CELSION CORP
Form 8-K
May 25, 2004

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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 25, 2004

Celsion Corporation

(Exact Name of Registrant as Specified in Charter)

Delaware	000-14242	52-1256615
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

10220-L Old Columbia Road, Columbia, Maryland	21046-1705
(Address of principal executive office)	(Zip Code)

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

(Former Name or Former Address, if Changed Since Last Report)

ITEM 5. OTHER EVENTS

At its Annual Meeting of Stockholders on May 25, 2004, Celsion Corporation (the "Company") made announcements with respect to the following:

(A) The Company has received a warning letter from the United States Food and Drug Administration, or FDA, regarding the Phase I and Phase II

clinical trials of its Prolieve(TM) Thermodilatation system for the treatment of benign prostatic hyperplasia, or BPH. The warning letter reflects matters that arose during the course of an inspection conducted by the FDA's Baltimore regional office from December 9 through December 18, 2003 under a program designed to ensure that data and information contained in applications for Investigational Device Exemptions, or IDEs, Premarket Approval, or PMA, applications and Premarket Notification, or 510(k), submissions are scientifically valid and accurate and to ensure that human subjects are protected from undue hazard or risk during scientific investigations.

The warning letter addressed four general areas--monitoring, investigational agreements, provision of information to certain investigators, and FDA reporting--in connection with the Prolieve studies, both of which were completed by January 2002. Subsequent to the inspection, the Company took certain actions to address the observations of the FDA inspector and on December 23, 2003, made a written submission to the agency regarding those corrective and compliance actions. In addition, since receipt of the warning letter, the Company has spoken with representatives of the FDA regarding compliance matters and has initiated short- and long-term corrective and compliance measures to address fully the issues raised by the FDA. In addition, the Company recently has added personnel, including a Senior Vice President-Product Development who will be responsible for oversight of the entire clinical process, a Vice President-Regulatory Affairs and experienced clinical monitors.

Under FDA regulations, the Company must make a written submission in response to the warning letter no later than 15 days following its receipt, subject to extension in the discretion of the agency. The Company is working to complete and submit its response in a timely manner. The warning letter indicates that the Company's failure to respond and take timely and appropriate corrective action could result in regulatory action by the FDA without further notice.

(B) On Tuesday, May 18, the Company completed treatment of the fourth cohort of prostate cancer patients in the dose escalation study for Thermodox(R), the Company's liposome encapsulation of the cancer drug doxorubicin. The study has now reached safe delivery of 30 mg per meter squared and the Company anticipates that maximum safe dosage should be reached some time during the summer of 2004.

(C) Effective May 25, 2004, the Company has suspended both branches of its pivotal Phase II trials using the Company's advanced phase array microwave technology in the treatment of small and late stage breast cancer tumors. The decision to suspend was taken after preliminary evaluation of interim (midpoint) data from

the trials. In the small tumor study, the Company determined that it was achieving the primary endpoint of reducing second incisions, but that it was not consistently meeting its secondary endpoint of reducing tumor burden as measured by tumor necrosis. The Company believes that these inconsistent results may be due to inconsistent delivery of an adequate thermal dose. In the late-stage study, the Company was encountering difficulties in enrolling sufficient patients in part due to a change in the prevailing standard of care specified in the study protocol and in part due to a shortage of late-stage tumor patients, due to earlier detection of breast cancer.

(D) Effective May 25, the Board of Directors has established a search committee to recruit a new chief executive officer for the Company. At such time as the Board retains a new chief executive officer, Dr. Augustine Cheung, the Company's chief executive officer, will assume the position of Vice Chairman of the Board of Directors. Dr. Cheung is expected to retain his position as Chief Scientific Officer.

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: May 25, 2004

By: /s/ Anthony P. Deasey

Executive Vice President and Chief Operating Officer