August 15, 2016

Celsion Corporation Reports Second Quarter 2016 Financial Results and Provides Business Update

Significant Progress in Immuno-oncology and Chemotherapy Clinical Research Complimented with a 20% Reduction in Operating Expenses

Company to Hold Conference Call on Monday, August 15, 2016 at 11:00 a.m. EDT

LAWRENCEVILLE, N.J., Aug. 15, 2016 (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, 2016 and provided an update on its development programs for ThermoDox®, the Company's proprietary heat-activated liposomal encapsulation of doxorubicin and GEN-1, an IL-12 DNA-based immunotherapy.

"We are extremely pleased with the momentum that we have built throughout the first half of this year; and especially proud of the meaningful developments in our two lead programs," said Michael H. Tardugno, Celsion's chairman, president and CEO. "The data from our immunotherapy program, particularly the initial data from our OVATION study in first line ovarian cancer, continue to provide important insights into GEN-1's favorable clinical and safety profile and reinforce our confidence in its potential to serve as an effective therapy in a broad range of cancers."

Mr. Tardugno continued, "We have also made great strides to advance our global Phase III OPTIMA Study evaluating ThermoDox® in primary liver cancer, with clinical sites currently enrolling patients in 13 countries worldwide. In addition, data presentations and publications in multiple peer-reviewed forums continue to highlight the potential for a curative approach of ThermoDox® plus optimized RFA. We are pleased to report that the most recent analysis of the HEAT Study data is consistent with a two year survival benefit in the ThermoDox® plus optimized RFA group versus optimized RFA alone."

Recent Developments

Immunotherapy - GEN-1

Announced Positive Data from the First Two Cohorts of the OVATION Study. In July 2016, the Company announced data from the second cohort of patients in its Phase Ib dose escalating clinical trial (the OVATION Study) combining GEN-1 with the standard of care for the treatment of newly-diagnosed patients with advanced ovarian cancer who will undergo neoadjuvant chemotherapy followed by interval debulking surgery. In the first six patients dosed, GEN-1 plus standard chemotherapy produced impressive results, with no dose limiting toxicities and highly promising efficacy signals in this difficult to treat cancer. The efficacy data included encouraging tumor response rates, successful surgical resections of the eligible patients' tumors, impressive pathological responses and dramatic drops in CA-125 protein levels. Enrollment in the third cohort is completed. Celsion expects the 4th, and final, Phase 1 cohort of the OVATION Study to be fully enrolled this year.

Presented Preclinical Data for GEN-1 IL-12 Immunotherapy in Combination with Avastin® and Doxil® at the American Association for Cancer Research (AACR) Annual Meeting 2016. In April 2016, the Company presented compelling preclinical data demonstrating significant synergistic anti-cancer effects when GEN-1 is combined with Avastin® and Doxil®, a current standard of care (SoC) for platinum resistant ovarian cancer patients. The presentation showed that the three drug combination resulted in a statistically significant reduction of tumor burden of greater than 98% compared to control, and a statistically significant 92% reduction in tumor burden compared to Avastin® plus Doxil® alone. These preclinical data will be used by the Company to support a comprehensive IND protocol filing for a Phase I/II clinical trial evaluating the combination in recurrent ovarian cancer later this year.

Established Manufacturing and Commercial Supply Agreement with Hisun for GEN-1. In August 2016, Celsion signed a long term technology transfer, manufacturing and commercial supply agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. The agreement relates to both the clinical and commercial manufacture and supply of GEN-1 for the greater China territory, with the option to expand into other countries in the rest of the world after all necessary regulatory approvals are in effect. With highly cost effective pricing, the agreement will help to support supply for ongoing and planned clinical studies in the United States and potential future studies of GEN-1 in China.

Chemotherapy - ThermoDox®

Announced Final Overall Survival Data from HEAT Study of ThermoDox® in Primary Liver Cancer. On August 15, 2016, the Company announced updated results from its final retrospective analysis of 701-patient HEAT Study. The overall survival (OS) analysis demonstrated that in a large, well bounded, subgroup of patients (n= 285, 41% of the HEAT Study patients), treatment with a combination of ThermoDox® and optimized RFA provided an average 54% risk improvement in OS compared to optimized RFA alone. The Hazard Ratio (HR) at this analysis is 0.65 (95% CI 0.45 - 0.94) with a p-value of 0.02. Median overall survival for the ThermoDox® group has been reached which translates into a two year survival benefit over the optimized RFA only group (projected to be greater than 80 months for the ThermoDox® plus optimized RFA group compared to less than 60 months projection for the optimized RFA only group). In the population of 154 patients with single lesions (70% of the HEAT Study Chinese patient cohort) who received optimized RFA treatment for 45 minutes or more showed a 53% risk improvement in OS (HR = 0.66) when treated with ThermoDox® plus optimized RFA. These data continue to support and further strengthen ThermoDox®'s potential to significantly improve OS compared to an RFA control in patients with lesions that undergo optimized RFA treatment for 45 minutes or more.

Announced a Peer Reviewed Publication in *Hepatic Oncology* Highlighting the Potentially Curative Potential of ThermoDox® in Primary Liver Cancer. On June 21, 2016, the Company announced publication of the article, *"RFA plus lyso-thermosensitive liposomal doxorubicin: In search of the optimal approach to cure intermediate-size hepatocellular carcinoma,"* in the June 10, 2016 issue of *Hepatic Oncology*. The article provided a comprehensive overview of the clinical evaluation conducted to date of ThermoDox® for the treatment of primary liver cancer and detailed learnings from the Company's 701 patient HEAT Study, a computational modeling study, an experimental animal study and the HEAT Study *post hoc* subgroup analysis. All of these studies are consistent with each other and collectively demonstrate ThermoDox's heat-based mechanism of action, that the longer the target tissue is heated, the greater the doxorubicin tissue concentration. Additionally, the article explores the potential for ThermoDox®, when used in combination with Radio Frequency Ablation (RFA) standardized to a minimum dwell time of 45 minutes, to increase the overall survival of patients with primary liver cancer.

Announced Presentation Highlighting Phase III OPTIMA Study at the Asia-Pacific Primary Liver Cancer Expert Meeting. On July 11, 2016, the Company announced that its ongoing Phase III OPTIMA trial evaluating ThermoDox® in primary liver cancer was featured during an oral presentation at the 7th Asia-Pacific Primary Liver Cancer Expert (APPLE) Meeting. The presentation highlighted the potential of ThermoDox® plus standardized RFA to significantly improve overall survival of newly diagnosed patients.

Corporate Developments

Raised $6 Million Through A Registered Direct Offering. In June 2016, the Company completed a $6 million registered direct equity offering of shares of common stock, or pre-funded warrants in lieu thereof, and a concurrent private placement of warrants to purchase common stock with an institutional healthcare investor. If exercised, the short dated (six months) private placement warrants will provide an additional $6 million of operating cash.

Financial Results

For the quarter ended June 30, 2016, Celsion reported a net loss of $4.5 million, or $(0.19) per share, compared to a net loss of $5.7 million, or $(0.27) per share, in the same period of 2015. Operating expenses were $4.9 million in the second quarter of 2016 compared to $5.4 million in the same period of 2015. For the six month period ended June 30, 2016, the Company reported a net loss of $10.2 million, or $(0.43) per share, compared to $12.7 million, or $(0.62) per share, in the same six month period of 2015. Operating expenses were $10.2 million in the first half of 2016 compared to $11.9 million in the same period of 2015. Net cash used in operations was $9.0 million in the first half of 2016 compared to $11.6 million in the same period last year. The Company ended the second quarter of 2016 with $14.5 million of total cash, investments and accrued interest on these investments, which included the proceeds of a $6 million registered direct offering completed during the second quarter.

Research and development costs were $3.3 million in the second quarter of 2016 compared to $3.6 million in the same period last year. Research and development costs were $6.8 million in the first half of 2016 compared to $8.1 million in the same period last year. The decreases in 2016 are primarily the result of lower clinical supply costs for the ThermoDox® and GEN-1 studies partially offset by increased costs associated with the enrollment in the OPTIMA and the OVATION studies. General and administrative expenses were $1.5 million in the second quarter of 2016 compared to $1.8 million in the same period of 2015. General and administrative expenses were $3.4 million in the first half of 2016 compared to $3.8 million in the same period of 2015. These decreases were primarily the result of lower personnel related costs and professional fees.

Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss second quarter 2016 financial results at 11:00 a.m. EDT on Monday, August 15, 2016. To participate in the call, interested parties may dial 1-877-723-9521(Toll-Free/North America) or 1-719-325-4925 (International/Toll) and ask for the Celsion Corporation Second Quarter 2016 Conference Call (Conference Code: 3335946) 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 August 15, 2016 and will remain available until August 29, 2016. The replay can be accessed at 1-888-203-1112 (Toll-Free/North America) or 1-719-457-0820 (International/Toll) using Conference ID: 3335946. An audio replay of the call will also be available on the Company's website, www.celsion.com, for 30 days after 2:00 p.m. EDT Monday, August 15, 2016.

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 and in Phase II development for the treatment of recurrent chest wall breast 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, including TheraPlas™ and TheraSilence™. 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, particularly in small subgroups that are not statistically significant; FDA and regulatory uncertainties and risks; 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 the 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,	
	2016	**2015**	**2016**	**2015**
Licensing revenue	$ 125	$ 125	$ 250	$ 250
Operating expenses:				
Research and development	3,336	3,568	6,777	8,074
General and administrative	1,530	1,802	3,392	3,834
Total operating expenses	4,866	5,370	10,169	11,908
Loss from operations	(4,741)	(5,245)	(9,919)	(11,658)
Other income (expense):				
Gain (loss) from valuation of common stock warrant liability	409	(69)	106	(242)
Loss from valuation of common stock warrant liability	-	(18)	-	(61)
Interest expense, investment income and other income (expense), net	(199)	(343)	(434)	(719)
Total other income (expense), net	210	(430)	(328)	(1,022)
Net loss	(4,531)	(5,675)	(10,247)	(12,680)
Net loss per common share				
Basic and diluted	$ (0.19)	$ (0.27)	$ (0.43)	$ (0.62)

Weighted average shares outstanding				
Basic and diluted	24,124	20,970	23,752	20,477

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

ASSETS	**June 30, 2016**	**December 31, 2015**
Current assets		
Cash and cash equivalents	$ 12,308	$ 9,265
Investment securities and interest receivable on investment securities	2,160	10,827
Prepaid expenses and other current assets	501	189
Total current assets	14,969	20,281
Property and equipment	658	855
Other assets		
In-process research and development	25,802	25,802
Goodwill	1,976	1,976
Deposits	100	100
Other assets	10	14
Total other assets	27,888	27,892
Total assets	$ 43,515	$ 49,028
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 5,328	$ 4,750
Deferred revenue - current portion	500	500
Note payable - current portion	4,579	4,073
Total current liabilities	10,407	9,323
Earn-out milestone liability	13,815	13,921
Notes payable - noncurrent portion	-	2,350
Other liabilities - noncurrent portion	2,781	3,048
Total liabilities	27,003	28,642
Stockholders' equity		
Common stock	258	234
Additional paid-in capital	245,973	239,668
Accumulated other comprehensive loss	-	(4)
Accumulated deficit	(228,755)	(218,130)
	17,476	21,768
Less: Treasury stock	(964)	(1,382)
Total stockholders' equity	16,512	20,386
Total liabilities and stockholders' equity	$ 43,515	$ 49,028

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Source: Celsion Corporation