IMUNON Reports Second Quarter 2024 Financial Results and Provides a Business Update

August 14, 2024

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

LAWRENCEVILLE, N.J., Aug. 14, 2024 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in late-stage development with its DNA-mediated immuno-oncology therapy, today reported financial results for the three and six months ended June 30, 2024. The Company also provided an update on its clinical development programs with IMNN-001, including positive topline results from the Phase 2 OVATION 2 Study in patients with advanced ovarian cancer and an update on IMNN-101, its seasonal COVID-19 booster candidate.

"The second quarter and recent weeks were exciting and highly rewarding," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "Positive topline results from our Phase 2 OVATION 2 Study with IMNN-001 in advanced ovarian cancer were the culmination of years of dedication by the IMUNON team and set our company's strategic plan going forward. We reported overall survival among patients treated with IMNN-001 of more than 11 months compared with patients treated with standard-of-care, and believe these results provide hope to women suffering from a disease with such a poor prognosis. Our next steps include holding an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) to clarify our path to a Phase 3 pivotal study."

Dr. Lindborg added, "The addition of approximately $9.3 million in net proceeds from a capital raise last month in a challenging market, along with the steps we have taken to conserve capital allows the Company to report many important catalysts, including the initiation of a planned Phase 3 study of IMNN-001."

RECENT DEVELOPMENTS

IMNN-001 Immunotherapy

Reported Positive Topline Results From OVATION 2 Study in Advanced Ovarian Cancer – On June 24, 2024, the Company announced database lock for the OVATION 2 Study. At that time, median overall survival (OS) and progression-free survival (PFS) had been reached, and all patients in the open-label study had achieved treatment observation duration of 16 months, as required per protocol to evaluate efficacy. On July 30, 2024, the Company announced positive topline results from the Phase 2 OVATION 2 Study. Highlights from patients treated with IMNN-001 plus standard-of-care in a first-line treatment setting include:

- 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 indicates 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.

The Company plans to hold an End-of-Phase 2 meeting with the FDA to discuss the protocol for a Phase 3 study, which is anticipated to begin in the first quarter of 2025. The Company also plans to present full OVATION 2 Study results at an upcoming medical conference and to submit the results for publication in a peer-reviewed medical journal.

MRD Study Advancing: Phase 1/2 Study of IMNN-001 in Combination with Bevacizumab, titled "Targeting Ovarian Cancer Minimal Residual Disease (MRD) Using Immune and DNA Repair Directed Therapies" – In February 2023, the Company and Break *Through* Cancer, a public foundation dedicated to supporting translational research in the most difficult-to-treat cancers that partners with top cancer research centers, announced the commencement of patient enrollment in a collaboration to evaluate IMNN-001 in combination with bevacizumab in patients with advanced ovarian cancer in the frontline, neoadjuvant clinical setting. MD Anderson Cancer Center, Dana-Farber Cancer Institute, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins and Memorial Sloan Kettering Cancer Center will be participating in the trial. In addition, The Koch Institute for Integrative Cancer Research at the Massachusetts Institute of Technology (MIT) will provide artificial intelligence services including biomarker and genomic analysis.

The study is expected to enroll 50 patients with Stage III/IV advanced ovarian cancer and is being led by principal investigator Amir Jazaeri, M.D., Vice Chair for Clinical Research and Director of the Gynecologic Cancer Immunotherapy Program in the Department of Gynecologic Oncology and Reproductive Medicine at MD Anderson. Patients are being randomized 1:1 in a two-arm trial. The trial's primary endpoint is detection of minimal residual disease (MRD) by second look laparoscopy (SLL), with secondary endpoints including overall survival (OS) and progression-free survival (PFS). SLL data are expected within one year following the completion of enrollment and final data are expected approximately three years following

the completion of enrollment.

As of June 30, 2024, seven patients were enrolled and had received treatment in the Phase 1 portion of this study at the University of Texas MD Anderson Cancer Center. Memorial Sloan Kettering Cancer Center was added as a clinical site for this study in the first quarter of 2024.

PlaCCine: Next Generation Prophylactic Vaccine Proof of Concept

First Participants Vaccinated in IMUNON's IMNN-101 Phase 1 Clinical Trial – On April 18, 2024, the Company announced that it received clearance from the FDA to begin a Phase 1 clinical trial with a seasonal COVID-19 booster vaccine. The primary objectives of this proof-of-concept study of the PlaCCine DNA Vaccine technology platform are to evaluate safety, tolerability, neutralizing antibody response and the vaccine's durability in healthy adults. Secondary objectives include evaluating the ability of the IMNN-101 vaccine to elicit binding antibodies and cellular responses and their associated durability. As currently planned, the Phase 1 study will enroll 24 subjects evaluating three escalating doses of IMNN-101. For this study, IMMN-101 has been designed to protect against the SARS-CoV-2 Omicron XBB1.5 variant. Assuming positive results, IMUNON will advance discussions with potential partners to continue development of the platform.

During the second quarter of 2024, the Company announced that DM Clinical Research in Philadelphia was the first clinical site activated and ready for patient recruitment for this Phase 1 study. DM Clinical Research is an integrated national network of clinical trial sites focused on delivering advanced, preventive medicine to underserved communities. Topline data are anticipated by year-end 2024.

Corporate Developments

Received Gross Proceeds of $10 Million in 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 agreed to issue and sell 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 agreed to issue to the Purchasers unregistered warrants to purchase shares of common stock. The warrants have an exercise price of $2.00 per share and will be exercisable immediately 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.

SECOND QUARTER FINANCIAL RESULTS

IMUNON reported a net loss for the second quarter of 2024 of $4.8 million, or $0.51 per share, compared with a net loss of $5.6 million, or $0.61 per share, for the second quarter of 2023. Operating expenses were $5.0 million for the second quarter of 2024, a decrease of $0.5 million or 8% from $5.5 million for the second quarter of 2023.

Research and development ("R&D") expenses were $2.8 million in the second quarter of 2024, compared with $3.1 million in the same period of 2023. Costs associated with the OVATION 2 Study were $0.4 million in the second quarter of 2024, compared with $0.3 million in the same period of 2023. Costs associated with the PlaCCine vaccine trial were $0.3 million in the second quarter of 2024. Other clinical and regulatory costs were $0.6 million in the second quarter of 2024, compared with $0.4 million in the same period of 2023.

R&D costs associated with the development of IMNN-001 to support the OVATION 2 Study were $0.2 million in the second quarter of 2024, compared with $0.4 million in the same period of 2023. The development costs of the PlaCCine DNA vaccine technology platform decreased to $0.7 million in the second quarter of 2024, compared with $1.3 million in the same period of 2023. CMC costs decreased to $0.5 million in the second quarter of 2024, compared with $0.7 million in the same period of 2023. The lower CMC costs were primarily due to the Company's establishment of internal capability to produce plasmid DNA.

General and administrative expenses were $2.2 million in the second quarter of 2024, compared with $2.3 million in the same period of 2023. The decrease was primarily attributable to lower non-cash stock compensation expenses of $0.1 million and employee-related expenses of $0.1 million, offset by an increase in legal fees of $0.1 million.

Other non-operating income was $0.2 million in the second quarter of 2024, compared with other non-operating expenses of $0.1 million in the same period of 2023. The Company incurred a loss on extinguishment of debt expense of $0.3 million on its loan facility with Silicon Valley Bank in the second quarter of 2023 upon the repayment in full of this loan facility. Investment income from the Company's short-term investments decreased by $0.1 million for the second quarter of 2024, compared with the same period in 2023.

The Company had $5.3 million in cash, investments and accrued interest receivable as of June 30, 2024. Combined with net proceeds of approximately $9.0 million from the registered direct offering announced in July 2024, the Company believes it has sufficient capital resources to fund its operations into the third quarter of 2025.

FIRST HALF FINANCIAL RESULTS

For the six months ended June 30, 2024, the Company reported a net loss was $9.7 million, or $1.03 per share, compared with a net loss of $11.2 million, or $1.28 per share, for the same six-month period of 2023.

Net cash used for operating activities was $10.4 million for the first six months of 2024, compared with $10.8 million for the same period in 2023. Cash used in financing activities for the first six months of 2023 resulted from the early repayments of the Company's loan facility with Silicon Valley Bank of $6.4 million, partially offset by sales of equity under the Company's At-the-Market Equity Facility of $2.7 million.

R&D expenses were $6.1 million in the first half of 2024, compared with $5.8 million in the same period of 2023. Costs associated with the OVATION 2 Study were $0.7 million in the first half of 2024, compared with $0.6 million in the same period of 2023. Costs associated with the PlaCCine vaccine trial were $0.9 million in the first half of 2024. Other clinical and regulatory costs were $1.1 million in the first half of 2024, compared with $0.7 million in the same period of 2023.

R&D costs associated with the development of IMNN-001 to support the OVATION 2 Study were $0.7 million in the first half of 2024, compared with $0.8 million in the same period in 2023. The development of the PlaCCine DNA vaccine technology platform decreased to $2.0 million in the first half of 2024 from $2.3 million in the same period of 2023. CMC costs decreased to $0.8 million in the first half of 2024 from $1.4 million in the same period

of 2023.

General and administrative expenses were $3.9 million in the first half of 2024, compared with $5.4 million in the same period of 2023. The decrease was primarily attributable to lower non-cash stock compensation expenses of $0.4 million, legal expenses of $0.4 million, employee-related expenses of $0.3 million and insurance expenses of $0.1 million.

Other non-operating income was $0.3 million in the first half of 2024, compared with $8,505 in the same period of 2023. The Company incurred interest expense of $0.2 million on its loan facility with Silicon Valley Bank in the first half of 2023. The Company incurred debt extinguishment expense on its loan facility with Silicon Valley Bank in the first half of 2023 of $0.3 million, which was repaid in full in the second quarter of 2023. Investment income from the Company's short-term investments decreased by $0.2 million for the first half of 2024 from the same period in 2023 due to lower investment balances.

Conference Call and Webcast

The Company is hosting a conference call at 11:00 a.m. Eastern time today to provide a business update, discuss second 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 Second Quarter 2024 Earnings Call. A live webcast of the call will be available here.

The call will be archived for replay until August 28, 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 1829664. 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 coding 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 delivery of DNA-coded 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 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 IL-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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 2,819	$ 3,134	$ 6,114	$ 5,754

General and administrative	2,194	2,340	3,911	5,405
Total operating expenses	5,013	5,474	10,025	11,159
Loss from operations	(5,013)	(5,474)	(10,025)	(11,159)
Other income (expense):				
Investment income	225	281	307	535
Interest expense	-	(37)		(197)
Loss on debt extinguishment	-	(329)	-	(329)
Total other (expense) income, net	225	(85)	307	9
Net loss	$ (4,788)	$ (5,559)	$ (9,718)	$ (11,150)
Net loss per common share				
Basic and diluted	$ (0.51)	$ (0.61)	$ (1.03)	$ (1.28)
Weighted average shares outstanding				
Basic and diluted	9,401	9,137	9,401	8,711

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

ASSETS	**June 30, 2024**	**December 31, 2023**
Current assets		
Cash and cash equivalents	$ 5,306	$ 5,839
Investment securities and interest receivable	-	9,857
Advances, deposits and other current assets	2,340	2,545
Total current assets	**7,646**	**18,241**
Property and equipment	**625**	**752**
Other assets		
Deferred tax asset	-	1,280
Operating lease right-of-use assets, net	1,370	1,595
Deposits and other assets	50	50
Total other assets	**1,420**	**2,925**
Total assets	**$ 9,691**	**$ 21,918**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable – trade accrued liabilities	$ 1,969	$ 3,515
Other accrued liabilities	2,592	3,391
Operating lease liabilities – current portion	516	485
Total current liabilities	**5,077**	**7,391**
Operating lease liabilities – non-current portion	873	1,139
Total liabilities	**5,950**	**8,530**
Stockholders' equity		
Common stock	94	94
Additional paid-in capital	401,633	401,501
Accumulated other comprehensive gain (loss)	-	61
Accumulated deficit	(397,901)	(388,183)
	3,826	13,473
Less: Treasury stock	(85)	(85)
Total stockholders' equity	**3,741**	**13,388**

Total liabilities and stockholders' equity		**$**	**9,691**	**$**	**21,918**

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Source: Imunon, Inc.