



May 12, 2015

## **Celsion Corporation Reports First Quarter 2015 Financial Results and Provides Business Update**

### **Recruitment for the OPTIMA Study is Well Underway in U.S., Europe and Asia Pacific On Track to Launch Euro-DIGNITY Trial and Phase Ib GEN-1 First-Line Trial Mid-Year Company to Hold Conference Call on Tuesday, May 12, 2015 at 11:00 a.m. EDT**

LAWRENCEVILLE, N.J., May 12, 2015 /PRNewswire/ -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the quarter ended March 31, 2015 and provided an update on its development programs, including ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin, and GEN-1, an IL-12 DNA-based immunotherapy encased in a synthetic nanoparticle delivery system, which is currently under development for the localized treatment of ovarian and brain cancers.Â

"Over the past quarter, we have reported meaningful progress with both ThermoDox® and GEN-1," said Michael H. Tardugno, Celsion's chairman, president and CEO.Â "Positive data for GEN-1 in platinum-resistant ovarian cancer provided important insights on its potential clinical utility and safety. Based on these impressive results, we are preparing to launch a Phase Ib trial in first-line ovarian cancer mid-year. We have also seen synergistic anti-cancer effects when combining GEN-1 with Avastin® in preclinical studies, and we look forward to launching a clinical study later this year to further explore this combination in platinum-resistant ovarian cancer patients."

Mr. Tardugno continued, "Remarkable interim data from our Phase II DIGNITY study reinforces our confidence in the potential of ThermoDox® in recurrent chest wall breast cancer.Â Consequently, we are accelerating our efforts in this indication with our upcoming Euro-DIGNITY study and our Early Access Program in Europe. In parallel, we continue to advance our global Phase III OPTIMA Study evaluating ThermoDox® in primary liver cancer. With enrollment well underway in North America, Europe and Asia Pacific, we are evaluating exciting strategic options for the China market."

#### **Recent Pipeline Developments**

##### **ThermoDox®**

**Reported Positive Interim Data from the Phase II US DIGNITY Study in RCW Breast Cancer.Â** In April 2015, Celsion announced positive interim data from its Phase II DIGNITY trial of ThermoDox® in recurrent chest wall (RCW) breast cancer.Â 12 of the original 16 patients enrolled and treated were eligible for evaluation.Â Based on available data, 67% of patients experienced a clinical benefit, with a local response rate of 58%, including 5 complete responses, 2 partial responses, and 1 patient with stable disease.Â These results are consistent with previous clinical data from the Company's Phase I DIGNITY Study and a Duke University sponsored Phase I trial of ThermoDox® in this same refractory patient population, and warrant our accelerated clinical study plans for Europe.

**Advancing Plans to Launch the Euro-DIGNITY Study in Europe.Â** Reflecting remarkable overall response rates in prior studies of patients with refractory disease,Â Celsion remains on track to initiate the Euro-DIGNITY Trial of ThermoDox® plus hyperthermia in patients with RCW breast cancer in mid-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. With hyperthermia as an accepted adjuvant treatment for cancer in Europe, Celsion anticipates a very receptive patient recruitment environment for the 100 patient study.

**Partnered with myTomorrows to Introduce the ThermoDox® Early Access Program (EAP) in Europe. Â** 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 and myTomorrows launched the ThermoDox Early Access Program in late April with ThermoDox® now available 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.Â Celsion will be allowed to price ThermoDox at commercial rates.

**Updated Overall Survival Data from Phase III HEAT Study Continues to Strongly Support the Clinical Protocol for the OPTIMA 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. These data continue to support the protocol for the Phase III OPTIMA Study, which is evaluating ThermoDox® in combination with optimized RFA, which will be standardized to a minimum of 45 minutes across all investigators and clinical sites for treating lesions 3 to 7 centimeters, versus standardized RFA alone. The study is expected to enroll up to 550 patients globally in up to 80 clinical sites in the United States, Europe, China and Asia Pacific.

## **GEN-1 IL-12 DNA-based Immunotherapy**

**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. Full data from this study will be presented at the upcoming ASCO meeting on May 29 to June 4, 2015.

**On Track to Initiate a Phase Ib Study for GEN-1 in First-Line Ovarian Cancer in Mid-2015.** Celsion expects to commence a Phase Ib dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer 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 II trial.

**Announced GEN-1 Plus Avastin® Clinical Strategy Based on the Combination's Synergistic Anti-Cancer Effects.** Celsion is expanding its ovarian cancer development program to include a Phase 1 dose escalating trial evaluating GEN-1 in combination with Avastin® and Doxil® in platinum-resistant ovarian cancer patients, expected to begin enrollment in the first half of 2016. The new trial is supported by preclinical studies demonstrating that the combination of GEN-1 with Avastin® may result in significant clinical benefit with a favorable safety profile.

**IND Filings for GEN-1 in Platinum Resistant Ovarian Cancer and GBM Brain Cancer Expected in Second Half of 2015.** Celsion is conducting comprehensive preclinical studies to support an Investigational New Drug (IND) application for clinical studies of its GEN-1 in platinum resistant ovarian cancer in combination with Doxil® and Avastin® and in glioblastoma multiforme (GBM). As currently conceived, the Phase I study for GBM may provide GEN-1 for local administration, recruiting the immune system to combination with standard of care to treat post-surgical patients.

## **Financial Results**

For the quarter ended March 31, 2015, Celsion reported a net loss of \$7.0 million, or \$0.35 per share, compared to a net loss of \$5.4 million, or \$0.33 per share, in the same period of 2014. Operating expenses were \$6.5 million in the first quarter of 2015 compared to \$5.3 million in the same period of 2014. Net cash used in operations was \$5.9 million in the first quarter of 2015 compared to \$4.8 million in the same period last year. The Company ended the first quarter of 2015 with \$30.0 million of total cash, investments and accrued interest on these investments.

Research and development costs were \$4.5 million in the first quarter of 2015 compared to \$2.9 million the same period last year. The increase in 2015 is primarily due to costs associated with the operations of EGEN, Inc., which the Company acquired in June 2014, and the costs associated with the initiation of the Phase III OPTIMA Study in the first quarter of 2014. General and administrative expenses were \$2.0 million in the first quarter of 2015 compared to \$2.4 million the same period of 2014. This decrease was primarily the result of lower insurance premiums. In the first quarter of 2015, Celsion recorded \$0.8 million in non-cash stock-based compensation expense compared to \$0.6 million in the same period of 2014.

## **Quarterly Conference Call**

The Company is hosting a conference call to provide a business update and discuss first quarter 2015 financial results at 11:00 a.m. EDT on Tuesday, May 12, 2015. To participate in the call, interested parties may dial 1-888-427-9411 (Toll-Free/North America) or 1-719-457-2661 (International/Toll) and ask for the Celsion Corporation First Quarter 2015 Conference Call (Conference Code: 5892530) 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 May 12, 2015 and will remain available until May 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:

5892530. 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 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.*

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

**Three Months Ended**  
**March 31,**

	<u>2015</u>	<u>2014</u>
<b>Licensing revenue</b>	\$ 125	\$ 125
<b>Operating expenses:</b>		
Research and development	4,506	2,893
General and administrative	2,032	2,434
Total operating expenses	<u>6,538</u>	<u>5,327</u>
<b>Loss from operations</b>	<u>(6,413)</u>	<u>(5,202)</u>
<b>Other income (expense):</b>		
(Loss) gain from valuation of common stock warrant liability	(43)	3
(Loss) from valuation of earn-out milestone liability	(172)	-
Interest, dividends and other income (expense), net	<u>(377)</u>	<u>(224)</u>
Total other income (expense), net	<u>(592)</u>	<u>(221)</u>
<b>Net Loss from operations</b>	<u>\$ (7,005)</u>	<u>\$ (5,423)</u>
<b>Net loss per common share -</b>		
<b>basic and diluted</b>	<u>\$ (0.35)</u>	<u>\$ (0.33)</u>
<b>Weighted average common shares outstanding - basic and diluted</b>	<u>19,990</u>	<u>16,371</u>

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**Celsion Corporation**  
**Selected Balance Sheet Information**  
(in thousands)

<b>ASSETS</b>	<b>March 31,</b>	<b>December 31,</b>
	<b>Â 2015</b>	<b>2014</b>
<b>Current assets</b>		
Cash and cash equivalents	\$ 7,614	\$ 12,687
Investment securities and interest receivable	22,434	24,383
Â on investment securities	625	436
Prepaid expenses and other current assets	30,673	37,506
Total current assets	<u>30,673</u>	<u>37,506</u>
<b>Property and equipment</b>	<u>1,106</u>	<u>1,171</u>
<b>Other assets</b>		
In-process research and development	25,802	25,802
Goodwill	1,976	1,976
Deposits	150	150
Other assets	77	90
Total other assets	<u>28,005</u>	<u>28,018</u>
<b>Total assets</b>	<u>\$ 59,784</u>	<u>\$ 66,695</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 6,036	\$ 5,937
Deferred revenue - current portion	500	500
Note payable - current portion	3,756	3,654
Total current liabilities	<u>10,292</u>	<u>10,091</u>
Earn-out milestone liability	13,836	13,664
Common stock warrant liability	318	275
Notes payable - noncurrent	5,188	6,053
Other liabilities - noncurrent portion	3,446	3,787
Total liabilities	<u>33,080</u>	<u>33,870</u>
<b>Stockholders' equity</b>		
Common stock	201	201
Additional paid-in capital	230,628	229,779
Accumulated other comprehensive loss	(8)	(16)
Accumulated deficit	(202,253)	(195,074)
	<u>28,568</u>	<u>34,890</u>
Less: Treasury stock	(1,864)	(2,065)
Total stockholders' equity	<u>26,704</u>	<u>32,825</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 59,784</u>	<u>\$ 66,695</u>

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