



Celsion Corporation Reports 2021 Financial Results and Provides Business Update

March 31, 2022

Focus on Cancer Immunotherapy and Next-Generation Vaccines and a Strong Balance Sheet
Conference Call Begins Today at 11:00 a.m. Eastern Time

LAWRENCEVILLE, N.J., March 31, 2022 (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 year ended December 31, 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 and preclinical studies with PLACCINE, a proprietary, multivalent DNA plasmid technology utilizing synthetic, non-viral vaccine delivery vectors, being evaluated for superiority over the current generation of nucleic acid vaccines.

"GEN-1 continues to show momentum as patient enrollment in OVATION 2, our randomized Phase II study of advanced ovarian cancer patients, is now over 80%. Full enrollment is expected by the third quarter of 2022. We remain encouraged by surgical resection scores among patients being treated at the 100 mg/m² dose cohort in the Phase II OVATION 2 Study. Early reports from the first 39 patients who have undergone interval debulking surgery showed a 27% improvement in the surgical resection (R0) rate in the GEN-1 treatment arm over the control arm. A complete R0 is a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer.

"At various vaccine conferences, we 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 is to demonstrate the superiority of Celsion's DNA vaccine over current mRNA vaccines with respect to the quality of immune response against SARS-CoV-2 variants, including a longer duration of immune response and a stable product at commercially favorable temperatures. To that end, we have engaged BIOQUAL, Inc., a preclinical testing contract research organization, to conduct a non-human primate (NHP) challenge study of our first of many vaccine candidates as protection against SARS-CoV-2. We expect first inoculation of NHP subjects to occur during the last week of March with the goal of generating important data to inform human clinical studies."

Recent Developments

GEN-1 Immunotherapy

Poster Presented at Cytokine-Based Cancer Immunotherapies Summit. In November 2021, the Company announced that Khursheed Anwer, Ph.D., executive vice president and chief science officer, made a presentation on the Company's GEN-1 interleukin 12 (IL-12) immunotherapy program at the Cytokine-Based Cancer Immunotherapies Summit held in Boston on November 30 to December 2, 2021. Dr. Anwer's presentation, was titled "A Non-Viral Gene Therapy Approach to IL-12 Delivery for The Treatment of Cancer." The Company was invited to submit a poster presentation which aligned with Dr. Anwer's oral presentation on the GEN-1 IL-12 program.

In his presentation, Dr. Anwer discussed how local delivery of IL-12 without significant systemic toxicity is feasible with a non-viral gene therapy approach that involves administration of an IL-12 plasmid with a synthetic DNA delivery system. Dr. Anwer also discussed how weekly intraperitoneal administration of GEN-1 yields durable increases in IL-12 and IFN- γ , and why repeated weekly administration of GEN-1 in combination with standard chemotherapy remodels the tumor immune environment to favor immune stimulation over immune suppression.

Dr. Anwer also participated in two panel discussions titled "What Do We Know & Where Do We Want to Go?" and "Side Effects – Mitigating Against Hypotension + Fever with Immune-Stimulating Agents (NK Cell Engagers, PD-1s, Cytokines, T-Cell Engagers) = Cytokine Release Syndrome (CRS)?"

Data Safety Monitoring Board's Unanimous Recommendation to Continue Dosing Patients in the Phase II Portion of the OVATION 2 Study with GEN-1 in Advanced Ovarian Cancer. In February 2022, the Company announced that following a pre-planned interim safety review of 81 as treated patients randomized in the Phase I/II OVATION 2 Study with GEN-1 in advanced (Stage III/IV) ovarian cancer, the Data Safety Monitoring Board (DSMB) unanimously recommended that the OVATION 2 Study continue treating patients with the dose of 100 mg/m². The DSMB also determined that safety is satisfactory with an acceptable risk/benefit, and that patients tolerate GEN-1 during a course of treatment that lasts up to six months. No dose-limiting toxicities were reported.

The Company also announced that over 75% of the projected 110 patients have been enrolled in the OVATION 2 Study. Interim clinical data from the first 39 patients who have undergone interval debulking surgery showed that the GEN-1 treatment arm is showing a 27% improvement in R0 surgical resection rate over the control arm. A complete tumor resection (R0) is a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed.

Vaccine Initiative

Oral Presentation on Celsion's Ongoing Work with DNA-based Vaccines at International Vaccines Congress. In October 2021, the Company announced that Dr. Anwer presented at the International Vaccines Congress. His 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.

Added Key Resources to the Company's Vaccine Development Initiative. In October 2021, the Company announced the strengthening of its management team with a new hire and a promotion in its vaccine development program as follows:

- Carlo Iavarone, Ph.D. joined as Senior Director, Non-Clinical Research
- Subeena Sood, Ph.D. promoted to Senior Manager, Biology and Preclinical Studies

Dr. Iavarone is project leader for the PLACCINE vaccine initiative. He brings to Celsion more than 15 years of experience investigating and leading the development of vaccines, including molecular target identification and characterization of RNA vaccines. Most recently, from 2019 until 2021 he was a science advisor for both Guidepoint and Clora, providing input for a viral target and RNA vaccine delivery system. Dr. Iavarone joined GlaxoSmithKline in 2015 as a senior scientist studying small molecules and RNA vaccines in animal and human cell lines. From 2007 until 2015 he held positions of increasing responsibility at Novartis, including as a principal scientist for a melanoma vaccine project.

Dr. Sood is responsible for assay development and *in vivo* experiments for the PLACCINE DNA vaccine and gene therapy program. She has experience with several pharmaceutical companies in experiment design, pharmacological and biochemical assays, manufacturing process design and development, and optimization and implementation of Quality by Design. Dr. Sood joined Celsion as manager of animal research in 2019, where she has designed and conducted all preclinical research. Prior to Celsion, since 2017 she was a Formulation Scientist at Novocol Healthcare. From 2016 to 2017, Dr. Sood was a Research Associate at Nektar Therapeutics, and from 2015 to 2016 she was a Quality Control Chemist at Par Pharmaceuticals. She also worked in regenerative medicine as a Research Fellow at Medstar Heart Institute, Washington Hospital Center in Washington, D.C. from 2010 to 2013.

Proof of Concept Vaccine Candidate Advanced to Non-Human Primate Challenge Study Against SARS-CoV-2. In January 2022, the Company announced it had engaged BIOQUAL, Inc., a preclinical testing contract research organization, to conduct a non-human primate (NHP) challenge study with Celsion's DNA-based approach for a SARS-CoV-2 vaccine. The NHP pilot study follows the generation of encouraging mouse data and will evaluate the Company's lead vaccine formulations for safety, immunogenicity and protection against SARS-CoV-2.

In completed preclinical studies, Celsion demonstrated safe and efficient immune responses including IgG response, neutralizing antibodies and T-cell responses that parallel the activity of commercial vaccines following intramuscular (IM) administration of novel vaccine compositions expressing a single viral antigen. In addition, vector development has shown promise of neutralizing activity against a range of SARS-CoV-2 variants. Celsion's novel DNA-based vaccines are based on a simple intramuscular injection that does not require viral encapsulation or special equipment for administration. Ongoing directional and technical guidance from our Vaccine Advisory Board, which is comprised of leaders in commercial vaccine development, virology, vector engineering and drug development, has been invaluable as we approach this critical advancement in our platform development program. We expect NHP studies to begin during the second quarter of 2022 with the goal of generating important data to inform human clinical studies.

Corporate Developments

Priced a \$30 Million Registered Direct Offering of Convertible Redeemable Preferred Stock. In January 2022, the Company announced that it has entered into a securities purchase agreement with certain institutional investors to purchase 50,000 shares of Series A convertible redeemable preferred stock and 50,000 shares of Series B convertible redeemable preferred stock. Each share of Series A and Series B preferred stock has a purchase price of \$285, representing an original issue discount of 5% of the \$300 stated value of each share. Each share of Series A preferred stock is convertible into shares of Celsion's common stock at an initial conversion price of \$0.91 per share. Each share of Series B preferred stock is convertible into shares of Celsion's common stock at an initial conversion price of \$1.00 per share. Shares of the Series A and Series B preferred stock are convertible at the option of the holder at any time following the Company's receipt of stockholder approval for a reverse stock split of the Company's common stock. Celsion will be permitted to compel conversion of the Series A and Series B preferred stock after the fulfillment of certain conditions and subject to certain limitations. Total net proceeds from the offerings, before deducting the placement agent's fees and other estimated offering expenses, is approximately \$28.5 million.

The Series A and Series B preferred stock permit the holders thereof to vote together with the holders of the Company's common stock on a proposal to effectuate a reverse stock split of the Company's common stock at a special meeting of Company stockholders to be held on February 24, 2022. The Series A preferred stock permits the holder to vote on such proposal on an as converted to common stock basis. The Series B preferred stock permits the holder to cast 45,000 votes per share of Series B preferred stock on such proposal. The Series A and Series B preferred stock will not be permitted to vote on any other matter. The holders of the Series A and B preferred stock agreed not to transfer their shares of preferred stock until after the special meeting of Company stockholders. The holders of the Series A preferred stock agreed to vote their shares in favor of that proposal and the holders of the Series B preferred stock agreed to vote their shares in the same proportions as the shares of common stock and Series A preferred stock are voted on that proposal. The holders of the Series A and Series B preferred stock have the right to require the Company to redeem their shares of preferred stock for cash at 105% of the stated value of such shares commencing after the earlier of the Company's stockholders' approval of the reverse stock split and 90 days after the closing of the issuances of the Series A and Series B preferred stock and until 120 days after such closing.

On March 3, 2022, the Company redeemed for cash at a price equal to 105% of the \$300 stated value per share all of its 50,000 outstanding shares of Series A Preferred Stock and its 50,000 Series B Preferred Stock. As a result, all shares of the Preferred Stock have been retired and are no longer outstanding and Celsion's only class of outstanding stock is its common stock, par value \$0.01 per share. Each share of common stock entitles the holder to one vote.

Announced Stock Consolidation. In February 2022, the Company announced that, as previously authorized by its shareholders, the Company implemented a consolidation (reverse stock split) of its outstanding Common Shares on the basis of one (1) new Common Share for every fifteen (15) currently outstanding Common Shares.

The new Common Shares was effective for trading purposes as of the commencement of trading on Tuesday, March 1, 2022, and will trade under a new CUSIP number 15117N 602. The Company's ticker symbol, CLSN, remained unchanged. The Company has filed a Certificate of Amendment to its Certificate of Incorporation to effect the stock consolidation.

The new number of outstanding common shares is approximately 5.8 million shares. The number of authorized shares (112.5 million) and the par value per share (\$0.01) were unchanged. The number of outstanding options and warrants were adjusted accordingly, with outstanding options being approximately 437,500 and outstanding warrants being approximately 168,500.

Received \$1.4 Million in Non-Dilutive Funding from the Sale of its New Jersey State Net Operating Losses, with an Additional \$3.5 Million Expected in 2022 - 2023. In February 2022, the Company announced it has received \$1.4 million in net cash proceeds from the sale of approximately \$1.5 million of its unused New Jersey net operating losses (NOLs). The NOL sales cover the tax year 2020 and are administered through the New Jersey Economic Development Authority's (NJEDA) Technology Business Tax Certificate Transfer Program. The Company plans to sell an additional \$3.5 million of unused New Jersey NOLs available to the Company under the program over the next 2 years.

The Technology Business Tax Certificate Transfer Program administered by the NJEDA enables qualified companies to sell up to \$20 million of their unused New Jersey net operating losses and R&D tax credits to unaffiliated, profit-generating corporate taxpayers in the state of New Jersey. The economic development program is designed to allow technology and biotechnology companies with NOLs to turn their tax losses and credits into cash proceeds to fund more R&D, expand its workforce, and cover other allowable expenditures.

Financial Results for the Year Ended December 31, 2021

Celsion reported a net loss of \$20.8 million (\$3.83 per share) in 2021, compared with a net loss of \$21.5 million (\$10.08 per share) in 2020. Operating expenses were \$21.5 million in 2021, which represented a \$2.5 million (13%) increase from \$19.0 million in 2020.

Net cash used for operating activities was \$16.2 million in 2021, compared with \$15.6 million 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. The Company raised approximately \$58.4 million in new financings during 2021 – (i) \$6.9 million in gross proceeds from the use of its JonesTrading Capital on DemandTM financing facility, (ii) \$35 million from a registered direct financing completed in January 2021, (iii) \$15 million from a registered direct financing completed on April 5, 2021, and (iv) \$1.5 million from warrant exercises. With \$56.9 million in cash and cash equivalents, restricted cash, short-term investments and interest receivable at December 31, 2021, the Company has sufficient capital resources to fund its operations through the end of 2024.

Research and development expenses decreased \$0.7 million from \$11.3 million in 2020 to \$10.6 million in 2021. Costs associated with the OVATION 2 Study were consistent at \$1.3 million in 2021 and 2020. Costs associated with the OPTIMA Study decreased to \$1.0 million in 2021 compared to \$2.2 million in 2020. In July 2020, the Company unblinded the OPTIMA Study at the recommendation of the DMC to halt the study due to futility. Other clinical and regulatory costs were \$2.5 million in 2021 and 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 vaccine technology platform increased to \$4.3 million in 2021 compared to \$3.1 million in the same period of 2020. CMC costs decreased to \$1.5 million in 2021 compared to \$2.1 million in 2020 due to the discontinuation of the ThermoDox[®] clinical development program in primary liver cancer.

General and administrative expenses increased to \$10.9 million in 2021 compared to \$7.6 million in 2020. This increase is primarily attributable to higher non-cash stock compensation expense of approximately \$1.3 million, an increase in professional fees of \$1.5 million (largely legal fees to defend various suits filed after the announcement in July 2020 of the OPTIMA Phase III clinical results) and an increase in premiums for directors' and officers' insurance of \$0.3 million in 2021 when compared to 2020.

Other expenses included the following:

- A non-cash credit of \$1.6 million for the change in valuation of the earn-out milestone liability for the GEN-1 ovarian product candidate during 2021, compared with a non-cash charge of \$1.3 million during 2020.
- A non-cash charge of \$2.0 million related to the impairment of goodwill recorded in the fourth quarter of 2021 compared with a \$2.4 million non-cash charge 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 \$0.6 million during 2021, compared with \$1.3 million during 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. In connection with the termination of the Horizon Technology Financing Facility in the second quarter of 2021, the Company paid early termination and end of term charges to Horizon and recognized \$0.2 million as a loss on debt extinguishment.

During the fourth quarter of 2021, the Company entered into an agreement to sell the approved portion of its New Jersey Net Operating Losses (NOLs) applied for in 2021 for \$1.4 million. At December 31, 2021, the Company evaluated the valuation reserve for its tax net operating losses associated with its New Jersey NOLs, reduced the valuation reserve, and recognized \$1.4 million as a deferred income tax asset from the sale of its New Jersey net operating losses and an income tax benefit. The Company completed the sale of these net operating losses in February of 2022. In 2020, the Company entered into an agreement to sell the approved portion of its New Jersey NOLs applied totaling \$1.9 million. At December 31, 2020, the Company evaluated the valuation reserve for its tax net operating losses associated with its New Jersey NOLs, reduced the valuation reserve and recognized \$1.9 million as a deferred income tax asset and an income tax benefit. The Company completed the sale of these net operating losses in May of 2021.

Conference Call

The Company is hosting a conference call to provide a business update, discuss 2021 financial results and answer questions at 11:00 a.m. EDT today. To participate in the call, interested parties may dial 1-888-394-8218 (Toll-Free/North America) or +1-323-794-2588 (International/Toll) and ask for the Celsion Corporation 2021 Earnings Call (Conference Code: 7900710) 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 Thursday, March 31, 2022, and will remain available until April 14, 2022. The replay can be accessed at +1-719-457-0820 or 1-888-203-1112 using Conference ID: 7900710. 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. ET Thursday, March 31, 2022.

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.

Forward Looking Statements

Forward-looking statements in this release are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including, 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 Celsion's periodic filings 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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Celsion Corporation Condensed Statements of Operations (in thousands except per share amounts)

	Year Ended December 31,	
	2021	2020
Licensing revenue	<u>\$ 500</u>	<u>\$ 500</u>
Operating expenses:		
Research and development	10,619	11,345
General and administrative	10,888	7,641
Total operating expenses	<u>21,507</u>	<u>18,986</u>
Loss from operations	<u>(21,007)</u>	<u>(18,486)</u>
Other income (expense):		
Gain (loss) from change in valuation of earn-out milestone liability	1,622	(1,300)
Impairment of goodwill and in-process research and development	(1,976)	(2,370)
Loss on debt extinguishment	(235)	-
Interest expense, investment income and other income (expense), net	(557)	(1,173)
Total other income (expense), net	<u>(1,146)</u>	<u>(4,843)</u>
Loss before income tax benefit	<u>(22,153)</u>	<u>(23,329)</u>
Income tax benefit	1,384	1,846
Net loss	<u>\$ (20,769)</u>	<u>\$ (21,483)</u>
Net loss per common share		
Basic and diluted	<u>\$ (3.83)</u>	<u>\$ (10.08)</u>
Weighted average shares outstanding		
Basic and diluted	<u>5,427</u>	<u>2,130</u>

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

ASSETS	December 31, 2021	December 31, 2020
Current assets		
Cash and cash equivalents	\$ 19,586	\$ 17,164
Investment securities and interest receivable on investment securities	29,912	-
Advances, deposits on clinical programs and other current assets	2,447	1,661
Total current assets	51,946	18,825
Property and equipment	477	295
Other assets		
Restricted cash invested in money market account	6,000	-
Deferred tax asset	1,383	1,845
In-process research and development	13,366	13,366
Goodwill	-	1,976
Operating lease right-of-use assets, deposits and other assets	875	1,220
Total other assets	21,624	18,407
Total assets	\$ 74,047	\$ 37,527
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 5,721	\$ 4,703
Notes payable – current portion	-	1,117
Operating lease liability – current portion	549	433
Deferred revenue - current portion	500	500
Total current liabilities	6,770	6,753
Earn-out milestone liability	5,396	7,018
Notes payable – noncurrent portion	5,854	3,935
Deferred revenue – noncurrent portion	-	500
Operating lease liability – noncurrent portion	231	710
Total liabilities	18,251	18,916
Stockholders' equity		
Common stock	58	27
Additional paid-in capital	388,601	330,669
Accumulated other comprehensive gain (loss)	(8)	-
Accumulated deficit	(332,770)	(312,000)
	55,881	18,696
Less: Treasury stock	(85)	(85)
Total stockholders' equity	55,796	18,611
Total liabilities and stockholders' equity	\$ 74,047	\$ 37,527

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Source: Celsion Corporation