Celsion Corporation Reports 2018 Financial Results

March 29, 2019

Celsion Enters 2019 with a Strong Balance Sheet, Clean Capitalization Structure and an Advancing Clinical Pipeline

Company to Hold Conference Call on Friday, March 29, 2019 at 11:00 a.m. EDT

LAWRENCEVILLE, N.J., March 29, 2019 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the year ended December 31, 2018 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 ovarian cancer.

"Celsion had an extraordinary 2018, making meaningful progress with our ongoing development programs for ThermoDox® and GEN-1, as well as strengthening our balance sheet and cleaning up our capitalization structure. Among our many accomplishments, enrollment of our pivotal 556-patient global Phase III OPTIMA Study in HCC was completed ahead of projections, in August 2018. We are now looking forward to the first of two preplanned, interim efficacy analyses for the OPTIMA Study expected in the second half of 2019 and mid-2020, respectively. Our Phase I/II OVATION Study was initiated in the second quarter, as planned. This promising clinical development program in immunotherapy has generated impressive results. During the first quarter of 2019, we reported final data from our Phase 1B immunotherapy program (the OVATION I Study) in ovarian cancer. These data showed a significant improvement in progression-free survival in patients treated per protocol, 100% objective response rate (PR/CR) in patients treated at the two highest dose cohorts and 88% R0 surgical resection scores in patients treated at the two highest dose cohorts," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "Entering 2019 with more than $27.7 million in cash and investments, we are well positioned with sound fundamentals, the right resources, and a sound capital structure sufficient to see our clinical programs through transformative milestones, and in doing so create significant value for our shareholders, patients and the medical community."

Recent Developments

ThermoDox®

Data Monitoring Committee (DMC) Completed its Planned Safety and Data Review of Celsion's Phase III OPTIMA Study . On December 18, 2018, the Company announced that the independent Data Monitoring Committee (DMC) for the Company's pivotal Phase III OPTIMA Study unanimously recommended that the study continue according to protocol to its data readout. The DMC's evaluation and recommendation were based on the Committee's assessment of safety and data integrity for all 556 patients enrolled in the multinational, double-blind, placebo-controlled trial as of October 4, 2018.

This DMC review analyzed blinded data from the intent-to-treat population, consolidated for both arms, which showed that median PFS for the OPTIMA Study had reached 21.2 months as of October 4, 2018. These blinded, consolidated data continue to compare favorably to the HEAT Study median PFS of 13.8 months (all 701 patients) and 16.8 months (for the 285 patients in the subgroup of patients treated with RFA > 45 minutes) and remain consistent with our projections based on protocol enhancements informed by the HEAT Study results and the HEAT Study post-hoc analysis subgroup, the same patient population that the current Phase III pivotal study design was built on.

The DMC consists of an independent group of medical and scientific experts responsible for reviewing and evaluating patient safety and efficacy data for the Company's Phase III OPTIMA Study. The DMC reviews study data at regular intervals in order to ensure the safety of all patients enrolled in the trial and to monitor the quality and overall conduct of the trial, including each site's compliance with the study protocol. The OPTIMA Study's design and statistical plan incorporates two pre-planned interim efficacy analyses by the DMC with the intent of evaluating safety, efficacy and futility to determine if there is overwhelming evidence of clinical benefit or a low probability of treatment success to continue, modify or terminate the study.

Publication of ThermoDox® Study Results in the Peer-Reviewed Journal, Radiology. On January 19, 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 volumes 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. 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.

The Phase I TARDOX 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.

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:

- GEN-1 is a novel new approach designed to deploy the anti-cancer mechanism of the potent, broad-spectrum immunotherapy, IL-12, without the toxicities associated with the recombinant IL-12 protein.
- 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.
- Pathological changes were assessed as part of the study, with the density of markers measured in tissue sections assessed via immunohistochemistry staining. Among patients administered the high doses of GEN-1 (n=8), pre-treatment to post-treatment reductions in key biomarkers were observed (FoxP3 -62.5%; IDO-1 -60%; PD-1 -62.5%; PD-L1 -37.5%). Reductions were also observed in patients administered the lower doses of GEN-1 (n=4) for all but one of the four key biomarkers (FoxP3 -40%; IDO-1 -40%; PD-1 +25%; PD-L1 -37.5%). The ratio of CD8+ cells to the four key immunosuppressive cell signals increased following treatment in 60 - 80% of patients.
- The study showed no serious systemic toxicities. Dose-limiting toxicity was not reached in the OVATION I Study. The most common adverse events attributed to GEN-1 in the OVATION I Study were nausea, abdominal pain/cramping, fatigue, vomiting, diarrhea and neutropenia.

Corporate Development

Celsion Signs Amendment to its June 6, 2014 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 will record this transaction in the first quarter of 2019.

Celsion Received $11.1 Million Allocation Through the New Jersey Technology Business Tax Certificate Transfer (NOL) Program and State NOLs for the Tax Years 2011 to 2017 Approved. **In December 2018, the Company** announced it received approval from the New Jersey Economic Development Authority's (NJEDA) Technology Business Tax Certificate Transfer (NOL) program to sell $11.1 million of its unused New Jersey NOLs for the tax years 2011 through 2017. The Company sold these New Jersey State NOLs to a qualified company with operations in New Jersey and received $10.4 million of net cash proceeds prior to the end of 2018.

Elimination of Warrant Overhang. In October 2018, the Company and certain investors holding warrants to collectively purchase 1.64 million shares of the Company's common stock, which were granted in the February 2017 Public Offering and the October 2017 Underwritten Offering, entered into warrant exchange agreements whereby the Company issued 820,714 shares of its common stock in exchange for the termination of the warrants. The Company exchanged 0.5 share of common stock for each of 1.64 million warrants with exercise prices between $3.00 per share and $3.22 per share. Doing so, the Company eliminated the warrant overhang on its share price and the potential to use these warrants as a vehicle to hedge a short

position. As of December 31, 2018, the Company has 18.8 million shares outstanding and 1.6 million warrants outstanding, of which 1.2 million of these outstanding warrants have an exercise price over $6.00 per share and will expire in early April 2019.

Financial Results

For the year ended December 31, 2018, Celsion reported a net loss attributable to common shareholders of $11.9 million ($0.68 per share) compared to a net loss of $20.7 million ($2.72 per share) for the year ended December 31, 2017. Operating expenses were $21.6 million for the year ended December 31, 2018, which represented a $2.6 million or 14% increase, from $19.0 million in the same period of 2017. During 2018, the Company incurred $4.6 million in non-cash stock option expense compared to $1.3 million in the comparable prior-year period.

Net cash used for operating activities was $7.0 million for the year ended December 31, 2018, compared to $16.6 million in the prior year. Cash and cash equivalents at December 31, 2018 were $27.7 million. Total cash provided by financing activities was approximately $11 million during 2018 which included $10 million in gross proceeds from the Company's venture debt facility completed on June 27, 2018 with Horizon Technology Finance Corporation (Horizon) and $1 million in net proceeds from sales of common stock. In addition, the Company received $10.4 million in non-dilutive capital from the sale of its New Jersey state NOLs in the fourth quarter of 2018.

Research and development costs decreased by $1.2 million or 9%, from $13.1 million for the year ended December 31, 2017 to $11.9 million for the year ended December 31, 2018. Clinical development costs for the Phase III OPTIMA Study were $4.7 million for the year ended December 31, 2018 compared to $6.7 million for the same period of 2017. This $2.0 million decrease resulted from cost concessions negotiated with the lead contract research organization (CRO) for the OPTIMA Study as well as lower monthly CRO fees after completion of enrollment of this Phase III study during the third quarter of 2018. Costs associated with GEN-1 were $0.4 million for the year ended December 31, 2018, compared to $0.2 million in the comparable prior-year period. 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 $2.8 million in 2018 compared to $2.3 million in 2017 as the Company expanded its manufacturing capabilities and reduced the costs to manufacture GEN-1 for its planned clinical study requirements beyond 2018. In 2018, other clinical costs included an increase of $0.5 million in non-cash stock compensation expense compared to the same period of 2017.

General and administrative expenses were $9.7 million for the year ended December 31, 2018, compared to $5.9 million for the year ended December 31, 2017. This $3.8 million increase was due to higher professional fees of approximately $0.7 million, higher travel expenses of $0.1 million, and higher compensation expenses totaling $2.9 million in 2018 compared to 2017. Compensation expenses include costs associated with new personnel additions as well as an increase of $2.3 million related to non-cash stock option compensation expense in 2018 compared to the prior year.
Other expenses included a non-cash charge of $4.5 million for the year ended December 31, 2018, compared to a non-cash charge of $2.5 million for the year ended December 31, 2017, 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 $3.6 million reduction in the earn-out liability related to potential milestone payments for the GBM product candidate in 2018, and a corresponding $0.6 million reduction in the earn-out liability in 2017.

The Company realized $0.4 million of interest income from its short-term investments during 2018. Investment income was negligible in 2017. In connection with its new debt facility with Horizon, the Company incurred interest expense of $0.7 million during 2018 compared to $0.1 million during 2017. In the second quarter of 2017, Company paid off its prior loan facility with Hercules Technology Growth Capital, Inc.

During the fourth quarter of 2018, the Company recognized a $10.4 million income tax benefit resulting from the sale of its cumulative New Jersey NOLs. The Company has approximately $3.9 million in future tax benefits remaining under the NOL Program for future years

During 2017, the Company recognized deemed dividends totaling $0.4 million related to multiple agreements with certain warrant holders, pursuant to which these warrant holders agreed to exercise, and the Company agreed to reprice, certain warrants. Warrants to purchase 790,410 shares of common stock were repriced at $2.70 and warrants to purchase 506,627 shares of common stock were repriced at $1.65. The Company received $3.0 million in gross proceeds from the sale of these repriced warrants.

Year-End Conference Call

The Company is hosting a conference call to provide a business update and discuss year-end 2018 financial results at 11:00 a.m. EDT on Friday, March 29, 2019. To participate in the call, interested parties may dial 1-800-239-9838 (Toll-Free/North America) or 1-929-477-0448 (International/Toll) and ask for the Celsion Corporation Fourth Quarter and Year-End 2018 Earnings Call (Conference Code: 3754184) 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 Friday, March 29, 2019 and will remain available until April 12, 2019. The replay can be accessed at 1-719-457-0820 or 1-888-203-1112 using Conference ID: 3754184. 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, March 29, 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)

	Year ended December 31, 2018	2017
Licensing revenue	$ 500	$ 500
Operating expenses:		
Research and development	11,865	13,079
General and administrative	9,700	5,890
Total operating expenses	21,565	18,969
Loss from operations	(21,065)	(18,469)
Other (expense) income:		
Gain from valuation of earn-out milestone liability	3,631	649
Loss from impairment of in-process research and development	(4,510)	(2,520)
Interest expense, investment income and other income (expense), net	(358)	(62)
Total other (expense) income, net	(1,237)	(1,933)
Net loss before income tax benefit	(22,032)	(20,402)
Income tax benefit	10,419	–
Net loss	(11,883)	(20,402)
Deemed Dividend related to warrant modifications	–	(346)
Net loss attributable to common shareholders	$ (11,883)	$ (20,748)
Net loss attributable to common shareholders per common share - basic and diluted	$ (0.68)	$ (2.72)
Weighted average common shares outstanding - basic and diluted	17,583	7,627

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

ASSETS	**December 31, 2018**	**December 31, 2017**

Current assets		
Cash and cash equivalents	$ 13,354	$ 11,444
Investment securities and interest receivable on investment securities	14,326	12,779
Prepaid expenses and other current assets	451	89
Total current assets	28,131	24,312
Property and equipment	185	176
Other assets		
In-process research and development	15,736	20,246
Goodwill	1,976	1,976
Other intangible assets, net	568	796
Other assets	259	9
Total other assets	18,540	23,027
Total assets	$ 46,856	$ 47,515
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 5,607	$ 5,700
Deferred revenue - current portion	500	500
Total current liabilities	6,107	6,200
Earn-out milestone liability	8,908	12,539
Notes payable - noncurrent portion	9,417	–
Deferred revenue and other liabilities - noncurrent portion	1,563	2,071
Total liabilities	25,995	20,810
Stockholders' equity		
Common stock	188	173
Additional paid-in capital	294,394	288,409
Accumulated other comprehensive gain (loss)	29	(10)
Accumulated deficit	(273,665)	(261,782)
	20,946	26,790
Less: Treasury stock	(85)	(85)
Total stockholders' equity	20,861	26,705
Total liabilities and stockholders' equity	$ 46,856	$ 47,515

®

Celsion Corporation

Source: Celsion CORP