

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 16, 2016

CELSION CORPORATION
(Exact name of registrant as specified in its 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
(Address of principal executive offices)

08648-2311
(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))
-

Item 2.02 Results of Operations and Financial Condition.

On May 16, 2016, Celsion Corporation issued a press release reporting its financial results for the three month period ended March 31, 2016. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On May 9, 2016, Celsion Corporation announced it would hold a conference call on May 16, 2016 to discuss its financial results for the three period ended May 16, 2016 and provide a business update. The conference call will also be broadcast live on the internet at <http://www.celsion.com>.

The information in this report, including the exhibit hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. Such information shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by Celsion Corporation, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

The press release contains forward-looking statements which involve certain risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Please refer to the cautionary note in the press release regarding these forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release titled “Celsion Corporation Reports First Quarter 2016 Financial Results and Provides Business Update ” issued by Celsion Corporation on May 16, 2016.

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 16, 2016

By: /s/ Jeffrey W. Church
Jeffrey W. Church
Senior Vice President and Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release titled “Celsion Corporation Reports First Quarter 2016 Financial Results and Provides Business Update ” issued by Celsion Corporation on May 16, 2016.



Celsion Corporation Reports First Quarter 2016 Financial Results and Provides Business Update

Company to Hold Conference Call on Monday, May 16, 2016 at 11:00 a.m. EDT

LAWRENCEVILLE, N.J., May 16, 2016 -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the quarter ended March 31, 2016 and provided an update on its development programs for ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin and GEN-1, an IL-12 DNA-based immunotherapy.

"We are extremely pleased with our product portfolio, our progress and the investment we have made in gene-based therapeutics," said Michael H. Tardugno, Celsion's chairman, president and CEO. "Over this past quarter alone, we have reported meaningful developments with both ThermoDox® and our immunotherapeutic, GEN-1. Positive clinical, preclinical and translational data for GEN-1 in both first line and second line ovarian cancer has provided important insights on its potential clinical utility and safety, and reinforced our confidence in the potential of this important investigational product. We are looking forward to continued meaningful data from our Phase I neoadjuvant trial, the OVATION Study, throughout the year and its support for launching the Phase I/II clinical study later this year to evaluate the combination of GEN-1 with Avastin® and Doxil® in platinum-resistant ovarian cancer patients."

Mr. Tardugno continued, "We have made great strides to advance our global Phase III OPTIMA Study evaluating ThermoDox® in primary liver cancer with clinical sites currently enrolling patients in 13 countries world-wide. With enrollment now open in China and approximately 50% of the 850,000 new cases of primary liver cancer diagnosed each year originating there, China represents a significant market opportunity and key element of our global development and commercialization strategy for ThermoDox®. We expect to add up to 20 additional clinical sites and enroll more than 200 patients in the China territory, the minimum number required by the China FDA to file a New Drug Application (NDA), assuming positive clinical results."

Recent Developments

ThermoDox®

Enrolled the first patient in the OPTIMA Study in China. On April 26, 2016, the Company announced that the first patient in China has been enrolled in its ongoing global Phase III OPTIMA Study. With China FDA's approval of Celsion's Phase III Study in first line primary liver cancer, the trial is now enrolling patients in 13 countries globally. With the addition of these Chinese clinical sites, the Company expects an increase in the rate of recruitment sufficient to complete enrollment in the OPTIMA Study by the end of 2017 or early 2018. Results from the OPTIMA Study, if successful, will provide the basis for a global registration filing and marketing approval.

GEN-1 Immunotherapy

Announced positive data from the first cohort of patients in the Phase 1b OVATION Study. In May 2016, the Company announced data from the first cohort of patients in its Phase 1b dose escalating clinical trial (the OVATION Study) combining GEN-1, the Company's DNA-based immunotherapy, with the standard of care for the treatment of newly-diagnosed patients with advanced ovarian cancer who will undergo neoadjuvant chemotherapy followed by interval debulking surgery. In the first three patients dosed, GEN-1 plus standard chemotherapy produced positive clinical results, with no dose limiting toxicities and promising efficacy signals leading to successful surgical outcomes.

- Of the three patients treated in the first cohort, two patients demonstrated stable disease (SD) and one patient demonstrated a complete response (CR), as measured by RECIST criteria.
- All patients had successful resections of their tumors, with two patients having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed, and one patient with Stage IV ovarian cancer having an optimal R1 resection.
- One patient demonstrated a pathological complete response (pCR). pCRs are typically seen in less than 7% of patients receiving neoadjuvant chemotherapy followed by surgical resection, and have been associated with a median overall survival (OS) of 72 months, which is more than three years longer than those who do not experience a pCR.
- All patients experienced a dramatic > 96% drop in their CA-125 protein levels as of their most recent study visit. CA-125 is used to monitor certain cancers during and after treatment. CA-125 is present in greater concentrations in ovarian cancer cells than in other cells. A 50% reduction in CA-125 levels is considered meaningful. All patients' CA-125 levels were below the standard cutoff level of 35 U/mL.

Presented preclinical data for GEN-1 IL-12 Immunotherapy in combination with Avastin® and Doxil® at the American Association for Cancer Research (AACR) Annual Meeting 2016. In April 2016, the Company presented compelling preclinical data demonstrating significant synergistic anti-cancer effects when GEN-1 is combined with Avastin® and Doxil®, a current standard of care (SoC) for platinum resistant ovarian cancer patients at the 2016 AACR Annual Meeting. The presentation showed that the three drug combination resulted in a statistically significant reduction of tumor burden of greater than 98% compared to control, and a statistically significant 92% reduction in tumor burden compared to Avastin® plus Doxil® alone. In contrast, Avastin® and GEN-1 produced a 39% and 50% reduction in tumor burden, respectively. These preclinical data are consistent with the mechanism of action for GEN-1, which exhibits certain anti-angiogenic properties in addition to its well-characterized immunomodulatory activities. The combination of GEN-1 with Avastin® and Doxil® was well-tolerated with no systemic toxicities. These preclinical data will be used by the Company to support a comprehensive IND protocol filing for a Phase I/II clinical trial evaluating the combination in recurrent ovarian cancer later this year.

Reported translational data from its Phase Ib Study of GEN-1 Immunotherapy in recurrent ovarian cancer. In January 2016, the Company announced new translational data from its Phase Ib study of GEN-1 in patients with platinum-resistant ovarian cancer. The new data indicated that intraperitoneally-administered GEN-1 produces an immunologically distinct IL-12 protein that is localized at the tumor site and lasts for up to one week after a single treatment. In addition, concomitant increases in IFN- α and TNF- α indicate that the IL-12 produced following treatment with GEN-1 treatment is immunologically active. Celsion intends to collect additional translational data, including cellular responses in primary tumor tissue and peritoneal ascites, in its ongoing OVATION Study, a Phase I dose escalation study in newly diagnosed ovarian cancer patients in the neoadjuvant setting.

Financial Results

For the quarter ended March 31, 2016, Celsion reported a net loss of \$5.7 million, or \$0.24 per share, compared to a net loss of \$7.0 million, or \$0.35 per share, in the same period of 2015. Operating expenses were \$5.3 million for the quarter ended March 31, 2016 compared to \$6.5 million in the same period of 2015. This decrease was primarily due to lower research and development and general and administrative expenses in the first quarter of 2016 compared to the first quarter of 2015.

Research and development costs were \$3.4 million in the first quarter of 2016 compared to \$4.5 million in the same period of the prior year. In the first quarter of 2015, the Company produced clinical supplies to support both its ThermoDox® and GEN-1 clinical programs. General and administrative expenses were \$1.9 million in the first quarter of 2016 compared to \$2.0 million in the same period of the prior year.

Net cash used in operations was \$4.7 million the first quarter of 2016 compared to \$5.9 million in the same period of the prior year. The Company ended the first quarter of 2016 with \$14.3 million of total cash and cash equivalents.

Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss first quarter 2016 financial results at 11:00 a.m. EDT on Monday, May 16, 2016. To participate in the call, interested parties may dial 1-888-359-3624 (Toll-Free/North America) or 1-719-457-2085 (International/Toll) and ask for the Celsion Corporation First Quarter 2016 Conference Call (Conference Code: 7064110) to register ten minutes before the call is scheduled to begin. The call will also be broadcast live on the internet at www.celsion.com.

The call will be archived for replay on May 16, 2016 and will remain available until May 30, 2016. The replay can be accessed at 1-888-203-1112 (Toll-Free/North America) or 1-719-457-0820 (International/Toll) using Conference ID: 7064110. An audio replay of the call will also be available on the Company's website, www.celsion.com, for 30 days after 2:00 p.m. EDT Monday, May 16, 2016.

About Celsion Corporation

Celsion is a fully-integrated oncology company focused on developing a portfolio of innovative cancer treatments, including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies. The Company's lead program is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in Phase III development for the treatment of primary liver cancer and in Phase II development for the treatment of recurrent chest wall breast cancer. The pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers. Celsion has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlas™ and TheraSilence™. For more information on Celsion, visit our website: <http://www.celsion.com> (CLSN-FIN).

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; the uncertainties of and difficulties in analyzing interim clinical data, particularly in small subgroups that are not statistically significant; FDA and regulatory uncertainties and risks; the significant expense, time, and risk of failure of conducting clinical trials; the need for Celsion to evaluate its future development plans; possible acquisitions or licenses of other technologies, assets or businesses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Celsion's periodic reports and prospectuses filed with the Securities and Exchange Commission. Celsion assumes no obligation to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

Celsion Investor Contact

Jeffrey W. Church
Sr. Vice President and CFO
609-482-2455
jchurch@celsion.com

Celsion Corporation
Condensed Statements of Operations
(in thousands except per share amounts)

	Three Months Ended	
	March 31,	
	<u>2016</u>	<u>2015</u>
Licensing revenue	\$ 125	\$ 125
Operating expenses:		
Research and development	3,441	4,506
General and administrative	1,863	2,032
Total operating expenses	5,304	6,538
Loss from operations	<u>(5,179)</u>	<u>(6,413)</u>
Other (expense) income:		
Loss from valuation of earn-out milestone liability	(303)	(172)
Loss from valuation of common stock warrant liability	-	(43)
Interest expense, investment income and other income (expense), net	(235)	(377)
Total other (expense) income, net	(538)	(592)
Net loss	<u>\$ (5,717)</u>	<u>\$ (7,005)</u>
Net loss per common share - basic and diluted	<u>\$ (0.24)</u>	<u>\$ (0.35)</u>
Weighted average common shares outstanding - basic and diluted	<u>23,389</u>	<u>19,990</u>

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	March 31, 2016	December 31, 2015
ASSETS		
Current assets		
Cash and cash equivalents	\$ 14,311	\$ 9,265
Investment securities and interest receivable on investment securities	-	10,827
Prepaid expenses and other current assets	371	189
Total current assets	<u>14,682</u>	<u>20,281</u>
Property and equipment	<u>757</u>	<u>855</u>
Other assets		
In-process research and development	25,802	25,802
Goodwill	1,976	1,976
Deposits	100	100
Other assets	12	14
Total other assets	<u>27,890</u>	<u>27,892</u>
Total assets	<u>\$ 43,329</u>	<u>\$ 49,028</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 4,862	\$ 4,750
Deferred revenue - current portion	500	500
Note payable - current portion	4,201	4,073
Total current liabilities	<u>9,563</u>	<u>9,323</u>
Earn-out milestone liability	14,224	13,921
Notes payable - noncurrent portion	1,319	2,350
Other liabilities - noncurrent portion	2,914	3,048
Total liabilities	<u>28,020</u>	<u>28,642</u>
Stockholders' equity		
Common stock	235	234
Additional paid-in capital	240,282	239,668
Accumulated other comprehensive loss	-	(4)
Accumulated deficit	<u>(224,024)</u>	<u>(218,130)</u>
Less: Treasury stock	16,493	21,768
Total stockholders' equity	<u>(1,184)</u>	<u>(1,382)</u>
Total liabilities and stockholders' equity	<u>\$ 43,329</u>	<u>\$ 49,028</u>