CELSION CORP

FORM 8-K
(Current report filing)

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Address	997 LENOX DRIVE SUITE 100 LAWRENCEVILLE, NJ 08648
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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 12, 2017

CELSION CORPORATION
(Exact name of registrant as specified in its Charter)

Delaware	001-15911	52-1256615
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 (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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 12, 2017, Celsion Corporation issued a press release reporting its financial results for the quarter ended March 31, 2017. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On May 5, 2017, Celsion Corporation announced it would hold a conference call on May 12, 2017 to discuss its financial results for the quarter ended March 31, 2017 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 Financial Results and Provides Business Update" issued by Celsion Corporation on May 12, 2017.

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 12, 2017

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

Exhibit 99.1

Celsion Corporation Reports First Quarter 2017 Financial Results and Provides Business Update

Company to Hold Confer ence Call on Friday, May 12, 2017 at 11:00 a.m. E T

LAWRENCEVILLE, N.J ., May 12, 2017 -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the quarter ended March 31, 2017 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 plasmid vector encased in a nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein. The Company's lead program is ThermoDox® which is 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 Company's immunotherapy program consists of GEN-1 and is currently in Phase I development for the localized treatment of ovarian cancer.

"Celsion continues to make major progress with respect to our ongoing global, pivotal Phase III OPTIMA Study in primary liver cancer. This ground-breaking study continues to attract interest and support from the medical community, international regulatory agencies, and research organizations like the National Institutes of Health," said Michael H. Tardugno, Celsion's chairman, president and CEO. "Our product development efforts in immuno-oncology are equally important. We have demonstrated the potential of our GEN-1 IL-12 immunotherapy program to be an effective adjuvant, in both first and second-line ovarian cancer. Recruiting the immune system to work in combination with the standard of care in this patient population has been the goal of medical researchers worldwide. With GEN-1, we believe there is the potential for a break-through and we look forward to reporting comprehensive clinical results and translational research data from our Phase 1B OVATION Study at the ASCO Annual Meeting in June 2017."

Recent Developments

ThermoDox ®

Announced the Publication of Preclinical Results of ThermoDox ® for the Treatment of Bladder Cancer in the International Journal of Hyperthermia. The Company reported results from porcine in vivo studies to evaluate ThermoDox® in combination with loco-regional mild hyperthermia for targeted drug delivery to the bladder wall as a potential treatment for bladder cancer. Doxorubicin accumulation and distribution within the bladder wall with ThermoDox® plus mild bladder hyperthermia was achieved at concentrations nearly ten times higher than with free intravenous doxorubicin combined with mild bladder hyperthermia. The study was conducted under a Cooperative Research and Development Agreement (CRADA) with the National Institutes of Health (NIH) to evaluate whether ThermoDox® combined with mild heating of the bladder can target drug delivery in the bladder.

Announced Support for the OPTIMA Study from the China FDA and Vietnam Ministry of Health. The Company discussed ThermoDox® and the OPTIMA Study with regulatory agencies in two key markets, China and Vietnam. The Company met with the China Food and Drug Administration (CFDA) to review the ongoing Phase III OPTIMA Study and regulatory pathway for ThermoDox® in China. CFDA was presented with the final overall survival data from the Chinese patient cohort of the HEAT study, which demonstrated a survival benefit in patients treated with ThermoDox® plus optimized RFA versus optimized RFA alone. The CFDA informed the Company that if the ongoing Phase III OPTIMA Study is successful, the trial could serve as the basis for a direct regulatory filing in China without the need to file for prior approval in the U.S. or European Union which is currently required for foreign company application. This would allow the Company to accelerate its plans for a regulatory filing in China and, if approved, provide for a significantly earlier launch date in China than originally expected. The Company's management team also met with the Ministry of Health in Vietnam and based on that meeting, it will move forward with launching additional trial sites for the OPTIMA Study in that country. The Company plans to activate 5 additional clinical trial sites in Vietnam by the second quarter of 2017. Vietnam represents a significant market for ThermoDox® where HCC incidence rates are among the highest in the world.

Announced the Issuance of Two New Patents for ThermoDox. In January 2017, the Company announced the issuance of two patents which are directly applicable to the method of treating cancer using our current ThermoDox® formulation. These new patents further strengthen the Company’s global patent portfolio around novel heat-sensitive liposome engineered to address a broad range of difficult-to-treat cancers.

GEN-1 Immunotherapy

Announced Continuing Positive Data from the OVATION Study in Newly Diagnosed Advanced Ovarian Cancer Patients. In January 2017, the Company announced data from the first four cohorts of patients in its Phase Ib dose escalating clinical trial (the OVATION Study) combining GEN-1 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 twelve patients dosed in the OVATION Study, GEN-1 plus standard chemotherapy produced impressive results, with no dose limiting toxicities and highly promising efficacy signals in this difficult to treat cancer. The efficacy data included highly encouraging tumor response rates - 100% disease control rate (DCR) and 75% objective response rate (ORR), successful surgical resections of the eligible patients’ tumors, impressive pathological responses and dramatic, clinically meaningful drops in CA-125 protein levels. In February 2017, the Company presented two posters at the American Society of Clinical Oncology (ASCO) - Society for Immunotherapy of Cancer (SITC) Clinical Immuno-Oncology Symposium held from February 23 - 25, 2017 in Orlando, FL. The ASCO-SITC Clinical Immuno-Oncology Symposium focused on the latest clinical and translational research in immuno-oncology and the implications for clinical care.

Corporate Development

Raised $6.8 Million Through Two Equity Offerings in December 2016 and February 2017. The Company completed two equity offerings of shares of common stock, or pre-funded warrants in lieu thereof, to purchase common stock with institutional healthcare and retail investors totaling $6.8 million in gross proceeds.

Financial Results

For the quarter ended March 31, 2017, Celsion reported a net loss of $5.2 million, or $0.12 per share, compared to a net loss of $5.7 million, or $0.24 per share, in the same period of 2016. Operating expenses were $4.9 million in the first quarter of 2017 compared to $5.3 million in the same period of 2016. This decrease was primarily due to lower general and administrative expenses.

Research and development (R&D) costs were relatively constant at $3.5 million and $3.4 million in the first quarters of 2017 and 2016, respectively. Clinical development costs for the Phase III OPTIMA Study were $1.6 million in the first quarter of 2017 compared to $1.0 million in the same period of 2016 due to higher patient enrollment and investigator grant expenses in the trial. R&D costs for other development programs were lower as a result of the Company's tighter clinical development focus around the pivotal Phase III OPTIMA Study for the treatment of primary liver cancer and the clinical development program for GEN-1 IL-12 immunotherapy for the localized treatment of ovarian cancer coupled with lower costs in the first quarter of 2017 associated with the production of ThermoDox® clinical supplies to support the OPTIMA Study. General and administrative expenses decreased $0.4 million, from $1.9 million in the first quarter of 2016 to $1.5 million in the first quarter of 2017. This 21% decrease in general and administrative expenses in 2017 is primarily the result of reduction in personnel costs and lower professional fees.

Net cash used in operations was $3.1 million in the first quarter of 2017 compared to $4.7 million in the same period of 2016. The Company ended the first quarter of 2017 with $4.5 million of total cash and cash equivalents. In February 2017, the Company raised $5 million in gross proceeds under a secondary public offering with various institutional and retail investors.

Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss year-end 2016 financial results at 11:00 a.m. ET on Friday, May 12, 2017. To participate in the call, interested parties may dial 1-888-282-4591 (Toll-Free/North America) or 1–719-457-2605 (International/Toll) and ask for the Celsion Corporation First Quarter 2017 Earnings Call (Conference Code: 4060768) 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 Friday, May 12, 2017 and will remain available until May 26, 2017. The replay can be accessed at 1-888-203-1112 (Toll-Free/North America) or 1-719-457-0820 (International/Toll) using Conference ID: 4060768. An audio replay of the call will also be available on the Company's website, www.celsion.com , for 90 days after 2:00 p.m. ET Friday, May 12, 2017.

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. 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 E nded March 31,	
	201 7	**201 6**
Licensing revenue	$ 125	$ 125
Operating expenses:		
Research and development	3,475	3,441
General and administrative	1,468	1,863
Total operating expenses	4,943	5,304
Loss from operations	(4,818)	(5,179)
Other (expense) income:		
Loss from valuation of earn-out milestone liability	(283)	(303)
Interest expense, investment income and other income (expense), net	(59)	(234)
Total other (expense) income, net	(342)	(537)
Net loss	$ (5,160)	$ (5,716)
Net loss per common share - basic and diluted	$ (0.12)	$ (0.24)
Weighted average common shares outstanding - basic and diluted	42,425	23,388

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	March 31, 201 7	December 31, 2016
ASSETS		
Current assets		
Cash and cash equivalents	$ 4,470	$ 2,624
Investment securities and interest receivable on investment securities	–	1,684
Prepaid expenses and other current assets	141	204
Total current assets	4,611	4,512
Property and equipment	370	463
Other assets		
In-process research and development	22,766	22,766
Other intangibles assets, net	967	1,023
Goodwill	1,976	1,976
Deposits	100	100
Other assets	9	9
Total other assets	25,818	25,874
Total assets	$ 30,799	$ 30,849
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 6,871	$ 5,363
Deferred revenue - current portion	500	500
Note payable - current portion	1,472	2,560
Total current liabilities	8,843	8,423
Earn-out milestone liability	13,472	13,188
Deferred revenue and other liabilities - noncurrent portion	2,378	2,513
Total liabilities	24,693	24,124
Stockholders' equity		
Common stock	555	312
Additional paid-in capital	252,176	247,878
Accumulated deficit	(246,540)	(241,380)
	6,191	6,810
Less: Treasury stock	(85)	(85)
Total stockholders' equity	6,106	6,725
Total liabilities and stockholders' equity	$ 30,799	$ 30,849