

**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): August 9, 2011

**Celsion Corporation**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-15911**  
(Commission File Number)

**52-1256615**  
(IRS Employer  
Identification No.)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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**52-1256615**  
(I.R.S. Employer  
Identification Number)

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

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**08648**  
(Zip Code)

**(609) 896-9100**  
(Registrant's telephone number, including area code)

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**10220-L Old Columbia Road**  
**Columbia, Maryland 21046**

(Former name, former address and former fiscal year, if changed since last report)

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

- Written communication 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 240.135-4(c))

**Item 2.02 Results of Operations and Financial Condition.**

On November 10, 2011, Celsion Corporation issued a press release reporting its financial results for the quarter ended September 30, 2011 (the "Earnings Release"). The Earnings Release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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 Statement and Exhibits.**

(d) Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
99.1	Earnings Release, dated November 10, 2011, furnished pursuant to Item 2.02 of Form 8-K.

**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.

Date: November 10, 2011

CELSION CORPORATION

By: /s/ Gregory Weaver

Gregory Weaver

Senior Vice President and Chief Financial Officer

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## Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Earnings Release, dated November 10, 2011, furnished pursuant to Item 2.02 of Form 8-K.

## Celsion Reports Third Quarter 2011 Financial Results and Provides Business Updates

Company to Hold Conference Call Thursday, November 10<sup>th</sup> at 11:00 a.m. ET

LAWRENCEVILLE, NJ – November 10, 2011 – Celsion Corporation (NASDAQ:CLSN), a leading oncology drug development company, today announced financial results for the third quarter ended September 30, 2011, and provided a business update including development progress with ThermoDox®, Celsion's proprietary heat-activated liposomal encapsulation of doxorubicin currently under evaluation in a pivotal Phase III study, the HEAT Study, in patients with non-resectable primary liver cancer. The Company recently announced that the HEAT Study, which is being conducted under a U.S. Food and Drug Administration (FDA) Special Protocol Assessment, has received FDA Fast Track Designation and has been designated as a Priority Trial for liver cancer by the National Institutes of Health, has reached its enrollment target of 600 patients.

"The third quarter was a pivotal period in our evolution as a biopharmaceutical company, having reached the enrollment objective in our Phase III HEAT Study," said Michael H. Tardugno, Celsion's President and Chief Executive Officer. "Celsion has taken great care over the past several years to conduct this study to the highest standards of clinical, statistical and regulatory rigor, in an effort to ensure a successful review process in a multitude of territories around the world, following a positive study outcome. These efforts are particularly significant as we approach the preplanned interim analysis, which is scheduled for the current quarter. The Company remains well funded to execute this study to final data readout, which we continue to anticipate in late 2012."

### Recent Business Developments

- In August, Celsion announced that it had reached its target enrollment of 600 patients in the Company's pivotal, Phase III HEAT study, a multinational, randomized, double-blind, placebo-controlled clinical study of ThermoDox® in combination with radio frequency ablation (RFA) for the treatment of primary liver cancer. The target enrollment figure is designed to ensure that the study's primary end point, progression-free survival, can be achieved with statistical significance, and is one of two triggers for an interim efficacy analysis by the study's independent Data Monitoring Committee, the second being a minimum of 190 progression-free survival events realized in the study population. The HEAT study is being conducted under a FDA Special Protocol Assessment, has received FDA Fast Track Designation and has been designated as a Priority Trial for liver cancer by the National Institutes of Health;
- During the third quarter ended September 30, 2011, the Company strengthened its balance sheet through the completion of the following two equity financing transactions:
  - o In July, a registered direct offering of \$6.6 million in common stock and warrants.
  - o In July, sales of an aggregate \$18.4 million of the Company's securities, of which \$13.0 million was from institutional investors in a registered direct offering and an additional \$5.4 million was from other investors in a private placement.

### Financial Results

For the third quarter ended September 30, 2011, Celsion reported a net loss of \$6.4 million, or \$0.25 per share, compared to a net loss of \$4.7 million, or \$0.38 per share, in the same period of 2010. For the first nine months of 2011, net cash used in operations was \$18.3 million. Celsion reported a net loss of \$17.1 million for the first nine months of 2011, compared to a net loss of \$13.5 million for the same period of 2010. In the third quarter of 2011, Celsion recorded a \$375,000 non-cash benefit related to the change in the common stock warrant liability compared to \$453,000 in the same period of last year. In the first nine months of 2011, Celsion recorded a \$42,000 non-cash charge related to the change in the common stock warrant liability compared to a non-cash benefit of \$712,000 in the same period last year.

Research and development costs, as expected, were \$1.5 million higher in the third quarter of 2011 compared to the prior year, primarily due to increased costs for investigator grants, monitoring costs and milestone payments associated with higher patient enrollment levels for the Company's Phase III HEAT study. Also contributing to this increase were activities associated with development expenses related to commercial manufacturing for ThermoDox®. General and administrative expenses were \$189,000 higher in the quarter ended September 30, 2011 compared to the prior year as a result of increased professional services and personnel costs to support the company's growth.

For the third quarter ended September 30, 2011, net cash used in operations was \$6.9 million. The Company ended the quarter with \$21.4 million of cash and investments. This figure included gross proceeds of \$19.6 million from two registered direct financings, \$5.4 million from a private placement financing and \$0.4 million from common stock warrant exercises completed during the third quarter of 2011.

### Other Business Highlights

- In August, Celsion convened a clinical symposium in Hong Kong to discuss the reach and market potential of ThermoDox® in the Asia Pacific region. In attendance at the symposium were 35 clinical investigators participating in the Phase III HEAT Study. The Asia Pacific region has the world's highest incidence of HCC, due primarily to the endemic status of chronic hepatitis B and C viruses, which lead to liver cirrhosis and an increased risk of liver cancer. With a growing incidence, it is projected that HCC will surpass lung cancer as the largest global cancer indication within the next decade;
- In August, Celsion announced the publication of a clinical and scientific review of ThermoDox® in the August 2011 issue of *Future Oncology* (Volume 7, Number 8). The article, titled "Lyso-Thermosensitive Liposomal Doxorubicin: An Adjuvant to Increase the Cure Rate of Radiofrequency Ablation (RFA) in Liver Cancer," provides an overview of current standard and investigational approaches to the treatment of HCC, focusing on the curative and synergistic potential of combining lyso-thermosensitive liposomal doxorubicin (LTLD or "ThermoDox®") and RFA as front-line therapy;
- In August, Celsion appointed Gary Renshaw, D.O., as Executive Medical Director. Dr. Renshaw possesses an extensive record of successful drug development in oncology, with industry experience in various clinical and regulatory positions at DelCath Systems, Celgene Corporation, Johnson & Johnson PRD, Eisai Co., and Eli Lilly and Company; and
- In late October, the Company moved into its new corporate headquarters at 997 Lenox Drive, Suite 100, Lawrenceville, New Jersey 08648, under attractive lease terms. The Company received a New Jersey Economic Development Authority Business Employment Incentive Program (BEIP) grant,

approved in August, to support the move. The grant provides for up to \$1.12 million in tax incentives for jobs created in, or relocated to the State. The Company's new telephone number is (609) 896-9100.

## **Quarterly Conference Call**

The Company is hosting a conference call to provide a business update and discuss the third quarter 2011 results at 11:00 a.m. Eastern Time Thursday, November 10, 2011. To participate in the call, interested parties may dial 1-888-427-9380 (Toll-Free/North America) or 1-719-785-1749 (International/Toll) and use Conference ID: 3247371 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 November 10, 2011 at 2:00 p.m. ET and will remain available until November 17, 2011. The replay can be accessed at 1-877-870-5176 (Toll-Free/North America) or 1-858-384-5517 (International/Toll) using Conference ID: 3247371. 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, November 10, 2011.

## **About Primary Liver Cancer**

Primary liver cancer is one of the most deadly forms of cancer and ranks as the fifth most common solid tumor cancer. The incidence of primary liver cancer is approximately 20,000 cases per year in the United States, approximately 40,000 cases per year in Europe and is rapidly growing worldwide at approximately 700,000 cases per year, due to the high prevalence of Hepatitis B and C in developing countries. The standard first-line treatment for liver cancer is surgical resection of the tumor; however, 90% of patients are ineligible for surgery. Radio frequency ablation (RFA) has increasingly become the standard of care for non-resectable liver tumors, but the treatment becomes less effective for larger tumors. There are few non-surgical therapeutic treatment options available as radiation therapy and chemotherapy are largely ineffective in the treatment of primary liver cancer.

## **About ThermoDox® and the Phase III HEAT Study**

ThermoDox® is a proprietary heat-activated liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. In the HEAT Study, ThermoDox® is administered intravenously in combination with RFA. Localized mild hyperthermia (39.5 - 42 degrees Celsius) created by the RFA releases the entrapped doxorubicin from the liposome. This delivery technology enables high concentrations of doxorubicin to be deposited preferentially in a targeted tumor.

For primary liver cancer, ThermoDox® is being evaluated in a 600 patient global Phase III study at 76 clinical sites under an FDA Special Protocol Assessment. The study is designed to evaluate the efficacy of ThermoDox® in combination with Radio Frequency Ablation (RFA) when compared to patients who receive RFA alone as the control. The primary endpoint for the study is progression-free survival (PFS) with a secondary confirmatory endpoint of overall survival. A pre-planned, unblinded interim efficacy analysis will be performed by the study's independent Data Monitoring Committee by year end. Additional information on the Company's ThermoDox® clinical studies may be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

## **About Celsion Corporation**

Celsion is a leading oncology company dedicated to the development and commercialization of innovative cancer drugs including tumor-targeting treatments using focused heat energy in combination with heat-activated drug delivery systems. Celsion has research, license, or commercialization agreements with leading institutions such as the National Institutes of Health, Duke University Medical Center, University of Hong Kong, the University of Pisa, and the North Shore Long Island Jewish Health System.

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 by others; possible acquisitions of other technologies, assets or businesses; possible actions by customers, suppliers, competitors, regulatory authorities; and other risks detailed from time to time in the Company's periodic reports filed with the Securities and Exchange Commission.*

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**Celsion Corporation**  
**Condensed Statements of Operations**

(in thousands except for per share amounts)  
(Unaudited)

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
<b>Licensing revenue</b>	\$ -	\$ -	\$ 2,000	\$ -
<b>Operating expenses:</b>				
Research and development	5,414	3,951	14,727	10,666
General and administrative	1,409	1,220	3,906	3,544
Total operating expenses	<u>6,823</u>	<u>5,171</u>	<u>18,633</u>	<u>14,210</u>
<b>Loss from operations</b>	<u>(6,823)</u>	<u>(5,171)</u>	<u>(16,633)</u>	<u>(14,210)</u>
<b>Other income (expense):</b>				
Gain (loss) from valuation of common stock warrant liability	375	453	(42)	712
Interest, dividends and other income (expense), net	55	1	(426)	6
Total other income (expense), net	<u>430</u>	<u>454</u>	<u>(468)</u>	<u>718</u>
<b>Net Loss</b>	<u>\$ (6,393)</u>	<u>\$ (4,717)</u>	<u>\$ (17,101)</u>	<u>\$ (13,492)</u>
<b>Net loss per common share –     basic and diluted</b>	<u>\$ (0.25)</u>	<u>\$ (0.38)</u>	<u>\$ (0.93)</u>	<u>\$ (1.10)</u>
<b>Weighted average common shares outstanding – basic and     diluted</b>	<u>25,150</u>	<u>12,340</u>	<u>18,360</u>	<u>12,303</u>

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

	<b>(Unaudited)</b>	
	<b>September</b>	<b>December</b>
<b>ASSETS</b>	<b>30,</b>	<b>31, 2010</b>
	<b>2011</b>	<b>2010</b>
<b>Current assets</b>		
Cash and cash equivalents	\$ 11,133	\$ 1,139
Short term investments	10,277	396
Prepaid expenses and other current assets	804	492
Total current assets	<u>22,214</u>	<u>2,027</u>
Property and equipment	<u>583</u>	<u>378</u>
<b>Other assets</b>		
Deposits and other assets	350	77
Patent license fees, net	38	43
Total other assets	<u>388</u>	<u>120</u>
<b>Total assets</b>	<u>\$ 23,185</u>	<u>\$ 2,525</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 4,549	\$ 6,673
Note payable - current portion	89	123
Total current liabilities	<u>4,638</u>	<u>6,796</u>
Common stock warrant liability	291	248
Other liabilities – noncurrent portion	-	57
Total liabilities	<u>4,929</u>	<u>7,101</u>
<b>Stockholders' equity (deficit)</b>		
Common stock	274	141
Additional paid-in capital	139,140	99,317
Accumulated other comprehensive loss	(157)	(18)
Accumulated deficit	(118,091)	(100,939)
Subtotal	<u>21,166</u>	<u>(1,499)</u>
Less: Treasury stock	(2,910)	(3,077)
Total stockholders' equity (deficit)	<u>18,256</u>	<u>(4,576)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 23,185</u>	<u>\$ 2,525</u>