



November 12, 2013

## **Celsion Corporation Reports Third Quarter 2013 Financial Results and Provides Business Update**

### **Strong Balance Sheet Supports Ongoing ThermoDox® Development Program Company to Hold Conference Call on Tuesday, November 12, 2013 at 11:00 a.m. EST**

LAWRENCEVILLE, N.J., Nov. 12, 2013 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the third quarter ended September 30, 2013 and provided an update from its retrospective analysis of the clinical trial results for ThermoDox®, Celsion's proprietary heat-activated liposomal encapsulation of doxorubicin. ThermoDox® is being evaluated in a global, multi-center Phase III clinical trial (the HEAT Study) in patients with non-resectable hepatocellular carcinoma (HCC), also known as primary liver cancer. ThermoDox® is also being evaluated in a Phase II trial for patients with recurrent chest wall breast cancer (the DIGNITY Study).

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

For the quarter ended September 30, 2013, Celsion reported a net loss of \$4.1 million compared to a net loss of \$6.0 million in the same period of 2012. Net loss for the quarter ended September 30, 2013 was favorably impacted by lower operating costs (\$1.4 million) coupled with a lower non-cash charge (\$0.4 million) from the change in valuation of the common stock warrant liability associated with registered direct equity offerings in September 2009 and June 2013. For the nine month period ended September 30, 2013, Celsion reported a net loss of \$4.3 million compared to a net loss of \$18.3 million in the same period of 2012. Net loss for the nine months ended September 30, 2013 was favorably impacted by lower operating costs (\$4.4 million) coupled with the non-cash benefit of \$8.1 million from the valuation of common stock warrant liability associated with equity financings in September 2009 and June 2013. The Statement of Operations 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 of \$8.9 million for the nine months ended September 30, 2013.

Revenue from licensing collaborations totaled \$125,000 in the third quarter of 2013 and \$375,000 in the nine month period ended September 30, 2013. Net cash used in operations was \$6.4 million for the nine months ended September 30, 2013 compared with \$16.2 million used to fund operations in the same period last year due to lower operating costs in the current year combined with the \$5 million payment from the Company's Chinese collaborator, Zhejiang Hisun Pharmaceutical Company received in January 2013. During the first nine months of 2013, the Company raised approximately \$30 million in new capital, net of issuance costs, from the sale of stock to certain institutional investors, the sale of common stock under a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co., and the exercise of common stock warrants and options. The Company ended the current quarter with \$45.5 million in cash, investments and accrued interest on short-term investments.

Research and development expenses decreased by \$1.2 million (36%), from \$3.5 million in the third quarter of 2012 to \$2.3 million in the third quarter of 2013. Research and development expenses decreased by \$4.8 million (39%), from \$12.3 million in the nine month period ended September 30, 2012 to \$7.5 million in the same period of 2013. These decreases were primarily due to reduced clinical development costs associated with the Phase III HEAT Study and activities related to the development of commercial manufacturing capabilities for ThermoDox®. General and administrative expenses of \$1,389,539 in the third quarter of 2013 decreased \$30,719 when compared to the same period of 2012 due to the impact of the Company's restructuring program announced in April 2013. General and administrative expenses for the nine months ended September 30, 2013 were \$5.0 million, a \$442,000 increase over the comparable period in 2012 due primarily to one-time severance charges associated with the Company's restructuring program announced in April 2013.

#### **Recent Business Developments**

In October 2013, the Company announced that the latest overall survival data from its post-hoc analysis of results from the Phase III HEAT Study supports continued clinical development through a prospective pivotal Phase III Study. Celsion expects to submit its proposed pivotal Phase III clinical protocol for FDA review in the fourth quarter of 2013 and anticipates initiating a multicenter global trial in the first half of 2014. The data from the HEAT Study post-hoc analysis suggests that ThermoDox® may markedly improve overall survival, when compared to the control group, in patients if their tumors

undergo optimal RFA treatment.Â This post-hoc analysis followed the announcement on January 31, 2013, that ThermoDox® in combination with radiofrequency ablation (RFA) did not meet the Study's primary endpoint, progression-free survival (PFS).Â The Company continues to follow patients in the Study to the secondary endpoint, overall survival (OS).Â Data from three OS sweeps have been conducted since the top line PFS data was announced in January 2013, with each showing progressive improvement in statistical significance. Emerging data from the HEAT Study post-hoc analysis has been presented at three scientific and medical conferences in 2013 by key HEAT Study investigators and leading liver cancer experts. The presentations and data are available on the Company's website at [www.celsion.com](http://www.celsion.com) and include:

- | World Conference on Interventional Oncology in May 2013
- | European Conference on Interventional Oncology in June 2013
- | International Liver Cancer Association Annual Conference in September 2013

These post-hoc findings apply to all single HCC lesions 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).Â Updated OS data from this subgroup of patients is summarized below:

- | In the patient subgroup treated in the ThermoDox® arm whose RFA procedure lasted longer than 45 minutes (285 patients or 63% of single lesion patients) clinical results indicate an improvement in overall survival with a Hazard Ratio of 0.63 (95% CI 0.393 — 1.011) and a P-value = 0.056. The median in this subgroup has not been reached.
- | In contrast, the patient subgroup treated with ThermoDox® whose RFA procedure lasted less than 45 minutes in duration (167 patients or 37% of single lesion patients) demonstrated a Hazard Ratio of 1.14 (95% CI 0.737 — 1.776) and a P-value = 0.547. The median in this subgroup has not been reached.
- | The Hazard Ratios reported above, while more than sufficient to support additional clinical development, should be viewed with caution since they are not statistically significant and the HEAT Study has not reached its median for overall survival analysis. Celsion continues to follow all patients in the HEAT Study to the secondary endpoint, overall survival, and will update the subgroup analysis based on RFA heating duration.

The Company also reports the completion of computer modeling with supplementary preclinical animal studies supporting the relationship between heating duration and clinical outcomes.

In July 2013, the Company reaffirmed its continued strategic partnership in China with Zhejiang Hisun Pharmaceutical Company (Hisun), with the announcement of the signing of a Memorandum of Understanding for the future development of ThermoDox® and other liposomal formulations.

"As the Overall Survival data in the HEAT Study matures, the trend we have seen in the subgroup of patients who received an optimal RFA treatment continues to demonstrate a significant improvement in survival rates over the control arm of RFA only.Â With the support from our medical advisors and liver cancer experts we have concluded that the post hoc analysis provides substantial support for the continued development of ThermoDox® for this very serious cancer. Â Assuming agreement from the FDA, we expect to initiate a prospective pivotal study in the first half of 2014," said Michael Tardugno, Celsion's President and Chief Executive Officer.Â "As we announced earlier, we have fully implemented our corporate restructuring program to adjust our spending and headcount to levels necessary to maintain the necessary competencies important to the execution of our current business strategy.Â We ended the quarter with a strong balance sheet and the recently announced reverse stock split provides the Company with the flexibility to evaluate opportunities to broaden our product pipeline through acquisition of complementary products and technologies."

### **Quarterly Conference Call**

The Company is hosting a conference call to provide a business update and discuss the third quarter 2013 financial results at 11:00 a.m. EST Tuesday, November 12, 2013. To participate in the call, interested parties may dial 1-800-723-6498 (Toll-Free/North America) or 1-785-830-7989 (International/Toll) and ask for the Celsion Corporation Third Quarter 2013 Financial Results Conference Call (Conference Code: 9720806) 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 Tuesday, November 12, 2013 at 2:00 p.m. EST and will remain available until Tuesday, November 26, 2013. The replay can be accessed at 1-888-203-1112 (Toll-Free/North America) or 1-719-457-0820 (International/Toll) using Conference Code: 9720806. 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. EST Tuesday, November 12, 2013.

### **About ThermoDox® and the Phase III HEAT Study**

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.Â ThermoDox® is being evaluated in a Phase III clinical trial for primary liver cancer (the HEAT study), a Phase II clinical trial for colorectal liver metastasis and a Phase II clinical trial for

recurrent chest wall breast cancer. Localized mild hyperthermia (39.5 - 42 degrees Celsius) created by radiofrequency ablation (RFA) releases the entrapped doxorubicin from the liposome. This delivery technology enables high concentrations of doxorubicin to be deposited preferentially in a targeted tumor. On January 31, 2013, Celsion announced that ThermoDox® in combination with RFA did not meet the primary endpoint of the HEAT study in patients with hepatocellular carcinoma, also known as primary liver cancer. Celsion is conducting additional analyses of the data from the HEAT study to assess the future strategic value of ThermoDox®.

## 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 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.*

## Investor Contact

Jeffrey W. Church  
Senior Vice President and  
Chief Financial Officer  
609-482-2455  
[jchurch@celsion.com](mailto:jchurch@celsion.com)

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

	Three Months		Nine Months	
	Ended September 30,		Ended September 30,	
	2013	2012	2013	2012
<b>Licensing revenue</b>	\$ 125	\$ —	\$ 375	\$ —
<b>Operating expenses:</b>				
Research and development	2,269	3,539	7,495	12,345
General and administrative	1,390	1,420	5,029	4,586
Total operating expenses	<u>3,659</u>	<u>4,959</u>	<u>12,524</u>	<u>16,931</u>
<b>Loss from operations</b>	<u>(3,534)</u>	<u>(4,959)</u>	<u>(12,149)</u>	<u>(16,931)</u>
<b>Other (expense) income:</b>				
(Loss) gain from change in valuation of common stock warrant liability	(518)	(881)	8,142	(1,251)
Interest, dividends and other income (expense), net	<u>(19)</u>	<u>(177)</u>	<u>(295)</u>	<u>(127)</u>
Total other (expense) income, net	<u>(537)</u>	<u>(1,058)</u>	<u>7,847</u>	<u>(1,378)</u>
<b>Net loss</b>	(4,071)	(6,017)	(4,302)	(18,309)

Non-cash deemed dividend from beneficial				
conversion feature on convertible preferred			(4,601)	
stock				
<b>Net loss attributable to common</b>				
<b>shareholders</b>	\$	<u>(4,071)</u>	\$	<u>(6,017)</u>
			\$	<u>(8,903)</u>
				<u>(18,309)</u>
<b>Net loss per common share attributable</b>				
<b>to common shareholders</b>				
Basic and Fully Diluted	\$	<u>(0.30)</u>	\$	<u>(0.80)</u>
			\$	<u>(0.76)</u>
				<u>(2.47)</u>
<b>Weighted average shares outstanding</b>				
Basic and Fully Diluted		<u>13,602</u>		<u>7,476</u>
				<u>11,756</u>
				<u>7,425</u>

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

	September 30, 2013 (Unaudited)	December 31, 2012
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 13,170	\$ 14,991
Short term investments and accrued interest	32,290	8,104
Other current assets	638	554
Total current assets	<u>46,098</u>	<u>23,649</u>
<b>Property and equipment</b>	<u>947</u>	<u>1,115</u>
<b>Other assets</b>		
Deposits and other assets	364	567
Patent license fees, net	23	28
Total other assets	<u>387</u>	<u>595</u>
<b>Total assets</b>	<u>\$ 47,432</u>	<u>\$ 25,359</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 3,643	\$ 3,595
Deferred revenue — current portion	500	—
Note payable - current portion	1,945	1,410
Total current liabilities	<u>6,088</u>	<u>5,005</u>
Common stock warrant liability	5,253	4,284
Note payable — non-current portion	2,347	3,661
Deferred revenue — noncurrent portion	4,125	—
Other liabilities — noncurrent portion	478	447
Total liabilities	<u>18,291</u>	<u>13,397</u>
<b>Stockholders' equity</b>		
Preferred stock	—	—
Common stock	137	84
Additional paid-in capital	197,083	170,958
Accumulated other comprehensive loss	(306)	(127)
Accumulated deficit	(165,303)	(156,263)
Subtotal	<u>31,611</u>	<u>14,652</u>
Less: Treasury stock	<u>(2,470)</u>	<u>(2,690)</u>
Total stockholders' equity	<u>29,141</u>	<u>11,962</u>

**Total liabilities and stockholders' equity**      \$ 47,432      \$ 25,359

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SOURCE Celsion Corporation

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