Celsion Corporation Reports 2020 Financial Results and Provides Business Update

March 19, 2021

Entered 2021 with a Focus on Cancer Immunotherapy and Next-Generation Infectious Vaccines and a Strong Balance Sheet

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

LAWRENCEVILLE, N.J., March 19, 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 year ended December 31, 2020 and provided an update on clinical development programs with GEN-1, a DNA-based immunotherapy in Phase I/II 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 infectious vaccines.

"Celsion entered 2021 with a renewed focus and prioritization on DNA-based immunotherapies for ovarian cancer and an initiative for next-generation vaccines for preventing or treating infections from a broad range of infectious agents, including coronaviruses, using our PLACCINE DNA vaccine technology platform. All of our work is supported by a strong balance sheet and a three-year cash operating runway," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer.

"Our Phase I/II OVATION 2 Study is over one-third enrolled. With 25 clinical sites to be activated by the end of the first quarter of 2021, encouraging trial data to date and the strong commitment of our clinical investigators, we expect to complete enrollment well 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 trial (the OVATION I Study) in ovarian cancer. 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 that are 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 currently used in our product candidate GEN-1. 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. On February 25, 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 progression and improve overall survival. To date, the Company has enrolled approximately one-third 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, or 81%, of patients 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%, of patients 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 I Study, the manuscript of which has been submitted for peer-review publication.

Received FDA Fast Track Designation for GEN-1 in Advanced Ovarian Cancer. On March 22, 2021, the Company announced receipt of Fast Track designation from the U.S. Food and Drug Administration (FDA) for GEN-1, its DNA-mediated interleukin-12 (IL-12) immunotherapy currently in Phase II development for the treatment of advanced ovarian cancer. 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. On January 28, 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 platform technology. 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 easily suitable for broad worldwide distribution.

Formed a Vaccine Advisory Board. On February 12, 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
- Dr. 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 a $35 Million Registered Direct Offering of Common Shares Priced At-The-Market Under NASDAQ Rules. 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. Celsion intends to use the net proceeds for general corporate purposes, including research and development activities, capital expenditures and working capital. This financing, coupled with the pending sale of its New Jersey net operating losses in the first half of 2021, will extend the Company's operating roadway through 2023, well beyond several important clinical and R&D milestones.

Received $2 Million Allocation Through the New Jersey Technology Business Tax Certificate Transfer (NOL) Program, with an Additional $5 Million Expected in 2021-2023. In December 2020, the Company received approval from the New Jersey Economic Development Authority's (NJEDA) Technology Business Tax Certificate Transfer program to sell its unused New Jersey net operating losses (NOLs) and R&D tax credits. In 2019, the Company received approval from the NJEDA to sell $1.9 million of its unused New Jersey NOLs and was able to transfer this credit and receive approximately $1.8 million of net cash proceeds in the first half of 2020. The Company anticipates it will be able to transfer this current year credit and receive net proceeds of approximately $1.85 million in the first half of 2021. An additional $5.0 million allocation of NOL sales will be available to the Company during 2021-2023.

Issued Letter to Stockholders with an Update on the Phase III OPTIMA Study with ThermoDox®. On February 11, 2021, the Company issued a letter to stockholders providing an update on the status of the Phase III OPTIMA Study and the decision to stop following patients in the Study. Since the surprising and incredibly disappointing second interim analysis results of the Phase III OPTIMA Study in primary liver cancer announced on July 9, 2020, in which the independent Data Monitoring Committee (DMC) found that the interim findings suggested futility, the Company continued to follow patients for overall survival (OS). Independent analyses conducted by a global biometrics contract research organization and by the National Institutes of Health (NIH) did not find any evidence of significance or factors that would justify continuing to follow patients for OS. Therefore, the Company has notified all clinical sites to discontinue following patients. The OPTIMA Study database of 556 patients was frozen at 185 patient deaths. While the analyses did identify certain patient subgroups that appear to have had a clinical benefit, the Company concluded that it would not be in its best interest to pursue these retrospective findings as the regulatory hurdles supporting further development will be significant.

Celsion will continue to work closely with and support investigations involving ThermoDox® by others throughout the world in breast cancer, pancreatic cancer and in solid tumors in children. Following inquiries from the NIH, the Company intends to renew its Cooperative Research and Development Agreement (CRADA) with the Institute at a nominal cost, one goal of which is to pursue the NIH's interest in a study of ThermoDox ® to treat patients with bladder cancer. Importantly, Celsion is developing a business model to support these investigator-sponsored studies in a manner that will not interfere with the Company's focus on its GEN-1 programs and vaccine development initiative.

Financial Results for the Year Ended December 31, 2020

Celsion reported a net loss of $21.5 million ($0.67 per share) in 2020, compared with a net loss of $16.8 million ($0.77 per share) in 2019. Operating expenses were $19.0 million in 2020, which represented a $2.1 million or 10% decrease from $21.1 million in 2019.

Research and development expenses were $11.3 million in 2020, a decrease of $1.8 million or 15% from $13.1 million in 2019. Clinical development costs for the Phase III OPTIMA Study decreased by $1.9 million to $2.2 million in 2020, compared with $4.1 million in 2019. Costs associated with the OVATION 2 Study increased to $1.3 million in 2020, compared with $0.6 million in 2019. Other costs related to ThermoDox® and GEN-1 clinical development programs decreased by $0.6 million in 2020, compared with 2019 due to lower regulatory costs for the ThermoDox® development program.

General and administrative expenses were $7.6 million in 2020, compared with $8.0 million in 2019. This $0.4 million or 5% decrease was primarily due to lower compensation expenses including non-cash stock option compensation expense compared with 2019.

Other expenses for 2020 included:

- a non-cash charge of $1.3 million, compared with a non-cash gain of $2.8 million, net of a $0.4 million charge for the issuance of 200,000 warrants related to an amendment for the potential milestone payments for the GEN-1 ovarian cancer product candidate in 2019;
- 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;
- interest expense of $1.3 million and $1.4 million in 2020 and 2019, respectively; and
- interest income of $0.1 million in 2020 and $0.5 million in 2019.

The Company recognized a $1.8 million income tax benefit resulting from the sale of its New Jersey net operating losses during each of the fourth quarter of 2020 and 2019. The Company has approximately $5.0 million in future tax benefits remaining under the NJEDA Technology Business Tax Certificate Transfer program for future years.

Net cash used for operating activities was $15.6 million in 2020, compared with $20.3 million in 2019. Cash, cash equivalents and investments as of December 31, 2020 were $17.2 million. Total cash provided by financing activities was approximately $18.0 million during 2020 from $22.8 million of net proceeds from sales of common stock, less $5.2 million payments on notes payable. Subsequent to year-end, the Company raised more than $40 million in net proceeds from sales of common stock during the first quarter of 2020. In addition, the Company expects to receive net proceeds of $1.85 million from the sale of its New Jersey state NOLs by the end of the first quarter of 2021.

Conference Call

The Company is hosting a conference call at 11:00 a.m. EDT today to provide a business update and discuss 2020 financial results. 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 fourth quarter 2020 Earnings Call (Conference Code: 1175518). The call will also be broadcast live on the internet at www.celsion.com. The call will be archived for replay on Friday, March 19, 2021 and will remain available until April 2, 2021. The replay can be accessed at 1-719-457-0820 or 1-888-203-1112 using Conference ID: 1175518. 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 Friday, March 19, 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.

Celsion Investor Contact
Jeffrey W. Church
609-482-2455
jchurch@celsion.com

LHA Investor Relations
Kim Sutton Golodetz
212-838-3777
kgolodetz@lhai.com

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

	Year ended December 31,	
	2020	**2019**
Licensing revenue	$ 500	$ 500
Operating expenses:		
Research and development	11,345	13,065
General and administrative	7,641	8,000

Total operating expenses	18,986	21,065
Loss from operations	(18,486)	(20,565)
Other income (expense):		
(Loss) gain from valuation of earn-out milestone liability	(1,300)	3,190
Loss from impairment of in-process research and development	(2,370)	-
Fair value of warrants issued for milestone amendment	-	(400)
Interest expense, investment income and other income (expense), net	(1,173)	(893)
Total other income (expense)	(4,843)	1,897
Net loss before income tax benefit	(23,329)	(18,668)
Income tax benefit	1,845	1,816
Net loss	$ (21,484)	$ (16,852)
Net loss per common share - basic and diluted	$ (0.67)	$ (0.77)
Weighted average common shares outstanding - basic and diluted	31,961	21,833

Celsion Corporation
Selected Balance Sheet Information
(in thousands)

	December 31, 2020	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 17,164	$ 6,875
Investment securities and interest receivable	-	8,007
Prepaid expenses and other current assets	1,661	1,353
Total current assets	**18,825**	**16,235**
Property and equipment	**295**	**405**
Other assets		
Deferred income tax asset	1,846	1,820
In-process research and development	13,366	15,736
Goodwill	1,976	1,976
Operating leases right-of-use	1,047	1,432
Other intangible assets, net	114	341
Other assets	59	333
Total other assets	**18,408**	**21,638**
Total assets	**$ 37,527**	**$ 38,278**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 4,703	$ 5,166
Deferred revenue – current portion	500	500
Operating lease liability – current portion	433	388
Notes payable - current portion	1,117	1,840
Total current liabilities	**6,753**	**7,894**
Earn-out milestone liability	7,018	5,718
Notes payable - noncurrent portion	3,935	7,963
Operating lease liability – noncurrent portion	710	1,144
Deferred revenue and other liabilities - noncurrent portion	500	1,000
Total liabilities	**18,916**	**23,719**
Stockholders' equity		
Common stock	407	232
Additional paid-in capital	330,290	304,886
Accumulated other comprehensive gain (loss)	-	43

Accumulated deficit	(312,000)	(290,517)
	18,696	14,644
Less: Treasury stock	(85)	(85)
Total stockholders' equity	**18,611**	**14,559**
Total liabilities and stockholders' equity	**$ 37,527**	**$ 38,278**

###

Source: Celsion CORP