



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

November 14, 2018

*ThermoDox® Phase III OPTIMA Study Fully Enrolled in August; First Pre-Planned Efficacy Analysis Expected in Mid-2019*

*GEN-1 Phase I/II OVATION 2 Study Enrolling Patients; First Look at Phase I Data Expected in First Quarter 2019*

*Company to Hold Conference Call on Thursday, November 15, 2018 at 11:00 a.m. EST*

LAWRENCEVILLE, N.J., Nov. 14, 2018 (GLOBE NEWSWIRE) -- [Celsion Corporation](#) (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the quarter and nine-month period ended September 30, 2018 and provided an update on development program progress for ThermoDox®, the company's lead product candidate currently in Phase III development for the treatment of primary liver cancer, and GEN-1, an immunotherapy currently in Phase I/II development for the localized treatment of ovarian cancer.

"During the last quarter Celsion made excellent progress with our clinical development programs, including completion of enrollment in our 550-patient global, pivotal Phase III OPTIMA Study of ThermoDox® in primary liver cancer in August 2018, as expected, and initiation of patient enrollment in our 130-patient follow-on Phase I/II randomized OVATION 2 Study of GEN-1 in patients newly diagnosed with ovarian cancer," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "We continue to maintain a tight operational focus that both conserves cash and enables the timely execution of clinical trials for both of our promising product candidates. In combination with a financing strategy that minimizes dilution and focuses on shareholder value, we have established a cash runway that extends well beyond the time frame necessary to realize the transformational milestones that lie ahead over the next 18 months. In October 2018, we took steps to eliminate the warrant overhang created from our earlier financings in 2016 and 2017 resulting in a clean capitalization structure."

### Recent Developments

**Enrollment Completed for 550-Patient Global, Pivotal Phase III OPTIMA Study of ThermoDox® in Primary Liver Cancer.** In September 2018, the Company announced completion of enrollment of 550 patients in the Company's pivotal, Phase III OPTIMA Study, a multinational, randomized, double-blind, placebo-controlled clinical trial of ThermoDox® in combination with radiofrequency ablation (RFA) for the treatment of patients with hepatocellular carcinoma (HCC), also known as primary liver cancer. The primary endpoint for the study is overall survival (OS). The first of two planned interim efficacy analyses by the study's Data Monitoring Committee (DMC) is expected in mid-2019.

**First Patient Randomized in the Gene-Mediated Immunotherapy (GEN-1) Study of Newly Diagnosed Patients With Stage III/IV Ovarian Cancer.** In September 2018, the first patient was dosed in the OVATION 2 Study, a randomized, Phase I/II clinical trial of GEN-1, the Company's DNA-based immunotherapy for the localized treatment of ovarian cancer as an adjuvant to chemotherapy current standard of care. OVATION 2 will be conducted at 10 treatment centers in the U.S. and will include up to 130 patients with Stage III/IV ovarian cancer, with 12 patients in the Phase I portion and up to 118 patients in Phase II.

**Final Progression-Free Survival (PFS) Data From GEN-1 Phase IB Gene-Mediated Immunotherapy Study of Patients With Stage III/IV Ovarian Cancer.** In October 2018, Celsion announced final clinical results from the dose escalating Phase IB OVATION I trial evaluating neoadjuvant chemotherapy (NAC) and GEN-1 in newly diagnosed patients with Stage III/IV ovarian cancer. Median PFS in patients treated per protocol (n=13) was 24.3 months and was 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, and two patients who did not receive full NAC and GEN-1 cycles.

**Program Overview of Celsion's Gene-Mediated Immunotherapy Designed to Improve Administration of IL-12 and PFS in Patients With Ovarian Cancer Published in the Peer-Reviewed Journal, *Future Oncology*.** In October 2018, an overview of GEN-1 was published in the peer-reviewed journal *Future Oncology*. The article, co-authored by Premal H. Thaker, M.D., M.S., associate professor of obstetrics and gynecology at the Siteman Cancer Center at the Washington University School of Medicine in St. Louis, Mo. and principal investigator in Celsion's GEN-1 development program, outlines the DNA plasmid, gene-based concept and the key attributes supporting GEN-1's mechanism of action characterized by local and persistent delivery of IL-12 and modulation of the tumor microenvironment favoring immune stimulation.

### Corporate Development

**Celsion's Application to Sell its New Jersey State Net Operating Losses (NOLs) for the Tax Years 2011 to 2017 Approved. In September 2018, the Company announced** it has received approval from the New Jersey Economic Development Authority's (NJEDA) Technology Business Tax Certificate Transfer program to sell the Company's unused New Jersey State NOLs and R&D tax credits, totaling \$12.5 million for the tax years 2011 to 2017. The Company anticipates that successful transfer of these credits will result in receipt of approximately \$10 million in net cash proceeds to the Company 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 received 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 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 believes that it has 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 November 14, 2018, the Company has 18.7 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 quarter ended September 30, 2018, Celsion reported a net loss attributable to common shareholders of \$4.7 million, or a loss of \$0.26 per share, compared to a loss of \$5.7 million, or a loss of \$0.70 per share, in the same period of 2017. Operating expenses were \$4.1 million in the third quarter of 2018, which represented an 8% decrease from \$4.5 million in the same period of 2017. During the third quarter ended September 30, 2018, the Company incurred \$0.6 million in non-cash stock option expense compared to \$0.1 million in the third quarter of 2017.

For the nine-month period ended September 30, 2018, the Company reported a net loss attributable to common shareholders of \$17.4 million, or a loss of \$1.00 per share, compared to a loss of \$16.1 million, or a loss of \$3.04 per share, in the same nine-month period of 2017. Operating expenses were \$16.7 million during the first nine months of 2018 compared to \$14.2 million in the same period of 2017. During the first nine months of 2018, the Company incurred \$4.0 million in non-cash stock option expense compared to \$1.0 million in the comparable nine-month period of 2017.

Net cash used for operating activities was \$13.1 million in the first nine months of 2018, compared to \$12.4 million in the same nine-month period in 2017. The Company ended the third quarter of 2018 with \$22.0 million of total cash, cash equivalents, investment securities and interest receivable, which included \$10 million in gross proceeds from the Company's venture debt facility completed on June 27, 2018 with Horizon Technology Finance Corporation. The Company expects to receive approximately \$10 million from the sale of its New Jersey state NOLs in the fourth quarter of 2018, which is expected to contribute to funding operations into the fourth quarter of 2020.

Research and development (R&D) expenses decreased by \$1.1 million, from \$3.3 million in the third quarter of 2017 to \$2.2 million in the third quarter of 2018. Costs associated with the OPTIMA Study decreased by \$1.1 million to \$0.7 million in the third quarter of 2018 compared to \$1.8 million in the same period of 2017. This decrease resulted from cost concessions negotiated with the Company's 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 the initiation of the OVATION 2 Study were \$0.2 million in the third quarter of 2018. Other R&D costs related to clinical supplies and regulatory support for the ThermoDox® development program decreased by \$0.2 million in the third quarter of 2018 when compared to the same prior-year period.

R&D expenses decreased by \$0.4 million, from \$9.9 million in the first nine months of 2017 to \$9.5 million in the first nine months of 2018. Clinical development costs for the Phase III OPTIMA Study decreased to \$4.0 million in the first half of 2018, compared to \$4.9 million in the first nine months of 2017. This decrease of \$0.9 million resulted from cost concessions negotiated with the lead 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 the initiation of the OVATION 2 Study were \$0.4 million in the first nine months of 2018. Other R&D costs related to clinical supplies and regulatory support for the ThermoDox® and GEN-1 clinical development programs increased by \$0.2 million in the first nine months of 2018 when compared to the same prior-year period. In the first nine months of 2018, the Company also incurred an increase of \$0.8 million in non-cash stock compensation expense, compared to the same period of 2017. Partially offsetting these increased costs was a plan implemented by the Company in the first half of 2017 designed to reduce costs associated with the support of ThermoDox® clinical studies and other initiatives in Europe. The majority of the \$0.5 million in cost savings for personnel and support services in Europe were realized in the first half of 2017.

General and administrative (G&A) expenses were \$2.0 million in the third quarter of 2018, compared to \$1.2 million in the same period of 2017. General and administrative expenses were \$7.2 million in the first nine months of 2018, compared to \$4.3 million in the same period of 2017. These increases were primarily attributable to (i) an increase in non-cash stock compensation expense totaling \$0.4 million in the third quarter of 2018 and \$2.0 million in the first nine months of 2018 when compared to the same periods in 2017 and (ii) an increase in professional fees of approximately \$0.2 million in the third quarter of 2018 and \$0.7 million in the first nine months of 2018 primarily related to recruiting fees for several new positions to support the anticipated regulatory and commercialization efforts for ThermoDox®.

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, 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 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 the nine-month period ended September 30, 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.

## Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss its third quarter 2018 financial results at 11:00 a.m. EST on Thursday November 15, 2018. To participate in the call, interested parties may dial 1-877-260-1479 (Toll-Free/North America) or +1-334-323-0522 (International/Toll) and ask for the Celsion Corporation Third Quarter 2018 Earnings Call (Conference Code: 6704591). Listeners are encouraged 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 Thursday, November 15, 2018 and will remain available until Thursday November 29, 2018. The replay can be accessed at 1-888-203-1112 (Toll-Free/USA) or +1-719-457-0820 (International/Toll) using Conference ID: 6704591. 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. EST on Thursday, November 15, 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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
<b>Licensing revenue</b>	\$ 125	\$ 125	\$ 375	\$ 375
<b>Operating expenses:</b>				
Research and development	2,187	3,349	9,522	9,871
General and administrative	1,960	1,174	7,168	4,291
<b>Total operating expenses *</b>	4,147	4,523	16,690	14,162
<b>Loss from operations</b>	(4,022 )	(4,398 )	(16,315 )	(13,787 )
<b>Other income (expense):</b>				
Gain from valuation of common stock warrant liability	4,115	1,246	3,568	670
(Loss) from impairment of in-process research and development	(4,510 )	(2,520 )	(4,510 )	(2,520 )
Interest expense, investment income and other income (expense), net	(239 )	1	(107 )	(84 )
<b>Total other income (expense), net</b>	(634 )	(1,273 )	(1,049 )	(1,934 )
<b>Net loss</b>	(4,656 )	(5,671 )	(17,364 )	(15,721 )
Deemed dividend related to warrant Modification	-	-	-	(346 )
<b>Net loss attributable to common shareholders</b>	\$ (4,656 )	\$ (5,671 )	\$ (17,364 )	\$ (16,067 )
<b>Net loss per common share</b>				
<b>Basic and diluted</b>	\$ (0.26 )	\$ (0.70 )	\$ (1.00 )	\$ (3.04 )
<b>Weighted average shares outstanding</b>				
<b>Basic and diluted</b>	17,801	8,055	17,448	5,172

\* Operating expenses for the three-month and nine-month periods ended September 30, 2018 include an increase of \$0.5 million and \$3.0 million, respectively in non-cash stock option expense compared to the same periods of 2017.

(in thousands)

	September 30,	December 31,
ASSETS	2018	2017
	(unaudited)	
<b>Current assets</b>		
Cash and cash equivalents	\$3,371	\$11,444
Investment securities and interest receivable on investment securities	18,656	12,779
Prepaid expenses and other current assets	225	89
Total current assets	22,252	24,312
<b>Property and equipment</b>	167	176
<b>Other assets</b>		
In-process research and development	15,737	20,246
Goodwill	1,976	1,976
Other intangible assets, net	625	796
Other assets	155	9
Total other assets	18,493	23,027
<b>Total assets</b>	\$49,912	\$47,515
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$5,300	\$5,700
Deferred revenue - current portion	500	500
Total current liabilities	5,800	6,200
Earn-out milestone liability	8,971	12,539
Notes payable – non-current portion	9,320	-
Deferred revenue and other liabilities - noncurrent portion	1,690	2,071
Total liabilities	25,781	20,810
<b>Stockholders' equity</b>		
Common stock	179	173
Additional paid-in capital	294,162	288,409
Accumulated other comprehensive income (loss)	21	(10)
Accumulated deficit	(279,146)	(261,782)
	15,216	26,790
Less: Treasury stock	(85)	(85)
Total stockholders' equity	15,131	26,705
<b>Total liabilities and stockholders' equity</b>	\$49,912	\$47,515



Source: Celsion CORP