

2024年10月2日

## Zacks Small-Cap Researchによる当社レポートの発表に関するお知らせ

現地時間の9月30日、米国シカゴに本拠を置く投資家向け情報サービス企業 Zacks Small-Cap Research の David Bautz 氏による、当社レポートが発表されましたので、参考情報としてお知らせいたします。

なお、当該レポートは、恐れ入りますが、権利の都合上、英文のままのご案内となりますので、ご了承ください。

【Zacks Small-Cap Research 公式 web サイト】

<https://scr.zacks.com/>

※当該レポートは、本書の下部にありますので、スクロールしてご確認ください。

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## MediciNova, Inc.

(MNOV-NASDAQ)

### **MNOV: MN-166 to be Evaluated in NIH-Sponsored Expanded Access Trial in ALS...**

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 (09/30/24) **\$1.91**  
Valuation **\$10.00**

### OUTLOOK

On September 30, 2024, MediciNova, Inc. (MNOV) announced that MN-166 (ibudilast) will be evaluated in a National Institutes of Health (NIH) – Neurological Disorders and Stroke (NINDS) sponsored Expanded Access Protocol (EAP) trial that will be supported by a \$22 million grant to an academic group. The EAP trial will enroll approximately 200 patients with amyotrophic lateral sclerosis (ALS) and will measure MN-166's effect on neurofilament light, a biomarker for neuron damage. MediciNova will provide investigational drug, regulatory support, and safety monitoring support. The EAP program allows patients with serious or life-threatening diseases or conditions to gain access to an investigational product for treatment outside of a clinical trial when no effective therapy options exist.

### SUMMARY DATA

52-Week High **\$2.12**  
52-Week Low **\$1.13**  
One-Year Return (%) **-8.61**  
Beta **0.72**  
Average Daily Volume (sh) **75,390**

Shares Outstanding (mil) **49**  
Market Capitalization (\$mil) **\$94**  
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 **Above Avg.**  
Type of Stock **Small-Value**  
Industry **Med-Biomed/Gene**

### ZACKS ESTIMATES

	Revenue				
	(In millions of \$)				
	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2023	0 A	0 A	1 A	0 A	1 A
2024	0 A	0 A	0 E	0 E	0 E
2025					0 E
2026					0 E

	Earnings per Share				
	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(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 E	-\$0.06 E	-\$0.23 E
2025					-\$0.24 E
2026					-\$0.24 E

## WHAT'S NEW

### Business Update

#### *MN-166 to be Evaluated in NIH-Sponsored EAP Trial in ALS*

On September 30, 2024, MediciNova, Inc. (MNOV) [announced](#) that MN-166 (ibudilast) will be evaluated in an Expanded Access Protocol (EAP) trial to evaluate its efficacy in patients with amyotrophic lateral sclerosis (ALS). The EAP is being supported through a \$22 million grant from the National Institutes of Health (NIH) – Neurological Disorders and Stroke (NINDS) to an academic group lead by the Mayo Clinic. MediciNova will provide MN-166 drug product, regulatory support, and safety monitoring support.

Approximately 200 ALS patients will be enrolled and treated with MN-166 for six months with the primary outcome being an evaluation of its effect on blood levels of neurofilament light (NfL), which is a biomarker of neuron damage that has previously been shown to be prognostic of ALS disease progression ([Gaiani et al., 2017](#)).

Support for this program derives from the Accelerating Access to Critical Therapies for ALS Act ([ACT for ALS](#)), a bill signed into law by President Biden in December 2021. The bill called for a research grant program at NIH that utilizes the U.S. Food and Drug Administrations (FDA) EAP to evaluate experimental drugs for individuals that are not eligible for ALS clinical trials.

MN-166 is currently being evaluated in the Phase 2b/3 COMBAT-ALS trial. MediciNova recently announced two upcoming poster presentations that will provide an overview and update of the trial:

- In October 2024, a poster will be presented at the 2024 Annual NEALS Meeting by lead Principal Investigator, Björn Oskarsson, MD, Associate Professor of Neurology
- In December 2024, Dr. Oskarsson will present a poster at the 35<sup>th</sup> International Symposium on ALS/MND

### Conclusion

The \$22 million grant to evaluate MN-166 in an additional cohort of ALS patients shows the NIH is committed to opening access to experimental treatments to as many ALS patients as possible. We will be interested to see how MN-166 affects NfL levels, particularly given the increased focus on that biomarker in recent years and we look forward to updates on the trial as warranted. With no changes to our model our valuation remains at \$10 per share.

## PROJECTED FINANCIALS

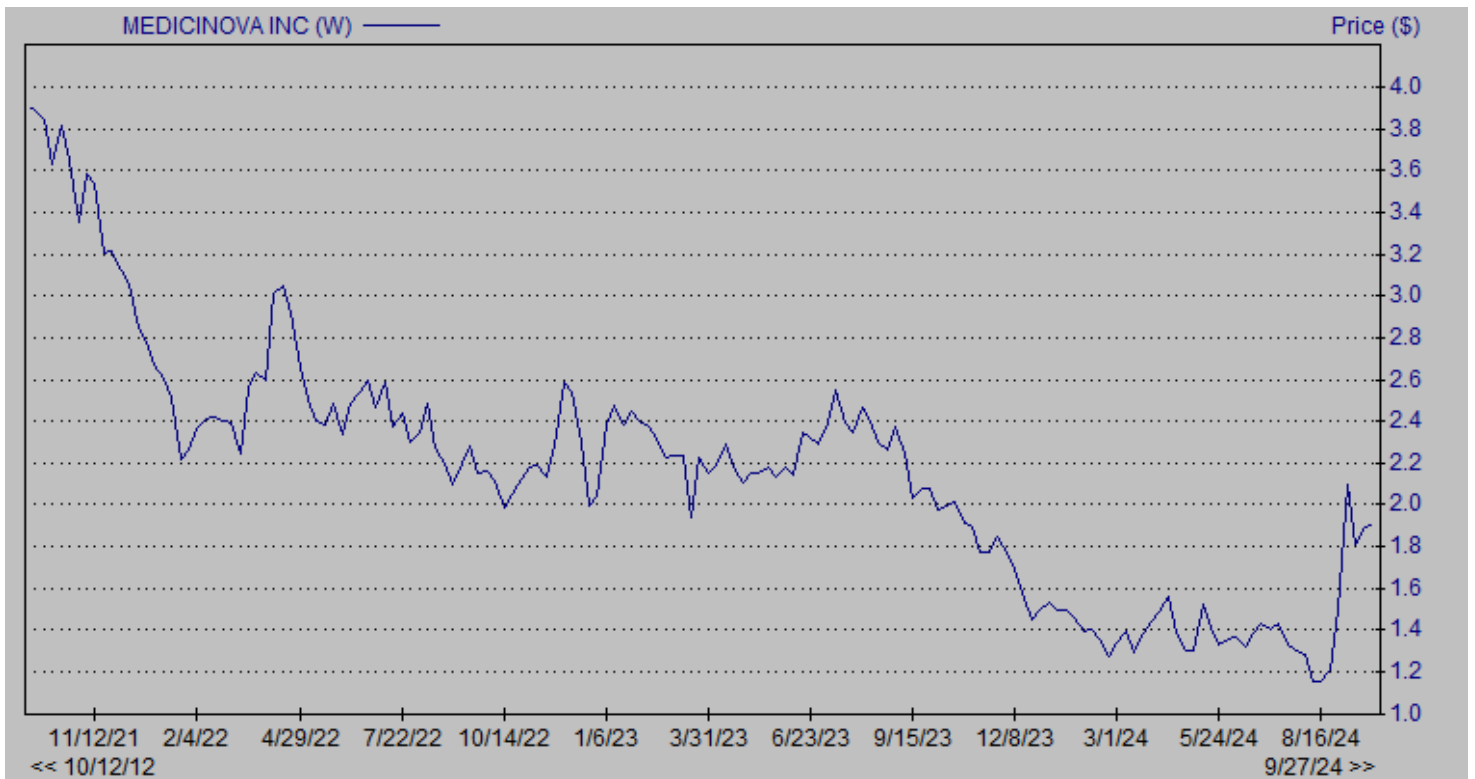
### MediciNova Inc. Income Statement

MediciNova, Inc.	2023 A	Q1 A	Q2 A	Q3 E	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
<b>Total Revenues</b>	<b>\$1</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>
Cost of Sales	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Product Gross Margin</i>	-	-	-	-	-	-	-	-
Research & Development	\$5.7	\$1.8	\$1.6	\$1.5	\$1.5	\$6.4	\$6.0	\$6.3
General & Administrative	\$5.2	\$1.4	\$1.4	\$1.4	\$1.5	\$5.6	\$5.7	\$5.8
Other Expenses	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<b>Operating Income</b>	<b>(\$9.9)</b>	<b>(\$3.1)</b>	<b>(\$3.0)</b>	<b>(\$2.9)</b>	<b>(\$3.0)</b>	<b>(\$12.0)</b>	<b>(\$11.7)</b>	<b>(\$12.1)</b>
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	\$1.3	\$0.4	\$0.4	\$0.0	\$0.0	\$0.8	\$0.0	\$0.0
<b>Pre-Tax Income</b>	<b>(\$8.6)</b>	<b>(\$2.8)</b>	<b>(\$2.6)</b>	<b>(\$2.9)</b>	<b>(\$3.0)</b>	<b>(\$11.2)</b>	<b>(\$11.7)</b>	<b>(\$12.1)</b>
Income Taxes Paid	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
<b>Net Income</b>	<b>(\$8.6)</b>	<b>(\$2.8)</b>	<b>(\$2.6)</b>	<b>(\$2.9)</b>	<b>(\$3.0)</b>	<b>(\$11.2)</b>	<b>(\$11.7)</b>	<b>(\$12.1)</b>
<i>Net Margin</i>	-	-	-	-	-	-	-	-
<b>Reported EPS</b>	<b>(\$0.17)</b>	<b>(\$0.06)</b>	<b>(\$0.05)</b>	<b>(\$0.06)</b>	<b>(\$0.06)</b>	<b>(\$0.23)</b>	<b>(\$0.24)</b>	<b>(\$0.24)</b>
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
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

# HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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