# Celsion Corporation Reports Second Quarter 2022 Financial Results and Provides Business Update

August 15, 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., Aug. 15, 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 three and six months ended June 30, 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 current mRNA vaccines.

"As we approach the second half of the year, I am pleased to report that Celsion is in a strong financial position, making important progress with our innovative development platforms in oncology and infectious disease. Our OVATION 2 Phase II study of GEN-1 in advanced ovarian cancer continues to advance, with complete enrollment anticipated in the third quarter. Our PLACCINE platform, which was highlighted at the recent World Vaccine Forum, continues to show promise for the potential to address a range of infection diseases as we evaluate its capability in a head to head comparison with commercial covid-19 vaccines," said Dr. Corinne Le Goff, Celsion's president and chief executive officer. "Moreover, given the uncertainty of the capital markets, it's clear that the steps that we have taken over the past 18 months to ensure a cash balance that provides a runway into 2025 was a smart strategy. We expect to report several value creating developments during this time frame."

**Recent Developments**

**GEN-1 Immunotherapy**

***Data Safety Monitoring Board Unanimously Recommends Continued Dosing Patients in the OVATION 2 Study.*** In June 2022, the Company announced that following a pre-planned interim safety review of 87 as treated patients (46 patients in the experimental arm and 41 patients in the control arm) 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 was satisfactory with an acceptable risk/benefit, and that weekly doses of GEN-1 were well tolerated during a course of treatment that is given over six months in combination with standard neoadjuvant chemotherapy. No dose-limiting toxicities were reported.

The Company also announced that more than 87% of the projected 110 patients have been enrolled in the OVATION 2 Study. Interim clinical data from patients who have undergone interval debulking surgery showed that the GEN-1 treatment arm is showing improvement in R0 surgical resection rates and CRS 3 chemotherapy response scores 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. The chemotherapy response score 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.

In February 2021, the Company announced that GEN-1 received FDA Fast Track Designation in advanced ovarian cancer. Celsion plans to request FDA Breakthrough Therapy Designation for GEN-1 based on the encouraging clinical data.

***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, 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**

***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**

***Dr. Corinne Le Goff Appointed as President and Chief Executive Officer; Michael H. Tardugno Appointed Executive Chairman of the Board.*** In July 2022, the Company announced that the Company's Board of Directors appointed biopharmaceutical leader Corinne Le Goff, Pharm D, MBA, as President and Chief Executive Officer and Director, effective July 18, 2022. Michael H. Tardugno will continue to serve as Executive Chairman of Celsion's Board of Directors.

Dr. Le Goff brings decades of global healthcare leadership experience to the Company across a range of therapeutic areas including oncology, vaccines, immunology, CNS and cardio-metabolism. She brings a wealth of experience in developing and launching successful drugs from her tenure at both large pharmaceutical companies and small, innovative biotech companies.

Prior to her Celsion appointment, Dr. Le Goff most recently served as the Chief Commercial Officer of Moderna, responsible for developing the global presence and capabilities necessary to ensure the global distribution of Moderna's COVID-19 vaccine. She also led the development of the Moderna's mRNA platform long-term commercial strategy. Dr. Le Goff joined Moderna from Amgen, where she served as President of the U.S. Business, driving the growth strategy with increased contributions from Repatha® and Aimovig®. During her 6-year tenure at Amgen, she also served as Senior Vice President of Global Product Strategy & Commercial Innovation and as President of the Europe Region overseeing 48 markets. Dr. Le Goff was actively engaged with the policy community and advocates for innovative, high-quality, and affordable healthcare. She represented Amgen as a member of the Healthcare Leadership Council. Prior to joining Amgen, Dr. Le Goff held a number of senior international roles at Roche, including President of Roche France, a major affiliate of the Roche Group, and Global Product Strategy Head of Neuroscience & Rare Diseases. Early in her career, Dr. Le Goff spent 11 years in various leadership roles at Sanofi and Pfizer in the United States.

Dr. Le Goff earned a PhD in pharmaceutical sciences from Rene Descartes University in Paris and an MBA from Sorbonne University and INSEAD. She also holds qualifications from Northwestern University and the Hong Kong University of Science and Technology. She received the distinction of being named a Chevalier de la Légion d'Honneur in 2014. She holds a U.S. patent and was recently recognized by Forbes Magazine as one of the women over the age of 50 who are changing the world.

***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.

**Second Quarter Financial Results**

Celsion reported a net loss for the second quarter of 2022 of $6.0 million ($0.87 per share) compared with a net loss of $5.4 million ($0.95 per share) in 2021. Operating expenses were $6.1 million for the second quarter in 2022, which represented a $0.9 million (17%) increase from $5.2 million for the second quarter of 2021.

The Company ended the second quarter of 2022 with $48.1 million in cash, investments, restricted cash, and accrued interest receivable. Coupled with future planned sales of the Company's State of New Jersey net operating losses, the Company believes it has sufficient capital resources to fund its operations into 2025.

Research and development expenses were $3.2 million for the second quarter of 2022, an increase of $0.6 million or 23% 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 $1.7 million in the second quarter of 2022 compared to $1.4 million in the same three-month period of 2021. Costs associated with the OPTIMA Study were $0.5 million in the second quarter of 2022 which represented expenses associated with closing out this Phase III study which was discontinued in the first quarter of 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, CMC and regulatory costs were $1.0 million in the second quarter of 2022 and 2021.

General and administrative expenses were $2.9 million in the second quarter of 2022, compared with $2.6 million in the same period of 2021. This $0.3 million increase was primarily attributable to 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 offset by lower non-cash stock compensation expense.

Other non-operating expenses were $65 thousand in the second quarter of 2022 compared to $0.4 million in the comparable prior year. This decrease was attributable to the payment of early termination fees to Horizon Technology Finance Corporation in June 2021. The Company entered into a $10 million loan facility with Silicon Valley Bank (SVB). The Company immediately used $6 million from the SVB facility to retire all outstanding indebtedness 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 early debt extinguishment.

**Financial Results for the Six Months Ended June 30, 2022**

For the six months ended June 30, 2022, the Company reported a net loss of $16.5 million ($2.59 per share), compared with a net loss of $11.1 million ($2.19 per share) in the same period of 2021. Operating expenses were $12.1 million during the first six months of 2022, which represented a $1.4 million (13%) increase from $10.7 million in the same six-month period of 2021.

Net cash used for operating activities was $13.4 million in the first six months of 2022, compared with $7.3 million in the same period in 2021. This increase was primarily due to the one-time payment of $4.6 million in interest expense resulting from the sale and subsequent redemption of $30 million of Series A & B convertible redeemable preferred stock in the first quarter of 2022. The Company's projected cash utilization for the balance of 2022 is approximately $5 million per quarter. Cash provided by financing activities of $6.3 million during the first six months of 2022 was derived from an at-the-market equity offering in April 2022. The Company also received net proceeds of $1.4 million from the sale of its unused New Jersey NOLs in February 2022.

Research and development expenses increased $1.1 million to $6.3 million in the first six months of 2022 from $5.2 million in the comparable prior-year period. 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 $3.7 million in the first six months of 2022, compared with $2.8 million in the comparable 2021 period. Costs for the Phase III OPTIMA Study increased $0.1 million to $0.5 million in the first six months of 2022, compared with $0.4 million in the first six months of 2021, due to closing out this Phase III study which was discontinued in the first quarter of 2021. Other costs related to clinical supplies and regulatory support for the Company's clinical development programs increased $0.1 million in the first six months of 2022, compared with the same prior year period.

General and administrative expenses were $5.7 million in the first six months of 2022, compared with $5.5 million in the same period of 2021. The $0.2 million increase was primarily attributable to higher legal and professional fees offset by lower non-cash stock compensation expense.

Other non-operating expenses were $4.7 million in the first six months of 2022 compared to $0.7 million in the comparable prior year period. This increase was attributable to the one-time payment of $4.6 million in interest expense resulting from the sale and subsequent redemption of $30 million of Series A & B convertible redeemable preferred stock in the first quarter of 2022.

**Conference Call**

The Company is hosting a conference call to provide a business update, discuss second quarter 2022 financial results and answer questions at 11:00 a.m. EDT today. To participate in the call, interested parties may dial 1-888-220-8451 (Toll-Free/North America) or +1-323-794-2588 (International/Toll) and ask for the Celsion Corporation Second Quarter 2022 Earnings Call (Conference Code: 5801156) 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, August 15, 2022, and will remain available until August 29, 2022. The replay can be accessed at +1-719-457-0820 or 1-888-203-1112 using Conference ID: 5801156. 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, August 15, 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)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| **Licensing revenue** | $ 125 | $ 125 | $ 250 | $ 250 |
| **Operating expenses:** | | | | |
| Research and development | 3,226 | 2,593 | 6,322 | 5,165 |
| General and administrative | 2,877 | 2,603 | 5,748 | 5,540 |
| **Total operating expenses** | 6,103 | 5,196 | 12,070 | 10,705 |
| **Loss from operations** | (5,978) | (5,071) | (11,820) | (10,455) |
| **Other income (expense):** | | | | |
| Gain (loss) from change in valuation of earn-out milestone liability | - | 81 | - | (70) |
| Interest expense | (105) | (221) | (4,751) | (379) |
| Loss on debt extinguishment | - | (235) | - | (235) |
| Other income (expense) | 40 | (2) | 54 | 1 |
| **Total other (expense) income, net** | (65) | (377) | (4,697) | (683) |
| **Net loss** | $ (6,043) | $ (5,448) | $ (16,517) | $ (11,138) |
| **Net loss per common share** | | | | |
| **Basic and diluted** | $ (0.87) | $ (0.95) | $ (2.59) | $ (2.19) |
| **Weighted average shares outstanding** | | | | |
| **Basic and diluted** | 6,982 | 5,728 | 6,373 | 5,078 |

**Celsion Corporation**
**Selected Balance Sheet Information**
**(in thousands)**

| **ASSETS** | **June 30, 2022 (Unaudited)** | **December 31, 2021** |
|---|---|---|
| **Current assets** | | |
| Cash and cash equivalents | $ 26,742 | $ 19,586 |
| Investment securities and interest receivable on investment securities | 15,401 | 29,912 |
| Advances, deposits on clinical programs and other current assets | 2,768 | 2,448 |
| **Total current assets** | **44,911** | **51,946** |
| **Property and equipment** | **562** | **477** |
| **Other assets** | | |
| Deferred tax asset | - | 1,383 |
| Restricted cash invested in money market account | 6,000 | 6,000 |
| In-process research and development | 13,366 | 13,366 |
| Operating lease right-of-use assets, deposits and other assets | 489 | 875 |
| **Total other assets** | **19,855** | **21,624** |
| **Total assets** | **$ 65,328** | **$ 74,047** |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **Current liabilities** | | |
| Accounts payable and accrued liabilities | $ 6,181 | $ 5,721 |
| Operating lease liability – current portion | 460 | 549 |

| | | |
|---|---|---|
| Deferred revenue - current portion | 250 | 500 |
| **Total current liabilities** | **6,891** | **6,770** |
| | | |
| Earn-out milestone liability | 5,396 | 5,396 |
| Notes payable – noncurrent portion | 5,945 | 5,854 |
| Operating lease liability – noncurrent portion | 53 | 231 |
| **Total liabilities** | **18,285** | **18,251** |
| **Stockholders' equity** | | |
| Common stock | 71 | 58 |
| Additional paid-in capital | 396,414 | 388,601 |
| Accumulated other comprehensive gain (loss) | (70) | (8) |
| Accumulated deficit | (349,287) | (332,770) |
| | 47,128 | 55,881 |
| Less: Treasury stock | (85) | (85) |
| **Total stockholders' equity** | **47,043** | **55,796** |
| **Total liabilities and stockholders' equity** | **$ 65,328** | **$ 74,047** |

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Source: Celsion Corporation