

# Celsion Corporation Reports Second Quarter 2013 Financial Results and Provides HEAT Study Update

Analysis of Overall Survival Data in the HEAT Study Continues to Show ThermoDox® Improves Survival Benefit when RFA Heating is Optimized Company to Hold Conference Call on Thursday, August 8, 2013 at 11:00 a.m. EDT

LAWRENCEVILLE, N.J., Aug. 8, 2013 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the second quarter ended June 30, 2013 and an update from its retrospective analysis of the clinical trial results for 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 has conducted a comprehensive analysis of the data from the Study supported by its key principal investigators as well as liver cancer and clinical data experts. The Company continues to follow patients enrolled in the HEAT Study to the secondary endpoint, Overall Survival (OS).Â

As of the June 30, 2013 cut off, the date of the latest OS patient follow-up, Celsion reports the following:

- Overall Survival has not yet reached the median for the full HEAT Study population. A total of 226 deaths have been recorded through June 30, 2013.
- Subgroup analysis based on RFA heating duration continues to suggest that ThermoDox® markedly improves Overall Survival, when compared to the control group, in patients if their lesions undergo RFA for 45 minutes or more. These findings apply to single HCC lesions (63% of the HEAT Study population) from both size cohorts of the HEAT Study (3-5 cm and 5-7 cm) and represent approximately 300 patients.
- While the Overall Survival data reported above should be viewed with caution since the HEAT Study has not reached its median point for Overall Survival analysis, there is a strong signal which our investigators consider to be encouraging and sufficient to warrant additional clinical investigation.
- Details of the retrospective OS findings will be presented at the upcoming International Liver Cancer Association (ILCA) 2013 Annual Conference in Washington, D.C. on September 14, 2013.Â

"As we continue to follow patients in the HEAT Study to the secondary endpoint, Overall Survival, there is clear evidence that ThermoDox® can benefit patients when RFA is optimized," said Dr. Nicholas Borys, Celsion's Chief Medical Officer. "It is impressive that a single dose of ThermoDox® can demonstrate a meaningful impact on patient survival. The influence of longer RFA heating time on local tissue concentration is consistent with the mechanism of ThermoDox® activity."

"We believe that the emerging data from our post hoc analysis of the HEAT Study may provide a rationale for continued development of ThermoDox® and a basis for discussion of a path forward for our HCC program with various regulatory agencies. While this important work continues, we have fully implemented our previously announced corporate restructuring program to adjust spending levels and headcount with the goal of reducing pressure on our cash resources while maintaining the necessary competencies important to the execution of our current business strategy," said Michael Tardugno, Celsion's President and Chief Executive Officer. "Our recent expense reduction initiatives ensure a strong balance sheet and positions the Company to fully explore the appropriate regulatory path forward for ThermoDox® and to evaluate opportunities with the potential to broaden our product pipeline through acquisition of complementary products and technologies."

# **Recent Business Developments**

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® improved progression-free survival (PFS) and overall survival (OS) in patients who had an optimized RFA procedure. Â The post-hoc analysis

indicates that if patients' lesions undergo RFA for 45 minutes or more, they clearly benefitted from ThermoDox®.A 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 approximately 300 patients. These findings were presented and discussed by two of the HEAT Study's lead investigators at scientific sessions of the World Conference on Interventional Oncology on May 16, 2013 and the European Conference on Interventional Oncology on June 19 and 20, 2013. The presentations and data are available on the Company's website at <a href="https://www.celsion.com">www.celsion.com</a>.

- 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<sup>®</sup> 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.

#### In May 2013,

- The Company announced the issuance of additional patents covering its ThermoDox® technologies in four of the largest markets for primary liver cancer China, Japan, South Korea and Taiwan. These new patents extend proprietary protection to 2026.
- The Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold, in an at-the-market registered direct offering, an aggregate of 6.3 million shares of its common stock for gross proceeds of \$9.8 million. There were no warrants issued as part of this financing transaction.

# In July 2013,

- The Company was notified that the International Liver Cancer Association (ILCA) has accepted the HEAT Study abstract for webcast oral presentation at the plenary session of its annual meeting in September 2013 in Washington, DC. Prospective and retrospective findings from the HEAT Study will be discussed by the Study's lead principal investigator in Asia, Professor Ronnie Poon, MD, PhD, professor of surgery at the Queen Mary Hospital in Hong Kong.
- The Company reaffirmed its continued strategic partnership in China with Zhejiang Hisun Pharmaceutical Company (Hisun), with the announcement of the signing of a Memorandum of Understanding for the future development of ThermoDox® and other liposomal formulations.

#### **Financial Results**

For the quarter ended June 30, 2013, Celsion reported net income of \$421,000 compared to a net loss of \$6.1 million in the same period of 2012. Net income for the quarter ended June 30, 2013 was favorably impacted by lower operating costs (\$1.7 million) coupled with the non-cash benefit of \$4.4 million from the valuation of the common stock warrant liability associated with registered direct equity offerings in September 2009 and June 2013. For the six month period ended June 30, 2013, Celsion reported a net loss of \$230,000 compared to a net loss of \$12.3 million in the same period of 2012. Net loss for the six months ended June 30, 2013 was favorably impacted by lower operating costs (\$3.1 million) coupled with the non-cash benefit of \$8.7 million from the valuation of common stock warrant liability associated with equity financings in September 2009 and June 2013. 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. Revenue from this collaboration totaled \$125,000 in the second quarter of 2013 and \$250,000 in the six month period ended June 30, 2013. The Statement of Operations was also impacted by a one-time, non-cash deemed dividend from the beneficial conversion feature of \$4.6 million on the preferred stock equity financing announced in February 2013, resulting in a net loss attributable to common shareholders of \$4.8 million for the six months ended June 30, 2013.

Net cash used in operations was \$3.6 million for the six months ended June 30, 2013 compared with \$10.9 million used to fund operations in the same period last year due to lower operating costs in the current year combined with the \$5 million payment from Hisun mentioned above. During the first six months of 2013, the Company raised \$30 million in new capital, net of issuance costs, from the sale of 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 \$48.9 million in cash, investments and accrued interest on short-term investments.

Research and development expenses decreased by \$2.1 million (50%), from \$4.1 million in the second quarter of 2012 to \$2.0 million in the second quarter of 2013. Research and development expenses decreased by \$3.6 million (41%), from \$8.8 million in the six month period ended June 30, 2012 to \$5.2 million in the same period of 2013. Â These decreases were 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 \$1.95

million in the second quarter of 2013 increased \$356,000 when compared to the same period of 2012 due to a one-time severance charge associated with the Company's restructuring program announced in April 2013.Â

#### **Quarterly Conference Call**

The Company is hosting a conference call to provide a business update and discuss the second quarter 2013 financial results at 11:00 a.m. EDT Thursday, August 8, 2013. To participate in the call, interested parties may dial 1-800-723-6498 (Toll-Free/North America) or 1-785-830-7989 (International/Toll) and ask for The Celsion Corporation Second Quarter 2013 Financial Results Conference Call (Conference Code: 3083628) approximately ten minutes before the call is scheduled to begin. The call will also be broadcast live on the internet at <a href="http://www.celsion.com">http://www.celsion.com</a>.

The call will be archived for replay on Thursday, August 8, 2013 at 2:00 p.m. EDT and will remain available until August 22, 2013. The replay can be accessed at 1-888-203-1112 (Toll-Free/North America) or 1-719-457-0820 (International/Toll) using Conference Code: 3083628. An audio replay of the call will also be available on the Company's website, <a href="http://www.celsion.com">http://www.celsion.com</a>, for 30 days after 2:00 p.m. EDT Thursday, August 8, 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: <a href="http://www.celsion.com">http://www.celsion.com</a>.

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. ChurchÂ
Senior Vice President andÂ
Chief Financial OfficerÂ
609-482-2455Â
jchurch@celsion.com

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# Celsion Corporation Condensed Statements of Operations (in thousands except per share amounts) (unaudited)

		Three Months Ended June 30,				Six Months Ended June 30,		
		2013		2012		2013		2012
Licensing revenue	\$	125	\$		\$	250	\$	
Operating expenses:								
Research and development		2,022		4,112		5,226		8,805
General and administrative		1,951	-	1,595		3,639		3,166
Total operating expenses		3,973		5,707		8,865		11,971
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Loss from operations		(3,848)		(5,707)		(8,615)		(11,971)
Other income (expense):  Gain (loss) from change in valuation of common								
stock warrant liability Interest, dividends and other income (expense),		4,380		(447)		8,660		(370)
net		(111)		50		(275)		50
Total other income (expense), net		4,269	-	(397)		8,385		(320)
Â Net income (loss)	\$	421	\$	(6,104)	\$	(230)	\$	(12,291)
$\hat{A}$ $\hat{A}$ $\hat{A}$ Non-cash deemed dividend from beneficial $\hat{A}$ $\hat{A}$ $\hat{A}$ $\hat{A}$ $\hat{A}$ $\hat{A}$ conversion feature on convertible preferred $\hat{A}$ $\hat{A}$ $\hat{A}$ $\hat{A}$ $\hat{A}$ stock			-		-	(4,601)		
Net income (loss) attributable to common Shareholders	\$	421	\$	(6,104)	\$	(4,831)	\$	(12,291)
Â Net income (loss) per common share attributableÂ to common shareholders Â Basic	•	0.04	•	(0.40)	•	(0.40)	•	(0.27)
Fully Diluted	\$ \$	0.01	\$ \$	(0.18)	\$ \$	(0.10)	\$	(0.37)
Weighted average shares outstanding Basic		54.392		33.236		48,632		33,211
Fully Diluted		61,280		33,236	:	48,632	:	33,211

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# Celsion Corporation Selected Balance Sheet Information (In thousands)

June 30, 2013 (Unaudited)		December 31, 2012 Â
\$ 6,021	\$	14,991
42,913		8,104
639		554
49,573		23,649
1,022		1,115
\$	\$ 6,021 42,913 639 49,573	\$ 6,021 \$ 42,913 639 49,573

Other assets

Deposits and other assets Patent license fees, net	396 24		567 28
Total other assets	420	•	595
Total assets	\$ 51,015	\$	25,359
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities			
Accounts payable and accrued liabilities	\$ 3,305	\$	3,595
Deferred revenue — current portion	500		_
Note payable - current portion	1,905		1,410
Total current liabilities	5,710		5,005
Common stock warrant liability	4,734		4,284
Note payable — non-current portion	2,848		3,661
Deferred revenue — noncurrent portion	4,250		_
Other liabilities — noncurrent portion	483		447
Total liabilities	18,025		13,397
Stockholders' equity Preferred stock			
Common stock	618		380
Additional paid-in capital	190,963		165,276
Accumulated other comprehensive loss	(213)		(127)
Accumulated deficit	(155,698)		(150,877)
Subtotal	35,670		14,652
Less: Treasury stock	(2,680)		(2,690)
Total stockholders' equity	32,990		11,962
Total liabilities and stockholders' equity	\$ 51,015	. \$	25,359

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