Zacks Small-Cap Research

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Imunon, Inc.

(IMNN-NASDAQ)

IMNN: Meeting with FDA in Preparation for Phase 3 Ovarian Cancer Trial…

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 $8/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 (11/11/24)	$0.80
Valuation	**$8.00**

OUTLOOK

On November 7, 2024, Imunon, Inc. (IMNN) announced financial results for the third quarter of 2024 and provided a business update. Following release of positive topline results from the OVATION 2 trial of IMNN-001, which showed an overall survival improvement of 11.1 months compared to standard of care treatment, the company will be meeting with the FDA this month as it finalizes designs of the planned Phase 3 registrational study of IMNN-001 in patients with advanced ovarian cancer. We continue to anticipate the 500-patient trial initiating in the first quarter of 2025. In addition, we anticipate results from the Phase 1 trial of IMNN-101 before the end of 2024 as the company is looking to enter into a partnership to continue its development.

SUMMARY DATA

52-Week High	**$3.32**
52-Week Low	**$0.49**
One-Year Return (%)	**-15.80**
Beta	**2.14**
Average Daily Volume (sh)	**186,128**
Shares Outstanding (mil)	**60**
Market Capitalization ($mil)	**$48**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**4**
Insider Ownership (%)	**5**
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	**-0.5**
P/E using 2025 Estimate	**-0.6**

Risk Level	**High**
Type of Stock	**Small-Growth**
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 A	0.0 A	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	-$0.51 A	-$0.34 A	-$0.43 E	-$1.74 E
2025					-$1.28 E
2026					-$0.95 E

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WHAT'S NEW

Business Update

Preparations Underway for Phase 3 Ovarian Cancer Trial; Set to Initiate in 1Q25

Imunon, Inc. (IMNN) previously reported positive topline results from the Phase 2 OVATION 2 trial of IMNN-001 in patients with newly diagnosed advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. IMNN-001 is a DNA immunotherapeutic drug that consists of an interleukin (IL)-12 plasmid that allows for targeted expression of IL-12 to avoid toxicities and poor pharmacokinetics of systemically administered IL-12.

The standard of cancer in ovarian cancer has not changed appreciably in the last 25 years. In addition, only recently has a treatment showed an overall survival (OS) benefit in ovarian cancer. With that context, we view the results from the OVATION 2 trial as an exciting advancement in the treatment of ovarian cancer, which were recently presented at the SITC 39th Annual Meeting. The results showed that treatment with IMNN-001 in addition to standard of care increased OS by 11.1 months and for those patients that received at least 20% of protocol-specified treatments the increase was 15.7 months. For the patients that were also on a PARP inhibitor (approximately 40%), the median OS was not reached for those also receiving IMNN-001 compared to 37.1 months for those not receiving IMNN-001. In regards to safety, IMNN-001 was well tolerated with the most common adverse events were abdominal pain, nausea, and vomiting. The abdominal pain was well controlled with standard of care pain medicines.

Imunon is now developing the protocol for a Phase 3 trial of IMNN-001 in ovarian cancer patients. As part of the process, the company will be conducting an 'End-of-Phase 2' meeting with the FDA later this month to get input from the agency on their proposed trial design. The study is likely to include approximately 500 patients, which will allow for stratification according to PARP inhibitor exposure. We anticipate the study initiating in the first quarter of 2025.

Financial Update

On November 7, 2024, Imunon announced financial results for the third quarter of 2024. As expected, the company did not report any revenue during the third quarter of 2024. R&D expenses in the third quarter of 2024 were $3.3 million compared to $2.0 million in the third quarter of 2023. The increase was primarily due to higher costs associated with the OVATION 2 study and CMC costs. G&A expenses in the third quarter of 2024 were $1.7 million compared to $1.9 million for the third quarter of 2023. The decrease was primarily due to lower legal fees.

As of September 30, 2024, Imunon had approximately $10.3 million in cash, cash equivalents, investments, and interest receivable. We estimate that the company has sufficient capital to fund operations into the third quarter of 2025. Imunon currently has approximately 14.5 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 21.2 million.

Conclusion

We anticipate an update on the upcoming Phase 3 study of IMNN-001 following the company's meeting with the FDA and receipt of the meeting minutes. Assuming Imunon can come into alignment with the FDA regarding the study design, we anticipate the trial initiating in the first quarter of 2025. We also expect an update on the company's plans for financing the Phase 3 study, however at this point there is sufficient capital to initiate the trial. With no changes to our model our valuation remains at $8.00 per share.

PROJECTED FINANCIALS

Imunon, Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
IMNN-001	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
IMNN-101	$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	$2.8	$3.3	$3.2	$12.6	$12.5	$14.0
SG&A	$11.3	$1.7	$2.2	$1.7	$3.0	$8.6	$13.0	$14.5
Operating Income	($21.0)	($5.0)	($5.0)	($5.0)	($6.2)	($21.2)	($25.5)	($28.5)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.2	$0.1	$0.2	$0.1	$0.0	$0.4	$0.0	$0.0
Pre-Tax Income	($20.8)	($4.9)	($4.8)	($4.8)	($6.2)	($20.8)	($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)	($4.8)	($4.8)	($6.2)	($20.8)	($25.5)	($28.5)
Reported EPS	**($2.16)**	**($0.52)**	**($0.51)**	**($0.34)**	**($0.43)**	**($1.74)**	**($1.28)**	**($0.95)**
Weighted Shares Outstanding	9.0	9.4	9.4	14.4	14.5	11.9	20.0	30.0

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

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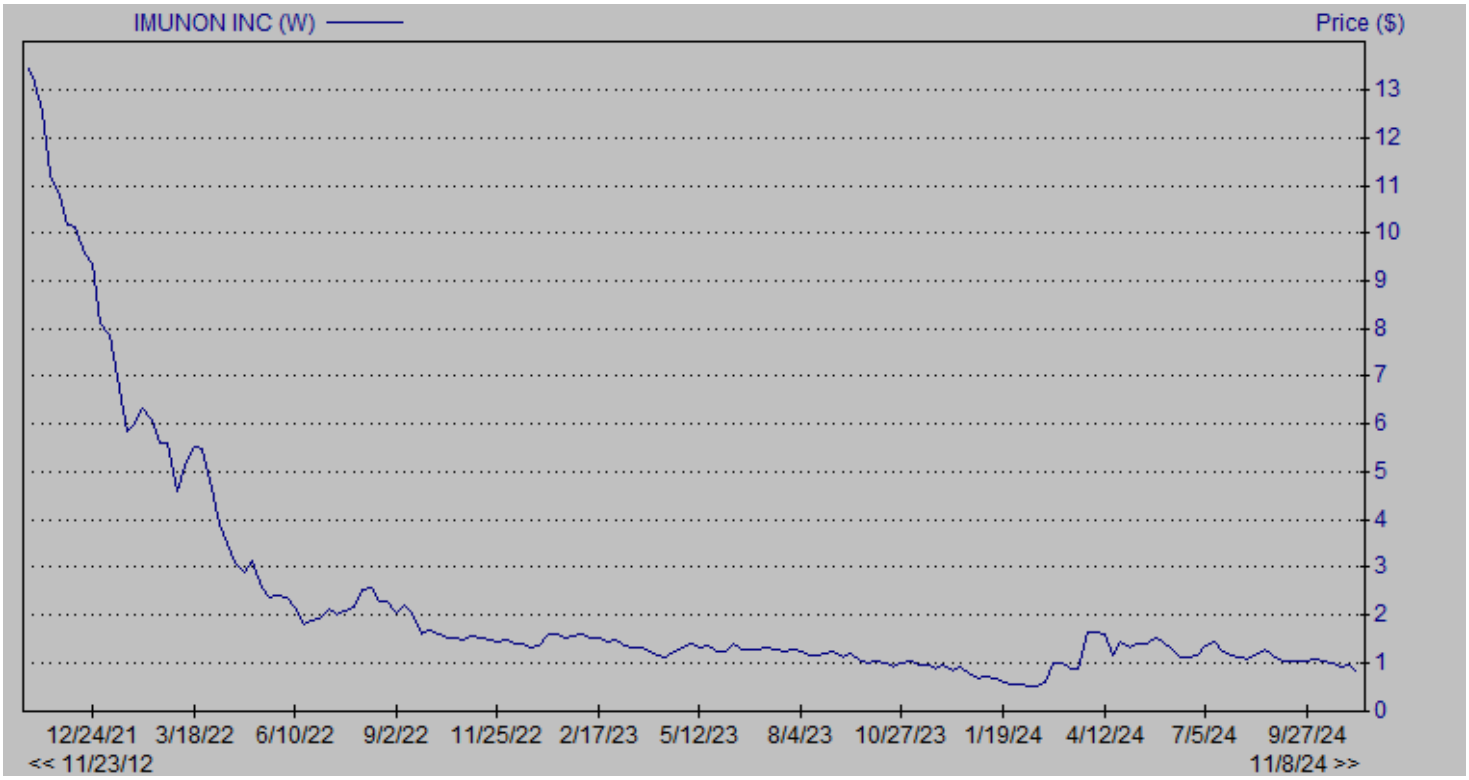
HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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