



Celsion Corporation Reports Third Quarter 2021 Financial Results and Provides Business Update

November 15, 2021

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

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

LAWRENCEVILLE, N.J., Nov. 15, 2021 (GLOBE NEWSWIRE) -- [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 nine months ended September 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®, 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 continues to show momentum as patient enrollment nears 70% with full enrollment targeted by the first half of 2022. We are encouraged with surgical resection results at the 100 mg/m² dose cohort in the Phase II OVATION 2 Study. From the first 36 patients with interval debulking surgery, 80% treated with GEN-1 at a dose of 100 mg/m² plus neoadjuvant chemotherapy (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; this compares with 56% of patients in the control arm having R0 resections. These results are reasonably consistent with those reported from our earlier Phase I trials in advanced-stage ovarian cancer," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer.

"At the International Vaccines Congress in October, Celsion announced results from preclinical *in vivo* studies showing production of antibodies and cytotoxic T-cell response specific to the spike antigen of SARS-CoV-2 when immunizing BALB/c mice with our next-generation PLACCINE DNA vaccine," added Mr. Tardugno. "Our goal over the next several quarters is to demonstrate the superiority of Celsion's multicistronic DNA vaccine over current mRNA vaccines with respect to the quality of immune response (higher affinity of neutralizing antibodies, IgG titers and T-cell response) against multiple SARS-CoV-2 variants, longer duration of immune response and a stable product at lower temperatures."

Recent Developments

GEN-1 Immunotherapy

Interim Data Reported on 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 R0 resections.
- 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 R0 Resections		
0, 36, 47 mg/m ² of GEN-1 plus NACT	n=22	50 %
61, 79, 100 mg/m ² 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.

Publication of OVATION 1 Study in the *Journal of Clinical Cancer Research*. In July 2021, the Company announced the publication of data from its Phase 1b OVATION 1 Study with GEN-1 in combination with NACT in patients with advanced ovarian cancer in *Clinical Cancer Research*, a journal of the American Association for Cancer Research. The study, authored by Premel H. Thaker, M.D. *et al.* and titled "GEN-1 in Combination with Neoadjuvant Chemotherapy for Patients with Advanced Epithelial Ovarian Cancer: A Phase I Dose-Escalation Study," is available [here](#). Dr. Thaker, Professor of Gynecologic Oncology and Director of Gynecologic Oncology Clinical Research at the Washington University School of Medicine in St. Louis, is the study chair for the OVATION program.

The OVATION 1 Study enrolled 18 patients with newly diagnosed stage IIIC and IV epithelial ovarian cancer in a standard 3+3 dose-escalation design testing four GEN-1 doses (36 mg/m², 47 mg/m², 61 mg/m² and 79 mg/m²) in combination with NACT (carboplatin-paclitaxel). There were 15 patients evaluable for safety, and 14 underwent interval debulking and were evaluable for RECIST.

As previously reported, there were no dose-limiting toxicities. As shown in the chart below, in the two highest doses of GEN-1 the objective response rate was 100% and the R0 resection rate was 88%. Newly published data show the CRS, which was analyzed in this paper for the first time, was 50% in the two highest doses of GEN-1, compared with 28% from a major publication evaluating CRS scoring.

Clinical Responses: Tumor Response, Surgical Outcome, Pathological Response and Chemotherapy Response Score with NAC/GEN-1 Escalating Doses

Radiographic Response		Total (n)	Cohort 1 36 mg/m ²	Cohort 2 47 mg/m ²	Cohort 3 61 mg/m ²	Cohort 4 79 mg/m ²
Tumor Response	CR	2	1	0	0	1
	PR	10	0	3	3	4
	SD	2	2	0	0	0
Objective Response Rate				67%		100%
Surgical Outcome	R0	9	2	0	2	5
	R1	3	1	2	0	0
	R2	2	0	1	1	0
R0 Resection Rate				33%		88%
Pathological Response	cPR	1	1	0	0	0
	Micro	8	1	2	1	4
	Macro	5	1	1	2	1
cPR/Micro Rate				60%		63%
Chemotherapy Response Score	CRS 3	5	1	0	2	2
	CRS 2	5	2	1	0	2
	CRS 1	4	0	2	1	1
CRS 3 Rate				17%		50%

Translational Responses: IL-12 and IFN-γ Levels, Response to Immune-Suppressive Agents; Ratio of CD8+ Cells to Immune Suppressive Agents

- A dose-dependent increase in immunostimulatory cytokines IL-12 and its downstream cytokine IFN-γ in ascitic fluid. The anticancer effects of these cytokines are widely recognized in human malignancies.
- The proportion of myeloid dendritic cells in the peritoneal fluid trended higher (3.1-fold) accompanied by a similar 3.0-fold rise in CD8+ cells.
- GEN-1 appeared to reduce four immunosuppressive signals (Foxp3, IDO1, PD-1 and PD-L1) within the tumor microenvironment, a trend not seen with NAC therapy alone.
- GEN-1 appeared to stimulate the body's immune system through the production of CD4 and CD8 cells.
- GEN-1 gene therapy was associated with an apparent increase in the cytotoxic state of T cells within the tumor microenvironment as indicated by the increases in the ratios of CD8+/CD4+ and CD8+/Treg cells. Indeed, higher CD8+/CD4+ T cell and CD8+/Treg ratios are considered prognostic for prolonged survival.

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 joined 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.

Results from In Vivo Studies with PLACCINE DNA Vaccine Platform Indicate Immune Response Against SARS-Cov-2. In September 2021, the Company announced results from preclinical *in vivo* studies showing production of antibodies and cytotoxic T-cell response specific to the spike antigen of SARS-CoV-2 when immunizing BALB/c mice with the Company's next-generation PLACCINE DNA vaccine platform. Moreover, the antibodies to SARS-CoV-2 spike antigen prevented the infection of cultured cells in a viral neutralization assay. The production of antibodies predicts

the ability of PLACCINE to protect against SARS-CoV-2 exposure, and the elicitation of cytotoxic T-cell response shows the vaccine's potential to eradicate cells infected with SARS-CoV-2. These findings demonstrate the potential immunogenicity of Celsion's PLACCINE DNA vaccine, which is hypothesized to provide broad-spectrum protection and resistance against variants by incorporating multiple viral antigens, to improve vaccine stability at storage temperatures of 4°C and above, and to facilitate cheaper and easier manufacturing. Celsion reported these data at the International Vaccines Conference in October 2021.

Agreement with Hainan Poly Pharm to Manufacture Celsion's DNA-based Vaccine. In September 2021, the Company announced an amendment to its existing contract manufacturing agreement with Hainan Poly Pharm Co. Ltd., a generics manufacturer dedicated to providing therapeutic-value products and services to patients and customers around the world, to include development work for the Company's investigational DNA-based COVID-19 vaccine. Under the terms of the amended agreement, Poly Pharm will manufacture clinical batches and, if approved for use, will also manufacture commercial batches for Celsion's vaccine based on its TheraPlas technology. Poly Pharm is experienced with chemistry, manufacturing and controls (CMC), process development and good manufacturing processes (cGMP), including process optimization and manufacturing services to help customers advance new drug development projects. Its sites and pharmaceutical compounds have been approved by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), China's National Medical Products Administration (NMPA) and the World Health Organization (WHO).

Oral Presentation on Celsion's Ongoing Work with DNA-based Vaccines at International Vaccines Congress. In October 2021, the Company announced that Khursheed Anwer, Ph.D., executive vice president and chief science officer, presented at the International Vaccines Congress. Dr. Anwer's presentation was titled "Immunogenicity of DNA Vaccines based on Multicistronic Vectors and Synthetic DNA Delivery Systems" and can be viewed [here](#). Dr. Anwer discussed ongoing proof-of-concept studies in SARS-CoV-2 with the Company's DNA-based vaccine approach utilizing its PLACCINE platform. PLACCINE, Celsion's proprietary design for DNA vectors, encompasses molecular elements designed to improve the immune response by targeting multiple antigens of a pathogen or multiple mutants of the same antigen. Dr. Anwer also reviewed the PLACCINE technology and the production of a family of DNA vaccine vectors expressing one or more SARS-CoV-2 surface antigens as a proof-of-concept target, verified vector composition and demonstrated expression of the encoded genes.

Corporate Developments

Presentations at Three Healthcare Investment Conferences. Celsion management made presentations at the following investment conferences in October:

- **Chardan's 5th Annual Genetic Medicines Conference.** Michael H. Tardugno, Celsion's chairman, president and chief executive officer, and Khursheed Anwer, Ph.D., Celsion's chief scientific officer, participated in a fireside chat.
- **LD Micro Main Event.** Jeffrey W. Church, Celsion's chief financial officer, presented virtually.
- **Alliance Global Partners' Virtual Healthcare Conference.** Mr. Tardugno participated in an oncology focused panel discussion moderated by James Molloy, Research Analyst.

Third Quarter Financial Results

For the quarter ended September 30, 2021, Celsion reported a net loss of \$5.4 million (\$0.06 per share), compared with a net loss of \$8.1 million (\$0.24 per share) in the same period of 2020. Operating expenses were \$5.2 million in the third quarter of 2021, which represented a \$0.9 million (21%) increase from \$4.3 million in the same period of 2020.

The Company ended the third quarter of 2021 with \$60.6 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 the end of 2024.

Research and development (R&D) expenses were \$2.5 million in the third quarter of 2021, consistent with \$2.5 million reported in the third quarter of 2020. Costs associated with the OVATION 2 Study were \$0.2 million in each of the third quarters of 2021 and 2020. R&D costs associated with both the development of GEN-1 to support the OVATION 2 Study and the development of the PLACCINE DNA technology platform increased to \$1.1 million in the third quarter of 2021, compared with \$0.7 million in the same period of 2020. Clinical development costs for the Phase III OPTIMA Study decreased \$0.3 million to \$0.2 million in the third quarter of 2021, compared with \$0.5 million in the third 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 \$1.0 million in the third quarter of 2021 from \$1.1 million in the third 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 OPTIMA Study.

General and administrative expenses were \$2.7 million in the third quarter of 2021, compared with \$1.8 million in the same period of 2020. The \$0.9 million increase was primarily attributable to higher non-cash stock-compensation expense (\$0.2 million), an increase in legal and professional fees (\$0.6 million) and an increase in Directors' and Officers' insurance premiums (\$0.1 million).

Non-operating expenses of \$0.3 million in the third quarter of 2021 decreased from \$3.9 million in the third quarter of 2020 due to (i) a non-cash charge of \$1.1 million for the change in valuation of the earn-out milestone liability for the GEN-1 ovarian product candidate recognized in the third quarter of 2020 compared with a \$0.3 million non-cash charge recognized in the current quarter; (ii) a non-cash charge of \$2.4 million related to the impairment of certain in-process research and development assets related to the development of the Company's glioblastoma multiforme (GBM) cancer product candidate in the third quarter of 2020; and (iii) lower interest expense of \$0.4 million on the Company's debt facilities in the current quarter, compared with 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 under the Company's venture debt facility entered in late June 2018 with Horizon Technology Finance Corporation.

Nine Month Financial Results

For the nine months ended September 30, 2021, the Company reported a net loss of \$16.5 million (\$0.21 per share), compared with a net loss of \$18.5 million (\$0.62 per share) in the same period of 2020. Operating expenses were \$15.9 million during the first nine months of 2021, which represented a \$1.8 million (13%) increase from \$14.1 million in the same period of 2020.

Net cash used for operating activities was \$11.1 million in the first nine months of 2021, compared with \$11.9 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 of \$54.8 million during the first nine months of 2021 was derived from equity offerings in January 2021 and April 2021, 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 \$0.9 million to \$7.6 million in the first nine months of 2021 from \$8.5 million in the comparable prior-year period. Costs associated with the OVATION 2 Study increased to \$1.0 million in the first nine months of 2021 compared to \$0.7 million in the same period of 2020. The Company initiated enrollment in the Phase 2 portion of the study during the third 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 \$3.1 million in the first nine months of 2021, compared with \$2.3 million in the comparable 2020 period. Costs for the Phase III OPTIMA Study decreased \$1.2 million to \$0.6 million in the first nine months of 2021, compared with \$1.8 million in the first nine months 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 \$0.8 million to \$2.9 million in the first nine months 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 \$8.3 million in the first nine months of 2021, compared with \$5.5 million in the same period of 2020. The \$2.8 million increase was primarily attributable to higher non-cash stock-compensation expense (\$1.0 million), an increase in legal and professional fees (\$1.4 million) and an increase in Directors' and Officers' insurance premiums (\$0.2 million).

Other expenses during the first nine months of 2021 included a non-cash charge of \$0.3 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 \$1.4 million during the comparable prior-year period and a non-cash charge of \$2.4 million related to the impairment of certain in-process research and development assets related to the development of the Company's GBM cancer product candidate in the third quarter of 2020. In connection with the Company's venture debt facilities, the Company incurred interest expense of \$0.5 million during the first nine months of 2021, compared with \$1.1 million during the same period in 2020. 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 under the Company's venture debt facility with Horizon Technology Finance Corporation.

Conference Call

The Company will host a conference call to provide a business update, discuss its third quarter 2021 financial results and answer questions at 11:00 a.m. ET today. To participate in the call, please dial 1-800-353-6461 (Toll-Free/North America) or +1-334-323-0501 (International/Toll) and ask for the Celsion Corporation Third Quarter 2021 Earnings Call (Conference Code: 4154518). The call will also be broadcast live on the internet at www.celsion.com. The call will be archived for replay through December 1, 2021. The replay can be accessed at +1-719-457-0820 or 888-203-1112 using Conference ID: 4154518. An audio replay will also be available on the Company's website, www.celsion.com, for 90 days after 2:00 p.m. ET on November 15, 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. 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 GmbH is Celsion's wholly owned, special purpose subsidiary based in Zug, Switzerland. Celsion GmbH is responsible for supporting studies of ThermoDox[®], a proprietary heat-activated liposomal encapsulation of doxorubicin, is under investigator-sponsored development for several cancer indications. For more information on Celsion GmbH, visit www.celsiongmbh.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.

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[Tables to Follow]

Celsion Corporation
Condensed Statements of Operations
(in thousands except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Licensing revenue	\$ 125	\$ 125	\$ 375	\$ 375
Operating expenses:				
Research and development	2,468	2,492	7,633	8,534
General and administrative	2,719	1,793	8,258	5,533
Total operating expenses	<u>5,187</u>	<u>4,285</u>	<u>15,891</u>	<u>14,067</u>
Loss from operations	<u>(5,062)</u>	<u>(4,160)</u>	<u>(15,516)</u>	<u>(13,692)</u>
Other income (expense):				
(Loss) from change in valuation of earn-out milestone liability	(257)	(1,100)	(327)	(1,397)
Impairment of in-process research and development	-	(2,370)	-	(2,370)
Loss on debt extinguishment	-	-	(235)	-
Interest expense, investment income and other income (expense), net	<u>(92)</u>	<u>(442)</u>	<u>(470)</u>	<u>(1,012)</u>
Total other income (expense), net	<u>(349)</u>	<u>(3,912)</u>	<u>(1,032)</u>	<u>(4,779)</u>
Net loss	\$ (5,411)	\$ (8,072)	\$ (16,548)	\$ (18,471)
Net loss per common share				
Basic and diluted	\$ (0.06)	\$ (0.24)	\$ (0.21)	\$ (0.62)
Weighted average shares outstanding				
Basic and diluted	86,558	34,112	79,668	29,935

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	September 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	\$ 25,649	\$ 17,164
Investment securities and interest receivable on investment securities	28,903	-
Advances, deposits on clinical programs and other current assets	<u>2,213</u>	<u>1,661</u>
Total current assets	<u>56,765</u>	<u>18,825</u>
Property and equipment	<u>486</u>	<u>295</u>
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	<u>876</u>	<u>1,220</u>
Total other assets	<u>22,218</u>	<u>18,407</u>
Total assets	<u>\$ 79,469</u>	<u>\$ 37,527</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 5,441	\$ 4,703
Notes payable – current portion	-	1,117
Operating lease liability – current portion	534	433
Deferred revenue - current portion	<u>500</u>	<u>500</u>
Total current liabilities	<u>6,475</u>	<u>6,753</u>
Earn-out milestone liability	7,345	7,018

Notes payable – noncurrent portion	5,809	3,935
Deferred revenue – noncurrent portion	125	500
Operating lease liability – noncurrent portion	373	710
Total liabilities	20,127	18,916
Stockholders' equity		
Common stock	866	407
Additional paid-in capital	387,107	330,289
Accumulated other comprehensive gain (loss)	2	-
Accumulated deficit	(328,548)	(312,000)
	59,427	18,696
Less: Treasury stock	(85)	(85)
Total stockholders' equity	59,342	18,611
Total liabilities and stockholders' equity	\$ 79,469	\$ 37,527

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Source: Celsion CORP