Zacks Small-Cap Research
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MediciNova, Inc. (MNOV-NASDAQ)

MNOV: Encouraging Interim Analysis for Phase 2b/3 ALS Trial…

Based on our probability adjusted DCF model that takes into account potential future revenues from MN-166 in ALS and as an MCM; and MN-001 in MASLD, MNOV is valued at $10.00/share. This model is highly dependent upon continued clinical success of the company's assets and will be adjusted accordingly based upon future clinical results.

Current Price (12/09/24)	$2.34
Valuation	**$10.00**

OUTLOOK

On December 5, 2024, MediciNova, Inc. (MNOV) announced a study update and interim analysis from the Phase 2b/3 COMBAT-ALS trial were scheduled to be presented at the 35th International Symposium on ALS/MND. As of Nov. 15, 2024, 217 participants had been enrolled and 183 participants were assigned to either MN-166 or placebo. Positive correlations were seen between the 6-month and 12-month data for the Combined Assessment of Function and Survival (CAFS) scores (0.71), modified CAFS score (0.70), and ASLFRS-R (0.69). The DSMB has recommended that the trial continue as per the protocol. Based on current enrollment, the study is expected to be fully enrolled by mid-2025 and trial results should be reported in 2026.

SUMMARY DATA

52-Week High	**$2.38**
52-Week Low	**$1.13**
One-Year Return (%)	**37.65**
Beta	**0.84**
Average Daily Volume (sh)	**174,635**
Shares Outstanding (mil)	**49**
Market Capitalization ($mil)	**$115**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**15**
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	**N/A**
P/E using 2025 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	0 A	0 A	1 A	0 A	1 A
2024	0 A	0 A	0 A	0 E	0 E
2025					0 E
2026					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.06 A	-$0.06 A	-$0.01 A	-$0.08 A	-$0.21 A
2024	-$0.06 A	-$0.05 A	-$0.06 A	-$0.06 E	-$0.23 E
2025					-$0.24 E
2026					-$0.24 E

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WHAT'S NEW

Business Update

Encouraging Interim Results from Phase 2b/3 COMBAT-ALS Trial

On December 5, 2024, MediciNova, Inc. (MNOV) announced a poster presentation at the 35th International Symposium on ALS/MND would feature a study update and interim analysis results from the ongoing Phase 2b/3 COMBAT-ALS trial of MN-166 (ibudilast).

As of November 15, 2024, the trial has enrolled a total of 217 participants and 183 participants have been randomly assigned to treatment with either placebo or MN-166. A pre-defined interim analysis was performed to evaluate the correlation between the 6-month and 12-month data as well as assessing the 12-month double blind phase trial design. A correlation analysis was performed on the (CAFS) scores, modified CAFS scores, and ALSFRS-R scores at six and 12 months.

There was a positive correlation for the 6- and 12-month data for CAFS score (0.71), modified CAFS score (0.70), and ALSFRS-R (0.69). The numbers in parentheses represent Spearman Rank Correlation coefficients, which indicates the strength and direction between two sets of data. In practical terms, a coefficient of 0.7 indicates a strong, positive correlation. Positive correlations were also seen for Bulbar score (0.74), fine motor score (0.71), and gross motor score (0.67), however no correlation was seen for respiratory score. Overall, these data support the company's use of a 12-month, double blind trial design. This was further validated by the Data Safety Monitoring Board (DSMB), which reviewed the data and recommended that the trial continue as per protocol.

Based on the current enrollment rate, we estimate that the trial will be fully enrolled by mid-2025, which would lead to release of topline results in 2026.

In addition to the COMBAT-ALS trial, we anticipate the initiation of an Expanded Access Protocol (EAP) trial to evaluate the effect of MN-166 treatment on blood levels of neurofilament light (NfL) in patients with ALS in 2025. That trial is being supported by a $22 million grant from the National Institutes of Health (NIH) – Neurological Disorders and Stroke (NINDS) with MediciNova providing drug product, regulatory support, and safety monitoring support.

Conclusion

The encouraging update on the Phase 2b/3 COMBAT-ALS trial is a good sign for the company as it moves to finish enrollment in the trial by mid-2025. It's not possible to draw any conclusions regarding the efficacy of MN-166 from the data, however a positive correlation between the 6- and 12-month data is indicative that it will be a robust data set. Assuming the trial can be fully enrolled by mid-2025 we anticipate topline results in 2026. With no changes to our model, our valuation remains at $10 per share.

PROJECTED FINANCIALS

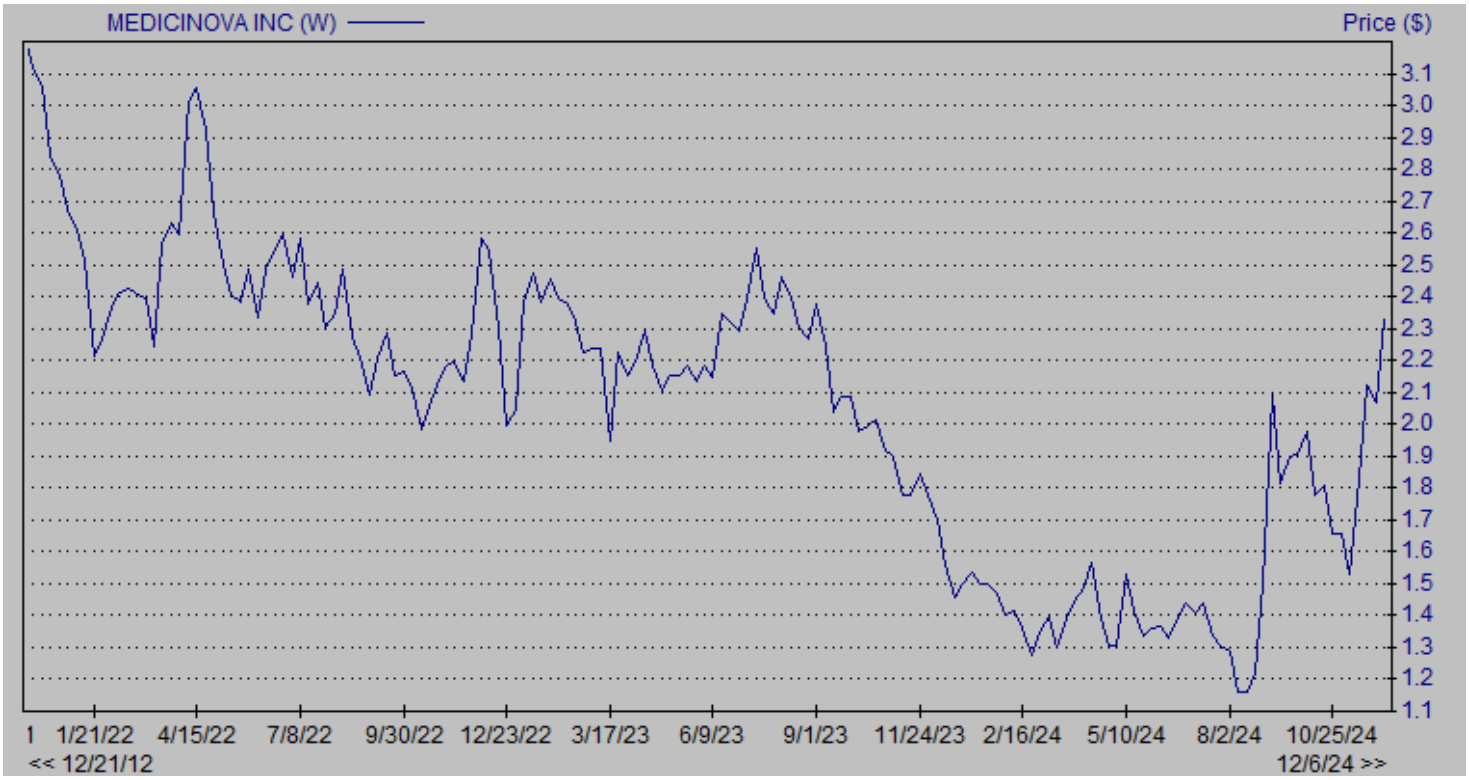
MediciNova Inc.
Income Statement

MediciNova, Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
MN-166 (ALS)	$0	$0	$0	$0	$0	$0	$0	$0
MN-166 (GBM)	$0	$0	$0	$0	$0	$0	$0	$0
MN-001 (NASH)	$0	$0	$0	$0	$0	$0	$0	$0
Grants & Collaborative Revenue	$1	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$1**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$5.7	$1.8	$1.6	$1.9	$1.5	$6.8	$6.0	$6.3
General & Administrative	$5.2	$1.4	$1.4	$1.4	$1.5	$5.7	$5.7	$5.8
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($9.9)	($3.1)	($3.0)	($3.3)	($3.0)	($12.5)	($11.7)	($12.1)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$1.3	$0.4	$0.4	$0.5	$0.0	$1.3	$0.0	$0.0
Pre-Tax Income	($8.6)	($2.8)	($2.6)	($2.9)	($3.0)	($11.2)	($11.7)	($12.1)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($8.6)**	**($2.8)**	**($2.6)**	**($2.9)**	**($3.0)**	**($11.2)**	**($11.7)**	**($12.1)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.17)**	**($0.06)**	**($0.05)**	**($0.06)**	**($0.06)**	**($0.23)**	**($0.24)**	**($0.24)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	49.046	49.046	49.046	49.046	49.050	49.047	49.200	49.500

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

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HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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