Celsion Corporation Reports Fourth Quarter and Full-Year 2017 Financial Results

March 27, 2018

Celsion Enters 2018 with Solid Fundamentals, a Strong Balance Sheet and an Advancing Clinical Pipeline

Company to Hold Conference Call on Tuesday, March 27, 2018 at 11:00 a.m. EDT

LAWRENCEVILLE, N.J., March 27, 2018 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ:CLSN), an oncology drug development company, today announced financial results for the year ended December 31, 2017 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 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 outstanding year in 2017, making meaningful progress with our ongoing development programs for ThermoDox® and GEN-1, as well as strengthening our balance sheet. Entering 2018 with more than $25 million in cash , we are well positioned with sound fundamentals, the right resources, and capital sufficient to complete enrollment of our ongoing global, pivotal Phase III OPTIMA Study in primary liver cancer, and continue the trial through the first preplanned, interim efficacy analysis expected in the first half of 2019," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "Our equally important efforts in immunotherapy are generating impressive results. During 2017, we reported data from our Phase 1b immunotherapy program (the OVATION I Study) in ovarian cancer. These data have provided key insights into GEN-1's clinical and safety profile and reinforce our confidence in GEN-1's potential to serve as a highly effective first-line therapy in newly diagnosed patients with ovarian cancer. We look forward to reporting early clinical findings and translational data from the first cohort of our 90 patient, randomized Phase I/II OVATION II Study in the second half of 2018."

Recent Developments

ThermoDox®

Presentation of ThermoDox® HEAT Study Manuscript by Lead Author, Dr. Won Young Tak, at Korean Liver Cancer Association's 12th Annual Scientific Meeting. On Feb. 12, 2018, the Company announced that an abstract discussing the Company's Phase III HEAT study evaluating ThermoDox® in combination with radiofrequency ablation (RFA) was one of six selected for presentation as part of the lecture of the Presidential Selection at the Korean Liver Cancer Association's 12th Annual Scientific Meeting in Seoul, South Korea. Dr. Tak's presentation highlighted learnings from the Company's 701 patient HEAT Study and included results from simulation studies and findings from the *post hoc* subgroup analysis. Dr. Tak noted that key findings from the study and analyses of ThermoDox® plus RFA suggested that the therapeutic effect of ThermoDox® plus RFA may be improved when the RFA dwell time for solitary lesions is greater than or equal to 45 minutes.

Publication of HEAT Study Manuscript. On October 16, 2017, the Company announced publication of the manuscript, "Phase III HEAT Study Adding Lyso-Thermosensitive Liposomal Doxorubicin to Radiofrequency Ablation in Patients with Unresectable Hepatocellular Carcinoma Lesions," in *Clinical Cancer Research*, a high impact, peer-reviewed medical journal. The article provided detailed learnings from the Company's 701-patient HEAT Study and included results from computer simulation studies and interesting findings from a *post hoc* subgroup analysis, all of which – when examined together – suggested a clearer understanding of a key ThermoDox® heat-based mechanism of action: the longer the target tissue is heated, the greater the doxorubicin tissue concentration.

Additionally, the article explored the hypothesis prompted by these findings: ThermoDox®, when used in combination with RFA standardized to a minimum dwell time of 45 minutes (sRFA ≥ 45 min), may increase the overall survival (OS) of patients with hepatocellular carcinoma (HCC). The final OS analysis demonstrated that in a large, well bounded, subgroup of patients (n=285 patients, 41% of the previous 701 patient HEAT Study), treatment with a combination of ThermoDox® and standardized RFA provided an average 58% improvement in OS compared to standardized RFA alone. The Hazard Ratio (HR) was 0.63 (95% CI 0.43 - 0.93) with a p-value of 0.0198. In this large subgroup, median OS for the ThermoDox® plus standardized RFA group translated into a 25.4-month (more than 2.1 years) survival benefit over the standardized RFA-only group - totaling approximately 80 months (6-1/2 years, which is considered a curative treatment for HCC) for the ThermoDox® plus standardized RFA group versus 53 months for the standardized RFA-only group.

GEN-1 Immunotherapy

Presentation of GEN-1 Clinical Development Program and Recent Clinical and Translation Research Data by Ovarian Cancer Expert at Oppenheimer & Co. Investor Event. On March 5, 2018, the Company announced that 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, and investigator in Celsion's GEN-1 development program presented, "Ovarian Cancer: New Horizons and Treatments" at an investor event hosted by Oppenheimer & Co. in New York City on March 1, 2018.

Dr. Thaker's presentation highlighted the following:

- GEN-1 is a novel new approach that is 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.

- In a Phase I study of GEN-1, 14 newly diagnosed patients with Stage III/IV ovarian cancer were intraperitoneally administered GEN-1 plus neoadjuvant chemotherapy. Results from the study demonstrated immunological changes consistent with the ability of GEN-1 to increase local (peritoneal) levels of IL-12 and its downstream anti-cancer cytokines and reduction in vascular endothelial growth factor (VEGF; potent angiogenic factor that contributes to tumor angiogenesis) levels with little change in systemic circulation.
- The study showed no serious systemic toxicities. These clinical findings, including a partial or complete response in 86% of patients, R0 resections in 100% of patients treated at the highest dose cohort and recently reported progression-free survival (PFS) of over 21 months compared to historical controls for PFS of approximately 12 months, support further evaluation of GEN-1's safety and efficacy in patients with Stage III/IV ovarian cancer.

Filing of Phase I/II Clinical Protocol for Evaluation of GEN-1 Immunotherapy to Treat Newly Diagnosed Ovarian Cancer. On November 13, 2017, the Company announced the submission of its Phase I/II clinical trial protocol to the U.S. Food and Drug Administration for GEN-1, the Company's DNA-based immunotherapy for the localized treatment of ovarian cancer. The protocol is designed with a single dose escalation to evaluate the safety and biological activity of GEN-1 at 100mg/m² in newly diagnosed Stage III/IV ovarian cancer patients, followed by a continuation at the selected dose in Phase II in a 90-patient 1 to 1 randomized study. The study protocol was unanimously supported by an expert medical advisory board and lead investigators from the Phase IB OVATION Study and is summarized below:

- Open label, 1:1 randomized design
- Enrollment in up to 90 patients with Stage III/IV ovarian cancer at ten U.S. centers
- Primary endpoint of improvement in PFS comparing GEN-1 with neoadjuvant chemotherapy versus neoadjuvant chemotherapy alone.

PFS for patients treated per protocol in the recently completed Phase IB OVATION Study continues to be followed. The Company expects to initiate enrollment in the Phase I portion of the OVATION II Study during the second quarter of 2018. The Phase I/II study will be powered to show a 33% improvement in the primary endpoint, PFS, when comparing GEN-1 with neoadjuvant chemotherapy to neoadjuvant chemotherapy alone.

In January 2018, the Company announced that after a two-month review period, the U.S. Food and Drug Administration (FDA) accepted the Company's submission with minor comments focusing primarily on the role of the Data Safety Monitoring Board and the need for a 3 + 3 evaluation of the single Phase I cohort and full evaluation of the maintenance treatment at the highest dose prior to initiation of the Phase II portion of the trial.

R&D Day. On October 12, 2017, the Company held a Research and Development (R&D) Day in New York City with presentations focused on the Company's development program using ThermoDox® for the treatment of primary liver cancer and GEN-1 for treatment of ovarian cancer. Leading OPTIMA Study clinical investigators representing various geographical regions (Asia-Pacific and Europe) and multiple medical disciplines (hepatology, interventional radiology and surgery) presented their past and current experiences with ThermoDox® for the treatment of primary liver cancer. The GEN-1 immunotherapy presentations focused on the Company's clinical and translational research data from its recently completed Phase IB OVATION Study. The lead clinical investigator for the OVATION Study and leading immuno-oncology experts from the Roswell Park Cancer Institute presented their current experience with GEN-1 immunotherapy for the treatment of ovarian cancer.

Corporate Development

Raised $42.6 Million in Gross Proceeds During 2017, Including $27.5 Million in Gross Proceeds During the Fourth Quarter. Recent minimally dilutive equity offerings totaling approximately $28.8 million in gross proceeds during the fourth quarter of 2017 through January 2018 have strengthened the Company's balance sheet and will be used to support the Company's development efforts and potentially significant clinical milestones for ThermoDox® and GEN-1 clinical programs into the third quarter of 2019.

- The Company raised $17.0 million in gross proceeds through the exercise of outstanding common stock warrants in early October 2017.
- In October 2017, the Company completed an underwritten equity offering of shares of common stock and warrants to purchase common stock with Oppenheimer & Co. The gross proceeds of the offering were approximately $6.6 million.
- In November 2017, the Company raised $3.9 million in gross proceeds off its ATM Equity Facility with Cantor Fitzgerald.

Financial Results

For the year ended December 31, 2017, Celsion reported a net loss attributable to common shareholders of $20.7 million, or a loss of $2.72 per share, compared to a net loss of $22.1 million, or a loss of $11.89 per share, for the year ended December 31, 2016.

Net cash used for operating activities was $16.6 million for the year ended December 31, 2017, compared to $18.4 million for the year ended December 31, 2016. Cash and cash equivalents at December 31, 2017 were $24.2 million. Total cash provided by financing activities was approximately $36.5 million during 2017 comprising $17.9 million in net proceeds from sales of common stock and $21.1 million in net proceeds from the exercise of common stock warrants in 2017, partially offset by $2.6 million in debt service payments under the Hercules Venture Debt Facility ("Hercules").

Research and development costs were $13.1 million for the year ended December 31, 2017, compared to $14.6 million for the year ended December 31, 2016. Clinical development costs for the Phase III OPTIMA Study were $6.7 million for the year ended December 31, 2017 compared to $5.6 million for the same period of 2016. This increase was due to patient costs and investigator grants associated with higher patient enrollment in the Phase III OPTIMA Study during 2017. R&D costs for other development programs were lower because of the Company's tighter clinical development focus around the pivotal Phase III OPTIMA Study for the treatment of primary liver cancer and the clinical development program for GEN-1 IL-12 immunotherapy for the localized treatment of ovarian cancer, as well as lower costs in 2017 associated with the production of ThermoDox® clinical supplies to support the OPTIMA Study.

General and administrative expenses were $5.9 million for the year ended December 31, 2017, compared to $6.5 million for the year ended December 31, 2016. This decrease was due to lower non-cash stock option compensation expense and reduced professional fees.

For the year ended December 31, 2017, other expenses included a non-cash charge of $2.5 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 $1.2 million reduction in the earn-out liability related to potential milestone payments for the GBM product candidate.

During 2017, the Company recognized deemed dividends totaling $0.4 million collectively regarding 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.

Interest expense decreased by $0.6 million for the year ended December 31, 2017 due to lower principal balances outstanding under the Company's Venture Debt Facility with Hercules. The loan balance and end of term charges on this debt facility were paid in full on June 1, 2017.

Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss year-end 2017 financial results at 11:00 a.m. EDT on Tuesday, March 27, 2018. To participate in the call, interested parties may dial 1-888-737-3628 (Toll-Free/North America) or 1-719-325-4879 (International/Toll) and ask for the Celsion Corporation Year-End 2017 Earnings Call (Conference Code: 1256084) 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 Tuesday, March 27, 2018 and will remain available until April 10, 2018. The replay can be accessed at 1-719-457-0820 or 1-719-785-5608 using Conference ID: 1256084. 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 Tuesday, March 27, 2018.

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 and brain cancers. Celsion has two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies. For more information on Celsion, visit our website: http://www.celsion.com (CLSN-FIN).

Celsion wishes to inform readers that forward-looking statements in this release are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, unforeseen changes in the course of research and development activities and in clinical trials; the uncertainties of and difficulties in analyzing interim clinical data; the significant expense, time, and risk of failure of conducting clinical trials; the need for Celsion to evaluate its future development plans; possible acquisitions or licenses of other technologies, assets or businesses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in Celsion's periodic reports and prospectuses filed with the Securities and Exchange Commission. Celsion assumes no obligation to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

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

	Year ended December 31, 2017	2016
Licensing revenue	$ 500	$ 500
Operating expenses:		
Research and development	13,079	14,623
General and administrative	5,890	6,527
Total operating expenses	18,969	21,150
Loss from operations	(18,469)	(20,650)
Other (expense) income:		

Gain from valuation of earn-out milestone liability	649	733
Loss from impairment of in-process research and development	(2,520)	(1,444)
Interest expense, investment income and other income (expense), net	(62)	(693)
Total other (expense) income, net	(1,933)	(1,404)
Net loss	$ (20,402)	$ (22,054)
Deemed Dividend related to warrant modifications	(346)	–
Net loss attributable to common shareholders	$ (20,748)	$ (22,054)
Net loss attributable to common shareholders per common share - basic and diluted	$ (2.72)	$ (11.89)
Weighted average common shares outstanding - basic and diluted	7,627	1,854

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

ASSETS	**December 31, 2017**	**December 31, 2016**
Current assets		
Cash and cash equivalents	$ 11,444	$ 2,624
Investment securities and interest receivable on investment securities	12,779	1,684
Prepaid expenses and other current assets	89	205
Total current assets	24,312	4,513
Property and equipment	176	463
Other assets		
In-process research and development	20,246	22,766
Goodwill	1,976	1,976
Other intangible assets, net	796	1,023
Deposits	100	100
Other assets	9	9
Total other assets	23,027	25,874
Total assets	$ 47,515	$ 30,850
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 5,700	$ 5,363
Deferred revenue - current portion	500	500
Note payable - current portion	–	2,560
Total current liabilities	6,200	8,423
Earn-out milestone liability	12,539	13,188
Notes payable - noncurrent portion	–	–
Deferred revenue and other liabilities - noncurrent portion	2,071	2,513
Total liabilities	20,810	24,124
Stockholders' equity		
Common stock	173	22
Additional paid-in capital	288,409	248,169
Accumulated other comprehensive loss	(10)	–
Accumulated deficit	(261,782)	(241,380)

	26,790	6,811
Less: Treasury stock	(85)	(85)
Total stockholders' equity	26,705	6,726
Total liabilities and stockholders' equity	$ 47,515	$ 30,850

Source: Celsion Corporation