

Celsion Reports Third Quarter 2010 Financial Results and Provides Business Update

Company to Hold Quarterly Conference Call Today at 3:00 p.m. ET

COLUMBIA, Md., Nov. 15, 2010 /PRNewswire-FirstCall/ -- Celsion Corporation (Nasdaq: CLSN), a biotechnology drug development company, today announced financial results for the third quarter and nine months ended September 30, 2010 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. Â ThermoDox® is currently being evaluated under a Special Protocol Assessment with the FDA in a 600 patient pivotal Phase III trial (the HEAT study) in patients with non-resectable primary liver cancer and in a Phase I/II trial for patients with recurrent chest wall breast cancer. Â The HEAT study has been designated as a Priority Trial for liver cancer by the National Institutes of Health.

"We are approaching 80% completion of patient enrollment into our Phase III primary liver cancer HEAT study of ThermoDox®. Â Together with our Special Protocol Assessment for the HEAT study, Celsion received Fast Track Designation from the FDA providing us with the opportunity to file our New Drug Application on a rolling basis. Â We now have an efficient clinical and regulatory pathway for commercialization of ThermoDox®," said Michael Tardugno, Celsion's President and Chief Executive Officer. Â Â

Financial Results

For the third quarter ended September 30, 2010, Celsion reported a net loss from operations of \$5.2 million compared to a net loss from operations of \$4.7 million for the same period of 2009. Â For the first nine months of 2010, net cash used in operations was \$10.6 million. Â Celsion reported a net loss from operations of \$14.2 million for the first nine months of 2010 compared to a net loss from operations of \$13.2 million for the same period of 2009. Â In the third quarter of 2010, Celsion recorded as other income a \$0.5 million non-cash benefit related to a mark-to-market change in the common stock warrant liability related to the stock offering completed in September 2009. Â In the first nine months of 2010, Celsion recorded a \$0.7 million non-cash benefit related to the change in the common stock warrant liability. Â In the same period of 2009, the Company recorded a non-cash indemnity reserve benefit of \$1.1 million related to the sale of its medical device business in 2007, which reduced general and administrative expenses in the nine month prior year period.

The Company ended the third quarter with \$3.2 million of cash and investments. Â In September 2010, the Company raised \$1.4 million from two draws under its June 2010 Committed Equity Financing Facility. Â The proceeds will be used to accelerate commercial manufacturing activities for ThermoDox®. Â On November 1, 2010, the Company was awarded a \$244,000 grant under the Qualifying Therapeutic Discovery Project (QTDP) program under The Patient Protection and Affordable Care Act of 2010. This maximum grant amount for a single program was awarded to Celsion for its Thermodox® clinical development program.

Recent Business Highlights

- Patient enrollment for the Phase III HEAT study to date is approaching 80% completion. Â Efforts to stimulate patient enrollment continue with full enrollment expected in the first quarter of 2011;
- The Committee for Orphan Medicinal Products of the European Medicines Agency (EMA) issued a positive opinion on the Company's application for Orphan Drug Designation for ThermoDox® for the treatment of HCC;
- The Independent Data Monitoring Committee unanimously recommended continuation of the Phase III HEAT study to treat Primary Liver Cancer after review of 401 patients enrolled in the trial;
- Fast Track designation received for ThermoDox® development program to Treat Primary Liver Cancer from the FDA:
- NCI Consensus published in Journal of Clinical Oncology recommended the Phase III HEAT study as a Priority Clinical Trial for HCC: Â
- Positive FDA guidance relating to 505(b)(2) regulatory submission received for the Company's New Drug Application for ThermoDox® to Treat Primary Liver Cancer;
- ThermoDox® clinical data presented at the 2010 Breast Cancer Symposium;
- SBIR grant received to expand technology platform; and
- Celsion presented at two Healthcare Conferences in New York City.

The Company is holding a conference call to provide a business update and discuss the third quarter 2010 results at 3:00 p.m. Eastern Time on November 15, 2010. To participate in the call, interested parties may dial 1-888-218-8172 (Toll free U.S./Canada) or 1-913-312-9313 (Toll/International) and use Conference ID: 4428936 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 Monday, November 15, 2010 at 6:00 p.m. Eastern Time and will remain available until Monday, November 22, 2010. The replay can be accessed at 1-877-870-5176 (Toll free U.S./Canada) or 1-858-384-5517 (Toll/International) using Replay Pin: 4428936. An audio replay of the call will also be available on the Company's website, http://www.celsion.com, for 30 days after 5:00 p.m. Eastern Time on November 15, 2010.

About ThermoDox®

ThermoDox® in combination with hyperthermia has the potential to provide local tumor control and improve quality of life. 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 including breast cancer. Localized mild hyperthermia (40-42 degrees Celsius) 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 600 patient global Phase III study at 76 clinical sites under an FDA Special Protocol Assessment. The study is designed to evaluate the efficacy of ThermoDox® in combination with Radio Frequency Ablation (RFA) when compared to patients who receive RFA alone as the control. The primary endpoint for the study is progression-free survival and enrollment is anticipated to be completed in the first quarter of 2011. For recurrent chest wall breast cancer, ThermoDox® is being evaluated in a pivotal Phase I/II open-label, dose-escalating trial that is designed to measure durable local complete response at the tumor site. Celsion expects to fully enroll the Phase I portion of the study in the fourth quarter of 2010. Additional information on the Company's ThermoDox® clinical studies may be found at http://www.clinicaltrials.gov.

About Celsion

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 drug delivery systems. 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, Cleveland Clinic, and the North Shore Long Island Jewish Health System.

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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 by others; 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 (Unaudited) (in thousands except for per share amounts)

		Three Months Ended September 30,				Nine Months Ended September 30,			
		2010		2009	_	2010		2009	
Operating expenses:									
Research and development	\$ÂÂÂÂ	3,951	\$	3,503	\$	10,666	\$	10,676	
General and administrative		1,220		1,224	_	3,544		2514	

Total operating expenses		5,171	4,727	14,210	13,190
Loss from operations		(5,171)	(4,727)	(14,210)	(13,190)
Other income (expense):					
Change in fair value of common stock warrants		453	-	712	-
Other income (expense), net		1	 10	5	265
Total other income (expense), net		454	10	217	265
Net Loss	\$ Â Â Â Â	(4,717)	\$ (4,717)	\$ (13,493)	\$ (12,925)
Net loss per common share — basic and diluted Weighted average common shares outstanding — basic and diluted	\$ÂÂÂÂ	(0.38)	\$ (0.47)	\$ (1.10)	\$ 10,166

Celsion Corporation Balance Sheets (in thousands except for per share amounts)

ASSETS	September 30, 2010 (Unaudited)		December 31, 2009
Current assets			
Cash and cash equivalents	\$ 1,824	\$	6,924
Short term investments	1,380		5,695
Refundable income taxes	-		806
Prepaid expenses and other receivables	460		695
Total current assets	3,664		14,120
Property and equipment	417		537
Other assets			
Deposits	77		97
Other assets	45		51
Total other assets	122		148
Total assets	\$ 4,203	\$	14,805
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities			
Accounts payable	\$ 2,742	\$	2,191
Other accrued liabilities	1,986		1,452
Note payable - current portion	119		108
Total current liabilities	4,847	-	3,751
Common stock warrant liability	110		822
Other liabilities — noncurrent	89		197
Total liabilities	5,046		4,770
Stockholders' equity			
Common stock, \$0.01 par value (75,000 shares authorized; 13,508 and 12,895 shares issued and 12,748 and 12,135 shares outstanding at September 30, 2010 and December 31, 2009,			
respectively)	135		129
Additional paid-in capital	97,755		95,035

(44)		68
(95,612)		(82,120)
 2,234		13,112
(3,077)		(3,077)
 (843)		10,035
\$ 4,203	\$	14,805
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