# 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 12, 2021

# **CELSION CORPORATION**

(Exact name of registrant as specified in its Charter)

Delaware	001-15911	52-1256615				
(State or other jurisdiction	(Commission	(IRS Employer				
of incorporation)	File Number)	Identification No.)				
997 Lenox Drive, Suite 100, Lawrencevi	lle, NJ	08648-2311				
(Address of principal executive office	es)	(Zip Code)				
(Regis	(609) 896-9100 strant's telephone number, including ar	rea code)				
(Former na	N/A ame or former address, if changed sinc	e 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):						
$\square$ Written communications pursuant to Rule 425 unde	er 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 Ru	ule 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))						
Securit	ties registered pursuant to Section 12(b) o	of the Act				
Title of each class	Trading symbol(s)	Name of each exchange on which registered				
Common stock, par value \$0.01 per share	CLSN	Nasdaq Capital Market				
Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).						
Emerging growth company $\square$						
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. $\Box$						

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

On August 12, 2021, Celsion Corporation issued a press release reporting its financial results for the quarter ended June 30, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On August 5, 2021, Celsion Corporation announced it would hold a conference call on August 12, 2021 to discuss its financial results for the quarter ended June 30, 2021 and provide a business update. The conference call will also be broadcast live on the internet at <a href="http://www.celsion.com">http://www.celsion.com</a>.

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 2021 Financial Results and Provides Business Update" issued by Celsion Corporation on August 12, 2021

# **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.

Dated: August 12, 2021

# **CELSION CORPORATION**

By: /s/ Jeffrey W. Church

Jeffrey W. Church

Executive Vice President and Chief Financial Officer



#### Celsion Corporation Reports Second Quarter 2021 Financial Results and Provides Business Update

Strong Balance Sheet Supports Focus in Immuno-Oncology and on Next-Generation Vaccine Initiative

Conference Call Begins Today at 11:00 a.m. Eastern Time

**LAWRENCEVILLE, N.J.** (August 12, 2021) – Celsion Corporation (NASDAQ: CLSN), a clinical-stage drug-development company focused on DNA-based immunotherapy and next-generation vaccines, today announced financial results for the three and six months ended June 30, 2021, and provided an update on clinical development programs with GEN-1, a DNA-based interleukin-12 (IL-12) immunotherapy in Phase II clinical development for the treatment of advanced-stage ovarian cancer (Stage III/IV), and ThermoDox<sup>®</sup>, a proprietary heat-activated liposomal encapsulation of doxorubicin under investigator-sponsored development for several cancer indications. In addition, Celsion has two feasibility-stage platform technologies for the development of novel nucleic acid-based immunotherapies and next-generation vaccines for infectious diseases.

"GEN-1, our oncology-focused immunotherapy, continues to show encouraging resection results at the 100 mg/m² dose cohort in the Phase II OVATION 2 Study. These results are consistent with those reported from our earlier Phase I trials in advanced-stage ovarian cancer. In July 2021, the Data Safety Monitoring Board (DSMB) unanimously recommended that the OVATION 2 Study continue treating patients with the 100 mg/m² dose. The DSMB also determined that safety was satisfactory with an acceptable risk/benefit and no dose-limiting toxicities," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "These findings were supported with positive R0 surgical resection scores from the first 36 patients with interval debulking surgery. Of those, 80% treated with GEN-1 at a dose of 100 mg/m² plus NACT had a complete tumor resection (R0), which indicates a microscopically margin-negative resection with no gross or microscopic tumor remaining in the tumor bed, compared with 56% of patients in the control arm having R0 resections.

"In recent weeks, Celsion strengthened its capabilities in vaccine development with the expansion of our Vaccine Advisory Board," continued Mr. Tardugno. "Drs. Dan H. Barouch and Luke D. Handke joined Drs. Britt A. Glaunsinger and Xinzhen Yang on the VAB, which was formed during the first quarter of this year. We're delighted to assemble a group of well-known and distinguished scientists to advise management's work in developing next-generation vaccines directed to COVID-19 and its variants, and other infectious diseases for which there are few or no preventive options."

Mr. Tardugno concluded, "Results of the OVATION 1 Study recently published in the *Journal of Clinical Research* showed complete/near complete chemotherapy response scores (CRS) of 50% in the two highest doses of GEN-1, compared with 28% from a major publication evaluating CRS scoring. CRS is a three-tier standardized scoring system for histological tumor regression into complete/near complete (CRS 3), partial (CRS 2) and no/minimal (CRS 1) response based on omental examination. While not an FDA recognized endpoint, like R0 resection rates, CRS 3 is believed to be a predictor of progression-free survival."

#### **Recent Developments**

# **GEN-1** Immunotherapy

**DSMB Recommends GEN-1 to Continue Dosing Patients in the Phase II Portion of the OVATION 2 Study in Advanced Ovarian Cancer.** The OVATION 2 Study combines GEN-1 with standard-of-care neoadjuvant chemotherapy (NACT) in patients newly diagnosed with Stage III/IV ovarian cancer. NACT is designed to shrink the cancer as much as possible for optimal surgical removal after three cycles of chemotherapy. Following NACT, patients undergo interval debulking surgery, followed by three additional cycles of chemotherapy to treat any residual tumor.

In July 2021, the Company announced that following a pre-planned interim safety review of 55 as-treated patients randomized in the Phase I/II OVATION 2 Study, the DSMB unanimously recommended that the OVATION 2 Study continue treating patients with the dose of 100 mg/m<sup>2</sup>. The DSMB also determined that safety is satisfactory with an acceptable risk/benefit, and that patients can tolerate up to 17 doses of GEN-1 during a course of treatment that lasts up to six months. No dose-limiting toxicities were reported.

More than 50% of the Projected 110 Patients Have Been Enrolled in the OVATION 2 Study. Interim clinical data from the first 36 patients who have undergone interval debulking surgery are as follows:

- 20 patients were treated with GEN-1 at a dose of 100 mg/m² plus NACT, with 16 out of 20 patients (80%) having a complete tumor resection (R0).
- 16 patients were treated with NACT only, with 9 out of 16 patients (56%) having R0 resections.
- When combining these results with the surgical resection rates observed in the Company's prior Phase Ib dose-escalation trial (the OVATION 1 Study), a population of patients with inclusion criteria identical to the OVATION 2 Study, the data reflect the strong dose-dependent efficacy of adding GEN-1 to NACT.

	_	% Patients with RU Resections			
0, 36, 47 mg/m <sup>2</sup> of GEN-1 plus NACT	n=22	50 <mark>%</mark>			
61, 79, 100 mg/m <sup>2</sup> of GEN-1 plus NACT	n=28	82%			

• The objective response rate (ORR) as measured by Response Evaluation Criteria in Solid Tumors (RECIST) criteria for the 16 patients treated with NACT only were comparable, as expected, to the 20 patients treated with GEN-1 at a dose of 100 mg/m² plus NACT, with both groups demonstrating an approximate 80% ORR.

Poster on Phase I/II OVATION 2 Study Presented at the Society of Gynecologic Oncology Virtual Annual Meeting on Women's Cancer. In April 2021, the Company announced that a poster highlighting its ongoing OVATION 2 Study was presented at the Virtual Annual Meeting on Women's Cancer, sponsored by the Society of Gynecologic Oncology. The poster, titled "A Phase I/II Study Evaluating Intraperitoneal GEN-1 in Combination with Neoadjuvant Chemotherapy [NACT] in Patients with Newly Diagnosed Advanced Epithelial Ovarian Cancer (EOC)," can be viewed here. The poster was presented by Premal Thaker, M.D., Study Chair of the OVATION 2 Study and Professor of Obstetrics and Gynecology, Director of Gynecological Oncology Clinical Research, Division of Gynecologic Oncology, Washington University School of Medicine.

The poster describes the OVATION 2 Study, which is an open-label, 1-to-1 randomized trial, 80% powered to show the equivalent of a 33% improvement in progression-free survival (PFS) (HR=0.75), the primary endpoint, when comparing the treatment arm (NACT + GEN-1) with the control arm (NACT).

Celsion announced in the first quarter of 2021 that GEN-1 had received Fast Track designation from the U.S. Food and Drug Administration. This designation is intended to facilitate the development and expedite the regulatory review of drugs to treat serious conditions and fill an unmet medical need.

#### **Vaccine Initiative**

*Vaccine Advisory Board Expanded.* In July 2021, the Company announced the addition of Dan H. Barouch, M.D., Ph.D. and Luke D. Handke, Ph.D. to its Vaccine Advisory Board (VAB). They join Britt A. Glaunsinger, Ph.D. and Xinzhen Yang, M.D., Ph.D. on the VAB, which was formed in February 2021.

Dr. Barouch is the principal investigator at the Barouch Laboratory, Director of the Center for Virology and Vaccine Research at Beth Israel Deaconess Medical Center and William Bosworth Castle Professor of Medicine at Harvard Medical School. In addition, he is a key participant in the Bill & Melinda Gates Foundation Collaboration for AIDS Vaccine Discovery, the National Institutes of Health Martin Delaney HIV-1 Cure Collaboratory and the Ragon Institute of MGH, MIT and Harvard. Dr. Barouch and his team were instrumental in developing the vector, a variant of an adenovirus called Ad26, that was used to make single-dose vaccines for HIV, tuberculosis and Zika, and ultimately, in conjunction with Johnson & Johnson researchers, SARS-CoV-2. He has authored numerous peer-reviewed articles.

Dr. Handke is a highly skilled molecular biologist and microbiologist with a decade of pharmaceutical industry experience including nine years with Pfizer's Vaccine Research and Early Development Unit. At Pfizer he served as molecular biology lead on an early phase viral vaccine program and was the lead reviewer of data sources and literature citations for licensure application for the Trumenba® meningococcal group B vaccine in the U.S. and in Europe. He began his career in vaccine research at Wyeth. He is co-author and co-inventor on various patent applications for a protein-based RSV vaccine and a SARS-CoV-2 detection assay and authored 10 peer-reviewed publications including six as first author. Dr. Handke is currently a Senior Scientist at the University of Nebraska Medical Center in Omaha. In addition to serving on the VAB, Dr. Handke will provide consulting services to Celsion in connection with its vaccine development program, which involves DNA-based vectors in combination with proprietary non-viral cellular delivery agents. He also will advise Celsion as it advances this program into human clinical studies.

# $\textbf{ThermoDox}^{\mathbb{R}}$

**Subsidiary Established to Manage Investigator-Sponsored Development of ThermoDox®.** In June 2021, the Company announced that its new wholly owned subsidiary, Celsion GmbH, will manage all current and future investigator-sponsored development of ThermoDox®. Andreas Voss, M.D., a leading oncology researcher, has been named Managing Director of Celsion GmbH and will step down from Celsion's board of directors later this year to head the subsidiary, which is based in Zug, Switzerland.

Establishing Celsion GmbH allows Celsion's management to focus solely on GEN-1 and PLACCINE, its nucleic acid vaccine platform. In addition to clinical and regulatory advice, Celsion's ongoing investment in ThermoDox<sup>®</sup> will be limited to providing clinical drug supply and modest financial support. ThermoDox<sup>®</sup> is currently under investigator-sponsored development for several cancer indications.

Commencement of Enrollment in Phase 1 Study with ThermoDox® and Focused Ultrasound in Pancreatic Cancer. In July 2021, Celsion GmbH announced the commencement of enrollment in Oxford University's Phase I PanDox study with ThermoDox® in conjunction with focused ultrasound in patients with pancreatic cancer.

This investigator-led study sponsored by the University of Oxford and supported by the National Institute for Health Research (NIHR) Oxford Biomedical Research Centre has now received ethics, MHRA and institutional R&D approval to commence (ClinicalTrials.gov Identifier: NCT04852367). PanDox is being carried out as a multi-disciplinary collaboration between Celsion, the Oxford University Institute of Biomedical Engineering, the Oncology Clinical Trials Office and the Oxford University Hospitals NHS Foundation Trust. Prof. Mark Middleton, M.D., Head of the Department of Oncology at the University of Oxford, is the chief clinical investigator and Prof. Constantin Coussios, FREng, Ph.D., Director of the Institute of Biomedical Engineering, is the lead scientific investigator.

The primary endpoint of the two-arm 18-subject PanDox study is enhanced uptake of doxorubicin in pancreatic tumors using ThermoDox $^{\$}$  and focused ultrasound (FUS), compared with systemic delivery of free doxorubicin. ThermoDox $^{\$}$  will be administered intravenously in 12 patients with non-resectable pancreatic ductal adenocarcinoma and locally activated by focused ultrasound-mediated hyperthermia. This will be compared with conventional systemic delivery of doxorubicin without FUS in 6 patients. Secondary endpoints include:

- Comparing radiologically assessed tumor activity and response with ThermoDox<sup>®</sup> and FUS to free drug alone.
- Examining the impact on patient symptoms of ThermoDox<sup>®</sup> plus FUS.
- Assessing the safety profile of both FUS and ThermoDox<sup>®</sup>.

The PanDox study is expected to be completed by December 2022 and is similar in design to Oxford's 10-patient TARDOX study, which demonstrated that ThermoDox<sup>®</sup> plus focused ultrasound increased doxorubicin tumor concentrations by up to 10-fold and enhanced nuclear drug uptake in patients with liver tumors. The findings of the TARDOX study are published in Lancet Oncology (Lyon et al., 2018) and Radiology (Gray et al., 2019).

# **Corporate Developments**

Strengthened Balance Sheet Through Two Registered Direct Offerings of Common Shares Totaling \$50 Million in Gross Proceeds. In January 2021, the Company announced the closing of a registered direct offering of 25,925,925 shares of common stock at a purchase price of \$1.35 per share, priced at-the-market under Nasdaq rules, resulting in net proceeds of \$32.6 million after deducting placement agents' fees but before expenses payable by the Company. In April 2021, the Company announced the closing of a registered direct offering of 11,538,462 shares of common stock at a purchase price of \$1.30 per share, resulting in net proceeds of \$13.9 million, after deducting placement agents' fees but before expenses payable by the Company.

Received \$1.85 Million in Non-Dilutive Funding from the Sale of New Jersey State Net Operating Losses. In May 2021, the Company announced it received \$1.85 million of net cash proceeds from the sale of approximately \$2.0 million of its unused New Jersey net operating losses (NOLs). The NOL sales cover the 2019 tax year and are administered through the New Jersey Economic Development Authority's (NJEDA) Technology Business Tax Certificate Transfer (NOL) Program. Additional sales of \$5.0 million of unused New Jersey NOLs are anticipated in 2022 – 2024, which will further increase Celsion's cash position on a non-dilutive basis.

**New \$10.0 Million Strategic Loan Facility with Silicon Valley Bank.** In June 2021, the Company announced it entered into a \$10.0 million loan facility with Silicon Valley Bank (SVB). Celsion immediately used \$6.0 million from this facility to retire all outstanding indebtedness with Horizon Technology Finance Corporation. The remaining \$4.0 million will be available to be drawn down up to 12 months after closing and will be used to fund the advancement of the Company's product pipeline, including GEN-1 for the treatment of newly diagnosed advanced ovarian cancer, as well as other strategic initiatives intended to broaden its product pipeline. The funding is in the form of money market secured indebtedness bearing interest at a calculated WSJ Prime-based variable rate (currently 3.25%). Payments under the loan agreement are interest only for the first 24 months after loan closing, followed by a 24-month amortization period of principal and interest through the scheduled maturity date.

Appointment of Two New Directors to the Celsion Board. In June 2021, the Company announced the appointment of Stacy R. Lindborg, Ph.D. and Christine A. Pellizzari to Celsion's Board of Directors.

Dr. Lindborg brings to Celsion more than 25 years of pharmaceutical industry experience with a particular focus on R&D, executive management and strategy. She has worked with biologics, small molecules and cell therapies to address a broad range of diseases and disorders, including multiple orphan drug products, along with extensive experience in early-stage development having taken molecules from first-in-man studies into the clinic through approval and launch. Dr. Lindborg is a graduate of Baylor University where she received a Ph.D. and M.A. in statistics and a B.A. in psychology with a minor in mathematics. A prolific researcher, she has authored more than 50 abstracts, 200 presentations and 40 manuscripts that have been published in peer-reviewed journals. She serves on several industry advisory boards related to statistics and biotechnology.

Ms. Pellizzari is Chief Legal Officer of Science 37, a developer of a leading decentralized clinical trial operating system where she has global responsibility for both legal and quality. Ms. Pellizzari brings more than 20 years of leadership in the global pharmaceutical industry to Celsion. Immediately prior to joining Science 37, Ms. Pellizzari was Chief Legal Officer of Insmed Incorporated, a global biopharmaceutical company dedicated to transforming the lives of patients with serious and rare diseases. At Insmed, Ms. Pellizzari had global responsibility for legal and government affairs including corporate governance, regulatory compliance, contracting, alliance management, clinical trial oversight, labor and employment, litigation management and intellectual property strategy and portfolio management. Ms. Pellizzari received a J.D. from the University of Colorado School of Law and a B.A. from the University of Massachusetts (Amherst). She is a member of Executive Women in Bio, Women Corporate Directors, National Association of Corporate Directors, Association of Corporate Counsel, Society for Corporate Governance and National Association of Stock Plan Professionals.

# **Second Quarter Financial Results**

For the quarter ended June 30, 2021, Celsion reported a net loss of \$5.4 million (\$0.06 per share), compared with a net loss of \$5.3 million (\$0.18 per share) in the same period of 2020. Operating expenses were \$5.2 million in the second quarter of 2021, which represented a \$0.3 million (6%) increase from \$4.9 million in the same period of 2020.

The Company ended the second quarter of 2021 with \$64.5 million in cash, investment securities, restricted cash and accrued interest receivable. Coupled with future sales of unused New Jersey NOL's, the Company believes it has sufficient capital resources to fund its operations through 2024.

Research and development (R&D) expenses decreased \$0.4 million to \$2.6 million in the second quarter of 2021 from \$3.0 million in the second quarter of 2020. R&D costs associated with the development of GEN-1 to support the OVATION 2 Study as well as development of the PLACCINE DNA technology platform increased to \$1.4 million in the second quarter of 2021, compared with \$0.9 million in the same period of 2021. Clinical development costs for the Phase III OPTIMA Study decreased \$0.4 million to \$0.2 million in the second quarter of 2021, compared with \$0.6 million in the second quarter of 2020, due to the discontinuation of this 556-patient trial in the first quarter of 2021. Other costs related to clinical supplies and regulatory support for the Company's clinical development programs decreased to \$0.9 million in the current quarter from \$1.5 million in the second quarter of 2020, largely driven by higher manufacturing costs for GEN-1 clinical supplies for the Phase II portion of the OVATION 2 Study offset by lower regulatory and manufacturing costs related to the discontinued OPTIMA Study.

General and administrative expenses were \$2.6 million in the second quarter of 2021, compared with \$1.9 million in the same period of 2020. The \$0.7 million increase was primarily attributable to higher non-cash stock-compensation expense (\$0.1 million), an increase in legal and professional fees (\$0.4 million) and an increase in Directors' and Officers' insurance premiums (\$0.1 million) incurred during the second quarter of 2021.

In connection with the Company's venture debt facility with Horizon Technology Finance Corporation entered in late June 2018, the Company incurred interest expense of \$0.2 million during the second quarter of 2021. This compares with interest expense of \$0.3 million in the comparable prior-year period. In June 2021, the Company entered into a new \$10.0 million loan facility with SVB, with a portion of the proceeds used to retire all outstanding indebtedness with Horizon. The Company recognized a \$0.2 million loss on this debt extinguishment.

# Six Month Financial Results

For the six months ended June 30, 2021, the Company reported a net loss of \$11.1 million (\$0.15 per share), compared with a net loss of \$10.4 million (\$0.37 per share) in the same period of 2020. Operating expenses were \$10.7 million during the first six months of 2021, which represented a \$0.9 million (10%) decrease from \$9.8 million in the same period of 2020.

Net cash used for operating activities was \$7.3 million in the first six months of 2021, compared with \$7.9 million in the same period in 2020. This was in line with the Company's projected cash utilization for 2021 of approximately \$17 million, or an average of approximately \$4.25 million per quarter. Cash provided by financing activities was \$54.8 million during the first six months of 2021 resulting from equity offerings in January 2021 and April 2021, and proceeds from the \$10 million loan facility with SVB in June 2021 and the sale of the Company's unused New Jersey NOLs in May 2021.

Research and development expenses decreased \$0.8 million to \$5.2 million in the first half of 2021 from \$6.0 million in the first half of 2020. R&D costs associated with the development of GEN-1 to support the OVATION 2 Study as well as development of the PLACCINE DNA technology platform increased to \$2.8 million in the first half of 2021, compared with \$2.1 million in the comparable six-month period in 2020. Costs for the Phase III OPTIMA Study decreased \$0.9 million to \$0.4 million in the first half of 2020, compared with \$1.3 million in the first half of 2020, due to the discontinuation of this trial in the first quarter of 2021. Other costs related to clinical supplies and regulatory support for the Company's clinical development programs decreased \$0.6 million in the first half of 2021, compared with the same prior-year period due to lower regulatory and manufacturing costs for the discontinued Phase III OPTIMA Study.

General and administrative expenses were \$5.5 million in the first half of 2021, compared with \$3.7 million in the same period of 2020. The \$1.8 million increase was primarily attributable to higher non-cash stock-compensation expense (\$0.8 million), an increase in legal and professional fees (\$0.7 million) and an increase in Directors' and Officers' insurance premiums (\$0.2 million) incurred during the six months ended June 30, 2021.

Other expenses during the first half of 2021 included a non-cash charge of \$0.1 million for the change in valuation of the earn-out milestone liability for the GEN-1 ovarian product candidate, compared with a non-cash charge of \$0.3 million during the comparable prior-year period. In connection with the Company's venture debt facility with Horizon entered in late June 2018, the Company incurred interest expense of \$0.4 million during the first six months of 2021, compared with \$0.7 million during the same six-month period in 2020.

#### **Second Quarter Conference Call**

The Company will host a conference call to provide a business update, discuss its second quarter 2021 financial results and answer questions at 11:00 a.m. EDT today. To participate in the call, interested parties may dial 1-800-353-6461 (Toll-Free/North America) or 1-334-323-0501 (International/Toll) 10 minutes before the call is scheduled to begin, and ask for the Celsion Corporation Second Quarter 2021 Earnings Call (Conference Code: 2901622). The call will also be broadcast live on the internet at www.celsion.com. The call will be archived for replay through August 26, 2021. The replay can be accessed at 1-719-457-0820 or 1-888-203-1112 using Conference ID: 290622. An audio replay of the call will also be available on the Company's website, www.celsion.com, for 90 days after 2:00 p.m. EDT Thursday, August 12, 2021.

### **About Celsion Corporation**

Celsion is a fully integrated, clinical-stage biotechnology company focused on advancing a portfolio of innovative cancer treatments, including immunotherapies and DNA-based therapies, and a platform for the development of nucleic acid vaccines currently focused on SARS-CoV-2. The company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer. ThermoDox<sup>®</sup>, a proprietary heat-activated liposomal encapsulation of doxorubicin, is under investigator-sponsored development for several cancer indications. Celsion also has two feasibility-stage platform technologies for the development of novel nucleic acid-based immunotherapies and other anticancer DNA or RNA therapies. Both are novel synthetic, non-viral vectors with demonstrated capability in nucleic acid cellular transfection. For more information on Celsion, visit 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; 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 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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#### **LHA Investor Relations**

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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,					
		2021		2020		2021		2020
Licensing revenue	\$	125	\$	125	\$	250	\$	250
Operating expenses:								
Research and development		2,593		2,991		5,165		6,043
General and administrative		2,603		1,901		5,540		3,740
Total operating expenses		5,196		4,892		10,705		9,783
Loss from operations		(5,071)	_	(4,767)		(10,455)		(9,533)
Other income (expense):								
Gain (loss) from change in valuation of earn-out milestone liability		81		(256)		(70)		(297)
Loss on debt extinguishment		(235)		-		(235)		-
Interest expense, investment income and other income								
(expense), net		(223)		(320)		(378)		(570)
Total other income (expense), net		(377)		(576)		(683)		(867)
Net loss	\$	(5,448)	\$	(5,343)	\$	(11,138)	\$	(10,400)
Net loss per common share								
Basic and diluted	\$	(0.06)	\$	(0.18)	\$	(0.15)	\$	(0.37)
Weighted average shares outstanding								
Basic and diluted		85,924		29,887	_	76,165		27,831

# Celsion Corporation Selected Balance Sheet Information (in thousands)

	e 30, 2021 1audited)	December 31, 2020		
ASSETS				
Current assets				
Cash and cash equivalents	\$ 26,437	\$	17,164	
Investment securities and interest receivable on investment securities	32,028		-	
Advances, deposits on clinical programs and other current assets	1,845		1,661	
Total current assets	60,310		18,825	
Property and equipment	459		295	
Other assets				
Deferred tax asset	-		1,845	
Restricted cash invested in money market account	6,000		-	
In-process research and development	13,366		13,366	
Goodwill	1,976		1,976	
Operating lease right-of-use assets, deposits and other assets	 899		1,220	
Total other assets	 22,241		18,407	
Total assets	\$ 83,010	\$	37,527	
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities				
Accounts payable and accrued liabilities	\$ 4,422	\$	4,703	
Notes payable – current portion	-		1,117	
Operating lease liability – current portion	458		433	
Deferred revenue - current portion	500		500	
Total current liabilities	5,380		6,753	
Earn-out milestone liability	7,088		7,018	
Notes payable – noncurrent portion	5,763		3,935	
Deferred revenue – noncurrent portion	250		500	
Operating lease liability – noncurrent portion	475		710	
Total liabilities	18,956		18,916	
Stockholders' equity	 	<u> </u>		
Common stock	866		407	
Additional paid-in capital	386,415		330,289	
Accumulated other comprehensive gain (loss)	(4)		-	
Accumulated deficit	 (323,138)		(312,000)	
	64,139		18,696	
Less: Treasury stock	 (85)		(85)	
Total stockholders' equity	64,054		18,611	
Total liabilities and stockholders' equity	\$ 83,010	\$	37,527	