

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 5, 2015

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 5, 2015, Celsion Corporation issued a press release reporting its financial results for the three and nine month periods ended September 30, 2015. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On October 29, 2015, Celsion Corporation announced it would hold a conference call on November 5, 2015 to discuss its financial results for the three and nine month periods ended September 30, 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.

Exhibit No.	Description
99.1	Press Release titled “Celsion Corporation Reports Third Quarter 2015 Financial Results and Provides Business Update” issued by Celsion Corporation on November 5, 2015.

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 5, 2015

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 2015 Financial Results and Provides Business Update

Company to Hold Conference Call on Thursday, November 5, 2015 at 11:00 a.m. EST

LAWRENCEVILLE, NJ – November 5, 2015 – Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the quarter ended September 30, 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 minimizes toxicity and maximizes the multiple antitumor effects of IL-12 and is currently under development for the localized treatment of ovarian and brain cancers.

“During the past quarter, we reported positive data highlighting the multiple development opportunities for our chemotherapy and immunotherapy products, broadened our European Early Access Program to include primary liver cancer and realigned our current organization structure, which we expect to provide the most efficient path forward for our broad, diversified product pipeline with a focus on generating clinical data from our GEN-1 platform,” said Michael H. Tardugno, Celsion’s chairman, president and CEO. “We plan to initiate multiple clinical studies over the next six to twelve months, including the Euro-DIGNITY study evaluating ThermoDox in breast cancer, a Phase 1b trial for GEN-1 in first-line ovarian cancer, and a second trial evaluating GEN-1 in combination with Avastin® and Doxil® in platinum-resistant ovarian cancer patients. Enrollment of patients in our global Phase III OPTIMA Study evaluating ThermoDox® in primary liver cancer is continuing to build momentum. Lastly, we plan to leverage our TheraSilence RNAi lung-directed delivery platform through non-dilutive licensing and co-development collaborations.”

Recent Developments

ThermoDox®

Reported Positive Interim Data from the Phase II US DIGNITY Study in RCW Breast Cancer.

In July 2015, Celsion announced continuing positive interim data from its Phase II DIGNITY trial of ThermoDox® in recurrent chest wall (RCW) breast cancer. Of the 17 patients enrolled and treated in the DIGNITY Study, 13 were eligible for evaluation of efficacy. Based on available data, every patient experienced a clinical benefit of their highly refractory disease with a local response rate of 69% observed in the 13 evaluable patients, including 5 complete responses, 4 partial responses and 4 patients with stable disease. Local tumor control in this population provides clinical benefit sufficient to warrant its designation as a primary endpoint for pivotal studies.

Announced Updated Overall Survival Data from Phase III HEAT Study, Providing Support for the Clinical Protocol for the Phase III OPTIMA Study.

In August 2015, Celsion announced the latest Overall Survival (OS) analysis (as of July 15, 2015) from the Phase III HEAT Study. The findings, which were demonstrated in a large, well bounded, well defined subgroup of patients (n=285, 41% of the study patients), showed that the combination of ThermoDox® and optimized RFA provided a 58% improvement in OS compared to optimized RFA alone. The Hazard Ratio at this analysis is 0.63 (95% CI 0.43 - 0.93) with a p-value of 0.0198. Median overall survival for the ThermoDox® group has been reached which translates into a 25.4 month (2.1 year) survival benefit over the optimized RFA only group (79 months for the ThermoDox® plus optimized RFA group versus 53.6 months for the optimized RFA only group). An overall survival benefit greater than 60 months is widely recognized as curative.

In September 2015, the Company announced presentations by three leading experts in the treatment of primary liver cancer at the 2015 International Liver Cancer Association (ILCA) 9th Annual Conference during a symposium entitled “*Intermediate HCC: Cure vs. Palliation.*” These experts noted that ThermoDox may represent a treatment with curative potential if the subgroup findings from the HEAT Study are confirmed.

Earlier this week, the Company announced several presentations by leading liver cancer experts in Asia highlighting the curative potential for ThermoDox plus optimized RFA at the 2nd Asian Conference on Tumor Ablation. The presentations at both of these meetings support the protocol for the Phase III OPTIMA Study which is expected to enroll up to 550 patients globally in up to 75 clinical sites in the United States, Europe, China and Asia Pacific. The Company noted that the presentations at ACTA now represent the fifth international medical conference and the seventh time that the Overall Survival data from the HEAT Study has been discussed by leading experts in HCC research.

Expanded the ThermoDox® Early Access Program (EAP) in Europe.

In August, the Company and myTomorrows expanded the ThermoDox European Early Access Program to include patients with primary liver cancer and liver cancer metastases in all countries in the European Union territory, Switzerland, Turkey and Israel. The Company’s original EAP with myTomorrows, formed in January 2015, provides eligible patients with access to ThermoDox® for the treatment of recurrent chest wall breast cancer. 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.

GEN-1 IL-12 DNA-Based Immunotherapy

Enrolled the First Patient in the OVATION Study

In October 2015, Celsion announced the enrollment of the first patient in its Phase Ib dose escalating clinical trial (the OVATION Study) combining GEN-1, the Company’s DNA-based immunotherapy, with standard of care for the treatment of newly diagnosed ovarian cancer patients who will undergo neoadjuvant chemotherapy. Interim results from this open label study will be available with patient evaluability and will continue through the first half of next year at higher doses of GEN-1.

Announced Confirmatory Preclinical Data for its GEN-1 IL-12 Immunotherapy in Combination with Avastin® and Doxil® for Ovarian Cancer

In October 2015, Celsion announced results from a large, comprehensive, preclinical program of the Company's GEN-1 IL-12 immunotherapy in combination with Avastin® and Doxil® for the treatment of platinum resistant ovarian cancer. The preclinical studies provide evidence of a robust and synergistic anti-cancer advantage compared to untreated animals and suggest a statistically significant improvement over the combination of Avastin® and Doxil®. These studies support an IND filing for a Phase I/II trial evaluating the combination in ovarian cancer later this year.

Corporate Developments

Completed Integration of June 2014 EGEN Acquisition

During the third quarter of 2015, the Company completed the integration of its June 2014 acquisition of EGEN, Inc. with the consolidation of all early stage preclinical assets at its Huntsville, AL facility. All clinical development, commercialization, business development and administrative functions are now located in Lawrenceville, NJ. From this reorganization, the Company expects to realize a 15 to 20 percent reduction in personnel and related annual operational costs.

Financial Results

For the quarter ended September 30, 2015, Celsion reported a net loss of \$4.3 million, or \$(0.19) per share, compared to a net loss of \$6.9 million, or \$(0.40) per share, in the same period of 2014. Operating expenses were \$4.4 million in the third quarter of 2015 compared to \$6.8 million in the same period of 2014. For the nine month period ended September 30, 2015, the Company reported a net loss of \$16.9 million, or \$(0.79) per share, compared to \$19.0 million, or \$(1.12) per share, in the same period of 2014. Operating expenses were \$16.3 million in the first nine months of 2015 compared to \$18.7 million in the same period of 2014. Net loss and operating expenses for the three-month and nine-month periods ended September 30, 2014 included \$0.1 million and \$1.2 million, respectively of one-time costs associated with the June 2014 acquisition of EGEN, Inc. Net cash used in operations was \$16.9 million in the first nine months of 2015 compared to \$14.8 million in the same period last year. The Company ended the third quarter of 2015 with \$24.4 million of total cash, investments and accrued interest on these investments.

Research and development (R&D) costs were \$2.8 million in the third quarter of 2015 compared to \$4.6 million the same period last year. Research and development costs were \$11.0 million in the first nine months of 2015 compared to \$10.7 million the same period last year. The increase in R&D costs in 2015 is primarily due to expenses associated with the operations of EGEN, Inc., the costs associated with the start-up and initiation of the Phase III OPTIMA Study in 2014 and the production of clinical supplies in 2015 for anticipated GEN-1 Phase I studies. General and administrative expenses were \$1.5 million in the third quarter of 2015 compared to \$2.0 million the same period of 2014. General and administrative expenses were \$5.3 million in the first nine months of 2015 compared to \$6.8 million the same period of 2014. These decreases were primarily the result of lower insurance premiums and lower personnel costs resulting from the reorganization and staff reductions announced during the third quarter of 2015.

Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss the third quarter 2015 financial results at 11:00 a.m. EST on Thursday, November 5, 2015. To participate in the call, interested parties may dial 1-877-419-6594 (Toll-Free/North America) or 1-719-325-4755 (International/Toll) and ask for the Celsion Corporation Third Quarter 2015 Conference Call (Conference Code: 939465) 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 Thursday, November 5, 2015 and will remain available until Thursday, November 19, 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: 939465. 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. EST Thursday November 5, 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 investigational 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, including timing, enrollment and data; 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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Licensing revenue	\$ 125	\$ 125	\$ 375	\$ 375
Operating expenses:				
Research and development	2,883	4,630	10,958	10,688
General and administrative	1,484	2,044	5,317	6,783
Acquisition costs	–	120	–	1,188
Total operating expenses	<u>4,367</u>	<u>6,794</u>	<u>16,275</u>	<u>18,659</u>
Loss from operations	<u>(4,242)</u>	<u>(6,669)</u>	<u>(15,900)</u>	<u>(18,284)</u>
Other (expense) income:				
Gain (loss) from change in valuation of common stock warrant liability	–	97	(61)	81
Gain from change in valuation of earn-out milestone liability	283	–	41	–
Investment income, net	15	27	49	57
Interest expense	(323)	(419)	(1,075)	(913)
Other expense	–	22	(1)	20
Total other (expense) income, net	<u>(25)</u>	<u>(273)</u>	<u>(1,047)</u>	<u>(755)</u>
Net loss	<u>(4,267)</u>	<u>(6,942)</u>	<u>(16,947)</u>	<u>(19,039)</u>
Net loss per common share				
Basic and diluted	<u>\$ (0.19)</u>	<u>\$ (0.40)</u>	<u>\$ (0.79)</u>	<u>\$ (1.12)</u>
Weighted average shares outstanding				
Basic and diluted	<u>23,023</u>	<u>17,527</u>	<u>21,335</u>	<u>16,932</u>

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

ASSETS	September 30, 2015	December 31, 2014
Current assets		
Cash and cash equivalents	\$ 7,575	\$ 12,687
Investment securities and interest receivable on investment securities	16,798	24,383
Prepaid expenses and other current assets	404	436
Total current assets	<u>24,777</u>	<u>37,506</u>
Property and equipment	<u>955</u>	<u>1,171</u>
Other assets		
In-process research and development	25,802	25,802
Goodwill	1,976	1,976
Deposits and other assets	149	240
Total other assets	<u>27,927</u>	<u>28,018</u>
Total assets	<u>\$ 53,659</u>	<u>\$ 66,695</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 3,952	\$ 5,937
Deferred revenue – current portion	500	500
Note payable - current portion	3,977	3,654
Total current liabilities	<u>8,429</u>	<u>10,091</u>
Earn-out milestone liability	13,622	13,664
Common stock warrant liability	–	275
Notes payable – noncurrent portion	3,344	6,053
Other liabilities – noncurrent portion	3,181	3,787
Total liabilities	<u>28,576</u>	<u>33,870</u>
Stockholders' equity		
Common stock	231	201
Additional paid-in capital	238,865	229,779
Accumulated other comprehensive loss	(2)	(16)
Accumulated deficit	(212,489)	(195,074)
Total stockholders' equity	<u>26,605</u>	<u>34,890</u>
Less: Treasury stock	(1,522)	(2,065)
Total stockholders' equity	<u>25,083</u>	<u>32,825</u>
Total liabilities and stockholders' equity	<u>\$ 53,659</u>	<u>\$ 66,695</u>