IMUNON Reports First Quarter 2025 Financial Results and Provides Business Update

May 12, 2025

First site initiated for Phase 3 OVATION 3 study of IMNN-001 in treatment of newly diagnosed advanced ovarian cancer

New data from Phase 2 OVATION 2 study of IMNN-001 accepted for oral presentation at 2025 ASCO Annual Meeting

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

LAWRENCEVILLE, N.J., May 12, 2025 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in Phase 3 development with its DNA-mediated immunotherapy, today reported financial results for the three months ended March 31, 2025 and highlighted recent business updates, including progress in advancing Phase 3 clinical development of its lead candidate IMNN-001 in newly diagnosed advanced ovarian cancer.

"IMUNON continues to make significant strides towards our goal of transforming the treatment landscape for women with advanced ovarian cancer. In 2024, our Phase 1/2 OVATION 2 Study delivered groundbreaking data, demonstrating that IMNN-001 is the first immunotherapy to extend both progression-free and overall survival in women newly diagnosed with ovarian cancer when combined with chemotherapy, and we continue to report promising results from the trial further supporting our therapeutic approach, including new translational and safety data this past quarter based on ongoing analyses," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON.

"We look forward to building on this data and momentum, with a strong first quarter in 2025. The initiation of the first trial site for our Phase 3 OVATION 3 pivotal study marks a critical step toward our goal of delivering a new frontline treatment for women with limited options and urgent unmet medical needs. The acceptance of our OVATION 2 results for an oral presentation at ASCO also underscores the scientific community's recognition of IMNN-001's potential. These milestones reflect the strength of our clinical program, the dedication of trial investigators and patients, and our productive engagement with the FDA to finalize our Phase 3 study design. As we advance this historic opportunity, IMUNON remains committed to bringing safe, effective therapies to women battling ovarian cancer," Dr. Lindborg continued.

RECENT DEVELOPMENTS

IMNN-001 Immunotherapy

First Trial Site Initiated for Phase 3 OVATION 3 Study of IMNN-001 in Newly Diagnosed Advanced Ovarian Cancer – On May 8, 2025, the Company announced initiation of the first trial site for the OVATION 3 Study and is working with trial investigators to begin enrolling study participants.

The Phase 3 OVATION 3 trial will assess the safety and efficacy of IMNN-001 (100 mg/m^2 administered intraperitoneally weekly) plus neoadjuvant and adjuvant chemotherapy (NACT) of paclitaxel and carboplatin compared to standard of care (SoC) NACT alone. Study participants will be randomized 1:1 and include women with newly diagnosed advanced ovarian cancer (stage 3C or 4) who are eligible for neoadjuvant therapy, the intent-to-treat (ITT) population, with a sub-group of women positive for homologous recombination deficiency (HRD), including BRCA1 or BRCA2 mutations. Participants who are HRD positive will receive poly ADP-ribose polymerase (PARP) inhibitors as part of standard maintenance therapy. The primary endpoint of the study is overall survival (OS), and secondary endpoints are surgical response score, chemotherapy response score, clinical response and time to second-line treatment. The study will also assess several exploratory endpoints.

IMNN-001 Data from Phase 1/2 OVATION 2 Study to be Published in Peer-Reviewed Journal Gynecologic Oncology – On May 6, 2025, the Company announced that data from the Phase 1/2 OVATION 2 clinical trial evaluating intraperitoneal IMNN-001 in combination with NACT in newly diagnosed patients with advanced epithelial ovarian cancer will be published in the peer-reviewed journal *Gynecologic Oncology*. The review of full data, entitled: *OVATION-2: A Randomized Phase I/II study Evaluating the Safety and Efficacy of IMNN-001 (IL-12 gene therapy) with Neo/Adjuvant Chemotherapy in Patients Newly- Diagnosed with Advanced Epithelial Ovarian Cancer*, is scheduled for publication on June 3, 2025.

IMNN-001 Abstract Accepted for Oral Presentation at 2025 ASCO Annual Meeting – On April 21, 2025, IMUNON announced that an abstract highlighting new data from the Phase 2 OVATION 2 Study of IMNN-001 to treat women with newly diagnosed advanced ovarian cancer was accepted for oral presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place May 30 - June 3, 2025, in Chicago, Illinois. Details of the ASCO oral presentation are as follows:

> **Abstract Title:** A phase I/II study of the safety and efficacy of intraperitoneal IMNN-001 in combination with neoadjuvant chemotherapy (NACT) of paclitaxel and carboplatin in patients newly diagnosed with advanced epithelial ovarian cancer (EOC): Updated survival analysis from OVATION-2 trial.
>
> **Presenting Author:** Premal H. 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, OVATION 2 Study Chair
>
> **Date:** Tuesday, June 3, 2025
>
> **Session Time:** 8:00-9:30 a.m. CT
>
> **Session Title:** Gynecologic Cancer
>
> **Abstract Number:** 5516

Translational Data from OVATION 2 Study of IMNN-001 in Newly Diagnosed Advanced Ovarian Cancer – reinforce dose-dependent mechanism with IMNN-001 100 mg/m^2 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 Phase 2 OVATION 2 Study of IMNN-001 for the treatment of newly diagnosed advanced ovarian cancer. Results reinforced the dose-dependent mechanism with the IMNN-001 100 mg/m^2 dose (administered intraperitoneally weekly) and continue to validate the Company's TheraPlas technology, demonstrating DNA-mediated production of key anti-cancer immune cytokines following treatment. The results also demonstrated a 20% increase in IL-12 levels in women treated with IMNN-001 plus SoC NACT compared to IL-12 levels in women treated with IMNN-001 (79 mg/m^2). 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.

PlaCCine® DNA Vaccine Technology

New Immunogenicity Data from Phase 1 Proof-of-Concept Clinical Trial of PlaCCine DNA Vaccine in COVID-19 – On February 26, 2025, the Company announced new safety and immunogenicity data from the first Phase 1 proof-of-concept clinical trial of IMNN-101, an 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. Study participants 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 of IMNN-101.

Corporate Highlights

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

FIRST QUARTER 2025 FINANCIAL RESULTS

Net loss for the first quarter of 2025 was $4.1 million, or $0.28 per share, compared with a net loss of $4.9 million, or $0.52 per share, for the first quarter of 2024. Operating expenses were $4.1 million for the first quarter of 2025, a decrease of $0.9 million or 18% from $5.0 million for the first quarter of 2024.

Research and development (R&D) expenses were $2.2 million for the first quarter of 2025, a decrease of $1.1 million from $3.3 million for the first quarter of 2024. The decrease was due primarily to lower costs associated with the OVATION 2 Study and the Phase 1 proof-of-concept PlaCCine DNA vaccine trial, a decrease in costs associated with the development of IMNN-001 to support the OVATION 2 Study, and lower costs associated with development of the PlaCCine DNA vaccine technology platform.

General and administrative expenses were $2.0 million for the first quarter of 2025, compared with $1.7 million for the first quarter of 2024. The increase was primarily attributable to higher employee-related expenses, partially offset by lower legal expenses.

Net cash used for operating activities was $2.8 million for the first quarter of 2025, compared with $5.9 million for the same period last year. This decrease was primarily due to lower R&D expenses and higher accounts payable and accrued liability balances.

As of March 31, 2025, cash and cash equivalents were $2.9 million. 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 first quarter 2025 financial results and provide a business update today, May 12, 2025, 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 First Quarter 2025 Financial Results Call. A live webcast of the call will also be available here.

The call will be archived for replay until May 26, 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 2322959. 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 multiple clinical trials including one Phase 2 clinical trial (OVATION 2). 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 completed dosing in a first-in-human study of its COVID-19 booster vaccine (IMNN-101). The Company will continue to leverage these modalities and to advance, either directly or through partnership, the technological frontier of plasmid DNA to better serve patients with difficult-to-treat conditions. 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 of 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)

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 2,165	$ 3,294
General and administrative	1,980	1,717
Total operating expenses	**4,145**	**5,011**
Loss from operations	**(4,145)**	**(5,011)**
Other income (expense):		
Investment and other income	43	82
Net loss	**$ (4,102)**	**$ (4,929)**
Net loss per common share		
Basic and diluted	**$ (0.28)**	**$ (0.52)**
Weighted average shares outstanding		
Basic and diluted	**14,558**	**9,400**

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

	March 31, 2025	December 31, 2024
ASSETS		
Current assets		
Cash and cash equivalents	$ 2,872	$ 5,873
Advances, deposits on clinical programs and other current assets	2,220	2,136
Total current assets	**5,092**	**8,009**
Property and equipment	**734**	**541**
Other assets		
Operating lease right-of-use assets	986	1,117
Deposits and other assets	50	50
Total other assets	**1,036**	**1,167**
Total assets	**$ 6,862**	**$ 9,717**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 5,402	$ 4,334
Operating lease liability – current portion	395	452
Total current liabilities	**5,797**	**4,786**
Operating lease liability – noncurrent portion	613	687
Total liabilities	**6,410**	**5,473**
Stockholders' equity		
Common stock	146	145
Additional paid-in capital	411,297	410,987
Accumulated deficit	(410,906)	(406,803)
	537	4,329
Less: Treasury stock	(85)	(85)
Total stockholders' equity	**452**	**4,244**
Total liabilities and stockholders' equity	**$ 6,862**	**$ 9.717**

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Source: Imunon, Inc.