

Celsion Corporation Reports First Quarter 2013 Financial Results and Provides Business Update

Company to Hold Conference Call on Thursday, May 9, 2013 at 11:00 a.m. ET

LAWRENCEVILLE, N.J., May 9, 2013 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the first quarter ended March 31, 2013 and provided a business update on its clinical trials of ThermoDox®, Celsion's proprietary heat-activated liposomal encapsulation of doxorubicin. ThermoDox® is being evaluated in a global, multi-center Phase III clinical trial (the HEAT Study) in patients with non-resectable hepatocellular carcinoma (HCC), also known as primary liver cancer. ThermoDox® is also being evaluated in a Phase II trial for patients with recurrent chest wall breast cancer, The DIGNITY Study.

Following the announcement on January 31, 2013, that ThermoDox® in combination with radiofrequency ablation (RFA) did not meet the HEAT Study's primary endpoint, the Company conducted a comprehensive analysis of the data from the Study which was reviewed by its key principal investigators as well as liver cancer and clinical data experts. These emerging findings from the HEAT Study suggest that RFA dwell time had a positive impact on progression free survival (PFS) and overall survival (OS) in patients treated with ThermoDox® plus RFA when compared to the control group. This analysis was conducted in a sizable patient subgroup. These findings will be discussed by two of the HEAT Study's lead investigators at scientific sessions of the World Conference on Interventional Oncology on May 16, 2013. Celsion's lead investigators agree that these are interesting findings which should be further pursued.

"With the support of our medical advisors, we have been working diligently to better understand the clinical data and findings from the Phase III HEAT Study. Concurrently, we have been taking appropriate measures to position Celsion for future success including reducing expenses and exploring acquisition opportunities," said Michael Tardugno, Celsion's President and Chief Executive Officer. "At this point, we have concluded that emerging findings from our post hoc analysis of the HEAT Study provide a basis for review with various regulatory agencies and an opportunity to discuss a path forward for our HCC development program. Our recent expense reduction initiatives ensure a strong balance sheet as we explore opportunities to broaden our product pipeline and mitigate risk."

Recent Business Developments

During the first quarter of 2013, the Company raised \$27 million in gross proceeds from several financing transactions as well as a new research and development collaboration:

- Celsion sold common stock through a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. and received gross proceeds of approximately \$7 million.
- Celsion entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold, in a registered offering, an aggregate of 15,000 shares of its Series A 0% convertible preferred stock and warrants to purchase approximately 6.0 million shares of its common stock at an exercise price of \$1.18 per share, for gross proceeds of \$15 million.
- Celsion entered into a Technology Development Agreement with Zhejiang Hisun Pharmaceutical Co., Ltd. (Hisun) for ThermoDox® for the greater China territory. Under the terms of the agreement, Hisun paid Celsion a \$5 million payment in support of ThermoDox® technology development.

In April 2013, the Company provided a comprehensive business update which included the following:

- Emerging findings from the HEAT Study post hoc analysis suggests that ThermoDox® markedly improved progression free survival (PFS) and overall survival (OS) in patients who had optimal RFA. Â The post hoc analysis indicated that if patients' lesions undergo RFA for 45 minutes or more, they clearly benefitted from ThermoDox®. These findings apply to HCC lesions from both size cohorts of the HEAT Study (3-5 cm and 5-7 cm) and represent a sizable subgroup of patients.
- The Company implemented a restructuring program to lower its operating costs to conserve capital. The program included the elimination of approximately one-third of Celsion's workforce and the deferral of expenses associated with the Company's Phase II study of ThermoDox[®] in combination with RFA for the treatment of colorectal liver

metastases (The ABLATE Study).

The Company engaged Cantor Fitzgerald & Co. to conduct a comprehensive review of merger and acquisition opportunities with the goal of identifying novel products with high potential, or companies, for Celsion to acquire.

Financial Results

For the quarter ended March 31, 2013, Celsion reported a net loss of \$651,000 compared to a net loss of \$6.2 million in the same period of 2012. Net loss for the quarter ended March 31, 2013 was favorably impacted by lower operating costs coupled with the non-cash benefit of \$4.3 million from the valuation of the common stock warrant liability associated with warrants issued in a registered direct equity offering in September 2009. Also in the first quarter of 2013, the Company entered into a Technology Development Agreement with Hisun, which included a payment of \$5 million from Hisun, to support technology development transfer of ThermoDox® in the China territory. The first quarter income statement was also impacted by a one-time, non-cash deemed dividend from the beneficial conversion feature of \$4.6 million on the preferred stock issued in February 2013, resulting in a net loss attributable to common shareholders of \$5.3 million.

For the quarter ended March 31, 2013, net cash provided by operations was \$1.8 million. During the first quarter of 2013, the Company raised \$20.8 million in new capital, net of issuance costs, from the sale of preferred stock to certain institutional investors, the sale of common stock under a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co., and the exercise of common stock warrants and options. The Company ended the current quarter with \$45.9 million in cash, investments and accrued interest on short-term investments.

Research and development expenses decreased by \$1.5 million (32%), from \$4.7 million in the first quarter of 2012 to \$3.2 million in the first quarter of 2013. This decrease was primarily due to reduced clinical development costs associated with the Phase III HEAT Study and activities related to the development of commercial manufacturing capabilities for ThermoDox®. General and administrative expenses of \$1.7 million in the first quarter of 2013 were relatively flat as compared to the same period of 2012.

Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss the first quarter 2013 results at 11:00 a.m. EDT Thursday, May 9, 2013. To participate in the call, interested parties may dial 1-888-329-8862 (Toll-Free/North America) or 1-719-325-2376 (International/Toll) and ask for The Celsion Corporation First Quarter 2013 Earnings Conference Call approximately 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 May 9, 2013 at 2:00 p.m. EDT and will remain available until May 23, 2013. The replay can be accessed at 1-877-870-5176 (Toll-Free/North America) or 1-858-384-5517 (International/Toll) using Conference ID: 2227568. 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. EDT Thursday, May 9, 2013.

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. ThermoDox® is being evaluated in a Phase III clinical trial for primary liver cancer (the HEAT study), a Phase II clinical trial for colorectal liver metastasis and a Phase II clinical trial for recurrent chest wall breast cancer. Localized mild hyperthermia (39.5 - 42 degrees Celsius) created by radiofrequency ablation (RFA) releases the entrapped doxorubicin from the liposome. This delivery technology enables high concentrations of doxorubicin to be deposited preferentially in a targeted tumor. On January 31, 2013, Celsion announced that ThermoDox® in combination with RFA did not meet the primary endpoint of the HEAT study in patients with hepatocellular carcinoma, also known as primary liver cancer. Celsion is conducting additional analyses of the data from the HEAT study to assess the future strategic value of ThermoDox®.

About Celsion Corporation

Celsion is 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, including the National Institutes of Health, Duke University Medical Center, University of Hong Kong, the University of Pisa, the UCLA Department of Medicine, the Kyungpook National University Hospital, the Beijing Cancer Hospital and the University of Oxford. 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; the significant expense, time, and risk of failure of conducting clinical trials; HEAT Study data is subject to further verification and review by the HEAT Study Data Management Committee; the need for Celsion to evaluate its future development plans; termination of the Technology Development Contract or collaboration between Celsion and Hisun at any time; possible changes in cost and timing of development and testing, capital structure, financial condition, working capital needs and other financial items; possible acquisitions or licenses of other technologies, assets or businesses or the possible failure to make such acquisitions or licenses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Celsion's periodic reports filed with the Securities and Exchange Commission. Celsion assumes no obligation to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

Investor Contact

Jeffrey W. Church Senior Vice President — Corporate Strategy and Investor Relations 609-482-2455 jchurch@celsion.com

Â

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

		Three Months Ended March 31,		
		2013		2012
Licensing revenue	\$	125	\$	
Operating expenses:				
Research and development		3,203		4,693
General and administrative		1,689		1,570
Total operating expenses		4,892		6,263
Â Â				
Loss from operations		(4,767)		(6,263)
•				
Other income (expense):				
Gain from valuation of common stock warrant liability		4,280		78
Interest, dividends and other income (expense), net		(164)		(1)
Total other income, net		4,116		77
Â Â				
Net loss		(651)		(6,186)
Â				
Non-cash deemed dividends from beneficial Â				
conversion feature on convertible preferred stock		(4,601)		_
Â				
Å Net loss attributable to common shareholders	\$	(5,252)	\$	(6,186)
Net 1055 attributable to common shareholders	Ψ	(0,202)	Ψ	(0,100)
Â				
Net loss attributable to common shareholders per				
common share — basic and diluted	\$	(0.12)	\$	(0.19)
Weble Leaves and the second of the second				
Weighted average common shares outstanding — basic and diluted		42,996		33,197
Dasic and unded		72,330		55,137

Celsion Corporation Selected Balance Sheet Information (In thousands)

ASSETS	March 31, 2013 (Unaudited)	_	December 31, 2012 Â
Current assets			
Cash and cash equivalents	\$ 20,367	\$	14,991
Short term investments and accrued interest	25,486		8,104
Other current assets	562	_	554
Total current assets	46,415		23,649
Property and equipment	1,040	-	1,115
Other assets			
Deposits and other assets	477		567
Patent license fees, net	26		28
Total other assets	503		595
Total assets	\$ 47,958	\$	25,359
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities			
Accounts payable and accrued liabilities	\$ 5,278	\$	3,595
Deferred revenue — current portion	500		_
Note payable - current portion	1,884		1,410
Total current liabilities	7,662		5,005
Common stock warrant liability	4		4,284
Note payable — non-current portion	3,173		3,661
Deferred revenue — noncurrent portion	4,375		_
Other liabilities — noncurrent portion	443		447
Total liabilities	15,657		13,397
Stockholders' equity			
Series A convertible preferred stock	1		_
Common stock	515		380
Additional paid-in capital	190,743		165,276
Accumulated other comprehensive loss	(159)		(127)
Accumulated deficit	(156,119)		(150,877)
Subtotal	34,981		14,652
Less: Treasury stock	(2,680)		(2,690)
Total stockholders' equity	32,301		11,962
Total liabilities and stockholders' equity	\$ 47,958	\$	25,359

Â

ÂÂ

SOURCE Celsion Corporation

News Provided by Acquire Media