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# Imunon, Inc.

**(IMNN-NASDAQ)**

***IMNN: Phase 3 Ovarian Cancer Trial to get Underway in Mar 2025…***

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 (02/28/25) | $0.81 |
| **Valuation** | **$8.00** |

## OUTLOOK

On February 27, 2025, Imunon, Inc. (IMNN) announced financial results for 2024 and provided a business update. The company is currently finishing preparations to conduct a Phase 3 clinical trial of its lead development compound, IMNN-001, in the treatment of advanced ovarian cancer. We anticipate the 500-patient trial will initiate before the end of the first quarter of 2025. The company is continuing to pursue all avenues for funding the trial and we continue to anticipate an update on its funding strategy in the near term. Imunon also recently announced immunogenicity data from the Phase 1 trial of IMNN-101, its investigational DNA plasmid vaccine. The Phase 1 study was conducted in 24 healthy volunteers as a seasonal COVID-19 vaccine. The results showed IMNN-101 was safe and well tolerated and generated a persistent 2- to 4-fold increase in serum neutralizing antibody titers. The company is continuing to seek potential partners for further development of IMNN-101.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$3.32** |
| **52-Week Low** | **$0.61** |
| **One-Year Return (%)** | **-28.95** |
| **Beta** | **2.03** |
| **Average Daily Volume (sh)** | **149,751** |
| **Shares Outstanding (mil)** | **15** |
| **Market Capitalization ($mil)** | **$12** |
| **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** | **-0.7** |
| **P/E using 2026 Estimate** | **-1.0** |

| | |
|---|---|
| **Risk Level** | **Above Avg.** |
| **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) |
|---|---|---|---|---|---|
| 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 |

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## WHAT'S NEW

**Business Update**

*Phase 3 Ovarian Cancer Trial to Initiate in March 2025*

Imunon, Inc. (IMNN) is continuing preparations to conduct a Phase 3 clinical trial of its lead development compound, IMNN-001, in patients with advanced ovarian cancer. IMNN-001 is a DNA immunotherapeutic drug that consists of an interleukin (IL)-12 expressing plasmid that allows for the durable, local, and targeted expression of IL-12 in the peritoneum. IL-12 is a potent pro-inflammatory cytokine that mediates a number of important cellular processes, including T cell and natural killer cell activation (Bashyam, 2007), the production of interferon-gamma (Zhao *et al*., 2012), and alteration of myeloid-derived suppressor cells in the tumor microenvironment (Kerkar *et al*., 2011). While shown to be effective in pre-clinical tumor models, IL-12 therapy initially showed underwhelming results in the clinic along with very high levels of toxicity when administered systemically. This is likely due to the fact that the direct targets of IL-12 are not circulating lymphocytes, but rather immune cells located within the tumor and lymph nodes. Thus, while systemic IL-12 therapy is not possible, localized delivery of IL-12 in and around the tumor has the potential to showcase its potent immune stimulating effects while minimizing toxic side effects.

Multiple strategies are currently being developed to deliver IL-12 to the tumor microenvironment and minimize systemic toxicity, including collagen-binding domain (CBD)-IL-12 (Mansurov *et al*., 2020), NHSAb-IL-12 (Franks *et al*., 2023), and mRNA (Liu *et al*., 2024). IMNN-001 leads to a durable increase in IL-12 at and near the tumor without accompanying systemic increases to help alleviate toxicity. These high local levels of IL-12 expression results in a more effective approach to counteracting the immunosuppressive environment. In addition, there has been no evidence of cytokine release syndrome due to this increased expression of IL-12. The use of a DNA plasmid results in sustained expression of IL-12 for several days, compared to continual infusions required with recombinant IL-12, and shorter expression times for mRNA therapies.

OVATION-2 Results

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 1/3$^{rd}$ 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.

Recently, the company announced new translational data from the OVATION-2 trial, including results showing a 20% increase in IL-12 levels in women treated with 100mg/m$^2$ IMNN-001 compared to IL-12 levels in women treated with 79 mg/m$^2$ IMNN-001. The IL-12 levels were measured in peritoneal fluid, where the primary tumors are located, and there were little to no changes in systemic IL-12 levels of treated patients. The increase in IL-12 levels was accompanied by localized increases in interferon-gamma (IFN-$\gamma$) and tumor necrosis factor-alpha (TNF-$\alpha$). These results are indicative of the broad immune-modulating activities of IMNN-001 that are confined to the tumor microenvironment to limit any potential systemic toxicities.

Planning for Phase 3 Trial

In November 2024, Imunon announced it had reached alignment with the U.S. Food and Drug Administration (FDA) following an 'End-of-Phase 2' meeting on the company's proposed plan for a Phase 3 trial of IMNN-001 in patients with advanced ovarian cancer, including the trial strategy, overall trial design, target patient population, treatment schedule, and primary endpoint. In addition, in December 2024 the company announced a positive Type C Chemistry, Manufacturing, and Controls (CMC) meeting with the U.S. FDA in which alignment was reached regarding the production of IMNN-001, including the acceptability of the company's potency assay that measures interferon gamma is acceptable for both the Phase 3 clinical study and in a commercial setting for release of the drug. We continue to expect the Phase 3 trial will initiate before the end of the first quarter of 2025.

*Immunogenicity Data for IMNN-101*

On February 26, 2025, Imunon announced results from the Phase 1 proof-of-concept trial of IMNN-101, the company's investigational DNA plasmid vaccine. This study was conducted in 24 healthy adult volunteers and was designed to test the ability of IMNN-101 to induce an immune response to the SARS-CoV-2 Omicron XBB1.5 spike antigen. IMNN-101 was administered as a single dose in participants that were previously vaccinated against the Omicron XBB1.5 variant. The results of the trial showed that IMNN-101 induced a robust immune response as exemplified by a persistent 2- to 4-fold increase in serum neutralizing antibody titers from baseline through Week 4. In addition, IMNN-101 appeared to be safe and well tolerated and there were no serious adverse events reported. The participants in this trial had high baseline immune characteristics, which is presumably from prior COVID-19 infections and multiple previous vaccinations against COVID-19, and there were modest increases in T cell responses observed. The data is consistent with the PlaCCine platform being safe and well tolerated and algns with the strong immunogenicity and protective effects observed in pre-clinical studies. Immunon is continuing discussions with potential partners to advance development of its PlaCCine platform.

## Financial Update

On February 27, 2025, Imunon announced financial results for 2024. As expected, the company did not report any revenues in 2024 or 2023. The net loss for the year ending December 31, 2024 was $18.6 million compared to $19.5 million for the year ending December 31, 2023. R&D expenses in 2024 were $11.6 million, compared to $11.3 million in 2023. The increase was primarily due to increased costs associated with the PlaCCine vaccine study. G&A expenses in 2024 were $7.5 million, compared to $9.7 million in 2023. The decrease was primarily due to lower legal expenses, employee related costs, and non-cash stock compensation costs.

Imunon exited 2024 with approximately $5.9 million in cash and cash equivalents. We estimate this is enough to fund operations into late second quarter of 2025, however the company will need to raise a substantial amount of capital to conduct the upcoming Phase 3 trial of IMNN-001. Imunon currently has approximately 14.6 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 21.5 million.

## Conclusion

We're looking forward to the initiation of the Phase 3 trial for IMNN-101. We anticipate that the study will enroll relatively quickly given the overall survival benefit seen in the OVATION-2 study, which should translate to enthusiasm from both clinical investigators and patients. The company is continuing to weight its options for how best to fund the trial and we expect an update on its financing plans in the near future. With no changes to our model our valuation remains at $8 per share.

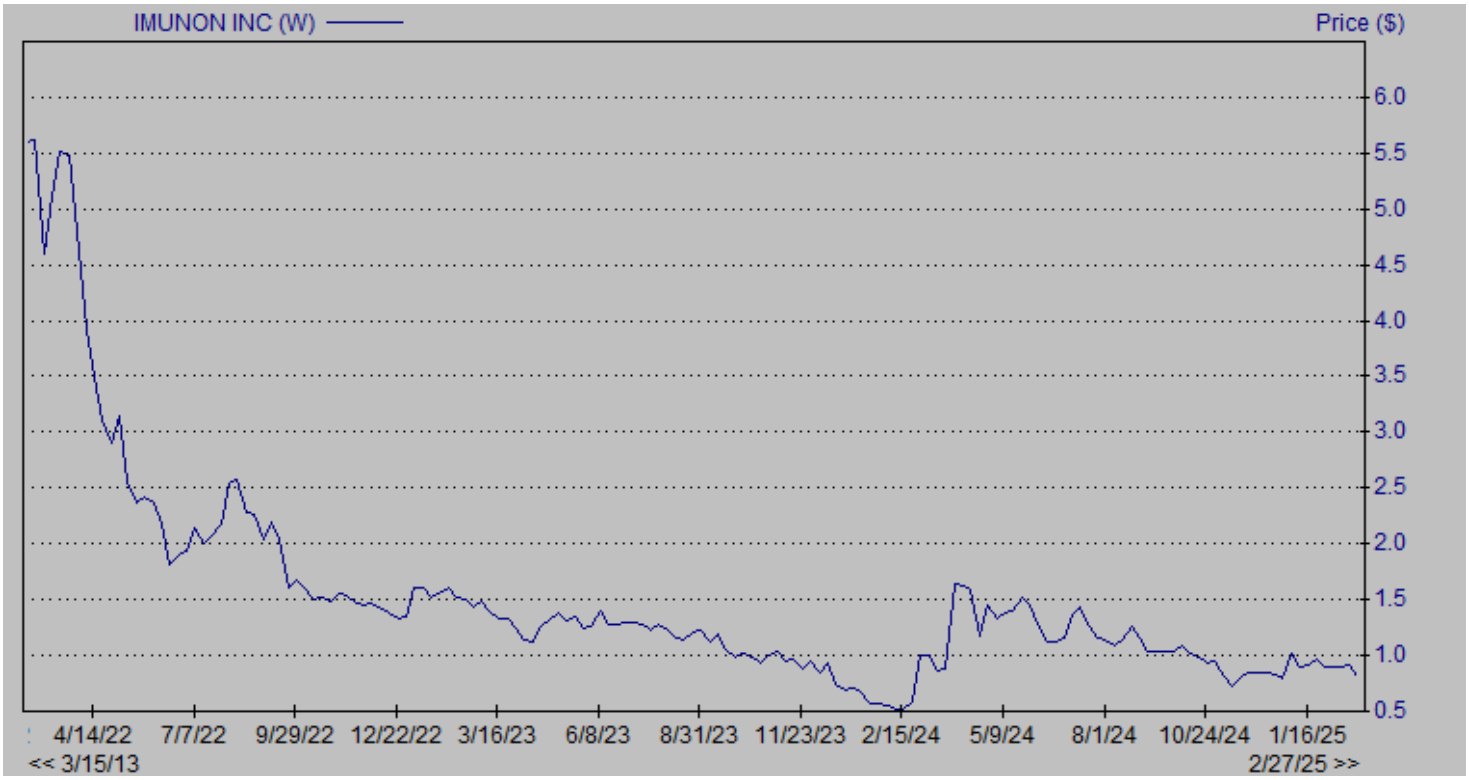
## PROJECTED FINANCIALS

| Imunon, Inc. | 2024 A | Q1 A | Q2 A | Q3 A | 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) |
| *Operating Margin* | - | - | - | - | - | - | - | - |
| 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 |
| *Tax Rate* | *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*

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## HISTORICAL STOCK PRICE




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