scientific") in 2007 for net aggregate payments of $43 million, receiving $13 million in 2007 and $15 million in each of 2008 and 2009. Since then, the Company has raised approximately $15.4 million in equity financing providing a total of $60 million to support its research and operations.

THERMODOX® (DOXORUBICIN ENCAPSULATED IN HEAT-ACTIVATED LIPOSOME)

Liposomes are manufactured submicroscopic vesicles consisting of a discrete aqueous central compartment surrounded by a membrane bilayer composed of naturally occurring fats. Conventional liposomes have been designed and manufactured to carry drugs and increase residence time thus allowing the drugs to remain in the bloodstream for extended periods of time before they are removed from the body. However, the current existing liposomal formulations of cancer drugs and liposomal cancer drugs under development do not provide for the immediate release of the drug and the direct targeting of organ specific tumors, two important characteristics that are required for improving the efficacy of cancer drugs such as doxorubicin. Through a perpetual, world-wide, exclusive development and commercialization license from Duke University, Celsion has licensed novel, heat-activated liposomal technology that is differentiated from other liposomes through its unique low heat-activated release of encapsulated chemotherapeutic agents. A team of research scientists at Duke University developed a heat-sensitive liposome which rapidly changes its structure when heated to a threshold minimum temperature of 40º to 42º Celsius. Heating creates channels in the liposome bilayer that allow an encapsulated drug to rapidly disperse into the surrounding tissue.

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

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

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

Liver Cancer Overview

Primary liver cancer (hepatocellular carcinoma or "HCC") is one of the most common and deadliest forms of cancer worldwide. It ranks as the fifth most common solid tumor cancer. It is estimated that up to 90% of liver cancer patients will die within five years of diagnosis. The incidence of primary liver cancer is approximately 20,000 cases per year in the United States, approximately 40,000 cases per year in Europe and is rapidly growing worldwide at approximately 750,000 cases per year. HCC has the fastest rate of growth of all cancers and is projected to be the most prevalent form of cancer by 2020. HCC is commonly diagnosed in patients with longstanding hepatic disease and cirrhosis (primarily due to hepatitis C in the U.S. and Europe and hepatitis B in Asia).

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

Celsion's Approach

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

Phase I Clinical Trial - Primary Liver Cancer

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

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

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

For primary liver cancer, ThermoDox® is being evaluated in a pivotal 600 patient double-blinded, placebo-controlled,GIN-RIGHT: 0pt" align="left">If a group has filed this schedule pursuant to §240.13d-1(b)(1)(ii)(J), so indicate under Item 3(j) and attach an exhibit stating the identity and Item 3 classification of each member of the group. If a group has filed this schedule pursuant to Rule 13d-1(c) or Rule 13d-1(d), attach an exhibit stating the identity of each member of the group.

N/A

Item 9. Notice of Dissolution of Group.

Notice of dissolution of a group may be furnished as an exhibit stating the date of the dissolution and that all further filings with respect to transactions in the security reported on will be filed, if required, by members of the group, in their individual capacity. See Item 5.

N/A

Item 10. Certification.

By signing below, each Reporting Person certifies that, to the best of its knowledge and belief, the securities referred to above were not acquired and are not held for the purpose of or with the effect of changing or influencing the control of the issuer of the securities and were not acquired and are not held in connection with or as a participant in any transaction having that purpose or effect.

SIGNATURE

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement is true, complete and correct.

February 11, 2013

Joel Lusman

/s/ Joel Lusman
Joel Lusman

Lusman Capital Management, LLC

By: /s/ Joel Lusman
Name: Joel Lusman
Title: Managing Member

The original statement shall be signed by each person on whose behalf the statement is filed or his authorized representative. If the statement is signed on behalf of a person by his authorized representative other than an executive officer or general partner of the filing person, evidence of the representative's authority to sign on behalf of such person shall be filed with the statement, provided, however, that a power of attorney for this purpose which is already on file with the Commission may be incorporated by reference. The name and any title of each person who signs the statement shall be typed or printed beneath his signature.

Note. Schedules filed in paper format shall include a signed original and five copies of the schedule, including all exhibits. See s.240.13d-7 for other parties for whom copies are to be sent.

Attention. Intentional misstatements or omissions of fact constitute Federal criminal violations (see 18 U.S.C. 1001).

Exhibit A

AGREEMENT

The undersigned agree that this Schedule 13G amendment dated February 11, 2013 relating to the Common Stock, par value $0.001 per share of Internet Patents Corporation, shall be filed on behalf of the undersigned.

Joel Lusman

/s/ Joel Lusman
Joel Lusman

Lusman Capital Management, LLC

By: /s/ Joel Lusman
Name: Joel Lusman
Title: Managing Member

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