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, 2020

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, 2020, Celsion Corporation issued a press release reporting its financial results for the quarter ended March 31, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On May 8, 2020, Celsion Corporation announced it would hold a conference call on May 15, 2020 to discuss its financial results for the quarter ended March 31, 2020 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 2020 Financial Results and Provides Business Update" issued by Celsion Corporation on May 15, 2020.

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, 2020

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

Exhibit 99.1

Celsion Corporation Reports First Quarter 2020 Financial Results and Provides Business Update

Phase III OPTIMA Study on Track for Interim Data Analysis in July

Conference Call Begins Today at 11:00 a.m. Eastern Time

LAWRENCEVILLE, N.J. (May 15, 2020) – Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the three months ended March 31, 2020, and provided an update on clinical development programs with ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin currently in Phase III development for the treatment of hepatocellular carcinoma (HCC), or primary liver cancer, and GEN-1, its DNA-mediated IL-12 immunotherapy, currently in Phase I/II development for the treatment of advanced stage ovarian cancer.

"During the first quarter and recent weeks, Celsion continued to make substantial progress with our ongoing development programs with ThermoDox® and GEN-1, while maintaining a strong balance sheet," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "With our pivotal 556-patient Phase III OPTIMA Study in HCC fully enrolled, we now look forward to the preplanned interim efficacy analysis in July 2020."

"Our GEN-1 immunotherapy product continued to show encouraging results at the 100 mg/m² dose cohort in the OVATION 2 Study, which is consistent with the results reported from our earlier Phase Ib trial (the OVATION 1 Study) in advanced stage ovarian cancer. These findings were reinforced by strong progression-free survival when comparing study patients to a statistically validated synthetic control arm of matched patients from prior studies. This unique means of evaluating efficacy holds great potential for clinical research, and we plan to use it in upcoming discussions with the U.S. Food and Drug Administration as part of our goal to accelerate GEN-1 clinical development. In addition, GEN-1 received Orphan Drug Designation from the European Medicines Agency in April 2020." Mr. Tardugno added, "Our fundamentals are strong, and we are well positioned with a capital structure sufficient to see our clinical programs through transformative milestones in 2020."

Recent Developments

ThermoDox®

Sufficient Number of Patient Deaths Were Reached for the Second Interim Analysis of the Phase III OPTIMA Study of ThermoDox® in Primary Liver Cancer. In April 2020 the Company announced that the prescribed minimum number of events (158 patient deaths) was reached for the second pre-specified interim analysis of the OPTIMA Phase III Study with ThermoDox® plus RFA (radiofrequency ablation) in patients with HCC. Following preparation of the data, the Independent Data Monitoring Committee (iDMC) is expected to meet in July to conduct the second interim analysis. Celsion expects to announce iDMC recommendations as soon as possible after the meeting. The hazard ratio (HR) and p-value necessary for success at 158 deaths are 0.70 and 0.022, respectively, which compare favorably with the hazard ratio and p-value observed in the prospective HEAT Study subgroup upon which the OPTIMA Study is based.

The OPTIMA Study was fully enrolled in August 2018 with 556 subjects from 65 clinical sites in 14 countries. The study design is based on the Company's HEAT Study, in which a prospective subgroup analysis of 285 subjects with a single lesion of 3-7 cm in size received a single ThermoDox® administration in combination with a 45 minute or longer RFA procedure. Followed prospectively for 3 years, those patients demonstrated a median survival of more than 7 ½ years and a survival benefit of more than 2 years over the control group. These data were published in the October 2017 issue of the peer-reviewed journal *Clinical Cancer Research*, and are available here.

GEN-1 Immunotherapy

GEN-1 Showed Strong Progression-Free Survival Treatment Effect Utilizing Medidata's Synthetic Control Arm. In March 2020 the Company announced that Medidata-matched patient data from a synthetic control arm (SCA) compared with results from the Company's completed Phase Ib dose-escalating OVATION 1 Study with GEN-1 in Stage III/IV ovarian cancer patients showed positive results in progression-free survival (PFS). The HR was 0.53 in the intent-to-treat group, showing strong signals of efficacy. Medidata is a globally recognized leader in clinical data management.

Celsion believes these data may warrant consideration of strategies to accelerate the clinical development for GEN-1 in newly diagnosed, advanced ovarian cancer patients by the U.S. Food and Drug Administration (FDA). In its March 2019 discussion with Celsion, the FDA noted that preliminary findings from the Phase Ib OVATION 1 Study were exciting but lacked a control group to evaluate GEN-1's independent impact on impressive tumor response, surgical results and PFS. The FDA encouraged Celsion to continue its GEN-1 development program and consult with FDA with new findings that may have a bearing on designations such as Fast Track and Breakthrough Therapy.

GEN-1's strong and encouraging treatment effect, evidenced by the synthetic control arm, suggests a potentially remarkable improvement in PFS, an FDA-recognized surrogate for overall survival, and appears to confirm the science behind IL-12's ability to recruit the innate and adaptive elements of the immune system to fight malignancies. The strong PFS trend is supported by previously published translational data that clearly demonstrate the pro-immune changes in the tumor micro-environment associated with loco-regional GEN-1 therapy. Celsion's randomized Phase II OVATION 2 Study in advanced ovarian cancer patients is expected to commence in the fourth quarter of 2020 and is designed to demonstrate a 33% improvement in PFS (HR = 0.75) over current standard of care. PFS is the primary endpoint for this study.

SCAs have the potential to revolutionize clinical trials in certain oncology indications and some other diseases where a randomized control is not ethical or practical. SCAs are formed by carefully selecting control patients from historical clinical trials to match the demographic and disease characteristics of the patients treated with the new investigational product. SCAs have been shown to mimic the results of traditional randomized controls so that the treatment effects of an investigational product can be visible by comparison to the SCA. SCAs can help advance the scientific validity of single-arm trials, and in certain indications, reduce time and cost, and expose fewer patients to placebos or existing standard-of-care treatments that might not be effective for them. Medidata is in a unique position to create fit-for-purpose synthetic controls because of access to a pool of more than six million anonymized patients from nearly 20,000 previous clinical trials.

PFS data generated from this analysis comparing GEN-1 with SCA showed the following:

GEN-1 Population	PFS Hazard Ratio (Confidence Interval)
Intent-to-treat, n=15	0.53 (95% CI 0.16, 1.73); log-rank p=0.29
Per-protocol, n=14	0.33 (95% CI 0.08, 1.37); log-rank p=0.11

Highly Encouraging Initial Clinical Results from the Phase I Portion of the Phase I/II OVATION 2 Study with GEN-1 in Patients with Advanced Ovarian Cancer. In March 2020 the Company announced highly encouraging initial clinical data from the first 15 patients enrolled in the ongoing Phase I/II OVATION 2 Study for patients newly diagnosed with Stage III and IV ovarian cancer. The OVATION 2 Study combines GEN-1, the Company's IL-12 gene-mediated immunotherapy, with standard-of-care neoadjuvant chemotherapy (NACT). Following NACT, patients undergo interval debulking surgery (IDS), followed by three additional cycles of chemotherapy.

GEN-1 plus standard NACT produced positive dose-dependent efficacy results, with no dose-limiting toxicities, which correlates well with successful surgical outcomes as summarized below:

- Of the 15 patients treated in the Phase I portion of the OVATION 2 Study, nine were treated with GEN-1 at a dose of 100 mg/m² plus NACT and six were treated with NACT only. All 15 had successful resections of their tumors, with seven out of nine patients (78%) in the GEN-1 treatment arm having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Only three out of six patients (50%) in the NACT only treatment arm had an R0 resection.

- When combining these results with the surgical resection rates observed in the Company's prior Phase Ib dose-escalation trial (the OVATION 1 Study), a population of patients with inclusion criteria identical to the OVATION 2 Study, the data reflect the strong dose-dependent efficacy of adding GEN-1 to the current standard of care NACT:

		% of Patients with R0 Resections
0, 36, 47 mg/m² of GEN-1 plus NACT	n=12	42%
61, 79, 100 mg/m² of GEN-1 plus NACT	n=17	82%

- The objective response rate (ORR) as measured by Response Evaluation Criteria in Solid Tumors (RECIST) criteria for the 0, 36, 47 mg/m² dose GEN-1 patients were comparable, as expected, to the higher (61, 79, 100 mg/m²) dose GEN-1 patients, with both groups demonstrating an approximate 80% ORR.

GEN-1 Received Orphan Drug Designation from the European Medicines Agency. In March 2020 the Company announced the European Medicines Agency (EMA) Committee for Orphan Medicinal Products recommended that GEN-1 be designated as an orphan medicinal product for the treatment of ovarian cancer. As established by the EMA, this designation provides for scientific advice and certain regulatory assistance during the product development phase, direct access to centralized marketing authorization and certain financial incentives for companies developing new therapies intended for the treatment of a life-threatening or chronically debilitating condition that affects no more than five in 10,000 people in the European Union (EU).

Benefits of the designation include:

- 10 years of market exclusivity (in which other industry sponsors are prevented from entering the market with a similar product for the same therapeutic indication);
- EMA protocol assistance for sponsors on the conduct of the tests and trials necessary to demonstrate their quality, safety and efficacy, or regulatory assistance;
- EMA advice will be free or given in return for reduced fees;
- Access to a centralized procedure allowing immediate marketing authorization in all Member States and facilitating the availability of medicines to all patients in the EU;
- Eligibility for a reduction of regulatory fees associated with pre-authorization inspections, as well as marketing authorization application fees and certain other fees for qualifying companies.

GEN-1 previously received orphan drug designation from the FDA.

Corporate Developments

Received $1.8 Million in Non-Dilutive Funding from the Sale of Its New Jersey State Net Operating Losses. In April 2020 the Company announced it received $1.82 million of net cash proceeds from the sale of approximately $1.9 million of its unused New Jersey net operating losses (NOLs). The NOL sales cover the tax years 2017 and 2018 and are administered through the New Jersey Economic Development Authority's (NJEDA) Technology Business Tax Certificate Transfer (NOL) Program. With this new non-dilutive funding, coupled with the $4.4 million in net proceeds from the recent registered direct equity offer completed on March 3, 2020, the Company strengthened its balance sheet at a time of capital markets uncertainty. An additional sale of $2.0 million of unused New Jersey NOLs anticipated in the second half of 2020 will further increase Celsion's cash reserves on a non-dilutive basis. In addition, the Company initiated several cost containment measures to ensure that it has sufficient cash to fund operations and clinical development programs through the second quarter of 2021, which includes all major Phase III OPTIMA Study readouts.

On April 21, 2020, we entered into a loan agreement with Silicon Valley Bank (the "PPP Loan"), pursuant to the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act. We thereafter received proceeds of $632,220 under the PPP Loan. The PPP Loan application required Celsion to certify that there was economic uncertainty surrounding the Company and that, as such, the PPP Loan was necessary to support our ongoing operations. Celsion made this certification in good faith after analyzing, among other things, its financial situation and access to alternative forms of capital, and believes that the Company satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan proceeds was consistent with the broad objectives of the PPP of the CARES Act. The certification given with respect to the PPP Loan does not contain any objective criteria and is subject to interpretation. In light of subsequent guidance issued by the U.S. Small Business Administration in consultation with the U.S. Department of the Treasury, out of an abundance of caution, we returned the proceeds of the PPP Loan in full on May 13, 2020. Celsion may choose to reapply for the loan if the SBA provides future applicable guidance.

Strengthened Balance Sheet Through a $4.8 Million Registered Direct Offering. In February 2020 the Company entered into securities purchase agreements with several institutional investors for the purchase and sale of 4,571,428 shares of the Company's common stock pursuant to a registered direct offering. Celsion also agreed to issue to such investors, in a concurrent private placement, warrants to purchase approximately 3.2 million shares of the Company's common stock. The warrants are exercisable on the six-month anniversary of the issuance date, will expire on the five-year anniversary of the initial exercise date and have an exercise price of $1.24 per share. Gross proceeds of the offering were $4.8 million before deducting placement agent fees and other estimated offering expenses.

First Quarter Financial Results

Celsion reported a net loss for the first quarter of 2020 of $5.1 million ($0.20 per share) compared with a net loss of $2.4 million ($0.12 per share) for the first quarter of 2019. Operating expenses were $4.9 million for the first quarter of 2020, which represented a $0.1 million (2%) decrease from $5.0 million in the same period of 2019. During the first quarter of 2020, the Company incurred $0.5 million in non-cash stock option expense compared with $0.7 million in the comparable prior-year period.

Cash, cash equivalents, short-term investments, interest receivable and receivable on sale of deferred tax asset as of March 31, 2020 was $17.5 million. In the second quarter of 2020, the Company received $1.8 million in net proceeds from the sale of its New Jersey net operating losses. The Company has approximately $2.0 million in future tax benefits remaining under the NJEDA Technology Business Tax Certificate Transfer program for future years. Cash provided by financing activities was $5.8 million and net cash used for operating activities was $5.0 million for the first quarter of 2020, compared with $5.5 million for the comparable prior-year period.

Research and development costs for the first quarter of 2020 were $3.1 million compared with $2.8 million for the first quarter of 2019. Clinical development costs for the Phase III OPTIMA Study were $0.7 million for the first quarter of 2020 compared with $0.9 million for the same period of 2019. These costs have decreased as the trial has moved into the follow-up phase after full patient enrollment in August 2018. Costs associated with the OVATION 2 Study increased to $0.3 million for the first quarter of 2020 compared with $0.1 million for the same period in 2019. The Company announced the initiation of the follow-on Phase I/II OVATION 2 Study in September 2018 with full enrollment of the Phase I portion of the trial completed in the first half of 2020. Costs associated with Celsion's wholly-owned subsidiary CLSN Laboratories, Inc. (which includes research and development activities for GEN-1, TheraPlas and TheraSilence) increased to $0.9 million in the first quarter of 2020 compared with $0.6 million in the first quarter of 2019 as the Company continued to expand its manufacturing capabilities and implemented programs to reduce manufacturing costs for GEN-1.

General and administrative expenses were $1.8 million for the first quarter of 2020 compared with $2.2 million for the first quarter of 2019. The $0.4 million decrease was primarily attributable to a decrease in personnel costs and lower compensation expenses related to non-cash stock option compensation expense, partially offset by an increase in premiums for directors' and officers' insurance for 2020.

Other expenses during the first quarter of 2020 included a non-cash charge of $41,000 for the change in valuation of the earn-out milestone liability for the GEN-1 ovarian product candidate compared with a non-cash gain of $2.7 million, net of charge of $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 first quarter of 2019. The Company realized $0.1 million of interest income from its short-term investments during both the first quarter of 2020 and 2019. In connection with the Company's new venture debt facility with Horizon in June 2018, the Company incurred interest expense of $0.3 million during both the first quarter of 2020 and 2019.

First Quarter Conference Call

The Company will host a conference call to provide a business update and discuss its first quarter 2020 financial results at 11:00 a.m. EDT today. To participate in the call, interested parties may dial 1-800-367-2403 (Toll-Free/North America) or 1-334-777-6978 (International/Toll) 10 minutes before the call is scheduled to begin, and ask for the Celsion Corporation First Quarter 2020 Earnings Call (Conference Code: 6901311). The call will also be broadcast live on the internet at www.celsion.com. The call will be archived for replay through May 29, 2020. The replay can be accessed at 1-719-457-0820 or 1-888-203-1112 using Conference ID: 6901311. 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 Friday, May 15, 2020.

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.

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[Tables to Follow]

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

	Three Months Ended March 31,	
	2020	**2019**
Licensing revenue	$ 125	$ 125
Operating expenses:		
Research and development	3,052	2,768
General and administrative	1,839	2,218
Total operating expenses	4,891	4,986
Loss from operations	(4,766)	(4,861)
Other (expense) income:		
Gain (loss) from valuation of earn-out milestone liability	(41)	3,130
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	(250)	(236)
Total other income (expense), net	(291)	2,494
Net loss	$ (5,057)	$ (2,367)
Net loss per common share - basic and diluted	$ (0.20)	$ (0.12)
Weighted average common shares outstanding - basic and diluted	25,804	19,105

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	March 31, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 5,746	$ 6,875
Investment securities and interest receivable on investment securities	9,910	8,007
Receivable on sale of deferred tax asset	1,820	–
Prepaid expenses and other current assets	1,401	1,353
Total current assets	**18,877**	**16,235**
Property and equipment	**375**	**405**
Other assets		
Deferred tax asset	–	1,820
In-process research and development	15,736	15,736
Goodwill	1,976	1,976
Operating lease right-of-use assets, net	1,339	1,432
Other intangible assets, deposits and other assets	634	674
Total other assets	**19,685**	**21,638**
Total assets	**$ 38,937**	**$ 38,278**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 4,255	$ 5,166
Notes payable – current portion	2,276	1,840
Operating lease liability – current portion	399	388
Deferred revenue - current portion	500	500
Total current liabilities	**7,430**	**7,894**
Earn-out milestone liability	5,759	5,718
Notes payable – noncurrent portion	7,624	7,963
Operating lease liability – non-current portion	1,040	1,144
Deferred revenue and other liabilities - noncurrent portion	875	1,000
Total liabilities	**22,728**	**23,719**
Stockholders' equity		
Common stock	293	232
Additional paid-in capital	311,571	304,886
Accumulated other comprehensive gain (loss)	4	43
Accumulated deficit	(295,574)	(290,517)
	16,294	14,644
Less: Treasury stock	(85)	(85)
Total stockholders' equity	**16,209**	**14,559**
Total liabilities and stockholders' equity	**$ 38,937**	**$ 38,278**

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