IMUNON Reports 2022 Financial Results and Provides Business Update

March 30, 2023

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

LAWRENCEVILLE, N.J., March 30, 2023 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage drug-development company focused on developing DNA-mediated immunotherapy and next-generation vaccines, today announced financial results for the year ended December 31, 2022, 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 with PLACCINE, a proprietary, multivalent DNA plasmid technology utilizing synthetic, non-viral vaccine delivery vectors being evaluated in preclinical studies for superiority over current generation of nucleic acid vaccines.

Highlights of 2022 and recent weeks include:

- Completed enrollment in the Phase 1/2 OVATION 2 Study with IMNN-001 in advanced ovarian cancer.
- Phase 1/2 Clinical Study of IMNN-001 in combination with Avastin in advanced ovarian cancer was opened to enrollment in the first quarter of 2023.
- Reported compelling results from a non-human primate (NHP) study confirming PLACCINE as a viable modality for the development of the next generation of prophylactic vaccines. PLACCINE is IMUNON's non-viral, non-device plasmid DNA-based vaccine modality targeting multiple antigens from a single vector.
- Signed new research collaborations with The Wistar Institute to develop new vaccine formulations utilizing the Company's PLACCINE modality for the development of vaccines for infectious diseases, and with Acuitas Therapeutics to evaluate IMUNON's plasmid DNA with Acuitas' lipid nanoparticle delivery system.
- Made strategic investment in Transomic Technologies to strengthen IMUNON's development capabilities of the PLACCINE DNA vaccine modality.
- Reported cash and cash equivalents of $38.9 million as of December 31, 2022, which is expected to fund operations into 2025.

"I am pleased to report that IMUNON made significant progress during 2022 in advancing our clinical programs in immuno-oncology with IMNN-001, our IL-12 gene-mediated immunotherapy. Earlier in the year we reported data from 46 patients in the experimental arm of our OVATION 2 Phase 1/2 study who had undergone interval debulking surgery, showing an improvement in R0 surgical resection rates and CRS 3 chemotherapy response scores over the 41 patients in the control arm. In September we reached full enrollment of 110 patients in this study and expect to report an additional set of interim, more mature data in the second half of 2023 and topline results by mid-2024," said Dr. Corinne Le Goff, IMUNON's President and Chief Executive Officer.

"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. We also completed the evaluation of our vaccines in non-human primates. I am pleased to report that the final data are consistent with the earlier data and show excellent immunological response and viral clearance. We 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 nine months into a 12-month PLACCINE stability study and have demonstrated continued drug stability at the standard refrigerated temperature of 4ºC, representing a significant commercial advantage over mRNA-based vaccines," she added. "With the continuing volatility of the public markets, our decision to raise capital earlier this year to strengthen our balance sheet and extend our operating runway into 2025 was well timed. We expect to report several value-creating developments during this period."

Dr. Le Goff continued, "This year we anticipate filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for our seasonal COVID-19 booster vaccine. Our objective is to confirm in a Phase 1 clinical study the safety of our PLACCINE modality. In the first half of 2023, we intend to apply for a pre-IND consultation with the FDA to receive guidance on our proposed program prior to submitting the IND.

"We also will select our next pathogen target for our PLACCINE modality. It is likely that we will choose a pathogen among 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 out-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."

"We have developed in-house pilot manufacturing capabilities for DNA plasmids and nanoparticle delivery systems. Our scientists can select any protein from the human or pathogen proteomes to be engineered. In combination, during recent months we made an investment in Transomic Technologies, which offers a comprehensive array of CRISPR, RNAi and gene expression tools and services. Our existing labs also have the ability to conduct testing and to run experiments in a variety of animal disease models. These capabilities are expected to allow us to realize our goal of attracting corporate partners while minimizing dependence on vendors so that we control both the costs and the development timelines. Our progress to date is evidence that IMUNON is a fully integrated clinical development company with expertise in running global mid-stage clinical programs," 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., the Company's Executive Vice President and Chief Science Officer, 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 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 4ºC for greater than nine months, and the ability for simple, rapid and scalable manufacturing.

Presentation at World Vaccine & Immunotherapy Congress Highlights PLACCINE Preclinical Proof of Concept and Key Competitive Advantages. In December 2022, Khursheed Anwer, Ph.D., the Company's Chief Science Officer, presented at the World Vaccine & Immunotherapy Congress. Dr. Anwer highlighted the PLACCINE modality and proof-of-concept rodent and non-human primate data in SARS-CoV-2. Slides from Dr. Anwer's presentation are available here.

Final Results from NHP Study and Additional Preclinical Studies Support PLACCINE as a Viable Prophylactic Vaccine Development Modality. In October 2022 the Company reported partial results from an ongoing NHP study designed to examine the immunogenicity of its proprietary DNA-based vaccine in support of PLACCINE as a viable alternative to commercial mRNA vaccines. The study examined a single plasmid DNA vector containing the SARS-CoV-2 Alpha variant spike antigen formulated with a synthetic DNA delivery system and administered by intramuscular injection.

In the study, cynomolgus monkeys were vaccinated with the PLACCINE vaccine or a commercial mRNA vaccine on Day 1, 28 and 84. Analysis of blood samples for IgG and neutralizing antibodies showed evidence of immunogenicity both in PLACCINE and mRNA vaccinated subjects. Analysis of bronchoalveolar lavage for viral load by quantitative PCR showed viral clearance by more than 90% of the non-vaccinated controls. Viral clearance from nasal swab followed a similar pattern in a majority of vaccinated animals and a similar clearance profile was observed when viral load was analyzed by the tissue culture infectious dose method. In a head-to-head comparison, the protection efficiency as measured by viral clearance following challenge with the SARS-CoV-2 virus was similar between PLACCINE and a commercial mRNA vaccine.

On March 1, 2023, IMUNON's CEO issued a Letter to Shareholders announcing the final results from the Company's evaluation of its vaccines in NHP. Dr. Le Goff reported that the final data are consistent with the earlier data and show excellent immunological response and viral clearance. The Company reported results from a recent mouse study that demonstrated a single dose of PLACCINE vaccine without a booster dose produced longer duration of IgG responses and higher T-cell activation than an mRNA vaccine as well as nine-month data from a 12-month PLACCINE stability study that demonstrates continued drug stability at 4ºC (standard refrigerated temperature), representing a significant commercial advantage over mRNA-based vaccines.

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.

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.

This new Phase 1/2 study, titled "A Phase I/II Study Evaluating the Effect of IMNN-001 (IL-12 Plasmid Formulated with PEG-PEI-Cholesterol Lipopolymer) on Minimal Residual Disease (MRD) as determined by Second Look Laparoscopy when Administered in Combination with Bevacizumab and Neoadjuvant Chemotherapy in Subjects Newly Diagnosed with Advanced Ovarian, Fallopian Tube or Primary Peritoneal Cancer," 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. The study will be partially funded by a third party.

Partnerships and Collaborations

Collaborative Research Agreement with The Wistar Institute's Vaccine & Immunotherapy Center , Acuitas Therapeutics and Transomic Technology. 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.

During the fourth quarter of 2022 the Company entered into an agreement with Acuitas Therapeutics to evaluate PLACCINE Plasmid DNA with Acuitas' lipid nanoparticle delivery system. Under this agreement, Acuitas will evaluate the administration of IMUNON's vector constructs formulated in various LNP formulations for gene expression and immunogenicity in murine models. The Company also announced a strategic investment in

Transomic Technology to utilize its custom vector construction services to continue to generate plasmids that are being developed and evaluated by IMUNON as part of the Company's DNA vaccine program. As a condition of the investment, Michael H. Tardugno, IMUNON's executive chairman, has joined the Transomic board of directors.

Corporate Developments

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.

Financial Results for the Year Ended December 31, 2022

IMUNON reported a net loss for 2022 of $35.9 million, or $5.03 per share, compared with a net loss for 2021 of $20.8 million, or $3.83 per share. Operating expenses were $25.4 million for 2022, an increase of $3.9 million or 18% from $21.5 million for 2021. The Company recognized tax benefits from the sale of its New Jersey NOLs of $1.6 million and $1.4 million in tax in 2022 and 2021, respectively.

Research and development (R&D) expenses were $11.7 million for 2022, an increase of $1.1 million from $10.6 million for 2021. Costs associated with the OVATION 2 Study were $1.5 and $1.3 million for 2022 and 2021, respectively. Costs associated with the Phase 3 OPTIMA Study decreased to $0.5 million for 2022, compared with $1.0 million for 2021. Other clinical and regulatory costs were $2.3 million for 2022, compared with $2.6 million for 2021. 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 $6.1 million for 2022, compared with $4.3 million for 2021. CMC costs decreased to $1.2 million for 2022, compared with $1.5 million for 2021 due to the discontinuation of the ThermoDox® clinical development program in primary liver cancer.

General and administrative expenses were $13.7 million for 2022, compared with $10.9 million for 2021. This $2.8 million increase was primarily attributable to 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 and higher staffing costs, which were partially offset by lower non-cash stock compensation expense.

Other non-operating expenses were $12.5 million for 2022, compared with $1.1 million for 2021. This increase was attributable to the following:

- Due to the continuing deterioration of the public capital markets in the biotech industry in 2021 and 2022 and its impact on the market capitalization of companies in this sector, the Company reviewed its In-Process Research & Development (IPR&D) asset for impairment. After conducting a detailed analysis, the Company determined that the IPR&D asset was impaired. As of December 31, 2022, the Company wrote off the $13.4 million carrying value of this asset, thereby recognizing a non-cash charge of $13.4 million.
- The Company wrote off the earn-out milestone liability because of the requirements not being achieved and recognized a non-cash gain of $5.4 million during 2022 as a result of the change in the fair value of the earn-out milestone liability.
- The Company recognized interest expense of $5.0 million for 2022, compared with $0.6 million for 2021. In June 2021, the Company entered into a $10.0 million loan facility with Silicon Valley Bank (SVB). The Company immediately used $6.0 million from this facility to retire all outstanding indebtedness with Horizon Technology Finance Corporation. In connection with the SVB and Horizon loan facilities, the Company incurred $0.5 million in interest expense in 2022, compared with $0.6 million in 2021. In connection with the termination of the Horizon loan facility in 2021, the Company paid early termination and end-of-term charges to Horizon and recognized $0.2 million as a loss on debt extinguishment.
- In 2022 the Company incurred additional interest expense attributable to the one-time payment of $4.5 million in interest and offering expenses resulting from the sale and subsequent redemption of $30.0 million of Series A & B convertible redeemable preferred stock.
- Investment income from the Company's short-term investments was $0.5 million for 2022. Investment income was insignificant for 2021.

Net cash used for operating activities was $23.1 million for 2022, compared with $16.2 million for 2021. This increase 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 Series A & B convertible redeemable preferred stock, as well as higher operating costs attributable to the development of IMNN-001 and the PLACCINE DNA technology platform and higher legal and professional fees. Cash provided by financing activities of $6.7 million during 2022 resulted from an at-the-market equity offering with no warrants and sales under the Company's At-the-Market Equity Facility.

The Company ended 2022 with $38.9 million in cash, investments, accrued interest receivable and restricted cash. Along with future planned sales of the Company's remaining New Jersey NOLs, the Company believes it has sufficient capital resources to fund its operations into 2025.

Conference Call and Webcast

The Company is hosting a conference call to provide a business update, discuss 2022 financial results and answer questions at 11:00 a.m. Eastern time today. To participate in the call, please dial 866-777-2509 (Toll-Free/North America) or 412-317-5413 (International/Toll), and ask for the IMUNON 2022 Earnings Call. A live webcast of the call will be available here.

The call will be archived for replay until April 13, 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 5236742. 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.

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(Tables to Follow)

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

	Year Ended December 31,	
	2022	**2021**
Licensing revenue	$ 500	$ 500
Operating expenses:		
Research and development	11,734	10,619
General and administrative	13,688	10,888
Total operating expenses	25,422	21,507
Loss from operations	(24,922)	(21,007)
Other income (expense):		
Gain from change in valuation of earn-out milestone liability	5,396	1,622
Impairment of goodwill and in-process research and development	(13,366)	(1,976)
Interest expense, investment income and other income (expense), net	(4,573)	(557)
Loss on debt extinguishment	-	(235)
Total other (expense) income, net	(12,543)	(1,146)
Loss before income tax benefit	(37,465)	(22,153)
Income tax benefit	1,567	1,384
Net loss	$ (35,898)	$ (20,769)
Net loss per common share		
Basic and diluted	$ (5.03)	$ (3.83)

Weighted average shares outstanding		
Basic and diluted	7,143	5,427

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

	December 31, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 11,493	$ 19,586
Investment securities and interest receivable on investment securities	21,384	29,912
Money market investments, restricted cash	1,500	-
Advances, deposits on clinical programs and other current assets	2,778	2,448
Total current assets	**37,155**	**51,946**
Property and equipment	**548**	**477**
Other assets		
Deferred tax asset	1,567	1,383
Restricted cash invested in money market account	4,500	6,000
In-process research and development	-	13,366
Operating lease right-of-use assets, deposits, and other assets	206	875
Total other assets	**6,273**	**21,624**
Total assets	**$ 43,976**	**$ 74,047**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 8,381	$ 5,721
Note payable – current portion	1,425	-
Operating lease liability – current portion	231	549
Deferred revenue - current portion	-	500
Total current liabilities	**10,037**	**6,770**
Earn-out milestone liability	-	5,396
Notes payable – noncurrent portion	4,611	5,854
Operating lease liability – noncurrent portion	-	231
Total liabilities	**14,648**	**18,251**
Stockholders' equity		
Common stock	74	58
Additional paid-in capital	397,980	388,601
Accumulated other comprehensive gain (loss)	27	(8)
Accumulated deficit	(368,668)	(332,770)
	29,413	55,881
Less: Treasury stock	(85)	(85)
Total stockholders' equity	**29,328**	**55,796**
Total liabilities and stockholders' equity	**$ 43,976**	**$ 74,047**

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Source: Imunon, Inc.