

**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): December 9, 2008

Celsion Corporation

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or other jurisdiction
of incorporation)

000-14242

(Commission File Number)

52-1256615

(IRS Employer
Identification No.)

10220-L Old Columbia Road, Columbia, Maryland

(Address of principal executive office)

21046-2364

(Zip Code)

Registrant's telephone number, including area code: **(410) 290-5390**

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 obligations of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communication 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 240.135-4(c))

Item 1.01 Entry into a Material Definitive Agreement.

On December 9, 2008 (the "Effective Date"), Celsion Corporation ("Celsion") entered into a Development, Product Supply and Commercialization Agreement for Thermodox® (the "Agreement") with Yakult Honsha Co., Ltd. ("Yakult") pursuant to which (i) Celsion granted to Yakult an exclusive license, solely in the Japanese market, to make, sell, import and use Thermodox® for the indications set forth in the Agreement; and (ii) Yakult agreed to use commercially reasonable efforts to develop and be solely responsible for the commercialization of Thermodox® in Japan for the indications set forth in the Agreement, including the treatment of primary liver cancer and recurrent chest wall breast cancer, all subject to the terms and conditions of the Agreement.

Under the terms of the Agreement, Celsion is entitled to receive a payment of \$2.5 million within one (1) month of the Effective Date and other payments upon the occurrence of certain milestones. The Agreement provides that Celsion is entitled to receive a payment of \$18 million upon approval of Thermodox® by the Japanese Ministry of Health, Labor and Welfare for the treatment of primary liver cancer. Additional milestone payments are tied to the achievement of certain levels of annual sales and the approval of other indications, one of which is recurrent chest wall breast cancer. The Agreement also provides that Yakult will pay Celsion a significant double-digit and escalating royalty rate on the sale of Thermodox® in Japan.

Yakult agreed to use commercially reasonable efforts to develop and to file for and obtain market authorization for Thermodox® in Japan for the indications set forth in the Agreement, including the treatment of both primary liver cancer and recurrent chest wall breast cancer. The terms of the Agreement also stipulate that Yakult will pay for all up-front clinical and pre-clinical development costs associated with Japanese registration and that the data obtained from any such clinical studies can be used to support Celsion's obligations, if any, in other geographies as well. If marketing authorization for Thermodox® is obtained for a certain indication in Japan, Yakult will be solely responsible for the commercialization of Thermodox® in Japan for such indication. Celsion will be the exclusive manufacturer (or cause a third party to manufacture) and supplier of Thermodox® for all clinical studies and commercial sales in Japan, the terms and conditions of which are to be set forth in a separate supply agreement.

A copy of the joint press release, dated December 15, 2008, announcing the Agreement is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statement and Exhibits

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Joint Press Release, dated December 15, 2008, of Celsion Corporation and Yakult Honsha Co., Ltd.

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: December 15, 2008

By: /s/ Sean F. Moran
Sean F. Moran
Sr. Vice President and Chief Financial Officer

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Joint Press Release, dated December 15, 2008, of Celsion Corporation and Yakult Honsha Co., Ltd.



**Celsion Corporation Announces Exclusive Japan License Agreement
with Yakult Honsha for ThermoDox®**

Agreement Includes \$20.5 Million in License Fees

Columbia, MD – December 15, 2008: Celsion Corporation (NASDAQ: CLSN) and Yakult Honsha Co., Ltd. (Tokyo: 2267) today announced the execution of definitive agreements relating to the commercialization of Celsion's proprietary ThermoDox® drug delivery platform for the Japanese market.

"We have worked diligently over the past few months to arrive at this significant agreement with Yakult and we are very pleased to announce its execution," said Michael H. Tardugno, Celsion's President and CEO. "This achievement is an example of the commitment of our two companies to a long term, mutually rewarding relationship. It is also an example of Celsion delivering on its stated goal of licensing ThermoDox® to pharmaceutical partners with the expertise and capabilities essential to market success. We view this partnership with Yakult as further validation of the ThermoDox® platform and its potential to treat the expanding hepatocellular carcinoma (HCC) population in Japan."

Dr. Kiyoshi Terada, Head, Pharmaceutical Division/Senior Managing Director, Member of the Board noted, "We are delighted to have reached an agreement with Celsion for an exclusive license to ThermoDox® for Japan. The remarkable evidence of clinical activity suggested by ThermoDox® in early phase clinical trials provides Yakult with the confidence necessary for the investment required to support marketing approval in Japan. With an annual incidence of over 40,000 HCC patients, if supported by data from the current randomized phase III trial, ThermoDox® has the potential to hold great promise for those suffering with this difficult cancer. We look forward to our work with Celsion and the potential to expand our partnership to address other cancers for which there is no current standard of care."

Agreement Terms

Under the agreement, Yakult will pay Celsion licensing fees to acquire the rights to ThermoDox® for the Japanese market. An amount of \$2.5 million will be paid immediately, followed by an \$18 million payment that is conditioned upon the approval of ThermoDox® for the treatment of primary liver cancer by the Japanese Ministry of Health, Labor and Welfare. Additional milestone payments are tied to the achievement of certain levels of sales and the approval of other indications.

In addition to the milestone payments, Yakult will pay Celsion a significant double-digit and escalating royalty rate on the sale of ThermoDox® in Japan. Celsion will also be the exclusive supplier of ThermoDox® to Yakult.

Tokyo-based Yakult is required to complete all development and clinical requirements in Japan and apply for marketing approval for the use of ThermoDox® in the treatment of primary liver cancer and other indications in Japan. The terms also stipulate that Yakult will pay for all up-front clinical and pre-clinical development costs associated with Japanese registration. The data from the studies in Japan can be used to support Celsion's obligations, if any, in other geographies as well.

About ThermoDox®

ThermoDox® is Celsion's proprietary heat-sensitive liposomal encapsulation of doxorubicin, an approved and frequently used anti-cancer drug used in the treatment of various cancers. Localized heat (at 40-42 degrees Celsius and above) releases the entrapped doxorubicin from the liposome. This delivery technology enables high concentrations of doxorubicin to be deposited locally in a targeted tumor.

Clinical Development Status

ThermoDox® is currently in a phase 3 clinical trial in the U.S. for liver cancer as well as a phase 2 trial for recurrent chest wall breast cancer. Additionally, Celsion recently obtained regulatory approval to conduct its global study titled "A Phase III, Randomized, Double-Blinded, Dummy-Controlled Study of the Efficacy and Safety of ThermoDox® (Thermally Sensitive Liposomal Doxorubicin) in Combination with Radiofrequency Ablation (RFA) Compared to RFA Alone in the Treatment of Non-Resectable Hepatocellular Carcinoma (HCC)" in Hong Kong, Taiwan, Korea, Canada, and Italy, and anticipates that a Clinical Trial Agreement will be obtained in China in early 2009.

About Primary Liver Cancer

Primary liver cancer is a type of cancer that begins in the cells of the liver and is not typically detected early, often resulting in a poor patient prognosis. According to the National Cancer Center of Japan, primary liver cancer is the third leading cause of cancer deaths in Japan among adults and more than 40,000 people are diagnosed with the disease annually.

About Celsion

Celsion is dedicated to the development and commercialization of oncology drugs including tumor-targeting treatments using focused heat energy in

combination with heat activated drug delivery systems. Celsion has research, license or commercialization agreements with leading institutions such as the National Institutes of Health, Duke University Medical Center, University of Hong Kong, and North Shore Hospital-Albert Einstein Medical School.

About Yakult

Yakult is a leading Japanese company focused on the development and marketing of pharmaceuticals, foods, beverages, and cosmetics with an emerging presence in oncology. For more information on Yakult, visit: www.yakult.co.jp or the following company profile: www.yakult.co.jp/english/pdf/profile2007-08.pdf.

Safe Harbor Statement

Celsion wishes to inform readers that forward-looking statements in this release, including, but not limited to those with respect to the agreement, are made pursuant to the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements typically include the words “expect,” “anticipate,” “believe,” “estimate,” “intend,” “may,” “will,” and similar expressions as they relate to Celsion or its management. Readers are cautioned that such forward-looking statements are based on our current expectations and assumptions, which are subject to numerous risks, uncertainties and other factors, which change over time. These risks, uncertainties and other factors include, but are not limited to: unforeseen changes in the course of research and development activities and in clinical trials conducted by others; whether clinical trials will positively support the benefits, efficacy and safety of the products covered by the agreement; the timing of any required authorizations, if obtained at all, including marketing approval of the products covered by the agreement; the timing or achievement of the milestones identified in the agreement; unexpected delays in commercial introduction and the commercial success of products covered by the agreement; 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.

The forward-looking statements in this press release speak only as of the date of this press release, and Celsion Corporation undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

For more information on Celsion, visit: <http://www.celsion.com>.

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SOURCE: Celsion Corporation, Yakult Honsha Co., Ltd.

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