IMUNON Reports Third Quarter 2023 Financial Results and Provides a Business Update

November 14, 2023

Advances Non-Viral DNA-Mediated Cancer Immunotherapy and Next-Generation Vaccine Programs, with More Potent and Durable Immunity, with Multiple Near-Term Milestones

Conference Call Begins Today at 10:00 a.m. ET

LAWRENCEVILLE, N.J., Nov. 14, 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 nine months ended September 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 first-line locally advanced ovarian cancer; on its PlaCCine modality, a proprietary mono- or multi-cistronic non-viral and synthetic DNA technology for the expression of pathogen antigens in preclinical studies for the development of next-generation vaccines; and on the early developments with its new FixPlas modality for cancer vaccines.

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

- Reported promising interim progression-free survival (PFS) and overall survival (OS) data with IMNN-001 in the Phase 1/2 OVATION 2 Study in advanced ovarian cancer. Interim data from the intent-to-treat (ITT) population showed efficacy trends in PFS, demonstrating a delay in disease progression in the treatment arm of approximately 33% compared with the control arm and preliminary OS data following a similar trend, showing an approximate nine-month improvement in the treatment arm over the control arm
- Enrolled the first patient in a Phase 1/2 clinical trial evaluating IMNN-001 in combination with bevacizumab in advanced ovarian cancer at the University of Texas MD Anderson Cancer Center
- Continued on track to submit an Investigational New Drug (IND) application in the first quarter of 2024 for a Phase 1/2 trial with IMNN-101, a seasonal COVID-19 booster vaccine, following positive pre-IND feedback from the U.S. Food and Drug Administration (FDA)
- Presented updated promising data on IMNN-101 at the 3rd Annual World Vaccines Congress
- Entered into a Cooperative Research and Development Agreement (CRADA) with the National Institute of Allergy and Infectious Diseases (NIAID) to evaluate the immunogenicity and efficacy of PlaCCine DNA vaccine constructs against Lassa virus in guinea pig and non-human primate disease models
- Held a virtual R&D Day with presentations by management and key opinion leaders (KOLs) on cancer and infectious disease vaccines
- Reported cash and cash equivalents of $19.5 million as of September 30, 2023

“The third quarter and recent weeks have been marked by excellent progress across all our platform modalities,” said Dr. Corinne Le Goff, IMUNON’s president and chief executive officer. “We reported interim data from our Phase 1/2 OVATION 2 Study that showed 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. This is not a pre-specified subgroup as PARP inhibitors were approved after this study was initiated. Although a small subgroup, the data support continued development and suggest that IMNN-001 may have a place in new treatment regimens and important commercial value. We expect to report final topline results in mid-2024.”

“Interest in IMNN-001 continues to be strong,” Dr. Le Goff continued, “as evidenced by the initiation of a Phase 1/2 clinical trial in advanced ovarian cancer in combination with bevacizumab, or Avastin, at the University of Texas MD Anderson Cancer Center. We are looking forward to adding prestigious cancer sites to this study, along with driving enrollment in this research with mainly third-party funding.”

“Development of our PlaCCine modality reached important milestones with confirmation of PlaCCine versatility as a plug-and-play modality by demonstrating preclinically the immunogenicity and safety of our vaccines against many pathogens of concern including COVID-19, Marburg, Lassa, monkeypox and influenza viruses. We expect to file our IND application and begin patient enrollment in a Phase 1/2 trial in the first half of 2024 for IMNN-101, a next-generation COVID-19 seasonal booster.”

“Our DNA infectious disease vaccines are well positioned to become the next generation of vaccines. I am excited about their potential with the preclinical demonstration of more durable antigen expression and T-cell responses versus protein and mRNA vaccines, and better antibody response kinetics following a single dose. In addition, our vaccines offer superior commercial handling and distribution properties versus mRNA vaccines, as well as greater manufacturing flexibility with better shelf-life of at least 12 months at 4°C, one month at room temperature and at least two weeks at 37°C. Our DNA cancer vaccines modality, FixPlas, is equally well positioned to play an important role in a new era of immunotherapy, with promising results in a mouse melanoma model.”

Dr. Le Goff concluded, “With exciting and deep technology directed toward important medical problems, IMUNON has a promising future. The collaborations we formed this year are a blueprint for future partnerships, particularly those with shared development expenses.”

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 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 (ORR), 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 33% compared with the control arm, with the hazard ratio nearing the per protocol value. Preliminary OS data follows a similar trend, showing an approximate nine-month improvement in the treatment arm over the control arm.
- Subgroup analyses show 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 20% 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 in Advanced Ovarian Cancer. In October 2023, the first patient was enrolled in this trial at the University of Texas MD Anderson Cancer Center, which 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 (SLL), and the secondary endpoint is PFS. Initial SLL data are expected within one year following the completion of enrollment and final PFS data are expected approximately three years following the completion of enrollment. 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.

PlaCCine: Developing the Prophylactic Vaccines of the Future

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," which described the multiple advantages of the PlaCCine modality over current commercial vaccine platforms. The presentation also described the versatility of the PlaCCine modality, demonstrating the activity against Marburg and influenza viruses in collaboration with the Wistar Institute, and activity against Lassa virus being evaluated at the NIH/NIAID.

Entered into a CRADA for Preclinical Studies of the PlaCCine Modality in Preventive Vaccines Against Lassa Virus. In August 2023, the Company announced it entered into a CRADA with the NIAID to evaluate the immunogenicity and efficacy of two IMUNON DNA-based Lassa virus vaccine candidates in animal models. Under the three-year agreement, the NIAID will assess the efficacy of PlaCCine DNA constructs against Lassa virus in guinea pig and non-human primate disease models, including both prime and prime-boost vaccine strategies. The Laboratory of Virology at the NIAID is researching a potential solution for combatting this life-threatening pathogen by evaluating a DNA-based vaccine approach for the treatment of the Lassa virus due to its durable antigen expression, longer shelf-life at workable, standard refrigerated temperatures and flexible manufacturing to potentially address the limitations of current commercial products, particularly in developing countries.

Preclinical Data with PlaCCine DNA-based Vaccines Modality Published Online on bioRxiv. In August 2023, a manuscript titled "Strong immunogenicity & protection in mice with PlaCCine: A COVID-19 DNA vaccine formulated with a functional polymer" was published 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 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, one month at room temperature and over two weeks at 38°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

Corporate Developments

Hosted a Virtual R&D Day. In September 2023, IMUNON management along with guest KOLs in immuno-oncology and vaccine development held a virtual R&D Day to discuss the Company's progress in developing its PlaCCine platform, IMNN-001 and other achievements. IMUNON's speakers included Dr. Le Goff and Dr. Anwer. Guest KOL presenters included:

- Sallie Permar, M.D., Ph.D., Chair of the Department of Pediatrics at Weill Cornell Medicine and Pediatrician-in-Chief at New York-Presbyterian/Weill Cornell Medical Center and New York-Presbyterian Komansky Children's Hospital.
- Patrick Ott, M.D., Ph.D., Clinical Director of the Melanoma Disease Center and the Director, Clinical Sciences, of the Center for Immuno-Oncology at the Dana-Farber Cancer Institute.

Dr. Permar's presentation focused on the "Vaccines of the Future" while Dr. Ott discussed "Immuno-Oncology: The remaining unmet need." A webcast of the event is available in the Scientific Presentations section of IMUNON's website or here.

Expanded Scientific Advisory Board with the Addition of Dr. Patrick Ott and Dr. Sachet Shukla. They join current scientific advisory board members Dan H. Barouch, M.D., Ph.D., Luke D. Handke, Ph.D. and John W. Shiver, Ph.D. As the Company advances FixPlas and IndiPlas into universal and personalized cancer vaccines, Drs. Ott and Shukla will provide invaluable assistance.

THIRD QUARTER FINANCIAL RESULTS

IMUNON reported a net loss for the third quarter of 2023 of $3.5 million, or $0.37 per share, compared with a net loss of $6.1 million, or $0.87 per share, for the third quarter of 2022. Operating expenses were $3.9 million for the third quarter of 2023, a decrease of $2.4 million, or 38%, from $6.3 million for the third quarter of 2022.

Net cash used for operating activities was $4.5 million for the third quarter of 2023 compared with $4.6 million for the comparable prior-year period. The decrease was primarily due to the decrease in net loss and change in accounts payable. Cash provided by financing activities of $0.1 million during the third quarter of 2023 resulted from equity sales under the Company's At-the-Market Equity Facility. The Company had $19.5 million in cash, investments and accrued interest receivable as of September 30, 2023. The Company also has approximately $1.8 million of future planned sales of its State of New Jersey net operating losses ($1.5 million in 2023 and $300,000 in 2024).

Research and development (R&D) expenses were $2.0 million for the third quarter of 2023 compared with $2.4 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 $0.1 million for the third quarter of 2023 compared with $0.6 million for the same period of 2022. Other clinical and regulatory costs were $0.3 million for the third quarter of 2023 compared with $0.4 million for the third quarter of 2022. R&D costs associated with the preclinical development of the PlaCCine DNA vaccine modality increased to $0.8 million for the third quarter of 2023 compared with $0.5 million for the same period of 2022. R&D costs associated with the preclinical development of IMNN-001 decreased to $0.3 million for the third quarter of 2023 compared with $0.6 million for the same period of 2022. Chemistry, manufacturing and controls (CMC) costs increased to $0.5 million for the third quarter of 2023 compared with $0.3 million for the third 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 $1.9 million for the third quarter of 2023 compared with $3.9 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 income was $0.4 million for the third quarter of 2023 compared with $26 thousand for the prior-year period. This increase was due to higher investment income from the Company's short-term investments.

NINE MONTH FINANCIAL RESULTS

For the nine months ended September 30, 2023, the Company reported a net loss of $14.6 million, or $1.64 per share, compared with a net loss of $22.7 million, or $3.42 per share, for the same period of 2022. Operating expenses were $15.1 million for the first nine months of 2023, a decrease of $3.3 million, or 18%, from $18.4 million for the same period of 2022.

Net cash used for operating activities was $15.3 million for the first nine months of 2023 compared with $18.1 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. Cash used by financing activities of $3.7 million during the first nine 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 ($2.8 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 $7.7 million for the first nine months of 2023 compared with $8.7 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 $0.7 million for the first nine months of 2023 compared with $2.2 million for the comparable 2022 period. Other clinical and regulatory costs were $1.1 million for the first nine months of 2023 compared with $1.7 million for the same period of 2022. R&D costs associated with the preclinical development of the PlaCCine DNA vaccine modality increased to $3.1 million for the first nine months of 2023 compared with $1.6 million for the same period of 2022. R&D costs associated with the preclinical development of IMNN-001 decreased to $1.0 million for the first nine months of 2023 compared with $2.4 million for the same period of 2022. CMC costs increased to $1.8 million for the first nine months of 2023 compared with $0.9 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 $7.3 million for the first nine months of 2023 compared with $9.6 million for the same period of 2022. The $2.3 million 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 and higher staffing costs.

Other non-operating income was $0.4 million for the first nine 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.

CONFERENCE CALL AND WEBCAST

The Company is hosting a conference call to provide a business update, discuss third quarter 2023 financial results and answer questions at 10:00 a.m. ET 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 Third Quarter 2023 Earnings Call. A live webcast of the call will be available here.

The call will be archived for replay until November 28, 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 7035449. 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 four 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. The fourth modality, IndiPlas®, is in the discovery phase and 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) and a treatment for the LASSA virus (IMNN-102). The Company has also initiated preclinical work 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 September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Licensing revenue	$ -	$ 125	$ -	$ 375
Operating expenses:				
Research and development	1,981	2,408	7,735	8,730
General and administrative	1,923	3,891	7,328	9,640
Total operating expenses	3,904	6,299	15,063	18,370
Loss from operations	(3,904)	(6,174)	(15,063)	(17,995)
Other income (expense):				

Investment and other income	427	153	962	207
Interest expense	-	(127)	(197)	(4,878)
Loss on debt extinguishment	-	-	(329)	-
Total other (expense) income, net	427	26	436	(4,671)
Net loss	$ (3,477)	$ (6,148)	$ (14,627)	$ (22,666)
Net loss per common share				
Basic and diluted	$ (0.37)	$ (0.87)	$ (1.64)	$ (3.42)
Weighted average shares outstanding				
Basic and diluted	9,377	7,099	8,926	6,622

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

ASSETS	**September 30, 2023**	**December 31, 2022**
Current assets		
Cash and cash equivalents	$ 12,884	$ 11,493
Investment securities and interest receivable	6,590	21,384
Money market investments, restricted cash	-	1,500
Advances, deposits and other current assets	2,251	2,403
Total current assets	**21,725**	**36,780**
Property and equipment	**824**	**548**
Other assets		
Restricted cash invested in money market account	-	4,500
Deferred tax asset	-	1,567
Operating lease right-of-use assets	1,664	156
Deposits and other assets	441	425
Total other assets	**2,105**	**6,648**
Total assets	**$ 24,654**	**$ 43,976**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 4,846	$ 8,381
Note payable – current portion	-	1,425
Operating lease liabilities – current portion	470	231
Total current liabilities	**5,316**	**10,037**
Notes payable – noncurrent portion	-	4,611
Operating lease liabilities – noncurrent portion	1,266	-
Total liabilities	**6,582**	**14,648**
Stockholders' equity		
Common stock	94	74
Additional paid-in capital	401,337	397,980
Accumulated other comprehensive gain (loss)	20	27
Accumulated deficit	(383,294)	(368,668)
	18,157	29,413
Less: Treasury stock	(85)	(85)
Total stockholders' equity	**18,072**	**29,328**
Total liabilities and stockholders' equity	**$ 24,654**	**$ 43,976**

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Source: Imunon, Inc.