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Imunon, Inc.

(IMNN-NASDAQ)

IMNN: IND Application Submitted for Phase 1/2 Trial of Seasonal COVID-19 Vaccine…

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 $15/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 (04/12/24)	$1.54
Valuation	**$15.00**

OUTLOOK

On March 28, 2024, Imunon, Inc. (IMNN) announced financial results for the year ending December 31, 2023 and provided a business update. The company recently submitted an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for IMNN-101 for a Phase 1/2 clinical study with a seasonal COVID-19 booster vaccine. We anticipate enrollment beginning in the second quarter of 2024. The company recently reported that a study conducted by the Wistar institute confirmed the robust IgG and neutralizing antibody responses induced by IMNN-101 in a dose-dependent manner following a single injection in mice. In addition, challenging mice with live virus 21 days after the second vaccination showed complete protection. Imunon recently published a manuscript in the journal *Vaccine* describing results from a study using a formulation against the spike proteins from two SARS-CoV-2 variants. Results from that study showed that the company's vaccine-induced immune response in mice was capable of suppressing viral replication.

SUMMARY DATA

52-Week High	**$1.93**
52-Week Low	**$0.49**
One-Year Return (%)	**36.28**
Beta	**2.03**
Average Daily Volume (sh)	**274,414**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$14**
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	**-0.9**

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 E	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	-$0.54 E	-$0.62 E	-$0.59 E	-$0.66 E	-$2.41 E
2025					-$2.55 E
2026					-$2.85 E

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WHAT'S NEW

Business Update

Update on IMNN-101

Imunon, Inc. (IMNN) is developing IMNN-101, which is a COVID-19 seasonal vaccine booster 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.

- 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.

- In March 2024, Imunon announced it filed an Investigational New Drug (IND) application with the U.S. FDA for IMNN-101 for a Phase 1/2 clinical study with a seasonal COVID-19 booster vaccine. The study is currently planned to enroll approximately 24 subjects evaluating three escalating doses of IMNN-101, which has been designed to protect against the SARS-CoV-2 Omicron XBB1.5 variant. We anticipate the trial initiating in the second quarter of 2024.

Update on IMNN-001

In September, 2023, Imunon announced interim progression-free survival (PFS) and overall survival (OS) data for IMNN-001 in the Phase 1/2 OVATION 2 trial. IMNN-001 is 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). The final readout of the study is expected in mid-2024, with positive results informing next development steps.

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. The company recently announced that four patients have been enrolled in the study to date and that MD Anderson Cancer Center has joined in enrolling patients.

Financial Update

On March 28, 2024, Imunon announced financial results for 2023. The company reported $0 in revenue in 2023 compared to $500,000 in technology development and licensing revenue in 2022. The $500,000 stemmed from a non-refundable technology transfer fee of $5 million paid by Hisun in January 2013 to support the development of ThermoDox® in China that was recorded as deferred revenue and was amortized over the ten-year term of the agreement. As of December 31, 2022, the contract has been fully amortized and recognized as revenue.

In 2023, the company reported a net loss of $19.5 million, or $2.16 per share, compared with a net loss of $35.9 million, or $5.03 per share, in 2022. R&D expenses in 2023 were $11.3 million, compared to $11.7 million in 2022. The decrease was primarily due to decreased costs associated with the OVATION 2 and OPTIMA studies. G&A expenses in 2023 were $9.7 million, compared to $13.7 million in 2022. The decrease was primarily due to lower non-cash stock compensation, lower employee-related costs, lower legal costs, and lower insurance and public company expenses.

Imunon exited 2023 with approximately $15.7 million in cash, cash equivalents, investments, and accrued interest receivable. Along with the future planned sale of the company's remaining $1.3 million in New Jersey Net Operating Losses (NOLs), we estimate that the company has sufficient capital to fund operations into the fourth quarter 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 10.7 million.

Conclusion

We look forward to the initiation of the Phase 1/2 clinical trial of IMNN-101 in the second quarter of 2024. IMNN-101 has shown promising preclinical results and we will be very interested to see if those results translate into the clinic. We also look forward to results from the IMNN-001 trial, which we anticipate in mid-2024. With no changes to our model our valuation remains at $15 per share.

PROJECTED FINANCIALS

Imunon, Inc.	2023 A	Q1 E	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	$2.2	$2.7	$3.0	$3.2	$11.1	$12.5	$14.0
SG&A	$11.3	$3.0	$3.0	$3.0	$3.0	$12.0	$13.0	$14.5
Operating Income	($21.0)	($5.2)	($5.7)	($6.0)	($6.2)	($23.1)	($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)	($5.1)	($5.8)	($5.6)	($6.2)	($22.7)	($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)	($5.1)	($5.8)	($5.6)	($6.2)	($22.7)	($25.5)	($28.5)
Reported EPS	**($2.16)**	**($0.54)**	**($0.62)**	**($0.59)**	**($0.66)**	**($2.41)**	**($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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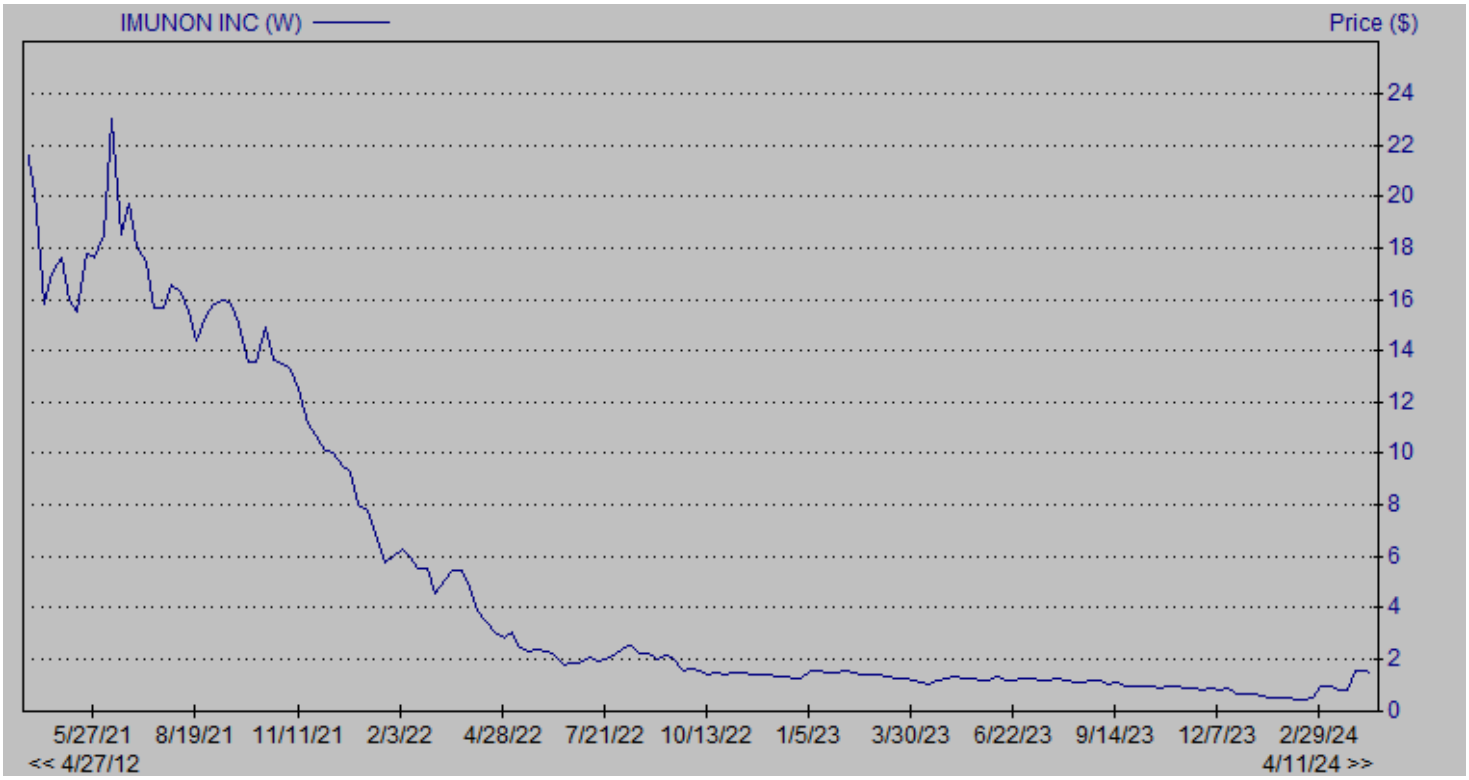
HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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