Celsion Corporation Reports Second Quarter 2019 Financial Results and Provides Business Update

August 14, 2019

First Pre-Planned Efficacy Analysis of the Phase III OPTIMA Study Planned for Mid-October

Strong Balance Sheet Plus the Non-Dilutive Sale of $4 Million of New Jersey State Net Operating Losses Will Fund Operations Into 2021

NIH Manuscript Provides Support for ThermoDox's Potential in the OPTIMA Study

Company to Hold Conference Call on Thursday, August 15, 2019 at 11:00 a.m. EDT

LAWRENCEVILLE, N.J, Aug. 14, 2019 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the three and six months ended June 30, 2019 and provided an update on its development programs for ThermoDox® and GEN-1. The Company's lead program is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin currently in Phase III development (the OPTIMA Study) for the treatment of hepatocellular carcinoma (HCC), or primary liver cancer. The Company's immunotherapy candidate, GEN-1, is 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. GEN-1 is currently in Phase I/II development (the OVATION 2 Study) for the localized treatment of newly diagnosed Stage III/IV ovarian cancer.

"With a clear focus on shareholder value, Celsion continues to execute its business plan for our ongoing clinical development programs with ThermoDox® and GEN-1. We are exceptionally well positioned on the fundamentals with a strong balance sheet that is expected to fund our clinical programs through transformative milestones over the next 18 months," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "We look forward to the first of two preplanned interim efficacy analyses for the OPTIMA Study expected in October 2019. At the current event rate, the second interim analysis, if needed, is expected to occur in early 2020. This global, pivotal study completed patient enrollment in August 2018 at more than 65 clinical sites in 14 countries, including all the major markets for primary liver cancer."

"The first cohort of patients in the dose-escalation portion of our OVATION 2 Study in newly diagnosed ovarian cancer has been enrolled. We continue to work through the activation of up to 30 clinical sites in the U.S. and Canada by the end of this year. Importantly, enrollment of patients in the Phase I portion of the study is expected to be completed and initial data reported by the end of 2019. This promising clinical development program in immunotherapy has generated impressive results in previous trials," Mr. Tardugno added.

Recent Developments

ThermoDox®

Results of the National Institutes of Health Analysis of ThermoDox® Published in the *Journal of Vascular and Interventional Radiology*. On August 13, 2019, the Company announced that results from an independent analysis of the Company's ThermoDox ® HEAT Study conducted by the National Institutes of Health (NIH) were published in the peer-reviewed publication,*Journal of Vascular and Interventional Radiology*. The analysis was conducted by the intramural research program of the NIH and the NIH Center for Interventional Oncology (CIO), with the full data set from the Company's HEAT Study. The analysis evaluated the full data set to determine if there was a correlation between baseline tumor volume and radiofrequency ablation (RFA) heating time (minutes/tumor volume in milliliters), with or without ThermoDox® treatment, for patients with HCC. The NIH analysis was conducted under the direction of Dr. Bradford Wood, MD, Director, NIH Center for Interventional Oncology and Chief, NIH Clinical Center Interventional Radiology.

The article titled, "*RFA Duration Per Tumor Volume May Correlate With Overall Survival in Solitary Hepatocellular Carcinoma Patients Treated With RFA Plus Lyso-thermosensitive Liposomal Doxorubicin*," discussed the NIH analysis of results from 437 patients in the HEAT Study (all patients with a single lesion representing 62.4% of the study population). The key finding was that increased RFA heating time per tumor volume significantly improved overall survival (OS) in patients with single-lesion HCC who were treated with RFA plus ThermoDox®, compared to patients treated with RFA alone. A one-unit increase in RFA duration per tumor volume was shown to result in about a 20% improvement in OS for patients administered ThermoDox®, compared to RFA alone. The authors conclude that increasing RFA heating time in combination with ThermoDox® significantly improves OS and establishes an improvement of over two years versus the control arm when the heating time per milliliter of tumor is greater than 2.5 minutes. This finding is consistent with the Company's own results, which defined the optimized RFA procedure as a 45-minute treatment for tumors with a diameter of 3 centimeters. Thus, the NIH analysis lends support to the hypothesis underpinning the OPTIMA Study.

Data Lock for First Prespecified Interim Analysis in OPTIMA Phase III Study of ThermoDox® in Primary Liver Cancer. On August 5, 2019, the Company announced the prescribed number of events has been reached for the first prespecified interim analysis of the OPTIMA Phase III Study with ThermoDox® plus radiofrequency ablation (RFA) in patients with HCC. Following preparation of the data, the first interim analysis will be conducted by the Independent Data Monitoring Committee (iDMC). The iDMC meeting is expected to occur by mid-October. This timeline is consistent with the Company's stated expectations and is necessary to provide a full and comprehensive data set that may represent the potential for a successful trial outcome. The iDMC recommendations will be announced as soon as possible after the meeting.

In accordance with the statistical plan, this initial interim analysis has a target of at least 118 events, or 60% of the total number required for the final analysis. At the time of the data cutoff, the Company received reports of 128 events. The hazard ratio for success at 128 events is approximately 0.63, which represents a 37% reduction in the risk of death compared with RFA alone, and is consistent with the 0.65 hazard ratio that was observed in the prospective HEAT Study subgroup, which demonstrated a two-year overall survival advantage and a median time to death of more than seven and a half years.

The OPTIMA Study was fully enrolled in August 2018 with 556 subjects from 65 clinical sites in 14 countries. The design of the OPTIMA Study is based on the Company's HEAT Study, in which a subgroup analysis of 285 subjects with a single lesion of 3-7 cm in size received a single ThermoDox® administration in combination with a 45-minute or longer RFA procedure. Followed prospectively for over 2.5 years, patients treated with ThermoDox® demonstrated a median survival of more than 7.5 years and a survival benefit of more than two years over the control group. These data were published in the October 2017 issue of the peer-reviewed journal *Clinical Cancer Research,* and are available here.

IRB Approval to Begin a Clinical Study of ThermoDox® Plus High Intensity Focused Ultrasound in Breast Cancer Patients at University Medical Center Utrecht in the Netherlands. On June 20, 2019, the Company announced that the University Medical Center Utrecht in the Netherlands received Institutional Review Board (IRB) approval to begin a Phase I study to determine the safety, tolerability and feasibility of ThermoDox® in combination with Magnetic Resonance Guided High Intensity Focused Ultrasound (MR-HIFU) hyperthermia and cyclophosphamide therapy for the local treatment of the primary tumor in metastatic breast cancer (mBC). The secondary objective of this study is to assess radiological objective response of distant metastases and of the primary breast tumor.

This single-site, investigator-sponsored study – image-guided targeted doxorubicin delivery with hyperthermia to optimize loco-regional control in breast cancer; the *i-GO Feasibility Study* – will enroll up to 12 newly diagnosed mBC patients. Study subjects will receive up to six cycles of the following regimen at three-week intervals:

- 60 minutes of MR-HIFU hyperthermia at 40^{o}C to 42^{o}C delivered to the primary tumor;
- 50 mg/m^2 of ThermoDox® as a 30-minute intravenous (IV) infusion during hyperthermia; and
- 600 mg/m^2 of cyclophosphamide as a 15-minute IV infusion after hyperthermia.

This study further reinforces the broad potential of ThermoDox® to treat a range of solid tumors with multiple localized heating sources.

Issuance of New U.S. Patent for ThermoDox®. On April 17, 2019, the Company announced that the United States Patent and Trademark Office granted U.S. Patent No. 10,251,901 B2 – *Thermosensitive Nanoparticle Formulations and Method of Making the Same* – which is directly applicable to the method of treating cancer using a new ThermoDox® formulation. The claim covers a method for preparing (as well as the composition of) a doxorubicin sulfate temperature-sensitive liposome and extends protection for the ThermoDox® patent portfolio to 2033. This new patent broadens the ThermoDox® intellectual property portfolio and provides for lifecycle management well into the future.

Corporate Development

Celsion Participated in Two Investor Conferences. During May 2019, the Company attended the ThinkEquity Conference in New York City and the Deutsche Bank 44th Annual Health Care Conference in Boston. A webcast of Celsion's presentation at the ThinkEquity Conference may be accessed by visiting the "News & Investors" section of Celsion's corporate website. The format of the Deutsche Bank Health Care Conference was comprised of one-on-one and small group meetings with leading institutional investors.

Second Quarter Financial Results

For the quarter ended June 30, 2019, Celsion reported a net loss of $5.9 million ($0.29 per share), compared with $8.2 million ($0.46 per share) in the same period of 2018. Operating expenses were $5.7 million in the second quarter of 2019, which represented a $2.4 million (30%) decrease from $8.1 million in the same period of 2018. During the second quarter of 2019, the Company incurred $0.6 million in non-cash stock option expense, compared with $3.2 million in the comparable prior-year period.

Research and development expenses decreased $1.0 million to $3.6 million in the second quarter of 2019, compared with $4.6 million in the second quarter of 2018. Clinical development costs for the Phase III OPTIMA Study decreased $0.8 million to $1.2 million in the second quarter of 2019, compared with $2.0 million in the second quarter of 2018, due to the completion of enrollment in this 556-patient trial in August 2018. Costs associated with the startup of the OVATION 2 Study were $0.1 million in the second quarter of 2019. Other costs related to clinical supplies and regulatory support for the ThermoDox® and GEN-1 clinical development programs increased by $0.3 million in the second quarter of 2019 compared with the prior-year period. In the second quarter of 2019, non-cash stock compensation expense decreased $2.6 million compared with the same period of 2018.

General and administrative expenses were $2.1 million in the second quarter of 2019, compared with $3.5 million in the same period of 2018. The decrease was primarily attributable to a $1.8 million decrease in non-cash stock compensation expense, offset by a $0.2 million increase in professional fees primarily related to recruiting fees for several new positions to support the anticipated regulatory and commercialization efforts for ThermoDox®.

The Company realized $0.1 million of interest income from its short-term investments during the second quarters of 2019 and 2018. In connection with the Company's venture debt facility with Horizon entered in late June 2018, the Company incurred interest expense of $0.3 million during the second quarter of 2019. This compares with interest expense of $15,000 in the comparable prior-year period.

The Company ended the second quarter of 2019 with $21.8 million in cash, investment securities and interest receivable. With $21.8 million in cash at June 30, 2019 coupled with future sales of the Company's New Jersey NOL's, the Company believes it has sufficient capital resources to fund its operations into the first quarter of 2021.

Six Month Financial Results

For the six months ended June 30, 2019, the Company reported a net loss of $8.3 million ($0.42 per share), compared with $12.7 million ($0.73 per share) in the same period of 2018. Operating expenses were $10.7 million during the first six months of 2019, which represented a $1.8 million (15%) decrease from $12.5 million in the same period of 2018. During the first half of 2019, the Company incurred $1.3 million in non-cash stock option expense, compared with $3.4 million in the comparable 2018 period.

Net cash used for operating activities was $10.7 million in the first six months of 2019, compared with $8.8 million in the same period in 2018. This

was in line with the Company's projected cash utilization for 2019 of approximately $18 million, or an average of approximately $4.5 million per quarter. Cash provided by financing activities was approximately $4.5 million during the first six months of 2019.

Research and development expenses decreased $1.0 million to $6.3 million in the first half of 2019 from $7.3 million in the first half of 2018. Clinical development costs for the Phase III OPTIMA Study decreased $1.2 million to $2.1 million in the first half of 2019, compared with $3.3 million in the first half of 2018, due to the completion of enrollment in this 556-patient trial in August 2018. Costs associated with the startup of the OVATION 2 Study were $0.2 million in the first half of 2019. Other 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 half of 2019 compared with the same prior-year period. In the first half of 2019, non-cash stock compensation expense decreased $2.1 million compared with the same period of 2018.

Other expenses in the first half of 2019 included a non-cash gain of $2.6 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 of $0.5 million for the comparable prior-year period.

The Company realized $0.2 million of interest income during the first half of 2019 and 2018. In connection with the Company's venture debt facility with Horizon entered in late June 2018, the Company incurred interest expense of $0.7 million during the first six months of 2019, compared with interest expense of $15,000 in the comparable prior-year period.

Conference Call

The Company is hosting a conference call to provide a business update and discuss its second quarter 2019 financial results at 11:00 a.m. EDT on Thursday, August 15, 2019. To participate in the call, dial 1-800-367-2403 (Toll-Free/North America) or 1-334-777-6978 (International/Toll) and use conference ID 2816618. The call will also be broadcast live on the internet at www.celsion.com. The call will be archived for replay until August 29, 2019 and can be accessed at 1-719-457-0820 or 1-888-203-1112 using conference ID 2816618. An audio replay will also be available for 90 days at www.celsion.com.

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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Licensing revenue	$ 125	$ 125	$ 250	$ 250
Operating expenses:				
Research and development	3,558	4,594	6,326	7,335

General and administrative	2,137	3,543	4,354	5,208
Total operating expenses	5,695	8,137	10,680	12,543
Loss from operations	(5,570)	(8,012)	(10,430)	(12,293)
Other income (expense):				
(Loss) from valuation of common stock warrant liability	(127)	(277)	2,600	(547)
Interest expense, investment income and other income (expense), net	(208)	58	(442)	132
Total other income (expense), net	(335)	(219)	2,158	(415)
Net loss	$ (5,904)	$ (8,231)	$ (8,272)	$ (12,708)
Net loss per common share				
Basic and diluted	$ (0.29)	$ (0.46)	$ (0.42)	$ (0.73)
Weighted average shares outstanding				
Basic and diluted	20,606	17,743	19,713	17,504

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

ASSETS	***June 30, 2019 (Unaudited)***	***December 31, 2018***
Current assets		
Cash and cash equivalents	*$ 6,013*	*13,354*
Investment securities and interest receivable on investment securities	*15,768*	*14,326*
Prepaid expenses and other current assets	*1,272*	*451*
Total current assets	*23,053*	*28,131*
Property and equipment	*387*	*185*
Other assets		
In-process research and development	*15,736*	*15,736*
Goodwill	*1,976*	*1,976*
Operating lease right-of-use assets, net	*1,610*	*-*
Other intangible assets, net	*455*	*568*
Other assets	*370*	*260*
Total other assets	*20,147*	*18,540*
Total assets	*$ 43,587*	*46,856*
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	*$ 5,782*	*$ 5,607*
Operating lease liability – current portion	*367*	*-*
Deferred revenue - current portion	*500*	*500*
Total current liabilities	*6,649*	*6,107*
Earn-out milestone liability	*5,904*	*8,908*
Operating lease liability – non-current portion	*1,343*	*-*
Notes payable - noncurrent portion	*9,609*	*9,417*
Deferred revenue and other liabilities - noncurrent portion	*1,250*	*1,563*
Total liabilities	*24,755*	*25,995*
Stockholders' equity		
Common stock	*210*	*188*
Additional paid-in capital	*300,550*	*294,393*
Accumulated other comprehensive gain (loss)	*94*	*30*
Accumulated deficit	*(281,937)*	*(273,665)*

	18,917	*20,946*
Less: Treasury stock	*(85)*	*(85)*
Total stockholders' equity	*18,832*	*20,861*
Total liabilities and stockholders' equity	*$ 43,587*	*$ 46,856*

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Source: Celsion CORP