



May 8, 2014

## **Celsion Corporation Reports First Quarter 2014 Financial Results and Provides Business Update**

### **Company on Track to Launch Phase III OPTIMA Study in Second Quarter Company to Hold Conference Call on Thursday, May 8, 2014 at 11:00 a.m. EDT**

LAWRENCEVILLE, N.J., May 8, 2014 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the first quarter ended March 31, 2014 and provided an update on its development program for ThermoDox®, the Company's proprietary heat-activated liposomal encapsulation of doxorubicin. ThermoDox is being evaluated in a Phase III program for primary liver cancer and a Phase II clinical trial for recurrent chest wall breast cancer.

"Since the beginning of the year, we have been focused on executing our clinical strategy for ThermoDox, and have made significant progress this quarter toward launching a well-designed, global and robust Phase 3 program for ThermoDox in primary liver cancer," said Michael Tardugno, Celsion's President and Chief Executive Officer. "The survival data emerging from our HEAT Study underscore the potential of ThermoDox in combination with an optimized radiofrequency ablation regimen. We worked closely with statisticians, regulators and leading experts in liver cancer to design our Phase III OPTIMA Study, which we believe establishes a clear path to approval. We also continue to work to identify strategic opportunities that provide synergistic and complementary assets supporting additional growth opportunities for our shareholders."

#### ***Financial Results***

For the quarter ended March 31, 2014, Celsion reported a net loss of \$5.4 million compared to a net loss of \$0.7 million in the same period of 2013. The net loss for the quarter ended March 31, 2013 included a non-cash benefit of \$4.3 million from the change in valuation of common stock warrant liability associated with an equity financing in September 2009. The Statement of Operations for the three months ended March 31, 2013 was also impacted by a non-cash deemed dividend from the beneficial conversion feature of \$4.6 million on the preferred stock equity financing announced in February 2013, resulting in a net loss attributable to common shareholders for the first quarter of 2013 of \$5.3 million.

Revenue from licensing collaborations totaled \$125,000 in each of the first quarters of 2014 and 2013. Net cash used in operations was \$4.8 million for the three months ended March 31, 2014 compared to net cash provided by operations of \$1.8 million in the same prior year period due to the \$5 million payment from the Company's Chinese collaborator, Zhejiang Hisun Pharmaceutical Company, received in January 2013. During the first three months of 2014, the Company raised approximately \$13.8 million in new capital, net of issuance costs, from the sale of stock to certain institutional investors. The Company ended the current quarter with \$52.2 million in cash, investments and accrued interest on short-term investments.

Research and development (R&D) expenses decreased by \$0.3 million from \$3.2 million in the first quarter of 2013 to \$2.9 million in the first quarter of 2014. The decrease in R&D expenses was due primarily to lower clinical trial costs from the HEAT Study offset by start-up costs associated with Company's Phase III OPTIMA Study during the first quarter of 2014. General and administrative expenses were \$2.4 million in the first quarter of 2014 compared to \$1.7 million in the first quarter of 2013. This increase is primarily the result of higher insurance premiums and personnel costs (which includes an increase of \$0.2 million in non-cash stock option expense) in the first quarter of 2014 compared to the same period of 2013.

#### **Recent Business Developments**

**Reported FDA Allowance to Launch Pivotal OPTIMA Study.** In February 2014, Celsion announced that the U.S. Food and Drug Administration (FDA), following its customary 30 day review, allowed the Company's planned pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox® in combination with radiofrequency ablation (RFA) in primary liver cancer, also known as hepatocellular carcinoma (HCC). The Phase III OPTIMA Study is expected to enroll 550 patients globally, with up to 100 sites in the United States, Europe, China and Asia Pacific and will evaluate ThermoDox in combination with RFA, which will be standardized to a minimum of 45 minutes across all investigators and sites for treating lesions 3 to 7

centimeters, versus standardized RFA alone. The primary endpoint for the trial is overall survival (OS).<sup>A</sup> The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee (iDMC).

**Strength and Consistency of Updated Survival Data from the HEAT Study Provides Strong Support for Continued Development of ThermoDox in HCC.** In April 2014, Professor Riccardo Lencioni, MD, FSIR, EBIR, Professor and Director of Diagnostic Imaging and Intervention at the Pisa University School of Medicine, presented the latest overall survival data from the HEAT Study at the 5th European Conference on Interventional Oncology. As of March 31, 2014, data from the latest HEAT Study post-hoc analysis suggest that ThermoDox may markedly improve overall survival, compared to RFA control, in patients whose lesions undergo RFA treatment for 45 minutes or more.<sup>Â</sup> These findings apply to patients with single HCC lesions (64.4% of the HEAT Study population) from both size cohorts of the HEAT study (3-5 cm and 5-7 cm) and represent a subgroup of 285 patients (41% of the patients in the HEAT Study).<sup>Â</sup> For this large subgroup, clinical results indicate a 50% improvement in overall survival, a Hazard Ratio of 0.666 (95% CI 0.434 - 1.022), and a p-Value of 0.06.<sup>Â</sup> Median overall survival for this subgroup has not yet been reached. The Company noted that it may choose to end this analysis of overall survival once the median is reached for either or both arms of the study.<sup>Â</sup>

**Submitted Application for Accelerated Trial Approval for the OPTIMA Study in the People's Republic of China.** The Company recently met with the China State Food and Drug Administration (CFDA) to discuss the OPTIMA Phase III trial, including minimum patient enrollment requirements supporting ThermoDox's registration in China. Based on those discussions, the Company has submitted an application for accelerated study approval in China. The Company plans to expand its clinical site footprint in Europe and will meet with the European Medicines Agency (EMA) during 2014 to discuss registrational strategy and trial design.

**Announced Presentation Supporting Development of ThermoDox Plus High Intensity Focused Ultrasound.**<sup>Â</sup> In April, Celsion announced that data supporting the development of ThermoDox plus high intensity focused ultrasound (HIFU) were highlighted in a presentation at the 14th International Symposium on Therapeutic Ultrasound in Las Vegas. Mark Dewhirst, D.V.M., Ph.D., the Gustavo S. Montana Professor of Radiation Oncology and Vice Director for Basic Science in the Duke Cancer Institute, presented data demonstrating the potential of ThermoDox plus HIFU to maximize drug delivery to the targeted tumor site.<sup>Â</sup> Celsion is exploring the potential of ThermoDox in combination with HIFU as a non-invasive treatment for a variety of cancers, including pancreatic cancer, Glioblastoma Multiforme (GBM), metastatic liver cancer, and breast cancer.

### **Quarterly Conference Call**

The Company is hosting a conference call to provide a business update and discuss the first quarter 2014 financial results at 11:00 a.m. EDT Thursday, May 8, 2014. To participate in the call, interested parties may dial 1-888-523-1225 (Toll-Free/North America) or 1-719-325-2329 (International/Toll) and ask for the Celsion Corporation First Quarter 2014 Financial Results Conference Call (Conference Code: 1639390) approximately ten minutes before the call is scheduled to begin. The call will also be broadcast live on the internet at <http://www.celsion.com>.

The call will be archived for replay on Thursday, May 8, 2014 at 2:00 p.m. EDT and will remain available until Thursday, May 22, 2014. The replay can be accessed at 1-888-203-1112 (Toll-Free/North America) or 1-719-457-0820 (International/Toll) using Conference Code: 1639390. An audio replay of the call will also be available on the Company's website, <http://www.celsion.com>, for 30 days after 2:00 p.m. EDT Thursday, May 8, 2014.

### **About ThermoDox®**

ThermoDox® is a proprietary heat-activated liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers.<sup>Â</sup> ThermoDox® is being evaluated in a Phase III clinical trial for primary liver cancer and a Phase II clinical trial for recurrent chest wall breast cancer.<sup>Â</sup> Localized mild hyperthermia (39.5 - 42 degrees Celsius) created by radiofrequency ablation (RFA) releases the entrapped doxorubicin from the liposome.<sup>Â</sup> This delivery technology enables high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.<sup>Â</sup>

### **About Celsion Corporation**

Celsion is dedicated to the development and commercialization of innovative cancer drugs, including tumor-targeting treatments using focused heat energy in combination with heat-activated liposomal drug technology.<sup>Â</sup> Celsion has research, license or commercialization agreements with leading institutions, including the National Institutes of Health, Duke University Medical Center, University of Hong Kong, the University of Pisa, the UCLA Department of Medicine, the Kyungpook National University Hospital, the Beijing Cancer Hospital and the University of Oxford.<sup>Â</sup> For more information on Celsion, visit our website: <http://www.celsion.com>.

*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.<sup>Â</sup> 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 significant expense, time, and risk of failure of conducting clinical trials; HEAT Study data is subject to further verification and review by the HEAT Study Data Management Committee; the need for Celsion to evaluate its future development plans; termination of the Technology Development Contract or collaboration between Celsion and Hisun at any time; possible changes in cost and timing of development and testing, capital structure, financial condition, working capital needs and other financial items; possible acquisitions or licenses of other technologies, assets or businesses or the possible failure to make such acquisitions or licenses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Celsion's periodic reports 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>2014</b>	<b>2013</b>
<b>Licensing revenue</b>	\$ 125	\$ 125
<b>Operating expenses:</b>		
Research and development	2,893	3,203
General and administrative	2,434	1,689
Total operating expenses	<u>5,327</u>	<u>4,892</u>
<b>Loss from operations</b>	<u>(5,202)</u>	<u>(4,767)</u>
<b>Other (expense) income:</b>		
Gain from change in valuation of common stock warrant liability	3	4,280
Interest, dividends and other income (expense), net	<u>(224)</u>	<u>(164)</u>
Total other (expense) income, net	<u>(221)</u>	<u>4,116</u>
<b>Net loss</b>	(5,423)	(651)
Non-cash deemed dividend from beneficial conversion feature on convertible preferred stock	<u>—</u>	<u>(4,601)</u>
<b>Net loss attributable to common shareholders</b>	\$ <u>(5,423)</u>	\$ <u>(5,252)</u>
<b>Net loss per common share attributable to common shareholders</b>		
Basic and Fully Diluted	\$ <u>(0.33)</u>	\$ <u>(0.55)</u>
<b>Weighted average shares outstanding</b>		
Basic and Fully Diluted	<u>16,371</u>	<u>9,555</u>

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

<b>ASSETS</b>	<b>March 31, 2014</b>	<b>December 31,</b>
	<b>(Unaudited)</b>	<b>2013</b>
<b>Current assets</b>		
Cash and cash equivalents	\$ 4,606	\$ 5,719
Short term investments and accrued interest	47,596	37,368
Other current assets	621	675
Total current assets	<u>52,823</u>	<u>43,762</u>
<b>Property and equipment</b>	<u>747</u>	<u>833</u>
<b>Other assets</b>		
Deposits and other assets	1,121	1,055
Patent license fees, net	19	21
Total other assets	<u>1,140</u>	<u>1,076</u>
<b>Total assets</b>	<u>\$ 54,710</u>	<u>\$ 45,671</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 4,308	\$ 4,160
Deferred revenue - current portion	500	500
Note payable - current portion	439	11
Total current liabilities	<u>5,247</u>	<u>4,671</u>
Common stock warrant liability	—	3
Note payable - non-current portion	4,561	5,000
Deferred revenue - noncurrent portion	3,875	4,000
Other liabilities - noncurrent portion	467	473
Total liabilities	<u>14,150</u>	<u>14,147</u>
<b>Stockholders' equity</b>		
Preferred stock	-	-
Common stock	173	137
Additional paid-in capital	217,536	203,139
Accumulated other comprehensive loss	(28)	(44)
Accumulated deficit	(174,744)	(169,287)
Subtotal	<u>42,937</u>	<u>33,945</u>
Less: Treasury stock	(2,377)	(2,421)
Total stockholders' equity	<u>40,560</u>	<u>31,524</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 54,710</u>	<u>\$ 45,671</u>

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