

Celsion CORP
Form 8-K
February 26, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 21, 2013

CELSION CORPORATION

(Exact name of registrant as specified in its Charter)

Delaware **001-15911** **52-1256615**
(State or other jurisdiction **(Commission** **(IRS Employer**
of incorporation) **File Number)** **Identification No.)**

997 Lenox Drive, Suite 100, Lawrenceville, NJ 08648-2311
(Address of principal executive offices) (Zip Code)

(609) 896-9100

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))



Item 1.01 Entry into a Material Definitive Agreement.

On February 22, 2013, Celsion Corporation, a Delaware corporation (Celsion), entered into a Securities Purchase Agreement (the Purchase Agreement) with certain institutional investors, pursuant to which Celsion agreed to sell, in a registered offering, an aggregate of 15,000.00422 shares of its Series A 0% convertible preferred stock, par value \$0.01 per share (Series A Preferred Stock), and the Common Stock Purchase Warrants (the Warrants) to purchase shares of its common stock, par value \$0.01 per share (Common Stock), for an aggregate purchase price of \$15,000,004.22 (the Offering). The closing of the Offering is expected to occur on or about February 26, 2013, subject to satisfaction of customary closing conditions set forth in the Purchase Agreement. The Purchase Agreement also contains representations, warranties, indemnification and other provisions customary for transactions of this nature.

Subject to certain ownership limitations, shares of Series A Preferred Stock are convertible, at the option of the holder thereof, into an aggregate of up to 12,072,438 shares of Common Stock, and the Warrants are exercisable to purchase an aggregate of up to 6,036,219 shares of Common Stock (equal to 50% of the shares of Common Stock issuable upon conversion of Series A Preferred Stock). Each Warrant has an exercise price of \$1.18 per share, equal to the closing bid price of Common Stock on February 21, 2013. The Warrants are immediately exercisable and expire five years after its issuance.

The issuance of Series A Preferred Stock, the Warrants and Common Stock issuable upon conversion or exercise thereof will be made pursuant to Celsion 's previously filed and effective Registration Statement on Form S-3 (File No. 333-183286), the base prospectus dated September 14, 2012, filed as part of such Registration Statement, and the prospectus supplement dated February 22, 2013. This Current Report on Form 8-K shall not constitute an offer to sell or the solicitation of an offer to buy securities, nor shall there be any sale of securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

On February 21, 2013, Celsion entered into a letter agreement with Dawson James Securities, Inc. (the Placement Agent), pursuant to which the Placement Agent agreed to serve as the exclusive investment bank for Celsion in connection with the proposed offerings by Celsion of its registered or unregistered securities, including the Offering. Celsion agreed to pay the Placement Agent a cash placement fee equal to 7.5% of the aggregate purchase price for the securities sold in such offerings.

The foregoing descriptions of the Purchase Agreement, the Warrants and the letter agreement with the Placement Agent are subject to, and qualified in their entirety by, such documents attached hereto as Exhibits 10.1, 4.1 and 1.1, respectively, which are incorporated herein by reference.

A copy of the opinion of O Melveny & Myers LLP relating to the legality of the securities issued in the Offering is attached hereto as Exhibit 5.1. A copy of the consent of Stegman & Company, independent registered public accounting firm for Celsion, is attached hereto as Exhibit 23.2.

Item 3.03 Material Modifications to Rights of Security Holders.

On February 25, 2013, Celsion filed the Certificate of Designation of Preferences, Rights and Limitations of Series A 0% Convertible Preferred Stock (the Certificate of Designation) with the Secretary of State of the State of Delaware, establishing and designating the Series A Preferred Stock. Each share of Series A Preferred Stock has a stated value of \$1,000. Each share of Series A Preferred Stock is convertible, at any time at the option of the holder thereof, into a number of shares of Common Stock determined by dividing the stated value by the conversion price of \$1.2425, subject to a 9.99% blocker provision. The conversion price equals the sum of \$1.18, the closing bid price of Common Stock on February 21, 2013, and \$0.0625. Series A Preferred Stock has no dividend rights, liquidation preference or other preferences over Common Stock and has no voting rights except as provided in the Certificate of Designation or as otherwise required by law. A copy of the Certificate of Designation is attached hereto as Exhibit 3.1 and incorporated herein by reference. The foregoing description of the Certificate of Designation is qualified in its entirety by reference to Exhibit 3.1 attached hereto.

Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

On February 25, 2013, Celsion filed the Certificate of Designation, a copy of which is attached hereto as Exhibit 3.1 and incorporated herein by reference. The Certificate of Designation, effective as of February 25, 2013, establishes and designates the Series A Preferred Stock and the rights, preferences, privileges and limitations thereof.

Item 8.01 Other Events.

We are filing the following information with the Securities and Exchange Commission for the purpose of updating certain aspects of our publicly disclosed descriptions of our risk factors. All references below to Celsion Corporation, Celsion, the Company, we, us, our and similar terms refer to Celsion Corporation, a Delaware corporation, unless context otherwise requires.

Risks Related to Our Business

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

Since our inception, our expenses have substantially exceeded our revenues, resulting in continuing losses and an accumulated deficit of \$124.2 million at December 31, 2011. We incurred a net loss of \$23.2 million for the year ended December 31, 2011 and a net loss of \$18.3 million for the nine months ended September 30, 2012. We presently have no product revenues and 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 U.S. Food and Drug Administration (FDA) and successfully marketed.

Drug development is an inherently 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. Drug development is very risky. It will take us several years to complete clinical trials. The start or end of a clinical trial 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 including insufficient efficacy, safety concerns, or our own financial constraints. On January 31, 2013, we announced that our lead product ThermoDox® in combination with radiofrequency ablation failed to meet the primary endpoint of the Phase III clinical trial for primary liver cancer (the HEAT study). We have not completed our analysis of the data and do not know the extent to which, if any, the failure of ThermoDox® to meet its primary endpoint in the Phase III trial could impact our other ongoing studies of ThermoDox®. ThermoDox® is also being evaluated in a Phase II clinical trial for colorectal liver metastasis, a Phase II clinical trial for recurrent chest wall breast cancer and other preclinical studies. Even with success in preclinical testing and previously completed clinical trials, the risk of clinical failure for any drug candidate remains high prior to regulatory approval. Even if ThermoDox® has positive results in its Phase II clinical trials, there is a substantial risk

that it will fail to have sufficiently positive results in Phase III clinical trials with regard to efficacy, safety or other clinical outcomes. One or more of our clinical studies could fail at any time, as evidenced by the failure of ThermoDox® to meet its primary endpoint in the HEAT study. The failure of one or more of our drug candidates or development programs could have a material adverse effect on our business, financial condition and results of operations.

If we do not obtain or maintain FDA and foreign 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 foreign 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 foreign 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 trials, 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.

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 and if our products are clinically tested, approved by the FDA or foreign regulatory agencies and successfully marketed. We cannot guarantee that any of our products will be successfully tested, approved by the FDA or foreign regulatory agencies 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 September 30, 2012, we had approximately \$22.7 million in cash, cash equivalents and short-term investments and related accrued interest on the short term investments. We have substantial future capital requirements to continue our research and development activities and advance our drug candidates through various development stages. For example, ThermoDox® is being evaluated in a Phase II clinical trial for colorectal liver metastasis, a Phase II clinical trial for recurrent chest wall breast cancer and other preclinical studies. We will conduct additional analyses of the data from the HEAT study to assess the future strategic value of ThermoDox® and are performing sub-group analysis of the Chinese cohort of patients in the HEAT study and other activities for further development of ThermoDox® for mainland China, Hong Kong and Macau. To complete the development and commercialization of our products, 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 and foreign regulatory agencies, 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.

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. Additionally, we have 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. If we breach any provisions of the license and research agreements, we may 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. Any loss of trade secret protection or other unpatented proprietary rights could harm our business, results of operations and financial condition.

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.

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

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

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

Many states in which we do or may do business in the future, 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 could 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 payors 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. health care system.

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

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

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

The commercial success of our products will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost effective and safe. Any or our drug candidates 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 clinical 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, which would have an adverse effect on our business, financial condition and results of operations.

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 predict 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 payor 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.

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.

If we engage in acquisitions, reorganizations or business combinations, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

We may consider strategic alternatives intended to further the development of our business, which may include acquiring businesses, technologies or products or entering into a business combination with another company. If we do pursue such a strategy, we could, among other things

issue equity securities that would dilute our current stockholders' percentage ownership;

incur substantial debt that may place strains on our operations;

spend substantial operational, financial and management resources in integrating new businesses, technologies and products;

assume substantial actual or contingent liabilities;

reprioritize our development programs and even cease development and commercialization of our drug candidates; or

merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company or a combination of both on terms that certain of our stockholders may not deem desirable.

Although we intend to evaluate and consider different strategic alternatives, we have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time.

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 the FDA and other regulatory approvals. One or more of these companies or institutions could succeed in developing products or other technologies that are more effective than the products and technologies that we have been or are developing, or which would render our technology and products obsolete and non-competitive. Furthermore, if we are permitted to commence commercial sales of any of our products, we will also be competing, with respect to manufacturing efficiency and marketing, with companies having substantially greater resources and experience in these areas.

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

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

Risks Related to Our Securities

We do not generate operating income and will require additional financing in the future. If additional capital is not available, we may have to curtail or cease operations.

Our business currently does not generate the cash necessary to finance our operations. Since our inception, our expenses have substantially exceeded our revenues, resulting in continuing losses and an accumulated deficit of \$124.2 million at December 31, 2011. We incurred a net loss of \$23.2 million for the year ended December 31, 2011 and a net loss of \$18.3 million for the nine months ended September 30, 2012. We presently have no product revenue. We may need to raise additional capital to fund research and development and to develop and commercialize our products. Our future capital needs depend on many factors, including the scope, duration and expenditures associated with our clinical trials, the outcome of potential licensing transactions, if any, competing technological developments and the regulatory approval process for our products.

We may seek to raise necessary funds through public or private equity offerings, debt financings or additional strategic alliances and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. The failure of the HEAT study to demonstrate clinical effectiveness, in addition to general market conditions, may make it very difficult for us to seek financing from the capital markets. We may be required to relinquish rights to our technologies or products, or grant licenses on terms that are not favorable to us, in order to raise additional funds through alliance, joint venture or licensing arrangements. If adequate funds are not available, we may have to delay, reduce or eliminate one or more of our research or development programs and reduce overall overhead expense. Such events could cause our independent registered public accounting firm to indicate that there may be substantial doubt about our ability to continue as a going concern in future periods.

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 of our common stock has been, and we expect it to continue to be, volatile. The failure of the HEAT study to demonstrate clinical effectiveness has resulted in significant volatility and a steep decline in the price of our common stock, a level of decline that may result in securities litigation. As of January 31, 2013, at least one plaintiffs securities litigation firm publicly announced that it is investigating potential securities fraud claims that it may wish to make against us. 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 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 prospects. The closing price of 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, and a high price of

\$8.83 and a low price of \$1.64 in the 52-week period ended December 31, 2012. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this Risk Factors section and other factors, including:

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

variance in our financial performance from the expectations of investors;

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

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

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

conditions and trends in the markets we serve;

changes in general economic, industry and market conditions;

success of competitive products and services;

changes in market valuations or earnings of our competitors;

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

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

changes in legislation or regulatory policies, practices or actions;

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

recruitment or departure of key personnel;

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

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

the trading volume of our common stock.

In addition, the stock markets 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.

Our stockholders may experience significant dilution as a result of future equity offerings or issuances and exercise of outstanding options and warrants.

In order to raise additional capital or pursue strategic transactions, we may in the future offer, issue or sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock. Our stockholders may experience significant dilution as a result of future equity offerings or issuance. Investors purchasing shares or other securities in the future could have rights superior to existing stockholders. In addition, we have a significant number of securities convertible into, or allowing the purchase of, our common stock, including 10,166,261 shares of common stock issuable upon exercise of warrants outstanding as of September 30, 2012. As of

September 30, 2012, 2,536,191 shares of common stock were reserved for future issuance under our stock incentive plans. As of that date, there were also 3,477,143 options to purchase shares of our common stock and restricted stock awards outstanding.

Future sales of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of September 30, 2012, we had 34,792,207 shares of common stock outstanding, all of which shares, other than shares held by our directors and certain officers, were eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including the volume limitations and manner of sale requirements. In addition, all of the shares of common stock issuable upon exercise of warrants will be freely tradable without restriction or further registration upon issuance.

We have never paid dividends on our common stock and we do not anticipate paying cash dividends on our common stock in the foreseeable future.

We have never declared or 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.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

We currently have significant net operating losses (NOLs) that may be used to offset future taxable income. In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code, which would significantly limit our ability to utilize NOLs to offset future taxable income.

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.

In April 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.

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 experienced extreme volatility and disruption in recent years. 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.

Anti-takeover provisions in our charter documents and Delaware law could prevent or delay a change in control.

Edgar Filing: Celsion CORP - Form 8-K

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. 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.

Safe Harbor Statement

This Current Report on Form 8-K contains forward-looking statements. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of risks and uncertainties, including, without limitation, unforeseen changes in the course of Celsion’s research and development activities and clinical trials; the satisfaction of the closing conditions to the Offering; the conversion of Series A Preferred Stock or exercise of the Warrants, if issued; any increase in Celsion’s cash needs; possible actions by customers, suppliers, competitors or regulatory authorities; and other risks detailed from time to time in Celsion’s periodic reports filed with the Securities and Exchange Commission. Celsion undertakes no obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

No.	Description
1.1	Letter agreement dated as of February 21, 2013, by and between Celsion Corporation and Dawson James Securities, Inc.
3.1	Certificate of Designation of Preferences, Rights and Limitations of Series A 0% Convertible Preferred Stock.
4.1	Form of Common Stock Purchase Warrant.
5.1	Opinion of O Melveny & Myers LLP.
10.1	Form of Securities Purchase Agreement dated as of February 22, 2013, by and among Celsion Corporation and the purchasers named therein.
23.1	Consent of O Melveny & Myers LLP (included in Exhibit 5.1).
23.2	Consent of Stegman & Company, independent registered public accounting firm for Celsion Corporation.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CELSION CORPORATION

Dated: February 26, 2013 By: */s/ Gregory Weaver*
Gregory Weaver
Senior Vice President and Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
1.1	Letter agreement dated as of February 21, 2013, by and between Celsion Corporation and Dawson James Securities, Inc.
3.1	Certificate of Designation of Preferences, Rights and Limitations of Series A 0% Convertible Preferred Stock.
4.1	Form of Common Stock Purchase Warrant.
5.1	Opinion of O Melveny & Myers LLP.
10.1	Form of Securities Purchase Agreement dated as of February 22, 2013, by and among Celsion Corporation and the purchasers named therein.
23.1	Consent of O Melveny & Myers LLP (included in Exhibit 5.1).
23.2	Consent of Stegman & Company, independent registered public accounting firm for Celsion Corporation.