



## Celsion Corporation Reports First Quarter 2018 Financial Results and Provides Business Update

May 11, 2018

*Significant Progress in Phase III Liver Cancer and Phase I/II Ovarian Cancer Studies  
Supported with Solid Fundamentals and a Strong Balance Sheet*

*Company to Hold Conference Call on Friday, May 11, 2018 at 11:00 a.m. EDT*

LAWRENCEVILLE, N.J., May 11, 2018 (GLOBE NEWSWIRE) -- [Celsion Corporation](#) (NASDAQ:CLSN), an oncology drug development company, today announced financial results for the quarter ended March 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 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 continues to make significant progress with our two ongoing clinical development programs for ThermoDox® and GEN-1. With sound fundamentals and a strong balance sheet, we are well positioned to complete enrollment in our ongoing 550 patient global, pivotal Phase III OPTIMA Study in primary liver cancer and to initiate our 130 patient Phase I/II randomized OVATION II Study in newly diagnosed patients with ovarian cancer in June 2018 and reporting clinical findings from the Phase I cohort of 12 patients of the OVATION II by the end of 2018," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "Our GEN-1 immunotherapy has generated impressive results to-date. We expect to report final progression-free survival data from our Phase IB clinical trial (the OVATION I Study) by the end of the second quarter of 2018. These data will provide additional 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."

### Recent Developments

#### ThermoDox®

***ThermoDox® Highlighted at the International Liver Congress™ 2018 Symposium.*** On April 12, 2018, the Company announced a presentation and discussion of ThermoDox® and the evolving treatment landscape for primary liver cancer or hepatocellular carcinoma (HCC), as part of a company-sponsored symposium at the International Liver Congress™ 2018, in Paris, France. The symposium titled, "*Emerging Horizons in HCC: From Palliation to Cure*," featured presentations by co-chairs and HCC experts, Ghassan Abou-Alfa, M.D., a board-certified medical oncologist at Memorial Sloan Kettering Cancer Center in New York City, and Riccardo Lencioni, M.D., FSIR, EBIR, professor at the University of Pisa School of Medicine.

Dr. Abou-Alfa's presentation, "*New Developments in Targeted Therapies for HCC: The Mounting Wave of Immuno-Oncology*," discussed recent developments in treating HCC, including the role of tyrosine kinase inhibitors (TKIs), immuno-oncology and CAR-T therapies, as well as advancements in chemotherapy and combination treatment with local therapy. Prof. Lencioni's presentation, "*Rethinking Our Approach to Intermediate-Size HCC*" focused on the increasing incidence and burden of HCC globally, the limited overall survival benefit with current therapies at later stages of disease progression, and the potential for ThermoDox® to provide enhanced survival benefit with standardized radiofrequency ablation. The slides from Prof. Lencioni's presentation are available on Celsion's corporate website at [www.celsion.com](http://www.celsion.com).

***Data Monitoring Committee Unanimously Recommended Continuation of the OPTIMA Study in Primary Liver after its Planned Safety and Data Review from 411 Patients; Enrollment Now at 85%.*** On April 9, 2018, the Company announced that the independent Data Monitoring Committee for the Company's 550-patient, pivotal Phase III clinical study of ThermoDox® in combination with radiofrequency ablation for primary liver cancer (the OPTIMA Study), unanimously recommended that the study continue according to protocol to its data readout. The DMC's recommendation was based on the Committee's assessment of safety and data integrity of the first 75% of patients randomized in the trial as of February 5, 2018 and concluded that the integrity of the study is intact and that ThermoDox® is safe for continued enrollment of newly diagnosed, intermediate-stage patients. An analysis of blinded data from the intent-to-treat population, consolidated for both arms, indicated that median progression free survival (PFS) was 20.8 months. This compares favorably to the HEAT Study median PFS of 13.8 months and is consistent with the hypothesis-generating estimates from the HEAT Study manuscript published in the October 2017 issue of the peer-reviewed medical journal, '*Clinical Cancer Research*.' 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.

The DMC analysis in April 2018 was the last planned interim analysis prior to enrollment completion in the third quarter of 2018 with results from the first interim efficacy analysis available in the first half of 2019.

***Presentation of ThermoDox® HEAT Study Manuscript by Lead Author, Dr. Won Young Tak, at Korean Liver Cancer Association's 12<sup>th</sup> 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 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.

Dr. Tak's presentation explored the hypothesis prompted by these findings: ThermoDox®, when used in combination with RFA standardized to a

minimum dwell time of 45 minutes (sRFA  $\geq$  45 min), may increase the overall survival (OS) of patients with hepatocellular carcinoma. The final OS analysis from the HEAT Study 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.

## **Corporate Development**

**Corporate Presentations at Two Investor Conferences.** In March 2018, the Company presented at two investor healthcare conferences:

- The B. Riley FBR Inaugural China Healthcare Investing & Partnering Symposium. The conference was held March 15-17, 2018 at The InterContinental Hotel Hangzhou, China.
- The Oppenheimer 28<sup>th</sup> Annual Healthcare Conference. The conference was held March 20-21, 2018 at The Westin New York Grand Central in New York City.

The webcast of Celsion's presentation at the Oppenheimer conference has been archived on the "News & Investors" section of Celsion's corporate website at [www.celsion.com](http://www.celsion.com).

**Raised \$27.5 Million in Gross Proceeds During the Fourth Quarter of 2017, and an Additional \$1.3 Million in Gross Proceeds During the First Quarter of 2018.** 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 and January 2018, the Company raised \$5.2 million in gross proceeds off its ATM Equity Facility with Cantor Fitzgerald.

## **Financial Results**

For the quarter ended March 31, 2018, Celsion reported a net loss of \$4.5 million, or a loss of \$0.25 per share, compared to a net loss of \$5.2 million, or a loss of \$3.09 per share, in the same period of 2017.

Net cash used for operating activities was \$4.7 million for the quarter ended March 31, 2018, compared to \$3.1 million for the same period of 2017. Cash, cash equivalents, short-term investments and interest receivable at March 31, 2018 was \$20.8 million. Cash provided by financing activities was approximately \$1.2 million during the quarter ended March 31, 2018.

Research and development costs were \$2.7 million for the quarter ended March 31, 2018, compared to \$3.5 million for the same period of 2017. Clinical development costs for the Phase III OPTIMA Study were \$1.3 million for the quarter ended March 31, 2018 compared to \$1.6 million for the same period of 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.

General and administrative expenses were \$1.7 million for the quarter ended March 31, 2018, compared to \$1.5 million for the same period of 2017.

This modest increase was due to higher professional fees and an increase in non-cash stock option compensation expense.

As the Company paid off its Venture Debt Facility with Hercules Technology Growth Capital, Inc. during 2017, the Company did not have any interest expense in the first quarter of 2018. Interest expense was \$0.1 million for the first quarter of 2017.

#### Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss its first quarter 2018 financial results at 11:00 a.m. EDT on Friday May 11, 2018. To participate in the call, interested parties may dial 1-888-298-3457 (Toll-Free/North America) or 1-719-325-4917 (International/Toll) and ask for the Celsion Corporation First Quarter 2018 Earnings Call (Conference Code: 6550185) 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](http://www.celsion.com).

The call will be archived for replay on Friday, May 11, 2018 and will remain available until Friday, May 25, 2018. The replay can be accessed at 1-719-457-0820 or 1-888-203-1112 (Toll-Free/USA) or 1-719-457-0820 (International/Toll) using Conference ID: 6550185. An audio replay of the call will also be available on the Company's website, [www.celsion.com](http://www.celsion.com), for 90 days after 2:00 p.m. EDT on Friday, May 11, 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)**  
**(unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Licensing revenue</b>	\$ 125	\$ 125
<b>Operating expenses:</b>		
Research and development	2,741	3,475
General and administrative	1,665	1,468
Total operating expenses	4,406	4,943
<b>Loss from operations</b>	(4,281)	(4,818)
<b>Other (expense) income:</b>		
Loss from valuation of earn-out milestone liability	(270)	(284)
Investment income, interest expense and other income (expense), net	74	(58)
Total other (expense) income, net	(196)	(342)

<b>Net loss</b>	<u>\$ (4,477)</u>	<u>\$ (5,160)</u>
<b>Net loss per common share - basic and diluted</b>	<u>\$ (0.25)</u>	<u>\$ (3.09)</u>
<b>Weighted average common shares outstanding - basic and diluted</b>	<u>17,684</u>	<u>1,671</u>

**Celsion Corporation**  
**Selected Balance Sheet Information**  
(in thousands)

<b>ASSETS</b>	<b>March 31, 2018 (unaudited)</b>	<b>December 31, 2017</b>
<b>Current assets</b>		
Cash and cash equivalents	\$ 2,285	\$ 11,444
Investment securities and interest receivable on investment securities	18,479	12,779
Prepaid expenses and other current assets	89	89
Total current assets	<u>20,853</u>	<u>24,312</u>
<b>Property and equipment</b>	<u>175</u>	<u>176</u>
<b>Other assets</b>		
In-process research and development	20,246	20,246
Goodwill	1,976	1,976
Other intangible assets, net	739	796
Other assets	9	9
Total other assets	<u>22,970</u>	<u>23,027</u>
<b>Total assets</b>	<u>\$ 43,998</u>	<u>\$ 47,515</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 5,134	\$ 5,700
Deferred revenue - current portion	500	500
Total current liabilities	<u>5,634</u>	<u>6,200</u>
Earn-out milestone liability	12,809	12,539
Deferred revenue and other liabilities - noncurrent portion	1,945	2,071
Total liabilities	<u>20,388</u>	<u>20,810</u>
<b>Stockholders' equity</b>		
Common stock	177	173
Additional paid-in capital	289,810	288,409
Accumulated other comprehensive loss	(33)	(10)
Accumulated deficit	<u>(266,259)</u>	<u>(261,782)</u>
	23,695	26,790
Less: Treasury stock	(85)	(85)
Total stockholders' equity	<u>23,610</u>	<u>26,705</u>

**Total liabilities and stockholders' equity**

\$ 43,998      \$ 47,515



Source: Celsion Corporation