IMUNON CEO Issues Letter to Shareholders

March 1, 2023

Reviews 2022 accomplishments; sets forth 2023 milestones and long-term vision

LAWRENCEVILLE, N.J., March 01, 2023 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage biotechnology company, today announced that Dr. Corinne Le Goff, the company's president and chief executive officer, has issued the following letter to shareholders.

To Our Shareholders:

Several transformative events during 2022 laid the foundation for establishing IMUNON as a platform company with a focus on key disease areas. I was delighted to be named President and Chief Executive Officer in July with the mandate to lead IMUNON through its next stage of growth, drawing upon my experiences at Moderna, Amgen and Roche in infectious diseases, immunology and oncology. I recognized the potential of DNA-based technology to address substantial unmet medical needs and market opportunities in immuno-oncology and infectious diseases.

2022, a Year of Transformation

The renaming of our company from Celsion to IMUNON last fall contributed to positioning IMUNON at the forefront of innovation in nucleic acid research, immunology and gene therapy. And our team is fired up by our mission to develop medicines that harness the building blocks of life to work in harmony with the body's immune system.

The transformation of the company is now well underway. It started two years ago with a recapitalization. In 2021 and 2022 the company raised more than $60 million through the sale of common stock at the market, with no warrants. We ended the third quarter of 2022 with $43.4 million in cash, investments, restricted cash and accrued interest receivable.

During the past year IMUNON made significant progress in advancing our clinical programs in immuno-oncology with IMNN-001 (previously GEN-1), our Interleukin-12 (IL-12) gene-mediated immunotherapy. Designed using our proprietary TheraPlas modality technology, IMNN-001 is an IL-12 DNA plasmid vector encased in a nanoparticle delivery system that enables cell transfection followed by persistent, local secretion of the IL-12 protein. We are conducting a Phase 1/2 study with IMNN-001 in women with advanced ovarian cancer, the OVATION 2 Study. In September 2022 we reached full enrollment of 110 patients and are expecting to report topline results by mid-2024.

We also demonstrated the validity of our proprietary technology PLACCINE in prophylactic vaccines, with impressive proof-of-concept data in a COVID-19 model. We notably have completed the evaluation of our vaccines in non-human primates. I am pleased to report that the final data are consistent with the earlier data and show excellent immunological response and viral clearance. We also demonstrated in a recent mouse study that a single dose of PLACCINE vaccine without a booster dose produced longer duration of IgG responses and higher T-cell activation than a mRNA vaccine. We are now nine months into a 12-month PLACCINE stability study and have demonstrated continued drug stability at 4°C (standard refrigerated temperature), representing a significant commercial advantage over mRNA-based vaccines.

Our Business Strategy and Approach to Capital Allocation

IMUNON is implementing a thoughtful four-pronged business strategy.

1- *Focus on immuno-oncology as an asset development opportunity for IMUNON*

We believe we are well positioned to create substantial value for patients and stockholders in the field of immuno-oncology. Immunotherapy has emerged as an effective approach in certain oncology indications, but considerable opportunities remain to address its limitations and challenges.

Our strategy is to pursue indications characterized by a high disease burden and substantive unmet medical needs where an immunological approach can improve both risk of progression and survival compared with current standard of care. The utilization of our proprietary technology in ovarian cancer for the in-situ expression of an IL-12 cytokine, which potently stimulates both natural killer cells in the innate immune system and CD8 T cells in the adaptive immune system, potentially offers a powerful therapeutic agent with a good safety profile. This program is a clear example of how IMUNON is pushing the boundaries of innovation in a difficult-to-treat tumor type.

Based on our well-characterized PLACCINE modality in prophylactic vaccines, we are exploring the potential of our multicistronic-formulated DNA vector in cancer vaccines. This new modality – based on antigen selection and optimization, along with the option to include a potent immune modifier on a single nucleic acid vector – may represent a promising strategy to induce a specific and long-lasting immune response against tumor antigens. The future of cancer vaccines is truly exciting as they hold the promise of becoming an important tool in the fight against cancer in the years to come.

2- *Focus on developing our DNA-based prophylactic vaccine platform as an out-licensing and partnership opportunity*

The need for new vaccine technologies is urgent. Since 1980 more than 80 pathogenic viruses have been discovered, yet fewer than 4% have a commercially available prophylactic vaccine. The PLACCINE modality has several characteristics that may address the shortcomings of current nucleic acid, attenuated virus and protein subunit vaccines. PLACCINE is engineered to be easily modified to create vaccines against a multitude of infectious diseases with benefits that include durability and breadth of protection, transmission advantage, safety and convenience (no virus vector or device required), flexible manufacturing (plug-and-play strategy) and stability at refrigerated temperatures.

Our objective is to establish the safety and efficacy of our platform in a Phase 1 human study, and then seek to out-license this powerful technology to pharmaceutical companies for the utilization of our platform and/or to establish non-dilutive partnerships to develop vaccines for pathogens of interest.

We have already engaged with the Biomedical Advanced Research and Development Authority (BARDA), a division of the U.S. Department of Health and Human Services, to pursue certain pathogens BARDA has identified as the most urgent and the most important. And we are pleased to report that BARDA is interested in our technology.

We believe that innovative new technologies are born in companies like IMUNON and that we are best positioned to develop the vaccine platform of the future. We will leave large, late-phase clinical trials to partners with the resources to conduct them and will view each program with an eye toward a licensing transaction.

3- *Vertical integration of the core elements of our business*

As a small company, IMUNON must be nimble and thoughtful in deploying capital, investing just enough in building and integrating our operations to bring portfolio products to licensing inflection points. Our goal is to attract the interest of corporate partners while minimizing dependence on vendors so that we control both the costs and the timelines for developing our product candidates. To that end, we have developed in-house pilot-scale manufacturing capabilities for DNA plasmids and nanoparticle delivery systems. Our scientists can select any protein from the human or pathogen proteomes to be engineered.

We now control the construction of our custom vectors through an investment in Transomic Technologies, as announced late last year. Transomic Technologies offers a comprehensive array of CRISPR, RNAi and gene expression tools and services. Our labs also have the capacity and expertise to conduct testing and to run experiments in a variety of animal disease models. IMUNON is also a fully integrated clinical development company with expertise in running global mid-stage clinical programs.

4- *Strategic collaborations: the bedrock of our business model*

Collaboration is an integral part of our success. We are looking to establish strategic alliances with pharmaceutical and biotech companies, government organizations, foundations and research institutes to help advance the development of DNA medicines. Theses collaborations are formed with specific objectives in mind:

- Joining forces with partners to expand our capabilities and obtain access to new technologies, expertise and resources.
- Partnering to enhance our research and development efforts and gain new insights and discoveries, with the possibility of generating new shared intellectual property.
- Accelerating the development of our programs and obtaining non-dilutive funding to execute our strategy.

As we continue to build our vaccine program, we have recently announced several important collaborations:

- We signed our first collaborative research agreement with the Wistar Institute, a global leader in biomedical research, through its Vaccine & Immunotherapy Center, to develop new vaccine formulations for infectious diseases utilizing our PLACCINE modality.
- We signed an agreement with Acuitas Therapeutics, a biotechnology company focused on developing delivery systems for nucleic acid vaccines and therapeutics based on lipid nanoparticles (LNP); under this agreement, we will explore the expansion of our technology to other types of delivery systems as we position our nucleic acid-based modality as the future of vaccinology.
- Our alliance with the Break *Through* Cancer Foundation (described below) as one of the currently six founding partners allows us to obtain non-dilutive funding to initiate innovative clinical programs in niche indications like ovarian cancer.

We are also actively scouting for new technologies or new assets in areas adjacent to our domain of expertise in immuno-oncology, gene therapy, oligonucleotides and nucleic acids. Our objective is to balance the risk profile of our pipeline by acquiring a third leg to our portfolio of technologies.

Continued Strong Financial Position

We have a history of careful cash stewardship along with opportunistic fundraising to advance our vision. In January 2023 we received approximately $1.6 million from the sale of New Jersey net operating losses (NOLs). Along with $1.8 million in future planned sales of New Jersey NOLs and a thoughtful budget, we believe we have sufficient capital resources to fund our operations into 2025.

Looking to 2023 and Beyond

We expect 2023 will be an active and productive year for IMUNON with the achievement of multiple important milestones. We anticipate filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for our seasonal COVID-19 booster vaccine. Our objective, as mentioned above, is to confirm in a Phase 1 clinical study the safety of our PLACCINE modality. In the coming months we will apply for a pre-IND consultation with the FDA to receive guidance on our proposed program prior to submitting the IND.

We will also announce our next pathogen target for our PLACCINE modality. It is likely that we will choose a pathogen among the list of priority pathogens established by CEPI (Coalition for Epidemic Preparedness Innovations).

We will continue to follow patients enrolled in our OVATION 2 Study and expect to report an additional set of interim, more mature data in the second half of 2023.

We recently announced a collaboration with the Break *Through* Cancer Foundation to evaluate in a Phase 1/2 clinical trial the benefits of IMNN-001 in combination with bevacizumab in ovarian cancer in the frontline, neoadjuvant setting. Working with four of the foremost comprehensive cancer centers in the world, the goal of this project is to transform the care of women with ovarian cancer by developing unprecedented capabilities for understanding and targeting persistent minimal residual disease (MRD), as explained here.

We look forward to enrolling the first patient in the coming weeks at the University of Texas MD Anderson Cancer Center, with expected additional participation at Dana-Farber Cancer Institute, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins and Memorial Sloan Kettering

Cancer Center. The Koch Institute for Integrative Cancer Research at the Massachusetts Institute of Technology will provide artificial intelligence services throughout the trial, including biomarker and genomic analyses. This will expand our knowledge of the treatment paradigm.

In summary, our technologies hold great promise for patients and their caregivers, and we are extremely excited about the prospects for IMUNON. We recognize that we cannot execute our strategy without the purposeful work and dedication of many talented colleagues – our scientists, financial professionals and administrators. And, of course, underlying our efforts are our shareholders, and we are deeply grateful for your support.

I look forward to keeping you apprised of our progress and accomplishments as the year progresses. In the meantime, I wish you a wonderful 2023!

Sincerely,

Corinne Le Goff, Pharm.D., M.B.A.
President & Chief Executive Officer

March 1, 2023

About IMUNON

IMUNON is a fully integrated, clinical-stage biotechnology company focused on advancing a portfolio of innovative treatments that harness the body's natural mechanisms to generate safe, effective and durable responses across a broad array of human diseases, constituting a differentiating approach from conventional therapies.

IMUNON has two platform technologies: the TheraPlas modality for the development of immunotherapies and other anti-cancer nucleic acid-based therapies, and the PLACCINE modality for the development of nucleic acid vaccines for infectious diseases and cancer. The company's lead clinical program, IMNN-001, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer currently in Phase 2 development. IMNN-001 works by instructing the body to produce safe and durable levels of powerful cancer-fighting molecules, such as interleukin-12 and interferon gamma, at the tumor site. Additionally, the company is conducting preclinical proof-of-concept studies on a nucleic acid vaccine candidate targeting the SARS-CoV-2 virus to validate its PLACCINE platform. IMUNON's platform technologies are based on the delivery of nucleic acids with novel synthetic delivery systems that are independent of viral vectors or devices. IMUNON will continue to leverage these platforms and to advance the technological frontier of nucleic acid-based products to better serve patients with difficult-to-treat conditions. For more information on IMUNON, visit www.imunon.com.

Forward-Looking Statements

IMUNON wishes to inform readers that forward-looking statements in this news release are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, unforeseen changes in the course of research and development activities and in clinical trials; the uncertainties of and difficulties in analyzing interim clinical data; the significant expense, time and risk of failure of conducting clinical trials; the need for IMUNON 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 IMUNON's periodic reports and prospectuses filed with the Securities and Exchange Commission. IMUNON 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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Source: Imunon, Inc.