Celsion CORP
Form 8-K
January 25, 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): January 18, 2013

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) (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 January 18, 2013, Celsion Corporation, a Delaware corporation ("Celsion"), entered into a Technology Development Contract (the "Development Contract") with Zhejiang Hisun Pharmaceutical Co., Ltd., a company organized under the laws of the PRC ("Hisun"), pursuant to which Hisun will pay Celsion a non-refundable research and development fee of $5 million to support Celsion's development of ThermoDox® and Celsion will provide research data and other technical support in relation to the regulatory filing by Hisun with the State Food and Drug Administration of the PRC ("SFDA") for approval of ThermoDox® for manufacturing and sale in mainland China, Hong Kong and Macau (the "Territory"). The $5 million non-refundable payment has been received by Celsion and comes in advance of Celsion's expected reporting of results from its pivotal Phase III trial (the HEAT Study) in hepatocellular carcinoma (HCC), also known as primary liver cancer, later in January 2013.

On January 18, 2013, Celsion and Hisun also entered into an exclusive option agreement, terminable at any time by Hisun, under which Celsion grants Hisun an option to enter into an exclusive license agreement (the "License Agreement") with Celsion for the manufacturing and commercialization of ThermoDox® with respect to all indications in the Territory under the terms and conditions set forth in the exclusive option agreement and other customary terms and conditions to be set forth in the License Agreement. Hisun has agreed to pay Celsion an additional $5 million within sixty days after the signing of the exclusive option agreement if it has not been terminated. The total $10 million Hisun has agreed to pay Celsion under the Development Contract and the exclusive option agreement will be credited towards the $25 million upfront license fee payable by Hisun to Celsion if they enter into the License Agreement. If Hisun elects to enter into the License Agreement and Celsion fails to do so, Celsion could be liable for liquidated damages.

The principal terms and conditions of the License Agreement, if entered into between Hisun and Celsion, contemplate that Hisun will pay Celsion an upfront license fee of $25 million, comprised of the aggregate of $10 million paid by Hisun to Celsion under the Development Contract and the exclusive option agreement. Celsion is also entitled to receive (a) milestone payments of up to $30 million with respect to ThermoDox® for the treatment of primary liver cancer upon satisfaction of certain regulatory approval milestones and the first commercial sale milestone in the Territory, (b) milestone payments tied to other potential indications of ThermoDox®, and (c) additional sales milestone performance bonus of up to $45 million if Hisun achieves certain annual net sales targets for all the ThermoDox® products Hisun is licensed to manufacture and distribute under the License Agreement in the Territory. In addition, Hisun will pay Celsion escalating double-digit royalties derived primarily from annual net sales of ThermoDox® products in the Territory.

The foregoing summary is qualified in its entirety by reference to the Development Contract and the exclusive option agreement, which will be filed as exhibits to Celsion's Quarterly Report on Form 10-Q for the period ended March 31, 2013.

FORWARD LOOKING STATEMENTS

In this Form 8-K Celsion makes certain forward-looking statements regarding the agreements entered into with Hisun. These forward-looking statements involve substantial risks and uncertainties including but not limited to: (i) laboratory research and clinical trials are long, expensive and uncertain processes, (ii) the risk of failure of any product that is in pre-clinical and clinical development and prior to regulatory approval is high and can occur at any stage due to efficacy, safety or other factors, (iii) any failure would likely result in reduced or no further payments to Celsion, (iv) competing alternative therapies that are currently on the market or under development could reduce the commercial potential of the products which could materially reduce Celsion's payments under the agreements, (v) Hisun may elect, at its sole discretion, not to enter into the License Agreement, (vi) if Hisun elects to enter into the License Agreement and Celsion fails to do so, Celsion could be liable for liquidated damages; (vii) the parties may not

be able to agree upon the terms and conditions of the License Agreement, (viii) Hisun and Celsion may be unsuccessful in obtaining regulatory approval of ThermoDox®, (ix) ThermoDox® may fail to achieve a minimally acceptable commercial profile based on results of clinical trials or competing therapies that target one or more of the same indications, (x) Celsion's patent applications for the products which have not already issued may not issue, or even if such patents issue, the claims contained in such pending patents and patents that have already been issued to Celsion may not provide sufficient market exclusivity, (xi) current patents and future patents that may issue may not be valid or enforceable, and (xii) potential future third-party intellectual property disputes. Other important risks and uncertainties are detailed in Celsion's reports and other filings with the SEC including its most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q. Actual results could differ materially from the forward-looking statements. Celsion undertakes no obligation to update forward-looking statements, whether as a result of new information, future events or otherwise.

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: January 25, 2013

By: /s/ Gregory Weaver
Gregory Weaver
Senior Vice President and Chief Financial Officer