

# **Celsion Corporation Reports Second Quarter 2014 Financial Results**

# Company Completes Acquisition of EGEN, Inc. Company to Hold Conference Call Today at 11:00 a.m. EDT

LAWRENCEVILLE, N.J., Aug. 7, 2014 /PRNewswire/ --Â Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the second quarter ended June 30, 2014. The Company also provided an update on its development programs for ThermoDox<sup>®</sup>, its proprietary heat-activated liposomal encapsulation of doxorubicin, and two newly acquired technology platforms, TheraPlas<sup>™</sup> and TheraSilence<sup>™</sup>, in immunotherapy and RNA delivery.

"Our significant progress over the past quarter is consistent with our previously stated objectives and has established a new growth trajectory for Celsion. With multiple opportunities to create long-term value for our shareholders, Celsion represents a development company of unique proportions," said Michael Tardugno, Celsion's President and Chief Executive Officer. "With our recent acquisition of EGEN, we have created a fully-integrated oncology company with a multi-phase pipeline of chemotherapies, immunotherapies and DNA or RNA-based therapies. We are now focused on successfully executing our Phase III OPTIMA Study for ThermoDox<sup>®</sup> plus optimized radiofrequency ablation in primary liver cancer. We will also be working to leverage the potential of ThermoDox<sup>®</sup> in additional indications, and advancing development of our newest clinical asset, EGEN-001, in both ovarian cancer and glioblastoma."

### **Recent Corporate Highlights**

Completed Acquisition of EGEN, Inc. In June, Celsion completed its acquisition of EGEN, Inc., a privately-held biopharmaceutical company focused on the development of nucleic acid-based therapeutics for the treatment of cancer and other difficult to treat diseases. The acquisition included EGEN's Phase Ib DNA-based immunotherapy product candidate EGEN-001 and its therapeutic platform technologies, TheraPlas™ for delivery of DNA and mRNA and TheraSilence™ for delivery of RNA.

Advanced Global Regulatory Efforts in Support of the OPTIMA Study. During the second quarter, Celsion received regulatory clearance to initiate its Phase III OPTIMA Study evaluating ThermoDox<sup>®</sup> in combination with optimized radiofrequency ablation (RFA) in patients with primary liver cancer at clinical trial sites in Taiwan, Hong Kong, South Korea, Malaysia and Canada. Celsion also announced that it has filed Clinical Trial Applications in the Philippines and Thailand, as well as a request for a Voluntary Harmonization Procedure (VHP) in Europe, which provides for the assessment of multinational clinical trial applications across several European countries, including Germany, France and Spain. Â The OPTIMA trial is designed to enroll 550 patients at up to 100 sites in the North America, Europe, China and Asia Pacific and support registration in key liver cancer markets worldwide.

Reported Positive Updated Survival Data from the HEAT Study. In July, Celsion announced updated results from its retrospective analysis of the Company's 701-patient HEAT Study of ThermoDox<sup>®</sup> in combination with RFA in primary liver cancer. As of June 30, 2014, the latest quarterly Overall Survival (OS) analysis demonstrated that in a large, well bounded, subgroup of patients (n=285, 41% of the study patients), the combination of ThermoDox<sup>®</sup> and optimized RFA provided a 57% improvement in OS compared to optimized RFA alone. The Hazard Ratio at this analysis is 0.639 (95% CI Â 0.419 - 0.974) with a p-value of 0.037. This data provides a strong rationale for the Company's ongoing Phase III OPTIMA Study.

Announced Positive Interim Data from Phase 2 DIGNITY Study. In July, Celsion reported remarkable interim data from its ongoing open-label Phase 2 DIGNITY Trial of ThermoDox<sup>®</sup> in combination with mild hyperthermiain refractory patients with recurrent chest wall breast cancer. Based on data available to date, 60% of 10 evaluable patients experienced a stabilization of their highly aggressive disease, with 3 complete responses (CR), 2 partial responses (PR) and 1 patient with stable disease (SD).

Initiation of Clinical Trial Evaluating ThermoDox<sup>®</sup> Plus HIFU in Metastatic Liver Cancer. In August, a proof of concept clinical study of ThermoDox<sup>®</sup> in combination with ultrasound-guided High Intensity Focused Ultrasound (HIFU), in

patients with metastatic liver cancer was initiated. The trial, which is supported by the National Institute for Health Research Oxford Biomedical Research Centre, will be carried out as a multi-disciplinary collaboration between Celsion, the Oxford University Institute of Biomedical Engineering, and the Oxford University Hospitals NHS Trust.

Announced \$1 Million NIH Grant for Glioblastoma Research with ThermoDox® and HIFU. In July, Celsion and Brigham and Women's Hospital, Harvard Medical School expanded their collaboration through the recent award of a \$1 million Career Development Grant from the National Institutes of Health's Center for Biomedical Imaging and Bioengineering (NIBIB). The grant will support preclinical studies evaluating ThermoDox® in combination with HIFU for the treatment of brain tumors.Â

Launched Commercialization of Reagent Products. In July, Celsion launched sales of its proprietary reagent products for life science research based on its newly acquired proprietary delivery platform technologies, TheraPlas™ and TheraSilence™, which are designed for optimal transfection (intra-cellular delivery) of plasmid DNA and RNA into human (and other mammalian) cells.Â

#### **Financial Results**

For the quarter ended June 30, 2014, Celsion reported a net loss of \$5.6 million net of acquisition costs compared to net income of \$421,000 in the same period of 2013. With \$1.1 million of acquisition costs, the net loss was \$6.7 million for the second quarter of 2014. Net income for the quarter ended June 30, 2013 was favorably impacted by lower operating costs (\$1.5 million) coupled with the non-cash benefit of \$4.4 million from the change in valuation of common stock warrant liability associated with equity financings in September 2009 and June 2013. In addition, the current quarter and six-month period ended June 30, 2014 included \$1.1 million of one-time costs associated with the acquisition of EGEN, Inc. in June 2014. For the six month period ended June 30, 2014, Celsion reported a net loss of \$12.1 million compared to a net loss of \$230,000 in the same prior year period. Net loss for the six months ended June 30, 2013 was favorably impacted by lower operating costs (\$1.9 million) coupled with the non-cash benefit of \$8.7 million from the change in valuation of common stock warrant liability associated with equity financings in September 2009 and June 2013. The Statement of Operations for the six month period ended June 30, 2013 was also impacted by a 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 for the six month period ended June 30, 2013 of \$4.8 million.

The Company ended the current quarter with \$50.1 million in cash, investments and accrued interest on short-term investments. Â Revenue from licensing collaborations totaled \$125,000 in each of the first two quarters of 2014 and 2013. Â Net cash used in operations was \$9.0 million for the six months ended June 30, 2014 compared to \$3.4 million in the same prior year period. Â This increase of \$5.6 million was due to a \$5 million payment from the Company's Chinese collaborator, Zhejiang Hisun Pharmaceutical Company, received in January 2013 for a non-refundable technology transfer fee. Â During the first six months of 2014, the Company raised approximately \$18.8 million in new capital, net of issuance costs, from the sale of stock to certain institutional investors in the first quarter and a second draw of \$5 million off its venture debt facility with Hercules Technology Growth Capital, Inc. in the second quarter.

Research and development (R&D) expenses increased by \$1.2 million from \$2.0 million in the second quarter of 2013 to \$3.2 million in the second quarter of 2014. R&D expenses increased by \$0.9 million from \$5.2 million in the six month period ended June 30, 2013 to \$6.1 million in the same period of 2014. The increase in R&D expenses was due primarily to start-up costs associated with Company's Phase III OPTIMA Study during the first half of 2014. General and administrative expenses were \$2.3 million in the second quarter of 2014 compared to \$2.0 million in the second quarter of 2013. General and administrative expenses were \$4.7 million in the first six months of 2014 compared to \$3.6 million in the comparable prior year period. These increases were primarily the result of higher insurance premiums and personnel costs (which includes an increase of \$0.9 million in non-cash stock option expense). The second quarter of 2014 included one-time costs of \$1.1 million for legal and banking fees and due diligence expenses associated with the June 2014 acquisition of EGEN, Inc.

# **Quarterly Conference Call**

The Company is hosting a conference call to provide a business update and discuss the second quarter 2014 financial results at 11:00 a.m. EDT Thursday, August 7, 2014. To participate in the call, interested parties may dial 1-800-533-7954 (Toll-Free/North America) or 1-785-830-1924 (International/Toll) and ask for the Celsion Corporation Second Quarter 2014 Financial Results Conference Call (Conference Code: 8283269) 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 7, 2014 at 2:00 p.m. EDT and will remain available until Thursday, August 21, 2014. The replay can be accessed at 1-888-203-1112 (Toll-Free/North America) or 1-719-457-0820 (International/Toll) using Conference Code: 8283269. 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. EST Thursday August 7, 2014.

#### **About Celsion Corporation**

Celsion is a fully-integrated oncology company focused on developing a portfolio of innovative cancer treatments, including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies. The Company's lead program is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in Phase III development for the treatment of primary liver cancer. The pipeline also includes EGEN-001, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers. Celsion has three platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlas™ and TheraSilence™. 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 uncertainties of and difficulties in analyzing interim clinical data, particularly in small subgroups that are not statistically significant; FDA and regulatory uncertainties and risks; the significant expense, time, and risk of failure of conducting clinical trials; the need for Celsion to evaluate its future development plans; 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 and prospectuses 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**

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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,		
	2014	2013	2014	2013	
Licensing revenue	\$ 125	\$ 125	\$ 250	\$ 250	
Operating expenses:					
Research and development	3,166	2,022	6,059	5,226	
General and administrative	2,305	1,951	4,739	3,639	
Acquisition costs	1,067		1,067		
Total operating expenses	6,538	3,973	11,865	8,865	
Loss from operations	(6,413)	(3,848)	(11,615)	(8,615)	
Other (expense) income:					
(Loss) gain from change in valuation of common stock warrant liability	(19)	4,380	(16)	8,660	
Investment income, net	24	67	31	84	
Interest expense	(263)	(176)	(494)	(357)	
Other expense	(2)	(2)	(2)	(2)	
Total other (expense) income, net	(260)	4,269	(481)	8,385	
Net income (loss)	(6,673)	421	(12,096)	(230)	

Non-cash deemed dividend from beneficial conversion

ÄÄÄÄ feature onÄ convertible preferred stock				(4,601)
Net (loss) income attributable to common shareholders	\$ (6,673)	\$ 421	\$ (12,096)	\$ (4,831)
Net income (loss) attributable to common $\hat{A} \ \hat{A} \ \hat{A} \ \hat{A} \ \hat{A}$ shareholders per common share Basic and diluted	\$ (0.38)	\$ 0.03	\$ (0.71)	\$ (0.45)
Weighted average shares outstanding				
Basic	17,527	12,087	16,932	10,807
Diluted	17,527	13,618	16,932	10,807

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## Celsion Corporation Selected Balance Sheet Information (In thousands)

ASSETS		June 30, 2014 (Unaudited)	-	December 31, 2013
Current assets  Cash and cash equivalents	\$	9,598	\$	5,719
Short term investments and accrued interest	φ	40,462	φ	37,368
Other current assets		486		675
Total current assets		50,546	-	43.762
Total outlett assets			-	
Property and equipment		851	-	833
Other assets				
In-process research and development		25,802		-
Goodwill		1,939		-
Deposits, deferred fees and other assets		424		1,055
Patent license fees, net		16	_	21
Total other assets		28,181	-	1,076
Total assets	\$	79,578	\$	45,671
Current liabilities  Accounts payable and accrued liabilities  Notes payable  - current portion  Deferred revenue - current portion  Total current liabilities	\$	5,490 1,777 500 7,767	\$	4,160 11 500 4,671
Earn-out milestone liability		13,878		-
Common stock warrant liability		495		3
Notes payable, net of discounts		7,868		5,000
Deferred revenue		3,750		4,000
Other non-current liabilities		461	-	473
Total liabilities		34,219	-	14,147
Stockholders' equity Preferred stock		-		-
Common stock		201		137
Additional paid-in capital		228,944		203,139
Accumulated other comprehensive loss		(12)		(44)
Accumulated deficit		(181,512)		(169,287)
Subtotal		47,621	-	33,945
Less: Treasury stock		(2,262)		(2,421)
Total stockholders' equity		45,359		31,524

Total liabilities and stockholders' equity \$ \_\_\_\_\_\_\$ \_ \_\_\_ \$ \_\_\_\_\_\$

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**SOURCE Celsion Corporation** 

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