

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): November 10, 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 November 10, 2016, Celsion Corporation issued a press release reporting its financial results for the three and nine month periods ended September 30, 2016. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On November 3, 2016, Celsion Corporation announced it would hold a conference call on November 10, 2016 to discuss its financial results for the three and nine month periods ended September 30, 2016 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.

Exhibit No.	Description
99.1	Press Release titled “Celsion Corporation Reports Third Quarter 2016 Financial Results and Provides Business Update ” issued by Celsion Corporation on November 10, 2016.

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: November 10, 2016

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

EXHIBIT INDEX

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Celsion Corporation Reports Third Quarter 2016 Financial Results and Provides Business Update

Meaningful Progress with the ThermoDox® OPTIMA Study and GEN-1 Immunotherapy Program, Including Highly Encouraging Data from Primary Liver and Ovarian Cancer Studies

Company to Hold Conference Call Today, November 10, 2016 at 11:00 a.m. ET

LAWRENCEVILLE, N.J., November 10, 2016 -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the quarter and nine month period ended September 30, 2016 and provided an update on its development programs for ThermoDox®, the Company's proprietary heat-activated liposomal encapsulation of doxorubicin and GEN-1, an IL-12 DNA-based immunotherapy.

"Over the last nine months, we have realized meaningful progress with respect to our two lead programs, ThermoDox® and GEN-1. Importantly, we are well positioned to sustain this momentum through the balance of 2016 and beyond," said Michael H. Tardugno, Celsion's chairman, president and CEO. "The initial data from our GEN-1 program provides highly valuable insights into its favorable clinical and safety profile indicating a great deal of potential in both first and second-line ovarian cancer, and we look forward to reporting additional data from our ongoing OVATION study before year-end."

Mr. Tardugno continued, "Our ongoing global, pivotal Phase III OPTIMA Study of ThermoDox® in primary liver cancer remains on track with clinical sites currently enrolling patients in 13 countries worldwide. Investigators continue to recognize the value of findings from the HEAT Study and their continued interest reinforces substantial and mounting support for the OPTIMA Study. The recent independent analysis conducted by the National Institutes of Health provides further confirmatory support indicating that the use of radiofrequency ablation (RFA) for more than 45 minutes in patients treated with ThermoDox® can have a correlative impact on reductions in tumor size and overall survival in patients with primary liver cancer."

Recent Developments

Immunotherapy - GEN-1

Announced Positive Data from the First Two Cohorts of the OVATION Study. In July 2016, the Company announced data from the second cohort of patients in its Phase Ib dose escalating clinical trial (the OVATION Study) combining GEN-1 with the standard of care for the treatment of newly-diagnosed patients with advanced ovarian cancer who will undergo neoadjuvant chemotherapy followed by interval debulking surgery. In the first six patients dosed, GEN-1 plus standard chemotherapy produced impressive results, with no dose limiting toxicities and highly promising efficacy signals in this difficult-to-treat cancer. The efficacy data included highly encouraging tumor response rates, successful surgical resections of the eligible patients' tumors, impressive pathological responses and dramatic, clinically meaningful drops in CA-125 protein levels.

Positive DSMB Review of OVATION Study in Ovarian Cancer. In September 2016, the independent Data Safety Monitoring Board (DSMB) completed its safety review of data from the first three patient cohorts in the ongoing Phase Ib OVATION Study. Based on the DSMB's recommendation, the study will continue as planned and the Company will proceed with dosing in its fourth and final patient cohort at an escalated dose. Celsion expects the fourth cohort to be fully enrolled this year.

Established a Manufacturing and Commercial Supply Agreement with Hisun for GEN-1. In August 2016, Celsion signed a long term technology transfer, manufacturing and commercial supply agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. The agreement relates to both the clinical and commercial manufacture and supply of GEN-1 for the greater China territory, with the option to expand into other countries in the rest of the world after all necessary regulatory approvals are in effect. With highly cost effective pricing, the agreement will support economically advantaged supply for ongoing and planned clinical studies in the United States and potential future studies of GEN-1 in China as well as Europe.

Chemotherapy - ThermoDox®

Announced the Final Overall Survival Data from HEAT Study of ThermoDox® in Primary Liver Cancer. In August 2016, the Company announced updated results from its final retrospective analysis of the 701-patient HEAT Study. The overall survival analysis demonstrated that in a large, well bounded, subgroup of 285 patients (41% of the HEAT Study patients), treatment with a combination of ThermoDox® and optimized RFA provided an average 54% risk improvement in overall survival compared to optimized RFA alone. The Hazard Ratio (HR) at this analysis is 0.65 (95% CI 0.45 - 0.94) with a p-value of 0.02. Importantly, after 3.5 years of follow up, the median overall survival for the ThermoDox® group has yet to be reached and is showing over 80 months survival benefit compared to less than 60 months projection for the optimized RFA only group, which translates into a two year survival benefit.

Announced the Independent NIH Analysis Showing Treatment with ThermoDox® Plus RFA may Significantly Improve Overall Survival of Patients with Primary Liver Cancer. In September 2016, the Company announced that the National Institutes of Health (NIH) has conducted an independent retrospective analysis of data from the Company's HEAT Study. The NIH analysis, which sought to evaluate the correlation between RFA burn time per tumor volume (min/ml) and clinical outcome in patients treated with ThermoDox®, concluded that increased RFA burn time per tumor volume substantially improved survival in patients with solitary lesions treated with RFA + ThermoDox® compared to patients treated with RFA alone. These findings are consistent with Celsion's analysis of the HEAT Study data showing that in patients treated with RFA for more than 45 minutes, standardized RFA plus ThermoDox® resulted in a statistically significant improvement in overall survival of over two years when compared to standardized RFA alone.

Detailed findings from the NIH study will be presented during oral sessions on Monday, November 28, 2016 at 1:50 pm CT during the 102nd Scientific Assembly and Annual Meeting of the Radiological Society of North America (RSNA) to be held on November 26 – December 2, 2016 in Chicago, IL.

Announced Presentations Highlighting Phase III OPTIMA Study at Two Asia-Pacific Primary Liver Cancer Expert Meetings.

In July 2016, the Company announced that its ongoing Phase III OPTIMA trial evaluating ThermoDox® in primary liver cancer was featured during an oral presentation at the 7th Asia-Pacific Primary Liver Cancer Expert (APPLE) Meeting in Hong Kong, China. The presentation highlighted the potential of ThermoDox® plus optimized RFA to significantly improve overall survival of newly diagnosed patients.

In October 2016, the Company announced the presentation of data from the Company's HEAT Study, highlighting the curative potential for ThermoDox® plus optimized RFA in intermediate primary liver cancer at the 3rd Asian Conference on Tumor Ablation (ACTA) in Seoul, Korea.

Announced Collaboration with the Children's Research Institute to Evaluate the Use of ThermoDox® and High Intensity Focused Ultrasound in the Treatment of Solid Tumors in Children and Young Adults. In October 2016, the Company announced a collaboration with the Children's Research Institute to conduct a clinical study of ThermoDox® in combination with magnetic resonance-guided high intensity focused ultrasound to treat relapsed or refractory solid tumors in children and young adults. This investigator-sponsored Phase I clinical study is being partially funded by the National Institutes of Health and is expected to commence in the fourth quarter of 2016.

Financial Results

For the quarter ended September 30, 2016, Celsion reported a net loss of \$6.4 million, or \$(0.23) per share, compared to a net loss of \$4.3 million, or \$(0.19) per share, in the same period of 2015. Operating expenses were \$5.7 million in the third quarter of 2016 compared to \$4.4 million in the same period of 2015. For the nine month period ended September 30, 2016, the Company reported a net loss of \$16.7 million, or \$(0.66) per share, compared to \$16.9 million, or \$(0.79) per share, in the same nine month period of 2015. Operating expenses were \$15.9 million in the first nine months of 2016 compared to \$16.3 million in the same period of 2015. Net cash used in operations was \$13.7 million in the first nine months of 2016 compared to \$16.9 million in the same period last year. The Company ended the third quarter of 2016 with \$8.7 million of total cash, investments and accrued interest on these investments, which included the proceeds of a \$6 million registered direct offering completed during the second quarter.

Research and development costs were \$4.2 million in the third quarter of 2016 compared to \$2.9 million in the same period last year. Research and development costs were \$11.0 million in the first nine months of 2016 and 2015. R&D costs in 2016 reflect lower clinical supply costs for the ThermoDox® and GEN-1 clinical studies offset by increased costs associated with the enrollment in the OPTIMA and the OVATION studies when compared to 2015. General and administrative expenses were \$1.5 million in the third quarter of 2016 and 2015. General and administrative expenses were \$4.9 million in the first nine months of 2016, down 8 percent when compared to the same period of 2015. This decrease was primarily the result of lower personnel related costs and professional fees.

Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss third quarter 2016 financial results at 11:00 a.m. ET on Thursday, November 10, 2016. To participate in the call, interested parties may dial 1-800-533-7619(Toll-Free/North America) or 1-785-830-1923 (International/Toll) and ask for the Celsion Corporation Third Quarter 2016 Conference Call (Conference Code: 9409290) 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.

The call will be archived for replay on November 10, 2016 and will remain available until November 24, 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: 9409290. An audio replay of the call will also be available on the Company's website, www.celsion.com, for 30 days after 2:00 p.m. ET Thursday, November 10, 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®, 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™ and TheraSilence™. For more information on Celsion, visit our website: <http://www.celsion.com> (CLSN-FIN).

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; the risk that if Celsion is not able to raise additional capital when needed, there would be a delay, reduction in the scope, or termination of our research, development, clinical programs and commercialization efforts; and other risks detailed from time to time in Celsion's most recent Form 10-K and Form 10-K/A that were filed with the Securities and Exchange Commission (SEC) on March 30, 2016 and April 29, 2016, respectively, and its other periodic filings with the SEC, including subsequent periodic reports on Forms 10-Q and 8-K. 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)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Licensing revenue	\$ 125	\$ 125	\$ 375	\$ 375
Operating expenses:				
Research and development	4,225	2,883	11,003	10,958
General and administrative	1,497	1,484	4,888	5,317
Total operating expenses	<u>5,722</u>	<u>4,367</u>	<u>15,891</u>	<u>16,275</u>
Loss from operations	<u>(5,597)</u>	<u>(4,242)</u>	<u>(15,516)</u>	<u>(15,900)</u>
Other income (expense):				
(Loss) gain valuation of common stock warrant liability	(662)	283	(557)	41
Loss from valuation of common stock warrant liability	-	-	-	(61)
Interest expense, investment income and other income (expense), net	(151)	(308)	(584)	(1,027)
Total other income (expense), net	<u>(813)</u>	<u>(25)</u>	<u>(1,141)</u>	<u>(1,047)</u>
Net loss	<u>\$ (6,410)</u>	<u>\$ (4,267)</u>	<u>\$ (16,657)</u>	<u>\$ (16,947)</u>
Net loss per common share				
Basic and diluted	<u>\$ (0.23)</u>	<u>\$ (0.19)</u>	<u>\$ (0.66)</u>	<u>\$ (0.79)</u>
Weighted average shares outstanding				
Basic and diluted	<u>27,905</u>	<u>23,023</u>	<u>25,146</u>	<u>21,335</u>

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	September 30, 2016	December 31, 2015
ASSETS		
Current assets		
Cash and cash equivalents	\$ 4,184	\$ 9,265
Investment securities and interest receivable on investment securities	4,516	10,827
Prepaid expenses and other current assets	331	189
Total current assets	<u>9,031</u>	<u>20,281</u>
Property and equipment	<u>544</u>	<u>855</u>
Other assets		
In-process research and development	25,802	25,802
Goodwill	1,976	1,976
Deposits	100	100
Other assets	8	14
Total other assets	<u>27,886</u>	<u>27,892</u>
Total assets	<u>\$ 37,461</u>	<u>\$ 49,028</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 5,671	\$ 4,750
Deferred revenue - current portion	500	500
Note payable - current portion	3,593	4,073
Total current liabilities	<u>9,764</u>	<u>9,323</u>
Earn-out milestone liability	14,478	13,921
Notes payable - noncurrent portion	-	2,350
Other liabilities - noncurrent portion	2,647	3,048
Total liabilities	<u>26,889</u>	<u>28,642</u>
Stockholders' equity		
Common stock	261	234
Additional paid-in capital	246,401	239,668
Accumulated other comprehensive loss	-	(4)
Accumulated deficit	<u>(235,673)</u>	<u>(218,130)</u>
	10,989	21,768
Less: Treasury stock	<u>(417)</u>	<u>(1,382)</u>
Total stockholders' equity	<u>10,572</u>	<u>20,386</u>
Total liabilities and stockholders' equity	<u>\$ 37,461</u>	<u>\$ 49,028</u>