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Imunon, Inc.

(IMNN-NASDAQ)

IMNN: Results from OVATION 2 Study in Mid-2024…

Based on our probability adjusted DCF model that takes into account potential future revenues of IMNN-001 and the PLACCINE technology, IMNN is valued at $10/share. This model is highly dependent upon continued clinical success of the development candidates and will be adjusted accordingly based on future clinical results.

Current Price (05/16/24)	$1.41
Valuation	**$10.00**

OUTLOOK

On May 13, 2024, Imunon, Inc. (IMNN) announced financial results for the first quarter of 2024 and provided a business update. The company is on track to report topline results from the OVATION 2 trial of IMNN-001, a DNA-based interleukin-12 (IL-12) immunotherapy as a first-line treatment of locally advanced ovarian cancer, in mid-2024. In addition, the company announced it has activated the first site for patient recruitment for the Phase 1 study of IMNN-101, a seasonal COVID-19 vaccine candidate. Topline data is expected before the end of 2024 and will include neutralizing antibody response along with the optimal dose to evaluate in the Phase 2 trial.

SUMMARY DATA

52-Week High	**$1.93**
52-Week Low	**$0.49**
One-Year Return (%)	**-12.33**
Beta	**2.04**
Average Daily Volume (sh)	**80,310**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$12**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**4**
Insider Ownership (%)	**4**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**-0.7**
P/E using 2025 Estimate	**-0.8**

Risk Level	**High**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2024	0.0 A	0.0 E	0.0 E	0.0 E	0.0 E
2025					0.0 E
2026					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.68 A	-$0.61 A	-$0.37 A	-$0.52 A	-$2.16 A
2024	-$0.52 A	-$0.62 E	-$0.59 E	-$0.66 E	-$2.39 E
2025					-$2.55 E
2026					-$2.85 E

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WHAT'S NEW

Business Update

Topline Data from OVATION 2 Trial Expected in Mid-2024

Imunon, Inc. (IMNN) is currently conducting the Phase 1/2 OVATION 2 trial of IMNN-001, the company's IL-12 gene-mediated immunotherapy that is based on the TheraPlas™ technology. The OVATION 2 study is evaluating the dosing, safety, efficacy, and biological activity of intraperitoneal IMNN-001 in combination with neoadjuvant chemotherapy (NACT) in patients with newly diagnosed advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. Full enrollment of 110 patients for the trial was reached in September 2022. Being a Phase 1/2 trial, it is not powered for significance. It was designed with an 80% confidence interval to show an approximately 33% improvement in PFS when comparing the treatment arm (NACT+IMNN-001) with the control arm (NACT only).

Interim data from the intent-to-treat population show efficacy trends in PFS, with a delay in disease progression in the treatment arm of approximately 33% compared with the control arm. Preliminary OS data showed a similar trend, with an approximately 9-month improvement in the treatment arm compared to the control arm. A non-prespecified subgroup analysis showed that 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 NACT only. The PARPi subgroup was not pre-defined before initiation of the OVATION 2 trial as PARPi's were first approved after the OVATION 2 trial had initiated.

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 had not yet been reached in the PARPi+NACT+IMNN-001 group. These data are preliminary, but patients treated with PARPi's along with IMNN-001 appear to have the greatest benefit and will likely be a focus for the company moving forward.

Additional positive trends were seen in secondary outcome measures, including an approximately 25% higher R0 tumor resection score and a doubling of the CRS 3 chemotherapy response score to approximately 30% in the treatment arm compared to 14% in the control arm. Safety data from the trial continues to show that IMNN-001 is well tolerated in this setting.

In October 2023, Imunon reported that the first patient was enrolled in the Phase 1/2 clinical trial of IMNN-001 in combination with bevacizumab in advanced ovarian cancer at the University of Texas MD Anderson Cancer Center. The trial is expected to enroll 50 patients with Stage III/IV advanced ovarian cancer. Patients undergoing frontline neoadjuvant therapy will be randomized 1:1 to receive standard chemotherapy plus bevacizumab or chemotherapy plus bevacizumab and IMNN-001. The 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 while final PFS data are expected approximately three years following completion of enrollment. Thus far, four patients have been enrolled in the study and Memorial Sloan Kettering Cancer center has been added as a clinical site in the first quarter of 2024.

Phase 1 Trial of IMNN-101 Underway

On May 15, 2024, Imunon announced that the first site was activated and ready for patient recruitment for the Phase 1 clinical trial of IMNN-101, the company's seasonal COVID-19 vaccine. The study is planned to enroll 24 subjects evaluating three escalating doses of IMNN-101. For this study, IMNN-101 was designed to protect against SARS-CoV-2 Omicron XBB1.5 variant, which was in accordance with the FDA's Vaccines and Related Biological Products Advisory Committee's June 2023 announcement. The primary objectives of the study are to evaluate safety and tolerability of the vaccine in healthy adults. Secondary objectives include neutralizing antibody response, cellular responses, and their associated durability. We anticipate topline results before the end of 2024.

IMNN-101 is based on the company's PlaCCine technology. It is a DNA vaccine that addresses a number of limitations of current vaccines, including the durability of antigen expression, stability, and flexibility to adapt to mutating viruses. Imunon previously reported positive preclinical results for the PlaCCine technology:

- In February 2024, Imunon announced the publication of a peer-reviewed article titled "Strong immunogenicity & protection in mice with PlaCCine: A COVID-19 DNA vaccine formulated with a functional polymer" (Sood *et al*., 2024). In the study, the spike antigens from COVID-19 variants D614G (pVAC15), Delta (pVAC16), or both (pVAC17) were cloned into DNA vectors. The plasmids were formulated with a functional polymer that resulted in protein expression for up to 85 days. Comparative studies between PlaCCine vectors and Moderna's mRNA vaccine (mRNA-1273) demonstrated that vaccination with PlaCCine induced antibody responses that were comparable to those induced by mRNA-1273. Immunization with pVAC17 resulted in the induction of cross neutralizing antibodies and protection in mice against both a D614G and Delta challenge.

- In February 2024, Imunon announced positive results from a live virus challenge study conducted by the Wistar Institute with IMNN-101 against the SARS-CoV-2 variant XBB.1.5. That variant was declared the variant of concern for the 2023-2024 vaccine by the U.S. FDA Vaccines and Related Biological Products Advisory Committee. The study conducted by the Wistar Institute confirmed that IMNN-101 elicited robust IgG and neutralizing antibody responses in a dose-dependent manner after a single injection and that challenging the mice with live virus 21 days after the second vaccination showed complete response.

New President and CEO

On May 8, 2024, Imunon announced the appointment of Dr. Stacy Lindborg as President and Chief Executive Officer (CEO). Dr. Lindborg has served on Imunon's board of directors since 2021. She has nearly 30 years of pharmaceutical and biotech industry experience. Previously, she served as co-CEO of BrainStorm Cell Therapeutics, where she will remain as a member of the board of directors. Prior to that, she was Vice President & Global Analytics and Data Sciences Head at Biogen. Her career began at Eli Lilly & Company where over 16 years she assumed positions of increasing responsibility, including Head of R&D strategy. Dr. Lindborg received an MA and PhD in statistics, and a BA in psychology and math from Baylor University. She has authored more than 90 manuscripts published in peer-reviewed journals, including 20 first-authored.

Financial Update

On May 13, 2024, Imunon announced financial results for the first quarter of 2024. As expected, the company did not report any revenue during the first quarter of 2024. R&D expenses in the first quarter of 2024 were $3.3 million compared to $2.6 million in the first quarter of 2023. The increase was primarily due to higher clinical and regulatory costs. G&A expenses in the first quarter of 2024 were $1.7 million compared to $3.1 million for the first quarter of 2023. The decrease was primarily due to lower non-cash stock-based compensation, legal costs, employee-related costs, consulting fees, and insurance costs.

As of March 31, 2024, Imunon had approximately $9.8 million in cash, cash equivalents, investments, and interest receivable. We estimate that the company has sufficient capital to fund operations to the end of 2024. Imunon currently has approximately 9.4 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 10.6 million.

Conclusion

We look forward to the results of the OVATION 2 trial, which we expect in mid-2024. These results will be used to plan a Phase 3 study, which the company is hoping to initiate in the first quarter of 2025. In addition, we anticipate results from the Phase 1 trial of IMNN-101 before the end of 2024. We've increased our estimate for the number of shares to be sold for the company's next financing, which has reduced our valuation to $10 per share.

PROJECTED FINANCIALS

Imunon, Inc.	2023 A	Q1 A	Q2 E	Q3 E	Q4 E	2024 E	2025 E	2026 E
GEN-1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
SARS-CoV-2 Vaccine	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
R&D	$9.7	$3.3	$2.7	$3.0	$3.2	$12.2	$12.5	$14.0
SG&A	$11.3	$1.7	$3.0	$3.0	$3.0	$10.7	$13.0	$14.5
Operating Income	($21.0)	($5.0)	($5.7)	($6.0)	($6.2)	($22.9)	($25.5)	($28.5)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.2	$0.1	$0.1	$0.4	$0.0	$0.4	$0.0	$0.0
Pre-Tax Income	($20.8)	($4.9)	($5.8)	($5.6)	($6.2)	($22.5)	($25.5)	($28.5)
Taxes & Other	($1.3)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($19.5)	($4.9)	($5.8)	($5.6)	($6.2)	($22.5)	($25.5)	($28.5)
Reported EPS	**($2.16)**	**($0.52)**	**($0.62)**	**($0.59)**	**($0.66)**	**($2.39)**	**($2.55)**	**($2.85)**
Weighted Shares Outstanding	9.0	9.4	9.4	9.4	9.4	9.4	10.0	10.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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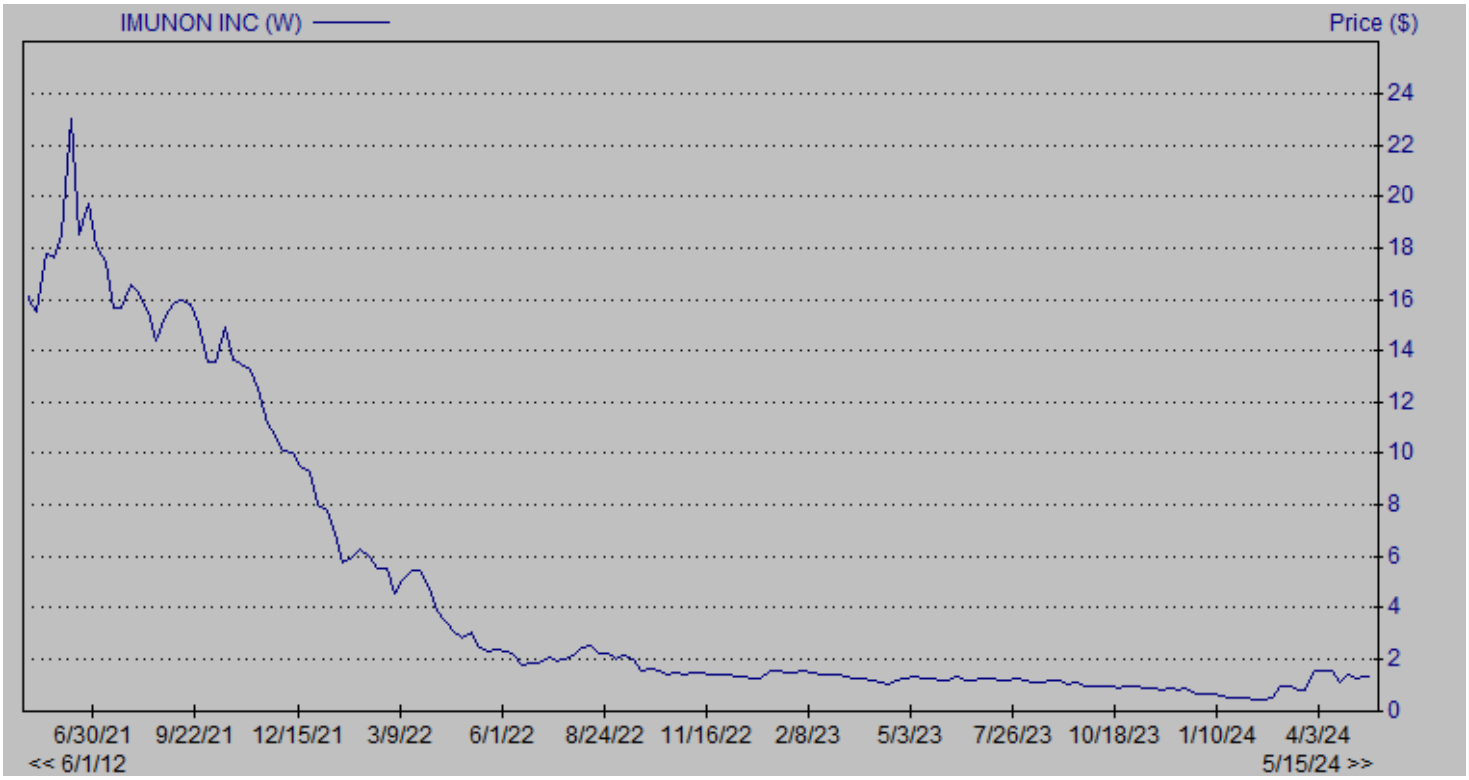

Source: Zacks Small Cap Research

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