2023年11月28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11月27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。

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https://scr.zacks.com/

※当該レポートは、本書の下部にございますので、スクロールしてご確認ください。

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Sponsored – Impartial - Comprehensive

November 27, 2023
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MediciNova, Inc. (MNOV-NASDAQ)

MNOV: Encouraging Phase 2 Glioblastoma Results Presented at SNO…

Based on our probability adjusted DCF model that takes into account potential future revenues from MN-166 in ALS, progressive MS, addiction, and as an MCM; and MN-001 in NAFLD, MNOV is valued at $27.00/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 (11/27/23)	$1.85
Valuation	**$27.00**

OUTLOOK

On November 19, 2023, MediciNova, Inc. (MNOV) announced new data and results of a Phase 2 clinical trial of MN-166 (ibudilast) in glioblastoma (GBM) were presented at the 28th Annual Meeting of the Society for Neuro-Oncology (SNO). The presentation included data from preclinical studies that evaluated the combination of MN-166 and anti-PD1 or anti-PD-L1 therapy in GBM mouse models. Results from the Phase 2 study showed progression-free survival at six months was 44% for new GBM patients and 31% for recurrent GBM patients. The preclinical results showed a statistically significant increase in survival for the mice treated with MN-166 and either an anti-PD1 or anti-PD-L1 antibody. These encouraging results may lead to development of MN-166 as a combination therapy for GBM.

SUMMARY DATA

52-Week High	**$2.66**
52-Week Low	**$1.74**
One-Year Return (%)	**-19.21**
Beta	**0.91**
Average Daily Volume (sh)	**252,576**
Shares Outstanding (mil)	**49**
Market Capitalization ($mil)	**$91**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**11**
Insider Ownership (%)	**17**
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 2023 Estimate	**N/A**
P/E using 2024 Estimate	**N/A**

Risk Level	**Average**
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 A	0 A	0 A	0 A	0 A
2023	0 A	0 A	1 A	0 E	1 E
2024					0 E
2025					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$0.07 A	-$0.08 A	-$0.07 A	-$0.06 A	-$0.29 A
2023	-$0.06 A	-$0.06 A	-$0.01 A	-$0.08 E	-$0.21 E
2024					-$0.32 E
2025					-$0.35 E

WHAT'S NEW

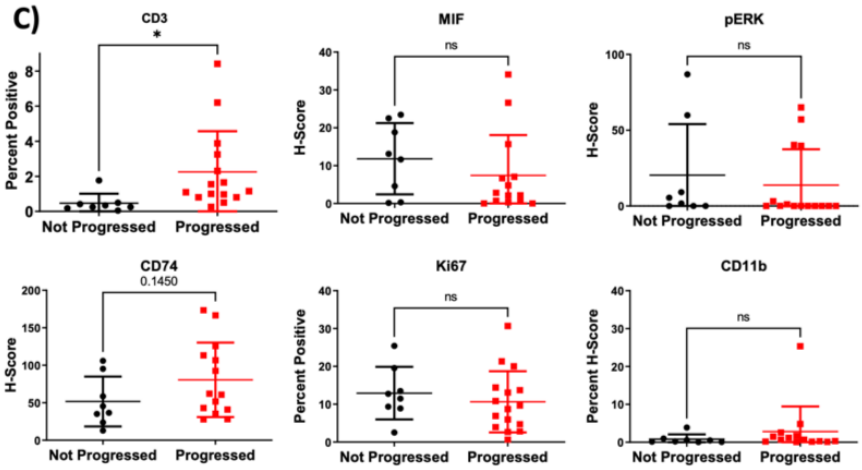
Business Update

New Data for MN-166 in GBM Presented at SNO

On November 19, 2023, MediciNova, Inc. (MNOV) announced new data and results of a Phase 2 clinical trial of MN-166 (ibudilast) in glioblastoma (GBM) were presented at the 28th Annual Meeting of the Society for Neuro-Oncology (SNO) (Lauko *et al*., 2023).

The Phase 2 clinical trial enrolled 62 GBM patients (36 newly diagnosed and 26 recurrent) who were treated with a combination of MN-166 and temozolomide (TMZ) until disease progression or withdrawal from the study for other reasons. The rationale for combining MN-166 with TMZ comes from previous studies in which it was shown that GBM patients who were "poor responders" overexpressed macrophage migration inhibitory factor (MIF) and that the combination of MN-166 with TMZ resulted in significant synergism in cell cycle arrest and apoptosis *in vitro* and resulted in significantly longer survival in a patient-derived xenograft mouse model (Ha *et al*., 2019). In addition, MN-166 is a MIF-CD74 interaction inhibitor that reduces immune-suppressive myeloid-derived suppressor cell (MDSC) generation and reverses their T cell suppressive capacity *in vitro* (Alban *et al*., 2020). The reversal of T cell suppressive activity also supports testing an immune checkpoint inhibitor in combination with MN-166 to determine if it can further increase immune cell activation and improve clinical outcomes.

Immunohistochemistry evaluation was performed with pre-treatment tumor tissue samples to determine any correlation between the expression of CD3, CD74, MIF, pERK, Ki67, and CD11b and patients that progressed following five months of treatment with MN-166 and those that did not. The following graph shows that CD3 expression correlated with response to MN-166 treatment (i.e., patients with tumor progression had higher CD3 tumor infiltration than patients with no progression, $P<0.05$) while expression of none of the other factors showed a significant correlation.



Source: Lauko *et al*, 2023

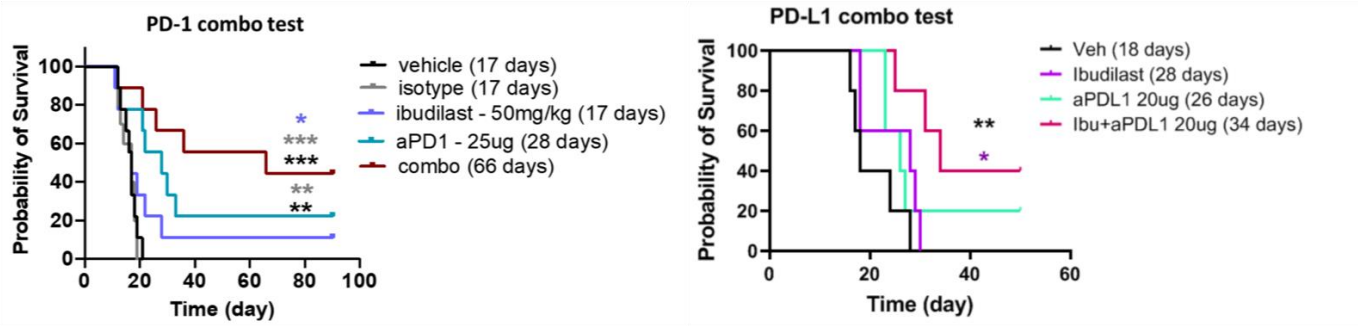
The following table shows six-month progression-free survival (PFS6) results for patients that received at least five cycles of MN-166. In patients with newly diagnosed GBM the PFS6 was 44% while for recurrent GBM the PFS6 was 31%.

Subject Type (N=62)	PFS6 n (%)
Newly Diagnosed (n=36)	16 (44%)
Recurrent (n=26)	8 (31%)

Table 2. Six-month progression free survival of patients that received at least 5 cycles of MN-166

Source: Lauko *et al*, 2023

Lastly, the combination of MN-166 and anti-PD-1 or anti-PD-L1 was examined in preclinical GBM models. The following graphs show that MN-166 and both anti-PD-1 and anti-PD-L1 show synergy in treating mice harboring SB28 tumor cells with substantial increases in survival when comparing the combination treatment to anti-PD-1 alone (66 days vs. 28 days) and to anti-PD-L1 alone (34 days vs. 26 days). These encouraging results support the potential testing of MN-166 and immune checkpoint inhibitor therapy in treating GBM patients.



Source: Lauko *et al*, 2023

Financial Update

On November 9, 2023, MediciNova filed Form 10-Q with financial results for the third quarter of 2023. The company reported revenues of $1.0 million in the third quarter of 2023 compared to $0.0 million of revenues for the third quarter of 2022. The revenue is derived from a milestone payment from MediciNova's partner Genzyme based on dosing the first patient in a clinical trial of SAR444836, a phenylalanine hydroxylase replacement gene therapy product based on adeno-associated virus (AAV) vector technology that is covered under MediciNova's assignment agreement with Genzyme Corporation. We believe that additional milestone payments may be possible in the future, which could serve as a source of additional non-dilutive capital.

R&D expenses in the third quarter of 2023 were $0.8 million compared to $2.5 million in the third quarter of 2022. The decrease was primarily due to a decrease in manufacturing expenses and the receipt of $0.7 million from BARDA for partial reimbursement of preclinical study costs. G&A expenses were $1.4 million in both the third quarter of 2023 and 2022.

Net cash used in operating activities was $1.4 million for the third quarter of 2023. MediciNova exited the third quarter of 2023 with approximately $51.5 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations for at least the next few years. As of November 7, 2023, the company had approximately 49.0 million shares outstanding and when factoring in stock options a fully diluted share count of approximately 57.3 million.

Conclusion

We expect that the encouraging results from the Phase 2 trial of MN-166 in GBM along with the preclinical results showing synergism between MN-166 and immune checkpoint inhibitor therapy could lead to an additional clinical trial of MN-166 in GBM and we look forward to updates from the company on that program. The gene therapy milestone payments are an excellent source of non-dilutive capital, something which is nice for the company to have during the current difficult market conditions. With no changes to our model our valuation remains at $27 per share.

PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2022 A	Q1 A	Q2 A	Q3 A	Q4 E	2023 E	2024 E	2025 E
MN-166 (Multiple Sclerosis)	$0	$0	$0	$0	$0	$0	$0	$0
MN-166 (ALS)	$0	$0	$0	$0	$0	$0	$0	$0
MN-166 (DCM)	$0	$0	$0	$0	$0	$0	$0	$0
MN-001 (NASH)	$0	$0	$0	$0	$0	$0	$0	$0
Grants & Collaborative Revenue	$0	$0	$0	$1	$0	$1	$0	$0
Total Revenues	**$0**	**$0**	**$0**	**$1**	**$0**	**$1**	**$0**	**$0**
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$9.1	$1.5	$1.7	$0.8	$2.6	$6.6	$10.0	$11.0
General & Administrative	$5.5	$1.5	$1.6	$1.4	$1.6	$6.0	$6.0	$6.5
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($14.6)	($3.0)	($3.3)	($1.1)	($4.2)	($11.6)	($16.0)	($17.5)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.6	$0.0	$0.4	$0.4	$0.2	$1.1	$0.1	$0.1
Pre-Tax Income	($14.1)	($2.9)	($2.9)	($0.7)	($4.0)	($10.5)	($15.9)	($17.4)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($14.1)**	**($2.9)**	**($2.9)**	**($0.7)**	**($4.0)**	**($10.5)**	**($15.9)**	**($17.4)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.29)**	**($0.06)**	**($0.06)**	**($0.01)**	**($0.08)**	**($0.21)**	**($0.32)**	**($0.35)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	49.045	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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