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

May 14, 2021

Focus on Immuno-Oncology and
Next-Generation Vaccines is Supported with a Strong Balance Sheet

Conference Call Begins at 10:00 a.m. Eastern Time Today

LAWRENCEVILLE, N.J., May 14, 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 months ended March 31, 2021, and provided an update on clinical development programs with GEN-1, a DNA-based interleukin-12 (IL-12) immunotherapy in Phase I/II clinical development for the localized treatment of ovarian cancer, 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.

"Celsion entered 2021 with a focus on a novel DNA-based immunotherapy for ovarian cancer and an initiative for next-generation vaccines with the potential to immunize against a broad range of infectious agents, including coronaviruses. Our platform technologies, TheraPlas and PlaCCine, are rich with promise for a pipeline of product candidates that have potential to address difficult and unaddressed diseases. During the first quarter, the Company extended its cash operating runway through 2024 and strengthened our balance sheet with the successful execution of its financing strategy by raising more than $58 million in gross proceeds from two well placed, registered direct offerings, sales under our at-the-market (ATM) equity facility, warrant exercises and the sale of our New Jersey State NOLs," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer.

"Our Phase I/II OVATION 2 Study is more than 40% enrolled. With 23 clinical sites activated, encouraging trial data to date and the strong commitment of our clinical investigators, we hope to complete enrollment before the end of 2021. Initial data at the 100 mg/m² dose cohort appear to be consistent with the directionally impressive results reported from our Phase Ib dose-escalating OVATION I Study in ovarian cancer. In the OVATION 2 study of 28 patients who completed interval debulking surgery, 81% of those treated with GEN-1 had an R0 resection, compared with 58% of control patients, a 41% improvement."

Mr. Tardugno added, "During the first quarter of 2021, we announced an initiative to focus our considerable DNA plasmid experience and competencies on DNA vaccine development, an approach we believe may represent an advance in nucleic acid immunotherapy. Leveraging our clinical-stage TheraPlas platform, we envision a vaccine characterized by a single-plasmid DNA with multiple coding regions. Celsion's plasmid vectors currently in development are designed to promote multiple antigens that are expressed by a single pathogen in combination with a potent immune modifier such as IL-12. IL-12 is the active ingredient in our GEN-1 product candidate. We are well positioned with a capital structure sufficient to support our planned R&D and clinical programs through transformative milestones. In doing so, we look to create significant value for our shareholders, patients and the medical community."

Recent Developments

GEN-1 Immunotherapy

Announced Encouraging Interim Clinical Update on Phase I/II OVATION 2 Study with GEN-1 in Patients with Advanced Ovarian Cancer. In February 2021, the Company provided an update on its Phase I/II OVATION 2 Study with GEN-1 in patients with advanced ovarian cancer. The OVATION 2 Study combines GEN-1 with standard-of-care neoadjuvant chemotherapy (NACT) in patients newly diagnosed with Stage III/IV ovarian cancer. NACT is designed to shrink the cancer as much as possible for optimal surgical removal after three cycles of chemotherapy. Following NACT, patients undergo interval debulking surgery, followed by three adjuvant cycles of chemotherapy and up to nine additional weekly GEN-1 treatments, the goal of which is to delay disease progression and improve overall survival. To date, the Company has enrolled more than 40% of the anticipated 110 patients to be enrolled into the OVATION 2 Study. Currently, 28 patients have had their interval debulking surgery with the following results:

- 13 of 16 patients, or 81%, treated with GEN-1 had a R0 resection, which indicates a microscopically margin-negative complete resection in which no gross or microscopic tumor remains in the tumor bed;
- Seven of 12 patients, or 58%, in the control arm had an R0 resection; and,
- These interim data represent a 41% improvement in R0 resection rates for GEN-1 patients compared with control arm patients and is consistent with the reported improvement in resection scores noted in the encouraging Phase I OVATION 1 Study, the manuscript of which has been submitted for peer-review publication.

Received FDA Fast Track Designation for GEN-1 in Advanced Ovarian Cancer. In February 2021, the Company announced receipt of Fast Track designation from the U.S. Food and Drug Administration (FDA) for GEN-1. Fast Track designation is intended to facilitate the development and expedite the regulatory review of drugs to treat serious conditions and fill an unmet medical need. According to the FDA, a Fast-Track Drug must show some advantage over available therapy, including:

- Showing superior effectiveness, effect on serious outcomes or improved effect on serious outcomes
- Avoiding serious side effects of an available therapy
- Decreasing a clinically significant toxicity of an available therapy that is common and causes discontinuation of treatment

Vaccine Initiative

Filed Provisional U.S. Patent Application for a Broad Range of Next-Generation DNA Vaccines. In January 2021, the Company announced the filing of a provisional U.S. patent application for a novel DNA-based, investigational vaccine for preventing or treating infections from a broad range of infectious agents, including coronaviruses, using its PLACCINE DNA vaccine technology platform. The provisional patent covers a family of novel composition of multi-cistronic vectors and polymeric nanoparticles that comprise the PLACCINE DNA vaccine platform technology for preventing or treating infectious agents that have the potential for global pandemics, including the SARS-CoV-2 virus and its variants, using the Company's technology platform. Celsion's vaccine approach is designed to optimize the quality of the immune response dictating the efficiency of pathogen clearance and patient recovery. Celsion has taken a multivalent approach in an effort to generate an even more robust immune response that not only results in a strong neutralizing antibody response, but also a more robust and durable T-cell response. Delivered with Celsion's synthetic polymeric system, the proprietary DNA plasmid is protected from degradation and its cellular uptake is facilitated.

PLACCINE is a natural extension of the Company's synthetic, non-viral TheraPlas delivery technology currently in a Phase II trial for the treatment of late-stage ovarian cancer with GEN-1. Celsion's proprietary multifunctional DNA vaccine technology concept is built on the flexible PLACCINE technology platform that is amenable to rapidly responding to the SARS-CoV-2 virus, as well as possible future mutations of SARS-CoV-2, other future pandemics, emerging bioterrorism threats and novel infectious diseases. Celsion's extensive experience with TheraPlas suggests that the PLACCINE-based nanoparticles are stable at storage temperatures of 4^{o}C to 25^{o}C, making vaccines developed on this platform suitable for broad worldwide distribution.

Formed Vaccine Advisory Board. In February 2021, the Company announced the formation of a Vaccine Advisory Board and the appointment of its first two members:

- Britt A. Glaunsinger, Ph.D., Professor, Virology & Molecular Biology, Howard Hughes Medical Institute, University of California, Berkeley; and
- Xinzhen Yang, M.D., Ph.D., Independent Professional Consultant for the Gerson Lehman Group and former Director of Viral Vaccines / Program Lead of the HCMV Vaccine Program at Pfizer Inc.

Corporate Developments

Strengthened Balance Sheet Through Two Registered Direct Offerings of Common Shares Totaling $50 Million in Gross Proceeds.

- On January 26, 2021, the Company announced the closing of a registered direct offering of 25,925,925 shares of common stock at a purchase price of $1.35 per share, priced at-the-market under Nasdaq rules, resulting in net proceeds of $32.6 million after deducting placement agents' fees but before expenses payable by the Company.
- On April 5, 2021, the Company announced the closing of a registered direct offering of 11,538,462 shares of common stock at a purchase price of $1.30 per share, resulting in net proceeds of $13.9 million, after deducting placement agents' fees but before expenses payable by the Company.

Celsion intends to use the net proceeds for general corporate purposes, including research and development activities, capital expenditures and working capital.

Received $2.0 Million Allocation Through the New Jersey Technology Business Tax Certificate Transfer (NOL) Program, with an Additional $5.0 Million Expected in 2021-2023. In February 2021, the Company received approval from the New Jersey Economic Development Authority's (NJEDA) Technology Business Tax Certificate Transfer (NOL) program to sell $2.0 million of its unused New Jersey net operating losses (NOLs) for the tax years 2018 and 2019. The NOLs are typically sold at a small, single-digit discount to qualified companies with operations in New Jersey. As a result, the Company was able to transfer this credit and receive approximately $1.85 million of net cash proceeds in May 2021. An additional $5.0 million allocation of NOL sales will be available to the Company during 2021-2023.

Participated in Two Investor Events. In March 2021, the Company held one-on-one meetings with investors during the Virtual 33rd Annual Roth Conference. A webcast of Celsion's presentation was pre-recorded and is available on the Company's website. In April 2021, Company management participated in Alliance Global Partners' (AGP) Virtual Series. Michael H. Tardugno and Dr. Kursheed Anwar were interviewed in a "Fireside Chat" by Matt Cross, Senior Biotech Research Analyst at AGP. The discussion focused on the Company's lead product, GEN-1and on its PLACCINE vaccine development platform. Requests to listen to a replay can be made by emailing agpevents@allianceg.com.

Financial Results for the Three Months Ended March 31, 2021

Celsion reported a net loss for the first quarter of 2021 of $5.7 million ($0.09 per share) compared with a net loss of $5.1 million ($0.20 per share) for the year-ago quarter. Operating expenses were $5.5 million for the first quarter of 2021, which represented a $0.6 million or 13% increase from $4.9 million for the first quarter of 2020.

Research and development expenses were $2.6 million for the first quarter of 2021, a decrease of $0.5 million or 16% from $3.1 million for the comparable period in 2020. Clinical development costs for the Phase III OPTIMA Study decreased to $0.1 million for the first quarter of 2021, compared with $0.7 million for the prior-year quarter. In July 2020, the Company unblinded the OPTIMA Study and at the recommendation of the Data Monitoring Committee halted the study due to futility. R&D costs associated with development of GEN-1 to support the OVATION 2 Study as well as development of the PLACCINE DNA vaccine technology platform increased to $1.0 million for the first quarter of 2021, compared with $0.9 million for the same period of 2020. Other costs related to the Company's clinical development programs decreased by $0.2 million for the first quarter of 2021 compared with 2020, due to lower regulatory and manufacturing costs for the ThermoDox development program.

General and administrative expenses were $2.9 million for the first quarter of 2021, compared with $1.8 million for the first quarter of 2020. This increase is primarily attributable to higher non-cash stock compensation expense of $0.8 million, an increase in professional fees of $0.2 million and an increase in premiums for directors' and officers' insurance.

The Company had $54.6 million in cash and cash equivalents, short-term investments and a receivable on the sale of NOLs as of March 31, 2021. Combined with $15 million of gross proceeds received from the sale of equity in a registered direct offering that closed on April 5, 2021 along with future planned sales of the Company's State of New Jersey NOLs, the Company believes it has sufficient capital resources to fund its operations through 2024.

Net cash used for operating activities was $4.7 million for the first quarter of 2021, compared with $5.0 million for the comparable prior-year period.

Total cash provided by financing activities was approximately $40.5 million during the first quarter of 2021, resulting from $39.0 million of net proceeds from sales of common stock and $1.5 million from the exercise of common stock warrants. The Company raised an additional $13.9 million in net proceeds from sales of common stock during the second quarter of 2021. The Company recognized a $1.85 million income tax benefit resulting from the sale of its New Jersey NOLs during the fourth quarter of 2020. Net proceeds from this sale are expected to be received in the second quarter of 2021. The Company has approximately $5.0 million in future tax benefits remaining under the NJEDA Technology Business Tax Certificate Transfer program for future years.

Conference Call

The Company is hosting a conference call at 10:00 a.m. EDT today to provide a business update, discuss first quarter 2021 financial results and answer questions. 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 first quarter 2021 Earnings Call (Conference Code: 8053366). The call will also be broadcast live on the internet at www.celsion.com. The call will be archived for replay on Friday, May 14, 2021 and will remain available until May 28, 2021. The replay can be accessed at 1-888-203-1112 or 1-719-457-0820 using Conference ID: 8053366. An audio replay of the call will also be available on the Company's website, www.celsion.com, for 90 days beginning 2:00 p.m. EDT Friday, May 14, 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-CoV2. The company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer. ThermoDox ®, a proprietary heat-activated liposomal encapsulation of doxorubicin, is under investigator-sponsored development for several cancer indications. Celsion also has two feasibility stage platform technologies for the development of novel nucleic acid-based immunotherapies and other anti-cancer 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 news 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 or regulatory authorities; and other risks detailed from time to time in the 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 March 31,	
	2021	**2020**
Licensing revenue	$ 125	$ 125
Operating expenses:		
Research and development	2,571	3,052
General and administrative	2,937	1,839
Total operating expenses	5,508	4,891
Loss from operations	(5,383)	(4,766)
Other income (expense):		
Loss from change in valuation of earn-out milestone liability	(151)	(41)
Interest expense, investment income and other income (expense), net	(155)	(250)
Total other expense	(306)	(291)
Net loss	$ (5,689)	$ (5,057)

Net loss per common share - basic and diluted	$ (0.09)	$ (0.20)
Weighted average common shares outstanding - basic and diluted	66,299	25,804

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	March 31, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 37,759	$ 17,164
Investment securities	15,000	-
Receivable on sale of tax asset and other current assets	3,489	1,661
Total current assets	**56,248**	**18,825**
Property and equipment	**390**	**295**
Other assets		
Deferred income tax asset	-	1,846
In-process research and development	13,366	13,366
Goodwill	1,976	1,976
Operating leases right-of-use and other assets, net	1,061	1,220
Total other assets	**16,403**	**18,408**
Total assets	**$ 73,041**	**$ 37,527**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 3,908	$ 4,703
Deferred revenue – current portion	500	500
Operating lease liability – current portion	446	433
Notes payable - current portion	1,836	1,117
Total current liabilities	**6,690**	**6,753**
Earn-out milestone liability	7,169	7,018
Notes payable - noncurrent portion	3,252	3,935
Other liabilities - noncurrent portions	970	1,210
Total liabilities	**18,081**	**18,916**
Stockholders' equity		
Common stock	750	407
Additional paid-in capital	371,982	330,289
Accumulated other comprehensive gain (loss)	2	-
Accumulated deficit	(317,689)	(312,000)
	55,045	**18,696**
Less: Treasury stock	(85)	(85)
Total stockholders' equity	**54,960**	**18,611**
Total liabilities and stockholders' equity	**$ 73,041**	**$ 37,527**

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Source: Celsion CORP