

Celsion Reports First Quarter 2011 Financial Results and Provides Business Update

Company to Hold Conference Call Friday, May 13th at 11:00 a.m. ET

COLUMBIA, MD -- (MARKET WIRE) -- 05/12/11 -- Celsion Corporation (NASDAQ: CLSN), a leading oncology drug development company, today announced financial results for the first quarter ended March 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 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. The HEAT study, which has been designated as a Priority Trial for liver cancer by the National Institutes of Health, has also received Fast Track Designation from the FDA and Orphan Drug Designation in both the U.S. and Europe.

"With enrollment in our HEAT study nearing completion, we look forward to the key event in our clinical timeline, a preplanned efficacy analysis mid-year, followed by the top-line results in 2012," said Michael H. Tardugno, Celsion's President and Chief Executive Officer. "As these important milestones approach, we continue to execute on a multi-faceted strategy for maximizing the value of our platform technologies. This includes the expansion of our intellectual property, our ThermoDox® clinical targets and the application of liposomal encapsulation. In recent months, we received two new patents extending the term and breadth of our patent estate, presented preclinical data supportive of ThermoDox® in combination with High Intensity Focused Ultrasound, and advanced our plans to initiate trials of ThermoDox® in multiple indications, including secondary liver, bone and superficial cancers."

Financial Results

For the first quarter ended March 31, 2011, Celsion reported a net loss of \$3.5 million, or \$0.26 per share, compared to a net loss of \$6.1 million, or \$0.50 per share, in the same period of 2010. In the first quarter of 2011, the Company recognized \$2 million in licensing revenue after amending its Development, Product Supply and Commercialization Agreement for ThermoDox® with Yakult Honsha Co. to provide for accelerated payments of up to \$4 million in future milestone payments, including \$2 million that was paid to the Company on January 12, 2011, in exchange for a reduction in product approval milestones that the Company may receive under the Yakult Agreement. Net loss in the first quarter of 2010 included a \$1.6 million non-cash warrant liability charge related to a mark-to-market change in the common stock warrant liability related to a stock offering completed in September 2009, compared to a \$168,000 non-cash benefit in 2011.

Research and development costs were \$1.1 million higher in the first quarter of 2011 primarily due to 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 late stage/commercial manufacturing for ThermoDox®. General and administrative expenses decreased slightly (6%) in the quarter ended March 31, 2011, as the Company continues to focus its efforts on completing enrollment in the Phase III HEAT study.

For the quarter ended March 31, 2011, net cash used in operations was \$4.4 million. The Company ended the quarter with a total of \$3.7 million of cash, investments and other receivables and current assets. Subsequent to March 31, 2011, the Company completed two draws and sales under its Committed Equity Financing Facility with Small Cap Biotech Value, Ltd. for gross proceeds of \$2.8 million at an average price of \$2.65 per share. Broker fees and other expenses associated with these draws totaled approximately \$90,500. The proceeds were used to fund clinical development costs and working capital needs.

Recent Business Highlights

-- Patient enrollment for the Phase III HEAT study is 93%. Enrollment is ongoing at 66 sites in ten countries, with enrollment completion

expected mid-year;

- In January, the Company completed a registered offering of \$5.1 million of convertible preferred stock and common stock warrants. Concurrent with this effort, the Company amended its Development, Product Supply and Commercialization Agreement for ThermoDox® with Yakult Honsha Co. to provide for accelerated payment of up to \$4 million in future milestone payments, including \$2 million that was paid to the Company on January 12, 2011, in exchange for a reduction in product approval milestones that the Company may receive under the Yakult Agreement;
- In February, the independent Data Monitoring Committee (DMC) reviewed clinical data on 482 randomized patients enrolled in the Phase III HEAT study and unanimously recommended that the trial continue to enroll patients with the goal of reaching 600 patients required to complete the study;
- -- In March, Celsion received Orphan Drug Designation in Europe for
 ThermoDox® to treat primary liver cancer. ThermoDox® will have

 10 year marketing exclusivity following EMA approval. A Scientific
 Advisory Committee Meeting is planned for the second quarter of 2011
 to outline a registrational pathway for ThermoDox®;
- -- In April, Celsion was granted an additional U.S. Patent in the "Needham Patent Family" covering Temperature-Sensitive Liposomal technologies, including the ThermoDox® formulation;
- -- In April, Celsion was granted the Japanese counterpart of the "Needham" composition of matter patent, "Temperature-Sensitive Liposomal Formulation," which is issued in various regions around the world, including the U.S. and European Union;
- -- Celsion presented preclinical data highlighting the efficacy for

 ThermoDox® with High Intensity Focused Ultrasound (HIFU) System in

 certain difficult-to-treat cancers at the Annual Meetings of the

 Society of Thermal Medicine (STM) and International Society of

 Therapeutic Ultrasound (ISTU). The data are supportive of the

Company's plan to initiate a clinical trial in metastatic bone cancer later in 2011 with partner, Phillips Healthcare.

Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss the first quarter 2011 results at 11:00 a.m. Eastern Time on Friday, May 13, 2011. To participate in the call, interested parties may dial 1-888-668-1647 (Toll-Free/North America) or 1-913-981-5568 (International/Toll) and use Conference ID: 1092576 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 Friday, May 13, 2011 at 2:00 p.m. ET and will remain available until Friday, May 20, 2011. The replay can be accessed at 1-877-870-5176 (Toll-Free/North America) or 1-858-384-5517 (International/Toll) using Conference ID: 1092576. 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 on Friday, May 13, 2011.

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 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 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 (PFS) with a secondary confirmatory endpoint of overall survival. A pre-planned, unblinded interim efficacy analysis will be performed by the independent Data Monitoring Committee when enrollment in the HEAT Study is complete and 190 PFS events are realized in the study population. Additional information on the Company's ThermoDox® clinical studies may be found at 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 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, Mayo Clinic, the University of Pisa, 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

(in thousands except for per share amounts)

(Unaudited)

Three Months Ended

March 31,

	rater 31,		
	2011		
Licensing revenue	\$ 2,000 \$	-	
Operating expenses:			
Research and development	4,349	3,275	
General and administrative	1,215	1,299	
Total operating expenses	5,564	4,574	
Loss from operations	(3,564)	(4,574)	
Other income (expense):			
Gain (loss) from valuation of common stock			
warrants	168	(1,570)	
Other expense, net	(368)	(1)	
Total other income (expense), net	(200)	(1,571)	
Net Loss	\$ (3,764) \$		
Net loss per common share - basic and diluted	\$ (0.28) \$		

basic and diluted 13,453 12,186

Celsion Corporation Selected Balance Sheet Information

(in thousands)

	(Unaudited)				
	Mai	March 31,		December	
ASSETS		2011	3	1, 2010	
Current assets					
Cash and cash equivalents	\$	1,965	\$	1,139	
Short term investments		131		396	
Prepaid expenses and other current assets		1,651		492	
Total current assets		3,747		2,027	
Property and equipment		338		378	
Other assets					
Deferred financing fees		605		-	
Deposits and other assets		77		77	

Patent license fees, net	41	43
Total other assets	 723	120
Total assets	\$	\$ 2,525
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 6,740	\$ 6,673
Note payable - current portion	127	123
Total current liabilities	 6,867	6,796
Common stock warrant liability	80	248
Other liabilities - noncurrent portion	23	57
8% Series A Redeemable Convertible Preferred		
Stock	2,878	-
Total liabilities	9,848	7,101
Stockholders' deficit		
Common stock	146	141
Additional paid-in capital	102,560	99,317
Accumulated other comprehensive (loss) income	19	(18)
Accumulated deficit	(104,716)	(100,939)
Subtotal		(1,499)
	(3,049)	
Less: Treasury stock	(3,049)	(3,0//)

Total liabilities and stockholders' deficit	\$ 4,808	\$ 2,525
Total stockholders' deficit	(5,040)	(4,576)

Investor Contact

David Pitts

Argot Partners

212-600-1902

Email Contact

Source: Celsion Corporation

News Provided by Acquire Media