Celsion Corporation Reports First Quarter 2022 Financial Results and Provides Business Update

May 16, 2022

DNA Mediated Immunotherapy and Next-Generation Vaccine Programs Supported with a Strong Balance Sheet

Conference Call Begins Today at 11:00 a.m. EDT

LAWRENCEVILLE, N.J., May 16, 2022 (GLOBE NEWSWIRE) -- Celsion Corporation (NASDAQ: CLSN), a clinical-stage drug-development company focused on DNA-mediated immunotherapy and next-generation vaccines, today announced financial results for the quarter ended March 31, 2022, and provided an update on its clinical development program of GEN-1, a DNA-based interleukin-12 (IL-12) immunotherapy in Phase II clinical development for the treatment of advanced-stage ovarian cancer, and its preclinical studies of PLACCINE, a proprietary, multivalent DNA plasmid technology utilizing synthetic, non-viral delivery vectors, being evaluated in proof of concept studies for superiority over the current generation of nucleic acid vaccines.

"Patient enrollment in OVATION 2, our randomized Phase II study of advanced ovarian cancer patients, continues to show momentum with 85% of patients enrolled as of May 15, 2022, and full enrollment expected to be completed by the third quarter of 2022. We remain encouraged by surrogate endpoints like surgical resection scores among patients being treated at the 100 mg/m² dose cohort in the study. Early reports from the first thirty-nine 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.

"We have presented results from preclinical studies which showed our next-generation PLACCINE DNA vaccine can target two different viral variants, demonstrating immunogenicity as determined by the levels of IgG, neutralizing antibodies, and T-cell responses. Our research shows that our multivalent PLACCINE vaccine was equally effective against two different variants of the COVID-19 virus while the commercial mRNA comparison vaccine appeared to have lost some activity against the newer variant," added Mr. Tardugno. "Our goal is to demonstrate PLACCINE's superiority 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 storage temperatures when compared to commercially available mRNA vaccines. 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. The first inoculation of NHP subjects occurred the last week of March with the goal of generating important data to inform human clinical studies by mid-June 2022."

Recent Developments

GEN-1 Immunotherapy

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 eighty-one 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/m^2. 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.

Findings from the Use of a Synthetic Control Arm to Estimate Treatment Effect in Phase Ib dose-escalating OVATION I Study presented at 2022 AACR Annual Meeting. In April 2022 Celsion demonstrated its commitment to innovation in clinical research. The Company and the premier global data management CRO, Medidata, announced findings on the use of a Synthetic Control Arm® (SCA) in a completed Phase Ib dose-escalating study of GEN-1 in the neoadjuvant treatment of patients with Stage III/IV ovarian cancer at the Annual Meeting of the American Association for Cancer Research (AACR). In a poster presentation entitled "Phase IB trial efficacy estimates via a clinical trial synthetic control arm," which took place on Monday April 11, 2022 from 9 AM through 12:00 PM EST, the research team's findings demonstrated how comparing patients from a single-arm trial can help enhance understanding of treatment effects in advance of randomized trials, inform drug development and trial design, and increase the scientific value of early phase trials.

A Synthetic Control Arm is a type of external control and is formed by carefully matching patients treated with a new investigational therapy to anonymized clinical trial patients from Medidata's extensive repository of historical clinical trials using baseline demographic and disease characteristics. Using this advanced statistical methodology, Celsion and Medidata found that progression-free survival was prolonged for the patients treated with the investigational therapy GEN-1 along with standard of care chemotherapy in the OVATION 1 Study compared to well-balanced historic control patients treated with the same standard of care chemotherapy alone (Hazard Ratio=0.53, 95% Confidence Interval (0.16, 1.73). This larger than expected effect size led to a decrease in the number of planned patients for Celsion's subsequent Phase II trial and was used in support of Fast Track Designation from the U.S. Food and Drug Administration (FDA) received in February 2021.

Vaccine Initiative

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 murine data and will evaluate the Company's 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.

PLACCINE Vaccine Platform Technology Highlighted During Oral Presentation at the World Vaccine Congress. In April 2022, the Company presented its PLACCINE platform technology at the World Vaccine Congress which took place in Washington D.C. In an oral presentation during a Session on Cancer and Immunotherapy, Dr. Khursheed Anwer, Celsion's Chief Science Officer, highlighted the Company's technology platform in his presentation entitled: "*Novel DNA Approaches for Cancer Immunotherapies and Multivalent Infectious Disease Vaccines*." PLACCINE is one of three platform technologies Celsion has for a range of therapeutics in oncology and immunotherapy. A copy of Dr. Anwer's presentation is available on the investor portion of the Celsion website under Scientific Presentations.

PLACCINE is demonstrating the potential to be a platform for a range of infectious disease that provides for rapid design capability for targeting two or more different variants of a single virus in one vaccine. There is a clear public health need for vaccines today that address more than one strain of viruses, like COVID-19, which have fast evolving variant capability. Murine model data has thus far been encouraging and suggests that the Company's approach provides not only flexibility, but also the potential for efficacy comparable to benchmark COVID-19 commercial vaccines with durability to protect expected to be greater than 6 months.

In the murine model, our multivalent PLACCINE vaccine targeted against two different variants showed to be immunogenic as determined by the levels of IgG, neutralizing antibodies, and T-cell responses. Additionally, our multivalent vaccine was equally effective against two different variants of the COVID-19 virus while the commercial mRNA vaccine appeared to have lost some activity against the newer variant. The Company continues to evaluate our technology and look forward to the results from our ongoing proof-of-concept non-human primate study evaluating our PLACCINE vaccine against the challenge from live SARS-CoV-2 virus in the second quarter, with durability results available in the second half of this year.

Corporate Developments

Issuance and Redemption of Convertible Redeemable Preferred Stock. In January 2022, the Company announced that it had entered into a securities purchase agreement with certain institutional investors to purchase Series A and B convertible redeemable preferred stock for approximately $28.5 million in gross proceeds. The Series A and Series B preferred stock permitted 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 held on February 24, 2022. The Series A and Series B preferred stock were not permitted to vote on any other matters.

The holders of the Series A and Series B preferred stock had the right to redeem their shares of preferred stock for cash at 105% of the stated value after the Company's stockholders' approval of the reverse stock split. 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 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.

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.

Strengthened Balance Sheet Through Registered Direct Offering of Common Shares totaling $7.0 Million in Gross Proceeds Priced At-The-Market under NASDAQ Rules. On April 8, 2022, the Company announced the closing of a registered direct offering of 1,328,274 shares of common stock at a purchase price of $5.27 per share, resulting in gross proceeds of $7.0 million, before deducting placement agents' fees and expenses. Celsion intends to use the net proceeds for general corporate purposes, including research and development activities, capital expenditures and working capital.

Financial Results for the Three Months Ended March 31, 2022

Celsion reported a net loss for the first quarter of 2022 of $10.5 million ($1.82 per share) compared with a net loss of $5.7 million ($3.31 per share) in 2021. Operating expenses were $6.0 million for the first quarter in 2022, which represented a $0.5 million (8%) increase from $5.5 million for the first quarter of 2021.

Net cash used for operating activities was $8.0 million for the first quarter of 2022, compared with $4.7 million for the comparable prior-year period. This increase is attributable to higher non-operating expenses (interest expense related to the one-time sale and subsequent redemption of $30 million convertible, redeemable preferred stock during the first quarter of 2022). The Company had $47.3 million in cash, investments and restricted cash as of March 31, 2021. Combined with $6.5 million of net proceeds received from the sale of equity in a registered direct offering that closed on April 8, 2022, along with $3.5 million in future planned sales of the Company's State of New Jersey NOLs, the Company believes it has sufficient capital resources to fund its operations into the second quarter of 2025.

Research and development expenses were $3.1 million for the first quarter of 2022, an increase of $0.5 million or 20% from $2.6 million for the comparable period in 2021. 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 $1.9 million in the first quarter of 2022 compared to $1.4 million in the same three-month period of 2021. Costs associated with the OPTIMA Study were $0.1 million in the first quarter of 2022 and 2021. 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 $0.8 million in the first quarter of 2022 and $0.6 million the first quarter of 2021. CMC costs decreased to $0.3 million in the first quarter of 2022 compared to $0.5 million in in the first quarter of 2021 due to the discontinuation of the ThermoDox® clinical development program in primary liver cancer.

General and administrative expenses were $2.9 million in each of the first quarters of 2022 and 2021. Lower non-cash stock compensation expense of $0.4 million was offset by higher salaries and benefits, higher professional fees (largely legal fees to defend various suits filed after the announcement in July 2020 of the OPTIMA Phase III clinical results) and higher premiums for directors' and officers' insurance in the first quarter of 2022 when compared to same prior year period.

Other non-operating expenses increased to $4.6 million in the first quarter of 2022 compared to $0.3 million in the comparable prior year. Interest expense increased by $4.5 million resulting from the sale and subsequent redemption of $30 million of Series A & B convertible redeemable preferred stock during the first quarter of 2022.

Conference Call

The Company is hosting a conference call to provide a business update, discuss first quarter 2022 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 First Quarter 2022 Earnings Call (Conference Code: 7615593) 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 Monday, May 16, 2022, and will remain available until May 30, 2022. The replay can be accessed at +1-719-457-0820 or 1-888-203-1112 using Conference ID: 7615593. 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 Monday, May 16, 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)

	Quarter Ended March 31,	
	2022	2021
Licensing revenue	$ 125	$ 125
Operating expenses:		
Research and development	3,095	2,571
General and administrative	2,872	2,937
Total operating expenses	5,967	5,508
Loss from operations	**(5,842)**	**(5,383)**
Other income (expense):		
Loss from change in valuation of earn-out milestone liability	-	(151)

Interest expense on preferred stock	(4,552)	-
Interest expense on loan facility	(94)	(158)
Investment and other income	14	3
Total other expense	(4,632)	(306)
Net loss	**$ (10,474)**	**$ (5,689)**
Net loss per common share		
Basic and diluted	**$ (1.82)**	**$ (3.31)**
Weighted average shares outstanding		
Basic and diluted	**5,770**	**1,720**

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

ASSETS	**March 31, 2022**	**December 31, 2021**
Current assets		
Cash and cash equivalents	$ 28,362	$ 19,586
Investment securities and interest receivable on investment securities	12,959	29,912
Advances, deposits on clinical programs and other current assets	2,545	2,448
Total current assets	**43,866**	**51,946**
Property and equipment	**488**	**477**
Other assets		
Restricted cash invested in money market account	6,000	6,000
Deferred tax asset	-	1,383
In-process research and development	13,366	13,366
Operating lease right-of-use assets, deposits and other assets	621	875
Total other assets	**19,987**	**21,624**
Total assets	**$ 64,341**	**$ 74,047**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 5,757	$ 5,721
Operating lease liability – current portion	517	549
Deferred revenue - current portion	375	500
Total current liabilities	**6,649**	**6,770**
Earn-out milestone liability	5,396	5,396
Notes payable – noncurrent portion	5,900	5,854
Operating lease liability – noncurrent portion	131	231
Total liabilities	**18,076**	**18,251**
Stockholders' equity		
Common stock	58	58
Additional paid-in capital	389,595	388,601
Accumulated other comprehensive gain (loss)	(59)	(8)
Accumulated deficit	(343,244)	(332,770)
	46,350	55,881
Less: Treasury stock	(85)	(85)
Total stockholders' equity	**46,265**	**55,796**
Total liabilities and stockholders' equity	**$ 64,341**	**$ 74,047**

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Source: Celsion Corporation