



Celsion Reports Third Quarter 2009 Financial Results and Business Update

Enrollment Continues to Accelerate in ThermoDox(R) Phase III Trial for Primary Liver Cancer with the Addition of New Clinical Sites in the Far East

COLUMBIA, Md., Nov 10, 2009 (BUSINESS WIRE) -- Celsion Corporation (NASDAQ: CLSN), a leading oncology drug development company, announced financial results for the third quarter ended September 30, 2009 and highlighted the progress made in the commercialization of ThermoDox(R), Celsion's heat activated liposomal encapsulation of doxorubicin for the treatment of hepatocellular carcinoma (HCC), the most common form of primary liver cancer, and recurrent chest wall breast cancer.

"We achieved key milestones during the quarter against our corporate objectives to advance the development and commercialization of ThermoDox to create inherent value for our shareholders," stated Michael H. Tardugno, Celsion's Chief Executive Officer. "We have expanded the HEAT trial (ThermoDox global Phase III HCC study) to the Asia Pacific region where the incidence of primary liver cancer is endemic. We recently received regulatory approval to treat liver cancer patients in China, Malaysia and the Philippines and the first patient has already been treated in Japan. To date, we have enrolled 196 patients (one third of the trial) and are on target to complete enrollment in the spring of 2010 and have sixty clinical sites activated by the end 2009. Radio frequency ablation (RFA) is emerging globally as a first-line treatment for early stage non-resectable HCC. Our HEAT trial has been designed to evaluate the efficacy of ThermoDox in combination with RFA to improve patient outcomes for this cost effective, minimally invasive procedure."

Financial Results

For the third quarter ended September 30, 2009, Celsion reported a net loss of \$4.7 million, or \$0.47 per diluted share, compared to a net loss of \$4.3 million, or \$0.43 per diluted share for the third quarter of 2008. For the nine months ended September 30, 2009, Celsion reported a net loss of \$12.9 million, or \$1.27 per diluted share, compared to a net loss of \$10.9 million, or \$1.07 per diluted share in 2008. The Company ended the quarter with a total of \$16.3 million in cash and short-term investments. In September 2009, the Company completed a registered direct offering with a select group of institutional investors that raised \$7.1 million of gross proceeds.

Recent Company Highlights

- Enrolled 196 patients (one third of target) in the ThermoDox primary liver cancer trial
- Received regulatory approvals in China, Malaysia and the Philippines to expand the ThermoDox primary liver cancer trial to these countries
- Treated the first patient in Japan with ThermoDox in the primary liver cancer trial
- Data Safety Monitoring Board recommended the continuation of the ThermoDox trial for primary liver cancer
- Partnered with the American Liver Foundation to Promote Awareness of primary liver cancer and the ThermoDox primary liver cancer trial
- Raised \$7.1 million from a registered direct offering
- Received positive FDA guidance to CMC submission which cleared way for the validation and scale-up of the ThermoDox manufacturing process
- Patient enrollment in Phase II DIGNITY trial for the treatment of recurrent chest wall breast cancer continues to progress; Company launched an innovative, integrated media outreach campaign.
- Completed feasibility testing with Phillips Medical for the combination of ThermoDox with Phillips MR-guided high intensity focused ultrasound device; IND submissions targeted for 2010 for the treatment of pancreatic cancer and cancer metastasis in bone.

The Company is holding a conference call to provide a business update and discuss the third quarter 2009 results at 11:00 a.m. Eastern Time on Tuesday, November 10, 2009. To participate in the call, interested parties may dial 1.877.852.6580 (Toll-free) or 1.719.325.4751 (Toll/International) and use Conference ID: 2474093 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 November 10, 2009 at 2:00 P.M. ET and will remain available until November 17, 2009. The replay can be accessed at 1.888.203.1112 (Toll-free) or 1.719.457.0820 (Toll/International) using Conference ID: 2474093. The call will also be available on the Company's website, www.celsion.com, for 30 days after 2:00 P.M. on Tuesday, November 10, 2009.

About the Phase III HEAT Clinical Trial

Celsion's global Phase III HEAT trial is evaluating the safety and efficacy of ThermoDox in combination with radiofrequency ablation (RFA) when compared to RFA alone. The trial is being conducted under a Special Protocol Assessment and the FDA has agreed to progression free survival as the primary and accelerated endpoint with overall survival being a secondary endpoint. The trial will enroll up to six hundred patients at clinical sites in Japan, China, Malaysia, Thailand, Philippines, Hong Kong, Korea, Taiwan, Italy, the United States and Canada

Additional information can be found at: <http://www.clinicaltrials.gov/>

About Primary Liver Cancer

Primary liver cancer is a type of cancer that begins in the cells of the liver and is not typically detected early, often resulting in a poor patient prognosis. Globally, primary liver cancer is one of the most deadly forms of cancer and ranks as the fifth most common solid tumor cancer. The incidence of primary liver cancer is approximately 20,000 cases per year in the United States and is rapidly growing worldwide at approximately 660,000 cases per year, due to the high prevalence of Hepatitis B and C in developing countries. The standard first line treatment for liver cancer is surgical resection of the tumor, but 80% to 90% of patients are ineligible for surgery. Radio frequency ablation (RFA) has increasingly become the standard of care for non-resectable liver tumors, but the treatment becomes less effective for larger tumors. There are few non-surgical therapeutic treatment options available as radiation therapy and chemotherapy are largely ineffective in the treatment of primary liver cancer.

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.

ThermoDox has demonstrated evidence of efficacy in a Phase I study for primary liver cancer and the FDA has granted Orphan Drug designation for this indication. 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.

ThermoDox(R) is a registered trademark of Celsion Corporation

About Celsion

Celsion is dedicated to the development and commercialization of innovative oncology drugs including tumor-targeting treatments using focused heat energy in combination with heat-activated drug delivery systems. Celsion has licensed ThermoDox(R) to Yakult-Honsha for the Japanese market and has a partnership agreement with Phillips Medical to jointly develop its heat activated liposomal technology in combination with high intensity focused ultrasound to treat difficult cancers. 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.

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.

(Unaudited)				
(in thousands except for per share amounts)				
	Three Months		Nine Months	
	Ended September 30,		Ended September 30,	
	2009	2008	2009	2008
Operating expenses:				
Research and development	\$ 3,503	\$ 3,840	\$ 10,676	\$ 8,422
General and administrative	1,224	510	2,514	1,586
Total operating expenses	<u>4,727</u>	<u>4,350</u>	<u>13,190</u>	<u>10,008</u>
Loss from operations	(4,727)	(4,350)	(13,190)	(10,008)
Other income (expense), net	10	10	265	(844)
Net loss before income taxes	(4,717)	(4,340)	(12,925)	(10,852)
Income taxes	-	-	-	-
Net Loss	<u>\$ (4,717)</u>	<u>\$ (4,340)</u>	<u>\$ (12,925)</u>	<u>\$ (10,852)</u>
Basic and diluted net loss per common share	<u>\$ (0.47)</u>	<u>\$ (0.43)</u>	<u>\$ (1.27)</u>	<u>\$ (1.07)</u>
Basic and diluted weighted average shares outstanding	<u>10,118</u>	<u>10,149</u>	<u>10,166</u>	<u>10,146</u>

Celsion Corporation
Balance Sheets

	September 30,	
	2009 (Unaudited)	December 31, 2008
ASSETS		
Current assets		
Cash and cash equivalents	\$ 12,098	\$ 3,456
Short term investments available for sale	4,204	4,061
Due from Boston Scientific Corporation	-	15,000
Prepaid expenses and other receivables	440	306
Total current assets	<u>16,742</u>	<u>22,823</u>
Property and equipment	<u>205</u>	<u>223</u>
Other assets		
Note receivable	-	221
Deposits	744	363
Other assets	52	58
Total other assets	<u>796</u>	<u>642</u>
Total assets	<u>\$ 17,743</u>	<u>\$ 23,688</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable - trade	\$ 2,840	\$ 1,187
Indemnity reserve	-	1,053
Other accrued liabilities	1,293	1,459
Note payable - current portion	-	235
Total current liabilities	<u>4,132</u>	<u>3,934</u>
Warrant liability	1,554	-
Other liabilities - noncurrent	19	28
Total liabilities	<u>5,705</u>	<u>3,962</u>
Stockholders' equity		
Common stock - \$0.01 par value (75,000,000 and 250,000,000 shares authorized; 12,874,241 and		

10,816,088 shares issued: 12,113,967 and 10,156,350 shares outstanding at September 30, 2009 and December 31, 2008, respectively)	129	108
Additional paid-in capital	94,776	89,183
Accumulated deficit	(79,790)	(66,924)
Subtotal	<u>15,115</u>	<u>22,367</u>
Less: Treasury stock - at cost	(3,077)	(2,641)
Total stockholders' equity	<u>12,038</u>	<u>19,726</u>
Total liabilities and stockholders' equity	\$ <u><u>17,743</u></u>	\$ <u><u>23,688</u></u>

SOURCE: Celsion Corporation

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