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 15, 2019

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))

Securities registered pursuant to Section 12(b) of the Act

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value $0.01 per share	CLSN	NASDAQ Capital Market

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 15, 2019, Celsion Corporation issued a press release reporting its financial results for the quarter ended March 31, 2019. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On May 8, 2019, Celsion Corporation announced it would hold a conference call on May 15, 2019 to discuss its financial results for the quarter ended March 31, 2019 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 2019 Financial Results and Provides Business Update" issued by Celsion Corporation on May 15, 2019.

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 15, 2019

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

Exhibit 99.1

Celsion Corporation Reports First Quarter 2019 Financial Results and Provides Business Update

Company to Hold Conference Call on Wednesday, May 15, 2019 at 11:00 a.m. EDT

LAWRENCEVILLE, N.J., May 15, 2019 — Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the quarter ended March 31, 2019 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 hepatocellular carcinoma (HCC), or primary liver cancer. The Company's immunotherapy candidate, GEN-1, is currently in Phase I/II development for the localized treatment of newly diagnosed Stage III/IV ovarian cancer.

"Celsion continues to make significant progress with our two ongoing clinical development programs for ThermoDox® and GEN-1. With sound fundamentals and a strong balance sheet, we are well positioned to see our clinical programs through transformative milestones over the next year. We are looking forward to the first of two preplanned, interim efficacy analyses for the Phase III OPTIMA Study expected in the second half of 2019 and mid-2020, respectively. This global, pivotal study completed patient enrollment in August 2018 at over 65 clinical sites in 14 different countries, including all of the markets where primary liver cancer is a major problem," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "Our Phase I/II OVATION 2 Study in newly diagnosed ovarian cancer is now recruiting patients and continues to work through the activation of up to 31 clinical sites by the end of this year. Importantly, enrollment of patients in the Phase I portion of the study is expected to be complete and initial data reported by the end of 2019. This promising clinical development program in immunotherapy has generated impressive results in previous trials."

Recent Developments

ThermoDox®

Issuance of New U.S. Patent for ThermoDox®. On April 17, 2019, the Company announced that the United States Patent and Trademark Office granted U.S. Patent No. 10,251,901 B2 – *Thermosensitive Nanoparticle Formulations and Method of Making the Same*, which is directly applicable to the method of treating cancer using a new ThermoDox® formulation. The claim covers a method for preparing (as well as the composition of) a doxorubicin sulfate temperature-sensitive liposome and extends coverage time over ThermoDox's current patent portfolio to 2033. This new patent broadens our intellectual property portfolio providing for life cycle management of ThermoDox® well into the future.

Publication of ThermoDox® Study Results in the Peer-Reviewed Journal, Radiology. On January 17, 2019, the Company announced that results from the Phase I TARDOX trial of ThermoDox® conducted at the University of Oxford, United Kingdom, were published in the peer-reviewed journal, *Radiology*. The findings published in *Radiology* serve as a companion paper to the groundbreaking work published in *Lancet Oncology* in July 2018. This was the first published study to evaluate ThermoDox® when combined with high-intensity focused ultrasound (HIFU). The *Radiology* publication was accompanied by an editorial highlighting the significance of utilizing HIFU to safely deliver oncologically relevant concentrations of doxorubicin with ThermoDox®.

The article, titled, *"Focused Ultrasound Hyperthermia for Targeted Drug Release from Thermosensitive Liposomes: Results from a Phase I Trial,"* included an evaluation of the TARDOX results and the safety, efficacy and utility of treatment with ThermoDox® plus targeted, non-invasive ultrasound in patients with solid liver tumors, with treatment plans based on patient-specific modeling.

The Phase I TARDOX study was carried out as a multi-disciplinary collaboration between Celsion, the Oxford University Institute of Biomedical Engineering, the Oncology Clinical Trials Office (OCTO) and the Oxford University Hospitals NHS Foundation Trust and evaluated patients with inoperable primary or secondary liver tumors who had previously received chemotherapy. In this trial, 10 patients received a single intravenous dose of 50 mg/m^2 of ThermoDox®, and ultrasonic heating of target tumors was monitored in six participants using a minimally invasive temperature sensor, while four patients were treated without real-time thermometry. The study demonstrated that focused ultrasound exposure with ThermoDox® resulted in increased chemotherapy concentrations within liver tumors that were an average of 3.7 times greater than preheating levels across all 10 patients in the study.

Safety was assessed by analysis of magnetic resonance imaging (MRI) and biopsy specimens for evidence of thermal ablation, as well as adverse event monitoring. There was no evidence of focused ultrasound-related adverse effects, including thermal ablation.

GEN-1 Immunotherapy

Presentation of GEN-1 Clinical Development Program at ASCO-SITC Clinical Immuno-Oncology Symposium. On March 4, 2019, the Company announced the oral presentation of data highlighting the safety, clinical response and translational data from the OVATION I Study by Premal H. Thaker, M.D., M.S., a nationally recognized expert in gynecologic oncology, Associate Professor of Obstetrics and Gynecology at the Siteman Cancer Center at the Washington University School of Medicine in St. Louis at the ASCO-SITC Clinical Immuno-Oncology Symposium.

Dr. Thaker's presentation highlighted the following:

- The Phase IB OVATION I Study, which evaluated escalating doses of GEN-1 (36 mg/m ^{2}, 47 mg/m^2, 61 mg/m^2 and 79 mg/m^2) administered intraperitoneally in combination with three cycles of neoadjuvant chemotherapy (NAC) prior to interval debulking surgery, followed by three cycles of NAC in the treatment of newly diagnosed patients with Stage III/IV ovarian cancer, demonstrated median PFS of 21 months in patients treated per protocol (n=14) and 17.1 months for the intent-to-treat population (n=18) for all dose cohorts, including three patients who dropped out of the study after 13 days or less, each of which compared favorably to the PFS historical average of 12 months for women with Stage III/IV ovarian cancer.
- Of the 14 patients who were evaluable for response, 100% of patients administered NAC plus the two higher doses of GEN-1 experienced an objective tumor response (defined as a partial or complete response) compared to only 60% of patients given the two lower doses.
- Patients in the two higher dose cohorts also had a high surgery success rate, with 88% of these patients achieving the optimal outcome of a complete (R0) resection. 100% of patients treated at the highest dose cohort had a complete R0 resection.
- Pre- and post-treatment levels of key ovarian cancer biomarkers were also measured as part of this study and showed marked reduction in immunosuppressive response across multiple biomarkers post-treatment, including FOXP3 and IDO-1 – an outcome not previously observed with NAC treatment alone.

Corporate Development

Celsion Participated in Two Investor Conferences. During May 2019, the Company attended the ThinkEquity Conference on May 2, 2019 at The Mandarin Oriental Hotel in New York City and the Deutsche Bank 44th Annual Health Care Conference on May 7-8, 2019 at The InterContinental Hotel in Boston. A webcast of Celsion's presentation at the ThinkEquity Conference may be accessed by visiting the "News & Investors" section of Celsion's corporate website. The format of the Deutsche Bank Health Care Conference was comprised of one-on-one and small group meetings with leading institutional investors.

Celsion Completed an Amendment to the Asset Purchase Agreement with EGEN, Inc. On March 28, 2019, the Company entered into an amendment to the June 6, 2014 Asset Purchase Agreement for the acquisition of substantially all of the assets of EGEN, Inc. The Amendment provides that payment of the $12.4 million earnout milestone liability under the Asset Purchase Agreement related to the Ovarian Cancer Indication can be made, at the Company's sole discretion, in the following manner:

a) 7.0 million in cash to EGWU within 10 business days of achieving the milestone; or

b) $12.4 million to EGWU, which is payable in cash, common stock of the Company, or a combination of either, within one year after achieving the milestone.

Additionally, the Amendment extends the Earnout Term as it applies to the Ovarian Cancer Milestone from seven (7) years to eight (8) years from the original signing date of the Asset Purchase Agreement. As consideration for entering into the Amendment, the Company will issue to EGWU 200,000 warrants to purchase common stock with an exercise price of $0.01 per share. The Company recorded this transaction in the first quarter of 2019.

Financial Results

For the quarter ended March 31, 2019, Celsion reported a net loss of $2.3 million ($0.12 per share) compared to a net loss of $4.5 million ($0.25 per share) for the quarter ended March 31, 2018. Operating expenses were $5.0 million for the quarter ended March 31, 2019, which represented a $0.6 million (13.6%) increase, from $4.4 million in the same period of 2018. During the first quarter of 2019, the Company incurred $0.7 million in non-cash stock option expense compared to $0.2 million in the comparable prior-year period.

Cash, cash equivalents, short-term investments and interest receivable at March 31, 2019 was $23.8 million. Cash provided by financing activities was approximately $1.8 million during the quarter ended March 31, 2019. Net cash used for operating activities was $5.5 million for the quarter ended March 31, 2019, compared to $4.6 million in the comparable prior-year period.

Research and development costs were $2.8 million for the quarter ended March 31, 2019 compared to $2.7 million for the quarter ended March 31, 2018. Clinical development costs for the Phase III OPTIMA Study were $0.9 million for the current quarter compared to $1.3 million for the same period of 2018. This $0.4 million decrease resulted from the completion of enrollment for this 556-patient trial in August 2018. Costs associated with the OVATION studies were $0.1 million for each of the quarters ended March 31, 2019 and 2018. The Company announced the completion of enrollment of all cohorts of the OVATION I Study in 2017 and the initiation of the follow-on Phase I/II OVATION 2 Study during 2018. Costs associated with Celsion's wholly-owned subsidiary, CLSN Laboratories, Inc. (which includes research and development activities for GEN-1, TheraPlas and TheraSilence) were $0.6 million in each of the quarters ended March 31, 2019 and 2018 as the Company continues to expand its manufacturing capabilities and implemented programs to reduce manufacturing costs for GEN-1. In the first quarter of 2019, other clinical costs included an increase of $0.2 million in non-cash stock compensation expense compared to the same period of 2018.

General and administrative expenses were $2.2 million for the quarter ended March 31, 2019, compared to $1.7 million for the quarter ended March 31, 2018. This $0.5 million increase was due to higher compensation expenses totaling $0.5 million in 2019 compared to 2018. Compensation expenses include costs associated with new personnel additions as well as an increase of $0.3 million related to non-cash stock option compensation expense in 2019 compared to the prior year.

Other expenses included a non-cash gain of $2.7 million, net of charge a $0.4 million for the 200,000 warrant issuance related to an amendment for the potential milestone payments for the GEN-1 ovarian product candidate during the quarter ended March 31, 2019, compared to a non-cash charge of $270,000 for the quarter ended March 31, 2018. The Company realized $0.1 million of interest income from its short-term investments during the first quarter of 2019 and 2018. In connection with the Company's new venture debt facility with Horizon in June 2018, the Company incurred interest expense of $0.4 million during the first quarter of 2019 compared to no interest expense in the first quarter of 2018.

First Quarter Conference Call

The Company is hosting a conference call to provide a business update and discuss its first quarter 2019 financial results at 11:00 a.m. EDT on Wednesday, May 15, 2019. To participate in the call, interested parties may dial 1-800-263-0877 (Toll-Free/North America) or 1-646-828-8143 (International/Toll) and ask for the Celsion Corporation First Quarter 2019 Earnings Call (Conference Code: 1231968) 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 Wednesday, May 15, 2019 and will remain available until May 29, 2019. The replay can be accessed at 1-719-457-0820 or 1-888-203-1112 using Conference ID: 1231968. 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. EDT Wednesday, May 15, 2019.

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. The pipeline also includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer. 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

Jeffrey W. Church
Executive Vice President, CFO and Corporate Secretary
609-482-2455
jchurch@celsion.com

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

	Three Months Ended March 31,	
	2019	**2018**
Licensing revenue	$ 125	$ 125
Operating expenses:		
Research and development	2,768	2,741
General and administrative	2,217	1,665
Total operating expenses	4,985	4,406
Loss from operations	(4,860)	(4,281)
Other (expense) income:		
Gain (loss) from valuation of earn-out milestone liability	3,130	(270)
Fair value of warrants issued in connection with amendment to modify earn-out milestone payments	(400)	-
Investment income, interest (expense) and other income (expense), net	(237)	74
Total other income (expense), net	2,493	(196)
Net loss	$ (2,367)	$ (4,477)
Net loss per common share - basic and diluted	$ (0.12)	$ (0.25)
Weighted average common shares outstanding - basic and diluted	19,105	17,684

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 3,575	$ 13,354
Investment securities and interest receivable on investment securities	20,245	14,326
Prepaid expenses and other current assets	1,041	451
Total current assets	24,861	28,131
Property and equipment	300	185
Other assets		
In-process research and development	15,736	15,736
Goodwill	1,976	1,976
Other intangible assets, net	511	568
Operating lease right-of-use assets, net	1,696	-
Other assets	316	260
Total other assets	20,235	18,540
Total assets	$ 45,396	$ 46,856
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 5,049	$ 5,607
Operating lease liability – current portion	344	-
Deferred revenue - current portion	500	500
Total current liabilities	5,893	6,107
Earn-out milestone liability	5,778	8,908
Operating lease liability – non-current portion	1,439	-
Notes payable - noncurrent portion	9,514	9,417
Deferred revenue and other liabilities - noncurrent portion	1,375	1,563
Total liabilities	23,999	25,995
Stockholders' equity		
Common stock	196	188
Additional paid-in capital	297,231	294,393
Accumulated other comprehensive gain (loss)	87	30
Accumulated deficit	(276,032)	(273,665)
	21,482	20,946
Less: Treasury stock	(85)	(85)
Total stockholders' equity	21,397	20,861
Total liabilities and stockholders' equity	$ 45,396	$ 46,856