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): July 13, 2020 (July 9, 2020)

CELSION CORPORATION
(Exact name of registrant as specified in its 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)	(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))

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value $0.01 per share	CLSN	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Item 8.01 Other Events

On July 13, 2020, Celsion Corporation (the "Company") issued a press release announcing that it had received a recommendation from the independent Data Monitoring Committee (the "DMC") to consider stopping the Phase III OPTIMA Study of ThermoDox® in combination with radiofrequency ablation for the treatment of hepatocellular carcinoma, or primary liver cancer (the "Study"). As further described below and in the press release, this recommendation is based on the July 9, 2020 pre-planned interim safety and efficacy analysis conducted by the DMC.

The recommendation was made following the second pre-planned interim safety and efficacy analysis by the DMC on July 9, 2020. The DMC analysis found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903. However, the 2-sided p-value of 0.524 for this analysis provides uncertainty, subsequently, the DMC has left the final decision of whether to stop the OPTIMA Study to Celsion. There were no safety concerns noted during the interim analysis. A copy of the press release is attached hereto as Exhibit 99.1, and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated July 13, 2020, announcing the DMC recommendation

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: July 13, 2020

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

Exhibit 99.1

Celsion Corporation Receives Recommendation from Independent Data Monitoring Committee to Consider Stopping the Phase III OPTIMA Study

Recommendation Based on DMC's Finding Following the Second Pre-Planned Interim Analysis that the OPTIMA Study is Unlikely to Meet its Primary Efficacy Endpoint of Overall Survival

Celsion to Conduct a Thorough Analysis of the Unblinded Study Data Before Making a Final Determination

Conference Call to be Held Wednesday, July 15

LAWRENCEVILLE, N.J. (July 13, 2020) – Celsion Corporation (NASDAQ: CLSN), an oncology focused drug-development company, today announced that it has received a recommendation from the independent Data Monitoring Committee (DMC) to consider stopping the global Phase III OPTIMA Study of ThermoDox® in combination with radiofrequency ablation (RFA) for the treatment of hepatocellular carcinoma (HCC), or primary liver cancer.

The recommendation was made following the second pre-planned interim safety and efficacy analysis by the DMC on July 9, 2020. The DMC analysis found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903. However, the 2-sided p-value of 0.524 for this analysis provides uncertainty, subsequently, the DMC has left the final decision of whether or not to stop the OPTIMA Study to Celsion. There were no safety concerns noted during the interim analysis.

"We are surprised and disappointed that the OPTIMA Study results were not found to be more robust at this analysis. Nonetheless, we intend to follow the advice of the DMC and will consider our options either to stop the study or continue to follow patients after a thorough review of the data, and an evaluation of our probability of success. Timing for this decision is made less urgent by the fact that the OPTIMA Study has been fully enrolled since August 2018 and that the vast majority of the trial expenses have already been incurred," stated Michael H. Tardugno, Celsion's chairman, president and chief executive officer.

"This, of course, is inconclusive and difficult news for the medical community, HCC patients and our shareholders, and confirms the complexity and challenge of treating primary liver cancer," he added. "The present development had never been anticipated by the Company or our advisors based on both the first pre-planned efficacy analysis and on tracking against the sub-group analysis of the Company's earlier HEAT Study upon which the OPTIMA Study is based. We will conduct additional analyses of the unblinded data from the trial to better understand the results and to develop our plan going forward. As always, we wish to acknowledge and thank all the patients and investigators for their participation in the trial."

The OPTIMA Study is a global, randomized, double-blind, placebo-controlled clinical trial assessing the efficacy of ThermoDox® in combination with RFA, which was standardized to a minimum of 45 minutes for treating patients with a lesion 3-7 cm in size, versus standardized RFA alone. The OPTIMA Study enrolled 554 patients at 65 clinical sites in North America, Europe, China and Asia Pacific. In addition to the primary overall survival endpoint, progression-free survival, time to disease progression, and safety are key secondary endpoints.

The statistical plan for the OPTIMA Study included two interim efficacy analyses by the DMC. The first interim analysis was announced in November 2019 following data lock in August 2019 after the prescribed minimum number of 128 patient events (deaths) was reached, and the second interim analysis was conducted in July 2020 following data lock in April 2020 after the prescribed minimum number of 158 events was reached.

Conference Call and Webcast

Celsion will be holding a conference call and webcast on Wednesday, July 15 to discuss its current observations about the results of the OPTIMA Study, the DMC's recommendations and the Company's next steps. Further information regarding the time of the call and dial-in instructions will be provided separately.

About ThermoDox®

Celsion's most advanced program is a heat-mediated drug delivery technology that employs a novel heat-sensitive liposome engineered to address a range of difficult-to-treat cancers. The first application of this platform is ThermoDox®, a lyso-thermosensitive liposomal doxorubicin (LTLD) whose novel mechanism of action delivers high concentrations of doxorubicin to a region targeted with the application of localized heat at 40°C, just above body temperature. ThermoDox® is positioned for use with multiple heating technologies and has the potential to treat of a broad range of cancers including metastatic liver, recurrent chest wall breast cancer and non-muscle invading bladder cancers.

Celsion's LTLD technology leverages two mechanisms of tumor biology to deliver higher concentrations of drug directly to the tumor site. In the first mechanism, rapidly growing tumors have leaky vasculature, which is permeable to liposomes and enables their accumulation within tumors. Leaky vasculature influences a number of factors within the tumor, including the access of therapeutic agents to tumor cells. Administered intravenously, ThermoDox® is engineered with a half-life to allow significant accumulation of liposomes at the tumor site as these liposomes recirculate in the blood stream.

In the second mechanism, when an external heating device heats tumor tissue to a temperature of 40°C or greater, the heat-sensitive liposome rapidly changes structure and the liposomal membrane selectively dissolves, creating openings that can release a chemotherapeutic agent directly into the tumor and the surrounding vasculature. Drug concentration increases as a function of the accumulation of liposomes at the tumor site, but only where the heat is present. This method damages only the tumor and the area subject to tumor invasion, supporting more precise drug targeting.

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 development for other cancer indications. The Company's product pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer. Celsion has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies.

Forward-looking Statements

Forward-looking statements in this news 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 risks and uncertainties including, without limitation, unforeseen changes in the course of research and development activities and in clinical trials; 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; possible actions by customers, suppliers, competitors or regulatory authorities; and other risks detailed from time to time in the Celsion's periodic filings 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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