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MediciNova, Inc. (MNOV-NASDAQ)

MNOV: Animal Trials Commence Testing MN-166 as an MCM…

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 (08/16/21)	$3.51
Valuation	**$27.00**

OUTLOOK

On August 12, 2021, MediciNova, Inc. (MNOV) announced financial results for the second quarter of 2021 and provided a business update. The company has recently initiated a preclinical study of MN-166 (ibudilast) as a medical countermeasure (MCM) for chlorine-gas induced lung injury through a partnership with BARDA. In addition, the company recently completed a safety review of Part 1 of the Phase 2 trial of MN-166 in combination with temozolomide for patients with recurrent glioblastoma, which showed encouraging data. There were no concerning safety signals and 5/15 subjects were progression-free at six months. Enrollment continues in multiple other trials including the COMBAT-ALS Phase 3 clinical trial of MN-166 for the treatment of amyotrophic lateral sclerosis (ALS) and the Phase 2 trial of MN-166 in patients hospitalized with COVID-19 at risk of developing ARDS.

SUMMARY DATA

52-Week High	**$8.74**
52-Week Low	**$3.44**
One-Year Return (%)	**-42.08**
Beta	**1.43**
Average Daily Volume (sh)	**159,133**
Shares Outstanding (mil)	**49**
Market Capitalization ($mil)	**$172**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**23**
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	**Above Avg.**
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)
2020	0 A	0 A	0 A	0 A	0 A
2021	4 A	0 A	0 E	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	-$0.09 E	-$0.10 E	-$0.28 E
2022					-$0.37 E
2023					-$0.39 E

WHAT'S NEW

Business Update

Preclinical Studies for BARDA Contract Underway

In June 2021, MediciNova, Inc. (MNOV) announced it initiated a sheep study and also reached an agreement to conduct a mouse study as part of its partnership with the Biomedical Advanced Research and Development Authority (BARDA). The partnership is set up to test the potential for MN-166 (ibudilast) as a medical countermeasure (MCM) for the treatment of chlorine gas-induced acute respiratory distress syndrome (ARDS) and acute lung injury (ALI). The sheep study will test MN-166 vs. control in an ovine model of chlorine-induced acute lung injury through evaluation of pulmonary function, lung injury and edema formation, cardiopulmonary hemodynamics, and systemic vascular permeability. The mouse model will evaluate survival, clinical outcomes, body weight, lung weight, and upper respiratory tract histopathology after exposure to chlorine gas and MN-166 or control.

Chlorine inhalation results in the formation of hydrochloric acid (HCl) and hypochlorous acid (HOCl) as it dissolves into the airway surface liquid. Both of those compounds can result in oxidative injury following the formation of reactive oxygen species, which can result in edema, inflammation, and immediate airway constriction. In addition, chlorine exposure results in the recruitment of inflammatory neutrophils and macrophages (Balakrishna *et al*., 2014). The inflammatory response is accompanied by increases in various inflammatory markers such as CXCL1, GM-CSF, IL-6, and VEGF.

The Department of Homeland Security estimates that a deliberate release of highly concentrated chlorine gas upwind of an urban area with 700,000 individuals would lead to approximately 5% being exposed to a lethal dose of chlorine with approximately 17,500 fatalities and 100,000 hospitalizations (Department of Homeland Security). Chlorine gas is fairly easy to produce, thus the U.S. government is interested in finding MCMs to treat lung injuries caused by chlorine exposure as the current treatment is mostly supportive care.

The potential market opportunity for MN-166 in chlorine gas-induced ALI is significant as the U.S. government would likely decide to purchase large quantities of the drug for public health emergencies in the homeland (Strategic National Stockpile) and to protect U.S. military personnel abroad.

Developing MN-166 as a treatment for chlorine gas-induced ARDS and ALI is being done according to the FDA's Animal Rule. The Animal Rule is designed for MCMs for bioterror and other threats (e.g., smallpox, anthrax, botulism, plague) for which traditional clinical trials to evaluate safety and efficacy would not be ethical. For these products, determinations of efficacy are primarily based on studies in animal models of the disease, with safety evaluations based on traditional toxicology studies, PK studies, or evaluations in other indications. Developing a drug through the Animal Rule speeds up timelines as there are no lengthy human clinical trials to conduct and the FDA can grant approval of a drug for an MCM indication based on well-controlled animal studies.

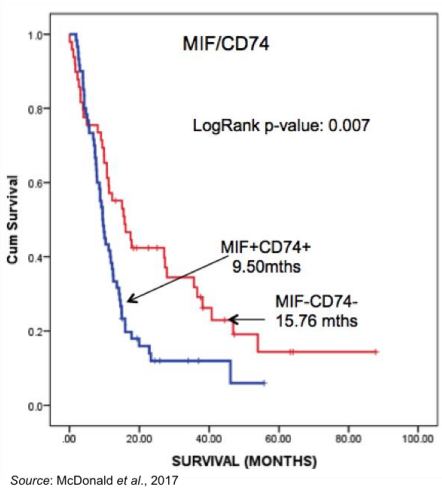
In addition to a potentially shortened development timeline, drugs approved as MCMs are eligible for a priority review voucher (PRV). A PRV allows the holder of the voucher to receive an expedited six-month review from the FDA for a new drug application (NDA) or biologics license application (BLA) instead of the usual ten-month review. PRVs are fully transferrable and in the past couple of years a number of them have sold for approximately $100 million each.

Encouraging Early Results for Glioblastoma Trial

MN-166 is currently being evaluated in a Phase 2 clinical trial in combination with temozolomide for the treatment of glioblastoma (GBM) (NCT03782415). Part 1 of the trial is evaluating the safety and tolerability of MN-166 in combination with temozolomide and determining the optimal dose of MN-166 to advance into Part 2 of the study. Part 2 will evaluate the efficacy of MN-166 and temozolomide as measured by the proportion of subjects who are progression-free at 6 months. Additional outcome measures will include overall survival, response rate, and median six-month progression-free survival.

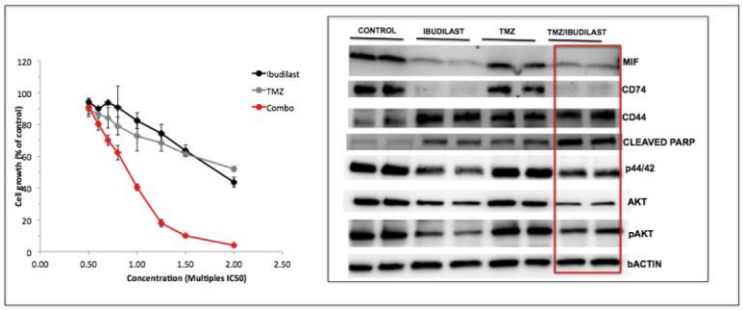
The company recently completed a safety review of Part 1 of the trial, which included data on 15 subjects with recurrent glioblastoma (rGBM). There were no concerning safety signals or serious adverse events related to MN-166 in Part 1 of the study. In addition, 33% (5/15) of the subjects were progression-free after 6 months of treatments. This is very encouraging as patients with rGBM typically have a very poor prognosis. While difficult to make direct comparisons, we did identify a paper that examined the rate of six-month progression-free survival in 16 trials that included 345 subjects (Ballman *et al*., 2006). Out of those trials, only approximately 9% of patients experienced progression-free survival ≥ 6 months.

The use of MN-166 in GBM is based on a proteomic profiling study of GBM samples from 30 GBM patients which was presented at the 2017 American Society of Clinical Oncology (ASCO) annual meeting (McDonald *et al*). The results showed that macrophage migration inhibitory factor (MIF) was expressed in "poor responders" (e.g., those that lived < 1 year). MIF is an inflammatory-related cytokine that is secreted by cancer stem cells. The researchers then examined an additional 168 GBM samples and found co-expression of MIF and its receptor CD74 in 57% of the samples. In addition, co-expression of MIF and CD74 was significantly associated with poor survival, as shown in the following graph. These results point to MIF being a suitable target for GBM treatment.



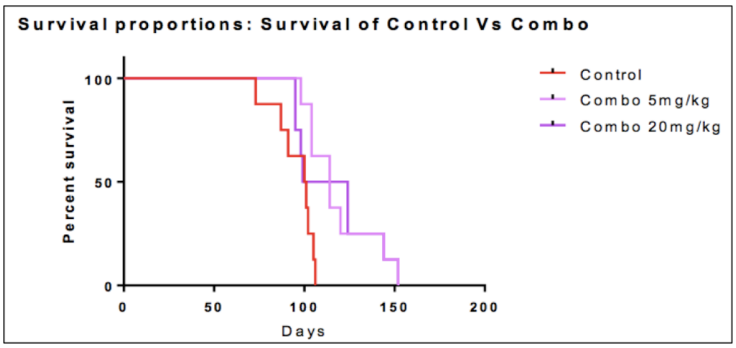
Source: McDonald *et al*., 2017

MN-166 is an inhibitor of MIF (Cho *et al*., 2010). To determine if MN-166 could show an effect in GBM, the researchers first treated patient derived GBM cell lines with MN-166, temozolomide (TMZ, the standard of care chemotherapeutic for GBM) or a combination of the two and evaluated the effect on cell growth and protein expression. Results showed that in all cell lines tested, the combination of MN-166 and TMZ resulted in significant synergy in inhibiting cell growth, as well as decreases in MIF, CD74, and AKT expression.



Source: McDonald *et al*., 2017

An *in vivo* study was performed using RN1 GBM cells, which were intracranially injected into the brains of mice followed by no treatment or a combination of TMZ and MN-166 at two different concentrations. Results showed that mice treated with the combination of TMZ and MN-166 had significantly enhanced survival (median overall survival 114 days vs. 100.5 days, *P*=0.005) with suppression of MIF and CD74 expression also noted.



Source: McDonald *et al.*, 2017

Enrollment Continues in ALS and COVID-19 Trials for MN-166

MediciNova is continuing to enroll patients in the Phase 3 COMBAT-ALS trial of MN-166 for the treatment of amyotrophic lateral sclerosis (ALS). This is a multi-center, randomized, double blind, placebo controlled trial that is evaluating the safety and efficacy of MN-166 after 12 months of treatment followed by a 6-month open label extension period. The primary endpoint of the trial is the change from baseline in the ALSFRS-R score at month 12 and survival time. A webinar with presentations from Dr. Björn Oskarsson, lead clinical investigator of the COMBAT-ALS trial, and Dr. Benjamin Brooks, who led the Phase 2 trial of MN-166 in ALS, can be accessed here.

MN-166 is also being evaluated as a treatment for patients with COVID-19 at risk for ARDS. The company has completed 75% of the planned enrollment in the Phase 2 randomized, double blind, placebo controlled trial in hospitalized COVID-19 patients. The primary endpoints of the trial include the proportion of subjects free from respiratory failure at Day 7, the mean change from baseline in the clinical status using the NIAID 8-point ordinal scale at Day 7, the percentage of patients with improvement in clinical status at Day 7, and the mean change in cytokine levels from baseline to Day 7.

MN-001 Update

IPF: MN-001 was evaluated in a randomized, double blind, placebo controlled, Phase 2 trial to evaluate its efficacy in patients with idiopathic pulmonary fibrosis (IPF) over a 26-week treatment period. A total of 10 patients were enrolled in the MN-001 group and 5 patients in the placebo group. The results showed that there were no clinically meaningful trends in favor of MN-001 for the majority of the clinical outcome measures; however, there were no worsening IPF events (acute exacerbation or hospitalization) in the MN-001 group compared to one worsening IPF event in the placebo group. In addition, treatment with MN-001 resulted in a substantial reduction in LOXL2 (IPF biomarker) while LOXL2 increased in the placebo group. Lastly, MN-001 was safe and well tolerated.

NASH: MediciNova is currently finalizing a protocol for a Phase 2 clinical trial in non-alcoholic steatohepatitis (NASH). The company previously tested MN-001 in a small Phase 2 trial in patients with NASH and non-alcoholic fatty liver disease (NAFLD) in which MN-001 showed a significant reduction in serum triglycerides (primary endpoint). Details of the upcoming trial will be announced upon initiation of the study.

Financial Results

On August 12, 2021, MediciNova (MNOV) announced financial results for the second quarter of 2021. As expected, the company did not report any revenue for the second quarter of 2021. R&D expenses in the second quarter of 2021 were $2.5 million, compared to $2.2 million for the second quarter of 2020. The increase was primarily due to higher clinical trial expenses for MN-166 in ALS. G&A expenses in the second quarter of 2021 were $1.8 million, compared to $2.3 million for the second quarter of 2020. The decrease was primarily due to lower stock-based compensation and consultant fees.

MediciNova exited the second quarter of 2021 with approximately $77.8 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 August 9, 2021, MediciNova had approximately 49.0 million shares outstanding and, when factoring in stock options, a fully diluted share count of approximately 57.2 million shares.

Conclusion

We're glad to see MediciNova continue to develop MN-166 according to the FDA Animal Rule for the treatment of chlorine gas inhalation which could lead to it being approved in an expedited manner. We look forward to updates regarding the animal trials and potential timelines for seeking approval in that indication. The early results from the GBM trial are encouraging and we look forward to additional updates as the trial moves into Part 2. We have removed MN-001 in IPF from our model, however we had only assigned a probability of success of 20% thus our valuation was minimally reduced from $28 to $27.

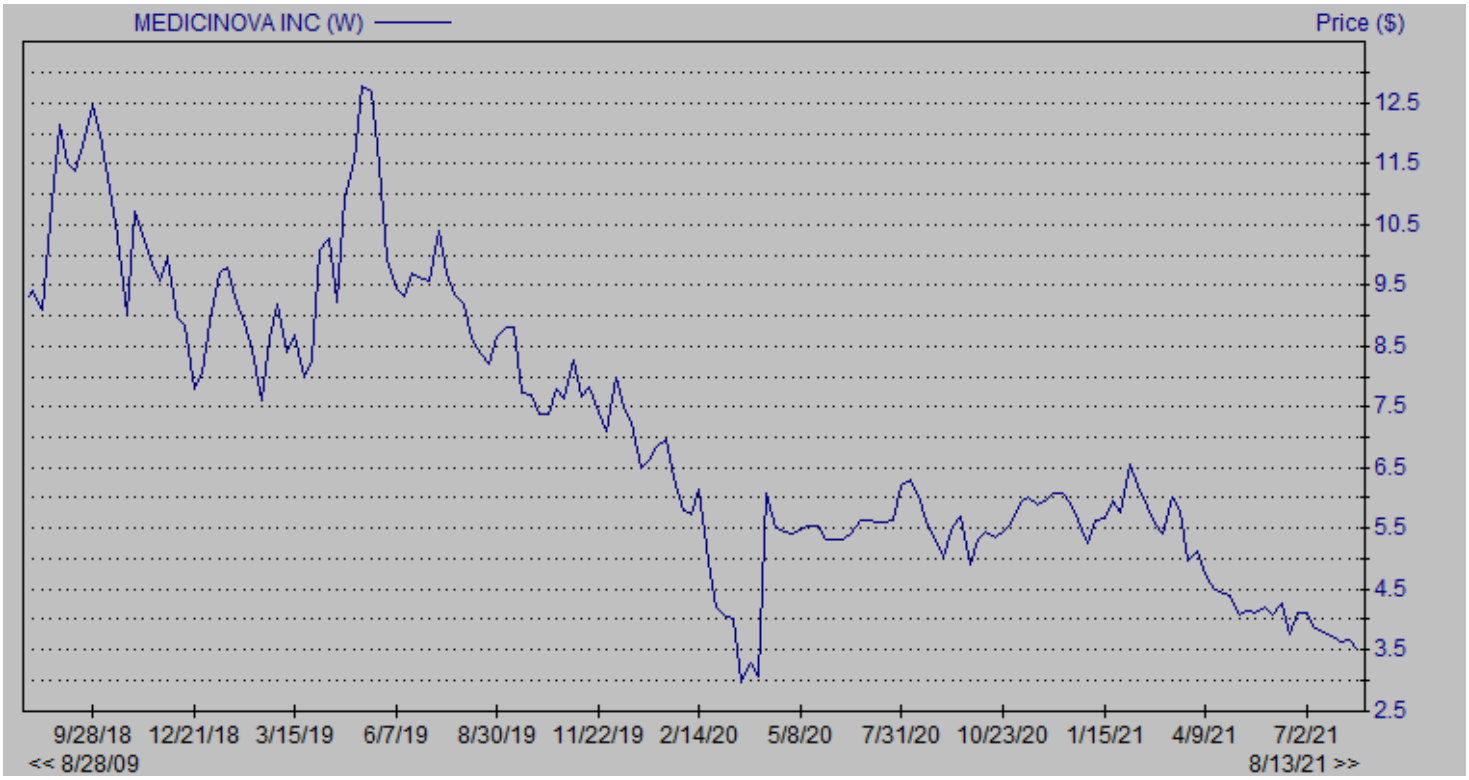
PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2020 A	Q1 A	Q2 A	Q3 E	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
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$7.5	$2.1	$2.5	$2.5	$2.8	$10.0	$11.0	$13.0
General & Administrative	$6.7	$2.1	$1.8	$1.9	$2.0	$7.7	$8.0	$9.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($14.2)	($0.2)	($4.3)	($4.4)	($4.8)	($13.7)	($19.0)	($22.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.3	$0.0	$0.0	$0.1	$0.1	$0.2	$0.4	$0.4
Pre-Tax Income	($13.9)	($0.2)	($4.3)	($4.3)	($4.7)	($13.5)	($18.6)	($21.6)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($13.9)**	**($0.2)**	**($4.3)**	**($4.3)**	**($4.7)**	**($13.5)**	**($18.6)**	**($21.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.31)**	**($0.00)**	**($0.09)**	**($0.09)**	**($0.10)**	**($0.28)**	**($0.37)**	**($0.39)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	44.413	47.535	48.798	49.000	49.200	48.633	50.000	55.000

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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