



March 12, 2015

## **Celsion Corporation Reports Year End 2014 Financial Results and Provides Business Update**

**Clinical Development Pathway Established for GEN-1 in Ovarian and Brain Cancer; Phase III OPTIMA Trial Actively Recruiting Patients in U.S., Europe and Asia Pacific; On Track to Launch Phase II Euro-DIGNITY Study for RCW Breast Cancer in Mid-2015  
Company to Hold Conference Call on Thursday, March 12, 2015 at 11:00 a.m. ET**

LAWRENCEVILLE, N.J., March 12, 2015 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the year ended December 31, 2014 and 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. The Company's lead program is ThermoDox® which is currently in Phase III development for the treatment of primary liver cancer and in Phase II development for the treatment of recurrent chest wall breast cancer. The Company's immunotherapy program consists of GEN-1, an IL-12 DNA plasmid vector encased in a nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein and is currently under development for the localized treatment of ovarian and brain cancers.

"We enter 2015 well-positioned as we continue to make significant progress in our ongoing clinical, regulatory and business strategies. With the substantial and growing support from the medical and scientific community, the encouragement of key regulatory bodies in the United States, Europe and Asia, a strong balance sheet, and impressive overall survival data from the HEAT Study, we are especially encouraged by progress in our clinical development program for ThermoDox in both primary liver cancer and RCW breast cancer," said Michael H. Tardugno, Celsion's president and CEO. "The immunotherapy and RNA therapy platforms that we gained when we acquired EGEN provide synergy, complementary assets and multiple opportunities to create additional value for our shareholders, and we look forward to advancing GEN-1 into a first-line ovarian cancer study mid-year and to the prospect of a high potential GBM program shortly thereafter."

### ***Recent Pipeline Developments***

#### **ThermoDox®**

**Reported Convincing Updated Survival Data from Phase III HEAT Study.** As of January 15, 2015, 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 59% improvement in OS compared to optimized RFA alone. The Hazard Ratio at this analysis is 0.628 (95% CI 0.420 - 0.939) with a p-value of 0.02. This data continues to suggest that ThermoDox® may significantly improve OS compared to a RFA control in patients whose lesions undergo optimized RFA treatment for 45 minutes or more.

"These findings provide a strong rationale for the ongoing OPTIMA Study and may also underscore the interest of clinical investigators to evaluate the potential of ThermoDox plus optimized RFA for curative intent among intermediate stage HCC patients," noted Riccardo Lencioni, MD, FSIR, EBIR, professor and director of the diagnostic imaging and intervention at the Pisa University School of Medicine in Italy.

**Partnered with myTomorrows to Introduce the ThermoDox® Early Access Program (EAP) in Europe.** In January 2015, Celsion announced a license and distribution agreement with myTomorrows to implement an EAP for ThermoDox® in all countries of the European Union territory plus Switzerland for the treatment of patients with recurrent chest wall (RCW) breast cancer. The Company expects to have ThermoDox® available in the second quarter of 2015 for sales to physicians who are treating patients with limited therapeutic options. The EAP provides physicians with access to products in later stage development demonstrating evidence of clinical benefit, with an acceptable safety profile and a quality manufacturing process in place. Celsion will be allowed to price ThermoDox at commercial rates.

**Advancing Plans to Launch the DIGNITY Study in Europe.** Reflecting remarkable overall response rates in prior studies of patients with refractory disease, Celsion remains on track to initiate the Euro-DIGNITY Trial of ThermoDox® plus hyperthermia in patients with RCW breast cancer in the first half of 2015. The study will be conducted in five countries with

the eventual objective of an RCW breast cancer label for ThermoDox. Celsion will conduct the trial with the support of key European investigators and with assistance from MedLogics Corporation, an Italian-based hyperthermia device company.

**Expanded Pivotal OPTIMA Study in Europe.** In September 2014, 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. In November 2014, the OPTIMA Study was approved via Europe's centralized Voluntary Harmonization Procedure, allowing the Company to begin enrolling patients at 14 clinical sites in Germany, Italy, France and Spain. The Company is aggressively initiating sites in North America, Europe and Asia Pacific and expects to enroll 550 patients at up to 100 clinical sites in 13 countries.

## **GEN-1 Immunotherapy**

**Announced Plans for a Phase Ib Study for GEN-1 in First-Line Ovarian Cancer.** In February 2015, Celsion announced that the U.S. Food and Drug Administration (FDA) has accepted, without comment, its planned Phase Ib dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer, which is expected to commence in mid-2015 at five to six U.S. clinical centers. The study will evaluate safety and efficacy and attempt to define an optimal dose and an enhanced patient population to carry forward into a Phase 2 trial.

**Presented Phase Ib Data for GEN-1 in Platinum-Resistant Ovarian Cancer.** The Company presented preliminary data from its recently completed study of GEN-1, its IL-12 coded DNA plasmid nanoparticle, in combination with pegylated doxorubicin in 16 patients with platinum-resistant ovarian cancer at the Molecular Medicine TRI-Conference in February 2015. The findings demonstrated that there were no overlapping toxicities between GEN-1, its subsequent immune system activation, and pegylated doxorubicin. An abstract for this study detailing efficacy findings and clinical response results has been submitted to ASCO for its upcoming annual conference in the second quarter.

**Ongoing Preclinical Studies in GBM to Support IND Filing in Mid-2015.** Celsion is conducting comprehensive preclinical studies to support an Investigational New Drug (IND) application for clinical studies of its immune system activator, GEN-1, in glioblastoma multiforme (GBM). As currently conceived, the Phase I study would provide GEN-1 for local administration, recruiting the immune system to combination with temozolomide to treat post-surgical patients. The study will recruit chemotherapy naive patients, whose immune system is theorized, will respond actively to IL-12 DNA-based immunotherapy.

## **TheraSilence**

**Presented Preclinical Data for TheraSilence™ Platform at the miRNA World Conference Workshop on miRNA Delivery.** In October 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 year ended December 31, 2014, Celsion reported a net loss of \$25.5 million, or \$1.38 per share, compared to a net loss of \$12.9 million, or \$0.95 per share, in 2013. Operating expenses were \$25.2 million in 2014 compared to \$15.9 million in 2013. Operating expenses in 2014 included a \$1.4 million one-time charge in connection with the acquisition of the assets of EGEN, Inc. In 2013, Celsion recorded an \$8.1 million non-cash gain related to the change in the common stock warrant liability compared to a \$0.2 million non-cash gain in the current year.

Research and development costs were \$15.0 million in 2014 compared to \$9.3 million in the prior year. The increase in 2014 is primarily due to costs associated with the startup of the Phase III OPTIMA Study and the integration of the operations associated with the acquisition of EGEN, Inc. in June 2014. General and administrative expenses were \$8.9 million in 2014 compared to \$6.5 million in the prior year due to higher personnel-related costs and professional fees. In 2014, Celsion recorded \$2.6 million in non-cash stock-based compensation expense compared to \$1.2 million in the same period of last year.

Net cash used in operations was \$21.4 million in 2014 compared to \$9.5 million in the prior year. The Company ended 2014 with \$37.1 million of total cash, investments and accrued interest on these investments.

## **Quarterly Conference Call**

The Company is hosting a conference call to provide a business update and discuss year-end 2014 financial results at 11:00 a.m. ET on Thursday, March 12, 2015. To participate in the call, interested parties may dial 1-888-428-9480 (Toll-Free/North America) or 1-719-785-1765 (International/Toll) and ask for the Celsion Corporation Year-End 2014 Conference Call (Conference Code: 3652186) 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 March 12, 2015 and will remain available until March 26, 2015. The replay can be accessed at 1-888-203-1112 (Toll-Free/North America) or 1-719-457-0820 (International/Toll) using Conference ID: 3652186. 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 Thursday, March 12, 2015.

## 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 and in Phase II development for the treatment of recurrent chest wall breast cancer. The pipeline also includes GEN-1, 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™, TheraSilence™ and RAST™. 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.*

## Celsion Investor Contact

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

	Year ended December 31,	
	2014	2013
<b>Licensing revenue</b>	\$ 500	\$ 500
<b>Operating expenses:</b>		
Research and development	14,969	9,364
General and administrative	8,861	6,547
Acquisition costs	1,385	-
Â Total operating expenses	25,215	15,911
<b>Loss from operations</b>	(24,715)	(15,411)
<b>Other income (expense):</b>		
Gain from valuation of common stock warrant liability	204	8,090
Gain from valuation of earn-out milestone liability	214	-
Interest, dividends and other income (expense), net	(1,197)	(930)
Total other income (expense), net	(779)	7,160
<b>Net Loss from operations</b>	(25,494)	(8,251)

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Â Â Non-cash deemed dividend from

AAA beneficial conversion feature on A

AAA convertible preferred stock offering

**Net loss attributable to common shareholders**

	-	(4,601)
	<u>\$(25,494)</u>	<u>\$(12,852)</u>

**Net loss per common share -**

**basic and diluted**

	<u>\$(1.38)</u>	<u>\$(0.95)</u>
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**Weighted average common shares outstanding - basic and diluted**

	<u>18,472</u>	<u>13,541</u>
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**Celsion Corporation**  
**Selected Balance Sheet Information**  
**(in thousands)**

<b>ASSETS</b>	<b>December 31,</b>	<b>December 31, 2013</b>
	<b>2014</b>	
<b>Current assets</b>		
Cash and cash equivalents	\$ 12,687	\$ 5,719
Investment securities and interest receivable on investment securities	24,383	37,368
Prepaid expenses and other current assets	436	675
Total current assets	<u>37,506</u>	<u>43,762</u>
<b>Property and equipment</b>	<u>1,171</u>	<u>833</u>
<b>Other assets</b>		
In-process research and development	25,802	-
Goodwill	1,976	-
Deposits	150	200
Other assets	90	876
Total other assets	<u>28,018</u>	<u>1,076</u>
<b>Total assets</b>	<u>\$ 66,695</u>	<u>\$ 45,671</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 5,937	\$ 4,160
Deferred revenue - current portion	500	500
Note payable - current portion	3,654	11
Total current liabilities	<u>10,091</u>	<u>4,671</u>
Earn-out milestone liability	13,664	-
Common stock warrant liability	275	3
Notes payable - noncurrent portion	6,053	5,000
Other liabilities - noncurrent portion	3,787	4,473
Total liabilities	<u>33,870</u>	<u>14,147</u>
<b>Stockholders' equity</b>		
Common stock	201	137
Additional paid-in capital	229,779	203,139
Accumulated other comprehensive loss	(16)	(44)
Accumulated deficit	(195,074)	(169,287)
	<u>34,890</u>	<u>33,945</u>
Less: Treasury stock	(2,065)	(2,421)
Total stockholders' equity	<u>32,825</u>	<u>31,524</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 66,695</u>	<u>\$ 45,671</u>

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