Celsion CORP
Form 10-K
March 12, 2015

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, 2014

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.)**

997 LENOX DRIVE, SUITE 100

LAWRENCEVILLE, NJ **08648**
(Address of Principal Executive Offices) **(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	Name of Each Exchange on Which Registered
COMMON STOCK, PAR VALUE $0.01 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

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

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

As of June 30, 2014, the aggregate market value of the common stock held by non-affiliates of the Registrant was approximately $68,261,264 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, 2014 were excluded. This determination of executive officers and directors as affiliates is not necessarily a conclusive determination for any other purpose.

As of March 11, 2015, 19,984,703 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 2015 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.

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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, product pipelines, clinical trials and research and development activities, the adequacy of capital reserves and anticipated operating results and cash expenditures, current and potential collaborations, strategic alternatives 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, timing and progress of development, preclinical studies, clinical trials and regulatory submissions; our or our collaborator's ability to obtain and maintain regulatory approval of any of our product candidates; possible changes in capital structure, financial condition, future working capital needs and other financial items; changes in approaches to medical treatment; introduction of new products by others; success or failure of our current or future collaboration arrangements, risks and uncertainties associated with possible acquisitions of other technologies, assets or businesses; our ability to obtain additional funds for our operations; our ability to obtain and maintain intellectual property protection for our technologies and product candidates and our ability to operate our business without infringing the intellectual property rights of others; our reliance on third parties to conduct preclinical studies or clinical trials; the rate and degree of market acceptance of any approved product candidates; possible actions by customers, suppliers, strategic partners, potential strategic partners, competitors and regulatory authorities; compliance with listing standards of The NASDAQ Capital Market; and 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, "could," "intend," "predict," "may," "should," "will," "would" 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. Except as required by law, we assume no obligation to revise or update any forward-looking statement that may be made from time to time by us or on our behalf for any reason, even if new information becomes available in the future.

Unless the context requires otherwise or unless otherwise noted, all references in this Annual Report on Form 10-K to "Celsion" "the Company", "we", "us", or "our" are to Celsion Corporation, a Delaware corporation and its wholly owned subsidiary, CLSN Laboratories, Inc., also a Delaware Corporation.

Trademarks

The Celsion Corporation ("Celsion" or "the Company") brand and product names, including but not limited to Celsion®, ThermoDox®, EGEN®, TheraPlas™ and TheraSilence™ contained in this document are trademarks, registered trademarks or service marks of Celsion Corporation or its subsidiary 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 is a fully-integrated oncology drug development company focused on developing a portfolio of innovative cancer treatments, including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies. Our lead program is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in a Phase III clinical trial for the treatment of primary liver cancer (the OPTIMA Study) and a Phase II clinical trial for the treatment of recurrent chest wall breast cancer (the DIGNITY Study). Our pipeline also includes GEN-1 (formerly known as EGEN-001), a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers. We have three platform technologies for the development of treatments for those suffering with difficult-to-treat forms of cancer, novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlas™ and TheraSilence™. We are working to develop and commercialize more efficient, effective and targeted oncology therapies based on our technologies, with the goal to develop novel therapeutics that 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 OPTIMA study) starting in the first half of 2014 and a Phase II clinical trial for recurrent chest wall breast cancer (the DIGNITY Study). 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 39.5° Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in and around the targeted tumor.

On January 31, 2013, we announced that ThermoDox® in combination with radio frequency ablation (RFA) did not meet the primary endpoint of Progression Free Survival (PFS) for the 701 patient clinical trial in patients with hepatocellular carcinoma (HCC), also known as primary liver cancer (the HEAT Study). Specifically, we determined, after conferring with the HEAT Study independent Data Monitoring Committee (iDMC), that the HEAT study did not meet the goal of demonstrating persuasive evidence of clinical effectiveness that could form the basis for regulatory approval. In the trial, ThermoDox® was well-tolerated with no unexpected serious adverse events. Following the announcement of the HEAT Study results, we continue to follow patients for overall survival (OS), the secondary endpoint of the HEAT Study, on a quarterly basis. We have conducted a comprehensive analysis of the data from the HEAT Study to assess the future strategic value of ThermoDox®. As part of this analysis, we also evaluated our product pipeline and research and development priorities. In April 2013, we announced the deferral of expenses associated with the Company's Phase II study of ThermoDox® in combination with RFA for the treatment of colorectal liver metastases (The ABLATE Study) until such time as the Company finalizes its plans for the continuation of its development program with ThermoDox® in HCC.

The data from the HEAT Study post-hoc analysis suggest that ThermoDox® may substantially improve overall survival, when compared to the control group, in patients if their lesions undergo a 45 minute RFA procedure standardized for a lesion greater than 3 cm in diameter. Data from seven OS sweeps have been conducted since the top line PFS data from the HEAT Study were announced in January 2013, with each data set showing progressive improvement in statistical significance. The most recent post-hoc OS analysis data from the HEAT Study (as of

January 15, 2015) announced in February 2015 demonstrated that in a large, well bounded, subgroup of patients (n=285, 41% of the study patients), the combination of ThermoDox® and standardized RFA provided a 59% improvement in OS compared to optimized RFA alone. The Hazard Ratio at this latest quarterly OS analysis is 0.628 (95% CI 0.420 - 0.939) with a p-value of 0.02. These data continue to strongly suggest that ThermoDox® may significantly improve overall survival compared to a RFA control in patients whose lesions undergo optimized RFA treatment for 45 minutes or more. These findings apply to patients with single HCC lesions (64.4% of the HEAT Study population) from both size cohorts of the HEAT Study (3-5 cm and 5-7 cm) and represent a subgroup of 285 patients. Median overall survival for the subgroup has not yet been reached. We may choose to end this analysis of overall survival once the median is reached for both arms of the study.

Data from the HEAT Study post-hoc analysis have been presented at five scientific and medical conferences in 2013 and 2014 by key HEAT Study investigators and leading liver cancer experts. The presentations include:

- World Conference on Interventional Oncology in May 2013
- European Conference on Interventional Oncology in June 2013 and April 2014
- International Liver Cancer Association Annual Conference in September 2013 and 2014
- American Society of Clinical Oncology 50th Annual Meeting in June 2014

We also completed computational modeling with supplementary prospective preclinical animal studies supporting the relationship between heating duration and clinical outcomes.

On February 24, 2014, we announced that the U.S. Food and Drug Administration (FDA), after its customary 30 day review period, accepted without comment, subject to compliance with regulatory standards, our pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox®, our proprietary heat-activated liposomal encapsulation of doxorubicin in combination with RFA in primary liver cancer, also known as HCC (the OPTIMA Study). The OPTIMA Study trial design is based on the comprehensive analysis of data from the HEAT study, which, as described previously, demonstrated that treatment with ThermoDox® resulted in a 59% improvement in overall survival in a large number of HCC patients that received an optimized RFA treatment for longer than 45 minutes. Designed with extensive input from globally recognized HCC researchers and clinicians and, after formal written consultation with the FDA, the OPTIMA Study was launched in the first half of 2014. The OPTIMA Study is expected to enroll up to 550 patients globally at up to 100 sites in the United States, Europe, China and elsewhere in the Asia Pacific region, and will evaluate ThermoDox® in combination with standardized RFA, which will require a minimum of 45 minutes across all investigators and clinical sites for treating lesions 3 to 7 centimeters, versus standardized RFA alone. The primary endpoint for the trial is overall survival, and the secondary endpoints for the trial are PFS and Safety. The statistical plan calls for two interim efficacy analyses by an independent DMC.

In addition, the Company has met with the China State Food and Drug Administration (CHINA FDA) to discuss the OPTIMA Phase III Study including minimum patient enrollment requirements supporting the registration of ThermoDox® in China. Based on those discussions, we have submitted an application for accelerated approval of the OPTIMA Study in China. We also filed a request for a Voluntary Harmonization Procedure (VHP) in Europe, which provides for the assessment of multinational clinical trial applications across several European countries, including Germany, Italy and Spain. Our request for a VHP in Europe was approved on October 23, 2014.

On June 20, 2014, we completed the acquisition of substantially all of the assets of EGEN, Inc., an Alabama Corporation (EGEN), pursuant to an Asset Purchase Agreement. CLSN Laboratories, Inc., a Delaware corporation and a wholly-owned subsidiary of ours (CLSN Laboratories), acquired all of EGEN's right, title and interest in and to substantially all of the assets of EGEN, including cash and cash equivalents, patents, trademarks and other intellectual property rights, clinical data, certain contracts, licenses and permits, equipment, furniture, office equipment, furnishings, supplies and other tangible personal property. In addition, CLSN Laboratories assumed certain specified liabilities of EGEN, including the liabilities arising out of the acquired contracts and other assets relating to periods after the closing date. The consideration of the acquisition include an initial payment of approximately $3.0 million in cash plus 2.7 million shares of Celsion's common stock. Additional consideration included contingent value rights totaling $30.4 million, payable in cash, shares of Celsion common stock or a combination thereof, at Celsion's option, upon acheivement of three major milestone events as follows:

a) Certain specified development milestones relating to GEN-1 to treat ovarian cancer patients ($12.0 million);

b) Certain specified development milestones relating to GEN-1 to treat GBM cancer patients ($12.0 million); and

c) A self-liquidating payment of 50% of all fees received from the licensing of TherSilence (up to $6.0 million).

With the acquisition, we purchased GEN-1 (formerly known as EGEN-001), a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers, and three platform technologies for the development of treatments for those suffering with difficult-to-treat forms of cancer, novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlas™ and TheraSilence™. In February 2015, we announced that the FDA accepted, without comment, the Phase I dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer. The clinical trial will identify a safe, tolerable and potentially therapeutically active dose of GEN-1 while maximizing an immune response. The trial is designed to enroll three to six patients per dose level and will evaluate safety and efficacy and attempt to define an optimal dose to carry forward into a Phase II trial. We expect to initiate enrollment for the trial in the second half of 2015 at five to six U.S. clinical centers.

In 2007, we sold our medical device franchise to Boston Scientific Corporation for net aggregate payments of $43 million, receiving $13 million in 2007 and $15 million in each of 2008 and 2009. Since this divesture, we have dedicated our efforts and resources to the development and commercialization of cancer drugs including tumor-targeting chemotherapy treatments using focused heat energy in combination with heat-activated drug delivery systems, immunotherapies and RNA-based therapies. To support our research and development, we raised gross proceeds of approximately $95 million in equity financings and warrant and option exercises in the years 2009 through 2013. In January 2014, we raised net proceeds of $14 million through an equity financing. We had cash, cash equivalents, short-term investments and interest receivable totaling $37 million at the end at December 31, 2014. We have one credit facility for a total principle amount of up to $20 million and have drawn down $10 million under this credit facility.

On December 5, 2008, we entered into a development, product supply and commercialization agreement with Yakult Honsha Co., Ltd. (the Yakult Agreement) under which we granted Yakult an exclusive right to commercialize and market ThermoDox® for the Japanese market. We received a $2.5 million upfront 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. 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, which included $2.0 million paid to us 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 agreed to reduce future drug approval milestone payments by approximately 40%. All other milestone payments were unaffected.

On May 6, 2012, we entered into a long-term commercial supply agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. (Hisun) for the production of ThermoDox® in mainland China, Hong Kong and Macau (the China territory). Hisun will be responsible for providing all of the technical and regulatory support services for the manufacture of ThermoDox® in the China territory and we will repay Hisun the related development costs and fees, which we expect to be approximately $1.2 million in total, commencing on the successful completion of three registrational batches of ThermoDox®. In March 2015, results of stability tests performed by Hisun demonstrated it successfully completed three registration batches of ThermoDox®, all of which show substantial chemical equivalence with investigational product produced by the Company’s current contract manufacturer. We plan to qualify and seek regulatory approval for HISUN to serve as an approved manufacturer for China and Europe.

On January 18, 2013, we broadened our relationship with Hisun by entering into a technology development contract, pursuant to which Hisun paid us a non-refundable research and development fee of $5.0 million to support our development of ThermoDox®. Following our announcement of the HEAT Study results on January 31, 2013, we and Hisun agreed that the technology development contract entered into on January 18, 2013 will remain in effect while the parties continue to collaborate the next steps in relation to ThermoDox®, which include the continued subgroup analysis of the Chinese cohort of patients in the HEAT Study for primary liver cancer and other activities to further the development of ThermoDox® for the China territory.

On July 19, 2013, we and Hisun entered into a Memorandum of Understanding to pursue ongoing collaborations for the continued clinical development of ThermoDox® and the technology transfer relating to the commercial manufacture of ThermoDox® for the China territory. This expanded collaboration includes development of the next generation liposomal formulation with the goal of creating safer, more efficacious versions of marketed cancer chemotherapeutics.

As a result of the risks and uncertainties discussed in this Annual Report on Form 10-K, among others, we are unable to estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete any of

our research and development activities, preclinical studies or clinical trials in a timely manner or our failure to enter into collaborative agreements when appropriate could significantly increase our capital requirements and could adversely impact our liquidity. While our estimated future capital requirements are uncertain and could increase or decrease as a result of many factors, including the extent to which we choose to advance our research, development activities, preclinical studies and clinical trials, or if we are in a position to pursue manufacturing or commercialization activities, we will need significant additional capital to develop our product candidates through development and clinical trials, obtain regulatory approvals and manufacture and commercialize approved products, if any. We do not know whether we will be able to access additional capital when needed or on terms favorable to us or our stockholders. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.