



Celsion Corporation Reports 2019 Financial Results and Provides Business Update

March 25, 2020

Enters 2020 with a Strong Balance Sheet and an Advancing Clinical Pipeline

Conference Call Begins at 11:00 a.m. Eastern Time on Thursday March 26, 2020

LAWRENCEVILLE, N.J., March 25, 2020 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the year ended December 31, 2019 and provided an update on clinical development programs with ThermoDox[®], its proprietary heat-activated liposomal encapsulation of doxorubicin, and GEN-1, 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. 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 a very productive 2019, making substantial progress with our ongoing development programs with ThermoDox[®] and GEN-1 while maintaining a strong balance sheet. Our pivotal 556-patient global Phase III OPTIMA Study in HCC was fully enrolled in August 2018. We are now looking forward to the second of two preplanned interim efficacy analyses, expected in June 2020. Our OVATION 2 Study has completed enrollment of the first 15 patients in the Phase I portion of this 130-patient Phase I/II randomized study. Initial data at the 100 mg/m² dose cohort are consistent with impressive results reported from our Phase Ib dose-escalating trial (the OVATION 1 Study) in ovarian cancer. Patients treated in the three highest dose cohorts demonstrated a high percent of R0 (complete) surgical outcomes associated with significant improvement in overall survival," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "Celsion's fundamentals are strong. Our financing approach is nothing short of investor friendly. We are well positioned with a capital structure sufficient to see our clinical programs through transformative milestones. In doing so, we look to create significant value for our shareholders, patients and the medical community."

Recent Developments

ThermoDox[®]

Independent Data Monitoring Committee (iDMC) Unanimously Recommended Continuation of Phase III OPTIMA Study with ThermoDox[®] in Primary Liver Cancer. In November 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 radiofrequency ablation (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) appear to be tracking with patient data observed at a similar point in the Company's well-balanced subgroup of 285 patients followed prospectively in the earlier Phase III HEAT 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 review, the Company believes the OPTIMA Study is well positioned for success at the next preplanned interim efficacy analysis, which will take place 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, which is below the hazard ratio of 0.65 observed for the 285 patients in the Prospective Subgroup treated with RFA > 45 minutes. Data review at the first interim efficacy analysis 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 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 Prospective Subgroup.

Publication of Research on Fluorescence Imaging of ThermoDox[®] Uptake in International Journal of Hyperthermia. In November 2019 results from an independent study of a lyso-thermosensitive liposomal doxorubicin (LTLTD) were published in the peer-reviewed publication *International Journal of Hyperthermia*. Results showed that real-time fluorescence imaging can visualize uptake of LTLTD during delivery and can predict tumor drug uptake in response to heat. These data clearly show that high concentrations of tumor-fighting doxorubicin can be delivered at unprecedented levels to tumors using ThermoDox[®] plus targeted heat, which helps explain why the Phase III HEAT Study Prospective Subgroup data is so impressive.

The article, titled "Real-time fluorescence imaging for visualization and drug uptake prediction during drug delivery by thermosensitive liposomes," can be found [here](#). The study used LTLTD to perform experiments and confirmed several characteristics of the compound and its delivery mechanism that support the use of ThermoDox[®] plus RFA in the treatment of HCC, as visualized by fluorescent imaging. Researchers used a custom designed hyperthermal probe to heat the tumors in nude mice carrying Lewis lung carcinoma. Key findings were as follows:

Fluorescence Intensity Tumor Region of Interest (ROI) of heated tumors was enhanced:

- 4.6-fold (at 15 mins)

- 9.3-fold (at 30 mins)
- 13.2-fold (at 60 mins)

Tumor doxorubicin concentration of heated tumors was enhanced:

- 1.9-fold (at 15 mins)
- 2.9-fold (at 30 mins)
- 5.2-fold (at 60 mins)

GEN-1 Immunotherapy

GEN-1 Receives Orphan Drug Designation from the European Medicines Agency. On March 23, 2020, the Company announced the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) has recommended that GEN-1 be designated as an orphan medicinal product for the treatment of ovarian cancer. GEN-1 previously received orphan designation from the U.S. Food and Drug Administration and is currently being evaluated in a Phase I/II clinical trial (the OVATION 2 Study) for the treatment of newly diagnosed patients with Stage III and IV ovarian cancer. As established by the EMA, Orphan Medicinal Product Designation (the “Designation”) by the European Commission 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 for the Designation are manifold and 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.

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 patients were treated with GEN-1 at a dose of 100 mg/m² plus NACT and six patients were treated with NACT only. All 15 patients 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 a 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:

		<u>% of Patients with R0 Resections</u>
0, 36, 47 mg/m ² of GEN-1 plus NACT	n=12	42 %
61, 79, 100 mg/m ² 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.

The OVATION 2 Study is an open-label, 130-patient, 1-to-1 randomized Phase I/II trial, 80% powered to show the equivalent of a 33% improvement in progression-free survival (PFS), the primary endpoint, when comparing the treatment arm (NACT + GEN-1) with the control arm (NACT alone). GEN-1 is a formulation of Celsion’s proprietary, synthetic, non-viral cell transfection platform TheraPlas, which incorporates DNA plasmids coded for the inflammatory protein interleukin-12 (IL-12). Cell transfection is followed by persistent, local secretion of the IL-12 protein at therapeutic levels.

Positive Data Safety Monitoring Board (DSMB) Review of Phase I Portion of OVATION 2 Study in Ovarian Cancer. In February 2020, the Company announced the DSMB had completed its initial safety review of data from the first 15 patients treated with the first four neoadjuvant

chemotherapy (NACT) doses of GEN-1 at 100 mg/m² in the ongoing OVATION 2 Study. As requested by the U.S. Food and Drug Administration, a follow-on Phase I review by the DSMB will evaluate the safety of GEN-1 in up to 17 weekly doses before initiating the Phase II portion of the Study. The Phase I/II OVATION 2 Study is 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. The OVATION 2 Study is an open-label, 130 patient, 1:1 randomized trial, 80% powered to show the equivalent of a 33% improvement in PFS, the primary endpoint, when comparing the treatment arm (NACT + GEN-1) with the control arm (NACT alone).

The OVATION 2 Study builds on promising clinical and translational research data from the Phase Ib OVATION 1 Study, in which enrolled patients received escalating weekly doses of GEN-1 (from 36 mg/m² to 79 mg/m²) for a total of eight treatments in combination with NACT, followed by interval debulking surgery (IDS). Data from the OVATION 1 Study were presented at the ASCO-SITC Clinical-Oncology Symposium by Premal H. Thaker, M.D., M.S. in May 2019 and can be reviewed [here](#). 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.

Corporate Developments

Strengthened Balance Sheet Through a Timely \$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, par value \$0.01 per share, pursuant to a registered direct offering. The Company 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 will be 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 approximately \$4.8 million before deducting placement agent fees and other estimated offering expenses. This financing coupled with recent and future sales of its New Jersey net operating losses will extend the Company's operating roadway to mid-2021, well beyond the final data readout of the OPTIMA Study (anticipated for the first quarter of 2021), if needed.

Received \$1.9 Million Allocation Through the New Jersey Technology Business Tax Certificate Transfer (NOL) Program; with an Additional \$2 Million More Expected in 2020. In December 2019 the Company received approval from the New Jersey Economic Development Authority's (NJEDA) Technology Business Tax Certificate Transfer program to sell its unused New Jersey net operating losses (NOLs) and R&D tax credits. 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 \$10.4 million of net cash proceeds in the fourth quarter of 2018. The Company anticipates it will be able to transfer this current year credit and receive net proceeds of approximately \$1.8 million in the first half of 2020. An additional \$2.0 million final allocation of NOL sales is fully expected in 2020.

Establishing a Subsidiary in China to Serve as Beachhead for Commercializing ThermoDox[®] in China and Southeast Asia. In December 2019, the Company signed a memorandum of understanding (MOU) with officials from the Hangzhou Yuhang Economic Development Area to establish a subsidiary in the Yuhang District of Hangzhou, the capital of China's Zhejiang Province. The Area, also known as the Qianjing Economic Development Area, is located in China's biotech hub, where the Chinese government has made the development of advanced medical technologies that address unmet patient needs a high priority.

The primary purpose of this new subsidiary is to commercialize innovative cancer therapies starting with ThermoDox[®]. In addition to China, the subsidiary will focus on all nearby developing markets including the Philippines, Malaysia, Thailand and Vietnam. Hisun, Celsion's local manufacturing partner, is expected to provide an economically viable ThermoDox[®] cost structure by establishing a low-cost base of production for these geographies. Registration of the subsidiary is expected to be completed in 2020, with full operation expected in the first half of 2021. The MOU provides numerous incentives from the Hangzhou municipal government under the central government's policy that are expected to benefit Celsion and the new subsidiary including reimbursement for personnel recruiting, rent-free office space for three years and tax abatements associated with certain capital investments. The Company's immediate financial obligation under the agreement will be offset by future grants tied to progress with clinical research programs.

Financial Results

For the year ended December 31, 2019, Celsion reported a net loss of \$16.9 million (\$0.77 per share) compared with a net loss of \$11.9 million (\$0.68 per share) for the year ended December 31, 2018. Operating expenses were \$21.1 million for 2019, which represented a \$0.5 million or 2% decrease from \$21.6 million for 2018. During 2019, the Company incurred \$2.3 million in non-cash stock option expense compared with \$4.6 million in 2018.

Research and development expenses were \$13.1 million in 2019, an increase of \$1.2 million or 10% from \$11.9 million in 2018. The prior year was favorably impacted by a \$0.8 million credit resulting from cost concessions negotiated with the Company's lead contract research organization (CRO) for the OPTIMA Study. Excluding this one-time credit, clinical development costs for the Phase III OPTIMA Study were \$4.1 million in 2019, a decrease of \$1.4 million from \$5.5 million in 2018. This 25% decrease was primarily due to the completion of enrollment of the OPTIMA Study in August 2018, which resulted in lower monthly CRO fees during the follow-up phase of the trial. Regulatory costs related to NDA preparation for ThermoDox[®] were \$1.1 million in 2019 compared with \$0.3 million in 2018. Costs associated with the production of ThermoDox[®] were \$1.5 million during 2019 compared with \$1.1 million in 2018 as the Company prepared registration batches at its contract manufacturing organizations assuming the successful outcome of the OPTIMA Study.

Costs associated with the OVATION 2 Study were \$0.6 million for 2019 compared with \$0.4 million in 2018. The Company announced the completion of enrollment of the Phase I portion of the Phase I/II OVATION 2 Study during the fourth quarter of 2019. Costs associated with Celsion's wholly-owned subsidiary, CLSN Laboratories, Inc. (which includes research and development activities for GEN-1 and TheraPlas), were \$3.3 million in 2019 compared with \$2.8 million in 2018 as the Company expanded its manufacturing capabilities in an effort to reduce the manufacturing cost of GEN-1 for its planned clinical study requirements in 2020 and beyond. In 2019, research and development costs included a decrease of \$0.6 million in non-cash stock compensation expense compared with the same period of 2018.

General and administrative expenses were \$8.0 million for 2019 compared with \$9.7 million for 2018. This \$1.7 million or 18% decrease was primarily due to lower compensation expenses related to non-cash stock option compensation expense in 2019 compared with 2018.

Other expenses for 2019 included a non-cash gain of \$2.8 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 for 2018 of \$4.5 million related to the impairment of certain in-process research and development assets related to the development of the Company's glioblastoma

multiforme cancer product candidate, offset by a \$3.6 million reduction in the earn-out liability related to potential milestone payments. The Company realized \$0.5 million of interest income for 2019 compared with \$0.4 million in 2018. In connection with its venture debt facility with Horizon entered into in late June 2018, the Company incurred interest expense of \$1.4 million in 2019 compared with \$0.7 million in 2018.

During the fourth quarter of 2019, the Company recognized a \$1.8 million income tax benefit resulting from the sale of its New Jersey net operating losses. 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 for the tax years 2011 to 2017. The Company has approximately \$2.0 million in future tax benefits remaining under the NJEDA Technology Business Tax Certificate Transfer program for future years.

Net cash used for operating activities was \$20.3 million in 2019 compared with \$7.0 million in 2018. In the fourth quarter of 2018, the Company received \$10.4 million in net proceeds from the sale of its New Jersey state net operating losses. Cash, cash equivalents and investments as of December 31, 2019 were \$14.9 million. Total cash provided by financing activities was approximately \$7.8 million during 2019 from sales of common stock. Subsequent to year-end, the Company raised \$6.0 million in net proceeds from sales of common stock during the first quarter of 2020. The Company expects to receive net proceeds of \$1.8 million from the sale of its 2017-2018 New Jersey state NOLs in the second quarter of 2020.

Conference Call

The Company is hosting a conference call at 11:00 a.m. EDT on Thursday, March 26, 2020 to provide a business update and discuss 2019 financial results. To participate in the call, please dial 1-800-367-2403 (Toll-Free/North America) or 1-334-777-6978 (International/Toll) and ask for the Celsion Corporation 2019 Earnings Call (Conference Code: 8257530). The call will also be broadcast live on the internet at www.celsion.com. The call will be archived for replay on Friday, March 27, 2020 and will remain available until April 10, 2020. The replay can be accessed at 1-719-457-0820 or 1-888-203-1112 using Conference ID: 8257530. 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 27, 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.

Celsion Investor Contact

Jeffrey W. Church
609-482-2455
jchurch@celsion.com

LHA Investor Relations

Kim Sutton Golodetz
212-838-3777
kgolodetz@lhai.com

[Tables to Follow]

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

	Year ended December 31,	
	2019	2018
Licensing revenue	\$ 500	\$ 500
Operating expenses:		
Research and development	13,065	11,865
General and administrative	8,000	9,700
Total operating expenses	21,065	21,565

Loss from operations	(20,565)	(21,065)
Other income (expense):		
Gain from valuation of earn-out milestone liability	3,190	3,631
Loss from impairment of in-process research and development	-	(4,510)
Fair value of warrants issued for milestone amendment	(400)	-
Interest expense, investment income and other income (expense), net	(893)	(358)
Total other income (expense)	1,897	(1,237)
Net loss before income tax benefit	(18,668)	(22,302)
Income tax benefit	1,816	10,419
Net loss	<u>\$ (16,852)</u>	<u>\$ (11,883)</u>
Net loss per common share - basic and diluted	<u>\$ (0.77)</u>	<u>\$ (0.68)</u>
Weighted average common shares outstanding - basic and diluted	<u>21,833</u>	<u>17,583</u>

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	<u>December 31, 2019</u>	<u>December 31, 2018</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 6,875	\$ 13,354
Investment securities and interest receivable	8,007	14,326
Prepaid expenses and other current assets	1,353	451
Total current assets	<u>16,235</u>	<u>28,131</u>
Property and equipment	<u>405</u>	<u>185</u>
Other assets		
Deferred income tax asset	1,820	-
In-process research and development	15,736	15,736
Goodwill	1,976	1,976
Operating leases right-of-use	1,432	-
Other intangible assets, net	341	568
Other assets	333	260
Total other assets	<u>21,638</u>	<u>18,540</u>
Total assets	<u>\$ 38,278</u>	<u>\$ 46,856</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities

Accounts payable and accrued liabilities	\$ 5,166	\$ 5,607
Deferred revenue – current portion	500	500

Operating lease liability – current portion	388	-
Notes payable - current portion	1,840	-
Total current liabilities	7,894	6,107
Earn-out milestone liability	5,718	8,908
Notes payable - noncurrent portion	7,963	9,417
Operating lease liability – noncurrent portion	1,144	-
Deferred revenue and other liabilities - noncurrent portion	1,000	1,563
Total liabilities	23,719	25,995
Stockholders' equity		
Common stock	232	188
Additional paid-in capital	304,886	294,394
Accumulated other comprehensive gain (loss)	43	29
Accumulated deficit	(290,517)	(273,665)
	14,644	20,946
Less: Treasury stock	(85)	(85)
Total stockholders' equity	14,559	20,861
Total liabilities and stockholders' equity	\$ 38,278	\$ 46,856

###



Source: Celsion CORP