

Celsion Reports Second Quarter 2009 Financial Results and Business Update

Patient Enrollment Accelerates in ThermoDox(R) Global Phase III Primary Liver Cancer Study 25% of Patient Enrollment Target Achieved

COLUMBIA, Md., Aug 05, 2009 (BUSINESS WIRE) -- Celsion Corporation (NASDAQ:CLSN), a leading oncology drug development company, today announced financial results for the second quarter ended June 30, 2009.

"In the second quarter of 2009 we made excellent progress towards the completion of enrollment in the ThermoDox(R) global Phase III clinical trial for primary liver cancer," commented Michael H. Tardugno, Celsion's President and Chief Executive Officer. "The rate of enrollment is consistent with our projections. We now have enrolled 151 patients, or 25% of that required to complete the study. We were pleased to recently have announced the expansion of the study to Japan under the direction of our exclusive Japanese license partner, Yakult. This will accelerate our time to approval in Japan while also providing non-diluting financing from Yakult which is in addition to an \$18 million milestone payment upon Japanese approval. Under our agreement, Yakult funds the cost of patients enrolled in Japan. Our pending China CTA remains under evaluation. We continue to be optimistic that we will receive approval for our trial in the near term. In addition, we are expanding the clinical study to the Philippines, Malaysia and Thailand and expect to have 55-60 clinical sites enrolling patients by year end. Assuming additional time is required to enroll the added minimum Japanese patient cohort, enrollment could be completed in the second quarter of 2010."

"Also in the second quarter of 2009, we enrolled our first patients in the Phase I/II recurrent chest wall (RCW) breast cancer clinical trial and we announced that ThermoDox(R) was the subject of three presentations at the Society for Thermal Medicine Annual Meeting, further increasing the drug's exposure within the physician and scientific communities."

Financial Results

For the second quarter ended June 30, 2009, Celsion reported a net loss of \$4.6 million, or \$0.45 per diluted share, compared to a net loss of \$2.4 million, or \$0.24 per diluted share for the second quarter of 2008. For the six months ended June 30, 2009, Celsion reported a net loss of \$8.2 million, or \$0.81 per diluted share, compared to a net loss of \$6.5 million, or \$0.64 per diluted share in 2008. The Company ended the quarter with a total of \$14.9 million in cash and short-term investments.

Recent Company Highlights

- Enrolled 151 patients, or 25% of target in the global Phase III ThermoDox(R) primary liver cancer trial.
- Expanded the global Phase III primary liver cancer study for ThermoDox(R) to Japan. Yakult, the exclusive licensor of ThermoDox(R) in Japan, will be initiating clinical trial sites and enrolling patients.
- Enrolled the first patients in the DIGNITY trial, a Phase I/II open-label registrational study to evaluate ThermoDox(R) for the treatment of RCW breast cancer.
- Received \$15 million from Boston Scientific for the previously reported sale of the Prolieve(R) Assets. This payment was the final payment to Celsion for a total of \$60 million.
- Reported that promising Phase I clinical results evaluating ThermoDox(R) for the treatment of RCW breast cancer were presented by Duke University investigators at the 2009 Annual Meeting of the Society for Thermal Medicine. The results showed that ThermoDox(R) demonstrated positive clinical activity in all of the evaluable patients.

The Company is holding a conference call to provide a business update and discuss the second quarter 2009 results at 11:00 a.m. Eastern Time on Wednesday, August 5, 2009. To participate in the call, interested parties may dial 1-800-289-0462 (Toll-free) or 1-913-312-1415 (Toll/International) and use Conference ID: 5488524 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 August 5, 2009 at 2:00 P.M. ET and will remain available until August 12, 2009. The replay can be accessed at 1-888-203-1112 (Toll-free) or 1-719-457-0820 (Toll/International) using Conference ID: #

5488524. 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. on Wednesday, August 5, 2009.

About ThermoDox(R)

ThermoDox(R) in combination with hyperthermia has the potential to provide local tumor control and improve quality of life. ThermoDox(R) 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 (39.5-42 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(R) is being evaluated in a 600 patient global Phase III study under an FDA Special Protocol Assessment. The study is designed to evaluate the efficacy of ThermoDox(R) 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. For recurrent chest wall breast cancer, ThermoDox(R) 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 enroll approximately 100 patients across the United States. Additional information on these ThermoDox(R) clinical studies may be found at http://www.clinicaltrials.gov

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.

Celsion Corporation Condensed Statements of Operations (Unaudited) (in thousands except for per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Operating expenses:				
Research and development	\$ 4,230 \$	5 1,615	\$ 7,172 \$	\$ 4,582
General and administrative	602	581	1,291	1,077
Total operating expenses	4,832	2,196	8,463	5,659
Loss from operations	(4,832)	(2,196)	(8,463)	(5,659)
Other income (expense), net	241	(234)	255	(853)
Net loss before income taxes	(4,591)	(2,430)	(8,208)	(6,512)
Income taxes	-	-	-	-
Net Loss	\$ <u>(4,591)</u> \$	§ (2,430) \$	\$ <u>(8,208)</u> \$	6,512)
Basic and diluted net loss per common share	\$ (0.45)	6 (0.24)	\$ <u>(0.81)</u> \$	6 (0.64)
Basic and diluted weighted average shares outstanding	10,196	10,146	10,194	10,145

Celsion Corporation

Balance Sheets (in thousands except for per share amounts)

ASSETS		June 30, 2009 Jnaudited)	December 31, 2008
Current assets	<u>(</u>	madancaj	
Cash and cash equivalents	\$	12,115\$	3,456
Short term investments available for sale	Ŧ	2,830	4,061
Due from Boston Scientific Corporation		-	15,000
Prepaid expenses and other receivables		148	306
Total current assets		15,093	22,823
Property and equipment		227	223
Other assets			
Note receivable		-	221
Deposits		751	363
Other assets		162	58
Total other assets	_	913	642
Total assets	\$	16,233\$	23,688
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities			
Accounts payable - trade	\$	3,139\$	1,187
Indemnity reserve		-	1,053
Other accrued liabilities		1,435	1,459
Note payable - current portion	_	-	235
Total current liabilities		4,574	3,934
Other liabilities - noncurrent		22	28
Total liabilities		4,596	3,962
Stockholders' equity			
Common stock - \$0.01 par value (75,000,000 and 250,000,000 shares authorized;			
10,856,088 and 10,816,088 shares issued: 10,095,814 and 10,156,350 shares outstanding a	at	400	400
June 30, 2009 and December 31, 2008, respectively)		109	108
Additional paid-in capital		89,737	89,183
Accumulated deficit		(75,132)	(66,924)
Subtotal		14,714	22,367
Less: Treasury stock - at cost	_	(3,077)	(2,641)
Total stockholders' equity	_	11,637	19,726
Total liabilities and stockholders' equity	\$	16,233\$	23,688

SOURCE: Celsion Corporation

Investors: Celsion Corporation Sean Moran, 410-290-5390 Senior Vice President and Chief Financial Officer <u>smoran@celsion.com</u> or The Trout Group Marcy Nanus, 646-378-2927

Copyright Business Wire 2009