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): May 11, 2023

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 May 11, 2023, Imunon, Inc. issued a press release reporting its financial results for the quarter ended March 31, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

On May 4, 2023, Imunon, Inc. announced it would hold a conference call on May 11, 2023 to discuss its financial results for the quarter ended March 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 First Quarter 2023 Financial Results and Provides Business Update" issued by Imunon, Inc. on May 11, 2023
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: May 11, 2023

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

Exhibit 99.1

IMUNON Reports First Quarter 2023 Financial Results and Provides Business Update

Non-Viral DNA-Mediated Immunotherapy and Next-Generation Vaccine Programs with Multiple Near-Term Milestones Supported by a Strong Balance Sheet

Conference Call Begins Today at 11:00 a.m. EDT

LAWRENCEVILLE, N.J. (May 11, 2023) – IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage drug-development company focused on developing non-viral DNA-mediated immunotherapy and next-generation vaccines, today announced financial results for the three months ended March 31, 2023, and provided an update on its clinical development programs with IMNN-001 (formerly GEN-1), a DNA-based interleukin-12 (IL-12) immunotherapy in Phase 2 clinical development for the treatment of advanced-stage ovarian cancer, and PLACCINE, a proprietary, multivalent DNA plasmid technology utilizing synthetic, non-viral vaccine delivery vectors being evaluated in preclinical studies for superiority over the current generation of nucleic acid vaccines.

Highlights of the first quarter of 2023 and recent weeks include:

- Opened enrollment in a Phase 1/2 clinical study of IMNN-001 in combination with Avastin in advanced ovarian cancer
- Announced compelling results from a non-human primate study confirming PLACCINE as a viable modality for the development of the next generation of prophylactic vaccines; PLACCINE is a non-viral, non-device plasmid DNA-based vaccine modality targeting multiple antigens from a single vector
- Reported data suggesting PLACCINE vaccines elicit robust and more durable T-cell responses than commercial mRNA vaccines, signaling that these vaccines may provide greater protection against reinfection, hospitalization or death
- Signed new research collaborations with The Wistar Institute to develop new vaccine formulations utilizing PLACCINE for infectious diseases
- Reported cash and cash equivalents of $37.3 million as of March 31, 2023, which is expected to fund operations into 2025

“Our PLACCINE modality continues to advance with very promising data. We demonstrated the validity of this proprietary technology in prophylactic vaccines, with impressive proof-of-concept data in a COVID-19 model coupled with final data from non-human primate studies showing excellent immunological response and viral clearance. We also demonstrated in a recent mouse study 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 are now more than nine months into a 12-month PLACCINE stability study and have demonstrated continued drug stability at the standard refrigerated temperature of 4°C, representing a significant commercial advantage over mRNA-based vaccines,” said Dr. Corinne Le Goff, IMUNON’s President and Chief Executive Officer.

“In March we applied for a pre-IND consultation with the U.S. Food and Drug Administration (FDA) to receive guidance on our proposed program for our seasonal COVID-19 booster vaccine prior to submitting an Investigational New Drug (IND) application with the FDA in the fourth quarter of 2023. Our objective is to confirm in a Phase 1 clinical study the safety of our PLACCINE modality. We will also select our next pathogen target for our PLACCINE modality. We likely will choose a pathogen from the list of priority pathogens established by the Coalition for Epidemic Preparedness Innovations. Our vaccine program objective is to establish the safety and efficacy of our platform in a Phase 1 human study, and then seek to license this powerful technology to pharmaceutical companies for the utilization of our platform and/or to establish non-dilutive partnerships to develop vaccines for pathogens of interest,” she added.

“We have now developed an in-house pilot manufacturing capability for DNA plasmids and nanoparticle delivery systems. Our scientists can select any protein from the human or pathogen proteomes to be engineered. Our existing labs also have the ability to conduct testing and to run experiments in a variety of animal disease models. These internal capabilities will allow us to control both the costs and the development timelines in support of our goal to attract corporate partners.

“With the continued volatility of the public equity markets, our decision to raise significant capital in 2021 and early 2022 to extend our cash runway into 2025 was well timed. We expect to report several value-creating developments over the next six to 18 months, among them reporting additional interim data on IMNN-001 from our OVATION 2 Study and the combination study with bevacizumab in advanced ovarian cancer, reporting topline data from the OVATION 2 Study, filing the IND for our SARS-CoV-2 vaccine and announcing proof-of-concept vaccine data for our next pathogen,” Dr. Le Goff concluded.

RECENT DEVELOPMENTS

PLACCINE: Developing the Prophylactic Vaccines of the Future

Presentation at Vaccine Technology Summit 2023 Describes Compelling Preclinical Data Supporting Continued Development of PLACCINE as a Differentiated, Next-Generation Vaccine. In March 2023 Khursheed Anwer, Ph.D., IMUNON’s Executive Vice President and Chief Science Officer, presented data on the Company’s PLACCINE platform at the Vaccine Technology Summit 2023. Dr. Anwer’s presentation is titled “A Novel DNA Vaccine Platform with Potential to Create Next Generation Vaccines,” and can be found on the Company’s website here.

Dr. Anwer reviewed the company’s work in advancing its PLACCINE modality and the promising preclinical data generated to date. Among topics presented was the ability of this multi-valent technology to achieve broad spectrum immunity from a single DNA plasmid with a synthetic delivery system. This ability is independent of virus, device or liquid nanoparticle formulations. The data presented showed:

- Robust immunogenicity and protection in SARS-CoV-2 models
- Durable cellular or humoral responses detectable for more than 12 months

- Comparable protection activity to a commercial mRNA vaccine in a booster-dose comparison
- Superior immune quality versus the mRNA vaccine in a single-dose comparison

In addition, the PLACCINE modality had important distinguishing advantages for a commercial vaccine, including a shelf-life at 4^{o}C for greater than nine months, and the ability for simple, rapid and scalable manufacturing.

IMNN-001 Immunotherapy

Phase 1/2 Clinical Study of IMNN-001 in Combination with Bevacizumab in Advanced Ovarian Cancer was Opened to Enrollment. In February 2023, the company announced a collaboration to evaluate IMNN-001 in a Phase 1/2 clinical trial in combination with bevacizumab in ovarian cancer in the frontline, neoadjuvant setting. Working with four of the foremost comprehensive cancer centers in the world, the goal of this project is to transform the care of women with ovarian cancer by developing unprecedented capabilities for understanding and targeting persistent minimal residual disease (MRD), as explained here.

This new Phase 1/2 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., Professor of Gynecologic Oncology and Reproductive Medicine at MD Anderson. A third party will partially fund the study.

The trial is open to enrollment at the University of Texas MD Anderson Cancer Center with expected additional participation at The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins and Memorial Sloan Kettering Cancer Center. The Koch Institute for Integrative Cancer Research at the Massachusetts Institute of Technology will provide artificial intelligence services throughout the trial, including biomarker and genomic analyses, which is expected to expand the company's knowledge of the treatment paradigm.

Presentation at American Association for Cancer Research (AACR) Describes Findings from Mouse Model of Peritoneally Disseminated Ovarian Cancer Suggest Biweekly Dosing Regimen for Further Evaluation in Human Clinical Studies. In April 2023 Jean Boyer, Ph.D., IMUNON's vice president of preclinical research, presented a poster titled "Efficacy of IMNN-001, an Interleukin-12 Immune Gene Therapy, at Different Dose Frequencies" at AACR. The poster can be found on the company's website here.

Researchers concluded that IMNN-001 demonstrated stimulation of the immune response in the ID8 ovarian tumor model. Of the three dosing regimens tested, the once every 2-week regimen demonstrated comparability to the weekly regimen while showing superiority to the once every 3-week regimen, particularly with respect to mortality and tumor burden. Thus, exploring once every 2-week dosing of IMNN-001 in human studies is warranted.

Partnerships. Collaborations and Corporate Developments

Collaborative Research Agreement Signed with The Wistar Institute's Vaccine & Immunotherapy Center. In January 2023, the Company announced a collaborative research agreement with The Wistar Institute, a global leader in biomedical research, through its Vaccine & Immunotherapy Center, to research and develop new vaccine formulations utilizing the Company's PLACCINE modality for the development of vaccines for infectious diseases. The Wistar Institute Vaccine & Immunotherapy Center possesses world-renowned expertise in cancer, immunology, infectious diseases and vaccine creation. They are uniquely positioned to advance new vaccine formulations and will facilitate further expansion and development of PLACCINE with the goal of expanding vaccine targets ideally matched for the Company's novel formulated DNA delivery platform.

Received $1.6 Million in Non-Dilutive Funding from the Sale of New Jersey Net Operating Losses. In January 2023, the Company announced it received $1.6 million in net cash proceeds from the sale of approximately $1.7 million of its unused New Jersey net operating losses (NOLs). The NOL sales cover the tax year 2021 and are administered through the New Jersey Economic Development Authority's (NJEDA) Technology Business Tax Certificate Transfer (NOL) program. This non-dilutive funding further strengthened the Company's balance sheet. The Company plans to sell an additional $1.9 million of unused New Jersey NOLs available to the Company under the program in 2023.

FIRST QUARTER FINANCIAL RESULTS

IMUNON reported a net loss for the first quarter of 2023 of $5.6 million, or $0.68 per share, compared with a net loss of $10.5 million, or $1.82 per share, for the first quarter of 2022. Operating expenses were $5.7 million for the first quarter of 2023, a decrease of $0.3 million or 5% from $6.0 million for the first quarter of 2022.

Net cash used for operating activities was $4.1 million for the first quarter of 2023, compared with $8.0 million for the comparable prior-year period. 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 $30.0 million of convertible, redeemable preferred stock during the first quarter of 2022.

Cash provided by financing activities of $2.5 million during the first quarter of 2023 resulted from equity sales under the Company's At-the-Market Equity Facility. The Company had $37.3 million in cash, investments and restricted cash as of March 31, 2023. Combined with $1.9 million in planned future sales of the Company's State of New Jersey NOLs, the Company believes it has sufficient capital resources to fund its operations into 2025.

Research and development (R&D) expenses were $2.6 million for the first quarter of 2023, a decrease of $0.5 million from $3.1 million for the comparable period in 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 increased to $1.7 million for the first quarter of 2023, compared with $1.9 million for the same period of 2022. Other clinical and regulatory costs were $0.3 million for the first quarter of 2023, compared with $0.8 million for the first quarter of 2022. CMC costs increased to $0.7 million for the first quarter of 2023, compared with $0.3 million for the first quarter of 2022 due to higher costs related to the development of in-house pilot manufacturing capabilities for DNA plasmids and nanoparticle delivery systems.

General and administrative expenses were $3.1 million for the first quarter of 2023, compared with $2.9 million for the comparable prior-year period. This increase was primarily attributable to lower non-cash stock compensation expense offset by higher professional fees, including legal fees to defend various lawsuits filed after the announcement in July 2020 of the OPTIMA Phase 3 study results, higher compensation expenses related to the CEO succession plan announced in July 2022 and higher staffing costs.

Other non-operating income was $93,085 for the first quarter of 2023, compared with other non-operating expenses of $4.6 million for the prior-year period. In the first quarter of 2022, the Company incurred a one-time payment of $4.5 million in interest and offering expenses resulting from the sale and subsequent redemption of $30.0 million of convertible redeemable preferred stock. The Company incurred higher interest expense on its loan facility with Silicon Valley Bank in the first quarter of 2023 due to rising interest rates. This loan facility has since been assumed by First Citizen Bank under the same terms. Investment income from the Company's short-term investments increased by $0.3 million for the first quarter of 2023 compared with the prior-year period due to higher returns on these investments.

Conference Call and Webcast

The Company is hosting a conference call to provide a business update, discuss first quarter 2023 financial results and answer questions at 11:00 a.m. EDT 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 First Quarter 2023 Earnings Call. A live webcast of the call will be available here.

The call will be archived for replay until May 25, 2023. 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 6902750. A webcast of the call will be available here for 90 days.

About IMUNON

IMUNON is a fully integrated, 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 has two platform technologies: the TheraPlas modality for the development of immunotherapies and other anti-cancer nucleic acid-based therapies, and the PLACCINE modality for the development of nucleic acid vaccines for infectious diseases and cancer. 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 conducting preclinical proof-of-concept studies on a nucleic acid vaccine candidate targeting the SARS-CoV-2 virus to validate its PLACCINE platform. IMUNON's platform technologies are based on the delivery of nucleic acids with novel synthetic delivery systems that are independent of viral vectors or devices. IMUNON will continue to leverage these platforms and to advance the technological frontier of nucleic acid-based products 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 periodic reports and prospectuses filed 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.

Contacts:

IMUNON
Jeffrey W. Church
Executive Vice President, CFO
and Corporate Secretary
609-482-2455
jchurch@imunon.com

LHA Investor Relations
Kim Sutton Golodetz
212-838-3777
Kgolodetz@lhai.com

(Tables to Follow)

IMUNON, Inc.
Condensed Consolidated Statements of Operations
(in thousands except per share amounts)

	Quarter Ended March 31,	
	2023	**2022**
Licensing revenue	**$ -**	**$ 125**
Operating expenses:		
Research and development	2,620	3,095
General and administrative	3,064	2,872
Total operating expenses	**5,684**	**5,967**
Loss from operations	**(5,684)**	**(5,842)**
Other income (expense):		
Interest expense on loan facility	(160)	(94)
Investment and other income (expense)	253	14
Interest expense on preferred stock	-	(4,552)
Total other expense	**93**	**(4,632)**
Net loss	**$ (5,591)**	**$ (10,474)**
Net loss per common share		
Basic and diluted	**$ (0.68)**	**$ (1.82)**
Weighted average shares outstanding		
Basic and diluted	**8,281**	**5,770**

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

	March 31, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 10,401	$ 11,493
Investment securities and interest receivable	20,892	21,384
Money market investments, restricted cash	2,250	1,500
Advances, deposits and other current assets	2,789	2,778
Total current assets	**36,332**	**37,155**
Property and equipment	**556**	**548**
Other assets		
Restricted cash invested in money market account	3,750	4,500
Deferred tax asset	-	1,567
Operating lease right-of-use assets, deposits, and other assets	1,468	206
Total other assets	**5,218**	**6,273**
Total assets	**$ 42,106**	**$ 43,976**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 7,887	$ 8,381
Note payable – current portion	2,181	1,425
Operating lease liability – current portion	350	231
Total current liabilities	**10,418**	**10,037**
Notes payable – noncurrent portion	3,899	4,611
Operating lease liability – noncurrent portion	1,142	-
Total liabilities	**15,459**	**14,648**
Stockholders' equity		
Common stock	91	74
Additional paid-in capital	400,776	397,980
Accumulated other comprehensive gain (loss)	124	27
Accumulated deficit	(374,259)	(368,668)
	26,732	29,413
Less: Treasury stock	(85)	(85)
Total stockholders' equity	**26,647**	**29,328**
Total liabilities and stockholders' equity	**$ 42,106**	**$ 43,976**

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