# 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 (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 ( <i>see</i> 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 7.01 Regulation FD Disclosure

On January 22, 2013, Celsion Corporation, a Delaware corporation ("Celsion"), issued a press release announcing the entry into a technology development agreement with Zhejiang HISUN Pharmaceutical Company Ltd., a company organized under the laws of the PRC ("Hisun"), pursuant to which Celsion will receive from Hisun an initial \$5 million payment for support of Hisun's ThermoDox® manufacturing development program. Concurrently with the entry into the technology development agreement, Celsion has granted Hisun an exclusive option to license from Celsion the manufacturing and commercialization rights for ThermoDox® products in mainland China, Hong Kong and Macau. The description of the technology development agreement and the exclusive option contained in this Current Report on Form 8-K, including Exhibit 99.1, is qualified in its entirety by reference to the applicable agreements between Celsion and Hisun, which will be filed as exhibits to Celsion's periodic reports to be filed with the Securities and Exchange Commission.

The information in this Current Report on Form 8-K, 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.

# 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 relevant agreements, (v) Hisun may elect, at its sole discretion, not to exercise the exclusive option to enter into a definitive agreement for the license of ThermoDox®, (vi) the parties may not be able to agree upon the terms and conditions of the definitive agreement if Hisun elects to exercises its option, (vii) Hisun and Celsion may be unsuccessful in obtaining regulatory approval of ThermoDox®, (viii) 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, (ix) 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, (x) current patents and future patents that may issue may not be valid or enforceable, and (xi) 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 mate

### Item 9.01 Financial Statements and Exhibits

**Exhibit** 

No.	Description
99.1	Press release titled "Celsion Corporation and Zhejiang Hisun Pharmaceutical Company Enter Into Technology Development Agreement for

ThermoDox® for the Greater China Territory" issued by Celsion Corporation on January 22, 2013.

# 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

By: /s/ Gregory Weaver

Dated: January 22, 2013

Gregory Weaver

Senior Vice President and Chief Financial Officer

# EXHIBIT INDEX

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# Celsion Corporation and Zhejiang Hisun Pharmaceutical Company Enter Into Technology Development Agreement for ThermoDox® for the Greater China Territory

Companies Also Anticipate 60-Day Exclusive Option Period for Commercial License for ThermoDox® for China Market

LAWRENCEVILLE, NJ and TAIZHOU CITY, CHINA – January 22, 2013 – Celsion Corporation (NASDAQ: CLSN), a leading oncology drug development company, and Zhejiang Hisun Pharmaceutical Company Ltd. (SSE Code: 600267), a leading Chinese pharmaceutical company, today announced that they have entered into a technology development agreement for ThermoDox® for the greater China territory. Under the terms of the agreement, Hisun will pay \$5 million to Celsion immediately, while Celsion will provide Hisun with support for its ThermoDox® manufacturing development program. This payment is non-refundable 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 this month.

In addition, the companies anticipate signing an agreement in which Celsion provides Hisun an exclusive option to license ThermoDox® for the Greater China market, which includes China, Hong Kong and Macau. This option period will be secured by a second \$5 million payment that must be received by Celsion from Hisun within 60 days after execution of the Technology Development Agreement. The key provisions of the anticipated license agreement have been negotiated and agreed to by the parties and provide a basis for a definitive contract. These provisions are:

- · A credit of \$10 million from the two payments (\$5 million for the technology development agreement and \$5 million for the exclusive option) toward a non-refundable upfront license payment of \$25 million due to Celsion at signing of the definitive license agreement.
- An approximate 10 year total value to Celsion of well over several hundred million US dollars, which includes:
  - o \$55 million in upfront milestone and regulatory milestone payments within the next 18 months;
  - o \$45 million in milestone payments for reaching certain sales targets; and
  - o Escalating double-digit royalties on net sales of ThermoDox® in the Greater China Territory.
- · Hisun will serve as both the manufacturer and distributor of the ThermoDox® drug product for the Greater China Territory, and also take responsibility for local regulatory activities including submitting approvals in China to the state Food and Drug Administration (sFDA).

"Pursuing this arrangement with Hisun allows us to evaluate the fastest path to the China market, potentially the largest opportunity in the world for ThermoDox®. A long-term partnership will provide the greatest synergies with respect to sales, marketing, distribution, and manufacturing, which could ensure significant value to the ThermoDox® asset," said Michael H. Tardugno, Celsion's President and Chief Executive Officer. "In addition, this partnership provides Hisun and Celsion with immediate access to an accelerated pathway for sFDA review and approval of ThermoDox®, a business strategy with exceptional potential to serve China's HCC population, and strong, uncompromised economics for both parties."

Mr. Hua Bai, CEO and Chairman of Hisun, stated, "We are extremely excited to pursue this arrangement with Celsion. Hisun is well positioned to provide ThermoDox® – potentially one of the most important and innovative drugs to treat HCC to patients in China, the world's largest market. China is one of the countries with the highest HCC incidence and mortality and, up until now, there has not been any standard of care for treating HCC in China. This joint effort will most likely facilitate the local manufacturing and commercial launch in China, thereby providing physicians with more options for better care and prolonging the survival of HCC patients. In the meantime, we are also hopeful that this collaboration will enable Hisun to increase its focus on more innovative drugs. Given the fact that we are a leading Chinese pharmaceutical company with international standards of R&D and manufacturing technology, Hisun will seek to manufacture and supply the global markets, along with distribution exclusivity in Greater China. This venture will help spearhead Hisun's globalization in manufacturing and commercialization capabilities."

The HEAT Study is being conducted under a U.S. Food and Drug Administration (FDA) Special Protocol Assessment (SPA), has received FDA Fast Track Designation, and has been designated as a Priority Trial for liver cancer by the National Institutes of Health. The European Medicines Agency (EMA) has confirmed the HEAT Study is acceptable as a basis for submission of a marketing authorization application (MAA). ThermoDox® has been granted orphan drug designation in both the U.S. and Europe. In addition to meeting the U.S. FDA and European EMA enrollment objectives, the HEAT Study has also enrolled a sufficient number of patients to support registration filings in China, South Korea and Taiwan, three of the largest potential markets for ThermoDox® around the world.

# **About Primary Liver Cancer**

Primary liver cancer is one of the most deadly forms of cancer and ranks as the fifth most common solid tumor cancer. The incidence of primary liver cancer today is approximately 26,000 cases per year in the United States, approximately 40,000 cases per year in Europe and is rapidly growing worldwide at approximately 750,000 cases per year, 55 percent of which are in China, due to the high prevalence of Hepatitis B and C in developing countries. The World Health Organization estimates that primary liver cancer may become the number one cancer worldwide, surpassing lung cancer, by 2020.

The standard first-line treatment for liver cancer is surgical resection of the tumor; however, 90% of patients are ineligible for surgery. Radio frequency ablation (RFA) has increasingly become the standard of care for non-resectable liver tumors, but the treatment becomes less effective for larger tumors. There are few non-surgical therapeutic treatment options available as radiation therapy and chemotherapy are largely ineffective in the treatment of primary liver cancer.

#### About ThermoDox® and the Phase III HEAT Study

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. In the HEAT Study, ThermoDox® is administered intravenously in combination with RFA. Localized mild hyperthermia (39.5 - 42 degrees Celsius) created by the RFA releases the entrapped doxorubicin from the liposome. This delivery technology enables high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

For primary liver cancer, ThermoDox® is being evaluated in a 700 patient global Phase III study at 79 clinical sites under an FDA Special Protocol Assessment. The study is designed to evaluate the efficacy of ThermoDox® in combination with RFA when compared to patients who receive RFA alone as the control. The primary endpoint for the study is progression-free survival (PFS) with a secondary confirmatory endpoint of overall survival. Additional information on the Company's ThermoDox® clinical studies may be found at www.clinicaltrials.gov.

# **About Celsion Corporation**

Celsion is a leading oncology company dedicated to the development and commercialization of innovative cancer drugs including tumor-targeting treatments using focused heat energy in combination with heat-activated liposomal drug technology. Celsion has research, license, or commercialization agreements with leading institutions including the National Institutes of Health, Duke University Medical Center, University of Hong Kong, the University of Pisa, the UCLA Department of Medicine, Kyungpook National University Hospital and the Beijing Cancer Hospital. For more information on Celsion, visit our website: <a href="http://www.celsion.com">http://www.celsion.com</a>.

## About Zhejiang Hisun Pharmaceutical Company Ltd.

Founded in 1956, the mission for Zhejiang Hisun Pharmaceuticals Co., Ltd. (stock code 600267) hereinafter called "Hisun" is to be persistent in pharmaceutical innovation for humans' well-being. The company's vision is to become a widely respected global pharmaceutical provider. It focuses on the integration of pharmaceutical research and development (R&D) with production resources in order to provide its global customers with outstanding products and services. To date, over 40 of the company's products have passed certification by many regulatory agencies such as the FDA (U.S.), EDQM (EU), TGA (Australia), and KFDA (Korea) and are sold to more than 30 countries worldwide.

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 risks and uncertainties including, without limitation, unforeseen changes in the course of research and development activities and in clinical trials by others; possible acquisitions of other technologies, assets or businesses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Company's periodic reports filed with the Securities and Exchange Commission.

# **Celsion Investor Contact**

Jeffrey W. Church Senior Vice President – Corporate Strategy and Investor Relations 609-482-2455 jchurch@celsion.com

#### **Hisun Investor Contact**

Madam Zhang Wei Stock600267@hisunpharm.com