

**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, 2019

CELSION CORPORATION

(Exact name of registrant as specified in its Charter)

Delaware

(State or other jurisdiction
of incorporation)

001-15911

(Commission
File Number)

52-1256615

(IRS Employer
Identification No.)

997 Lenox Drive, Suite 100, Lawrenceville, NJ

(Address of principal executive offices)

08648-2311

(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 14, 2019, Celsion Corporation (the “Company”) issued a press release reporting its financial results for the quarter ended September 30, 2019. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On November 8, 2019, the Company announced it would hold a conference call on November 15, 2019 to discuss its financial results for the quarter ended September 30, 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 the Company, 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 2019 Financial Results and Provides Business Update” issued by Celsion Corporation on November 14, 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: November 14, 2019

By: */s/ Jeffrey W. Church*

Jeffrey W. Church

Senior Vice President and Chief Financial Officer



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

- *Independent Data Monitoring Committee (iDMC) Unanimously Recommends Continuation of Phase III OPTIMA Study at First Pre-Planned Efficacy Analysis*
- *Independent Data Safety Monitoring Board (DSMB) Unanimously Recommends Continuation of Phase I Portion of OVATION 2 Study*
- *Strong Balance Sheet Plus the Sale of New Jersey State Net Operating Losses Expected to Fund Operations into First Half of 2021*
- *Company to Hold Conference Call on Friday, November 15, 2019 at 11:00 a.m. EST*

LAWRENCEVILLE, N.J. (November 14, 2019) – Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the three-month and nine-month periods ended September 30, 2019 and provided an update on its development programs for ThermoDox[®] and GEN-1.

The Company's lead program is ThermoDox[®], a proprietary heat-activated liposomal encapsulation of doxorubicin currently in Phase III development (the OPTIMA Study) for the treatment of hepatocellular carcinoma (HCC), or primary liver cancer. The Company's immunotherapy candidate, GEN-1, is an IL-12 DNA plasmid vector encased in a nanoparticle delivery system that enables cell transfection followed by persistent, local secretion of the IL-12 protein. GEN-1 is currently in Phase I/II development (the OVATION 2 Study) for the localized treatment of newly diagnosed Stage III and IV ovarian cancer.

"Recent weeks have been particularly gratifying for the team at Celsion, with encouraging news on two clinical development programs, along with maintaining a strong balance sheet and ready access to cash at our discretion," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer.

"Our focus on shareholder value remains uncompromised as Celsion continues to deliver results from our ongoing clinical development programs for ThermoDox[®] and GEN-1. Our smart use of venture debt to leverage the holdings of our equity investors, along with our strategy to avoid punitive financing deals has worked well for us and our shareholders. We enter the fourth quarter with sound fundamentals and a strong balance sheet that is expected to fund our clinical programs through transformative milestones over the next 16 months," added Mr. Tardugno. "With the first of two preplanned interim efficacy analyses for the OPTIMA Study successfully behind us, we look forward to the promise and potential for success at the 2nd preplanned analysis, now expected to occur in the second quarter of 2020. The OPTIMA Study, a global, pivotal study completed patient enrollment in August 2018 at more than 65 clinical sites in 14 countries, including all the major markets for primary liver cancer and represents the first and only first line treatment for newly diagnosed primary liver cancer patients. For this indication alone, ThermoDox[®] represents a billion-dollar annual revenue opportunity."

“Last week, our second product candidate, GEN-1, received the go-ahead from its DSMB to proceed with patient enrollment in the Phase I portion of the OVATION 2 study. With the first cohort of patients in the dose-escalation portion of our OVATION 2 Study in newly diagnosed ovarian cancer enrolled and evaluated by the DSMB, we look forward to finalizing the dose for the balance of the 130-patient randomized study by year-end. We expect that surgical results and tumor response data will be available shortly thereafter. Meanwhile, we continue to work through the activation of up to 25 clinical sites in the U.S. and Canada by the end of January 2020. This promising clinical development program in immunotherapy has generated impressive results in previous trials,” Mr. Tardugno concluded.

Recent Developments

ThermoDox®

iDMC Unanimously Recommends Continuation of Celsion’s Phase III OPTIMA Study for ThermoDox® in Primary Liver Cancer. On November 4, 2019 the Company announced that the iDMC unanimously recommended the OPTIMA Study continue according to protocol. The recommendation was based on a review of blinded safety and data integrity from 556 patients enrolled in the Company’s multinational, double-blind, placebo-controlled pivotal Phase III study with ThermoDox® plus RFA in patients with HCC.

The iDMC’s pre-planned interim efficacy review followed 128 patient events, or deaths, which occurred in August 2019. Data presented demonstrated that progression-free survival (PFS) and overall survival (OS) data appear to be tracking with patient data observed at a similar point in the Company’s 285 patient, well-balanced subgroup of patients followed prospectively in the earlier Phase III study (the “Prospective Subgroup”) upon which the OPTIMA Study is based. This Prospective Subgroup demonstrated a 2-year overall survival advantage and a median time to death of more than 7 ½ years.

From the data review, the Company believes that the OPTIMA Study is well positioned for success at the next pre-planned interim efficacy analysis, which is intended after a minimum of 158 patient deaths and is projected to occur during the second quarter of 2020. The hazard ratio for success at 158 events is 0.70. This is below the hazard ratio of 0.65 observed for the 285 patients in the HEAT Study Prospective Subgroup treated with RFA > 45 minutes.

The data review demonstrated the following:

- The OPTIMA Study patient demographics and risk factors are consistent with what the Company observed in the Prospective Subgroup with all data quality metrics meeting expectations.
 - Median PFS for the OPTIMA Study reached 17.3 months as of August 2019. These blinded data compare favorably with median PFS of 16.8 months for the 285 patients in the HEAT Study Prospective Subgroup treated with RFA > 45 minutes and followed prospectively for OS.
 - At this time point, combined OS for both treatment arms is consistent with that observed in the 285-patient HEAT Study Prospective Subgroup.
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Celsion Co-sponsored Hepatocellular Carcinoma Symposium at the International Liver Cancer Association (ILCA) Annual Conference. On September 23, 2019, the Company announced it co-sponsored a symposium focused on HCC at the 13th Annual Conference of the International Liver Cancer Association. Other sponsors of the symposium included Bayer Healthcare Pharmaceuticals, Inc. and Exelixis, Inc., both of whom provide therapeutics for the treatment of advanced HCC. The program, titled “Master Class & Tumor Board: Composing Personalized HCC Treatment Strategies, Insights on Harmonizing Patient Care with a Multidisciplinary Ensemble,” featured four speakers. The program was chaired by Ghassan Abou-Alfa, MD, MBA, Memorial Sloan Kettering Cancer Center and Professor, Weill Medical College at Cornell University, both in New York City. The other participants were: Prof. Riccardo Lencioni, MD, FSIR, EBIR, Department of Radiology, University of Pisa, Italy, Hon. Res. Prof. Interventional Oncology, Miami Cancer Institute; Amit Singal, MD, MS, Medical Director of Liver Tumor Program, Associate Professor of Medicine, UT Southwestern Medical Center, Dallas; and Robin K. (Katie) Kelley, MD, Associate Professor of Clinical Medicine, Helen Diller Family Comprehensive Cancer Center, Division of Hematology/Oncology, University of California, San Francisco.

Dr. Abou-Alfa and Prof. Lencioni have been involved in the development of Celsion’s lead product ThermoDox[®] for the treatment of HCC. A review of the data supporting Celsion’s Phase III trial with ThermoDox[®] plus radiofrequency ablation in newly diagnosed HCC patients (the OPTIMA Study) was presented by Prof. Lencioni.

Findings from Single-Site Study in China of ThermoDox[®] Plus RFA Published in the *Journal of Cancer Research and Therapeutics*. On August 27, 2019, the Company announced that a study from a single site in China titled “Thermosensitive liposomal doxorubicin plus radiofrequency ablation increased tumor destruction and improved survival in patients with medium and large hepatocellular carcinoma: A randomized, double-blinded, dummy-controlled clinical trial in a single center” was published in the *Journal of Cancer Research and Therapeutics*. These data were generated as part of the Phase III HEAT Study sponsored by Celsion Corporation. The data from this single site at the Peking University Cancer Hospital and Institute in Beijing show an OS improvement of 22.5 months in patients with 3-7 cm unresectable hepatocellular carcinoma tumors receiving ThermoDox[®] plus RFA, compared with RFA alone.

In this study, patients received 50 mg/m² of ThermoDox[®] or placebo, plus RFA for 45 minutes or longer. Patients were followed for 11 to 80 months (average: 49.1 ± 24.8 months), with 18 of 22 patients completing the study. The mean OS for the ThermoDox[®] plus RFA group was 68.5 ± 7.2 months, which was significantly greater than the placebo plus RFA group (46.0 ± 10.6 months, p=0.045). At the end of the follow-up period, the percentage of patients alive after 1, 3 and 5 years were as follows:

	ThermoDox [®] + RFA	RFA Alone
% of patients alive at 1 year	90.0%	87.5%
% of patients alive at 3 years	90.0%	50.0%
% of patients alive at 5 years	77.1%	37.5%

The publication can be found in the *Journal of Cancer Research and Therapeutics* | Year: 2019 | Volume: 15 | Issue: 4 | Page 773 – 783. The authors are Yang W, Lee JC, Chen MH, Zhang ZY, Bai XM, Yin SS, et al. from the Departments of Ultrasound and Radiology, Key Laboratory of Carcinogenesis and Translational Research (Ministry of Education), Peking University Cancer Hospital and Institute in Beijing. Prof. Min-Hua Chen was a principal investigator in Celsion’s Phase III HEAT Study, from which these data are derived, and is also a principal investigator in the Company’s Phase III OPTIMA Study.

Results of the National Institutes of Health Analysis of ThermoDox[®] Published in the *Journal of Vascular and Interventional Radiology*. On August 13, 2019, the Company announced that results from an independent analysis of the Company's ThermoDox[®] HEAT Study conducted by the National Institutes of Health (NIH) were published in the peer-reviewed publication *Journal of Vascular and Interventional Radiology*. The analysis was conducted by the intramural research program of the NIH and the NIH Center for Interventional Oncology, with the full data set from the Company's HEAT Study. The analysis evaluated the full data set to determine if there was a correlation between baseline tumor volume and RFA heating time (minutes/tumor volume in milliliters), with or without ThermoDox[®] treatment, for patients with HCC. The NIH analysis was conducted under the direction of Bradford Wood, MD, Director, NIH Center for Interventional Oncology and Chief, NIH Clinical Center Interventional Radiology.

The article, titled "RFA Duration Per Tumor Volume May Correlate with Overall Survival in Solitary Hepatocellular Carcinoma Patients Treated with RFA Plus Lyso-thermosensitive Liposomal Doxorubicin," discussed the NIH analysis of results from 437 patients in the HEAT Study (all patients with a single lesion representing 62.4% of the study population). The key finding was that increased RFA heating time per tumor volume significantly improved OS in patients with single-lesion HCC who were treated with ThermoDox[®] plus RFA, compared to patients treated with RFA alone. A one-unit increase in RFA duration per tumor volume was shown to result in about a 20% improvement in OS for patients administered ThermoDox[®], compared to RFA alone. The authors conclude that increasing RFA heating time in combination with ThermoDox[®] significantly improves OS and establishes an improvement of over 2 years versus the control arm when the heating time per milliliter of tumor is greater than 2.5 minutes. This finding is consistent with the Company's own results, which defined the optimized RFA procedure as a 45-minute treatment for tumors with a diameter of 3 centimeters. Thus, the NIH analysis lends support to the hypothesis underpinning the OPTIMA Study.

GEN-1 Immunotherapy

Positive DSMB Review of Phase I Portion of OVATION 2 Study in Ovarian Cancer. On November 5, 2019, the Company announced that the DSMB has completed its safety review of data from the first eight patients enrolled in the ongoing Phase I/II OVATION 2 Study. Based on the DSMB's recommendation, the study will continue as planned and the Company will proceed with completing enrollment in the Phase I portion of the trial. The OVATION 2 Study is a Phase I/II study designed with a single dose escalation phase to 100 mg/m² of GEN-1 in the Phase I portion, followed by a continuation at the selected dose in Phase II, in an open-label, 1:1 randomized design.

Developed with extensive input from the Company's Medical Advisory Board, the OVATION 2 Study builds on promising clinical and translational research data from the Phase IB dose-escalation OVATION 1 Study in which enrolled patients received escalating weekly doses of GEN-1 up to 79 mg/m² for a total of eight treatments in combination with neoadjuvant chemotherapy (NACT), followed by interval debulking surgery (IDS). In addition to exploring a higher dose of GEN-1 in the OVATION 2 study, patients will continue to receive GEN-1 after their IDS in combination with adjuvant chemotherapy.

Of the eight patients treated in the Phase I portion of the OVATION 2 Study, five were treated with GEN-1 plus NACT and three were treated with NACT only. The Company previously reported data from its Phase IB dose escalating trial (the OVATION I Study) which showed that of the 14 evaluable patients, 100% administered NAC plus the two higher doses of GEN-1 experienced an objective tumor response, defined as a partial or complete response. Only 60% of patients given the two lower doses had such a response. In addition, patients in the higher-dose cohorts had a high surgery success (R0) rate, with 88% achieving the optimal outcome of a complete resection.

Celsion's GEN-1 Immunotherapy Highlighted. On August 9, 2019, the Company announced that Premal H. Thaker, MD, MSc, Professor of Obstetrics and Gynecology-Division of Gynecologic Oncology at Washington University School of Medicine in St. Louis, led an expert call on the ovarian cancer treatment landscape and emerging opportunities hosted by Oppenheimer & Co. Inc. Dr. Thaker is active in the development of GEN-1, Celsion's DNA-based, IL-12 immunotherapy for the treatment of ovarian cancer. She is Study Chair and member of the DSMB for the OVATION 2 study and was a Principal Investigator for the OVATION 1 study. Hartaj Singh, Managing Director and Senior Analyst covering biotechnology for Oppenheimer, moderated the call for the bank's institutional clients.

Dr. Thaker discussed results from the Company's recently completed Phase IB dose-escalation OVATION 1 study which evaluated patients newly diagnosed with Stage III or IV ovarian cancer and treated with four different doses of GEN-1. Pre- and post-treatment levels of key ovarian cancer biomarkers showed a marked reduction in immunosuppressive response across multiple biomarkers post-treatment, indicating GEN-1 may alter the tumor microenvironment and may improve ovarian cancer outcomes in combination with NAC.

Corporate Development

Celsion Strengthens its 2019 Balance Sheet. On October 1, 2019, the Company announced it received approval from the New Jersey Economic Development Authority's (NJEDA) Technology Business Tax Certificate Transfer (NOL) program to sell its unused New Jersey net operating losses (NOLs) and R&D tax credits. The exact percentage of NOLs to be sold will be determined by the NJEDA after reviewing all qualified applications. In 2018, the Company received approval from the NJEDA to sell \$11.1 million of its unused New Jersey NOLs for the tax years 2011 through 2017 and was able to transfer this credit and receive approximately \$10.5 million of net cash proceeds in the fourth quarter of 2018. The NOLs are typically sold at a single-digit discount to qualified companies with operations in New Jersey. As a result, the Company anticipates it will be able to transfer this current year credit for approximately \$2.0 million prior to the end of 2019.

Celsion Participated in Two Investor Conferences. During October 2019, the Company attended the Chardan 3rd Annual Genetic Medicines Conference in New York City and the Dawson James Securities 5th Annual Small Cap Growth Conference in Jupiter, Fla. A webcast of Celsion's fireside chat at the Chardan Conference may be accessed by visiting the "News & Investors" section of Celsion's corporate website.

Third Quarter Financial Results

For the quarter ended September 30, 2019, Celsion reported a net loss of \$5.5 million (\$0.25 per share), compared with a net loss of \$4.7 million (\$0.26 per share) in the same period of 2018. Operating expenses were \$5.5 million in the third quarter of 2019, which represented a \$1.4 million increase from \$4.0 million in the same period of 2018. This increase was attributable to higher salary and benefits (\$0.4 million) for several new positions to support the anticipated regulatory and commercialization efforts for ThermoDox[®] as well as higher costs (\$0.2 million) associated with the technology transfer of GEN-1 to new contract manufacturing organizations. During the third quarter of 2018, the Company recorded a one-time \$0.8 million credit resulting from cost concessions negotiated with the Company's lead contract research organization (CRO) for the OPTIMA Study.

Research and development expenses increased \$1.5 million to \$3.7 million in the third quarter of 2019, compared with \$2.2 million in the third quarter of 2018. Clinical development costs for the Phase III OPTIMA Study in the third quarter of 2018 were favorably impacted by a \$0.8 million one-time credit resulting from cost concessions negotiated with the Company's lead CRO for the OPTIMA Study. Also contributing to this increase was higher salary and benefits for several new positions and other professional advisory costs to support the anticipated global regulatory filing for ThermoDox[®] as well as higher costs associated with the technology transfer of GEN-1 to new contract manufacturing organizations.

General and administrative expenses were \$1.8 million in the third quarter of 2019, compared with \$2.0 million in the same period of 2018. The decrease was primarily attributable to a \$0.2 million decrease in non-cash stock compensation expense in the current quarter.

During the third quarter ended September 30, 2018, other expenses included a non-cash charge of \$4.5 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 \$4.1 million reduction in the earn-out liability related to potential milestone payments for the GBM product candidate. During the third quarter ended September 30, 2019, the Company recorded a gain of \$86,000 from the reduction in the earn-out liability related to potential milestone payments. The Company realized \$0.2 million of interest income from its short-term investments during the third quarter of 2019 compared to \$0.1 million of interest income in the comparable prior year period. In connection with the Company's venture debt facility with Horizon entered into in late June 2018, the Company incurred interest expense of \$0.35 million during the third quarters of 2019 and 2018.

The Company ended the third quarter of 2019 with \$18.8 million in cash, investment securities and interest receivable. With this \$18.8 million coupled with planned future sales of the Company's New Jersey NOLs totaling approximately \$4 million in 2019 and 2020, the Company believes it has sufficient capital resources to fund its operations into the first half of 2021.

Nine Month Financial Results

For the nine months ended September 30, 2019, the Company reported a net loss of \$13.7 million (\$0.67 per share), compared with a net loss of \$17.4 million (\$0.73 per share) in the same period of 2018. Operating expenses were \$16.2 million during the first nine months of 2019, which represented a \$0.5 million decrease from \$16.3 million in the same period of 2018. The decrease was primarily attributable to (i) lower non-cash stock compensation expense in the current year period, (ii) lower monthly CRO fees after completion of enrollment of the Phase III OPTIMA study during the third quarter of 2018, and (iii) a non-cash gain of \$2.7 million, net of a \$0.4 million charge for the issuance of 200,000 warrants related to an amendment for the potential milestone payments for the GEN-1 ovarian product candidate. During the third quarter of 2018, the Company recorded a \$0.8 million credit resulting from cost concessions negotiated with the Company's lead CRO for the OPTIMA Study.

Net cash used for operating activities was \$14.6 million in the first nine months of 2019, compared with \$13.0 million used in the same period in 2018. The Company's cash utilization is projected to be approximately \$19.5 million for 2019 and approximately \$16 million for 2020. Cash provided by financing activities was approximately \$6.2 million during the first nine months of 2019.

Research and development expenses increased \$0.5 million to \$10.0 million in the first nine months of 2019 from \$9.5 million in the comparable prior-year period. The prior-year period was favorably impacted by a \$0.8 million credit resulting from cost concessions negotiated with the Company's lead CRO for the OPTIMA Study. Excluding this one-time credit, clinical development costs for the Phase III OPTIMA Study decreased \$1.5 million to \$3.3 million in the first nine months of 2019, compared with \$4.8 million in the comparable prior-year period, due to the completion of enrollment in this 556-patient trial in August 2018. Costs associated with the startup of the OVATION 2 Study were \$0.4 million in the first nine months of 2019. Other costs related to clinical supplies and regulatory support for the ThermoDox[®] and GEN-1 clinical development programs increased by \$1.1 million in the first nine months of 2019 compared with the same prior-year period. In the first nine months of 2019, non-cash stock compensation expense decreased \$0.7 million, compared with the same period of 2018.

General and administrative expenses were \$6.2 million for the nine months ended September 30, 2019, compared with \$7.2 million for the same period of 2018. The decrease was primarily attributable to a \$1.7 million decrease in non-cash stock compensation expense offset by higher salary, benefit and travel costs related to regulatory and commercialization efforts for ThermoDox[®].

Other expenses in the first nine months of 2019 included a non-cash gain of \$2.7 million, net of a \$0.4 million charge for the issuance of 200,000 warrants related to an amendment for the potential milestone payments for the GEN-1 ovarian product candidate, compared with a non-cash charge of \$4.5 million related to the impairment of certain in-process research and development assets related to the development of our GBM cancer product candidate offset by a \$3.6 million reduction in the earn-out liability related to potential milestone payments in the comparable prior-year period. The Company realized \$0.4 million of interest income during the first nine months of 2019 and compared with \$0.3 million of interest income in the comparable nine-month period in 2018. In connection with the Company's venture debt facility with Horizon entered into in late June 2018, the Company incurred interest expense of \$1.0 million during the first nine months of 2019, compared with interest expense of \$0.4 million in the comparable prior-year period.

Conference Call

The Company is hosting a conference call to provide a business update and discuss its third quarter 2019 financial results at 11:00 a.m. EST on Friday, November 15, 2019. To participate in the call, dial 1-800-667-5617 (Toll-Free/North America) or 1-334-323-0501 (International/Toll) and use conference ID 5419619. The call will also be broadcast live on the internet at www.celsion.com. The call will be archived for replay until November 29, 2019 and can be accessed at 1-719-457-0820 or 1-888-203-1112 using conference ID 5419619. An audio replay will also be available for 90 days at www.celsion.com.

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

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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,	
	2019	2018	2019	2018
Licensing revenue	\$ 125	\$ 125	\$ 375	\$ 375
Operating expenses:				
Research and development	3,674	2,187	10,000	9,522
General and administrative	1,839	1,960	6,193	7,168
Total operating expenses	<u>5,513</u>	<u>4,147</u>	<u>16,193</u>	<u>16,690</u>
Loss from operations	<u>(5,388)</u>	<u>(4,022)</u>	<u>(15,818)</u>	<u>(16,315)</u>
Other income (expense):				
Gain from valuation of earn-out milestone liability	86	4,115	3,089	3,568
Impairment of IPR&D	-	(4,510)	-	(4,510)
Fair value of warrants issued in connection with amendment to modify earn-out milestone payments	-	-	(400)	-
Interest expense, investment income and other income (expense), net	(175)	(239)	(620)	(107)
Total other income (expense), net	<u>(89)</u>	<u>(634)</u>	<u>2,069</u>	<u>(1,049)</u>
Net loss	<u>\$ (5,476)</u>	<u>\$ (4,656)</u>	<u>\$ (13,749)</u>	<u>\$ (17,364)</u>
Net loss per common share				
Basic and diluted	<u>\$ (0.25)</u>	<u>\$ (0.26)</u>	<u>\$ (0.67)</u>	<u>\$ (0.73)</u>
Weighted average shares outstanding				
Basic and diluted	<u>21,663</u>	<u>17,801</u>	<u>20,525</u>	<u>17,448</u>

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	September 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	\$ 8,522	13,354
Investment securities and interest receivable on investment securities	10,317	14,326
Prepaid expenses and other current assets	1,272	451
Total current assets	<u>20,111</u>	<u>28,131</u>
Property and equipment		
	<u>430</u>	<u>185</u>
Other assets		
In-process research and development	15,736	15,736
Goodwill	1,976	1,976
Operating lease right-of-use assets, net	1,522	-
Other intangible assets, net	398	568
Other assets	391	260
Total other assets	<u>20,023</u>	<u>18,540</u>
Total assets	<u>\$ 40,564</u>	<u>46,856</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 6,332	\$ 5,607
Notes payable - current portion	579	-
Operating lease liability – current portion	377	-
Deferred revenue - current portion	500	500
Total current liabilities	<u>7,788</u>	<u>6,107</u>
Earn-out milestone liability	5,819	8,908
Operating lease liability – non-current portion	1,245	-
Notes payable - noncurrent portion	9,127	9,417
Deferred revenue and other liabilities - noncurrent portion	1,125	1,563
Total liabilities	<u>25,104</u>	<u>25,995</u>
Stockholders' equity		
Common stock	220	188
Additional paid-in capital	302,705	294,393
Accumulated other comprehensive gain (loss)	34	30
Accumulated deficit	(287,414)	(273,665)
	<u>15,545</u>	<u>20,946</u>
Less: Treasury stock	(85)	(85)
Total stockholders' equity	<u>15,460</u>	<u>20,861</u>
Total liabilities and stockholders' equity	<u>\$ 40,564</u>	<u>\$ 46,856</u>

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