

Celsion Reports First Quarter 2012 Financial Results

Company to Hold Conference Call on Tuesday, May 15th at 11:00 a.m. ET

LAWRENCEVILLE, NJ -- (Marketwire) -- 05/15/12 -- Celsion Corporation (NASDAQ: CLSN), a leading oncology drug development company, today announced financial results for the first quarter ended March 31, 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.

"With the HEAT Study moving toward final data readout later this year, we have spent this first quarter focused on the realization of global enrollment objectives and preparing for a successful clinical and regulatory process to follow," said Michael Tardugno, Celsion's President and Chief Executive Officer. "Beyond the HEAT Study, we are strategically expanding our pipeline development efforts into additional areas of significant unmet need in which ThermoDox® may offer benefit. Since the beginning of 2012, we enrolled the first patient in our Phase II ABLATE Study of ThermoDox® in colorectal liver metastases, announced our support, in collaboration with the Focused Ultrasound Foundation, for preclinical studies evaluating ThermoDox® as an adjuvant to HIFU in pancreatic cancer and, together with Philips Heathcare, submitted an IND/IDE application for a Phase II study of ThermoDox® and HIFU in prostate metastases to the bone."

Recent Business Developments

- In May, Celsion announced 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.
- In May, following extensive evaluation of high intensity focused ultrasound (HIFU) in bone cancer patients, Celsion announced the joint resubmission with Philips Healthcare of a combined IND/IDE proposal for a Phase II Study in prostate metastases to the bone, and the Company's long term intent to pursue this important combination therapy through multiple programs.
- In May, the Company and the Focused Ultrasound Foundation announced their support 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, Celsion announced that 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. Concurrently, Celsion announced that 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 protocol.
- In February, Celsion announced that the first patient was enrolled in a randomized Phase II study of ThermoDox® in combination with radiofrequency ablation (RFA) for the treatment of colorectal liver metastases (CRLM).

Financial Results

For the quarter ended March 31, 2012, Celsion reported a net loss of \$6.2 million, or \$0.19 per share, compared to a net loss of \$3.7 million, or \$0.28 per share, in the same period of 2011. In the first quarter 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. For the quarter ended March 31, 2012, net cash used in operations was \$5.7 million.

Research and development costs increased by approximately \$0.4 million to \$4.7 million in the first quarter of 2012 compared to \$4.3 million in the same period of 2011. These increased costs were primarily due to three ongoing clinical studies and activities related to the development of commercial manufacturing capabilities for ThermoDox®. General and administrative expenses increased by approximately \$0.4 million to \$1.6 million, from \$1.2 million for the same period in 2011. This increase is largely the result of an increase in professional fees and personnel costs to support the company's growth.

The Company ended the quarter with \$24.6 million in cash and investments.

Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss the first quarter 2012 results at 11:00 a.m. Eastern Time Tuesday, May 15, 2012. To participate in the call, interested parties may dial 1-877-741-4241 (Toll-Free/North America) or 1-719-325-4934 (International/Toll) and ask for the Celsion Corporation First 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 May 15, 2012 at 2:00 p.m. ET and will remain available until May 22, 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: 3066549. An audio replay of the call will also be available on the Company's website, <u>http://www.celsion.com</u>, for 30 days after 2:00 p.m. ET Tuesday, May 15, 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 <u>www.clinicaltrials.gov</u>.

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: <u>http://www.celsion.com</u>.

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.

Condensed Statements of Operations

(in thousands except per share amounts)

(unaudited)

	Three Months Ended			
		March 31,		
			2011	
Licensing revenue	\$		2,000	
Operating expenses:				
Research and development		4,693	4,349	
General and administrative		1,570	1,215	
Total operating expenses		6,263	5,564	
Loss from operations		(6,263)	(3,564)	
Other income (expense):				
Gain from valuation of common stock warrant				
liability		78	168	
Interest, dividends and other income				
(expense), net			(368)	
Total other income (expense), net		77	(200)	

Net Loss	\$ (6,186)	\$ (3,764)
Net loss per common share - basic and diluted	\$ (0.19)	\$ (0.28)
Weighted average common shares outstanding -		
basic and diluted	33,197	13,453

Celsion Corporation

Selected Balance Sheet Information

(in thousands)

	Mar	March 31,		December 31,	
		2012		2011	
ASSETS	(una	udited)			
Current assets					
Cash and cash equivalents	\$	9,122	\$	20,146	
Short term investments		15,472		10,401	
Other current assets		1,179		961	
Total current assets		25,773		31,508	
Property and equipment		908		783	

Other assets

Deposits and other assets	323	323
Patent license fees, net	33	35
Total other assets	356	358
Total assets	\$ 27,037	\$ 32,649
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 6,320	\$ 6,042
Note payable - current portion	78	110
Total current liabilities	6,398	6,152
Common stock warrant liability	89	166
Other liabilities - noncurrent portion	188	137
Total liabilities	6,675	6,455
Stockholders' equity		
Common stock	339	339
Additional paid-in capital	153,532	153,237
Accumulated other comprehensive loss	(278)	(276)
Accumulated deficit	(130,473)	(124,222)
Subtotal	23,120	29,078
Less: Treasury stock	(2,758)	(2,884)

Total stockholders' equity		20,362	26,194
Total liabilities and stockholders' equity	\$ =====	27,037	\$ 32,649

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Source: Celsion Corporation

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