Celsion CORP
Form 8-K
January 20, 2015
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	**001-15911**	**52-1256615**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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))

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 Impatients N.V., a company formed and registered under the laws of The Netherlands ("Impatients"). Pursuant to the Agreement, Impatients will develop and execute through its brand myTomorrows an "early access program" (the "Early Access Program") for ThermoDox®, 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, Impatients will engage in activities to secure authorization, exemption or waiver from regulatory authorities for patient use of ThermoDox® 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® to Impatients for use in such Early Access Programs and Impatients will distribute and sell ThermoDox® pursuant to such authorization, exemptions or waivers.

Under the terms of the Agreement, the Company granted to Impatients 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®. The parties agreed to share applicable clinical and non-clinical data and cooperate on pharmacovigilance activities. In addition, the Company granted to Impatients an option to negotiate an exclusive license to distribute ThermoDox® in the Territory, after ThermoDox® receives regulatory approval in a country within the Territory.

In consideration for Impatients' services to implement the Early Access Program and in the event the Company receives regulatory authorization to sell, distribute or market ThermoDox® in the Territory, the Company is obligated to pay Impatients, subject to a maximum cap, a low single-digit royalty of net sales of ThermoDox® 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®. 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 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.

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® Early Access Program in Europe for Patients with Recurrent Chest Wall Breast Cancer" issued by Celsion Corporation on January 20, 2015.

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

EXHIBIT INDEX

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