

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 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): **January 13, 2015**

**CELSION CORPORATION**

(Exact Name of Registrant as Specified in Charter)

**Delaware**

(State or Other Jurisdiction of Incorporation)

**001-15911**

(Commission File Number)

**52-1256615**

(IRS Employer Identification No.)

**997 Lenox Drive, Suite 100**

**Lawrenceville, NJ 08648-2311**

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (609) 896-9100

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:

- 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))
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## Item 1.01 Entry into a Material Definitive Agreement

On January 13, 2015, Celsion Corporation (“Celsion” or the “Company”), entered into an Early Access Agreement (the “Agreement”) with Impatiens N.V., a company formed and registered under the laws of The Netherlands (“Impatiens”). Pursuant to the Agreement, Impatiens will develop and execute through its brand myTomorrows an “early access program” (the “Early Access Program”) for ThermoDox<sup>®</sup>, the Company’s proprietary heat-activated liposomal encapsulation of doxorubicin, in all countries of the European Union (EU) territory, and in Iceland, Liechtenstein, Norway and Switzerland (the “Territory”) for the treatment of patients with recurrent chest wall (“RCW”) breast cancer. Under the Early Access Program, Impatiens will engage in activities to secure authorization, exemption or waiver from regulatory authorities for patient use of ThermoDox<sup>®</sup> that may otherwise be subject to approvals from such regulatory authority before its sale and distribution. The Company will be responsible for the manufacture and supply of quantities of ThermoDox<sup>®</sup> to Impatiens for use in such Early Access Programs and Impatiens will distribute and sell ThermoDox<sup>®</sup> pursuant to such authorization, exemptions or waivers.

Under the terms of the Agreement, the Company granted to Impatiens specifically for the treatment of RCW breast cancer in the Territory, an exclusive, royalty-free right to perform the Early Access Program activities, reference regulatory documentation and approvals that the Company owns, and use the Company’s trademarks relating to ThermoDox<sup>®</sup>. The parties agreed to share applicable clinical and non-clinical data and cooperate on pharmacovigilance activities. In addition, the Company granted to Impatiens an option to negotiate an exclusive license to distribute ThermoDox<sup>®</sup> in the Territory, after ThermoDox<sup>®</sup> receives regulatory approval in a country within the Territory.

In consideration for Impatiens’ services to implement the Early Access Program and in the event the Company receives regulatory authorization to sell, distribute or market ThermoDox<sup>®</sup> in the Territory, the Company is obligated to pay Impatiens, subject to a maximum cap, a low single-digit royalty of net sales of ThermoDox<sup>®</sup> in the countries where such regulatory authorization has been obtained. The term of the Agreement is for a period of five years, with automatic renewals for consecutive two-year periods, unless earlier terminated by either party with notice or in the event of material breach, bankruptcy, or insolvency without notice.

Under the Agreement, the parties agreed to establish a joint steering committee which will oversee the Early Access Program, resolve disputes, and coordinate the parties’ activities. The Agreement contains various representations, warranties, covenants, indemnities, confidentiality provisions, and other provisions customary for transactions of this nature.

The foregoing summary is qualified in its entirety by reference to the Agreement, a copy of which will be filed as an exhibit to Celsion’s Quarterly Report on Form 10-Q for the period ended March 31, 2015.

## FORWARD LOOKING STATEMENTS

In this Form 8-K, certain forward-looking statements are made regarding the Early Access Program and ThermoDox<sup>®</sup>. Such forward-looking statements involve significant risks and uncertainties including, without limitation, ThermoDox<sup>®</sup> is an investigational and not an approved drug, unforeseen changes in the course of research and development activities, in clinical trials, and the Early Access Program; the uncertainties of and difficulties in analyzing interim clinical data, particularly in subgroups that are not statistically significant; FDA and regulatory uncertainties and risks; the significant expense, time, and risk of failure of conducting clinical trials; the need for Celsion to evaluate its future development plans; possible acquisitions or licenses of other technologies, assets or businesses or the possible failure to make such acquisitions or licenses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Celsion's periodic reports and prospectuses filed with the Securities and Exchange Commission. Celsion assumes no obligation to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

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**Item 7.01. Regulation FD Disclosure**

On January 20, 2015, Celsion issued a press release announcing entry into the Agreement, which is filed herewith as Exhibit 99.1 to this Current Report. The information in this Item 7.01, including Exhibit 99.1, is being furnished and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall such information be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise stated in such filing.

**Item 9.01 Financial Statements and Exhibits****(d) Exhibits****Exhibit      Description**

99.1	Press Release titled "Celsion Corporation and myTomorrows Partner to Introduce ThermoDox <sup>®</sup> Early Access Program in Europe for Patients with Recurrent Chest Wall Breast Cancer" issued by Celsion Corporation on January 20, 2015.
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**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

Date: January 20, 2015

By: /s/ Jeffrey W. Church  
Jeffrey W. Church  
Senior Vice President and  
Chief Financial Officer

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## EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Description</b>
99.1	Press Release titled "Celsion Corporation and myTomorrows Partner to Introduce ThermoDox <sup>®</sup> Early Access Program in Europe for Patients with Recurrent Chest Wall Breast Cancer" issued by Celsion Corporation on January 20, 2015.



## **Celsion Corporation and myTomorrows Partner to Introduce ThermoDox® Early Access Program in Europe for Patients with Recurrent Chest Wall Breast Cancer**

**Lawrenceville, NJ** -- January 20, 2015 /PR Newswire/ -- Celsion Corporation (NASDAQ:CLSN), a fully-integrated oncology company focused on the development of a portfolio of innovative cancer treatments, today announced that it has signed a license and distribution agreement with myTomorrows to implement an Early Access Program for ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin, in all countries of the European Union (EU) territory plus Switzerland for the treatment of patients with recurrent chest wall (RCW) breast cancer.

RCW breast cancer is difficult to treat and has a poor prognosis with a significant impact on a patient's quality of life. Patients with highly resistant tumors found on the chest wall often see their cancer progress despite previous treatment attempts including chemotherapy, radiation therapy and hormone therapy. There are approximately 25,000 to 35,000 incidence of RCW breast cancer in the EU alone and thermal therapy is a well-accepted strategy for treating patients. Recent findings from two Phase I studies and an ongoing open label Phase II study indicate that when combined with thermal therapy, ThermoDox can demonstrate significant overall response rates and tumor control in post mastectomy, refractory patients.

Early Access Programs (EAP) allow biopharmaceutical companies to provide eligible patients with ethical access to investigational medicines for unmet medical needs within the scope of the existing early access legislation. Access is provided in response to physician requests in a fully compliant manner, where no alternative treatment options are available to these patients. Celsion will provide ThermoDox® to centers of excellence in the EU and Switzerland through its Early Access Program with myTomorrows, at prices that are comparable to chemotherapeutics used to treat this and other aggressive form of cancer. The Company expects to have ThermoDox® available for the EAP in the second quarter of 2015.

"We are very excited to make ThermoDox® available to patients with breast cancer who have few options once the tumors have progressed to the chest wall. Patients with highly resistant tumors found on the chest wall often see their cancer progress despite treatment which typically involves chemotherapy, radiation therapy and hormone therapy," stated Dr. Nicolas Borys, Celsion's Senior Vice President and Chief Medical Officer. "ThermoDox® coupled with mild hyperthermia therapy appears to be active in these heavily pre-treated patients with RCW breast cancer. I look forward to working with prescribing physicians and myTomorrows to bring this promising and innovative medicine to the European medical community."

"Celsion is honored and proud to be part of this important Early Access Program that affects the lives of thousands of women each year. This Early Access Program emphasizes our commitment to addressing refractory RCW breast cancer and to providing patients and their physicians with early access to our promising therapeutic approach," said Michael H. Tardugno, Celsion's Chairman, President and Chief Executive Officer. "In addition to the Early Access Program, we are expanding our development efforts in this indication and plan to initiate a European-based Phase II clinical trial in RCW breast cancer patients. Our common goal is to develop and provide the most effective therapies to improve and prolong the quality of life."

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## **About ThermoDox®**

ThermoDox® is a proprietary heat-activated liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. ThermoDox® is being evaluated in a Phase III clinical trial for primary liver cancer and a Phase II clinical trial for recurrent chest wall breast cancer. Localized mild hyperthermia (39.5 - 42 degrees Celsius) releases the entrapped doxorubicin from the liposome. This delivery technology enables high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

## **About myTomorrows**

myTomorrows is an online patient platform that is creating freedom of choice for patients with unmet medical needs by offering earlier access to medicines that show promising results during clinical trials, but are not officially registered yet. With the support of their doctors, patients who suffer from cancer, a neurological disorder, a rare disease or a severe depression, can have earlier access to such medicines. For more information about myTomorrows, please visit the website [www.mytomorrows.com](http://www.mytomorrows.com).

## **About Celsion Corporation**

Celsion is a fully-integrated oncology company focused on developing a portfolio of innovative cancer treatments, including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies. The Company's lead program is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in Phase III development for the treatment of primary liver cancer and in Phase II development for the treatment of RCW breast cancer. The pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers. Celsion has three platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlas™, TheraSilence™ and RAST™. For more information on Celsion, visit our website: <http://www.celsion.com>.

*Celsion wishes to inform readers that forward-looking statements in this release are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned that such forward-looking statements involve significant risks and uncertainties including, without limitation, ThermoDox® is an investigational and not an approved drug, unforeseen changes in the course of research and development activities, in clinical trials, and the EAP; the uncertainties of and difficulties in analyzing interim clinical data, particularly in small subgroups that are not statistically significant; FDA and regulatory uncertainties and risks; the significant expense, time, and risk of failure of conducting clinical trials; the need for Celsion to evaluate its future development plans; possible acquisitions or licenses of other technologies, assets or businesses or the possible failure to make such acquisitions or licenses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Celsion's periodic reports and prospectuses filed with the Securities and Exchange Commission. Celsion assumes no obligation to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.*

## **Celsion Investor Contact**

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