IMUNON Reports Third Quarter 2024 Financial Results and Provides Business Updates

November 7, 2024

Conference call today at 11:00 a.m. ET

LAWRENCEVILLE, N.J., Nov. 07, 2024 (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 three and nine months ended September 30, 2024. The Company also provided an update on its clinical development of IMNN-001 including progress toward commencing a Phase 3 study in advanced ovarian cancer, and an update on IMNN-101, its seasonal COVID-19 booster candidate.

"The third quarter was a period of important milestones and outstanding progress for IMUNON, driven largely by presentation of highly compelling topline results from our OVATION 2 Study with IMNN-001 in advanced ovarian cancer," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "In this study, treatment with IMNN-001 was associated with an overall survival improvement of 11.1 months compared to treatment with standard of care, and results were even stronger in the subset of patients who were also treated with PARP inhibitors. Building on this momentum, we have been highly encouraged by the interest in these results among global leaders from the medical and scientific communities. We have also engaged with the U.S. Food and Drug Administration to craft the design of our planned registrational study and are preparing for an in-person End-of-Phase 2 meeting with the agency later this month. We remain on track to begin our planned 500-patient pivotal Phase 3 study during the first quarter of 2025."

"Tomorrow afternoon we will be presenting new OVATION 2 data at the Society for Immunotherapy of Cancer 39th Annual Meeting. Our abstract is being highlighted as a late-breaking acceptance, so compelling that it was accepted after the deadline. Given the strength of the data, we are unsurprised with SITC's decision to include our data for presentation. This is an exceptional opportunity to gain further awareness for IMNN-001 and our trial results."

"In summary, IMUNON is extraordinarily well-positioned to address the unmet need in a deadly cancer while also playing an important role in public health. We are justifiably excited about our prospects for patients and shareholders alike," Dr. Lindborg concluded.

RECENT DEVELOPMENTS

IMNN-001 Immunotherapy

Presenting Additional Phase 2 data for IMNN-001 at SITC – On October 30, 2024 the Company announced the acceptance of a late-breaking presentation featuring new clinical data from the Phase 2 OVATION 2 Study of IMNN-001 at the Society for Immunotherapy of Cancer (SITC) 39th Annual Meeting, being held in Houston, TX. The presentation, titled "Phase I/II study of Safety and Efficacy of Intraperitoneal IMNN-001 with Neoadjuvant Chemotherapy of Paclitaxel and Carboplatin in Patients Newly Diagnosed with Advanced Epithelial Ovarian Cancer," will be made on Friday, November 8, 2024 from 12:15-1:45 p.m. and 5:30-7:30 p.m. CST by Jennifer Scalici, M.D., Professor, Division of Gynecological Oncology, Emory University School of Medicine and a principal investigator in the trial.

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 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 topline results and their clinical significance.

Positive topline results from the OVATION 2 Study in advanced ovarian cancer – On July 30, 2024, the Company announced topline results from the study that provide strong further validation of the potential safety and efficacy of IMNN-001 in the treatment of advanced ovarian cancer. Highlights from patients treated with IMNN-001 plus standard of care in a first-line treatment setting included:

- An 11.1 month increase in median OS compared with standard of care alone in the intent-to-treat (ITT) population.
- A hazard ratio in the ITT population of 0.74, which represents a 35% improvement in survival.

- Among the approximately 90% of trial participants who received at least 20% of specified treatments per-protocol in both study arms, patients in the IMNN-001 arm had a 15.7 month increase in median OS, representing a further extension of life with a hazard ratio of 0.64, a 56% improvement in survival.
- For the nearly 40% of trial participants treated with a poly ADP-ribose polymerase (PARP) inhibitor, the hazard ratio decreased further to 0.41, with median OS in the IMNN-001 treatment arm not yet reached at the time of database lock, compared with median OS of 37.1 months in the standard-of-care treatment arm.

The PFS results, the trial's primary endpoint, support the OS results with:

- A three-month improvement in PFS compared with standard of care alone.
- A hazard ratio in the ITT population of 0.79, indicating a 27% improvement in delaying progression for the IMNN-001 treatment arm.

CORPORATE DEVELOPMENTS

Raised gross proceeds of $10 million in a registered direct financing – On July 30, 2024, the Company entered into a Securities Purchase Agreement with certain institutional and accredited investors, pursuant to which the Company issued, in a registered direct offering, an aggregate of 5,000,000 shares of the Company's common stock at an offering price of $2.00 per share for gross proceeds of $10.0 million. In a concurrent private placement (together with the registered direct offering) and also pursuant to the Securities Purchase Agreement, the Company issued to the Purchasers unregistered warrants to purchase shares of common stock. The warrants have an exercise price of $2.00 per share and became exercisable immediately after the issuance for a term of five and one-half years following the date of issuance. The closing of the registered direct offering occurred on August 1, 2024.

Additions to leadership team to ensure operational excellence and support future plans – On October 7, 2024, Susan Eylward was named General Counsel and Corporate Secretary. She was most recently Senior Counsel at Science 37, Inc., a solutions organization focused on decentralized clinical trials, where she was responsible for a variety of complex legal matters, including corporate governance, securities compliance, executive compensation and acquisitions.

Kristin Longobardi was named Senior Vice President of Operations, bringing more than two decades of experience in enhancing business processes and operations across the biotech and pharmaceutical sectors. Previously, she served as Vice President of R&D Quality, Operations and Performance at Biogen. Her expertise in portfolio management, financial planning and operational excellence will be pivotal in driving IMUNON's operational frameworks toward supporting ambitious company growth.

THIRD QUARTER FINANCIAL RESULTS

The Company had $10.3 million in cash, investments and accrued interest receivable as of September 30, 2024. The Company believes it has sufficient capital resources to fund its operations into the third quarter of 2025.

Research and development expenses were $3.3 million for the third quarter of 2024, compared with $2.0 million for the third quarter of 2023. General and administrative expenses were $1.7 million for the third quarter of 2024, compared with $1.9 million for the third quarter of 2023.

Net loss was $4.9 million, or $0.34 per share, for the third quarter of 2024, compared with a net loss of $3.5 million, or $0.37 per share, for the third quarter of 2023.

YEAR-TO-DATE FINANCIAL RESULTS

Research and development expenses were $9.4 million for the nine months ended September 30, 2024, compared with $7.7 million for the nine months ended September 30, 2023. General and administrative expenses were $5.6 million for the nine months ended September 30, 2024, compared with $7.3 million for nine months ended September 30, 2023.

Year-to-date net loss was $14.6 million, or $1.39 per share, compared with a net loss of $14.6 million, or $1.64 per share, for the same period of 2023.

Conference Call and Webcast

The Company is hosting a conference call at 11:00 a.m. ET today to provide a business update, discuss third quarter 2024 financial results and answer questions. 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 third quarter 2024 earnings call. A live webcast of the call will be available here.

The call will be archived for replay until November 21, 2024. 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 10193110. A webcast of the call will 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 outcome of the Company's End-of-Phase 2 meeting with the FDA, 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 of 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 Statements of Operations
(in thousands except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 3,293	$ 1,981	$ 9,407	$ 7,735
General and administrative	1,668	1,923	5,579	7,328
Total operating expenses	4,961	3,904	14,986	15,063
Loss from operations	(4,961)	(3,904)	(14,986)	(15,063)
Other income (expense):				
Investment income	116	427	423	962
Interest expense	-	-	-	(197)
Loss on debt extinguishment	-	-	-	(329)
Total other (expense) income, net	116	427	423	436
Net loss	$ (4,845)	$ (3,477)	$ (14,563)	$ (14,627)
Net loss per common share Basic and diluted	$ (0.34)	$ (0.37)	$ (1.39)	$ (1.64)
Weighted average shares outstanding Basic and diluted	14,445	9,377	10,503	8,926

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

	September 30, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 10,312	$ 5,839
Investment securities and interest receivable	-	9,857
Advances, deposits and other current assets	2,220	2,545
Total current assets	**12,532**	**18,241**
Property and equipment	**564**	**752**
Other assets		
Deferred tax asset	-	1,280
Operating lease right-of-use assets, net	1,245	1,595
Deposits and other assets	50	50
Total other assets	**1,295**	**2,925**
Total assets	**$ 14,391**	**$ 21,918**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable – trade accrued liabilities	$ 2,360	$ 3,515
Other accrued liabilities	2,573	3,391
Operating lease liabilities – current portion	509	485
Total current liabilities	**5,442**	**7,391**
Operating lease liabilities – non-current portion	758	1,139
Total liabilities	**6,200**	**8,530**
Stockholders' equity		
Common stock	145	94
Additional paid-in capital	410,877	401,501
Accumulated other comprehensive gain (loss)	-	61
Accumulated deficit	(402,746)	(388,183)
	8,276	13,473
Less: Treasury stock	(85)	(85)
Total stockholders' equity	**8,191**	**13,388**
Total liabilities and stockholders' equity	**$ 14,391**	**$ 21,918**

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Source: Imunon, Inc.