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April 14, 2020
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MediciNova, Inc.

(MNOV-NASDAQ)

MNOV: MN-166 Trial in ARDS to Initiate at Yale University…

Based on our probability adjusted DCF model that takes into account potential future revenues from MN-166 in ALS, progressive MS and addiction and MN-001 in NASH and IPF, MNOV is valued at $24/share. This model is highly dependent upon continued clinical success of both MN-166 and MN-001 and will be adjusted accordingly based upon future clinical results.

Current Price (04/14/20)	$7.06
Valuation	**$24.00**

OUTLOOK

On April 8, 2020, MediciNova, Inc. (MNOV) announced plans for a clinical trial of MN-166 for acute respiratory distress syndrome (ARDS) caused by COVID-19. We previously discussed preclinical data showing that MN-166 is able to reverse histological changes, reduce inflammatory cytokines, reduce pulmonary edema, and reduce cell apoptosis in a mouse model of ARDS. In this report we discuss additional preclinical and clinical data showing how macrophage migration inhibitory factor (MIF), which MN-166 is an inhibitor of, is involved in a number of different viral pathologies and how MN-166 could exhibit antiviral as well as anti-inflammatory properties and make it an excellent candidate for treatment of ARDS caused by COVID-19.

SUMMARY DATA

52-Week High	**$13.22**
52-Week Low	**$2.90**
One-Year Return (%)	**-31.85**
Beta	**1.52**
Average Daily Volume (sh)	**268,158**
Shares Outstanding (mil)	**44**
Market Capitalization ($mil)	**$310**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**22**
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 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**

Risk Level	**Above Avg.**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 E	0 E	0 E	0 E	0 E
2021					0 E
2022					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.11 A	-$0.09 A	-$0.05 A	-$0.04 A	-$0.30 A
2020	-$0.08 E	-$0.08 E	-$0.09 E	-$0.09 E	-$0.34 E
2021					-$0.34 E
2022					-$0.35 E

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WHAT'S NEW

Business Update

Clinical Trial to Initiate for MN-166 in Patients with COVID-19 ARDS

On April 8, 2020, MediciNova, Inc. (MNOV) announced that a clinical trial of MN-166 (ibudilast) will be initiated in patients with acute respiratory distress syndrome (ARDS) caused by COVID-19 (coronavirus disease 2019). The trial will be conducted by the Yale University Advanced Therapies Group. The purpose of the study is to determine the optimal dose and route of administration of MN-166 in ARDS patients.

ARDS is a serious condition caused by the small blood vessels of the lung leaking fluid that fills up the alveoli, thus preventing proper oxygen exchange (Stevens *et al*., 2018). It can be caused by many conditions, including infections, severe burns, pancreatitis, inhalation of smoke or chemicals, or other serious illnesses. Infections, which may include influenza, coronavirus, or other viruses, are the most common cause of ARDS. Current treatment options involve supportive care while the lungs try to heal, which consists of oxygen therapy supplied through a ventilator. There are no pharmacological treatments specifically for ARDS and approximately 40% of hospitalized ARDS patients die from it (Siegel *et al*., 2020). ARDS appears to be a common complication of COVID-19, with a high fatality rate in those that develop the condition (Chen *et al*., 2020).

We previously reported on the efficacy of MN-166 in a preclinical mouse model of ARDS. In this report, we discuss a number of publications we identified on the role of MIF in viral infections and how inhibiting MIF may help to improve outcomes in these cases. We believe this data is directly relevant to the potential use of MN-166 in treating ARDS caused by SARS-CoV-2 (the virus responsible for COVID-19) since MN-166 is an inhibitor of MIF (Cho *et al*., 2010).

MIF is a protein that exhibits cytokine, endocrine, chaperone-like, and enzyme-like properties (Stosic-Grujicic *et al*., 2009). It binds to its high-affinity cell receptor CD74, leading to recruitment of CD44 and the mediation of a number of intracellular signaling pathways, including those involving the inflammatory cascade and the innate immune response (Calandra *et al*., 2003). MIF promotes the release of pro-inflammatory cytokines, such as tumor necrosis factor (TNF)-α, interleukin (IL)-6, and prostaglandin E_2. Elevated serum MIF concentrations are found in many infectious and inflammatory diseases. For example, MIF concentrations in sepsis patients correlate with disease severity (Bernhagen *et al*., 1993; Sprong *et al*., 2007) and anti-MIF antibodies protect mice in an *in vivo* model of septic shock (Calandra *et al*., 2000).

Numerous studies have shown the role of MIF in viral pathogenesis, thus potentially making MIF inhibition a suitable target for treating viral diseases, with a few of those discussed below:

- Arjona *et al*., 2007: This study investigated the role of MIF in the pathogenesis of West Nile Virus (WNV). The research showed that WNV patients had increased MIF levels in their plasma and cerebrospinal fluid. Blockade of MIF through three distinct mechanisms (antibody, small molecule, genetic deletion) increased resistance to WNV lethality in mouse models. The researchers concluded that MIF is involved in the pathogenesis of WNV and that targeting MIF could be useful in the treatment of WNV encephalitis.

- Assunção-Miranda *et al*., 2010: This study examined the involvement of MIF in dengue virus (DENV) infection and pathogenesis. Just as with WNV, patients with dengue hemorrhagic fever had elevated levels of MIF in their plasma and *mif*-deficient ($Mif^{-/-}$) mice showed less severe disease following DENV infection, including a significant delay in lethality and lower viral loads compared to wild-type mice. These results again support inhibiting MIF as a therapeutic approach to treating DENV infection.

- Regis *et al*., 2010: This study investigated the role of MIF in patients with HIV-1 infection. Those with HIV-1 infection had elevated plasma levels of MIF and the HIV-1 protein gp120 induced MIF secretion from uninfected peripheral blood mononuclear cells (PMBCs). In addition, viral replication in PBMCs declined when the cells were treated with anti-MIF antibodies while viral replication was enhanced when recombinant MIF was added to HIV-1 infected PBMCs, thus showing that MIF is involved in promoting viral activity and inhibiting MIF could lead to decreased viral activity.

- Fox *et al*., 2018: The SPRINT-MS trial in patients with progressive multiple sclerosis (MS) showed that treatment with MN-166 resulted in a statistically significant decrease in the rate of decline in brain volume along with a 26% reduction in confirmed disability progression. In addition, an analysis of adverse events during the trial showed a statistically significant difference in upper respiratory tract infections, with only 10% of MN-166 treated patients reporting an upper respiratory tract infection compared to 19% of placebo treated patients (*P*=0.045).

The aforementioned studies show that MIF activity is related to viral pathogenesis, and viral replication, for a wide range of viruses and thus provides adequate support for using a MIF inhibitor in the treatment of viral diseases, including COVID-19 caused by the SARS-CoV-2 virus. The data from the SPRINT-MS trial is not related to any one particular virus, but is a real-world example of how MN-166 treatment can decrease overall viral infections, adding support to the notion that inhibiting MIF with MN-166 could be useful in treating viral infections.

Conclusion

Following our analysis of the positive preclinical study of MN-166 in a mouse model of ARDS, we have identified additional studies that add support to the use of MN-166 in treating viral infections. The studies that we found include both preclinical and clinical data showing the role of MIF in viral replication and pathogenesis, including its role in promoting the expression of inflammatory cytokines that are associated with the development of ARDS, such as IL-6. Since MN-166 is an inhibitor of MIF, we believe there is ample evidence to support its use in treating ARDS caused by infection with SARS-CoV-2, the virus that causes COVD-19, with the added benefit of it potentially exhibiting anti-viral activity. We believe that anti-inflammatory and anti-viral activities are a powerful and ideal combination in a drug as it can treat both the hyperinflammatory response as well as the underlying viral infection in ARDS patients. We look forward to the results of the trial as the world desperately needs additional treatment options for COVID-19. Our valuation for MNOV remains at $24 per share.

PROJECTED FINANCIALS

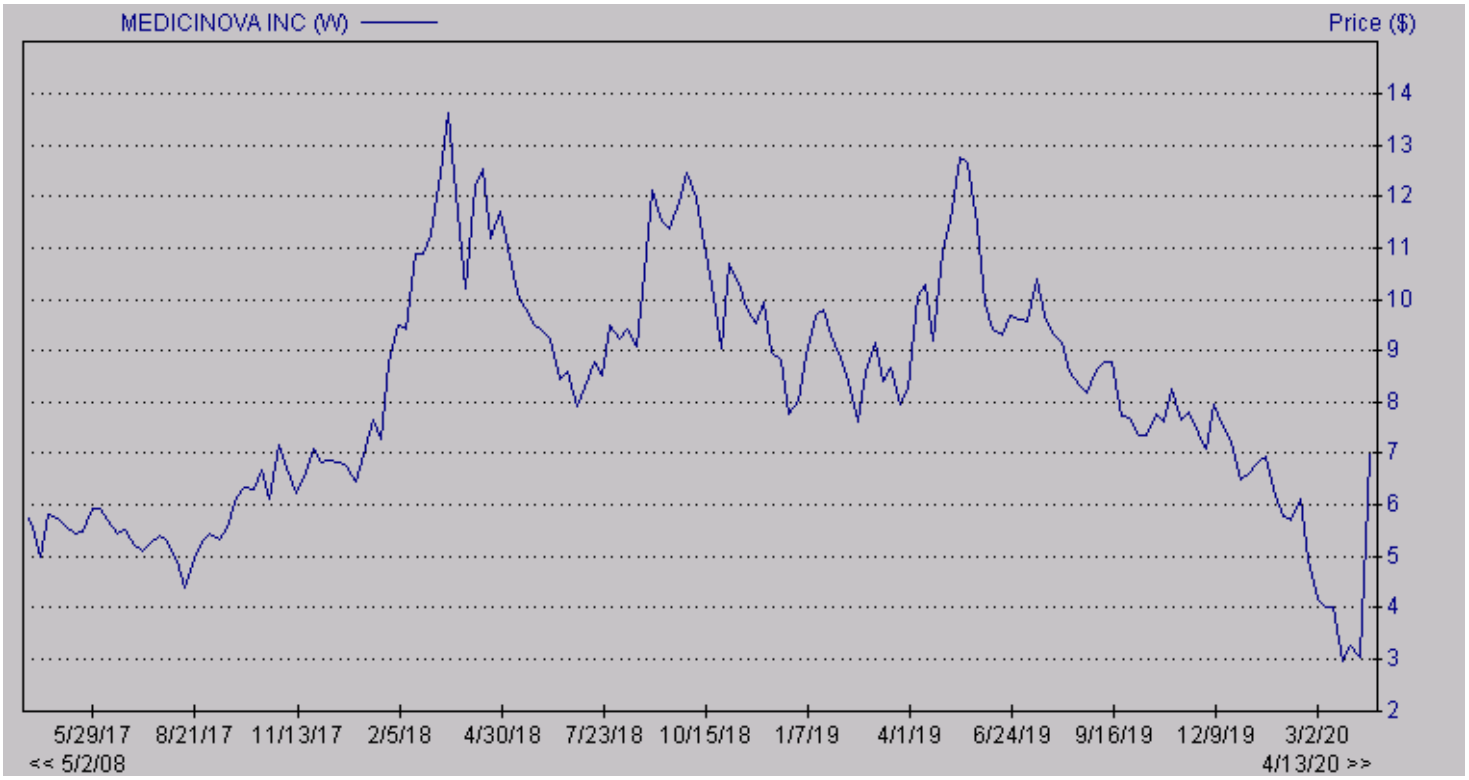
MediciNova Inc.
Income Statement

MediciNova, Inc.	2019 A	Q1 E	Q2 E	Q3 E	Q4 E	2020 E	2021 E	2022 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	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$6.079	$1.800	$1.800	$1.800	$1.800	$7.200	$9.000	$10.000
General & Administrative	$7.952	$1.800	$2.000	$2.200	$2.400	$8.400	$8.500	$9.000
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($14.0)	($3.6)	($3.8)	($4.0)	($4.2)	($15.6)	($17.5)	($19.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$1.1	$0.1	$0.1	$0.1	$0.1	$0.4	$0.4	$0.4
Pre-Tax Income	($12.9)	($3.5)	($3.7)	($3.9)	($4.1)	($15.2)	($17.1)	($18.6)
Income Taxes Paid	($0)	$0	$0	$0	($0)	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($12.9)**	**($3.5)**	**($3.7)**	**($3.9)**	**($4.1)**	**($15.2)**	**($17.1)**	**($18.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.30)**	**($0.08)**	**($0.08)**	**($0.09)**	**($0.09)**	**($0.34)**	**($0.34)**	**($0.35)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	43.159	43.900	44.000	44.200	44.400	44.125	50.000	53.000

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

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HISTORICAL STOCK PRICE



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