IMUNON Reports Second Quarter 2023 Financial Results and Provides Business Update

August 10, 2023

Advances 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., Aug. 10, 2023 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage drug-development company focused on developing non-viral DNA-mediated immuno-oncology therapies and next-generation vaccines, today announced financial results for the three and six months ended June 30, 2023. The Company also 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 on its PlaCCine modality, a proprietary mono- or multi-cistronic non-viral and synthetic DNA technology for the expression of pathogen antigens, being evaluated in preclinical studies for the development of next-generation vaccines.

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

- On track to submit an Investigational New Drug (IND) application in the first quarter of 2024 for a proposed Phase 1/2 program with a seasonal COVID-19 booster vaccine, following positive pre-IND feedback from the U.S. Food and Drug Administration (FDA)
- 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
- Unveiled new current Good Manufacturing Practices (cGMP) clinical materials production facility to support R&D efficiencies and lower costs for infectious disease and cancer vaccines, and non-viral DNA-based immune-oncology therapies
- Reported cash and cash equivalents of $24.1 million as of June 30, 2023, which along with planned sales of State of New Jersey net operating losses (NOLs) is expected to fund operations through 2024

“We have now successfully de-risked our PlaCCine modality preclinically across many pathogens of interest by demonstrating in animal models the immunogenicity and safety of our vaccines. We have generated compelling data in SARS-CoV-2 and with IMNN-101, a next-generation COVID-19 seasonal booster, and expect to be in the clinic in first quarter of 2024. In addition, we have generated excellent immunological responses for vaccines against other pathogens of concern including monkeypox, flu and arenaviruses. Our DNA vaccines are well positioned to become the next generation of vaccines and I am excited about their potential with the demonstration preclinically of durability of IgG antibody response, without a booster dose, and higher T-cell activation than mRNA vaccines. Another significant advantage over commercial mRNA vaccines is the demonstration of more than 12 months stability at standard refrigerated temperature of 4°C,” said Dr. Corinne Le Goff, IMUNON’s President and Chief Executive Officer.

“Based on positive FDA feedback in July from a pre-IND meeting for our seasonal COVID-19 booster vaccine, we are on track to submit an IND application in the first quarter of 2024. The FDA confirmed in a written response that our plug-and-play strategy for our platform approach was acceptable. This confirms the flexibility and versatility of our platform, which allows for the rapid production and development of any vaccine simply by changing the antigen coding cassette. In addition, we expect to announce our next pathogen target for our PlaCCine modality in the coming weeks.”

Dr. Le Goff continued, “In June we unveiled our new pilot manufacturing capability for DNA plasmids and nanoparticle delivery systems. Our scientists are now able to 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 process. The objective of our vaccine program is to establish the platform’s safety and efficacy in various Phase 1 studies, and then seek to license this powerful technology and/or establish non-dilutive partnerships to develop vaccines for pathogens of interest,” she added.

“We expect to reach several value-creating milestones over the next six to 18 months. Among them is 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 target. We intend to discuss all of this and more during a virtual R&D Day event we are planning for this fall,” Dr. Le Goff concluded.

RECENT DEVELOPMENTS

PlaCCine: Developing the Prophylactic Vaccines of the Future

Publication of Preclinical Data with PlaCCine DNA-based Vaccines Modality Available Online on bioRxiv. In August 2023 the Company announced that a manuscript titled “Strong immunogenicity & protection in mice with PlaCCine: A COVID-19 DNA vaccine formulated with a functional polymer” is available on the preprint server bioRxiv [here]. The study used IMUNON’s proprietary formulation against the spike proteins from two SARS-CoV-2 variants, both alone and in combination. These results add to the growing body of preclinical data confirming the efficacy and superior desirable features of IMUNON’s PlaCCine vaccine modality. Data from the study show:

- IMUNON’s proprietary formulation of functionalized polymer protected DNA from degradation, while the combination with an adjuvant led to an increase in protein expression

- DNA formulated with PlaCCine resulted in a DNA vaccine product that was stable for up to one year at 4°C
- DNA formulated in 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

Presentation at the 2023 Viruses and Cells – Gordon Research Conference Describes Compelling Preclinical Data Showing Continued Durability of Response Over 14 Months with Humoral Immune Response Increasing Over Time. In May 2023 Khursheed Anwer, Ph.D., IMUNON's Executive Vice President and Chief Science Officer, presented new PlaCCine preclinical data at the 2023 Viruses and Cells – Gordon Research Conference in Barcelona. Dr. Khursheed's presentation, titled "A Novel DNA Vaccine Approach to Prophylactic and Therapeutic Vaccines," described IMUNON'S PlaCCine technology platform for the development of next-generation vaccines, and is available **here**.

Results from preclinical studies in a PlaCCine COVID-19 vaccine demonstrated characteristics that address the limitations of current commercial vaccines by offering enhanced breadth of protection to emerging variants, persistence and robust cellular immunity, as well as stability at workable temperatures. Importantly, humoral immune responses specific to the SARS-CoV-2 spike antigen were persistent over a 14-month post-vaccination period in mice, while the T-cell responses from PlaCCine COVID-19 vaccines after 14 months were higher than a commercial mRNA vaccine. In another mouse study, the humoral response to a single dose of a commercial mRNA vaccine plateaued within 14 days after vaccination while the response continued to increase over time with a PlaCCine vaccine, demonstrating improved durability. In addition, PlaCCine was stable for at least nine months at refrigerated temperatures and for at least one month at room temperature.

Presentation at the Vaccine Technology Summit 2023 Describes Compelling Preclinical Data Supporting Continued Development of PlaCCine as a Differentiated, Next-Generation Vaccine. In March 2023 Dr. Anwer presented data on the Company's PlaCCine platform at the Vaccine Technology Summit 2023 in Boston. Dr. Anwer's presentation is titled "A Novel DNA Vaccine Platform with Potential to Create Next Generation Vaccines" and is available 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 that 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 advantages for a commercial vaccine, including a shelf-life at 4ºC for greater than nine months, and the ability for simple, rapid and scalable manufacturing.

IMNN-001 Immunotherapy

Presentation at the American Association for Cancer Research (AACR) Describes Findings from Mouse Model of Peritoneally Disseminated Ovarian Cancer that 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 the AACR in Orlando, which is available 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 over the once every 3-week regimen, particularly with respect to mortality and tumor burden. These findings suggest exploring once every 2-week dosing of IMNN-001 in human studies, which is already incorporated into the protocol of a new study evaluating IMNN-001 in combination with bevacizumab in the treatment of advanced ovarian cancer. This study is sponsored by the Break *Through* Cancer Foundation.

Corporate Developments

IMUNON Unveils New Manufacturing Facility at Huntsville's HudsonAlpha Biotech Campus . In June 2023, the Company unveiled its new cGMP clinical materials production facility on the Huntsville, Alabama campus of the HudsonAlpha Institute for Biotechnology. The facility is intended to support R&D efficiencies and lower development costs for infectious disease and cancer vaccines, and non-viral DNA-based immune-oncology therapies. This new capability complements the Company's existing cGMP quality control facility for testing clinical products at the Huntsville site.

IMUNON has designed and built its own manufacturing capabilities to produce GMP-grade plasmid DNA (pDNA) and DNA-facilitating agents to support Phase 1 clinical studies with its PlaCCine infectious disease modality and its IndiPlas and FixPlas cancer vaccine modalities. The new facility's specifications follow the 2008 FDA guidance cGMP for Phase 1 investigational drugs. The pDNA and DNA facilitating agents are key components of the final vaccine formulation, with GMP fill and finish carried out at a CDMO partner site.

IMUNON's CEO Presents Business Overview at BIO 2023 International Convention and Mass General Brigham World Medical Innovation Forum 2023. Dr. Le Goff provided an overview of IMUNON's business progress to an audience of investors and biopharmaceutical professionals at the BIO 2023 International Convention and at the Mass General Brigham World Medical Innovation Forum 2023, both in Boston. She highlighted the strength of IMUNON's leadership team, and the status of the Company's TheraPlas nucleic acid therapeutics platform and its PlaCCine nucleic acid vaccine platform while providing context on the promise of DNA as a therapeutic and a vaccine. For the PlaCCine and TheraPlas technologies, Dr. Le Goff described mechanisms of action and provided a closer look at the promising clinical results generated to-date. She provided background on the use of DNA in these medicines, characterizing its performance in terms of durability, development speed and ease of manufacturing, shipping and storage. Dr. Le Goff also highlighted the potential of IMNN-001 for the treatment of ovarian cancer during a panel discussion. Dr. Le Goff's presentation is available here.

SECOND QUARTER FINANCIAL RESULTS

IMUNON reported a net loss for the second quarter of 2023 of $5.6 million, or $0.61 per share, compared with a net loss of $6.0 million, or $0.87 per share, for the second quarter of 2022. Operating expenses were $5.5 million for the second quarter of 2023, a decrease of $0.6 million, or 10%, from $6.1 million for the second quarter of 2022.

Net cash used for operating activities was $6.8 million for the second quarter of 2023 compared with $5.4 million for the comparable prior-year period. The increase was primarily due to the cash settlement in April 2023 along with related legal fees for arbitration with a former contract manufacturer for ThermoDox. Cash used by financing activities of $6.2 million during the second quarter of 2023 resulted from the early repayment of the Company's loan facility with Silicon Valley Bank, offset by equity sales under the Company's At-the-Market Equity Facility. The Company had $24.1 million in cash, investments and accrued interest receivable as of June 30, 2023. Combined with $1.8 million in planned future sales of IMUNON's State of New Jersey NOLs, the Company believes it has sufficient capital resources to fund its operations through 2024.

Research and development (R&D) expenses were $3.1 million for the second quarter of 2023 compared with $3.2 million for the comparable period in 2022. R&D costs to support the OVATION 2 Study as well as the Phase 3 OPTIMA Study decreased to $0.3 million for the second quarter of 2023 compared with $0.8 million for the same period of 2022. Other clinical and regulatory costs were $0.4 million for the second quarter of 2023 compared with $0.7 million for the second quarter of 2022. R&D costs associated with the preclinical development of the PlaCCine DNA vaccine modality increased to $1.3 million for the second quarter of 2023 compared with $0.6 million for the same period of 2022. R&D costs associated with the preclinical development of IMNN-001 decreased to $0.4 million for the second quarter of 2023 compared with $0.8 million for the same period of 2022. Chemistry, manufacturing and controls (CMC) costs increased to $0.7 million for the second quarter of 2023 compared with $0.3 million for the second 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 $2.3 million for the second quarter of 2023 compared with $2.9 million for the comparable prior-year period. The decrease was primarily due to lower non-cash stock-compensation expense and lower professional fees, including legal fees to defend various lawsuits filed after the announcement in July 2020 of the Phase 3 OPTIMA Study results, offset by higher compensation expenses related to the CEO succession plan announced in July 2022 and higher staffing costs.

Other non-operating expenses were $85 thousand for the second quarter of 2023 compared with $65 thousand for the prior-year period. The Company incurred early debt extinguishment expense on its loan facility with Silicon Valley Bank totalling $0.3 million, offset by higher investment income from the Company's short-term investments due to higher returns on these investments.

FIRST HALF FINANCIAL RESULTS

For the six months ended June 30, 2023, the Company reported a net loss of $11.2 million, or $1.28 per share, compared with a net loss of $16.5 million, or $2.59 per share, for the same period of 2022. Operating expenses were $11.2 million for the first six months of 2023, a decrease of $0.9 million, or 8%, from $12.1 million for the same period of 2022.

Net cash used for operating activities was $10.8 million for the first six months of 2023 compared with $13.4 million for the same period in 2022. The 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 million of Series A & B convertible redeemable preferred stock in the first quarter of 2022. The Company's projected cash utilization for the balance of 2023 is approximately $4.5 million per quarter. Cash used by financing activities of $3.7 million during the first six months of 2023 resulted from the early repayment of the Company's loan facility with Silicon Valley Bank ($6.4 million), offset by sales of equity under the Company's At-the-Market Equity Facility ($2.7 million). The Company also received net proceeds of $1.6 million from the sale of its unused New Jersey NOLs in the first quarter of 2023.

R&D expenses were $5.8 million for the first six months of 2023 compared with $6.3 million for the comparable period in 2022. R&D costs to support the OVATION 2 Study as well as the Phase 3 OPTIMA Study decreased to $0.6 million for the first six months of 2023 compared with $1.3 million for the comparable 2022 period. Other clinical and regulatory costs were $0.7 million for the first six months of 2023 compared with $1.5 million for the same period of 2022. R&D costs associated with the preclinical development of the PlaCCine DNA vaccine modality increased to $2.3 million for the first six months of 2023 compared with $1.2 million for the same period of 2022. R&D costs associated with the preclinical development of IMNN-001 decreased to $0.8 million for the first half of 2023 compared with $1.7 million for the same period of 2022. CMC costs increased to $1.4 million for the first six months of 2023 compared with $0.6 million for the comparable 2022 period 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 $5.4 million for the first six months of 2023 compared with $5.7 million for the same period of 2022. The $0.3 million decrease was primarily attributable to lower non-cash stock-compensation expense, offset by higher compensation expenses related to the CEO succession plan announced in July 2022 and higher staffing costs.

Other non-operating income was $9 thousand for the first six months of 2023 compared with $4.7 million for the comparable prior-year period. The decrease was primarily attributable to the one-time payment of $4.5 million in interest expense resulting from the sale and subsequent redemption of $30 million of Series A & B convertible redeemable preferred stock in the first quarter of 2022.

VIRTUAL R&D DAY EVENT

IMUNON management along with several guest key opinion leaders plan to host a virtual R&D Day event this fall to discuss the Company's progress in developing its PlaCCine platform, IMNN-001, and other achievements. Presenters will also review strategic plans and opportunities for IMUNON. Additional information including date, time of day and instructions to participate will be announced in a separate news release.

CONFERENCE CALL AND WEBCAST

The Company is hosting a conference call to provide a business update, discuss second 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 Second Quarter 2023 Earnings Call. A live webcast of the call will be available here.

The call will be archived for replay until August 24, 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 1202020. 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 is developing its non-viral DNA technology across 4 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 third modality, Fixplas®, concerns the application of our DNA technology to produce universal cancer vaccines also called tumor associated antigen cancer vaccines. Finally, the fourth modality, which is still in the discovery phase, Indiplas®, will focus on the development of personalized cancer vaccines, or neoepitope cancer vaccines.

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 IND enabling preclinical studies for the development of a COVID-19 booster vaccine: IMNN-101. The Company has also initiated preclinical studies to develop a Trp2 tumor associated antigen cancer vaccine in melanoma: IMNN-201. 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 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.

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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,	
	2023	**2022**	**2023**	**2022**
Licensing revenue	$ -	$ 125	$ -	$ 250
Operating expenses:				
Research and development	3,134	3,226	5,754	6,322
General and administrative	2,340	2,877	5,405	5,748
Total operating expenses	5,474	6,103	11,159	12,070
Loss from operations	(5,474)	(5,978)	($ 11,159)	(11,820)
Other income (expense):				
Investment income	281	40	535	52
Interest expense	(37)	(105)	(197)	(4,751)
Loss on debt extinguishment	(329)	-	(329)	-
Other income	-	-	-	2
Total other (expense) income, net	(85)	(65)	9	(4,697)
Net loss	$ (5,559)	$ (6,043)	$ (11,150)	$ (16,517)
Net loss per common share				
Basic and diluted	$ (0.61)	$ (0.87)	$ (1.28)	$ (2.59)

Weighted average shares outstanding				
Basic and diluted	9,137	6,982	8,711	6,373

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

	June 30, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 6,611	$ 11,493
Investment securities and interest receivable	17,480	21,384
Money market investments, restricted cash	-	1,500
Advances, deposits and other current assets	2,640	2,778
Total current assets	**26,731**	**37,155**
Property and equipment	**651**	**548**
Other assets		
Restricted cash invested in money market account	-	4,500
Deferred tax asset	-	1,567
Operating lease right-of-use assets, deposits, and other assets	1,339	206
Total other assets	**1,339**	**6,273**
Total assets	**$ 28,721**	**$ 43,976**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 5,846	$ 8,381
Note payable – current portion	-	1,425
Operating lease liabilities – current portion	278	231
Total current liabilities	**6,124**	**10,037**
Notes payable – noncurrent portion	-	4,611
Operating lease liabilities – noncurrent portion	1,082	-
Total liabilities	**7,206**	**14,648**
Stockholders' equity		
Common stock	92	74
Additional paid-in capital	401,164	397,980
Accumulated other comprehensive gain (loss)	162	27
Accumulated deficit	(379,818)	(368,668)
	21,600	29,413
Less: Treasury stock	(85)	(85)
Total stockholders' equity	**21,515**	**29,328**
Total liabilities and stockholders' equity	**$ 28,721**	**$ 43,976**

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Source: Imunon, Inc.