



March 15, 2012

## **Celsion Reports Year End 2011 Financial Results and Provides Business Update**

### **Company to Hold Conference Call Today, March 15, 2012 at 11:00 a.m. ET**

LAWRENCEVILLE, NJ -- (MARKET WIRE) -- 03/15/12 -- Celsion Corporation (NASDAQ: CLSN), a leading oncology drug development company, today announced financial results for the year ended December 31, 2011 and addressed the progress of its clinical trials of 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. ThermoDox® is also being evaluated in two Phase II trials for patients with recurrent chest wall breast cancer and colorectal liver metastases. 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.

"The interim efficacy analysis of the HEAT Study by the Company's independent Data Monitoring Committee in the fourth quarter of 2011 reinforces our confidence in ThermoDox® as a potential first line treatment for HCC," said Michael Tardugno, Celsion's President and Chief Executive Officer. "As always, our focus is on reaching our clinical, regulatory and financial objectives while maintaining fiscal discipline, with the goal of building value for our shareholders. The Company's financings in 2011 provide us with the necessary operating horizon to complete enrollment of the HEAT Study, obtain top line-data and evaluate our strategic and financial options for bringing ThermoDox® to market."

#### *Recent Business Developments*

- | In November 2011, Celsion announced that the independent Data Monitoring Committee (DMC) for the HEAT Study completed a pre-planned interim analysis for safety, efficacy and futility and unanimously recommended that the study continue to its final analysis as planned. The DMC evaluated data from 613 patients in its review, which was conducted following realization of 219 progression-free survival (PFS) events within the study population. A total of 380 progression events are required to reach the planned final analysis of the study which the Company reconfirmed was projected to occur in late 2012. Concurrent with its review, the DMC weighed the potential of an additional interim efficacy analysis to accelerate data readout, a potential which the Company discussed with the FDA. In March 2012, the Company reported that, based on feedback from the FDA, its special protocol assessment would remain unchanged, and that the HEAT Study would continue to its planned final analysis.
- | In December 2011, Celsion completed its consultative review process with the European Medicines Agency (EMA) for the HEAT Study and received written scientific advice from the EMA confirming that the Company's HEAT Study is acceptable as a basis for submission of a marketing authorization application. Other important feedback received from this review process were:
  - | Future results demonstrating a convincing magnitude of improvement in PFS along with a favorable benefit-risk ratio would be sufficient as a primary basis for registration of ThermoDox® in Europe, and
  - | The EMA also supported the Company's manufacturing strategy and technology transfer protocols which will allow the Company to establish multiple manufacturing sites to support commercialization of ThermoDox® outside the United States.
- | In January 2012, the Company announced the enrollment of the first patient in its randomized Phase II study of ThermoDox® in combination with radiofrequency ablation for the treatment of colorectal liver metastases.

#### *Financial Results*

For the year ended December 31, 2011, Celsion reported a net loss of \$23.2 million, or \$1.11 per share, compared to a net loss of \$18.8 million, or \$1.52 per share, in 2010. For the year ended December 31, 2011, net cash used in operations was \$22.7 million. In 2011, Celsion recorded a \$82,000 non-cash benefit related to the change in the common stock warrant liability compared to \$574,000 non-cash benefit in the same period of last year.

Research and development costs were \$5.2 million higher in 2011 compared to the prior year, primarily due to expected increased costs for investigator grants, monitoring costs and milestone payments associated with higher patient enrollment levels for the Company's Phase III HEAT Study. Also contributing to this increase were activities associated with development expenses related to commercial manufacturing for ThermoDox®. General and administrative expenses were \$232,000 higher in 2011 compared to the prior year as a result of increased professional services and personnel costs to support the Company's growth.

The Company ended the year with \$30.5 million of cash and investments. During the year ended December 31, 2011, the Company strengthened its balance sheet by raising approximately \$58 million in aggregate gross proceeds through the completion of the following equity financing transactions:

- | In January 2011, a registered offering of \$5.1 million of convertible preferred stock and common stock warrants;
- | During the first quarter of 2011, three draws totaling \$3.4 million under our committed equity financing facility with Small Cap Biotech Value Ltd.;
- | In June 2011, a private placement offering of \$8.6 million in common stock and warrants;
- | In July 2011, a registered direct offering of \$6.6 million in common stock and warrants;
- | In July 2011, sales of an aggregate \$18.4 million of the Company's securities, of which \$13.0 million was from institutional investors in a registered direct offering and an additional \$5.4 million from other investors in a private placement;
- | In December 2011, a private placement of \$15 million in common stock and warrants; and
- | Approximately \$0.4 million from common stock warrant exercises during 2011.

#### *Quarterly Conference Call*

The Company is hosting a conference call to provide a business update and discuss the year end 2011 results at 11:00 a.m. Eastern Time Thursday, March 15, 2012. To participate in the call, interested parties may dial 1-888-359-3622 (Toll-Free/North America) or 1-719-325-2487 (International/Toll) and use Conference ID: 3234714 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 15, 2012 at 2:00 p.m. ET and will remain available until March 29, 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: 3234714. 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 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 [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 such as the National Institutes of Health, Duke University Medical Center, University of Hong Kong, the University of Pisa, the UCLA Department of Medicine, 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)

	Year ended	
	December 31,	
	2011	2010
	-----	-----
Licensing revenue	\$ 2,000	\$ -
	-----	-----
Operating expenses:		
Research and development	19,864	14,714
General and administrative	5,155	4,923
	-----	-----
Total operating expenses	25,019	19,637
	-----	-----
Loss from operations	(23,019)	(19,637)
	-----	-----
Other income (expense):		
Gain from valuation of common stock warrant		
liability	82	574

Interest, dividends and other income (expense), net	(286)	245
	-----	-----
Total other income (expense), net	(204)	819
	-----	-----
Net Loss	\$ (23,223)	\$ (18,818)
	=====	=====
Net loss per common share - basic and diluted	\$ (1.11)	\$ (1.52)
	=====	=====
Weighted average common shares outstanding - basic and diluted	20,918	12,375
	=====	=====

Celsion Corporation

Selected Balance Sheet Information

(in thousands)

ASSETS	December 31,	December 31,
	2011	2010
	-----	-----
Current assets		
Cash and cash equivalents	\$ 20,146	\$ 1,139
Short term investments	10,401	396
Prepaid expenses and other current assets	961	492
	-----	-----
Total current assets	31,508	2,027
	-----	-----

Property and equipment	783	378
	-----	-----
Other assets		
Deposits and other assets	323	77
Patent license fees, net	35	43
	-----	-----
Total other assets	358	120
	-----	-----
Total assets	\$ 32,649	\$ 2,525
	=====	=====

#### LIABILITIES AND STOCKHOLDERS' EQUITY

##### Current liabilities

Accounts payable and accrued liabilities	\$ 6,042	\$ 6,673
Note payable - current portion	110	123
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Total current liabilities	6,152	6,796

Common stock warrant liability	166	248
Other liabilities - noncurrent portion	137	57
	-----	-----
Total liabilities	6,455	7,101
	-----	-----

##### Stockholders' equity (deficit)

Common stock	339	141
Additional paid-in capital	153,237	99,317

Accumulated other comprehensive loss	(276)	(18)
Accumulated deficit	(124,222)	(100,939)
	-----	-----
Subtotal	29,078	(1,499)
Less: Treasury stock	(2,884)	(3,077)
	-----	-----
Total stockholders' equity (deficit)	26,194	(4,576)
	-----	-----
Total liabilities and stockholders' equity	\$ 32,649	\$ 2,525
	=====	=====

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Source: Celsion Corporation

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