# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

# FORM 8-K

## **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 7, 2024

# Imunon, Inc.

(Exact name of registrant as specified in its Charter)

Delaware	001-15911	52-1256615	
(State or other jurisdiction	(Commission	(IRS Employer	
of incorporation)	File Number)	Identification No.)	
997 Lenox Drive, Suite 100, Lawrenceville, NJ		08648-2311	
(Address of principal executive offices)		(Zip Code)	

(609) 896-9100

(Registrant's telephone number, including area code)

N/A

#### (Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act

Title of each class	Trading symbol(s)	Name of each exchange on which registered				
Common stock, par value \$0.01 per share	IMNN	Nasdaq Capital Market				

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company  $\Box$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.  $\Box$ 

#### Item 2.02 Results of Operations and Financial Condition.

On November 7, 2024, Imunon, Inc. issued a press release reporting its financial results for the quarter ended September 30, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On October 31, 2024, Imunon, Inc. announced it would hold a conference call on November 7, 2024 to discuss its financial results for the quarter ended September 30, 2024 and provide a business update. The conference call will also be broadcast live on the internet at <u>http://www.imunon.com</u>.

The information in this report, including the exhibit hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. Such information shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by Imunon, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

The press release contains forward-looking statements which involve certain risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Please refer to the cautionary note in the press release regarding these forward-looking statements.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release titled "Imunon Reports Third Quarter 2024 Financial Results and Provides Business Updates" issued by Imunon, Inc. on November 7, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

# IMUNON INC.

Dated: November 7, 2024

By: /s/ David Gaiero

David Gaiero Chief Financial Officer



#### IMUNON Reports Third Quarter 2024 Financial Results and Provides Business Updates

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

LAWRENCEVILLE, N.J., Nov. 7, 2024 – <u>IMUNON</u>, Inc. (NASDAQ: IMNN), a clinical-stage company in late-stage development with its DNAmediated 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 39<sup>th</sup> 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) 39<sup>th</sup> 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 progressionfree 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 <u>here</u>.

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 <u>here for 90 days</u>.

#### 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 <u>www.imunon.com</u>.

#### **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.

#### **Contacts:**

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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	\$ 10,3	12 \$ 5,839
Investment securities and interest receivable		- 9,857
Advances, deposits and other current assets	2,22	20 2,545
Total current assets	12,5	32 18,241
Property and equipment	5	64 752
Other assets		
Deferred tax asset		- 1,280
Operating lease right-of-use assets, net	1,24	
Deposits and other assets		50 50
Total other assets	1,22	
Total assets	\$ 14,3	91 \$ 21,918
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable – trade accrued liabilities	\$ 2,30	60 \$ 3,515
Other accrued liabilities	2,5'	73 3,391
Operating lease liabilities – current portion	50	09 485
Total current liabilities	5,44	42 7,391
Operating lease liabilities – non-current portion	7:	58 1,139
Total liabilities	6,2	
Stockholders' equity		
Common stock	14	45 94
Additional paid-in capital	410,8	77 401,501
Accumulated other comprehensive gain (loss)	,	- 61
Accumulated deficit	(402,74	46) (388,183)
	8,2'	
Less: Treasury stock		85) (85)
Total stockholders' equity	8,1	
Total liabilities and stockholders' equity	\$ 14,3	

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