

MediciNova, Inc.

(MNOV-NASDAQ)

MNOV: Addition of MN-166 to PD-1 Treatment Extends Survival in Preclinical GBM Model...

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 NASH, 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 (11/23/21) **\$3.07**
Valuation \$27.00

OUTLOOK

On November 22, 2021, MediciNova, Inc. (MNOV) announced a presentation on new preclinical data for MN-166 (ibudilast) in a preclinical model of glioblastoma (GBM). The study analyzed a PD-1 inhibitor alone and in combination with MN-166. Treatment with the PD-1 inhibitor extended survival to 28 days, compared to 17 days with vehicle control or a non-specific antibody. Combination therapy of MN-166 and a PD-1 inhibitor led to a statistically significant increase in survival time to 66 days ($P < 0.001$). Prior research showed that MN-166 reduced myeloid-derived suppressor cells (MDSCs) and increased CD8+ T cells. MN-166 is currently being evaluated in a Phase 2 GBM clinical trial in combination with temozolomide with an additional clinical trial of MN-166 in combination with a PD-1 inhibitor likely.

SUMMARY DATA

52-Week High **\$8.74**
 52-Week Low **\$3.07**
 One-Year Return (%) **-48.23**
 Beta **1.33**
 Average Daily Volume (sh) **99,978**

Shares Outstanding (mil) **49**
 Market Capitalization (\$mil) **\$151**
 Short Interest Ratio (days) **N/A**
 Institutional Ownership (%) **17**
 Insider Ownership (%) **16**

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 2018 Estimate **N/A**
 P/E using 2019 Estimate **N/A**

Risk Level
 Type of Stock
 Industry
 Average Small-Value Med-Biomed/Gene

ZACKS ESTIMATES

	Revenue (In millions of \$)				
	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	0 A	0 A	0 A	0 A	0 A
2021	4 A	0 A	0 A	0 E	0 E
2022					0 E
2023					0 E

	Earnings per Share				
	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-\$0.06 A	-\$0.10 A	-\$0.08 A	-\$0.07 A	-\$0.31 A
2021	-\$0.00 A	-\$0.09 A	-\$0.07 A	-\$0.10 E	-\$0.26 E
2022					-\$0.37 E
2023					-\$0.39 E

WHAT'S NEW

Business Update

MN-166 in Combination with PD-1 Inhibitor Extends Survival in Preclinical Model

On November 22, 2021, MediciNova, Inc. (MNOV) [announced](#) results from a preclinical study of MN-166 (ibudilast) in combination with a PD-1 inhibitor presented at the 26th Annual Meeting of the Society for Neuro-Oncology (SNO). The data were from a study of MN-166 and a PD-1 inhibitor in a glioblastoma (GBM) preclinical model. Following injection of GBM orthotopic tumors, mice were treated with control, a non-specific antibody, or a PD-1 antibody alone and in combination with MN-166. Treatment initiated seven days following tumor engraftment and consisted of three intraperitoneal injections three days apart. Median survival for mice treated with control or a non-specific antibody was 17 days. For mice treated with the PD-1 antibody, median survival was 28 days. However, when MN-166 was used in combination with the PD-1 antibody, median survival was significantly extended to 66 days ($P<0.001$). In earlier research, MN-166 reduced myeloid-derived suppressor cells (MDSCs) and increased CD8⁺ T cells in the tumor microenvironment.

This data builds upon previous preclinical data presented for MN-166 showing its efficacy in a preclinical GBM model when used in combination with temozolomide. MN-166 is currently being evaluated in a Phase 2 clinical trial in newly diagnosed and recurrent GBM patients in combination with temozolomide. We believe a separate clinical trial of MN-166 in combination with a PD-1 inhibitor is likely based upon the new results discussed above.

Investigation of Mechanism of MN-001 in Triglyceride Metabolism

On November 11, 2021, MediciNova announced the presentation of results from a study investigating the mechanism by which MN-001 (tipelukast) alters triglyceride (TG) metabolism in hepatocytes at The Liver Meeting 2021. The study involved the treatment of HepG2 cells with arachidonic acid (AA), LXR agonist T0901317, and MN-001 either alone or in various combinations. Compared to vehicle, T0901317 increased TG synthesis by 3.8-fold, AA alone increased TG synthesis by 15.3-fold, and the combination of T0901317 + AA increased TG synthesis by 24.3-fold. The addition of MN-001 decreased TG synthesis when added in combination with T0901317 or AA. Compared to MN-001 alone, MN-001 + T0901317 increased TG synthesis by 1.7-fold, AA + MN-001 increased TG synthesis by 3.7-fold, and the combination of T0901317 + AA + MN-001 increased TG synthesis by 3.7-fold.

The mechanism by which MN-001 decreases TG synthesis appears to be due to a decrease in CD36 expression. CD36 is one of the receptors responsible for fatty acid uptake into hepatocytes, thus the inhibition of CD36 expression may explain its ability to lower TG levels.

As reported previously by MediciNova, MN-001 reduced TG in 14/15 patients in the company's Phase 2 clinical trial in patients with non-alcoholic steatohepatitis (NASH) and non-alcoholic fatty liver disease (NAFLD). The average pre-treatment serum triglyceride level was 328.6 mg/dL, which was reduced to an average 192.9 mg/dL following eight weeks of treatment (-41.3%, $P=0.02$). The company is in the planning stage for a clinical trial of MN-001 in patients with NASH.

New Data Presented on MN-166 in Uveal Melanoma

On Nov. 10, 2021, MediciNova [announced](#) the presentation of data regarding MN-166 in a uveal melanoma (UV) model study at the 10th Annual CURE OM Global Science Meeting. Uveal melanoma is a cancer of the eye and is the second most common primary malignant melanoma in the body. There are currently no effective treatments for uveal melanoma, and approximately 50% of patients will develop metastasis, typically to the liver.

UM exosomes were investigated in a co-culture migration assay and in a mouse metastatic model. They induce activation of cell signaling pathways and the release of cytokines and growth factors from hepatocytes. Macrophage migration inhibitory factor (MIF) was involved in these mechanisms and blocking it inhibited cell migration and prevented metastases *in vivo*. MN-166, a MIF inhibitor, decreased bioluminescence intensity for each animal in a mouse model of UM ($P<0.05$) and also prevented metastasis. These data suggest that MN-166 may be effective in treating UM.

Financial Results

On November 12, 2021, MediciNova (MNOV) filed form 10-Q with financial results for the third quarter of 2021. R&D expenses in the third quarter of 2021 were \$2.1 million, compared to \$2.2 million for the third quarter of 2020. The decrease was primarily due to lower stock-based compensation. G&A expenses in the third quarter of 2021 were \$1.6 million, compared to \$1.5 million for the third quarter of 2020. The increase was primarily due to higher legal and consulting fees.

MediciNova exited the third quarter of 2021 with approximately \$75.0 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations at least through the end of 2022. As of November 9, 2021, MediciNova had approximately 49.0 million shares outstanding and, when factoring in stock options, a fully diluted share count of approximately 57.1 million shares.

Conclusion

The new data recently presented for MN-166 show its potential in a number of different indications and we look forward to updates about these programs. In addition to the aforementioned, MediciNova is continuing to advance MN-166 in a Phase 3 trial in amyotrophic lateral sclerosis (ALS), a Phase 3 trial for degenerative cervical myelopathy (DCM), a Phase 2 trial for chemotherapy-induced peripheral neuropathy (CIPN), and is Phase 3 ready for progressive multiple sclerosis (MS). With no changes to our model our valuation remains at \$27.

PROJECTED FINANCIALS

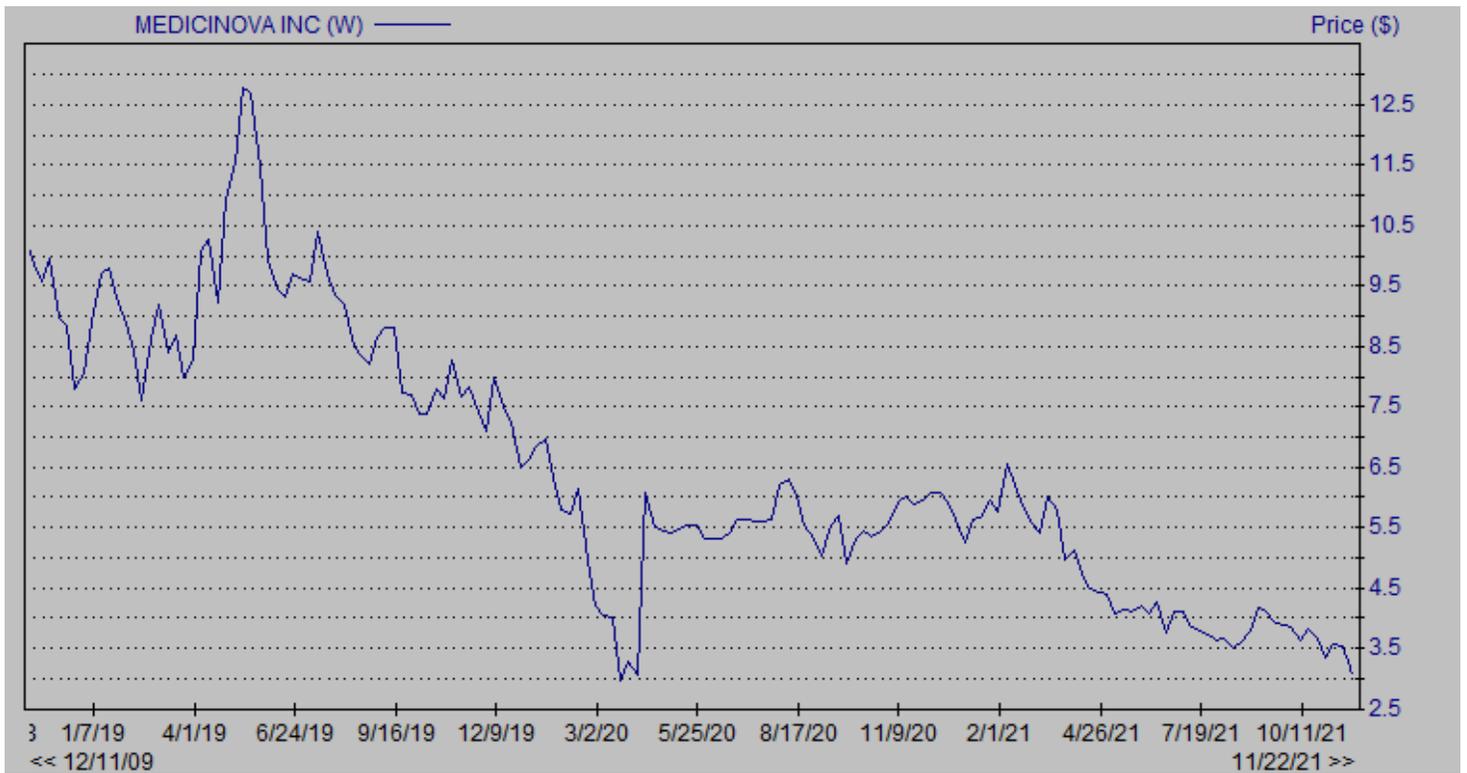
MediciNova Inc. Income Statement

MediciNova, Inc.	2020 A	Q1 A	Q2 A	Q3 A	Q4 E	2021 E	2022 E	2023 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 (Addiction)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
MN-001 (NASH)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
MN-001 (IPF)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Grants & Collaborative Revenue	\$0	\$4	\$0	\$0	\$0	\$4	\$0	\$0
Total Revenues	\$0	\$4	\$0	\$0	\$0	\$4	\$0	\$0
Cost of Sales	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Product Gross Margin</i>	-	-	-	-	-	-	-	-
Research & Development	\$7.5	\$2.1	\$2.5	\$2.1	\$2.8	\$9.6	\$11.0	\$13.0
General & Administrative	\$6.7	\$2.1	\$1.8	\$1.6	\$2.0	\$7.4	\$8.0	\$9.0
Other Expenses	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Operating Income	(\$14.2)	(\$0.2)	(\$4.3)	(\$3.6)	(\$4.8)	(\$12.9)	(\$19.0)	(\$22.0)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	\$0.3	\$0.0	\$0.0	\$0.0	\$0.1	\$0.2	\$0.4	\$0.4
Pre-Tax Income	(\$13.9)	(\$0.2)	(\$4.3)	(\$3.6)	(\$4.7)	(\$12.8)	(\$18.6)	(\$21.6)
Income Taxes Paid	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$13.9)	(\$0.2)	(\$4.3)	(\$3.6)	(\$4.7)	(\$12.8)	(\$18.6)	(\$21.6)
<i>Net Margin</i>	-	-	-	-	-	-	-	-
Reported EPS	(\$0.31)	(\$0.00)	(\$0.09)	(\$0.07)	(\$0.10)	(\$0.26)	(\$0.37)	(\$0.39)
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Basic Shares Outstanding	44.413	47.535	48.798	48.988	49.200	48.630	50.000	55.000

Source: Zacks Investment Research, Inc.

David Bautz, PhD

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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