



August 14, 2012

## **Celsion Corporation Reports Second Quarter 2012 Financial Results and Business Update**

### **Company to Hold Conference Call on Tuesday, August 14, 2012 at 11:00 a.m. ET**

LAWRENCEVILLE, NJ -- (Marketwire) -- 08/14/12 -- Celsion Corporation (NASDAQ: CLSN), a leading oncology drug development company, today announced financial results for the second quarter ended June 30, 2012 and provided a business update including development progress with ThermoDox®, Celsion's proprietary heat-activated liposomal encapsulation of doxorubicin for the treatment of hepatocellular carcinoma (HCC), commonly referred to as primary liver cancer. ThermoDox® is currently being evaluated under a Special Protocol Assessment with the U.S. Food and Drug Administration (FDA) in a global, multi-center, randomized, pivotal Phase III trial (the HEAT Study) in patients with non-resectable primary liver cancer. The HEAT Study has been designated as a Priority Trial for liver cancer by the National Institutes of Health, has received Fast Track Designation from the FDA and has received Orphan Drug Designation in both the U.S. and Europe. ThermoDox® is also being evaluated in two Phase II trials for patients with recurrent chest wall breast cancer and colorectal liver metastases.

"Celsion has had a productive, if not pivotal, quarter in its development program for ThermoDox®, an investigational drug with the potential to provide a first line therapy for patients with HCC, the largest unmet need in oncology. Having successfully completed patient enrollment in the HEAT Study, secured a commercial supply agreement for ThermoDox® in China, entered into a \$10 million loan agreement which strengthens our balance sheet well beyond data, and advanced several important collaborations with leading industry and academic players, we are well positioned for success," said Michael H. Tardugno, Celsion's President and Chief Executive Officer. "Our continued progress underscores the momentum and enthusiasm behind our ThermoDox® program, and its advancement toward the key clinical, regulatory and commercial milestones ahead. Among the most important of these near-term milestones, we look forward to top line results from the pivotal HEAT Study."

A total of 380 events of progression are required to reach the planned final analysis of the HEAT Study, which are projected to occur in late 2012. Top line results will be announced following review by the study's independent Data Monitoring Committee.

Mr. Tardugno added, "Beyond the HEAT Study, we are very encouraged by the progress being made with ThermoDox® in multiple indications using a variety of heat-based modalities in collaboration with some of the top names in science and healthcare, including Royal Philips Electronics, Oxford University and the University of Washington. These collaborations, along with our own clinical programs, we believe will bear out ThermoDox®'s significant clinical potential as it progresses through the commercialization process."

#### *Recent Business Developments*

In August, the Company and Royal Philips Electronics (Philips) announced FDA clearance to commence a Phase II Study of ThermoDox® and Philip's Sonalleve MR-Guided HIFU technology for the palliation of painful metastases to the bone caused by lung, prostate or breast cancers.

In June, the Company announced:

- ┆ A \$10 million loan facility with Oxford Finance LLC and Horizon Technology Finance Corporation. Under the terms of the loan agreement, Celsion received \$5 million upon closing, with the remaining \$5 million available following positive data from the HEAT Study. The funds will further ensure a strong balance sheet following the announcement of the HEAT Study results, and adds to the Company's ability to conduct pre-commercialization activities and preparation activities related to a New Drug Application (NDA) for ThermoDox®.
- ┆ A collaboration with the University of Oxford to begin a clinical study of ThermoDox® in combination with ultrasound-guided High Intensity Focused Ultrasound (HIFU) to treat metastatic liver cancer.

In May, the Company announced:

- ┆ The HEAT Study reached its global enrollment objective of 700 patients.
- ┆ The signing of a long-term commercial supply agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. for the China territory. The agreement provides for Hisun funding of costs necessary to complete the technology transfer of the Company's proprietary manufacturing process and the production of registration batches for the Chinese territory.
- ┆ A collaboration with the Focused Ultrasound Foundation for preclinical studies designed to explore the use of ThermoDox® in combination with MR-guided HIFU for the treatment of pancreatic cancer. The studies are being conducted at the University of Washington School of Medicine by Joo Ha Hwang, M.D., Ph.D., Director, Endoscopic Research, Associate Professor of Medicine and Adjunct Professor of Bioengineering and Radiology.

In April, the Company announced:

- ┆ The HEAT Study achieved its 200 patient enrollment target in the People's Republic of China (PRC), a key milestone for the Company's global regulatory strategy as it allows for regulatory filing in China -- a market which accounts for over 50% of the 750,000 annual incidences of liver cancer.
- ┆ The HEAT Study's Independent Data Monitoring Committee (DMC) completed a safety review of 652 patients and unanimously recommended that the study continue according to the study protocol.

### *Financial Results*

For the quarter ended June 30, 2012, Celsion reported a net loss of \$6.1 million, or \$0.18 per share, compared to a net loss of \$6.9 million, or \$0.42 per share, in the same period of 2011. For the six months ended June 30, 2012, Celsion reported a net loss of \$12.3 million, or \$0.37 per share, compared to a net loss of \$10.7 million, or \$0.72 per share, in the same period of 2011. For the first six months of 2012, net cash used in operations was \$10.9 million. The Company reported \$24.0 million in cash and investments as of June 30, 2012. In June 2012, the Company entered into a \$10 million loan facility with Oxford Finance LLC and Horizon Technology Finance Corporation whereby it received \$5 million upon closing.

In the second quarter of 2012, the Company recorded a \$447,000 non-cash charge related to the change in the common stock warrant liability compared to a \$586,000 non-cash charge in the same period of last year. In the first six months of 2012, Celsion recorded a \$370,000 non-cash charge related to the change in the common stock warrant liability compared to a non-cash charge of \$418,000 in the same period last year. In the first half of 2011, the Company recognized \$2 million in licensing revenue as a result of its Development, Product Supply and Commercialization Agreement for ThermoDox® with Yakult Honsha Co.

Research and development costs decreased by approximately \$0.9 million to \$4.1 million in the second quarter of 2012 compared to \$5.0 million in the same period of 2011. Research and development costs decreased by approximately \$0.5 million to \$8.8 million in the first six months of 2012 compared to \$9.3 million in the same period of 2011. The decreased costs in each of these periods were primarily due to lower investigator grants and related monitoring activities associated with the HEAT Study partially offset by increased activities related to the development of commercial manufacturing capabilities for ThermoDox®, including the production of registration batches. General and administrative expenses increased by approximately \$0.3 million to \$1.6 million in the second quarter of 2012, from \$1.3 million for the same period in 2011. General and administrative expenses increased by approximately \$0.7 million to \$3.2 million in the first six months of 2012, from \$2.5 million for the same period in 2011. This increase in each of these periods is largely the result of an increase in professional fees and personnel costs to support the Company's growth.

### *Quarterly Conference Call*

The Company is hosting a conference call to provide a business update and discuss the second quarter 2012 results at 11:00 a.m. Eastern Time Tuesday, August 14, 2012. To participate in the call, interested parties may dial 1-888-504-7965 (Toll-Free/North America) or 1-719-325-2493 (International/Toll) and ask for the Celsion Corporation Second Quarter 2012 Earnings Conference Call 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 August 14, 2012 at 2:00 p.m. ET and will remain available until August 28, 2012. The replay can be accessed at 1-877-870-5176 (Toll-Free/North America) or 1-858-384-5517 (International/Toll) using Conference ID: 8709649. 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 Tuesday, August 14, 2012.

### *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. In the HEAT Study, ThermoDox® is administered intravenously in combination with Radio Frequency Ablation (RFA). Localized mild hyperthermia (39.5 - 42 degrees Celsius) created by the RFA releases the entrapped doxorubicin from the liposome. This delivery technology enables high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

For primary liver cancer, ThermoDox® is being evaluated in a global, multi-center, randomized, pivotal Phase III HEAT Study at 79 clinical sites under an FDA Special Protocol Assessment. The study is designed to evaluate the efficacy of ThermoDox® in combination with RFA when compared to patients who receive RFA alone as the control. The primary endpoint for the study is progression-free survival with a secondary confirmatory endpoint of overall survival. Additional information on the Company's ThermoDox® clinical studies may be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

#### *About Celsion Corporation*

Celsion is a leading oncology company 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 and the Beijing Cancer Hospital. 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; FDA and regulatory risks; the need to raise funds for planned drug development; the Company's history of losses and its expectation of continuing to incur such losses; possible acquisitions of other technologies, assets or businesses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Company's periodic reports filed with the Securities and Exchange Commission.

#### Celsion Corporation

#### Condensed Statements of Operations

(in thousands except per share amounts)

(unaudited)

	Three Months		Six Months	
	Ended June 30,		Ended June 30,	
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	2012	2011	2012	2011
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Licensing revenue	\$ -	\$ -	\$ -	\$ 2,000
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Operating expenses:

Research and development	4,112	4,964	8,805	9,313
General and administrative	1,596	1,282	3,166	2,497
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Total operating expenses	5,708	6,246	11,971	11,810
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Loss from operations	(5,708)	(6,246)	(11,971)	(9,810)
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Other (expense) income:

Loss from valuation of common stock warrant liability	(447)	(586)	(370)	(418)
Interest, dividends and other income (expense), net	51	(112)	50	(480)
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Total other expense, net	(396)	(698)	(320)	(898)
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Net Loss	\$ (6,104)	\$ (6,944)	\$ (12,291)	\$ (10,708)
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Net loss per common share - basic

and diluted	\$ (0.18)	\$ (0.42)	\$ (0.37)	\$ (0.72)
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Weighted average common shares

outstanding - basic and diluted	33,236	16,366	33,211	14,914
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Celsion Corporation

Selected Balance Sheet Information

(in thousands)

	June 30,	December 31,
	2012	2011
ASSETS	(unaudited)	
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Current assets		
Cash and cash equivalents	\$ 11,708	\$ 20,146
Short term investments	12,288	10,401
Other current assets	939	961
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Total current assets	24,935	31,508
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Property and equipment	1,049	783
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Other assets		
Deposits and other assets	520	323
Patent license fees, net	32	35
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Total other assets	552	358
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Total assets	\$ 26,536	\$ 32,649
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# LIABILITIES AND STOCKHOLDERS' EQUITY

## Current liabilities

Accounts payable and accrued liabilities	\$ 6,196	\$ 6,042
Notes payable - current portion	494	110

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Total current liabilities	6,690	6,152
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Common stock warrant liability	536	166
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Notes payable - noncurrent portion & other liabilities	4,734	137
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Total liabilities	11,960	6,455
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## Stockholders' equity

Common stock	339	339
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Additional paid-in capital	153,868	153,237
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Accumulated other comprehensive loss	(316)	(276)
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Accumulated deficit	(136,598)	(124,222)
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Subtotal	17,293	29,078
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Less: Treasury stock	(2,717)	(2,884)
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Total stockholders' equity	14,576	26,194
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Total liabilities and stockholders' equity	\$ 26,536	\$ 32,649
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Source: Celsion Corporation

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