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 16, 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 November 16, 2020, Celsion Corporation issued a press release reporting its financial results for the quarter ended September 30, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On November 9, 2020, Celsion Corporation announced it would hold a conference call on November 16, 2020 to discuss its financial results for the quarter ended September 30, 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 Third Quarter 2020 Financial Results and Provides Business Update" issued by Celsion Corporation on November 16, 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: November 16, 2020

By: */s/ Jeffrey W. Church*

Jeffrey W. Church
Executive Vice President and Chief Financial Officer

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

Initiates Phase II OVATION 2 Study of GEN-1 in Advanced Ovarian Cancer

Continues Following Patients for Overall Survival in Phase III OPTIMA Study

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

LAWRENCEVILLE, N.J. (November 16, 2020) – Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the three and nine months ended September 30, 2020, and provided an update on clinical development programs with GEN-1, its DNA-mediated IL-12 immunotherapy currently in Phase II development for the treatment of advanced ovarian cancer, and 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.

"The OVATION 2 Study with our GEN-1 immunotherapy continues recruitment into the 100 mg/m² dose cohort," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "This study is based on encouraging results from our Phase Ib OVATION 1 Study in advanced ovarian cancer. In June 2020, the Data Safety Monitoring Board (DSMB) for the OVATION 2 Study recommended that the Phase II portion proceed with the dose of 100 mg/m^2, and in July 2020, we announced the randomization of the first two patients in this portion of the Study. This milestone was achieved approximately five months ahead of our previously announced schedule. We have a very aggressive recruitment program in place and anticipate completing enrollment of approximately 110 patients in the second or third quarter of 2021. Importantly, as an open-label study, clinical updates will be provided throughout the course of treatment, including response rates and surgical resection scores," Mr. Tardugno added.

Continuing his comments, Mr. Tardugno noted, "Since the DMC's finding that the OPTIMA Study crossed the futility boundary, albeit with substantial uncertainty, and leaving the decision to terminate the Study up to the Company, we have determined to continue following patients for overall survival (OS) until such time as futility is either confirmed or dispelled."

Mr. Tardugno added, "As promised, Celsion has engaged a global biometrics contract research organization (CRO), with forensic statistical analysis capability that specializes in data management, statistical consulting, statistical analysis and data sciences. They have particular expertise in evaluating unusual data from clinical trials, and experience with associated regulatory issues. The primary objective of the CRO's work is to determine the basis and reasoning behind continuing to follow patients for OS. Also as promised, and in parallel, the Company has submitted all OPTIMA Study clinical trial data to the National Institutes of Health (NIH) for an independent evaluation using a Cox Regression Analysis for minimum burn time per tumor volume. This evaluation is similar to the hypothesis generated from the NIH paper published in the *Journal of Vascular and Interventional Radiology.*"

In conclusion, Mr. Tardugno stated, “Celsion feels strongly that we owe it to patients, physicians and our investors to continue examining the data from the OPTIMA Study, particularly given how surprising the recommendation was to Celsion from the DMC. While the trial outcome as predicted by the second interim analysis may not change, and as unlikely as it may be, in the event we see substantial clinical benefit from the CRO and NIH analyses, we will carefully review our options with the 14 regulatory agencies under which the OPTIMA Study is being conducted. We expect to report findings from these independent analyses before the end of the year, either or both of which will guide our decision to continue to follow patients to the final analysis at 197 or more deaths, a milestone we expect to be reached in mid-2021.”

Recent Developments

GEN-1 Immunotherapy

Initiation of Phase II OVATION 2 Study in Advanced Ovarian Cancer. In July 2020, the Company announced the randomization of the first two patients in the Phase II portion of the OVATION 2 Study with GEN-1 in advanced ovarian cancer. The Company anticipates completing enrollment of up to 118 patients in mid-summer 2021. Because this is an open-label study, clinical updates will be provided throughout the course of treatment including response rates and surgical resection scores. The OVATION 2 Study combines GEN-1 with standard-of-care neoadjuvant chemotherapy (NACT) in patients newly diagnosed with Stage III/IV ovarian cancer. NACT is designed to shrink the tumor as much as possible for optimal surgical removal after three cycles of chemotherapy. Following NACT, patients undergo interval debulking surgery, followed by three adjuvant cycles of chemotherapy and up to nine additional weekly GEN-1 treatments, the goal of which is to delay progression and improve OS. The OVATION 2 Study is an open-label, 1-to-1 randomized trial, 80% powered to show the equivalent of a 33% improvement in progression-free survival (PFS) (HR=0.75), the primary endpoint, when comparing the treatment arm (standard of care + GEN-1) with the control arm (standard of care alone).

ThermoDox®

Patients in Phase III OPTIMA Study Continue to be Followed for Overall Survival. In August 2020, the Company provided an update on its ongoing review of unblinded data from the second pre-planned interim analysis of the global Phase III OPTIMA Study. The Company announced it will continue following patients for OS, noting that the unexpected and marginally crossed futility boundary suggested by the Kaplan-Meier analysis at the second interim analysis on July 9, 2020 may be associated with a data maturity issue.

Recommendation from the Independent DMC to Consider Stopping the Phase III OPTIMA Study of ThermoDox® in Primary Liver Cancer. In July 2020, the Company announced that it received a recommendation from the independent DMC to consider stopping the global Phase III OPTIMA Study. The recommendation was made following the second pre-planned interim safety and efficacy analysis by the DMC on July 9, 2020. The DMC analysis found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903. However, the p-value of 0.524 for this analysis provides uncertainty. The DMC left the final decision of whether or not to stop the OPTIMA Study to Celsion. There were no safety concerns noted during the interim analysis.

The statistical plan for the OPTIMA Study included two interim efficacy analyses by the DMC. The first interim analysis was announced in November 2019 following data lock in August 2019 after the prescribed minimum number of 128 patient events (deaths) was reached, and the second interim analysis was conducted on July 9, 2020 following data lock in April 2020 after the prescribed minimum number of 158 events was reached.

Corporate Developments

New Common Stock Purchase Agreement with Lincoln Park Capital. In September 2020, the Company announced a common stock purchase agreement for the issuance and sale, from time to time, of up to $26 million of shares of common stock with Lincoln Park Capital Fund, LLC (LPC). In connection with the execution of the purchase agreement, LPC made an initial purchase of $1 million of common stock at $1.00 per share, representing a significant premium to the then-current market price. Under the terms of the new purchase agreement with LPC, the Company has the right at its sole discretion, but not the obligation, to sell to LPC up to $26 million worth of shares (including the $1 million initially purchased) over the 36-month term of the agreement, subject to certain conditions. There are no upper limits to the price per share LPC may pay to purchase the shares, and the purchase price of the shares will be based on the prevailing market prices at the time of each sale to LPC. Celsion controls the timing and amount of any future sales of its stock to LPC. There are no warrants, derivatives, financial or business covenants associated with the agreement, and LPC has agreed not to cause or engage in any direct or indirect short selling or hedging of Celsion's common stock.

Strategic Loan Facility with Horizon Technology Finance Corporation Restructured. In September 2020, the Company announced an amendment to its $10 million loan agreement with Horizon Technology Finance Corporation. Consistent with its target to leverage equity capital, the Company elected to reduce its outstanding debt under the loan by $5 million and restructure the terms of the remaining $5 million loan balance. The Company's restructured $5 million loan is in the form of secured indebtedness bearing interest at a LIBOR-based variable rate. Payments under the loan agreement are interest only for the first 12 months through July 2021, followed by a 21-month amortization period of principal and interest through the scheduled maturity date of April 2023. In conjunction with the amended loan agreement, Celsion issued to Horizon warrants exercisable for 247,525 shares of Celsion's common stock at an exercise price of $1.01 per share. Warrants previously issued to Horizon exercisable for 95,057 shares at an exercise price of $2.63 per share were cancelled.

Third Quarter Financial Results

For the quarter ended September 30, 2020, Celsion reported a net loss of $8.1 million ($0.24 per share), compared with $5.5 million ($0.25 per share) in the same period of 2019.

Research and development expenses decreased $1.2 million to $2.5 million in the third quarter of 2020, compared with $3.7 million in the third quarter of 2019. Clinical development costs for the Phase III OPTIMA Study decreased $0.7 million to $0.5 million in the third quarter of 2020, compared with $1.2 million in the third quarter of 2019, due to the completion of enrollment in this 556-patient trial in August 2018. Costs associated with the OVATION 2 Study were $0.2 million in each of the third quarters of 2020 and 2019. Other costs related to clinical supplies and regulatory support for the ThermoDox® and GEN-1 clinical development programs decreased to $1.3 million in the current quarter from $1.4 million in the third quarter of 2019, largely driven by lower regulatory costs for ThermoDox®. General and administrative expenses were $1.8 million in each of the third quarters of 2020 and 2019.

Operating expenses were $4.3 million in the third quarter of 2020, which represented a $1.2 million (21.8%) decrease from $5.5 million in the same period of 2019. These lower operating expenses were offset by the following non-operating expenses: (i) a non-cash charge of $1.1 million for the change in valuation of the earn-out milestone liability for the GEN-1 ovarian product candidate; and (ii) a non-cash charge of $2.4 million related to the impairment of certain in-process research and development assets related to the development of the Company's GBM cancer product candidate.

In connection with the Company's venture debt facility with Horizon entered in late June 2018, the Company repaid $5.0 million of the loan and restructured the remaining $5.0 million for one-year interest only payments and 21-month payback period thereafter. The Company incurred interest expense of $0.5 million during the third quarter of 2020. This compares with interest expense of $0.3 million in the comparable prior-year period.

The Company ended the third quarter of 2020 with $18.3 million in cash and cash equivalents. Coupled with future planned sales of its New Jersey NOL's, the Company believes it has sufficient capital resources to fund its operations through the end of 2021. The Company has based its estimates on assumptions that may prove to be wrong and, accordingly, the Company may need to obtain additional funds sooner or in greater amounts than is currently anticipated.

Nine Month Financial Results

For the nine months ended September 30, 2020, the Company reported a net loss of $18.5 million ($0.62 per share), compared with $13.7 million ($0.67 per share) in the same period of 2019.

Research and development expenses decreased $1.5 million to $8.5 million in the first nine months of 2020 from $10.0 million in the comparable prior year period. Clinical development costs for the Phase III OPTIMA Study decreased by $1.5 million to $1.8 million in the first nine months of 2020, compared with $3.3 million in the first nine months of 2019, due to the completion of enrollment in this 556-patient trial in August 2018. Costs associated with the OVATION 2 Study increased to $0.7 million in the first nine months of 2020, compared with $0.4 million in the comparable nine-month period in 2019. Other costs related to ThermoDox® and GEN-1 clinical development programs decreased by $0.2 million in the first nine months of 2020, compared with the same prior-year period due to lower regulatory costs for the ThermoDox development program.

General and administrative expenses were $5.5 million in the first nine months of 2020, compared with $6.2 million in the same period of 2019. This 11% decrease was primarily attributable to lower professional fees.

Operating expenses were $14.1 million during the first nine months of 2020, which represented a $2.1 million (13%) decrease from $16.2 million in the same period of 2019. These lower operating expenses in the first nine months of 2020 were offset by the following non-operating expenses: (i) a non-cash charge of $1.4 million 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 comparable prior-year period; and, (ii) a non-cash charge of $2.4 million related to the impairment of certain in-process research and development assets related to the development of the Company's GBM cancer product candidate.

The Company realized $0.1 million of interest income during the first nine months of 2020 and $0.4 million in the comparable prior-year period. The Company incurred interest expense of $1.2 million and $1.0 million during the first nine months of 2020 and 2019, respectively.

Net cash used for operating activities was $11.9 million in the first nine months of 2020, compared with $16.2 million in the same period in 2019. This was in line with the Company's projected cash utilization for 2020 of approximately $15.6 million, or an average of approximately $3.9 million per quarter. Cash provided by financing activities was $15.4 million during the first nine months of 2020 resulting from equity offerings in March 2020 and June 2020, and proceeds from (i) the sale of equity from its ATM facility with Jones Trading, (ii) the sale of equity from its Common Stock Purchase Agreement with Lincoln Park Capital, including a $1 million sale at 22% premium to market in September 2020, and (iii) the exercise of stock options.

Third Quarter Conference Call

The Company will host a conference call to provide a business update and discuss third quarter 2020 financial results at 11:00 a.m. EST 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 Third Quarter 2020 Earnings Call (Conference Code: 8337630). The call will also be broadcast live on the internet at www.celsion.com.

The call will be archived for replay on November 16, 2020 and will remain available until November 30, 2020. The replay can be accessed at 1-719-457-0820 or 1-888-203-1112 using Conference ID: 8337630. 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. EST on November 16, 2020.

About Celsion Corporation

Celsion is a fully integrated oncology company focused on developing a portfolio of innovative cancer treatments, including immunotherapies, DNA-based therapies and directed chemotherapies. The Company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer and ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in Phase III development for the treatment of primary liver cancer and in development for other cancer indications. Celsion has two feasibility stage platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies. Both are novel synthetic, non-viral vectors with demonstrated capability in nucleic acid cellular transfection. For more information on Celsion, visit: 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, investors, competitors or 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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Celsion Corporation
Condensed Statements of Operations
(in thousands except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Licensing revenue	$ 125	$ 125	$ 375	$ 375
Operating expenses:				
Research and development	2,492	3,674	8,535	10,000
General and administrative	1,793	1,839	5,533	6,193
Total operating expenses	4,285	5,513	14,068	16,193
Loss from operations	(4,160)	(5,388)	(13,693)	(15,818)
Other income (expense):				
(Loss) gain from change in valuation of earn-out milestone liability	(1,100)	86	(1,397)	3,089
Loss from impairment of in-process research and development	(2,370)	–	(2,370)	–
Fair value of warrants issued in connection with amendment to modify GEN-1 earn-out milestone payment	–	–	–	(400)
Interest expense, investment income and other income (expense), net	(442)	(175)	(1,011)	(620)
Total other income (expense), net	(3,912)	(89)	(4,778)	2,069
Net loss	$ (8,072)	$ (5,477)	$ (18,471)	$ (13,749)
Net loss per common share				
Basic and diluted	$ (0.24)	$ (0.25)	$ (0.62)	$ (0.67)
Weighted average shares outstanding				
Basic and diluted	34,112	21,663	29,935	20,525

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 18,340	$ 6,875
Investment securities and interest receivable on investment securities	–	8,007
Advances, deposits on clinical programs and other current assets	1,566	1,353
Total current assets	**19,906**	**16,235**
Property and equipment	**302**	**405**
Other assets		
Deferred tax asset	-	1,820
In-process research and development	13,366	15,736
Goodwill	1,976	1,976
Operating lease right-of-use assets, net	1,147	1,432
Other intangible assets, deposits and other assets	578	674
Total other assets	**17,067**	**21,638**
Total assets	**$ 37,275**	**$ 38,278**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 4,088	$ 5,166
Notes payable – current portion	416	1,840
Operating lease liability – current portion	422	388
Deferred revenue - current portion	500	500
Total current liabilities	**5,426**	**7,894**
Earn-out milestone liability	7,115	5,718
Notes payable	4,627	7,963
Operating lease liability	823	1,144
Deferred revenue and other liabilities	625	1,000
Total liabilities	**18,616**	**23,719**
Stockholders' equity		
Common stock	362	232
Additional paid-in capital	327,370	304,886
Accumulated other comprehensive gain (loss)	–	43
Accumulated deficit	(308,988)	(290,517)
	18,744	14,644
Less: Treasury stock	(85)	(85)
Total stockholders' equity	**18,659**	**14,559**
Total liabilities and stockholders' equity	**$ 37,275**	**$ 38,278**

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