

Celsion CORP
Form 8-K
December 15, 2008

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)

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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):

- o Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.135-4(c))
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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.

Exhibit Number	Description
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

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