



November 11, 2014

Celsion Corporation Reports Third Quarter 2014 Financial Results

Company Completes Acquisition and Integration of EGEN, Inc.; Enrollment Underway in Phase III OPTIMA Study; Initiates Phase II Euro-DIGNITY Study for RCW Breast Cancer; Establishes Clinical Study Plans for EGEN-001

Company to Hold Conference Call on Tuesday, November 11, 2014 at 4:30 p.m. ET

LAWRENCEVILLE, N.J., Nov. 11, 2014 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the third quarter ended September 30, 2014. The Company also provided an update on its development programs for ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin, and two newly acquired technology platforms, TheraPlas™ and TheraSilence™, in immunotherapy and RNA delivery.

"We have successfully completed our integration of EGEN's operations and development programs. Our organization is now fully positioned to execute our strategy for ThermoDox® and to build momentum as we advance our multi-stage pipeline of high value oncology programs," said Michael H. Tardugno, Celsion's Chairman, President and Chief Executive Officer. "Our pivotal Phase III OPTIMA Study for ThermoDox® in primary liver cancer is progressing nicely, with sites actively enrolling patients and tangible progress in our global regulatory strategy. Enrollment in our Phase II DIGNITY Study for recurrent chest wall (RCW) breast cancer is nearing completion. Based on the extraordinary tumor response findings observed to date in this trial, we are working with noted thought leaders to launch a similar RCW breast cancer study in Europe. For EGEN-001, with guidance from investigators from MD Anderson, Roswell Park, University of Chicago, and Washington University, among others, our clinical plans in ovarian cancer and GBM remain on track to initiate studies in both indications next year. We were also pleased to share encouraging data from our TheraSilence™ program at the miRNA World Conference in October, and look forward to reporting additional data from all our development programs before year-end."

Recent Corporate Highlights

Successfully Integrated EGEN, Inc. Operations and Development Programs. 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 "investor friendly" acquisition provides for milestone-based payments and includes: EGEN's Phase Ib DNA-based immunotherapy product candidate EGEN-001; GEN-2, an RNA interference (RNAi) therapeutic for the treatment of lung cancer; the TheraPlas™ platform for delivery of DNA and mRNA; and TheraSilence™ for the delivery of RNA.

Enrolled First Patient in the Phase III OPTIMA Study. In early September, Celsion announced that the first patient had been enrolled in its pivotal Phase III OPTIMA Study of ThermoDox® in combination with optimized radiofrequency ablation (RFA) in patients with primary liver cancer. The trial is expected to enroll 550 patients at up to 100 sites in North America, Europe, China and Asia Pacific. The primary endpoint for the trial is Overall Survival. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee (iDMC).

Received Authorization for the OPTIMA Study in Europe through the rigorous Virtual Harmonization Procedure (VHP). In October, Celsion received approval for VHP request, which provided for the assessment of multinational clinical trial applications across several European countries. The approval allows Celsion to broaden its footprint in Europe and activate clinical sites in Spain, France, Germany and Italy. The Company is aggressively initiating sites in North America, Europe and Asia Pacific for the OPTIMA Study.

Presented HEAT Study Overall Survival Data at the 2014 International Liver Cancer Association (ILCA) Annual Conference. In September, Celsion announced three presentations highlighting ThermoDox® at the 2014 ILCA Annual Conference, including results from a retrospective analysis of the 701-patient HEAT Study of ThermoDox® in combination with RFA in primary liver cancer, which strongly supports the rationale for an optimized RFA regimen when using ThermoDox®. 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® 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 0.419 - 0.974) with a p-value of 0.037.

Reported Clinical Data on ThermoDox® in Recurrent Chest Wall Breast Cancer. In September, Celsion published data from two Phase I studies on ThermoDox® in recurrent chest wall breast cancer in the *International Journal of Hyperthermia*. The article describes the combined results of two similarly designed Phase I trials with one study conducted at Duke University and the second study conducted at other major breast cancer centers in the U.S., in which eligible patients with unresectable chest wall recurrences had progressed on the chest wall after prior hormone therapy, chemotherapy, and radiotherapy.

Announced Plans to Launch a Registration-Enabling DIGNITY Study in Europe. Celsion today announced plans to initiate the Euro-DIGNITY Trial of ThermoDox plus hyperthermia in patients with recurrent chest wall breast cancer. The study will be conducted in five countries, and has the potential to support a MAA filing in Europe. The trial will be conducted by Celsion with the support of key European investigators and with assistance from MedLogics Corporation, an Italian based hyperthermia device company. The trial is expected to launch in the first half of 2015.

Presented Preclinical Data for TheraSilence™ Platform at the miRNA World Conference Workshop on miRNA Delivery. On October 28, 2014, Celsion highlighted formulation characteristics of its TheraSilence™ delivery platform, preclinical proof-of-concept data and data supportive of GEN-2 at the miRNA World Conference Workshop on miRNA Delivery.

Financial Results

For the quarter ended September 30, 2014, Celsion reported a net loss of \$6.9 million net of acquisition costs compared to a net loss of \$4.1 million in the same period of 2013. Net loss for the quarter ended September 30, 2014 was impacted by higher operating costs associated with the initiation of the OPTIMA Study (\$1.7 million), the inclusion of operating costs of CLSN Labs (\$0.7 million) and higher interest expense (\$0.3 million). For the nine month period ended September 30, 2014, Celsion reported a net loss of \$19.0 million compared to a net loss of \$4.3 million in the same prior year period. The nine month period ended September 30, 2014 included \$1.2 million of one-time costs associated with the June 2014 acquisition of EGEN, Inc. The net loss for the nine months ended September 30, 2014 included higher operating costs associated with the initiation of the OPTIMA Study (\$2.4 million) and operating costs of CLSN Labs (\$0.9 million) whereas during the nine month period ended September 30, 2013, net loss was favorably impacted by lower operating costs (\$4.9 million) coupled with the non-cash benefit of \$8.1 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 nine month period ended September 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 nine month period ended September 30, 2013 of \$8.9 million.

The Company ended the current quarter with \$43.8 million in cash, investments and accrued interest on short-term investments. Revenue from licensing collaborations totaled \$125,000 in each of the first three quarters of 2014 and 2013. Net cash used in operations was \$14.8 million for the nine months ended September 30, 2014 compared to \$6.1 million in the same prior year period. This \$8.7 million increase in 2014 was due to higher operating costs in 2014 related to the initiation of the Phase III OPTIMA Study, the inclusion of post-acquisition operations for CLSN Laboratories (EGEN, Inc.) and the one-time acquisition costs associated with the EGEN acquisition. In addition, cash used in operations during 2013 was favorably impacted by a \$5 million cash payment from Celsion's Chinese collaborator, Zhejiang Hisun Pharmaceutical Company, received in January 2013 for a non-refundable technology transfer fee. During the first nine 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 January 2014 and a second draw of \$5 million off its venture debt facility with Hercules Technology Growth Capital, Inc.

Research and development (R&D) expenses increased by \$2.3 million from \$2.3 million in the third quarter of 2013 to \$4.6 million in the third quarter of 2014. R&D expenses increased by \$3.2 million from \$7.5 million in the nine month period ended September 30, 2013 to \$10.7 million in the same period of 2014. The increase in R&D expenses was due primarily to start-up costs associated with the Company's Phase III OPTIMA Study during 2014. General and administrative expenses were \$2.0 million in the third quarter of 2014 compared to \$1.4 million in the third quarter of 2013. General and administrative expenses were \$6.8 million in the first nine months of 2014 compared to \$5.0 million in the comparable prior year period. These increases were primarily the result of higher insurance premiums and personnel costs (which included an increase of \$0.7 million in non-cash stock compensation expense). The 2014 expenses included one-time transaction costs of \$1.2 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 third quarter 2014 financial results at 4:30 p.m. EST Tuesday, November 11, 2014. To participate in the call, interested parties may dial 1-888-430-8709 (Toll-

Free/North America) or 1-719-457-1512 (International/Toll) and ask for the Celsion Corporation Third Quarter 2014 Financial Results Conference Call (Conference Code: 3981708) 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 November 12, 2014 and will remain available until November 26, 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: 3981708. An audio replay of the call will also be available on the Company's website, <http://www.celsion.com>, for 30 days after November 11, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Licensing revenue	\$ 125	\$ 125	\$ 375	\$ 375
Operating expenses:				
Research and development	4,630	2,269	10,688	7,495
General and administrative	2,044	1,390	6,783	5,029
Acquisition costs	120	-	1,187	-
Total operating expenses	6,794	3,659	18,658	12,524
Loss from operations	(6,669)	(3,534)	(18,283)	(12,149)
Other (expense) income:				
Gain (loss) from change in valuation of common Â stock warrant liability	97	(519)	81	8,142
Investment income, net	27	145	57	228

Interest expense	(419)	(163)	(912)	(520)
Other expense	22	(1)	19	(3)
Total other (expense) income, net	<u>(273)</u>	<u>(538)</u>	<u>(755)</u>	<u>7,847</u>
Net income (loss)	(6,942)	(4,072)	(19,038)	(4,302)
Non-cash deemed dividend from beneficial conversion feature on convertible preferred stock	-	-	-	(4,601)
Net (loss) income attributable to common shareholders	<u>\$ (6,942)</u>	<u>\$ (4,072)</u>	<u>\$ (19,038)</u>	<u>\$ (8,903)</u>
Net income (loss) attributable to common shareholders per common share				
Basic and diluted	<u>\$ (0.35)</u>	<u>\$ (0.30)</u>	<u>\$ (1.06)</u>	<u>\$ (0.76)</u>
Weighted average shares outstanding				
Basic and diluted	<u>19,964</u>	<u>13,602</u>	<u>17,949</u>	<u>11,756</u>

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Celsion Corporation
Selected Balance Sheet Information
(In thousands)

	September 30, 2014	December 31, 2013
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 4,558	\$ 5,719
Short term investments and accrued interest	39,254	37,368
Other current assets	687	675
Total current assets	<u>44,499</u>	<u>43,762</u>
Property and equipment	<u>1,044</u>	<u>833</u>
Other assets		
In-process research and development	25,802	-
Goodwill	1,976	-
Deposits, deferred fees and other assets	236	1,055
Patent license fees, net	15	21
Total other assets	<u>28,029</u>	<u>1,076</u>
Total assets	<u>\$ 73,572</u>	<u>\$ 45,671</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 6,211	\$ 4,160
Notes payable - current portion	2,701	11
Deferred revenue - current portion	500	500
Total current liabilities	<u>9,412</u>	<u>4,671</u>
Earn-out milestone liability	13,878	-
Common stock warrant liability	398	3
Notes payable, net of discounts	6,888	5,000
Deferred revenue	3,625	4,000
Other non-current liabilities	454	473
Total liabilities	<u>34,655</u>	<u>14,147</u>
Stockholders' equity		
Preferred stock	-	-
Common stock	201	137

Additional paid-in capital	229,447	203,139
Accumulated other comprehensive loss	(26)	(44)
Accumulated deficit	(188,501)	(169,287)
^ Subtotal	41,121	33,945
Less: Treasury stock	(2,204)	(2,421)
Total stockholders' equity	<u>38,917</u>	<u>31,524</u>
Total liabilities and stockholders' equity	\$ <u>73,572</u>	\$ <u>45,671</u>

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SOURCE Celsion Corporation

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