

CELSION CORP

FORM 8-K (Current report filing)

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Address	997 LENOX DRIVE SUITE 100 LAWRENCEVILLE, NJ 08648
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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 16, 2017

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 16, 2017, Celsion Corporation issued a press release reporting its financial results for the year ended December 31, 2016. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On March 9, 2017, Celsion Corporation announced it would hold a conference call on March 16, 2017 to discuss its financial results for the year ended December 31, 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 Year End 2016 Financial Results and Provides Business Update” issued by Celsion Corporation on March 16, 2017.

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 16, 2017

By: /s/ Jeffrey W. Church

Jeffrey W. Church

Senior Vice President and Chief Financial Officer



Celsion Corporation Reports Year End 2016 Financial Results and Provides Business Update

Company to Hold Conference Call on Thursday, March 16, 2017 at 11:00 a.m. E T

LAWRENCEVILLE, N.J., March 16, 2017 -- Celsion Corporation (NASDAQ: CLSN), an oncology drug development company, today announced financial results for the year ended December 31, 2016 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 an exceedingly productive 2016 as our accomplishments, one after another, established meaningful progress with respect to our two leading-edge technology platforms designed to enhance clinically powerful therapies. With sound fundamentals, the superb execution of our ongoing global, pivotal Phase III OPTIMA Study in primary liver cancer, continues to attract interest and support from the medical community, international regulatory agencies, and research organizations like the National Institutes of Health for this ground-breaking study," said Michael H. Tardugno, Celsion's chairman, president and CEO. "Our efforts in immuno-oncology are equally important. Over the past year, we have demonstrated the potential of our GEN-1 program to be an effective adjuvant, in both first and second-line ovarian cancer. Recruiting the immune system to work in combination with the standard of care in this patient population has been the goal of medical researchers worldwide. With GEN-1, we believe there is the potential for a break-through and we look forward to reporting comprehensive clinical findings and translational data from our nearly complete OVATION Study in the first half of 2017."

Recent Developments

ThermoDox®

Announced the Independent NIH Analysis Showing Treatment with ThermoDox® Plus RFA may Significantly Improve Overall Survival of Patients with Primary Liver Cancer. In November 2016, the Company announced the presentation of results from an independent retrospective analysis conducted by the National Institutes of Health (NIH) on the intent-to-treat population of the Company's HEAT Study during The Interventional Oncology Series: Hepatocellular Carcinoma and Cholangiocarcinoma at the 102nd Scientific Assembly and Annual Meeting of the Radiological Society of North America (RSNA). The NIH analysis, which sought to evaluate the correlation between RFA burn time per tumor volume (min/ml) and clinical outcome, concluded that increased burn time per tumor volume significantly improved overall survival (OS) in patients with solitary lesions treated with RFA + ThermoDox® compared to patients treated with RFA alone. More specifically, the analysis showed that a one unit increase in RFA duration per tumor volume improved OS by 20% in patients treated with optimized RFA + ThermoDox® compared to 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.

Announced Support for the OPTIMA Study from the China FDA and Vietnam Ministry of Health. The Company discussed ThermoDox® and the OPTIMA Study with regulatory agencies in two key markets, China and Vietnam. The Company met with the China Food and Drug Administration (CFDA) to review the ongoing Phase III OPTIMA Study and regulatory pathway for ThermoDox® in China. CFDA was presented with the final overall survival data from the Chinese patient cohort of the HEAT study, which demonstrated a survival benefit in patients treated with ThermoDox® plus optimized RFA versus optimized RFA alone. The CFDA informed the Company that if the ongoing Phase III OPTIMA Study is successful, the trial could serve as the basis for a direct regulatory filing in China without the need to file for prior approval in the U.S. or European Union which is currently required for foreign company application. This would allow the Company to accelerate its plans for a regulatory filing in China and, if approved, provide for a significantly earlier launch date in China than originally expected. In addition, the Company's management team met with the Ministry of Health in Vietnam and based on that meeting, it will move forward with launching additional trial sites for the OPTIMA Study in that country. The Company expects to have approximately 5 additional clinical trial sites in Vietnam activated in early 2017. Vietnam represents a significant market for ThermoDox® where HCC incidence rates are among the highest in the world.

Announced the Issuance of Two New Patents for ThermoDox. In January 2017, the Company announced the issuance of two patents which are directly applicable to the method of treating cancer using our current ThermoDox® formulation. These new patents further strengthen the Company's global patent portfolio around novel heat-sensitive liposome engineered to address a broad range of difficult-to-treat cancers.

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 commenced in the fourth quarter of 2016.

GEN-1 Immunotherapy

Announced Continuing Positive Data from the OVATION Study in Newly Diagnosed Advanced Ovarian Cancer Patients. In January 2017, the Company announced data from the first four cohorts 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 twelve patients dosed in the OVATION Study, 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 - 100% disease control rate (DCR) and 75% objective response rate (ORR), successful surgical resections of the eligible patients' tumors, impressive pathological responses and dramatic, clinically meaningful drops in CA-125 protein levels.

Announced the Issuance of Two New U.S. Patents for GEN-1 Immuno-Oncology Product. In November 2016, the Company announced the issuance of two patents which expand the use of GEN-1 into additional cancer treatment modalities in combination with other chemotherapeutics and extends previous patent claims on the making of and composition of formulations consisting of our PPC delivery polymer and nucleic acids. These new patents further strengthen coverage of GEN-1 for the localized treatment of ovarian cancer and glioblastoma multiforme (GBM), which is already covered by a composition of matter patent in the United States.

Corporate Development

Raised \$6.8 Million Through Two Equity Offerings in December 2016 and February 2017. The Company completed two equity offerings of shares of common stock, or pre-funded warrants in lieu thereof, to purchase common stock with institutional healthcare and retail investors totaling \$6.8 million in gross proceeds.

Financial Results

For the year ended December 31, 2016, Celsion reported a net loss of \$22.1 million, or \$0.85 per share, compared to a net loss of \$22.5 million, or \$1.03 per share, in 2015. Operating expenses were \$21.1 million in 2016 compared to \$21.3 million in 2015. This decrease was primarily due to lower general and administrative expenses and clinical supply costs offset by higher clinical development costs for the Phase III OPTIMA Study.

Research and development (R&D) costs were constant at \$14.6 million in 2016 and 2015. Clinical development costs for the OPTIMA Study were \$5.6 million in 2016 compared to \$3.6 million in 2015 due to higher patient enrollment, investigator grants and site initiation expenses in the trial. R&D costs for other development programs were lower 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 coupled with lower costs in 2016 associated with the production of ThermoDox® to support the OPTIMA Study. General and administrative expenses decreased \$0.2 million, from \$6.7 million in 2015 to \$6.5 million in the current year. This decrease in general and administrative expenses in 2016 is primarily the result of reductions in personnel costs and professional fees offset by \$0.6 million of non-cash amortization expense related to the covenant not to compete from the June 2014 EGEN acquisition.

Other expenses included a non-cash charge of \$1.4 million related to the impairment of in process research and development for the Company's RNA delivery system (TheraSilence) offset by a \$0.7 million reduction in the earn-out liability related to potential milestone payments for the TheraSilence asset. Interest expense decreased by \$0.7 million in 2016 due to lower principal balances outstanding under the Company's current debt facility.

Net cash used in operations was \$18.4 million in 2016 compared to \$20.8 million in the prior year. The Company ended 2016 with \$4.5 million of total cash, investments and accrued interest on these investments. In February 2017, the Company raised an additional \$5 million in gross proceeds under a secondary public offering.

Quarterly Conference Call

The Company is hosting a conference call to provide a business update and discuss year-end 2016 financial results at 11:00 a.m. ET on Thursday, March 16, 2017. To participate in the call, interested parties may dial 1-888-490-2763 (Toll-Free/North America) or 1-719-325-2481 (International/Toll) and ask for the Celsion Corporation 2016 Year-End Earnings Call (Conference Code: 8052561) 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 March 16, 2017 and will remain available until March 30, 2017. The replay can be accessed at 1-888-203-1112 (Toll-Free/North America) or 1-719-457-0820 (International/Toll) using Conference ID: 8052561. 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, March 16, 2017.

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; 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,	
	2016	2015
Licensing revenue	\$ 500	\$ 500
Operating expenses:		
Research and development	14,623	14,660
General and administrative	6,527	6,687
Total operating expenses	21,150	21,347
Loss from operations	(20,650)	(20,847)
Other (expense) income:		
Gain (loss) from valuation of earn-out milestone liability	733	(258)
Loss from impairment of in-process research and development	(1,444)	-
(Loss) from valuation of common stock warrant liability	-	(61)
Interest expense, investment income and other income (expense), net	(693)	(1,295)
Total other (expense) income, net	(1,404)	(1,614)
Net loss	\$ (22,054)	\$ (22,461)
Net loss per common share - basic and diluted	\$ (0.85)	\$ (1.03)
Weighted average common shares outstanding - basic and diluted	25,957	21,813

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	December 31, 2016	December 31, 2015
ASSETS		
Current assets		
Cash and cash equivalents	\$ 2,624	\$ 9,265
Investment securities and interest receivable on investment securities	1,684	10,827
Prepaid expenses and other current assets	204	189
Total current assets	<u>4,512</u>	<u>20,281</u>
Property and equipment		
	<u>463</u>	<u>855</u>
Other assets		
In-process research and development	22,766	24,211
Other intangible assets, net	1,023	1,591
Goodwill	1,976	1,976
Deposits	100	100
Other assets	9	14
Total other assets	<u>25,874</u>	<u>27,892</u>
Total assets	<u>\$ 30,849</u>	<u>\$ 49,028</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 5,363	\$ 4,750
Deferred revenue - current portion	500	500
Note payable - current portion	2,560	4,073
Total current liabilities	<u>8,423</u>	<u>9,323</u>
Earn-out milestone liability	13,188	13,921
Notes payable - noncurrent portion	-	2,350
Deferred revenue and other liabilities - noncurrent portion	2,513	3,048
Total liabilities	<u>24,124</u>	<u>28,642</u>
Stockholders' equity		
Common stock	312	234
Additional paid-in capital	247,878	239,668
Accumulated other comprehensive loss	-	(4)
Accumulated deficit	(241,380)	(218,130)
	<u>6,810</u>	<u>21,768</u>
Less: Treasury stock	(85)	(1,382)
Total stockholders' equity	<u>6,725</u>	<u>20,386</u>
Total liabilities and stockholders' equity	<u>\$ 30,849</u>	<u>\$ 49,028</u>