Zacks Small-Cap Research
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David Bautz, PhD
(312) 265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Imunon, Inc. (IMNN-NASDAQ)

IMNN: Promising Interim PFS and OS Data for IMNN-001 in OVATION 2 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 $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 (11/17/23)	$0.94
Valuation	**$15.00**

OUTLOOK

On September 28, 2023, Imunon, Inc. (IMNN) announced interim progression-free survival (PFS) and overall survival (OS) data for IMNN-001 in the Phase 1/2 OVATION 2 trial. The trial is evaluating the dosing, safety, and efficacy of intraperitoneal IMNN-001 in combination with neoadjuvant chemotherapy (NACT) in patients with newly diagnosed advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. The data showed 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 also followed a similar trend, showing an approximate 9-month improvement in the treatment arm over the control arm. A subgroup analysis showed that patients treated with a PARP inhibitor as maintenance therapy had longer PFS and OS if they were also treated with IMNN-001 compared to patients treated with NACT only. We continue to anticipate topline results from the trial in mid-2024.

SUMMARY DATA

52-Week High	**$1.66**
52-Week Low	**$0.93**
One-Year Return (%)	**-36.74**
Beta	**2.06**
Average Daily Volume (sh)	**24,686**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$9**
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 (%)	**-0.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2021 Estimate	**-0.4**
P/E using 2022 Estimate	**-0.5**

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)
2022	0.1 A	0.1 A	0.1 A	0.1 A	0.5 A
2023	0.0 A	0.0 A	0.0 A	0.0 E	0.0 E
2024					0.0 E
2025					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$1.82 A	-$0.87 A	-$0.87 A	-$1.70 A	-$5.03 A
2023	-$0.68 A	-$0.61 A	-$0.37 A	-$0.74 E	-$2.38 E
2024					-$2.84 E
2025					-$2.85 E

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WHAT'S NEW

Business Update

Encouraging Interim PFS and OS Data for IMNN-001 in OVATION 2 Trial

On September 28, 2023, Imunon, Inc. (IMNN) 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 was 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 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 20% 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. We continue to anticipate topline results from the trial in mid-2024.

IMNN-001 Combination Trial with Bevacizumab Underway

Imunon recently 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.

Update on PlaCCine Technology

IMNN-101 is the company's seasonal COVID-19 vaccine candidate that is derived from the PlaCCine platform. 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. The company has generated pre-clinical data showing robust immunogenicity in mice and complete viral clearance in non-human primates. Please see our previous report for an in-depth discussion of IMNN-101. Imunon continues on

track to file an Investigational New Drug (IND) application in the first quarter of 2024 for a Phase 1/2 trial with IMNN-101.

In August 2023, Imunon announced it entered into a Cooperative Research and Development Agreement (CRADA) with the National Institute of Allergy and Infectious Diseases (NIAID) to evaluate the immunogenicity and efficacy of two DNA-based Lassa virus vaccine candidates. Lassa virus causes Lassa fever, a viral hemorrhagic fever disease that causes approximately 5,000 deaths annually. Approximately 60 million people in West Africa are estimated to be at risk of contracting Lassa fever. The three year agreement calls for the NIAID to assess the efficacy of DNA constructs against Lass virus in guinea pig and non-human primate disease models, including both prime and prime-boost strategies.

Financial Update

On November 14, 2023, Imunon announced financial results for the third quarter of 2023. As expected, the company did not report any revenue during the third quarter of 2023. R&D expenses in the third quarter of 2023 were $2.0 million compared to $2.4 million in the third quarter of 2022. The decrease was primarily due to lower costs associated with the OVATION 2 study, the OPTIMA study, and other clinical and regulatory costs partially offset by increases in costs associated with the Placcine DNA vaccine technology platform and CMC cost increases. G&A expenses in the third quarter of 2023 were $1.9 million compared to $3.9 million for the third quarter of 2022. The decrease was primarily due to lower non-cash stock based compensation, employee-related costs, legal expenses, and insurance costs.

As of September 30, 2023, Imunon had approximately $19.4 million in cash, cash equivalents, and accrued interest. The company also has approximately $1.8 million of future planned sales of its State of New Jersey net operating losse. We estimate that the company has sufficient capital to fund operations into 2025. 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

The preliminary PFS and OS data from the OVATION 2 trial are very encouraging and we look forward to topline results from the trial in mid-2024. The Placcine technology could represent a major improvement in vaccine technology and we look forward to updates from the company on the IND submission and the Phase 1/2 clinical trial next year. With no changes to our model our valuation remains at $15 per share.

PROJECTED FINANCIALS

Imunon, Inc.	2022 A	Q1 A	Q2 A	Q3 A	Q4 E	2023 E	2024 E	2025 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	$0.5	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.5**	**$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	$11.7	$2.6	$3.1	$2.0	$3.3	$11.0	$13.5	$14.0
SG&A	$13.7	$3.1	$2.3	$1.9	$3.7	$11.0	$14.3	$14.5
Operating Income	($24.9)	($5.7)	($5.5)	($3.9)	($7.0)	($22.1)	($27.8)	($28.5)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	($12.5)	$0.1	$0.1	$0.4	$0.0	$0.4	$0.0	$0.0
Pre-Tax Income	($37.5)	($5.6)	($5.6)	($3.5)	($7.0)	($21.6)	($27.8)	($28.5)
Taxes & Other	($1.6)	$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	($35.9)	($5.6)	($5.6)	($3.5)	($7.0)	($21.6)	($27.8)	($28.5)
Reported EPS	**($5.03)**	**($0.68)**	**($0.61)**	**($0.37)**	**($0.74)**	**($2.38)**	**($2.84)**	**($2.85)**
Weighted Shares Outstanding	7.1	8.3	9.1	9.4	9.5	9.1	9.8	10.0

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

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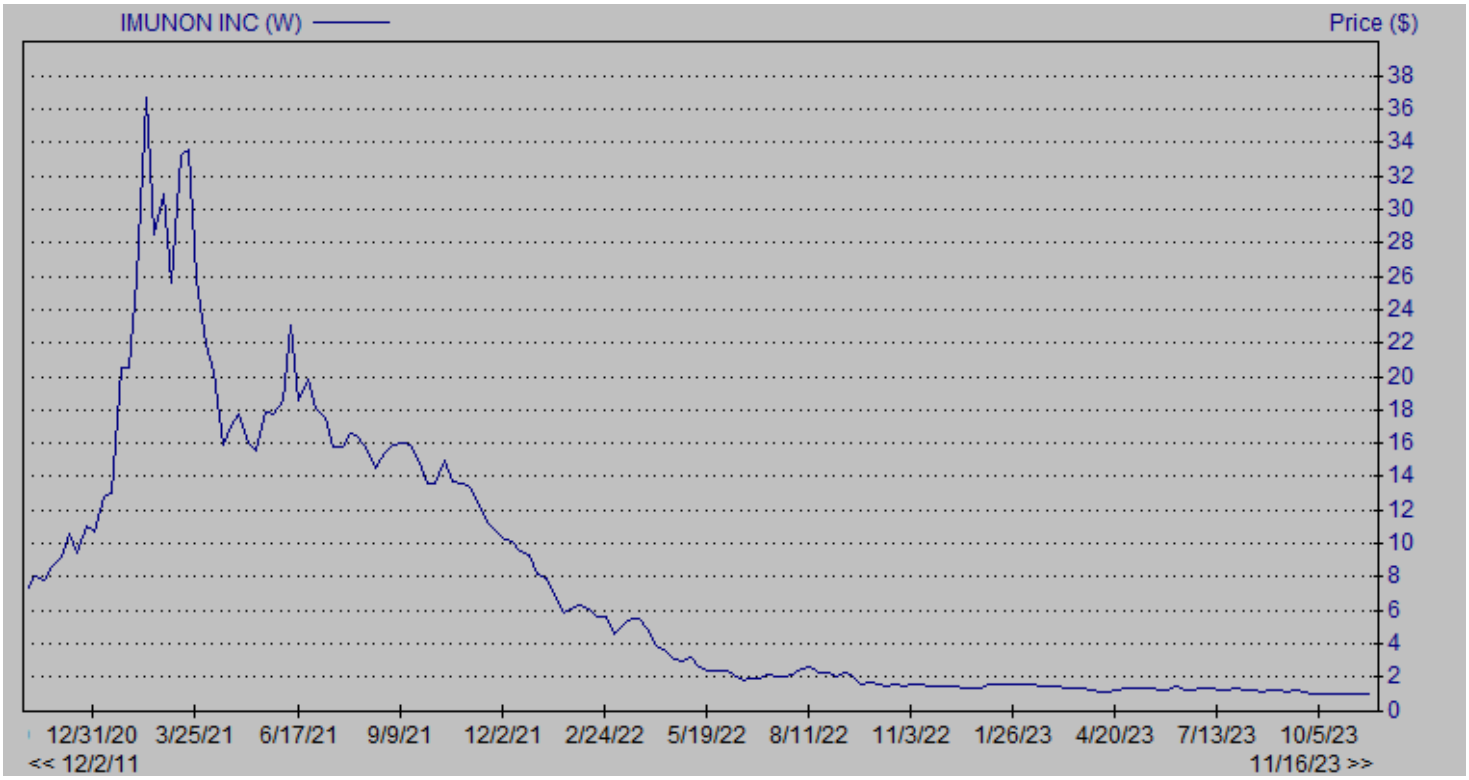
HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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