



IMUNON Reports 2024 Financial Results and Provides Business Update Highlighting Significant Progress Towards the Initiation of a Pivotal Phase 3 Study

February 27, 2025

IMNN-001 remains the first immunotherapy to achieve a meaningful overall survival benefit in advanced ovarian cancer

Patient enrollment in Phase 3 pivotal trial of IMNN-001 scheduled to begin in Q1 2025

Company to hold conference call today at 11:00 a.m. ET

LAWRENCEVILLE, N.J., Feb. 27, 2025 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in late-stage development with its DNA-mediated immunotherapy, today reported financial results for the year ended December 31, 2024 and highlighted recent business updates including progress in advancing the IMNN-001 development program toward initiation of a Phase 3 clinical trial in advanced ovarian cancer.

"2024 was a pivotal year for IMUNON. We reported robust and unprecedented data from our Phase 2 OVATION 2 Study, demonstrating that IMNN-001 is the first immunotherapy to consistently show clinical benefits in both progression-free and overall survival in ovarian cancer when combined with chemotherapy," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "Treated patients achieved an overall survival of 13 months, compared to the current standard of care. Even more remarkable, the survival extension was greater among patients treated with IMNN-001 plus PARP inhibitors."

"We stand at the threshold of a historic advance in the frontline treatment of women with advanced ovarian cancer, a group with limited options and a desperate need for safe, effective treatments," Dr. Lindborg continued. "The most recent advances in ovarian cancer treatment have focused on maintenance treatment for those who have already responded to chemotherapy. However, our results in newly diagnosed patients with advanced disease are unprecedented and highly encouraging. The rapid clinical progress we have made reflects our compelling data and the strong support from trial investigators, patients, regulators, and global scientific leaders. We have engaged with the U.S. Food and Drug Administration through an End-of-Phase 2 meeting to finalize the design of our planned registrational study. As we look forward to an exciting year ahead, we are preparing to initiate a Phase 3 pivotal study of IMNN-001 in the first quarter of 2025."

RECENT DEVELOPMENTS

IMNN-001 Immunotherapy

Translational Data from OVATION 2 Study reinforce dose-dependent mechanism with IMNN-001 100mg/m² dose and continue to validate TheraPlas[®] technology, demonstrating DNA-mediated production of key anti-cancer immune cytokines following treatment - On February 19, 2025, IMUNON announced new translational data from ongoing analyses of results from the Company's Phase 2 OVATION 2 Study of IMNN-001 for the treatment of newly diagnosed advanced ovarian cancer. Results demonstrated a 20% increase in IL-12 levels in women treated with IMNN-001 (100 mg/m² administered intraperitoneally weekly) plus standard-of-care (SoC) neoadjuvant and adjuvant chemotherapy (NACT) compared to IL-12 levels in women treated with IMNN-001 (79 mg/m²). In this analysis increases in IL-12 levels were sampled in the peritoneal fluid cavity, which is the primary tumor microenvironment. Little to no changes were observed in the systemic blood stream of treated patients. In addition, the rise in IL-12 levels was accompanied by local increases in interferon-gamma (IFN- γ) and tumor necrosis factor-alpha (TNF- α), key downstream anti-cancer immune cytokines. Results showed no reports of serious immune-related adverse events including cytokine release syndrome.

Positive CMC Meeting with FDA for IMNN-001 - On December 19, 2024, IMUNON announced the positive outcome of a Type C Chemistry, Manufacturing, and Controls (CMC) meeting with the U.S. Food and Drug Administration (FDA) regarding production of IMNN-001 for the treatment of women with newly diagnosed advanced ovarian cancer. The goal of the meeting was to seek alignment and agreement with the FDA on key CMC topics to support IMNN-001 production for the planned Phase 3 pivotal trial and a potential future new biologics license application (BLA) submission. The meeting with the FDA included a review of IMUNON's current good manufacturing practice (cGMP) clinical-scale and commercial manufacturing processes for IMNN-001, conducted at the Company's manufacturing facility based in Huntsville, Alabama. The FDA agreed that IMUNON's potency assay, which measures interferon-gamma (IFN- γ), is acceptable for the Phase 3 trial and for use in a commercial setting for release of drug product. The agency also agreed with the Company's strategy to establish comparability of the core components of IMNN-001 produced by IMUNON with product previously produced through an external contract development and manufacturing organization.

Continued Improvement in Overall Survival Data from OVATION 2 Study of IMNN-001 - On December 10, 2024, the Company announced additional clinical data based on ongoing analyses of results from the Phase 2 OVATION 2 Study of IMNN-001 in the treatment of advanced ovarian cancer. The updated results, which were based on an additional seven months of patient monitoring, showed the hazard ratio (HR) decreased from 0.74 to 0.69, with an increase in median overall survival (OS) from 11.1 to 13 months following treatment with IMNN-001 plus standard-of-care (SoC) neoadjuvant and adjuvant chemotherapy (NACT) versus SoC alone. More than one-third of patients in the trial survived more than 36 months from the point of study enrollment, with 62% of those surviving patients from the IMNN-001 treatment arm and 38% from the SoC arm. More than 10% of trial participants reached 48 months or beyond at the time of this data assessment. Results also continued to demonstrate a favorable safety and tolerability profile, with no reports of cytokine release syndrome or any other serious immune-related adverse events. Initial results from the OVATION 2 Study were reported in July 2024 and results were presented in a late-breaking session at the Society for Immunotherapy of Cancer (SITC) 39th Annual Meeting.

End-of-Phase 2 Meeting with the FDA for IMNN-001 Clinical Program - On November 25, 2024, IMUNON announced a positive outcome of its End-of-Phase 2 in-person meeting with the FDA, supporting the advancement of IMNN-001 for the treatment of advanced ovarian cancer into a Phase

3 pivotal study. IMUNON remains on track to initiate the Phase 3 trial in the first quarter of 2025. The interaction with the FDA included an extensive review of data generated to date, including the positive results from the Phase 2 OVATION 2 Study.

IMUNON Ovarian Cancer R&D Day – On September 18, 2024, the Company held an Ovarian Cancer R&D Day in New York City that included presentations from executive management and a panel of renowned leaders in oncology research and patient care including:

- Sid Kerkar, M.D., T cell biology review editor, *Frontiers in Immunology*. Dr. Kerkar discussed the important role of interleukin-12 (IL-12) in treating cancer.
- William Bradley, M.D., Professor, Obstetrics and Gynecology, Gynecologic Oncology, Medical College of Wisconsin. Dr. Bradley discussed the safety and efficacy of IMNN-001.
- L.J. Wei, Ph.D., Professor of Biostatistics, Harvard T.H. Chan School of Public Health. Dr. Wei discussed the opportunity to combine progression-free survival (PFS) and overall survival (OS) to provide a clinically interpretable evaluation of the IMNN-001 treatment effect.
- Amir Jazaeri, M.D., Vice Chair for Clinical Research, Director, Gynecologic Cancer Immunotherapy Program, Department of Gynecologic Oncology and Reproductive Medicine, University of Texas MD Anderson Cancer Center. Dr. Jazaeri discussed the ongoing Phase 1/2 study of IMNN-001 in combination with bevacizumab in advanced ovarian cancer, for which he serves as principal investigator, including the importance of minimal residual disease and early translational insights.
- Premal Thaker, M.D., Interim Chief of Gynecologic Oncology, David & Lynn Mutch Distinguished Professor of Obstetrics & Gynecology, Director of Gynecologic Oncology Clinical Research, Washington University School of Medicine, and the OVATION 2 Study Chair. Dr. Thaker discussed the OVATION 2 top-line results and their clinical significance.

A webcast of the Ovarian Cancer R&D Day is available [here](#).

PlaCCine: Next Generation Vaccine Proof of Concept

Data from PlaCCine DNA Vaccine Phase 1 Proof-of-Concept Clinical Study Demonstrate Persistent Immunogenicity in Trial Participants, Show an Acceptable Safety Profile and Further Validate PlaCCine® Technology – On February 26, 2025, the Company announced safety and immunogenicity data from the Company's first Phase 1 proof-of-concept clinical trial of IMNN-101, its investigational DNA plasmid vaccine based on the Company's proprietary PlaCCine[®] technology platform. The Phase 1 study was conducted in 24 healthy volunteers as a seasonal COVID-19 vaccine, targeting the SARS-CoV-2 Omicron XBB1.5 spike antigen. IMNN-101 was administered as a single dose vaccine without a booster dose in study participants who were previously vaccinated against the Omicron XBB1.5 variant. Results demonstrated that IMNN-101 is safe and well-tolerated with no serious adverse effects. IMNN-101 induced a persistent 2- to 4-fold increase in serum neutralizing antibody (NAb) titers from baseline through Week 4, further increasing NAb titers between Week 2 and Week 4. The immune response was observed against the XBB1.5 variant and many newer variants following treatment, demonstrating the IMNN-101 vaccine's cross-reactivity. The participants in the Phase 1 trial had high baseline immune characteristics presumably from prior infection and multiple previous vaccinations against COVID-19 and ongoing infection as evidenced by the rise in viral nucleocapsid antigen during the study period. Modest increases in T cell responses were observed in this setting of trial participants having received multiple immunizations prior to the study.

The Phase 1 clinical data of IMNN-101 is consistent with strong evidence of immunogenicity and protection for the PlaCCine platform in rodents and non-human primates, with prior preclinical results showing that protection exceeded 95% in non-human primates, which is comparable to mRNA vaccines. The robust immunogenicity profile, expected durability of protection, comparative ease of manufacturing, and stability at workable temperatures (up to one year at 4°C and one month at 37°C) suggest that a vaccine based on the PlaCCine technology platform may be a potential viable alternative to available messenger RNA (mRNA) vaccines. The Company plans to seek potential partners for further development.

Corporate Development

Addition to Leadership Team to Support Future Clinical Programs – On February 10, 2025, Douglas V. Faller, M.D., Ph.D. was appointed Chief Medical Officer effective February 18, 2025. Dr. Faller joins IMUNON with more than 30 years of industry, academic and laboratory experience, with specialized expertise in oncology and immunology. Dr. Faller will lead the Company's clinical strategy including advancing the IMNN-001 program for the treatment of newly diagnosed advanced ovarian cancer.

Dr. Faller joins IMUNON with more than 30 years of experience at biotechnology and pharmaceutical companies leading strategies across discovery, preclinical, clinical and regulatory stages of small molecule development in several therapeutic areas including oncology, immunology and hematology. He also brings more than 25 years of experience in academic clinical and laboratory research settings with a focus on drug discovery and development, oncology and hematology, and cell and molecular biology. Dr. Faller most recently served as chief medical officer at Skyhawk Therapeutics, where he was responsible for global clinical and regulatory development of novel small molecule RNA-splicing modifiers for the treatment of hematological and solid tumors and rare neurological diseases. Before that, he served as chief medical officer at Oryzon Genomics, Inc. Previously, he worked at Takeda for more than five years in roles of increasing responsibility, most recently serving as executive medical director where he led the development of multiple late-stage therapies including a CAR-T program for leukemias and lymphomas and solid tumor programs including in gynecologic oncology.

Dr. Faller received an M.D. from Harvard Medical School and a Ph.D. and B.S. from the Massachusetts Institute of Technology. He was professor of medicine at Harvard Medical School, and subsequently he founded and served as first director of Boston University Comprehensive Cancer Center where he was also Grunebaum Professor for Cancer Research and professor of medicine, biochemistry, pediatrics, microbiology, pathology and laboratory medicine. Dr. Faller is the scientific founder of multiple biotechnology and pharmaceutical companies.

Financial Results for the Year Ended December 31, 2024

IMUNON reported a net loss for 2024 of \$18.6 million, or \$1.62 per share compared with a net loss for 2023 of \$19.5 million, or \$2.16 per share. Operating expenses were \$19.1 million for 2024, a decrease of \$1.9 million or 9% from \$21.0 million for 2023. The Company recognized tax benefits from the sale of its New Jersey net operating losses of \$1.3 million in 2023.

Research and development (R&D) expenses were \$11.6 million for 2024, a decrease of \$0.3 million from \$11.3 million for 2023. Costs associated with the OVATION 2 Study were \$1.4 million and \$1.2 million for 2024 and 2023, respectively. Costs associated with our PlaCCine[®] vaccine initiative were \$1.4 million in 2024. Other clinical and regulatory costs, which include start up costs for OVATION 3, were \$2.4 million for 2024 compared with \$1.8 million for 2023. R&D costs associated with the development of IMNN-001 to support the OVATION 2 Study were \$1.8 million for 2024 compared with \$1.5 million for 2023. The development of the PlaCCine DNA vaccine technology platform decreased to \$2.6 million in 2024 compared to \$4.5 million in 2023. CMC costs were \$2.0 million for 2024 compared with \$2.3 million for 2023 due to the development of in-house cGMP manufacturing capabilities for DNA plasmids and nanoparticle delivery systems and product development costs for OVATION 3.

General and administrative expenses were \$7.5 million for 2024 compared with \$9.7 million for 2023. This 23% decrease was primarily attributable to lower legal costs (\$1.4 million), lower employee-related costs (\$0.4 million), lower non-cash stock compensation expense (\$0.3 million), lower public company franchise expenses (\$0.2 million) and lower insurance costs (\$0.1 million), offset by higher consulting fees (\$0.2 million).

Other non-operating income was \$0.5 million for 2024 compared with \$0.2 million for 2023. This increase was primarily attributable to the following:

- Investment income from the Company's short-term investments was \$0.5 million for 2024 compared with \$1.2 million for 2023.
- In June 2021, the Company entered into a \$10.0 million loan facility with Silicon Valley Bank (SVB). IMUNON immediately used \$6.0 million from this facility to retire all outstanding indebtedness with Horizon Technology Finance Corporation. In connection with the loan facility, the Company incurred \$0.2 million in interest expense in the first half of 2023. In the second quarter of 2023, the Company terminated the SVB Loan Facility, paid early termination and end-of-term charges and recognized \$0.3 million as a loss on debt extinguishment.

Net cash used for operating activities was \$18.9 million for 2024 compared with \$19.0 million for 2023. Cash provided by financing activities of \$9.1 million for 2024 resulted from an at-the-market equity offering in July 2024 and sales under the Company's At-the-Market Equity Facility compared with cash used in financing activities of \$3.6 million for 2023 resulting from the pay-off of the SVB loan (\$6.4 million), offset by sales under the Company's At-the-Market Equity Facility (\$2.8 million).

The Company ended 2024 with \$5.9 million in cash and cash equivalents. The Company believes it has sufficient capital resources to fund its operations into late second quarter of 2025.

Conference Call and Webcast

The Company is hosting a conference call to review 2024 financial results and provide business updates today at 11:00 a.m. ET. To participate in the call, please dial 833-816-1132 (Toll-Free/North America) or 412-317-0711 (International/Toll) and ask for the IMUNON 2024 Earnings Call. A live webcast of the call will also be available [here](#).

The call will be archived for replay until March 12, 2025. The replay can be accessed at 877-344-7529 (U.S. Toll-Free), 855-669-9658 (Canada Toll-Free) or 412-317-0088 (International Toll), using the replay access code 7147564. An audio replay of the call will also be available [here](#) for 90 days.

About IMUNON

IMUNON is a 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 is developing its non-viral DNA technology across its modalities. The first modality, TheraPlas[®], is developed for the gene-based delivery of cytokines and other therapeutic proteins in the treatment of solid tumors where an immunological approach is deemed promising. The second modality, PlaCCine[®], is developed for the gene delivery of viral antigens that can elicit a strong immunological response.

The Company's lead clinical program, IMNN-001, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer that has completed 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 has entered a first-in-human study of its COVID-19 booster vaccine (IMNN-101). IMUNON will continue to leverage these modalities and to advance the technological frontier of plasmid DNA to better serve patients with difficult-to-treat conditions, and to further strengthen IMUNON's balance sheet through attractive business development opportunities. For more information, please 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. All statements, other than statements of historical fact, including, but not limited to, statements regarding the timing for commencement of a Phase 3 trial of IMNN-001, the timing and enrollment of the Company's clinical trials, the potential of any therapies developed by the Company to fulfill unmet medical needs, the market potential for the Company's products, if approved, the potential efficacy and safety profile of our product candidates, and the Company's plans and expectations with respect to its development programs more generally, are forward-looking statements. We generally identify forward-looking statements by using words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances). Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, uncertainties relating to unforeseen changes in the course of research and development activities and in clinical trials, including the fact that interim results are not necessarily indicative of final results; the uncertainties of and difficulties in analyzing interim clinical data; the significant expense, time and risk of failure in conducting clinical trials; the need for IMUNON to evaluate its future development plans; possible actions by customers, suppliers, competitors or regulatory authorities; and other risks detailed from time to time in IMUNON's filings with the Securities and Exchange Commission. IMUNON assumes no obligation, except to the extent required by law, to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

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(Tables to Follow)

IMUNON, Inc.
Condensed Consolidated Statements of Operations
 (in thousands except per share amounts)

	Year Ended December 31,	
	2024	2023
Operating expenses:		
Research and development	\$ 11,639	\$ 11,287
General and administrative	7,493	9,743
Total operating expenses	19,132	21,030
Loss from operations	(19,132)	(21,030)
Other income (expense):		
Investment income, interest expense and other expense, net	512	564
Loss on debt extinguishment	-	(329)
Total other income (expense), net	512	235
Loss before income tax benefit	(18,620)	(20,795)
Income tax benefit	-	1,280
Net loss	\$ (18,620)	\$ (19,515)
Net loss per common share		
Basic and diluted	\$ (1.62)	\$ (2.16)
Weighted average shares outstanding		
Basic and diluted	11,508	9,045

IMUNON, Inc.
Selected Balance Sheet Information
 (in thousands)

	December 31, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	\$ 5,873	\$ 5,839
Investment securities and interest receivable on investment securities	-	9,857
Advances, deposits on clinical programs and other current assets	2,136	2,545
Total current assets	8,009	18,241
Property and equipment	541	752
Other assets		
Deferred tax asset	-	1,280
Operating lease right-of-use assets, deposits, and other assets	1,167	1,645
Total other assets	1,167	2,925

Total assets	\$ <u>9,717</u>	\$ <u>21,918</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	\$ 4,334	\$ 6,906
Operating lease liability – current portion	<u>452</u>	<u>485</u>
Total current liabilities	4,786	7,391
Operating lease liability – noncurrent portion	<u>687</u>	<u>1,139</u>
Total liabilities	5,473	8,530
Stockholders' equity		
Common stock	145	94
Additional paid-in capital	410,987	401,501
Accumulated other comprehensive gain	-	61
Accumulated deficit	<u>(406,803)</u>	<u>(388,183)</u>
	4,329	13,473
Less: Treasury stock	<u>(85)</u>	<u>(85)</u>
Total stockholders' equity	4,244	13,388
Total liabilities and stockholders' equity	\$ <u>9,717</u>	\$ <u>21,918</u>

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