

Celsion CORP
Form 8-K
May 10, 2012

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): May 6, 2012

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) (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))
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Item 1.01

Entry into a Material Definitive Agreement.

On May 6, 2012, Celsion Corporation, a Delaware corporation (“Celsion”), entered into a Technology Development Agreement (the “Agreement”) with Zhejiang Hisun Pharmaceutical Co. Ltd., a company organized under the laws of the PRC (“Hisun”), and Hisun Pharmaceutical USA, Inc., a Delaware corporation.

Subject to the terms and conditions of the Agreement, upon approval of ThermoDox®, Celsion’s heat-activated liposomal encapsulation of doxorubicin, and related products (collectively, the “Product”) by the State Food and Drug Administration of the PRC (the “SFDA”), Hisun will manufacture and supply to Celsion the Product in quantities required by Celsion for sale in mainland China, Hong Kong and Macau (collectively, the “Territory”) at the purchase price set forth in the Agreement. Celsion grants Hisun a non-exclusive, royalty-free license to develop, manufacture and supply the Product to Celsion in the Territory. Hisun agrees to not compete within a specified field of use, whether inside or outside the Territory, for the longer of the term of the Agreement or 10 years after Product approval in the Territory.

Hisun will be responsible for clinical and non-clinical studies required by the SFDA and other regulatory authorities in the Territory for approval of the Product for manufacturing and sale in the Territory. Hisun will provide technical and regulatory support services set forth in the Agreement, and Celsion will pay Hisun for the aggregate amount of these development costs and certain fees calculated on a cost-plus basis commencing on the successful completion of three registration batches of the Product, to be paid within four years.

Subject to the terms and conditions of the Agreement, Celsion commits to purchasing certain minimum quantities of the Product from Hisun pursuant to forecasts provided by Celsion, some of which are binding, except that Celsion may seek alternative sourcing of any Product shortfall if Celsion determines that Hisun will be unable to meet the requirements for Product deliveries in either requested quantity or timeframe. Hisun may, and Celsion may request Hisun to, manufacture and supply the Product to Celsion in markets outside the Territory, subject to, among other conditions, the execution by the parties of definitive agreements reflecting mutually agreed upon terms.

The Agreement contains various representations, warranties, covenants, indemnities and other provisions customary for transactions of this nature. The Agreement will continue in effect for a term of ten (10) years after the date that the Product is approved for sale in China by the SFDA, provided that either party may terminate the Agreement early in the event of (i) an uncured material breach by the other party or (ii) the insolvency or bankruptcy of the other party.

The foregoing summary is qualified in its entirety by reference to the Agreement, which will be filed as an exhibit to Celsion’s Quarterly Report on Form 10-Q for the period ended June 30, 2012.

FORWARD LOOKING STATEMENTS

In this Form 8-K Celsion makes certain forward-looking statements regarding the collaboration with Hisun. These forward-looking statements involve substantial risks and uncertainties including but not limited to: (i) 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) competing alternative therapies that are currently on the market or under development could reduce the commercial potential of the Product, (iv) the Agreement could be terminated under customary conditions, (v) Hisun and Celsion may be unsuccessful in obtaining regulatory approval of the products, (vi) the Territory is subject to rapidly changing marketplace and regulatory conditions, and (vii) patent risks or 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. 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: May 10, 2012

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