

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington , DC 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 30, 2016

CELSION CORPORATION  
(Exact name of registrant as specified in its Charter)

Delaware

(State or other jurisdiction  
of incorporation)

001-15911

(Commission  
File Number)

52-1256615

(IRS Employer  
Identification No.)

997 Lenox Drive, Suite 100, Lawrenceville, NJ  
(Address of principal executive offices)

08648-2311  
(Zip Code)

(609) 896-9100

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 2.02 Results of Operations and Financial Condition.**

On March 30, 2016, Celsion Corporation issued a press release reporting its financial results for the year ended December 31, 2015. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On March 23, 2016, Celsion Corporation announced it would hold a conference call on March 30, 2016 to discuss its financial results for the year ended December 31, 2015 and provide a business update. The conference call will also be broadcast live on the internet at <http://www.celsion.com>.

The information in this report, including the exhibit hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. Such information shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by Celsion Corporation, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

The press release contains forward-looking statements which involve certain risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Please refer to the cautionary note in the press release regarding these forward-looking statements.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release titled “Celsion Corporation Reports Year End 2015 Financial Results and Provides Business Update” issued by Celsion Corporation on March 30, 2016.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CELSION CORPORATION

Dated: March 30, 2016

By: /s/ Jeffrey W. Church  
Jeffrey W. Church  
Senior Vice President and Chief Financial Officer



## **Celsion Corporation Reports Year End 2015 Financial Results and Provides Business Update**

*Company to Hold Conference Call on Wednesday, March 30, 2016 at 11:00 a.m. EDT*

**LAWRENCEVILLE, N.J.**, March 30, 2016 -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the year ended December 31, 2015 and provided an update on its development programs for ThermoDox®, its proprietary heat-activated liposomal encapsulation of doxorubicin and 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. 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 and is currently in Phase I development for the localized treatment of ovarian cancer.

"Celsion had a very productive 2015. We entered 2016 with a clear vision for leveraging two leading-edge technology platforms designed to enhance clinically powerful therapies. These approaches provide us with an opportunity to deliver cutting edge therapeutics that address prevalent cancers with high unmet needs, while at the same time driving growth for the Company and value for our shareholders," said Michael H. Tardugno, Celsion's chairman, president and CEO. "Over the past year, we have demonstrated the potential of ThermoDox and GEN-1, and we plan to build on this progress in 2016, as we focus our efforts on the pivotal Phase III OPTIMA Study and the Phase II Euro-DIGNITY Study for ThermoDox, and advancing GEN-1 in ovarian cancer."

### **Recent Developments**

#### **ThermoDox®**

**Announced the launch of the OPTIMA Study in China.** On March 5, 2016, the Company held an Investigators' Meeting for the OPTIMA Study in Shanghai, China. Professor Ronnie T.P. Poon, MD, MBBS, MS, PhD, FRCS (Edin), FACS, Medical Director at the Hong Kong Integrated Oncology Center, Honorary Professor of Surgery at the University of Hong Kong Queen Mary Hospital, and member of the International Liver Cancer Association (ILCA) Governing Board provided the Keynote Address entitled "*Treatment Strategies for Early/Intermediate HCC.*" Professor Poon discussed strategies for treating different stages of primary liver cancer. Investigators and their staff from 20 sites in mainland China and Hong Kong were in attendance. With the addition of these Chinese clinical sites, the Company expects to complete enrollment in the OPTIMA Study by the end of 2017. Results from the OPTIMA Study, if successful, will provide the basis for a global registration filing and marketing approval.

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**Received CFDA approval to conduct the OPTIMA Study in China.** In December 2015, Celsion announced that it has received Clinical Trial Application (CTA) approval from the China Food and Drug Administration (CFDA) to conduct the ongoing Phase III OPTIMA Study at clinical sites in China. This approval by the CFDA represents another important validation of the Company's development program for ThermoDox®, which shows the potential for improvement in overall survival in HCC patients. The Phase III OPTIMA Study is expected to enroll up to 550 patients globally, and has been successfully enrolling patients at 50 clinical sites in 12 different countries in North America, Europe and Asia Pacific. The CTA approval will now allow Celsion to enroll patients at up to 20 additional clinical sites in China.

**Presented DIGNITY Phase I/II ThermoDox® Data at the 2015 San Antonio Breast Cancer Symposium.** In December 2015, the Company presented results from its ongoing Phase I/II US DIGNITY Study of ThermoDox® in combination with mild hyperthermia in patients with recurrent chest wall (RCW) breast cancer which demonstrated a combined local response rate of 62% among evaluable patients treated with ThermoDox®. In addition to a local response rate of 62% among evaluable patients, a combined local response rate was observed in 46% of the intent-to-treat population (13/28), notably consisting of five patients demonstrating a durable local response lasting greater than three months. The Company plans to initiate a 70 patient Phase II study in Europe and Israel in less advanced, less heavily pretreated patients as part of the Euro-DIGNITY Trial. The Euro-DIGNITY Trial will evaluate ThermoDox® plus radiation and hyperthermia in RCW breast cancer patients.

### **GEN-1 Immunotherapy**

**Reported translational data from its Phase Ib Study of GEN-1 Immunotherapy in recurrent ovarian cancer.** In January 2016, the Company announced new translational data from its Phase Ib study of GEN-1 in patients with platinum-resistant ovarian cancer. The new data indicated that intraperitoneally-administered GEN-1 produces an immunologically distinct IL-12 protein that is localized at the tumor site and lasts for up to one week after a single treatment. In addition, concomitant increases in IFN- $\alpha$  and TNF- $\alpha$  indicate that the IL-12 produced following treatment with GEN-1 treatment is immunologically active. Celsion intends to collect additional translational data, including cellular responses in primary tumor tissue and peritoneal ascites, in its ongoing OVATION Study, a Phase I dose escalation study in newly diagnosed ovarian cancer patients in the neoadjuvant setting.

**Announced completion of enrollment of the first cohort of patients in the Phase 1b OVATION Study.** In February 2016, the Company reported that the first two patients in the OVATION Study who completed treatment have shown promising results. Both patients reported stable disease with a dramatic drop in their CA-125 protein levels of 89% and 98%. Cancer antigen 125 (CA-125) is used to monitor certain cancers during and after treatment. A 50% reduction in CA-125 levels is considered meaningful. Both patients' CA-125 levels were below the normal healthy level of 35 U/mL. In addition, both patients experienced successful surgical resections of their tumors with one patient reporting a R0 resection which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed.

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**Announced presentation of preclinical data for GEN-1 IL-12 Immunotherapy in combination with Avastin® and Doxil® at the American Association for Cancer Research (AACR) Annual Meeting 2016.** In March 2016, the Company announced that preclinical data for GEN-1 in combination with Avastin® and Doxil® for the treatment of ovarian cancer will be presented at the upcoming AACR Annual Meeting 2016. The presentation will summarize results from preclinical studies demonstrating significant synergistic anti-cancer effects when GEN-1 is combined with Avastin® and Doxil®, a current Standard of Care (SoC) for platinum resistant ovarian cancer patients. The preclinical studies show that GEN-1 when combined with Avastin® and Doxil® indicated a greater than 98% reduction in tumor burden when compared to the untreated control group. The findings represent a statistically significant reduction in tumor burden and disease progression when compared to the combination of Avastin® and Doxil®. These preclinical data will be used by the Company to support a comprehensive IND protocol filing for a Phase I/II clinical trial evaluating the combination in recurrent ovarian cancer later this year.

### **TheraSilence**

**Announced the issuance of a key U.S. Patent covering its novel TheraSilence™ RNA Program.** In March 2016, the Company announced that the U.S. Patent and Trademark Office issued a key patent (U.S. Patent No. 9,254,334 B2) which provides broad intellectual property protection covering the therapeutic use of the Company's proprietary TheraSilence™ lung-specific delivery system in a broad range of therapeutic entities, including the delivery of synthetically-generated inhibitory RNA (RNAi) such as small inhibitory RNAs (siRNAs), microRNAs, microRNA mimics, anti-microRNAs and related molecules that can regulate protein expression at the transcript level by exploiting endogenous cell mechanisms.

### **Corporate Development**

**Appointment of two new members to Celsion's Board of Directors.** In December 2015, the Company announced the appointment of Donald P. Braun, Ph.D. and Andreas Voss, M.D., to the Company's Board of Directors. Dr. Braun brings over 30 years of research expertise in oncology, with a focus on immunotherapy and the effectiveness and impact of chemotherapy protocols on various cancers and tumor types, and currently serves as Vice President Translational Research and Chief Science Officer at the Cancer Treatment Centers of America. Dr. Voss currently serves as Vice President of Clinical Affairs in Europe at Caris Life Sciences, a biotechnology company focused on implementing personalized medicine in oncology through its liquid biopsy technology. Prior to joining Caris in 2010, he was responsible for the global clinical development of Avastin® and a member of the Corporate Drug Safety Board at F. Hoffmann-La Roche.

### **Financial Results**

For the year ended December 31, 2015, Celsion reported a net loss of \$22.5 million, or \$1.03 per share, compared to a net loss of \$25.5 million, or \$1.38 per share, in 2014. Operating expenses were \$21.3 million in 2015 compared to \$25.2 million in 2014. This decrease was primarily due to lower general and administrative expenses coupled with a \$1.4 million one-time charge in connection with the acquisition of the assets of EGEN, Inc. in 2014.

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Research and development costs were \$14.7 million in 2015 compared to \$15.0 million in the prior year as a result of the Company's tighter clinical development focus around the pivotal Phase III OPTIMA Study for the treatment of primary liver cancer and the clinical development program for GEN-1 IL-12 immunotherapy for the localized treatment of ovarian cancer. General and administrative expenses were \$6.7 million in 2015 compared to \$8.9 million in the prior year. This \$2.2 million decrease in general and administrative expenses in 2015 is primarily the result of lower insurance premiums, reductions in personnel costs and reduced marketing expenses when compared to 2014.

Net cash used in operations was \$20.8 million in 2015 compared to \$21.4 million in the prior year. The Company ended 2015 with \$20.1 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 2015 financial results at 11:00 a.m. ET on Wednesday, March 30, 2016. To participate in the call, interested parties may dial 1-800-505-9587 (Toll-Free/North America) or 1-416-204-9524 (International/Toll) and ask for the Celsion Corporation Year-End 2015 Conference Call (Conference Code: 4103364) to register ten minutes before the call is scheduled to begin. The call will also be broadcast live on the internet at [www.celsion.com](http://www.celsion.com).

The call will be archived for replay on March 30, 2016 and will remain available until April 13, 2016. The replay can be accessed at 1-888-203-1112 (Toll-Free/North America) or 1-719-457-0820 (International/Toll) using Conference ID: 4103364. An audio replay of the call will also be available on the Company's website, [www.celsion.com](http://www.celsion.com), for 30 days after 2:00 p.m. ET Wednesday, March 30, 2016.

### **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<sup>®</sup>, 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 two platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlas<sup>™</sup> and TheraSilence<sup>™</sup>. For more information on Celsion, visit our website: <http://www.celsion.com> (CLSN-FIN).

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*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; 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,	
	2015	2014
<b>Licensing revenue</b>	\$ 500	\$ 500
<b>Operating expenses:</b>		
Research and development	14,660	14,969
General and administrative	6,687	8,861
Acquisition costs	-	1,385
Total operating expenses	<u>21,347</u>	<u>25,215</u>
<b>Loss from operations</b>	<u>(20,847)</u>	<u>(24,715)</u>
<b>Other (expense) income:</b>		
(Loss) gain from valuation of earn-out milestone liability	(258)	214
(Loss) gain valuation of common stock warrant liability	(61)	204
Interest expense, investment income and other income (expense), net	(1,295)	(1,197)
Total other (expense) income, net	<u>(1,614)</u>	<u>(779)</u>
<b>Net loss</b>	<u>\$ (22,461)</u>	<u>\$ (25,494)</u>
<b>Net loss per common share - basic and diluted</b>	<u>\$ (1.03)</u>	<u>\$ (1.38)</u>
<b>Weighted average common shares outstanding - basic and diluted</b>	<u>21,813</u>	<u>18,472</u>

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

<b>ASSETS</b>	<b>December 31, 2015</b>	<b>December 31, 2014</b>
<b>Current assets</b>		
Cash and cash equivalents	\$ 9,265	\$ 12,687
Investment securities and interest receivable on investment securities	10,827	24,383
Prepaid expenses and other current assets	189	436
Total current assets	<u>20,281</u>	<u>37,506</u>
<b>Property and equipment</b>	855	1,171
<b>Other assets</b>		
In-process research and development	25,802	25,802
Goodwill	1,976	1,976
Deposits	100	150
Other assets	41	90
Total other assets	<u>27,919</u>	<u>28,018</u>
<b>Total assets</b>	<u>\$ 49,055</u>	<u>\$ 66,695</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 4,750	\$ 5,937
Deferred revenue - current portion	500	500
Note payable - current portion	4,100	3,654
Total current liabilities	<u>9,350</u>	<u>10,091</u>
Earn-out milestone liability	13,921	13,664
Common stock warrant liability	-	275
Notes payable - noncurrent portion	2,350	6,053
Other liabilities - noncurrent portion	3,048	3,787
Total liabilities	<u>28,669</u>	<u>33,870</u>
<b>Stockholders' equity</b>		
Common stock	234	201
Additional paid-in capital	239,668	229,779
Accumulated other comprehensive loss	(4)	(16)
Accumulated deficit	(218,130)	(195,074)
	<u>21,768</u>	<u>34,890</u>
Less: Treasury stock	(1,382)	(2,065)
Total stockholders' equity	<u>20,386</u>	<u>32,825</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 49,055</u>	<u>\$ 66,695</u>