



March 13, 2014

## **Celsion Corporation Reports Year End 2013 Financial Results and Provides Business Update**

### **Overall Survival Data from the HEAT Study Supports Continued Clinical Development of ThermoDox in Primary Liver Cancer**

### **Well Positioned, Financing Ensures a Strong Balance Sheet**

### **Company to Hold Conference Call on Thursday, March 13, 2014 at 11:00 a.m. ET**

LAWRENCEVILLE, N.J., March 13, 2014 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the year ended December 31, 2013, and provided an update on its clinical trials of ThermoDox®, Celsion's proprietary heat-activated liposomal encapsulation of doxorubicin. 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.

The Company is on track to launch its planned pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox in combination with RFA in primary liver cancer, also known as the OPTIMA study, in the first half of 2014. The trial design is based on a comprehensive analysis of data from the 701-patient clinical trial (the HEAT study), which demonstrated that treatment with ThermoDox resulted in a 55 percent improvement in overall survival in a substantial number of patients that received an optimized RFA treatment. In addition, the Company recently met with the China State Food and Drug Administration (SFDA) to discuss the Phase III trial, including minimum patient enrollment requirements supporting ThermoDox's registration in China. Based on those discussions, the Company is submitting an application for accelerated approval of the study in China. The Company plans to expand its clinical site footprint in Europe for the OPTIMA study and meet with the European Medicines Agency (EMA) in the first half of 2014.

"In 2013, we focused on defining our clinical strategy for ThermoDox, a drug technology that has shown remarkable potential in one of the most difficult and prevalent cancers, and positioning the Company to deliver on the ThermoDox value proposition," said Michael H. Tardugno, Celsion's President and Chief Executive Officer. "We enter 2014 well-positioned to execute our clinical, regulatory and business development strategies. With the growing support of the medical and scientific community, the encouragement of key regulatory bodies in the United States and Asia, a strong balance sheet, and impressive survival data we are confident in our clinical development program for ThermoDox in HCC, and are optimistic that we will identify additional pipeline opportunities that provide synergy, complementary assets and improved valuation potential for our shareholders."

### ***Recent Business Developments***

**Reported FDA Allowance to Launch Pivotal OPTIMA Study.** In February 2014, we announced that the U.S. Food and Drug Administration (FDA) has reviewed and has allowed the Company's planned pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin in combination with 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). The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee (iDMC).

**Reported Compelling Updated Data from Phase III HEAT Study.** In January 2014, Celsion reported updated data from its post-hoc data from the Company's HEAT Study. As provided for in the HEAT Study's Special Protocol Assessment (SPA) agreement with the FDA, the Company continues to follow patients for overall survival, the secondary endpoint of the study. Data from the updated HEAT Study analysis suggests that ThermoDox may significantly improve overall survival, compared to control, in patients whose lesions undergo RFA treatment for 45 minutes or more. Specifically, the patient subgroup in the ThermoDox arm whose RFA procedure lasted longer than 45 minutes (285 patients or 63% of single lesion patients) experienced a 55% improvement in overall survival, with a Hazard Ratio of 0.64 (95% CI 0.41 - 1.00) and a P-value = 0.0495. Median overall survival for this subgroup has not yet been reached. Celsion will continue to follow patients in the HEAT Study on a quarterly basis.

**Reported Positive Interim Data Phase II DIGNITY Trial in Breast Cancer.** In February 2014, Celsion reported positive interim data from its ongoing open-label Phase II DIGNITY Trial of ThermoDox in Recurrent Chest Wall Breast Cancer (RCWBC). The trial will enroll 20 patients at 5 clinical sites in the United States and is evaluating ThermoDox in combination with mild hyperthermia. Based on data available to date, a local response rate of 80% has been observed in the 5 evaluable patients with refractory disease, notably 2 complete responses (CR), 2 partial responses (PR) and 1 patient with stable disease (SD).

**Reported Promising Phase 1 Data for ThermoDox in Breast Cancer.** In December 2013, Celsion reported combined clinical data from two Phase I trials, the Company's Phase I DIGNITY Study and the Duke University sponsored Phase I trial of ThermoDox plus hyperthermia in BCRCW. There were 29 patients treated in the two trials (11 patients in the Company's DIGNITY study and 18 patients in the Duke study). Of the 29 patients treated, 23 were eligible for evaluation of efficacy. A local response rate of over 60% was reported in 14 of the 23 evaluable patients with 5 complete responses and 9 partial responses. These data were presented in December at the San Antonio Breast Cancer Conference by the Study's lead principal investigator, Hope Rugo MD, of the UC San Francisco Medical Center.

**Initiated Development for Glioblastoma Brain Tumors with ThermoDox and HIFU.** In January 2014, the Company announced plans to pursue the development of ThermoDox to investigate applications for treating brain cancer tumors, notably Glioblastoma Multiforme or GBM. In addition to jointly submitting multiple grant applications, the company is also pursuing preclinical studies in collaboration with Dr. Costas D. Arvanitis at the Brigham and Women's Hospital and Harvard Medical School. Experiments will study the use of ThermoDox in combination with MR guided High Intensity Focused Ultrasound (HIFU) to treat brain tumors, initially in animal models.

**Strengthened Balance Sheet with Strategic Loan Facility and Registered Direct Offering.** In January 2014, Celsion raised approximately \$15 million in an at-the-market registered direct offering. In November 2013, Celsion entered into a loan agreement with Hercules Technology Growth Capital, Inc. that would permit up to \$20 million in new capital distributable in multiple tranches with agreement from Hercules. Celsion drew the first tranche of \$5 million upon closing of the loan agreement on November 25, 2013.

## Financial Results

For the year ended December 31, 2013, Celsion reported a net loss of \$12.9 million, or \$0.95 per share, compared to a net loss of \$26.6 million, or \$3.44 per share, in 2012. Net cash used in operations was \$9.5 million in 2013 compared to \$22.3 million in the prior year. Operating expenses dropped to \$15.9 million in 2013 compared to \$22.1 million in 2012. In 2013, Celsion recorded an \$8.1 million non-cash gain related to the change in the common stock warrant liability compared to a \$4.1 million non-cash charge in the same period of last year. In 2013, the Company recognized \$0.5 million in licensing revenue related to the technology development collaboration with Zhejiang Hisun Pharmaceutical Company Ltd., compared to zero revenue in 2012.

Research and development costs were \$6.4 million lower in 2013 compared to the prior year, primarily due to the completion of patient enrollment in the HEAT Study in the first half of 2012. General and administrative expenses were relatively constant at \$6.5 million in 2013 compared to prior year levels as a result of the corporate restructuring program implemented in April 2013.

The Company ended 2013 with \$43.8 million of total cash, investments and accrued interest on these investments. Subsequent to year-end, the Company strengthened its balance sheet by raising an additional \$13.8 million in aggregate net proceeds through a common stock equity offering in January 2014.

## Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss year-end 2013 financial results at 11:00 a.m. ET on Thursday, March 13, 2014. To participate in the call, interested parties may dial 1-888-572-7033 (Toll-Free/North America) or 1-719-325-2469 (International/Toll) and ask for the Celsion Corporation 4<sup>th</sup> Quarter 2013 Conference Call (Conference Code: 6632100) to register 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 March 13, 2014 and will remain available until March 27, 2014. The replay can be accessed at 1-888-203-1112 (Toll-Free/North America) or 1-719-457-0820 (International/Toll) using Conference ID: 6632100. 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. ET Thursday, March 13, 2014.

## 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. 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. 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. 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; 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; 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 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 Investor Contact

Jeffrey W. Church  
Sr. Vice President and CFO  
609-482-2455  
[jchurch@celsion.com](mailto:jchurch@celsion.com)

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

	Year ended December 31,	
	2013	2012
<b>Licensing revenue</b>	\$ 500	\$ -
<b>Operating expenses:</b>		
Research and development	9,364	15,770
General and administrative	6,547	6,373
Â Total operating expenses	<u>15,911</u>	<u>22,143</u>
<b>Loss from operations</b>	<u>(15,411)</u>	<u>(22,143)</u>
<b>Other income (expense):</b>		
Gain (loss) from valuation of common stock warrant liability	8,090	(4,118)
Interest, dividends and other income (expense), net	(931)	(307)
Total other income (expense), net	<u>7,160</u>	<u>(4,425)</u>
<b>Net Loss from operations</b>	<u>(8,251)</u>	<u>(26,568)</u>
Â Â Non-cash deemed dividend from Â Â Â Â beneficial conversion feature onÂ Â Â Â Â Â convertible preferred stock offering	<u>(4,601)</u>	<u>-</u>
<b>Net loss attributable to common shareholders</b>	<u>\$ (12,852)</u>	<u>\$ (26,568)</u>
<b>Net loss per common share -     basic and diluted</b>	<u>\$ (0.95)</u>	<u>\$ (3.44)</u>
<b>Weighted average common shares outstanding -     Â Â Â Â Â Â Â Â basic and diluted</b>	<u>13,541</u>	<u>7,731</u>

**Selected Balance Sheet Information**  
(in thousands)

<b>ASSETS</b>	<u>December 31,</u> <u>2013</u>	<u>December 31,</u> <u>2012</u>
<b>Current assets</b>		
Cash and cash equivalents	\$ 5,719	\$ 14,991
Investment securities and interest receivable on		
investment securities	37,368	8,104
Prepaid expenses and other current assets	675	554
Total current assets	<u>43,762</u>	<u>23,649</u>
<b>Property and equipment</b>	<u>833</u>	<u>1,115</u>
<b>Other assets</b>		
Deposits	200	250
Other assets	876	345
Total other assets	<u>1,076</u>	<u>595</u>
<b>Total assets</b>	<u>\$ 45,671</u>	<u>\$ 25,359</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 4,160	\$ 3,595
Deferred revenue - current portion	500	-
Note payable - current portion	11	1,410
Total current liabilities	<u>4,671</u>	<u>5,005</u>
Common stock warrant liability	3	4,284
Notes payable - noncurrent portion	5,000	3,661
Other liabilities - noncurrent portion	4,473	447
Total liabilities	<u>14,147</u>	<u>13,397</u>
<b>Stockholders' equity</b>		
Common stock	137	380
Additional paid-in capital	203,139	165,276
Accumulated other comprehensive loss	(44)	(127)
Accumulated deficit	(169,287)	(150,877)
	<u>33,945</u>	<u>14,652</u>
Less: Treasury stock	(2,421)	(2,690)
Total stockholders' equity	<u>31,524</u>	<u>11,962</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 45,671</u>	<u>\$ 25,359</u>

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