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CELSION CORP

FORM 8-K
(Current report filing)

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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): August 15, 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 August 15, 2017, Celsion Corporation issued a press release reporting its financial results for the quarter ended June 30, 2017. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On August 8, 2017, Celsion Corporation announced it would hold a conference call on August 15, 2017 to discuss its financial results for the quarter ended June 30, 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 Second Quarter Financial Results and Provides Business Update" issued by Celsion Corporation on August 15, 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: August 15, 2017

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

Exhibit 99.1

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

Company to Hold Conference Call on Tuesday, August 15, 2017 at 11:00 a.m. ET

LAWRENCEVILLE, N.J ., August 15, 2017 -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the quarter and six month period ended June 30, 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. The Company's immunotherapy program consists of GEN-1 and is currently in Phase I development for the localized treatment of ovarian cancer.

"We are extremely pleased with the momentum that we have built and the meaningful developments in our two lead programs," said Michael H. Tardugno, Celsion's chairman, president and CEO. "The data from our immunotherapy program, both the clinical data as well as the recently announced translational data from our OVATION Study in first line ovarian cancer, continue to provide important insights into GEN-1's favorable clinical and safety profile and reinforce our confidence in its potential to serve as an effective therapy in a broad range of cancers."

Mr. Tardugno continued, "We have also made great strides to advance our global Phase III OPTIMA Study evaluating ThermoDox® in primary liver cancer, with clinical sites currently enrolling patients in 14 countries worldwide. In addition, we are pleased to report that the independent Data Monitoring Committee recently recommended continuation of the OPTIMA Study after their review of the safety and efficacy data for 275 patients enrolled in the study. Enrollment momentum continues to improve with the addition of new clinical sites in China and Vietnam."

Recent Developments

ThermoDox ®

OPTIMA Study Update . On August 7, 2017, the Company announced that the independent Data Monitoring Committee (DMC) for the Company's OPTIMA Study completed a regularly scheduled review of the first 50% of patients enrolled in the trial as of April 2017 and has unanimously recommended that the OPTIMA Study continue according to protocol to its final data readout. The DMC reviewed study data at regular intervals, with the primary responsibilities of ensuring the safety of all patients enrolled in the study, the quality of the data collected, and the continued scientific validity of the study design. As part of its review, the DMC monitored a quality matrix relating to the total clinical data set, confirming the timely collection of data, that all data are current as well as other data collection and quality criteria.

The Company hosted an Investigators Meeting with physicians in SE Asia and key opinion leaders on July 22-23, 2017 in Bangkok, Thailand. A second Investigators Meeting is being planned for October with physicians in China. The Company has initiated approximately 70 clinical sites in 14 countries with plans to activate up to 8 additional clinical trial sites in China or Vietnam by the end of 2017. China and Vietnam represent significant markets for ThermoDox® where HCC incidence rates are among the highest in the world.

In addition, the Company announced that patient enrollment in the 550 patient Phase III global study has reached over 60%. Based on current enrollment rates, the Company expects to complete enrollment of the OPTIMA Study by mid - 2018.

GEN-1 Immunotherapy

Announced Latest Translational Data from the OVATION Study Showing That Patients in All Cohorts Showed Convincing Evidence of IL-12 Gene Transfer and Immune System Activity. On August 2, 2017, the Company reported that translational research data from its Phase Ib dose escalating clinical trial was reviewed with leading immuno-oncology experts from the Roswell Park Cancer Institute. The data showed evidence of IL-12 gene transfer by dose dependent increases in IL-12 levels and immune system activity and significant increases in interferon-gamma (IFN- ã) and decreases in VEGF levels. The treatment-related changes in immune activating cytokines and pro-tumor VEGF levels followed a dose-dependent trend and were predominantly in the peritoneal fluid compartm ent with little to no changes observed in the patients' systemic blood stream.

Key translational research findings from the first 12 of 15 patients enrolled in four patient cohorts are summarized below:

- The treatment-related changes in immune activating cytokines and pro-tumor VEGF and IFN- ã levels followed a dose-dependent trend and were predominantly in the peritoneal fluid compartment with little to no changes observed in the patients' systemic circulation. The observed immunological changes are consistent with an IL-12 based mechanism.

- Effects observed in the immunohistochemistry (IHC) analysis were pronounced decreases in the density of immunosuppressive T-cell signals (FoxP3, PD-1, PDL-1, IDO-1) and increases in CD8+ cells in the tumor microenvironment.

- The ratio of CD8+ cells to immunosuppressive cells was increased in approximately 75% of patients suggesting an overall shift in the tumor microenvironment from immunosuppressive to pro-immune stimulatory following treatment with GEN-1. An increase in CD8+ to immunosuppressive T-cell populations is a leading indicator and believed to be a good predictor of improved overall survival.

Presented OVATION Study Findings in Newly Diagnosed Advanced Ovarian Cancer Patients at the ASCO 2017 Annual Meeting . In June 2017, the Company reported clinical data from the first fourteen patients who have completed treatment in the OVATION Study. GEN-1 plus standard chemotherapy produced positive results, with no dose limiting toxicities and promising dose dependent efficacy signals which appear to correlate well with successful surgical outcomes as summarized below:

- Of the fourteen patients treated to date in the entire study, two (2) patients demonstrated a complete response, ten (10) patients demonstrated a partial response and two (2) patients demonstrated stable disease, as measured by RECIST criteria. This translates to a 100% disease control rate ("DCR") and an 86% objective response rate ("ORR"). Of the five patients treated in the highest dose cohort, there was a 100% objective response rate with one (1) complete response and four (4) partial responses.

- Fourteen patients had successful resections of their tumors, with nine (9) patients (64%) having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Of the five patients treated at the highest dose cohort, all five patients (100%) experienced a R0 surgical resection. Seven out of eight (87%) patients in the highest two dose cohorts experienced a R0 surgical resection.

- All patients experienced a clinically significant decrease 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.

- Of the seven patients who have received GEN-1 treatment over one year ago and are being followed, only one patient's cancer has progressed after 11.7 months. This compares favorably to the historical median progression free survival (PFS) of 12 months for newly-diagnosed patients with Stage III and IV ovarian cancer that undergo neoadjuvant chemotherapy followed by interval debulking surgery. Of the remaining six patients who have been on the study for over one year, their average PFS is 16.4 months with the longest progression-free patient at over 22 months.

Corporate Development

Raised $10.1 Million t hrough Warrant Exercises and Registered Direct Offering . During the second quarter of 2017, the Company raised $5.1 million through the exercise of outstanding common stock warrants. In July 2017, the Company completed a $5 million registered direct equity offering of shares of common stock, or pre-funded warrants in lieu thereof, and a concurrent private placement of warrants to purchase common stock with several institutional healthcare investors.

Financial Results

For the quarter ended June 30, 2017, Celsion reported a net loss of $4.9 million, or $(0.79) per share, compared to a net loss of $4.5 million, or $(2.63) per share, in the same period of 2016. Operating expenses were $4.7 million in the second quarter of 2017 compared to $4.9 million in the same period of 2016. This decrease was primarily due to a tighter clinical development focus coupled with lower general and administrative and interest expenses. For the six month period ended June 30, 2017, the Company reported a net loss of $10.1 million, or $(1.75) per share, compared to $10.2 million, or $(6.04) per share, in the same six month period of 2016. Operating expenses were $9.6 million in the first half of 2017 compared to $10.2 million in the same period of 2016. Net cash used in operations was $7.3 million in the first half of 2017 compared to $9.0 million in the same period last year. The Company ended the second quarter of 2017 with $3.6 million of total cash and investments, which was subsequently increased with proceeds from a $5 million registered direct offering completed in early July 2017.

Research and development costs were $3.0 million in the second quarter of 2017 compared to $3.3 million in the same period last year. Research and development costs were $6.5 million in the first half of 2017 compared to $6.8 million in the same period last year. Clinical development costs for the Phase III OPTIMA Study remained relatively unchanged at $1.5 million in each of the second quarter of 2017 and 2016. 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 half of 2017 associated with the production of ThermoDox® clinical supplies to support the OPTIMA Study.

General and administrative expenses were $1.6 million in the second quarter of 2017 compared to $1.5 million in the same period of 2016. The increase during the second quarter of 2017 was due to higher non-cash stock compensation expense partially offset by reduced professional fees. General and administrative expenses were $3.1 million in the first half of 2017 compared to $3.4 million in the same period of 2016. The decrease during the first six months of 2017 was primarily the result of lower personnel costs and professional fees.

During the three and six months ended June 30, 2017, the Company recognized deemed dividends totaling $0.4 million collectively in regard to multiple agreements with certain warrant holders, pursuant to which these warrant holders agreed to exercise, and the Company agreed to reprice, certain warrants. Warrants to purchase 790,410 shares of common stock were repriced at $2.70 and warrants to purchase 506,627 shares of common stock were repriced at $1.65. The Company received $3.0 million in gross proceeds from the sale of these repriced warrants.

Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss second quarter 2017 financial results at 11:00 a.m. ET on Tuesday, August 15, 2017. To participate in the call, interested parties may dial 1-888-576-4382 (Toll-Free/North America) or 1–719-325-2460 (International/Toll) and ask for the Celsion Corporation Second Quarter 2017 Earnings Call (Conference Code: 7987329) 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 Tuesday, August 15, 2017 and will remain available until August 29, 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: 7987329. 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 Tuesday, August 15, 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; 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 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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	201 7	**201 6**	**201 7**	**201 6**
Licensing revenue	$ 125	$ 125	$ 250	$ 250
Operating expenses:				
Research and development	3,047	3,336	6,522	6,777
General and administrative	1,649	1,530	3,117	3,392
Total operating expenses	4,696	4,866	9,639	10,169
Loss from operations	(4,571)	(4,741)	(9,389)	(9,919)
Other income (expense):				
Gain (loss) from valuation of common stock warrant liability	(292)	409	(576)	106
Interest expense, investment income and other income (expense), net	(27)	(199)	(85)	(434)
Total other income (expense), net	(319)	210	(661)	(328)
Net loss	(4,890)	(4,531)	(10,050)	(10,247)
Deemed dividend related to warrant Modification	(346)	-	(346)	-
Net loss attributable to common shareholders	$ (5,236)	$ (4,531)	$ (10,396)	$ (10,247)
Net loss per common share				
Basic and diluted	$ (0.79)	$ (2.63)	$ (1.75)	$ (6.04)
Weighted average shares outstanding				
Basic and diluted	6,629	1,723	5,949	1,697

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	June 30, 2017	December 31, 2016
ASSETS		
Current assets		
Cash and cash equivalents	$ 3,629	$ 2,624
Investment securities and interest receivable on investment securities	-	1,684
Prepaid expenses and other current assets	110	204
Total current assets	3,739	4,512
Property and equipment	257	463
Other assets		
In-process research and development	22,766	22,766
Other intangibles assets, net	909	1,023
Goodwill	1,976	1,976
Deposits	-	100
Other assets	9	9
Total other assets	25,660	25,874
Total assets	$ 29,656	$ 30,849
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 6,456	$ 5,363
Deferred revenue - current portion	500	500
Note payable - current portion	-	2,560
Total current liabilities	6,956	8,423
Earn-out milestone liability	13,764	13,188
Deferred revenue and other liabilities - noncurrent portion	2,287	2,513
Total liabilities	23,007	24,124
Stockholders' equity		
Common stock	59	22
Additional paid-in capital	258,105	248,168
Accumulated deficit	(251,430)	(241,380)
	6,734	6,810
Less: Treasury stock	(85)	(85)
Total stockholders' equity	6,649	6,725
Total liabilities and stockholders' equity	$ 29,656	$ 30,849