Celsion Corporation Reports Second Quarter 2018 Financial Results and Provides Business Update

August 14, 2018

Strong Balance Sheet With Cash Sufficient to Fund Operations Into the First Half of 2020

Quarterly and Year-to-Date Cash Expenses Consistent With Prior Guidance

Company to Hold Conference Call on Tuesday, August 14, 2018 at 11:00 a.m. EDT

LAWRENCEVILLE, N.J., Aug. 14, 2018 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the quarter and six-month period ended June 30, 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, designed to enable 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, and its 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. We expect to complete enrollment in our 550-patient global, pivotal Phase III OPTIMA Study in primary liver cancer and initiate patient enrollment in our 130-patient Phase I/II randomized OVATION II Study in newly diagnosed patients with ovarian cancer during the third quarter," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "We have a strong balance sheet and are well positioned financially to continue to advance these key programs, with several important announcements for both of our clinical programs expected over the next six to 12 months, including the final progression-free survival data from our OVATION I Phase IB clinical trial of GEN-1 and the first pre-planned interim analysis of the ThermoDox® Phase III OPTIMA Study."

Recent Developments

ThermoDox® Phase I Clinical Study Results Published in The Lancet Oncology. On July 10, 2018, the Company announced that results from a Phase I trial of ThermoDox® were published in the peer-reviewed journal, *The Lancet Oncology*. Conducted by a multi-disciplinary team of biomedical engineers, oncologists, radiologists and anesthetists at the University of Oxford, United Kingdom, the trial evaluated the safety and efficacy of ThermoDox® with focused ultrasound for the treatment of liver cancer.

Referred to as the TARDOX Study, the trial demonstrated that the ThermoDox® plus focused ultrasound technique increased doxorubicin delivery to tumors between two- and ten-fold in the majority of patients in this 10-patient trial. A lysolipid thermally sensitive liposome encapsulating the chemotherapy agent, doxorubicin, ThermoDox® is designed to release targeted levels of doxorubicin into and around liver tumors with heat activation. In this Phase I study, and consistent with the ThermoDox® heat-activated design, the amount of drug passively reaching the tumor was low and estimated to be below therapeutic levels before ultrasound exposure. Following focused ultrasound application with ThermoDox®, chemotherapy concentrations within the liver tumor were between two and ten times higher in seven out of 10 patients, with an average increase of 3.7 times across all patients.

The Phase I trial evaluated patients with inoperable primary or secondary liver tumors and who had previously received chemotherapy. The procedure was carried out under general anesthesia, and patients received a single intravenous dose of 50 mg/m^2 of ThermoDox®. The target tumor was selectively heated to over 39.5^o C using an approved ultrasound-guided focused ultrasound device at the Churchill Hospital in Oxford. In six patients, the temperature at the target tumor was monitored using a temporarily implanted probe, while in the remaining four patients, ultrasonic heating was carried out non-invasively. Side effects were monitored for 30 days after the procedure, and apart from the existing side effects caused by general anesthetic and chemotherapy, no additional side effects were observed.

The TARDOX Study, supported by the National Institute for Health Research (NIHR) Oxford Biomedical Research Centre, was carried out as a multi-disciplinary collaboration between Celsion, the Oxford University Institute of Biomedical Engineering, the Oncology Clinical Trials Office (OCTO) and the Oxford University Hospitals NHS Foundation Trust.

Data Monitoring Committee Unanimously Recommended Continuation of the OPTIMA Study in Primary Liver Cancer Following its Planned Safety and Data Review from 411 Patients. On April 9, 2018, the Company announced that the independent Data Monitoring Committee (DMC) for the Company's 550-patient, pivotal Phase III clinical study of ThermoDox® in combination with radiofrequency ablation (RFA) 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 was intact and that ThermoDox® was 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 compared favorably to the HEAT Study subgroup (285 patients treated with RFA greater than 45 minutes) median PFS of 19.7 months and was 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, which is currently expected in the third quarter of 2018, with results from the first interim efficacy analysis expected in the first half of 2019.

Corporate Development

***Raised $10 Million From A Strategic Loan Facility with Horizon Technology Finance Corporation*. On June 28, 2018, the Company** announced it entered into a $10 million loan agreement with Horizon Technology Finance Corporation which it drew down upon closing. The Company will use the funding provided under the agreement for working capital and advancement of its product pipeline, including ThermoDox® and GEN-1, as well as other strategic initiatives designed to broaden its product pipeline. The funding is in the form of secured indebtedness bearing interest at a calculated LIBOR-based variable rate. Payments under the loan agreement are interest only for the first twenty-four (24) months after loan closing, followed by a 24-month amortization period of principal and interest through the scheduled maturity date.

***Celsion Added to the Russell Microcap® Index.* On June 25, 2018, the Company** was added to the Russell Microcap® Index as part of the Russell indexes annual reconstitution, effective after the U.S. market opens today. Membership in the Russell Microcap® Index, which remains in place for one year, means automatic inclusion in the appropriate growth and value style indexes. FTSE Russell determines membership for its Russell U.S. Indexes primarily by objective, market-capitalization rankings and style attributes.

Financial Results

For the quarter ended June 30, 2018, Celsion reported a net loss attributable to common shareholders of $8.2 million, or a loss of $0.46 per share, compared to $4.9 million, or a loss of $0.79 per share, in the same period of 2017. Operating expenses were $8.1 million in the second quarter of 2018 compared to $4.7 million in the same period of 2017. During the second quarter of 2018, the Company incurred $3.2 million in non-cash stock option expense compared to $0.7 million in the same comparable period of 2017.

For the six-month period ended June 30, 2018, the Company reported a net loss attributable to common shareholders of $12.7 million, or a loss of $0.73 per share, compared to $10.4 million, or a loss of $1.75 per share, in the same six-month period of 2017. Operating expenses were $12.5 million during the first six months of 2018 compared to $9.6 million in the same period of 2017. During the first half of 2018, the Company incurred $3.4 million in non-cash stock option expense compared to $0.8 million in the same comparable six-month period of 2017.

Net cash used for operating activities was $8.8 million in the first six months of 2018, compared to $7.3 million in the same period in 2017. This was in line with our projected cash utilization for 2018 of approximately $16 million, averaging approximately $4 million per quarter. The Company ended the second quarter of 2018 with $26.3 million of total cash, cash equivalents, investment securities and interest receivable, which included the $10 million in gross proceeds from the Company's new venture debt facility completed on June 27, 2018 with Horizon Technology Finance Corporation. The Company believes it has sufficient capital resources to fund its operations into the first half of 2020.

Research and development costs increased $1.6 million, from $3.0 million in the second quarter of 2017 to $4.6 million in the second quarter of 2018. Clinical development costs for the Phase III OPTIMA Study increased to $2.0 million in the second quarter of 2018, compared to $1.5 million in the second quarter of 2017. This $0.5 million increase was attributable to higher patient enrollment in this pivotal Phase III trial during the first half of 2018. Costs associated with the startup of the OVATION II Study were $0.1 million in the second quarter of 2018. 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 second quarter of 2018 when compared to the same prior-year period. In the second quarter of 2018, the Company also incurred an increase of $0.7 million in non-cash stock compensation expense compared to the same period of 2017.

Research and development costs increased $0.8 million, from $6.5 million in the first six months of 2017 to $7.3 million in the first half of 2018. Clinical development costs for the Phase III OPTIMA Study increased to $3.3 million in the first half of 2018, compared to $3.0 million in the first half of 2017. This $0.3 million increase was attributable to higher patient enrollment in the pivotal Phase III trial during 2018. Costs associated with the startup of the OVATION II Study were $0.2 million in the first half of 2018. Other costs related to for clinical supplies and regulatory support for the ThermoDox® and GEN-1 clinical development programs increased by $0.2 million in the first half of 2018 when compared to the same prior-year period. In the first half 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 Company initiated plan 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 expenses were $3.5 million in the second quarter of 2018, compared to $1.6 million in the same period of 2017. General and administrative expenses were $5.2 million in the first six months of 2018, compared to $3.1 million in the same period of 2017. These increases were primarily attributable to (i) an increase in non-cash stock compensation expense totaling $1.8 million in the second quarter and first half of 2018 when compared to the same periods in 2017 and (ii) an increase in professional fees of approximately $0.2 million primarily related to recruiting fees for several new positions to support the anticipated regulatory and commercialization efforts for ThermoDox®.

During the three-months and six-months ended June 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 second quarter 2018 financial results at 11:00 a.m. EDT on Tuesday August 14, 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 Second Quarter 2018 Earnings Call (Conference Code: 1373876). 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.

The call will be archived for replay on Tuesday, August 14, 2018 and will remain available until Tuesday August 28, 2018. The replay can be accessed at 1-888-203-1112 (Toll-Free/USA) or +1-719-457-0820 (International/Toll) using Conference ID: 1373876. 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 on Tuesday, August 14, 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Licensing revenue	$ 125	$ 125	$ 250	$ 250
Operating expenses:				
Research and development	4,594	3,047	7,335	6,522
General and administrative	3,543	1,649	5,208	3,117
Total operating expenses *	8,137	4,696	12,543	9,639
Loss from operations	(8,012)	(4,571)	(12,293)	(9,389)
Other income (expense):				
(Loss) from valuation of common stock warrant liability	(277)	(292)	(547)	(576)
Interest expense, investment income and other income (expense), net	58	(27)	132	(85)
Total other income (expense), net	(219)	(319)	(415)	(661)
Net loss	(8,231)	(4,890)	(12,708)	(10,050)
Deemed dividend related to warrant Modification	–	(346)	–	(346)
Net loss attributable to common shareholders	$ (8,231)	$ (5,236)	$ (12,708)	$ (10,396)
Net loss per common share				
Basic and diluted	$ (0.46)	$ (0.79)	$ (0.73)	$ (1.75)
Weighted average shares outstanding				
Basic and diluted	17,743	6,629	17,504	5,949

* Operating expenses for the three-month and six-month periods ended June 30, 2018 include an increase of $2.5 million and $2.6 million, respectively in non-cash stock option expense compared to the same periods of 2017.

Celsion Corporation

Selected Balance Sheet Information
(in thousands)

	June 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets		
Cash and cash equivalents	$ 12,754	$ 11,444
Investment securities and interest receivable on investment securities	13,499	12,779
Prepaid expenses and other current assets	89	89
Total current assets	26,342	24,312
Property and equipment	193	176
Other assets		
In-process research and development	20,246	20,246
Goodwill	1,976	1,976
Other intangible assets, net	682	796
Other assets	71	9
Total other assets	22,975	23,027
Total assets	$ 49,510	$ 47,515
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 5,735	$ 5,700
Deferred revenue - current portion	500	500
Total current liabilities	6,235	6,200
Earn-out milestone liability	13,086	12,539
Notes payable – non-current portion	9,222	-
Deferred revenue and other liabilities - noncurrent portion	1,819	2,071
Total liabilities	30,362	20,810
Stockholders' equity		
Common stock	177	173
Additional paid-in capital	293,549	288,409
Accumulated other comprehensive loss	(4)	(10)
Accumulated deficit	(274,489)	(261,782)
	19,233	26,790
Less: Treasury stock	(85)	(85)
Total stockholders' equity	19,148	26,705
Total liabilities and stockholders' equity	$ 49,510	$ 47,515

Celsion Investor Contact

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Primary Logo

Source: Celsion CORP