

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 10, 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 August 10, 2015, Celsion Corporation issued a press release reporting its financial results for the three and six month periods ended June 30, 2015. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On August 3, 2015, Celsion Corporation announced it would hold a conference call on August 10, 2015 to discuss its financial results for the three and six month periods ended June 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 Second Quarter 2015 Financial Results and Provides Business Update” issued by Celsion Corporation on August 10, 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: August 10, 2015

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



Celsion Corporation Reports Second Quarter 2015 Financial Results and Provides Business Update

ThermoDox® and GEN-1 Advancing Toward Key Trials Later this Year

Company to Hold Conference Call on Monday, August 10, 2015 at 11:00 a.m. EDT

LAWRENCEVILLE, NJ – August 10, 2015 – Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the quarter ended June 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 is currently under development for the localized treatment of ovarian and brain cancers.

“Over the past few months, we reported positive data highlighting the multiple development opportunities for our portfolio, launched our European Early Access Program for ThermoDox in recurrent chest wall breast cancer and strengthened our balance sheet, providing a strong foundation as we advance our pipeline,” said Michael H. Tardugno, Celsion's chairman, president and CEO. “We remain on track to initiate key clinical studies this year, including the Euro-DIGNITY study evaluating ThermoDox in breast cancer, a Phase 1b trial for GEN-1 in first-line ovarian cancer, and a trial evaluating GEN-1 with Avastin® in platinum-resistant ovarian cancer patients. In parallel, we continue enroll patients from North America, Europe and Asia Pacific in our global Phase III OPTIMA Study evaluating ThermoDox® in primary liver cancer. Finally, we continue to evaluate ways to leverage our TheraSilence technology platform to advance the development of RNAi therapeutics that can be delivered directly to the lung.”

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, notably 5 complete responses, 4 partial responses and 4 patients with stable disease.

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

As of July 15, 2015, the latest 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 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). 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 75 clinical sites in the United States, Europe, China and Asia Pacific.

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

The Company and myTomorrows launched the ThermoDox Early Access Program in the second quarter, making ThermoDox® 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. Celsion will be allowed to price ThermoDox at commercial rates.

GEN-1 IL-12 DNA-Based Immunotherapy

Presented Phase Ib Data for GEN-1 in Platinum-Resistant Ovarian Cancer at ASCO.

In May 2015, Celsion presented clinical results from the Phase Ib trial for GEN-1 in combination with pegylated doxorubicin in 16 patients with platinum-resistant ovarian cancer in a poster session at the 2015 American Society of Clinical Oncology (ASCO) Meeting in Chicago. The clinical findings demonstrated an overall clinical benefit of 57% for all treatment arms, with a partial response (PR) rate of 21% and a stable disease (SD) rate of 36%. The overall clinical benefit observed at the highest dose cohort in this difficult-to-treat patient population was 100% (PR=33% and SD=67%) in all six evaluable patients. GEN-1 was well tolerated, with no dose limiting toxicities and no overlapping toxicities between GEN-1 and pegylated doxorubicin.

TheraSilence™

Demonstrated Potent, Durable Preclinical Lung Expression Data for Its TheraSilence™.

In May 2015, Celsion reported data from a preclinical study confirming that its TheraSilence™ technology platform can safely and effectively deliver RNA to the lungs in non-human primates, enabling the development of RNA therapeutics for lung diseases. In the study, TheraSilence-formulated signaling RNA resulted in preferential expression in the lungs, with expression in the liver at less than 15% of expression levels observed in the lungs, and expression levels in tissues other than the lung, spleen and liver at very low or background levels. A liver-directed delivery system, used as a positive control for the study, yielded preferential expression in liver and spleen, with only background expression levels observed in the lung.

Published Preclinical Data Demonstrating Lung Specific Delivery of microRNA-145 Inhibitor Using the TheraSilence™ Platform.

In May 2015, an abstract published in the *Journal of Controlled Release* summarized findings from a preclinical study confirming effective delivery of RNA to lung cells. In the study, the Company's TheraSilence™ technology platform safely and effectively delivered an inhibitor of microRNA-145 (miR-145) in a well-established model of severe occlusive pulmonary arterial hypertension (PAH). Treatment was associated with significant delivery of miR-145 inhibitor in the lung, inhibition of miR-145 levels and reversal of the pulmonary hypertension associated with the advanced stages of the disease leading to a normalization of cardiovascular function.

Corporate Developments

Raised \$8 Million Through Registered Direct Equity Offering priced “at the market”.

During the second quarter of 2015, the Company completed an \$8 million at-the-market registered direct equity offering and a concurrent private placement of warrants to purchase common stock with two institutional healthcare investors.

Financial Results

For the quarter ended June 30, 2015, Celsion reported a net loss of \$5.7 million, or \$(0.27) per share, compared to a net loss of \$6.7 million, or \$(0.38) per share, in the same period of 2014. Operating expenses were \$5.4 million in the second quarter of 2015 compared to \$6.5 million in the same period of 2014. For the six month period ended June 30, 2015, the Company reported a net loss of \$12.7 million, or \$(0.62) per share, compared to \$12.1 million, or \$(0.71) per share, in the same period of 2014. Operating expenses were \$11.9 million in the first half of 2015 compared to \$11.9 million in the same period of 2014. Net loss and operating expenses for the three-month and six-month periods ended June 30, 2014 included \$1.1 million of one-time costs associated with the acquisition of EGEN, Inc. Net cash used in operations was \$11.6 million in the first half of 2015 compared to \$9.0 million in the same period last year. The Company ended the second quarter of 2015 with \$30.8 million of total cash, investments and accrued interest on these investments, which included the proceeds of an \$8 million registered direct offering that was completed during the quarter.

Research and development costs were \$3.6 million in the second quarter of 2015 compared to \$3.2 million the same period last year. Research and development costs were \$8.1 million in the first half of 2015 compared to \$6.1 million the same period last year. The increases 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 2014 and the production of clinical supplies in the first half of 2015 for the three GEN-1 Phase I studies. General and administrative expenses were \$1.8 million in the second quarter of 2015 compared to \$2.3 million the same period of 2014. General and administrative expenses were \$3.8 million in the first half of 2015 compared to \$4.7 million the same period of 2014. These decreases were primarily the result of lower insurance premiums and lower personnel costs.

Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss second quarter 2015 financial results at 11:00 a.m. EDT on Monday, August 10, 2015. To participate in the call, interested parties may dial 1-800-768-6490 (Toll-Free/North America) or 1-785-830-7987 (International/Toll) and ask for the Celsion Corporation Second Quarter 2015 Conference Call (Conference Code: 9366896) 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 August 10, 2015 and will remain available until August 24, 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: 9366896. 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 Monday, August 10, 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; 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 June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Licensing revenue	\$ 125	\$ 125	\$ 250	\$ 250
Operating expenses:				
Research and development	3,568	3,165	8,074	6,059
General and administrative	1,802	2,305	3,834	4,739
Acquisition costs	–	1,067	–	1,067
Total operating expenses	<u>5,370</u>	<u>6,538</u>	<u>11,908</u>	<u>11,865</u>
Loss from operations	<u>(5,245)</u>	<u>(6,413)</u>	<u>(11,658)</u>	<u>(11,615)</u>
Other (expense) income:				
Loss from valuation of common stock warrant liability	(69)	–	(242)	–
Loss from change in valuation of common stock warrant liability	(18)	(18)	(61)	(16)
Investment income, net	17	24	33	31
Interest expense	(360)	(263)	(753)	(494)
Other expense	–	(3)	1	(2)
Total other (expense) income, net	<u>(430)</u>	<u>(260)</u>	<u>(1,022)</u>	<u>(481)</u>
Net loss	<u>(5,675)</u>	<u>(6,673)</u>	<u>(12,680)</u>	<u>(12,096)</u>
Net loss per common share Basic and diluted	<u>\$ (0.27)</u>	<u>\$ (0.38)</u>	<u>\$ (0.62)</u>	<u>\$ (0.71)</u>
Weighted average shares outstanding Basic and diluted	<u>19,964</u>	<u>13,602</u>	<u>17,949</u>	<u>11,756</u>

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	June 30, 2015	December 31, 2014
ASSETS		
Current assets		
Cash and cash equivalents	\$ 11,951	\$ 12,687
Investment securities and interest receivable on investment securities	18,830	24,383
Prepaid expenses and other current assets	684	436
Total current assets	<u>31,465</u>	<u>37,506</u>
Property and equipment	<u>1,009</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	162	240
Total other assets	<u>27,940</u>	<u>28,018</u>
Total assets	<u>\$ 60,414</u>	<u>\$ 66,695</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 5,439	\$ 5,937
Deferred revenue – current portion	500	500
Note payable - current portion	3,865	3,654
Total current liabilities	<u>9,804</u>	<u>10,091</u>
Earn-out milestone liability	13,905	13,664
Common stock warrant liability	–	275
Notes payable – noncurrent portion	4,286	6,053
Other liabilities – noncurrent portion	3,314	3,787
Total liabilities	<u>31,309</u>	<u>33,870</u>
Stockholders' equity		
Common stock	231	201
Additional paid-in capital	238,645	229,779
Accumulated other comprehensive loss	(4)	(16)
Accumulated deficit	<u>(208,075)</u>	<u>(195,074)</u>
	30,797	34,890
Less: Treasury stock	<u>(1,692)</u>	<u>(2,065)</u>
Total stockholders' equity	<u>29,105</u>	<u>32,825</u>
Total liabilities and stockholders' equity	<u>\$ 60,414</u>	<u>\$ 66,695</u>