# IMUNON Reports First Quarter 2024 Financial Results and Provides Business Update

May 13, 2024

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

**LAWRENCEVILLE, N.J., May 13, 2024 (GLOBE NEWSWIRE) -- 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 three months ended March 31, 2024. 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 first-line treatment of locally advanced 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 for the development of next-generation vaccines.

“Potential key value-creating milestones are upon us. We expect that this summer will be rewarding and busy as we look to improve the treatment paradigm in late-stage ovarian cancer and to offer an “mRNA-better” vaccine platform technology with excellent commercial promise,” said Mr. Michael H. Tardugno, IMUNON’s Executive Chairman.

“We remain on track to report topline results from the OVATION 2 Study with IMNN-001 in advanced ovarian cancer in mid-2024. If interim data are confirmed, the observed progression-free survival (PFS) benefit would represent a clinically meaningful outcome. In September, we reported interim PFS and overall survival (OS) data suggesting an approximate 30% delay in disease progression or death in the treatment arm 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 PARP inhibitor (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 Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for our seasonal COVID-19 booster vaccine (IMNN-101) was accepted by the Agency. The Company has begun a Phase 1 proof-of-concept study in two investigational centers. Our goal is to confirm the safety and immunogenicity of this DNA-based vaccine as an annual booster with long-lasting protection. The first patients are expected to be enrolled during the current quarter, and based on the results, we intend to advance discussions with potential partners for further development. Our optimism is based, in part, on final data from non-human primate studies that showed excellent immunological response and viral clearance. In a recent mouse study, we demonstrated that a single dose of IMNN-101, 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 advantage over commercial mRNA-based vaccines.”

**Stacy Lindborg, PhD appointed President and Chief Executive Officer**

With great pleasure, the Company announced the appointment of Stacy R. Lindborg, Ph.D. as President and Chief Executive Officer, effective May 13, 2024. Dr. Lindborg has served on IMUNON’s board of directors since 2021 and was most recently Co-Chief Executive Officer of BrainStorm Cell Therapeutics, where she remains a director.

“We are delighted that Dr. Lindborg has agreed to deepen her ties with IMUNON as President and CEO,” said Mr. Tardugno. “We have benefited significantly from her counsel as a director, where she has played an integral role in establishing our strategic priorities. Stacy joins the Company at a particularly important time. We now look forward to benefiting from her expertise in a more meaningful way, especially as our near-term data readouts will require important decisions with respect to advancing various programs and assets.”

Dr. Lindborg, a globally recognized biostatistician, has nearly 30 years of pharmaceutical and biotech industry experience with a particular focus on R&D, regulatory affairs, executive management and strategy development. She has worked with biologics, small molecules and cell therapies to address a range of diseases and disorders. She has extensive experience in early-stage development, having taken molecules from first-in-human studies into the clinic, through regulatory approval and commercial launch.

**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 chemotherapy prior to tumor reduction surgery (known as: 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 tumor debulking surgery, followed by three additional cycles of chemotherapy to treat any remaining tumor tissue.

The open-label study is directional and is designed to show an approximate 33% improvement in PFS when comparing the treatment arm with the control arm. Key secondary endpoints include OS, and the objective response rate. The final readout of this study is expected in mid-2024. A positive readout would inform the Phase 3 study design.

- Interim data from the intent-to-treat 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, commissioned as a result of the evolving standard of care for this population, 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.

**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 joined MD Anderson Cancer Center in enrolling patients in this clinical trial.

**PlaCCine: Developing the Prophylactic Vaccines of the Future**

**IND Application Cleared by the FDA to Begin Human Testing of IMNN-101.** In April 2024, the Company announced receipt of FDA clearance to begin a Phase 1 proof-of-concept clinical trial with IMNN-101, a seasonal COVID-19 booster vaccine. Pending resolution of limited comments from the FDA, IMUNON expects to commence patient enrollment in the second quarter of 2024.

IMNN-101 utilizes the company's PlaCCine platform, a proprietary mono- or multi-valent DNA plasmid that regulates the expression of key pathogen antigens and is delivered via a unique synthetic DNA delivery system. The primary objectives of the Phase 1 study are to evaluate safety, tolerability, neutralizing antibody response and the vaccine's durability (duration of immunogenicity) in healthy adults. Secondary objectives include evaluating the ability of IMNN-101 to elicit binding antibodies and cellular responses and their associated durability. Based on reported preclinical data, durability of immune protection is expected to be superior to published mRNA vaccine data.

As currently planned, the Phase 1 study will enroll 24 subjects evaluating three escalating doses of IMNN-101 at two U.S. clinical trial sites. For this study, IMMN-101 has been designed to protect against the SARS-CoV-2 Omicron XBB1.5 variant, in accordance with the FDA's Vaccines and Related Biological Products Advisory Committee's June 2023 announcement of the framework for updated COVID-19 doses.

**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.

**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 THREE MONTHS ENDED MARCH 31, 2024**

IMUNON reported a net loss for the first quarter of 2024 of $4.9 million, or $0.52 per share, compared with a net loss of $5.6 million, or $0.68 per share, for the first quarter of 2023. Operating expenses were $5.0 million for the first quarter of 2024, a decrease of $0.7 million or 12% from $5.7 million for the first quarter of 2023.

Research and development (R&D) expenses were $3.3 million for the first quarter of 2024, an increase of $0.7 million from $2.6 million for the comparable period in 2023. Costs associated with the OVATION 2 Study were $0.3 million for both the first quarters of 2024 and 2023. Other clinical and regulatory costs were $1.1 million for the first quarter of 2024 compared with $0.3 million for the prior-year period. 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 $1.6 million for the first quarter of 2024, compared with $1.4 million for the same period last year. CMC costs were $0.3 million for the first quarter of 2024, compared with $0.6 million for 2023 due to the development of in-house pilot manufacturing capabilities for DNA plasmids and nanoparticle delivery systems.

General and administrative expenses were $1.7 million for the first quarter of 2024, compared with $3.1 million for the comparable prior-year period. This decrease was primarily attributable to lower non-cash stock compensation expense ($0.3 million), lower legal costs ($0.5 million), lower employee-related costs ($0.2 million), lower consulting fees ($0.2 million) and lower insurance costs ($0.1 million).

Other non-operating income was $81,921 for the first quarter of 2024, compared with $93,085 for the comparable prior-year period. Investment income decreased $0.2 million due to lower balances of short-term investments in the current quarter. Interest expense decreased $0.2 million due to the repayment of the Company's loan facility with Silicon Valley Bank in the second quarter of 2023.

Net cash used for operating activities was $5.9 million for the first quarter of 2024, compared with $4.0 million for the comparable prior-year period. This increase was primarily due to the final payment of CRO costs associated with the Phase III OPTIMA Study.

The Company ended the first quarter of 2024 with $9.8 million in cash, investments and accrued interest receivable. The Company believes it has sufficient capital resources to fund its operations to the end of 2024.

**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 first 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 First Quarter 2024 Earnings Call. A live webcast of the call will be available here.

The call will be archived for replay until May 27, 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 9343581. 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)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2024** | **2023** |
| **Licensing revenue** | **$ -** | **$ -** |
| **Operating expenses:** | | |
| Research and development | 3,294 | 2,620 |
| General and administrative | 1,717 | 3,064 |
| **Total operating expenses** | **5,011** | **5,684** |

| | | |
|---|---|---|
| **Loss from operations** | **(5,011)** | **(5,684)** |
| **Other income (expense):** | | |
| Interest expense on loan facility | - | (160) |
| Investment and other income | 82 | 253 |
| **Total other income (expense), net** | **82** | **93** |
| **Net loss** | **$ (4,929)** | **$ (5,591)** |
| **Net loss per common share** | | |
| **Basic and diluted** | **$ (0.52)** | **$ (0.68)** |
| **Weighted average shares outstanding** | | |
| **Basic and diluted** | **9,400** | **8,281** |

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

| | March 31, 2024 | December 31, 2023 |
|---|---|---|
| **ASSETS** | | |
| **Current assets** | | |
| Cash and cash equivalents | $ 2,347 | $ 5,839 |
| Investment securities and interest receivable on investment securities | 7,462 | 9,857 |
| Advances, deposits on clinical programs and other current assets | 2,285 | 2,545 |
| **Total current assets** | **12,094** | **18,241** |
| **Property and equipment** | **694** | **752** |
| **Other assets** | | |
| Deferred tax asset | - | 1,280 |
| Operating lease right-of-use assets, deposits, and other assets | 1,537 | 1,645 |
| **Total other assets** | **1,537** | **2,925** |
| **Total assets** | **$ 14,325** | **$ 21,918** |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **Current liabilities** | | |
| Accounts payable and accrued liabilities | $ 4,316 | $ 6,906 |
| Operating lease liability – current portion | 501 | 485 |
| **Total current liabilities** | **4,817** | **7,391** |
| Operating lease liability – noncurrent portion | 1,008 | 1,139 |
| **Total liabilities** | **5,825** | **8,530** |
| **Stockholders' equity** | | |
| Common stock | 94 | 94 |
| Additional paid-in capital | 401,470 | 401,501 |
| Accumulated other comprehensive gain (loss) | 133 | 61 |
| Accumulated deficit | (393,112) | (388,183) |
| | 8,585 | 13,473 |
| Less: Treasury stock | (85) | (85) |
| **Total stockholders' equity** | **8,500** | **13,388** |
| **Total liabilities and stockholders' equity** | **$ 14,325** | **$ 21,918** |

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Source: Imunon, Inc.