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): March 28, 2024

Imunon, Inc.
(Exact name of registrant as specified in its Charter)

Delaware	001-15911	52-1256615
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer 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 ☐

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. ☐

Item 2.02 Results of Operations and Financial Condition.

On March 28, 2024, Imunon, Inc. issued a press release reporting its financial results for the year ended December 31, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On March 21, 2024, Imunon, Inc. announced it would hold a conference call on March 28, 2024 to discuss its financial results for the year ended December 31, 2023 and provide a business update. The conference call will also be broadcast live on the internet at http://www.imunon.com.

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 2023 Financial Results and Provides Business Update" issued by Imunon, Inc. on March 28, 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: March 28, 2024

By: */s/ Jeffrey W. Church*
Jeffrey W. Church
Executive Vice President and Chief Financial Officer

Exhibit 99.1

IMUNON Reports 2023 Financial Results and Provides Business Update

Conference Call Begins Today at 10:00 a.m. Eastern Time

LAWRENCEVILLE, N.J. (March 28, 2024) – IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage drug-development company focused on developing DNA-mediated immuno-oncology therapies and next-generation vaccines, today reported financial results for the year ended December 31, 2023. The Company also provided an update on its clinical development programs with IMNN-001, a DNA-based interleukin-12 (IL-12) immunotherapy in Phase 2 clinical development for the treatment of first-line, locally advanced-stage ovarian cancer, and on its PlaCCine modality, a proprietary mono- or multi-cistronic DNA plasmid and a synthetic DNA delivery technology for the expression of pathogen antigens in preclinical studies for the development of next-generation vaccines.

Highlights of 2023 and recent weeks include the following:

- Reported interim progression-free survival (PFS) and overall survival (OS) data with IMNN-001 in the Phase 2 OVATION 2 Study in patients with advanced ovarian cancer. Interim data from the intent-to-treat (ITT) population showed an approximate 30% delay in disease progression or death in the treatment arm compared with the control arm, and preliminary OS data showed an approximate nine-month improvement in the treatment arm over the control arm.

- Enrolled four patients in a Phase 1/2 clinical trial evaluating IMNN-001 in combination with bevacizumab in patients with advanced ovarian cancer at the University of Texas MD Anderson Cancer Center, and recently added Memorial Sloan Kettering Cancer Center as a clinical site for this study.

- Announced results from a non-human primate study confirming PlaCCine as a viable modality for the development of the next generation of prophylactic vaccines.

- Reported pre-clinical data demonstrating PlaCCine vaccines elicit robust and more durable T cell responses than commercial mRNA vaccines in animal models, signaling that PlaCCine vaccines may provide greater protection against reinfection, hospitalization or death.

- Submitted an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) in the first quarter of 2024 for a Phase 1/2 proof-of-concept clinical trial with a seasonal COVID-19 booster vaccine.

- Launched a new current Good Manufacturing Practices production facility to efficiently support R&D with significantly lower costs for infectious disease vaccines, and DNA-based immuno-oncology therapies.

“IMUNON has a dedicated management team to advance our two platform technologies and execute our strategic plan,” said Mr. Michael Tardugno, IMUNON’S Executive Chairman. “We remain on track to report topline results mid-year from the OVATION 2 Study with IMNN-001 in advanced ovarian cancer. If the interim data are confirmed in the final readout, the observed PFS benefit would represent a clinically meaningful outcome. We also remain on track to begin a Phase 1 proof-of-concept clinical study in the second quarter of 2024 with a seasonal COVID-19 booster vaccine, following FDA clearance of our IND application. Our objective is to confirm the safety and immunogenicity of our clinical vaccine in humans. Based on these results, we will advance discussions with potential partners to continue development of the platform.”

“IMUNON made significant progress during 2023, in particular with advancing our clinical programs in immuno-oncology with IMNN-001, our gene-mediated IL-12 immunotherapy. In September we reported interim PFS and OS data in our OVATION 2 Study suggesting a delay in disease progression or death in the treatment arm of approximately 30% compared with the control arm, with the hazard ratio nearing the study objective. Preliminary OS data followed a similar trend, showing an approximate nine-month improvement in the treatment arm over the control arm. Subgroup analyses suggest patients treated with a PARPi as maintenance therapy had longer PFS and OS if they were also treated with IMNN-001, compared with patients treated with neoadjuvant chemotherapy (NACT) only,” he added.

Our PlaCCine modality continues to advance with very encouraging data. We demonstrated the validity of this proprietary technology in prophylactic vaccines, with impressive preclinical proof-of-concept data not only in COVID-19, but also in a multiple of other pathogenic viruses. We also completed the evaluation of our vaccines in non-human primates. The final data from these studies show excellent immunological response and viral clearance. In a recent mouse study, we demonstrated that a single dose of our PlaCCine vaccine without a booster dose produced longer duration of IgG responses and higher T cell activation than an mRNA vaccine. We have also demonstrated continued drug stability at standard refrigerated temperature of 4°C for more than 12 months, representing a significant commercial advantage over commercial mRNA-based vaccines.

Given the high costs and long lead times of third party CMOs, we have strategically invested in, and completed development of in-house pilot manufacturing capabilities for DNA plasmids and synthetic delivery systems. Our scientists can now select any protein from the human or pathogen proteomes to be engineered. Our labs also can conduct testing and run experiments in a variety of animal disease models independently supporting bench-to-bedside development of our novel therapies and vaccines. These capabilities are expected to allow us to realize our goal of attracting strategic partners while minimizing dependence on vendors so that we control both the costs and the development timelines.

“We are excited about the key value-creating milestones we face in 2024. The potential for advances in treating late-stage ovarian cancer may be within reach, while a better vaccine platform technology holds tremendous commercial promise. We look forward to continuing to create value for our stockholders and for patients,” Mr. Tardugno concluded.

RECENT DEVELOPMENTS

IMNN-001 Immunotherapy

Reported Interim PFS and OS Data in OVATION 2 Study in Advanced Ovarian Cancer. In September 2023, the Company announced interim PFS and OS data with IMNN-001 in its OVATION 2 Study. This study is evaluating the dosing, safety, efficacy and biological activity of intraperitoneal IMNN-001 in combination with NACT in patients newly diagnosed with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer. NACT is designed to shrink the tumors as much as possible for optimal surgical removal after three cycles of chemotherapy. Following NACT, patients undergo interval debulking surgery, followed by three additional cycles of chemotherapy to treat any residual tumor.

The open-label study is directional and designed with an 80% confidence interval to show an approximate 33% improvement in PFS, when comparing the treatment arm (NACT + IMNN-001) with the control arm (NACT only). The secondary endpoints include OS, objective response rate, pathological response, surgical response and serologic response. The final readout of this study is expected in mid-2024. A positive readout would inform next development steps.

- Interim data from the ITT population showed efficacy trends in PFS, demonstrating a delay in disease progression in the treatment arm of approximately three months compared with the control arm, with the hazard ratio nearing the study objective. Preliminary OS data followed a similar trend, showing an approximate nine-month improvement in the treatment arm over the control arm.
- Non-prespecified subgroup analyses suggest that patients treated with a PARPi as maintenance therapy had longer PFS and OS if they were also treated with IMNN-001, compared with patients treated with NACT only.
    - The median PFS in the PARPi + NACT group and the PARPi + NACT + IMNN-001 group was 15.7 months and 23.7 months, respectively.
    - The median OS in the PARPi + NACT group was 45.6 months and has not yet been reached in the PARPi + NACT + IMNN-001 group.

Continued benefits were seen in other secondary endpoints including an approximately 25% higher R0 tumor resection score and a doubling of the CRS 3 chemotherapy response score to approximately 30% in the treatment arm, versus 14% in the control arm. A complete tumor resection (R0) is a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Chemotherapy response score is considered a good prognostic indicator in ovarian cancer. Safety analyses continue to show good tolerability of IMNN-001 in this setting.

Began Treatment in a Phase 1/2 Clinical Trial Evaluating IMNN-001 in Combination with Bevacizumab (Avastin®) in Advanced Ovarian Cancer. In October 2023, the first patient was enrolled in this trial at the University of Texas MD Anderson Cancer Center. This trial is expected to enroll 50 patients with Stage III/IV ovarian cancer. Patients undergoing frontline neoadjuvant therapy will be randomized 1:1 to receive standard chemotherapy plus bevacizumab, or standard chemotherapy plus bevacizumab and IMNN-001. The trial's primary endpoint is detection of minimal residual disease (MRD) by second-look laparoscopy and the secondary endpoint is PFS. This trial will also include a wealth of translational endpoints aimed at understanding the clonal evolution and immunogenomic features of the MRD phase of ovarian cancer that is currently undetectable by imaging or tumor markers.

In February 2024, the Company announced that Memorial Sloan Kettering Cancer Center has joined MD Anderson Cancer Center in enrolling patients in this clinical trial. A total of four patients have been enrolled in the study to date.

PlaCCine: Developing the Prophylactic Vaccines of the Future

Preclinical Data for IMUNON's PlaCCine DNA-Based Vaccine in SARS-CoV-2 Published in Peer-Reviewed Journal *Vaccine*. In February 2024, the Company announced that an article titled "Strong immunogenicity & protection in mice with PlaCCine: A COVID-19 DNA vaccine formulated with a functionalized polymer" was published in the peer-reviewed journal *Vaccine,* by Elsevier.

The article is available at https://authors.elsevier.com/sd/article/S0264-410X(24)00077-X.

The study described in the article used IMUNON's proprietary formulation against the spike proteins from two SARS-CoV-2 variants, both alone and in combination. Data from the study show:

- IMUNON's proprietary formulation of functionalized polymer protected DNA from degradation and enhanced protein expression, while the combination with an adjuvant led to an increase in immunogenicity.
- PlaCCine vaccines are stable for up to one year at 4°C and at least one month at 37°C.
- Vaccination with PlaCCine resulted in the induction of spike-specific neutralizing antibodies and cytotoxic T cells.
- In the *in vivo* challenge model, the vaccine-induced immune response was capable of suppressing viral replication.
- Multiple inserts can be cloned into the PlaCCine backbone (a plug-and-play strategy), therefore allowing for an immune response with broader protection.

IMUNON's Vice President of R&D Presented at the Vaccines Summit-2023. In November 2023, Jean Boyer, Ph.D. delivered a presentation titled "Robust Immunogenicity and Protection with PlaCCine: A Novel DNA Vaccine Delivered with a Functionalized Polymeric Delivery System" during the "New Vaccine Development" session at the Vaccines Summit-2023 in Boston. The presentation included updated data related to IMUNON's PlaCCine SARS-CoV-2 DNA vaccine, including studies showing PlaCCine expresses spike proteins in mice and primates demonstrating induction of spike-specific neutralizing antibody responses and CD8 and CD4 spike-specific cellular responses. The induced immune responses in vaccinated mice were maintained for up to 14 months after vaccination. The presentation also showed that in both primates and mice, the induced immune responses reduced lung viral loads by more than 90%. In mouse studies, robust immune responses were observed following a single intramuscular injection of either PlaCCine SARS-CoV-2 DNA vaccine or a novel PlaCCine Lassa Virus DNA vaccine.

IMUNON's Chief Science Officer Presented at the 3rd International Vaccines Congress. In October 2023, Khursheed Anwer, Ph.D. delivered a presentation titled "A DNA-based Vaccine Technology Independent of Virus or Device" at the 3rd International Vaccines Congress in Boston. The presentation described the multiple advantages of the PlaCCine modality over current commercial vaccine platforms. The presentation also described the versatility of the PlaCCine modality, demonstrating activity against Marburg and influenza viruses in collaboration with the Wistar Institute, and activity against Lassa virus being evaluated at the NIH/NIAID.

Corporate Developments

Received $1.3 Million in Non-Dilutive Funding from the Sale of New Jersey Net Operating Losses. In March 2024, the Company received $1.3 million in net cash proceeds from the sale of approximately $1.4 million of its unused New Jersey net operating losses (NOLs). The NOL sales cover the tax year 2022 and are administered through the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer (NOL) program. This non-dilutive funding further strengthened the Company's balance sheet.

Financial Results for the Year Ended December 31, 2023

IMUNON reported a net loss for 2023 of $19.5 million, or $2.16 per share, compared with a net loss for 2022 of $35.9 million, or $5.03 per share. Operating expenses were $21.0 million for 2023, a decrease of $4.4 million or 17% from $25.4 million for 2022. The Company recognized tax benefits from the sale of its New Jersey NOLs of $1.3 million and $1.6 million in 2023 and 2022, respectively.

Research and development (R&D) expenses were $11.3 million for 2023, a decrease of $0.4 million from $11.7 million for 2022. Costs associated with the OVATION 2 Study were $1.2 million and $1.5 million for 2023 and 2022, respectively. Costs associated with the Phase 3 OPTIMA Study were de minimis for 2023 compared with $1.0 million for 2022. Other clinical and regulatory costs were $1.8 million for 2023 compared with $1.9 million for 2022. R&D costs associated with the development of IMNN-001 to support the OVATION 2 Study, as well as development of the PlaCCine DNA vaccine technology platform, were $6.0 million for 2023 compared with $6.1 million for 2022. CMC costs increased to $2.3 million for 2023 compared with $1.2 million for 2022 due to the development of in-house pilot manufacturing capabilities for DNA plasmids and nanoparticle delivery systems in 2023.

General and administrative expenses were $9.7 million for 2023 compared with $13.7 million for 2022. This decrease was primarily attributable to lower non-cash stock compensation expense ($1.3 million), lower employee-related costs ($0.8 million), lower legal costs ($1.0 million), lower insurance costs ($0.6 million) and lower public company expenses ($0.2 million), offset by higher consulting fees ($0.2 million).

Other non-operating income was $0.2 million for 2023 compared with other non-operating expenses of $12.5 million for 2022. This increase was attributable to the following:

- Investment income from the Company's short-term investments was $1.2 million for 2023 and $0.5 million for 2022.
- In June 2021, the Company entered into a $10.0 million loan facility with Silicon Valley Bank (SVB). The Company 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 2023 compared with $0.5 million in 2022. 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.
- In 2022, the Company recognized (i) an impairment charge of $13.4 million due to the write off of In-Process Research & Development (IPR&D) assets and (ii) a non-cash gain of $5.4 million due to the write-off of the earnout milestone liability because of the requirements not being achieved.

- In 2022, the Company incurred additional interest expense attributable to the one-time payment of $4.5 million in interest and offering expenses resulting from the sale and subsequent redemption of $28.5 million of Series A & B convertible redeemable preferred stock.

Net cash used for operating activities was $19.0 million for 2023 compared with $23.1 million for 2022. This decrease was primarily due to the one-time payment of $4.5 million in interest expense resulting from the sale and subsequent redemption of $28.5 million of Series A & B convertible redeemable preferred stock in the first quarter of 2022. Cash used in financing activities was $3.6 million for 2023 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). This compares with cash provided by financing activities of $6.7 million for 2022 resulting from an at-the-market equity offering ($6.2 million) and sales under the Company's At-the-Market Equity Facility ($0.5 million).

The Company ended 2023 with $15.7 million in cash, investments and accrued interest receivable. Along with future planned sales of the Company's remaining $1.3 million of New Jersey NOLs, the Company believes it has sufficient capital resources to fund its operations into the fourth quarter of 2024.

Conference Call and Webcast

The Company is hosting a conference call to provide a business update, discuss 2023 financial results and answer questions at 10:00 a.m. Eastern time today. To participate in the call, please dial 866-777-2509 (Toll-Free/North America) or 412-317-5413 (International/Toll) and ask for the IMUNON 2023 Earnings Call. A live webcast of the call will be available here.

The call will be archived for replay until April 11, 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 8601697. 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 proteins and cytokines in the treatment of solid tumors where an immunological approach is deemed promising. The second modality, PlaCCine®, is developed for the coding of viral antigens that can elicit a strong immunological response. This technology may represent a promising platform for the development of vaccines in infectious diseases.

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 interleukin-12 and interferon gamma, at the tumor site. Additionally, the Company is entering a first-in-human study of its COVID-19 booster vaccine (IMNN-101). We will continue to leverage these modalities and to advance the technological frontier of plasmid DNA to better serve patients with difficult-to-treat conditions. For more information on IMUNON, 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. Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, unforeseen changes in the course of research and development activities and in clinical trials; 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 acquisitions or licenses of other technologies, assets or businesses; 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 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,	
	2023	**2022**
Licensing revenue	**$ -**	**$ 500**
Operating expenses:		
Research and development	11,287	11,734
General and administrative	9.743	13,688
Total operating expenses	**21,030**	**25,422**
Loss from operations	**(21,030)**	**(24,922)**
Other income (expense):		
Gain from change in valuation of earnout milestone liability	-	5,396
Impairment of goodwill and in-process research and development	-	(13,366)
Interest expense, investment income and other income (expense), net	960	(4,575)
Loss on debt extinguishment	(329)	
Other (loss) income	(396)	2
Total other income (expense), net	**235**	**(12,543)**
Loss before income tax benefit	(20,795)	(37,465)
Income tax benefit	1,280	1,567
Net loss	**$ (19,515)**	**$ (35,898)**
Net loss per common share		
Basic and diluted	**$ (2.16)**	**$ (5.03)**
Weighted average shares outstanding		
Basic and diluted	**9,045**	**7,143**

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

	December 31, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 5,839	$ 11,493
Investment securities and interest receivable on investment securities	9,857	21,384
Money market investments, restricted cash	-	1,500
Advances, deposits on clinical programs and other current assets	2,545	2,403
Total current assets	**18,241**	**36,780**
Property and equipment	**752**	**548**
Other assets		
Deferred tax asset	1,280	1,567
Restricted cash invested in money market account	-	4,500
Operating lease right-of-use assets, deposits, and other assets	1,645	581
Total other assets	**2,925**	**6,648**
Total assets	**$ 21,918**	**$ 43,976**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 6,906	$ 8,381
Note payable – current portion	-	1,425
Operating lease liability – current portion	485	231
Total current liabilities	**7,391**	**10,037**
Notes payable – noncurrent portion	-	4,611
Operating lease liability – noncurrent portion	1,139	-
Total liabilities	**8,530**	**14,648**
Stockholders' equity		
Common stock	94	74
Additional paid-in capital	401,501	397,980
Accumulated other comprehensive gain (loss)	61	27
Accumulated deficit	(388,183)	(368,668)
	13,473	29,413
Less: Treasury stock	(85)	(85)
Total stockholders' equity	**13,388**	**29,328**
Total liabilities and stockholders' equity	**$ 21,918**	**$ 43,976**

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