IMUNON Reports Third Quarter 2022 Financial Results and Provides Business Update

November 14, 2022

Conference Call Today at 11:00 a.m. ET

LAWRENCEVILLE, N.J., Nov. 14, 2022 (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 three-month and nine-month periods ended September 30, 2022. Highlights of the quarter and recent weeks include:

- Compelling results from ongoing NHP study confirms PLACCINE as a viable modality for the development of the next generation of prophylactic vaccines
- Agreement with Acuitas Therapeutics to evaluate IMUNON's plasmid DNA with Acuitas lipid nanoparticle delivery system
- Enrollment of Phase I/II OVATION 2 study with GEN-1 in advanced ovarian cancer fully completed
- Cash runway expected into 2025

The Company also provided an update on its preclinical studies of PLACCINE, a proprietary DNA-based plasmid technology powered by synthetic, non-viral delivery systems, being evaluated in proof-of-concept studies in COVID-19; its clinical development of GEN-1, a DNA-based interleukin-12 (IL-12) immunotherapy in Phase II clinical development for the treatment of advanced-stage ovarian cancer; and, recent partnership agreements aiming at strengthening the development of our DNA plasmid platform.

"I am pleased to report that IMUNON is making excellent progress with our innovative development modalities in infectious diseases and immuno-oncology, while maintaining a strong financial position," said Dr. Corinne Le Goff, IMUNON's President and Chief Executive Officer. "Our PLACCINE modality continues to advance with very promising data from a non-human primate proof-of-concept study comparing our vaccine with commercial mRNA vaccines. Furthermore, I am looking forward to productive collaborations to continue developing our next generation DNA plasmid platform. Enrollment in our 110-patient OVATION 2 Study of GEN-1 in advanced ovarian cancer was completed during the third quarter." She added: "With the continuing volatility of the public markets, our decision to raise additional capital earlier this year to strengthen our balance sheet and extend our operating roadway into 2025 was well timed. We expect to report several value-creating developments during this period."

Recent Developments

PLACCINE: Development of the prophylactic vaccines of the future

Partial Results from Ongoing Non-Human Primate Study Support PLACCINE as Viable Prophylactic Vaccine Development Modality. In October 2022, the Company reported partial results from an ongoing non-human primate 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. In an ongoing stability study, the physio-chemical properties and immunogenicity of the Company's PLACCINE vaccine did not change during storage at 4° C for up to three months.

PLACCINE DNA-based Vaccine Demonstrated Robust Response in Murine Model. In September 2022, the Company provided an update on the development of a DNA-based vaccine using its PLACCINE platform technology.

Final data from its completed proof-of-concept mouse challenge study confirmed that a PLACCINE DNA-based vaccine can produce robust levels of IgG, neutralizing antibodies and T-cell responses. The data demonstrated the ability of the PLACCINE vaccine to protect a SARS-CoV-2 mouse model in a live viral challenge. In the study, mice were vaccinated with a PLACCINE vaccine expressing the SARS-CoV-2 spike antigen from the D614G variant, the Delta variant or a combination vaccine expressing both the D614G and Delta spike variants. The vaccinations were administered by intramuscular injection on Day 0 and Day 14, followed by challenge with live SARS-CoV-2 virus on Day 42. All three vaccines, including the single and dual antigen vaccines, were found to be safe and elicited IgG responses and inhibited the viral load by 90-95%. The dual-antigen vaccine was equally effective against both variants of the SARS CoV-2 virus. The murine model data suggest that the Company's approach provides not only flexibility, but also the potential for efficacy comparable to benchmark COVID-19 commercial vaccines with durability to protect expected to exceed six months.

GEN-1 Immunotherapy

Full Enrollment Reached in Phase I/II OVATION 2 Study with GEN-1 in Advanced Ovarian Cancer. In September 2022, the Company announced its Phase I/II OVATION 2 Study with GEN-1 in advanced ovarian cancer completed enrollment with 110 patients. GEN-1 is the Company's IL-12 gene-mediated immunotherapy. Topline results are expected in the first half of 2024.

The OVATION 2 Study combines GEN-1 with standard-of-care neoadjuvant chemotherapy (NACT) in patients newly diagnosed with Stage III/IV ovarian 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. IL-12 is a pluripotent cytokine associated with the stimulation of innate and adaptive immune response against cancer. The GEN-1 nanoparticle comprises a DNA plasmid encoding IL-12 and a synthetic polymer facilitating plasmid delivery vector. Cell transfection is followed by persistent, local secretion of the IL-12 protein at therapeutic levels.

In October 2022, following a pre-planned interim safety review, the Data Safety Monitoring Board (DSMB) unanimously recommended that the OVATION 2 Study continue treating patients with the dose of 100 mg/m^2. The DSMB also determined that safety is satisfactory with an acceptable risk/benefit. No dose-limiting toxicities were reported. The Company also announced that interim clinical data from 87 patients who underwent interval debulking surgery showed that those in the GEN-1 treatment arm had improvement in R0 surgical resection rates and CRS 3 chemotherapy response scores versus 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. The chemotherapy response score is a three-tier standardized scoring system for histological tumor regression into complete/near complete (CRS 3), partial (CRS 2) and no/minimal (CRS 1) response based on examination of the omentum. However, with only 50% of the PFS events so far, the data are still very immature.

In 2021 the Company announced GEN-1 received FDA Fast Track Designation in advanced ovarian cancer. The Company plans to request FDA Breakthrough Therapy Designation for GEN-1 based on the encouraging clinical data.

Partnerships and Collaborations

IMUNON 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.

Corporate Developments

During the third quarter of 2022, Company management presented at two healthcare conferences. They are:

- Chardan's 6 th Annual Genetic Medicines Conference held October 3-4, 2022.
- H.C. Wainwright 24th Annual Global Investment Conference held September 12-14, 2022.

Dr. Le Goff presented a corporate overview and members of senior management participated in the conferences.

James E. Dentzer, CEO of Curis, appointed to IMUNON's Board of Directors. In October 2022, the Company announced the appointment of James E. Dentzer to its Board of Directors. Mr. Dentzer is the chief executive officer of Curis, Inc., a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer and brings to IMUNON more than 20 years of leadership in the global pharmaceutical industry.

Mr. Dentzer has been President and Chief Executive Officer and a member of the Board of Directors of Curis, Inc. since September 2018. From March 2018 to September 2018, Mr. Dentzer served as Curis' Chief Operating Officer and Chief Financial Officer. From March 2016 to March 2018, Mr. Dentzer served as Curis' Chief Administrative Officer and Chief Financial Officer. Prior to joining Curis, Mr. Dentzer served as Chief Financial Officer of Dicerna Pharmaceuticals, Inc. from December 2013 to December 2015, and of Valeritas and Amicus Therapeutics, Inc. from October 2006 to October 2009. In prior positions, he spent six years as Corporate Controller of Biogen Inc. and six years in various senior financial roles at E.I. du Pont de Nemours and Company in the U.S. and Asia.

Dr. Corinne Le Goff Appointed as President and Chief Executive Officer; Michael H. Tardugno Appointed Executive Chairman of the Board. In July 2022, the Company announced its Board of Directors appointed biopharmaceutical executive Corinne Le Goff, Pharm. D., MBA as President, Chief Executive Officer and Director, effective July 18, 2022. Michael H. Tardugno continues to serve as Executive Chairman of IMUNON's Board of Directors. Dr. Le Goff brings decades of global healthcare leadership experience to the Company across a range of therapeutic areas including oncology, vaccines, immunology, CNS and cardio-metabolism. She brings a wealth of experience in developing and launching successful drugs from her tenure at large pharmaceutical companies and small, innovative biotech companies.

Prior to IMUNON, Dr. Le Goff most recently served as Chief Commercial Officer of Moderna, responsible for developing the global presence and capabilities necessary to ensure the global distribution of Moderna's COVID-19 vaccine. She also led the development of Moderna's mRNA platform long-term commercial strategy. Dr. Le Goff joined Moderna from Amgen, where she served as President of the U.S. business, driving the growth strategy with increased contributions from Repatha® and Aimovig®.

Dr. Le Goff was recently recognized by Forbes magazine as one of the women over the age of 50 who are changing the world.

Third Quarter Financial Results

IMUNON reported a net loss for the third quarter of 2022 of $6.1 million ($0.87 per share), compared with a net loss of $5.4 million ($0.94 per share) for the third quarter of 2021. Operating expenses were $6.3 million for the third quarter in 2022, an increase of $1.1 million (21%) from $5.2 million for the comparable prior-year period.

Research and development expenses were $2.4 million for the third quarter of 2022, a decrease of $0.1 million (2%) from $2.5 million for the comparable period in 2021. R&D costs associated with the development of GEN-1 to support the OVATION 2 Study as well as development of the PLACCINE DNA vaccine technology platform increased to $1.5 million for the third quarter of 2022, compared with $1.3 million for the same period of 2021. Costs associated with the OPTIMA Phase III study were $0.1 million for the third quarter of 2022, which represented expenses associated with closing out this previously discontinued study. Other clinical, CMC and regulatory costs were $0.8 million for the third quarter of 2022, compared with $1.0 million for the comparable period of 2021.

General and administrative expenses were $3.9 million for the third quarter of 2022, compared with $2.7 million for the same period of 2021. This $1.2

million increase was primarily attributable to higher professional fees (largely legal fees to defend various suits filed after the announcement in July 2020 of the OPTIMA Phase III study results), higher premiums for directors' and officers' insurance and higher compensation expenses related to the CEO succession plan announced in July 2022, offset by lower non-cash stock compensation expense.

Other non-operating income was $26,276 for the third quarter of 2022, compared with other non-operating expenses of $0.3 million for the comparable prior-year period. This increase was attributable to higher investment income in the current quarter.

Nine Month Financial Results

For the nine months ended September 30, 2022, the Company reported a net loss of $22.7 million ($3.42 per share), compared with a net loss of $16.5 million ($3.12 per share) for the same period of 2021. Operating expenses were $18.4 million for the first nine months of 2022, a $2.5 million (16%) increase from $15.9 million for the comparable prior-year period.

Research and development expenses increased $1.1 million for the first nine months of 2022 to $8.7 million, compared with $7.6 million for the comparable prior-year period. R&D costs associated with the development of GEN-1 to support the OVATION 2 Study as well as development of the PLACCINE DNA technology platform increased to $5.3 million for the first nine months of 2022, compared with $4.1 million for the comparable 2021 period. Costs for the OPTIMA Phase III study increased $0.4 million to $1.0 million for the first nine months of 2022, compared with $0.6 million for the first nine months of 2021, due to closing out this discontinued study in the first quarter of 2021. Other costs related to clinical supplies and regulatory support for the Company's clinical development programs decreased $0.5 million for the first nine months of 2022, compared with the same prior-year period.

General and administrative expenses were $9.6 million for the first nine months of 2022, compared with $8.3 million for the same period of 2021. The $1.4 million increase was primarily attributable to higher legal and professional fees coupled with higher compensation expenses related to the CEO succession plan announced in July 2022, offset by lower non-cash stock compensation expense.

Other non-operating expenses were $4.7 million for the first nine months of 2022, compared with $1.0 million for the comparable prior-year period. The increase was primarily attributable to the one-time payment of $4.5 million in interest and offering expenses resulting from the sale and subsequent redemption of $30 million of Series A & B convertible redeemable preferred stock in the first quarter of 2022 offset by higher investment income.

Net cash used for operating activities was $18.1 million for the first nine months of 2022, compared with $11.4 million for the same period in 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 million of Series A & B convertible redeemable preferred stock in the first quarter of 2022, as well as higher operating costs attributable to the development of GEN-1 and the PLACCINE DNA technology platform and higher legal and professional fees. Cash provided by financing activities of $6.3 million during the first nine months of 2022 resulted from an at-the-market equity offering (with no warrants) in April 2022. The Company also received net proceeds of $1.4 million from the sale of its unused 2020 New Jersey NOLs in February 2022. The Company's projected cash utilization for the balance of 2022 is approximately $5 million.

The Company ended the third quarter of 2022 with $43.4 million in cash, investments, restricted cash and accrued interest receivable. Along with future planned sales of the Company's State of 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 third quarter 2022 financial results and answer questions at 11:00 a.m. ET today. To participate in the call, please dial 866-777-2509 (Toll-Free/North America) or 412-317-5413 (International/Toll). The call will also be broadcast live at www.imunon.com.

The call will be archived for replay until November 28, 2022 at 877-344-7529 (U.S. Toll Free), 855-669-9658 (Canada Toll Free) or 412-317-0088 (International Toll), using replay access code 8042590. An audio replay will also be available at www.imunon.com for 90 days.

About IMUNON, Inc.

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® platform for the development of immunotherapies and other anti-cancer nucleic acid-based therapies, and the PLACCINE platform for the development of nucleic acid vaccines for infectious diseases and cancer. The company's lead clinical program, GEN-1, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer currently in Phase II development. GEN-1 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 in order to validate its PLACCINE platform by using a vaccine design comprising a single plasmid DNA molecule containing a sequence encoding more than one of the SARS-CoV-2 spike antigen variants. 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 plasmid DNA to better serve patients with difficult-to-treat conditions. For more information, 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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IMUNON, Inc.
Condensed Statements of Operations
(in thousands except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Licensing revenue	$ 125	$ 125	$ 375	$ 375
Operating expenses:				
Research and development	2,408	2,468	8,730	7,633
General and administrative	3,891	2,719	9,640	8,258
Total operating expenses	6,299	5,187	18,370	15,891
Loss from operations	(6,174)	(5,062)	(17,995)	(15,516)
Other income (expense):				
Loss from change in valuation of earn-out milestone liability	-	(257)	-	(327)
Interest expense	(127)	(96)	(4,878)	(474)
Loss on debt extinguishment	-	-	-	(235)
Other income (expense)	153	4	207	4
Total other (expense) income, net	26	(349)	(4,671)	(1,032)
Net loss	$ (6,148)	$ (5,411)	$ (22,666)	$ (16,548)
Net loss per common share				
Basic and diluted	$ (0.87)	$ (0.94)	$ (3.42)	$ (3.12)
Weighted average shares outstanding				
Basic and diluted	7,099	5,771	6,622	5,311

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

	September 30, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 26,938	$ 19,586
Investment securities and interest receivable on investment securities	10,445	29,912
Advances, deposits on clinical programs and other current assets	2,811	2,448
Total current assets	**40,194**	**51,946**

Property and equipment	**582**	**477**
Other assets		
Deferred tax asset	-	1,383
Restricted cash invested in money market account	6,000	6,000
In-process research and development	13,366	13,366
Operating lease right-of-use assets, deposits, and other assets	389	875
Total other assets	**19,755**	**21,624**
Total assets	**$ 60,531**	**$ 74,047**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued liabilities	$ 7,295	$ 5,721
Operating lease liability – current portion	374	549
Note payable – current portion	670	-
Deferred revenue - current portion	125	500
Total current liabilities	**8,464**	**6,770**
Earn-out milestone liability	5,396	5,396
Notes payable – noncurrent portion	5,320	5,854
Operating lease liability – noncurrent portion	-	231
Total liabilities	**19,180**	**18,251**
Stockholders' equity		
Common stock	71	58
Additional paid-in capital	396,826	388,601
Accumulated other comprehensive gain (loss)	(26)	(8)
Accumulated deficit	(355,435)	(332,770)
	41,436	55,881
Less: Treasury stock	(85)	(85)
Total stockholders' equity	**41,351**	**55,796**
Total liabilities and stockholders' equity	**$ 60,531**	**$ 74,047**

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Source: Imunon, Inc.