

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): November 14 , 201 7

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

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-15911</u> (Commission File Number)	<u>52-1256615</u> (IRS Employer Identification No.)
<u>997 Lenox Drive, Suite 100, Lawrenceville, NJ</u> (Address of principal executive offices)		<u>08648-2311</u> (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 November 14, 2017, Celsion Corporation issued a press release reporting its financial results for the quarter ended September 30, 2017. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On November 7, 2017, Celsion Corporation announced it would hold a conference call on November 14, 2017 to discuss its financial results for the quarter ended September 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 Third Quarter Financial Results and Provides Business Update” issued by Celsion Corporation on November 14, 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: November 14, 2017

By: /s/ Jeffrey W. Church

Jeffrey W. Church

Senior Vice President and Chief Financial Officer



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

Recent Minimally Dilutive Financings Substantially Strengthen Balance Sheet and Provide Runway to Significant Clinical Milestones for ThermoDox® and GEN-1 Clinical Programs

Company to Hold Conference Call on Tuesday, November 14, 2017 at 11:00 a.m. ET

LAWRENCEVILLE, N.J., November 14, 2017 -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the quarter and nine month period ended September 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 meaningful developments in our two lead clinical programs and the capital infusion of over \$38 million in 2017 to help drive these important development efforts," said Michael H. Tardugno, Celsion's chairman, president and CEO. "Because of our highly efficient, largely research focused use of funds, we believe that we now have sufficient capital to complete enrollment of our Phase III OPTIMA Study and through the first efficacy analysis expected in the first quarter of 2019. Further, expect that our current funds will allow us to make substantial progress in our open label, randomized, 86 patient Phase I/II study of GEN-1 in newly diagnosed stage III and IV ovarian cancer patients."

"Our global Phase III OPTIMA Study evaluating ThermoDox® in primary liver cancer is currently enrolling patients in 14 countries worldwide. In August 2017, the independent Data Monitoring Committee (DMC) recommended continuation of the OPTIMA Study after their review of the safety and efficacy data for 275 patients enrolled in the study," stated Mr. Tardugno. "The final data from our Phase 1b immunotherapy program in ovarian cancer continue to provide important insights into GEN-1's clinical and safety profile and reinforce our confidence in its potential to serve as an effective front line therapy in newly diagnosed ovarian cancer patients."

Recent Developments

ThermoDox®

Publication of HEAT Study Manuscript. On October 16, 2017, the Company announced publication of the manuscript, "Phase III HEAT Study Adding Lyso-Thermosensitive Liposomal Doxorubicin to Radiofrequency Ablation in Patients with Unresectable Hepatocellular Carcinoma Lesions," in *Clinical Cancer Research*, a high impact, peer-reviewed medical journal. The article provided detailed learnings from the Company's 701 patient HEAT Study and included results from computer simulation studies and interesting findings from a *post hoc* subgroup analysis, all of which – when examined together -- suggest a clearer understanding of a key ThermoDox® heat-based mechanism of action: the longer the target tissue is heated, the greater the doxorubicin tissue concentration.

Additionally, the article explored the hypothesis prompted by these findings: ThermoDox®, when used in combination with Radiofrequency Ablation (RFA) standardized to a minimum dwell time of 45 minutes (sRFA \geq 45 min), may increase the overall survival (OS) of patients with hepatocellular carcinoma (HCC). The final OS analysis demonstrated that in a large, well bounded, subgroup of patients (n=285 patients, 41% of the previous 701 patient HEAT Study), treatment with a combination of ThermoDox® and standardized RFA provided an average 58% improvement in OS compared to standardized RFA alone. The Hazard Ratio (HR) is 0.63 (95% CI 0.43 - 0.93) with a p-value of 0.0198. In this large subgroup, median OS for the ThermoDox® plus standardized RFA group translates into a 25.4 month (more than 2.1 years) survival benefit over the standardized RFA only group - totaling approximately 80 months (6-1/2 years), which is considered a curative treatment for HCC for the ThermoDox® plus standardized RFA group versus 53 months for the standardized RFA only group.

The lead author of the HEAT Study manuscript is Won Young Tak, M.D., Ph.D., Professor Internal Medicine, Gastroenterology & Hepatology, Kyungpook National University Hospital Daegu, Republic of Korea, and there are 22 HEAT Study co-authors along with Nicholas Borys, M.D., Celsion's senior vice president and chief medical officer.

R&D Day. On October 12, 2017, the Company made various ThermoDox®-related presentations during the Research and Development (R&D) Day held in New York City. The presentations focused on the Company's development program using ThermoDox® for the treatment of primary liver cancer. Leading OPTIMA Study clinical investigators representing various geographical regions (Asia-Pacific and Europe) and multiple medical disciplines (hepatology, interventional radiology and surgery) presented their past and current experiences with ThermoDox® for the treatment of primary liver cancer.

Update on OPTIMA Study. On September 27, 2017, the Company announced that enrollment in the OPTIMA Study was approaching 70% of the 550 patients necessary to ensure that the study's primary end point, overall survival, could be evaluated with statistical significance. The statistical plan for the OPTIMA Study calls for two interim efficacy analyses by the independent Data Monitoring Committee (DMC). The Company projected full patient enrollment by mid-2018 and the first pre-planned efficacy analysis after 118 overall survival events by the first quarter of 2019.

DMC Review of OPTIMA Study . On August 7, 2017, the Company announced that the 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 unanimously recommended that the OPTIMA Study continue according to protocol to its final data readout based on the risk to benefit analysis by the Committee. 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 also hosted Investigators Meetings with physicians and key opinion leaders in Bangkok, Thailand and Shanghai, 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 potentially significant markets for ThermoDox® where HCC incidence rates are among the highest in the world.

GEN-1 Immunotherapy

R&D Day. On October 12, 2017, the Company made various GEN-1 immunotherapy-related presentations during the Research and Development (R&D) Day held in New York City. The GEN-1 immunotherapy presentations focused on the Company's clinical and translational research data from its recently completed Phase IB OVATION Study. The lead clinical investigator for the OVATION Study and leading immuno-oncology experts from the Roswell Park Cancer Institute presented their current experience with GEN-1 immunotherapy for the treatment of ovarian cancer.

Presented Final OVATION Study Findings at the American Association of Cancer Research (AACR) Special Conference . On October 3, 2017, the Company announced final clinical and translational research data from the OVATION Study at the AACR Special Conference entitled "Addressing Critical Questions in Ovarian Cancer Research and Treatment" in Pittsburgh, PA. The Company also held an Advisory Board Meeting on September 27, 2017 with the clinical investigators and scientific experts to review and finalize clinical, translational research and safety data from the OVATION Study in order to determine the next steps forward for this exciting new immunotherapy. With the endorsement and recommendations from the Advisory Board, the Company expects to file a next phase protocol with FDA later this year.

Key translational research findings from all evaluable patients are consistent with the earlier reports from partial analysis of the data and are summarized below:

- The intraperitoneal treatment of GEN-1 in conjunction with neoadjuvant chemotherapy resulted in dose dependent increases in IL-12 and Interferon-gamma (IFN-g) levels that were predominantly in the peritoneal fluid compartment with little to no changes observed in the patients' systemic circulation. These and other post-treatment changes including decreases in VEGF levels in peritoneal fluid are consistent with an IL-12 based immune mechanism.
- Consistent with the previous partial reports, the effects observed in the 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.
- Analysis of peritoneal fluid by cell sorting, not reported before, shows treatment-related decrease in the percentage of immunosuppressive T-cell (Foxp3+), which is consistent with the reduction of Foxp3+ T-cells in the primary tumor tissue, and a shift in tumor naïve CD8+ cell population to more efficient tumor killing memory effector CD8+ cells.

Celsion also reported highly encouraging clinical data from the first fourteen patients who have completed treatment in the OVATION Study. GEN-1 plus standard chemotherapy produced positive clinical results, with no dose limiting toxicities and promising dose dependent efficacy signals which correlate well with successful surgical outcomes as summarized below:

- Of the fourteen patients treated 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. Seven out of eight (87%) patients in the highest two dose cohorts experienced a R0 surgical resection. All five patients treated at the highest dose cohort experienced a R0 surgical resection.
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- 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 eight patients who have received GEN-1 treatment over one year ago (cohort 1 - 3) and are being followed; only two patients' cancer has progressed. 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 as of September 30, 2017 is 18 months with the longest progression-free patient at 24 months.

Corporate Development

Raised Approximately \$28.6 Million in Gross Proceeds in the Third Quarter and Through October 2017. Recent equity offerings totaling approximately \$28.6 million in gross proceeds have strengthened the Company's balance sheet and provide a roadway to potentially significant clinical milestones for ThermoDox® and GEN-1 clinical programs through the second quarter of 2019.

- The Company raised \$17.0 million in gross proceeds through the exercise of outstanding common stock warrants in October 2017.
- 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.
- In October 2017, the Company completed an underwritten equity offering of shares of common stock and warrants to purchase common stock with Oppenheimer & Co. The gross proceeds of the offering were approximately \$6.6 million.

Financial Results

For the quarter ended September 30, 2017, Celsion reported a net loss of \$5.7 million, or \$(0.70) per share, compared to a net loss of \$6.4 million, or \$(3.22) per share, in the same period of 2016. Operating expenses were \$4.4 million in the third quarter of 2017 compared to \$5.6 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 nine month period ended September 30, 2017, the Company reported a net loss attributable to common shareholders of \$16.1 million, or \$(3.04) per share, compared to \$16.7 million, or \$(9.27) per share, in the same nine month period of 2016. Operating expenses were \$13.8 million in the first nine months of 2017 compared to \$15.5 million in the same period of 2016.

Net cash used for operating activities was \$12.4 million in the first nine months of 2017 compared to \$13.7 million in the same period last year. The Company ended the third quarter of 2017 with \$2.7 million of total cash and cash equivalents, which was subsequently increased with aggregate gross proceeds of \$17.0 million from warrant exercises and an underwritten equity offering with gross proceeds of \$6.6 million completed in October 2017.

Research and development costs were \$3.3 million in the third quarter of 2017 compared to \$4.2 million in the same period last year. Research and development costs were \$9.9 million in the first nine months of 2017 compared to \$11.0 million in the same period last year. Clinical development costs for the Phase III OPTIMA Study remained relatively unchanged at \$1.8 million in the third quarter of 2017 compared to \$1.9 million in the same period of 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 nine months of 2017 associated with the production of ThermoDox® clinical supplies to support the OPTIMA Study.

General and administrative expenses were \$1.2 million in the third quarter of 2017 compared to \$1.5 million in the same period of 2016. This 22 percent decrease during the third quarter of 2017 was due to lower non-cash stock compensation expense and reduced professional fees. General and administrative expenses were \$4.3 million in the first nine months of 2017 compared to \$4.9 million in the same period of 2016. The decrease during the first nine months of 2017 was primarily the result of lower personnel costs and professional fees.

During the third quarter ended September 30, 2017, other expenses included a non-cash charge of \$2.5 million related to the impairment of certain in process research and development assets related to the development of our glioblastoma multiforme (GBM) cancer product candidate offset by a \$1.2 million reduction in the earn-out liability related to potential milestone payments for the GBM product candidate.

During the nine months ended September 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.

Interest expense decreased by \$0.5 million in 2017 due to lower principal balances outstanding under the Company's current debt facility with Hercules. The loan balance and end of term charges on its debt facility was paid in full on June 1, 2017.

Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss third quarter 2017 financial results at 11:00 a.m. ET on Tuesday, November 14, 2017. To participate in the call, interested parties may dial 1-877-830-2649 (Toll-Free/North America) or 1-785-424-1824 (International/Toll) and ask for the Celsion Corporation Third Quarter 2017 Earnings Call (Conference Code: 3840213) 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, November 14, 2017 and will remain available until November 28, 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: 3840213. 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, November 14, 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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Licensing revenue	\$ 125	\$ 125	\$ 375	\$ 375
Operating expenses:				
Research and development	3,349	4,225	9,871	11,003
General and administrative	1,174	1,497	4,291	4,888
Total operating expenses	<u>4,523</u>	<u>5,722</u>	<u>14,162</u>	<u>15,891</u>
Loss from operations	<u>(4,398)</u>	<u>(5,597)</u>	<u>(13,787)</u>	<u>(15,516)</u>
Other income (expense):				
Gain (loss) from valuation of common stock warrant liability	1,246	(662)	670	(556)
(Loss) from impairment of in-process research and development	(2,520)	-	(2,520)	-
Interest expense, investment income and other income (expense), net	1	(151)	(84)	(585)
Total other income (expense), net	<u>(1,273)</u>	<u>(813)</u>	<u>(1,934)</u>	<u>(1,141)</u>
Net loss	<u>(5,671)</u>	<u>(6,410)</u>	<u>(15,721)</u>	<u>(16,657)</u>
Deemed dividend related to warrant Modification	-	-	(346)	-
Net loss attributable to common shareholders	<u>\$ (5,671)</u>	<u>\$ (6,410)</u>	<u>\$ (16,067)</u>	<u>\$ (16,657)</u>
Net loss per common share				
Basic and diluted	<u>\$ (0.70)</u>	<u>\$ (3.22)</u>	<u>\$ (3.04)</u>	<u>\$ (9.27)</u>
Weighted average shares outstanding				
Basic and diluted	<u>8,055</u>	<u>1,993</u>	<u>5,172</u>	<u>1,796</u>

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	September 30, 2017	December 31, 2016
ASSETS		
Current assets		
Cash and cash equivalents	\$ 2,685	\$ 2,624
Investment securities and interest receivable on investment securities	-	1,684
Prepaid expenses and other current assets	89	204
Total current assets	<u>2,774</u>	<u>4,512</u>
Property and equipment		
	<u>143</u>	<u>463</u>
Other assets		
In-process research and development	20,247	22,766
Other intangibles assets, net	852	1,023
Goodwill	1,976	1,976
Deposits	-	100
Other assets	9	9
Total other assets	<u>23,084</u>	<u>25,874</u>
Total assets	<u>\$ 26,001</u>	<u>\$ 30,849</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 5,497	\$ 5,363
Deferred revenue - current portion	500	500
Note payable - current portion	-	2,560
Total current liabilities	<u>5,997</u>	<u>8,423</u>
Earn-out milestone liability	12,518	13,188
Deferred revenue and other liabilities - noncurrent portion	2,199	2,513
Total liabilities	<u>20,714</u>	<u>24,124</u>
Stockholders' equity		
Common stock	83	22
Additional paid-in capital	262,390	248,168
Accumulated deficit	<u>(257,101)</u>	<u>(241,380)</u>
	5,372	6,810
Less: Treasury stock	<u>(85)</u>	<u>(85)</u>
Total stockholders' equity	<u>5,287</u>	<u>6,725</u>
Total liabilities and stockholders' equity	<u>\$ 26,001</u>	<u>\$ 30,849</u>