

Imunon, Inc.

(IMNN-NASDAQ)

IMNN: Protocol in Place for Phase 3 Trial of IMNN-001 in Ovarian Cancer...

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 (03/28/25) **\$1.14**
Valuation **\$8.00**

OUTLOOK

On March 25, 2025, Imunon, Inc. (IMNN) held a conference call to discuss the finalized protocol for a Phase 3 clinical trial of IMNN-001 in patients with newly diagnosed ovarian cancer. The study will mirror the Phase 2 OVATION 2 trial that reported benefits in both progression-free and overall survival. It will initially focus on those patients who are positive for homologous recombination deficiency (HDR) positive, including BRCA1 and BRCA2 mutations. HRD positive patients will receive poly ADP-ribose polymerase (PARP) inhibitors as part of the standard of care maintenance therapy. The primary endpoint of the study is overall survival (OS), with secondary endpoints of surgical response score, chemotherapy response score, clinical response, and time to second-line treatment. Imunon previously reported that IMNN-001 plus neoadjuvant and adjuvant chemotherapy (NACT) increased median OS to 46 months vs. 33 months for standard-of-care NACT with an excellent safety profile.

SUMMARY DATA

52-Week High **\$3.32**
52-Week Low **\$0.68**
One-Year Return (%) **-30.49**
Beta **1.96**
Average Daily Volume (sh) **124,193**

Shares Outstanding (mil) **15**
Market Capitalization (\$mil) **\$17**
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 2025 Estimate **-0.9**
P/E using 2026 Estimate **-1.2**

Risk Level

Type of Stock
Industry

Above Avg.
Small-Growth
Med-Biomed/Gene

ZACKS ESTIMATES

Revenue

(In millions of \$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2025	0.0 E	0.0 E	0.0 E	0.0 E	0.0 E
2026					0.0 E
2027					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	-\$0.52 A	-\$0.51 A	-\$0.34 A	-\$0.32 A	-\$1.62 A
2025	-\$0.32 E	-\$0.25 E	-\$0.18 E	-\$0.19 E	-\$1.02 E
2026					-\$0.55 E
2027					-\$0.48 E

WHAT'S NEW

Business Update

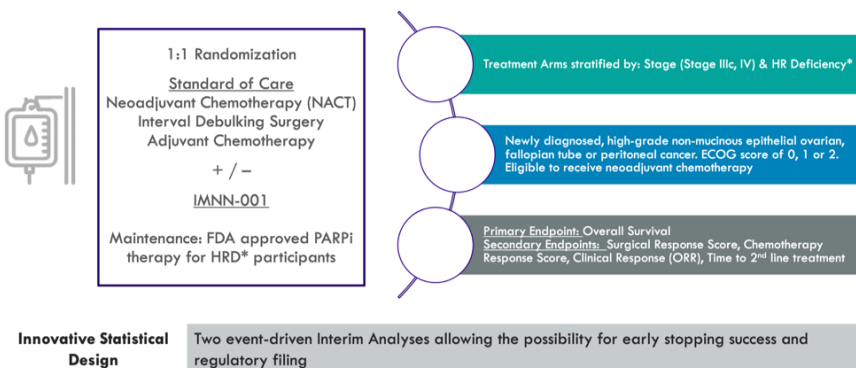
Protocol in Place for Phase 3 Trial of IMNN-001 in Ovarian Cancer

On March 24, 2025, Imunon, Inc. (IMNN) [announced](#) it reached alignment with the U.S. FDA on the protocol for a Phase 3 clinical trial, referred to as OVATION 3, of its lead candidate IMNN-001 for the treatment of women with newly diagnosed advanced ovarian cancer. Trial sites are currently being initiated with the first patient to be enrolled in the near term.

The following slide provides the overall design of the trial. Eligible patients will have either Stage IIIc and IV advanced ovarian cancer and will be randomized to receive neoadjuvant chemotherapy (NACT), interval debulking surgery, and adjuvant chemotherapy. Patients who are positive for homologous recombination deficiency (HRD) are also eligible and will receive poly ADP-ribose polymerase (PARP) inhibitor therapy as part of standard-of-care (SOC) maintenance therapy. The primary endpoint is overall survival (OS), with secondary endpoints evaluating surgical response score, chemotherapy response score, clinical response (ORR), and time to second-line treatment.

OVATION-3 Pivotal Trial: Finalized Phase 3 Study Design with FDA

Randomized, multicenter Phase 3 trial to evaluate the safety and efficacy of IMNN-001 (100 mg/m²) plus standard of care neoadjuvant and adjuvant chemotherapy (NACT) vs SOC NACT alone



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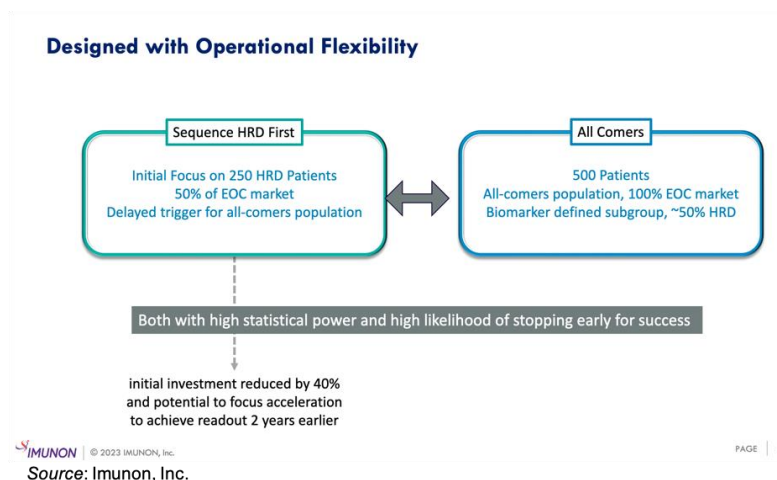
Source: Imunon, Inc.

*HR Deficiency: Homologous Recombinant Deficiency PAGE | 3

The company is utilizing a statistical design with two planned interim analyses. The goal is to minimize risk and maximize the chance for success. The FDA has agreed with both the overall study design and the statistical plan, which in the literature is referred to as a Group Sequential Design (GSD) ([Hatfield et al., 2016](#)). GSD has been utilized in a number of other clinical trials. For example, in a study of blinatumomab (a CD3/CD19 bi-specific T cell engager) in children with high-risk first-relapse B cell acute lymphoblastic lymphoma (B-ALL) the trial was terminated during the first prespecified interim analysis after only enrolling half of its maximum sample size as children receiving blinatumomab had significantly improved event-free survival compared to those receiving standard chemotherapy ([Locatelli et al., 2021](#)). Thus, we do not anticipate any additional regulatory risk from the use of a GSD in the OVATION 3 trial.

The study was designed to maximize operational flexibility as it is powered at >95% to examine either a 250-patient cohort of HRD positive individuals or a 500-patient all-comers population. The company has decided to initially focus on the HRD positive subgroup as it potentially offers cost savings of up to 40% and could lead to a data readout up to two years earlier. HRD positive patients constitute approximately 50% of the advanced ovarian cancer population, thus it is still a sizeable market opportunity. The company is still committed to examining IMNN-001 in a broader population of patients, however that will need to come at a later time when sufficient financing is available to conduct that study. The decision to target the HRD positive subgroup will help to conserve cash, targeting the highest probability subgroup, and delivering results as quickly as

possible. In summary, this design allows Imunon to decrease the initial investment required, decrease the timeline to data readout, and allows the company to be more aggressive with site engagement.



In regards to financing the study, the company currently has cash into late June 2025. Imunon has a number of options available for financing, including some non-dilutive options. We are confident that management will be able to fund the study in a way that is most beneficial for shareholders and we anticipate an update from the company as soon as is warranted.

Phase 2 Results Support Advancement to Phase 3

Initial results for the Phase 2 OVATION-2 Trial were released in July 2024 and for a full analysis of the results please see our previous report [here](#). Briefly, the results showed that in the intent-to-treat (ITT) population, treatment with IMNN-001 resulted in an 11.1 month increase in overall survival (OS) with a hazard ratio (HR) of 0.74. Since the release of the data the company has continued to follow-up with patients, and in December 2024 [announced](#) that the increase in OS went up further from 11.1 months to 13 months and the HR decreased from 0.74 to 0.69. Importantly, these are the first study results for this patient population to show an increase in OS.

A subgroup analysis was performed for those patients that received PARP inhibitor (PARPi) therapy. Those results showed that the median OS was not reached for the PARPi group receiving IMNN-001 and standard of care compared to 37.1 months for the PARPi group only receiving standard of care (HR=0.41).

In addition to the increase in OS, the follow-up results showed that more than 1/3rd of patients survived more than 36 months, with 62% of those patients from the IMNN-001 cohort and 38% from the standard-of-care cohort. The updated results also continued to show a favorable safety profile with no reports of serious immune-related adverse events.

Conclusion

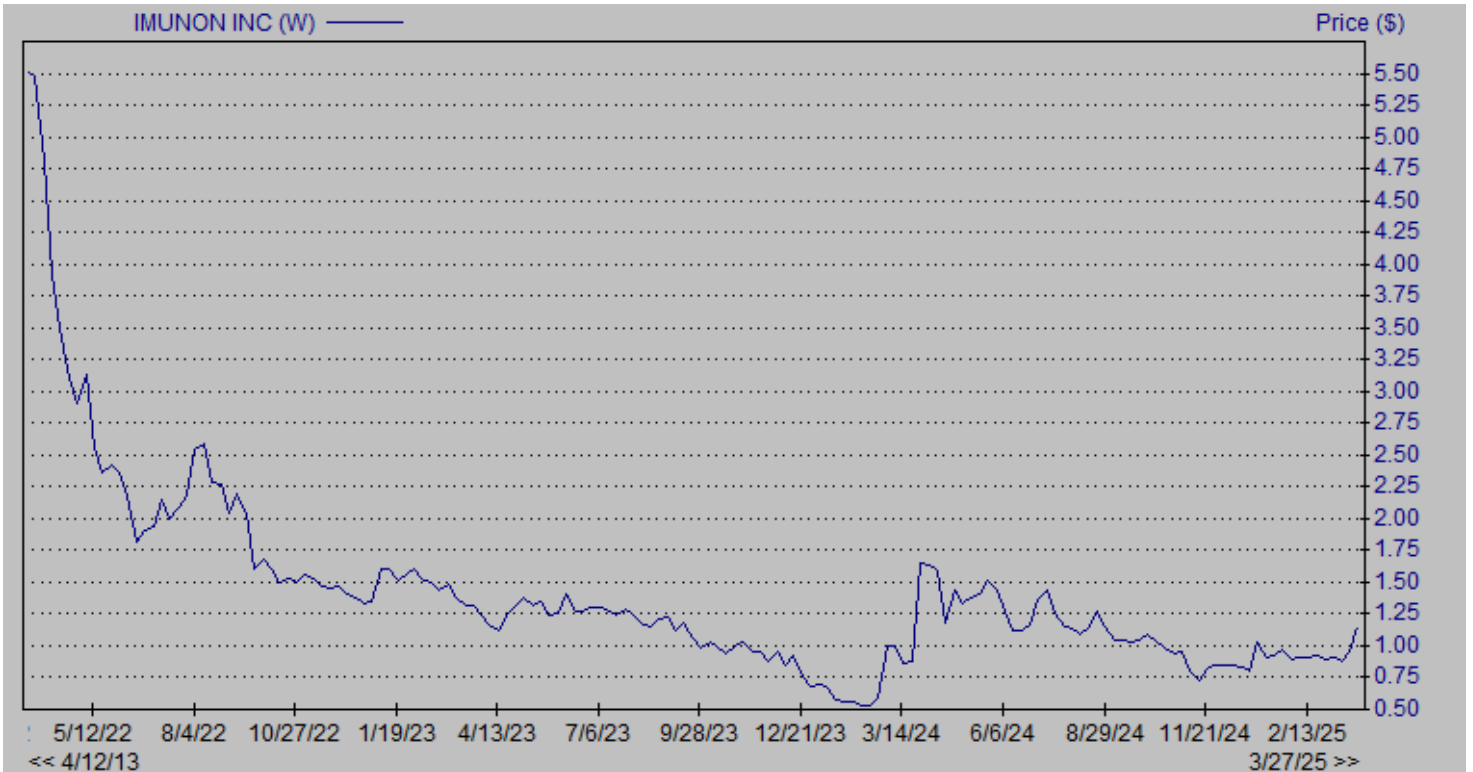
We're looking forward to the initiation of the Phase 3 trial for IMNN-101. The company has provided a comprehensive overview of the various aspects of the study, and we believe that targeting the HRD positive population is the best way forward at this juncture as it maximizes the chance for success while being the most cost-effective option.

PROJECTED FINANCIALS

Imunon, Inc.	2024 A	Q1 E	Q2 E	Q3 E	Q4 E	2025 E	2026 E	2027 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	\$11.6	\$3.0	\$3.2	\$3.4	\$3.6	\$13.2	\$14.0	\$15.0
SG&A	\$7.5	\$1.7	\$1.8	\$2.0	\$2.1	\$7.6	\$8.0	\$9.0
Operating Income	(\$19.1)	(\$4.7)	(\$5.0)	(\$5.4)	(\$5.7)	(\$20.8)	(\$22.0)	(\$24.0)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
Interest & Other Income	\$0.5	\$0.1	\$0.1	\$0.1	\$0.1	\$0.4	\$0.0	\$0.0
Pre-Tax Income	(\$18.6)	(\$4.6)	(\$4.9)	(\$5.3)	(\$5.6)	(\$20.4)	(\$22.0)	(\$24.0)
Taxes & Other	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$18.6)	(\$4.6)	(\$4.9)	(\$5.3)	(\$5.6)	(\$20.4)	(\$22.0)	(\$24.0)
Reported EPS	(\$1.62)	(\$0.32)	(\$0.25)	(\$0.18)	(\$0.19)	(\$1.02)	(\$0.55)	(\$0.48)
Weighted Shares Outstanding	11.5	14.6	20.0	30.0	30.0	20.0	40.0	50.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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