Zacks Small-Cap Research
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MediciNova, Inc. (MNOV-NASDAQ)

MNOV: Positive Results for MN-166 (Ibudilast) in Patients at Risk of Acute Respiratory Distress Syndrome…

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 (06/13/22)	$2.49
Valuation	**$27.00**

OUTLOOK

On June 8, 2022, MediciNova, Inc. (MNOV) announced positive results for the Phase 2 clinical trial of MN-166 (ibudilast) in hospitalized COVID-19 patients at risk for developing acute respiratory distress syndrome (ARDS). The trial achieved statistical significance for one of the co-primary endpoints (the proportion of subjects free of respiratory failure), and achieved statistical significance for the proportion of subjects discharged from the hospital. A total of 34 subjects were randomized 1:1 to receive MN-166 or placebo for seven days, and on Day 7 71% of subjects in the MN-166 group and 35% of the placebo group were free of respiratory failure (*P*=0.02). Based on these results, we expect the company to meet with the FDA to discuss the development path forward for MN-166 in patients at risk for ARDS.

SUMMARY DATA

52-Week High	**$4.42**
52-Week Low	**$2.19**
One-Year Return (%)	**-41.82**
Beta	**1.16**
Average Daily Volume (sh)	**30,920**
Shares Outstanding (mil)	**49**
Market Capitalization ($mil)	**$122**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**16**
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	**Below Avg.**
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)
2021	4 A	0 A	0 A	0 A	0 A
2022	0 A	0 E	0 E	0 E	0 E
2023					0 E
2024					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.00 A	-$0.09 A	-$0.07 A	-$0.04 A	-$0.21 A
2022	-$0.07 A	-$0.08 E	-$0.09 E	-$0.09 E	-$0.33 E
2023					-$0.36 E
2024					-$0.40 E

WHAT'S NEW

Business Update

Positive Results for MN-166 (Ibudilast) in COVID-19 Patients at Risk for ARDS

On June 8, 2022, MediciNova, Inc. (MNOV) announced positive topline results for the Phase 2 clinical trial of MN-166 (ibudilast) in hospitalized COVID-19 patients at risk for developing acute respiratory distress syndrome (ARDS). A total of 34 subjects were randomized 1:1 to receive either MN-166 or placebo for a total of seven days. Study subjects also received standard of care, including anticoagulation therapy, with inclusion criteria including:

- A positive PCR test for SARS-CoV-2 infection
- Chest imaging with abnormalities consistent with COVID-19 pneumonia
- $SpO_2 \leq 92\%$ on room air, respiratory rate ≥ 24 breaths per minute, and/or requirement for supplemental oxygen
- At least one of the following risk factors: age > 65, underlying serious heart disease, chronic lung disease, moderate to severe asthma, BMI ≥ 40, or diabetes

The topline results included two pre-defined co-primary endpoints and two additional endpoints. The trial achieved statistical significance for one of the co-primary endpoints (the proportion of subjects free of respiratory failure), and showed large improvements compared to placebo for all four clinical endpoints analyzed.

- For the co-primary endpoint of the proportion of subjects free from respiratory failure at Day 7, 71% of MN-166-treated subjects and 35% of placebo-treated subjects were free of respiratory failure at Day 7 (*P*=0.02).

- For the co-primary endpoint of clinical status (defined as improvement on the NIAID scale) at Day 7, 71% of MN-166-treated subjects and 47% of placebo-treated subjects had improved clinical status at Day 7 (*P*=0.08).

- For the proportion of subjects discharged from the hospital at Day 7, 65% of MN-166-treated subjects and 29% of placebo-treated subjects were discharged from the hospital at Day 7 (*P*=0.02).

- For the proportion of subjects with worsening clinical status at Day 7, 0% of MN-166-treated subjects and 24% of placebo-treated subjects had worsened clinical status at Day 7 (*P*=0.05).

- There were a total of two deaths in the placebo-treated group and 0 deaths in the MN-166-treated group.

- There were no serious adverse events related to MN-166 treatment.

These results are very encouraging, as the treatment options available to patients who enter the hospital at risk of developing ARDS are very limited. While this study was conducted in COVID-19 positive patients, the market for those at risk of developing ARDS is quite large (see below), as ARDS can be caused by a number of different viral and bacterial pathogens.

MN-166 Previously Showed Efficacy in ARDS Mouse Model

The clinical trial to evaluate MN-166 in patients at risk for developing ARDS was conducted due to positive results seen in a preclinical study using a mouse model of ARDS induced with lipopolysaccharide (LPS) (Yang *et al*., 2020). The results of that study showed that MN-166 decreased the overexpression of PDE4 in lung tissue in mice, decreased the abnormal overexpression of different inflammatory cytokines (including TNF-a, IL-1b, IL-6, and MCP-1, and inflammatory chemokines, including CXCL1, CXCR4, and CXCR5), significantly

reduced pulmonary edema, and decreased lung cell apoptosis (cell death), thus showing the drug's ability to protect against pulmonary injury. Please see our previous report for a full write-up on those results.

We highlight this preclinical study as it formed the basis for pursuing the development of MN-166 to prevent ARDS. This reflects well on management's ability to identify the proper indications to allocate resources towards and not just haphazardly pursue indications that are unlikely to be successful.

Large Opportunity in Preventing ARDS

ARDS is a serious lung disorder that results from the small blood vessels of the lung leaking fluid that fills up the alveoli, thus preventing proper oxygen exchange (Stevens *et al*., 2018). There are many causes of ARDS, including infections (e.g., pneumonia), severe burns, pancreatitis, inhalation of smoke or chemicals, or other serious illnesses. An excessive inflammatory response appears to be involved in the pathogenesis of ARDS (Li *et al*., 2019). Current treatment options involve supportive care while the lungs heal, which involves oxygen therapy supplied through a ventilator. There are no pharmacological treatments specifically for ARDS and approximately 40% of hospitalized patients die from it (Siegel *et al*., 2020).

According to the NIH, infections are the most common risk factors for ARDS (NIH). The most common infections are due to influenza (and other respiratory viruses), pneumonia, and sepsis. There are approximately one million adults hospitalized in the U.S. each year for pneumonia (ATS), approximately 400,000 hospitalizations due to influenza each year in the U.S. (CDC), and approximately 1 million hospitalizations due to sepsis (UMich). While not all of these patients will go on to develop ARDS, it is this pool of patients that are at a high-risk of developing ARDS that will be the target market for MediciNova.

Conclusion

The positive results from the Phase 2 clinical trial of MN-166 in patients at risk for ARDS are very encouraging and we look forward to updates from the company as it looks to advance this indication forward. We also look forward to results from the ongoing preclinical studies of MN-166 in chemical gas-induced lung damage, which are being supported through a partnership with the U.S. Biomedical Advanced Research and Development Authority (BARDA). We also anticipate the company meeting with the FDA to determine the regulatory path forward for MN-166 for the prevention of ARDS. With no changes to our model, our valuation remains at $27 per share.

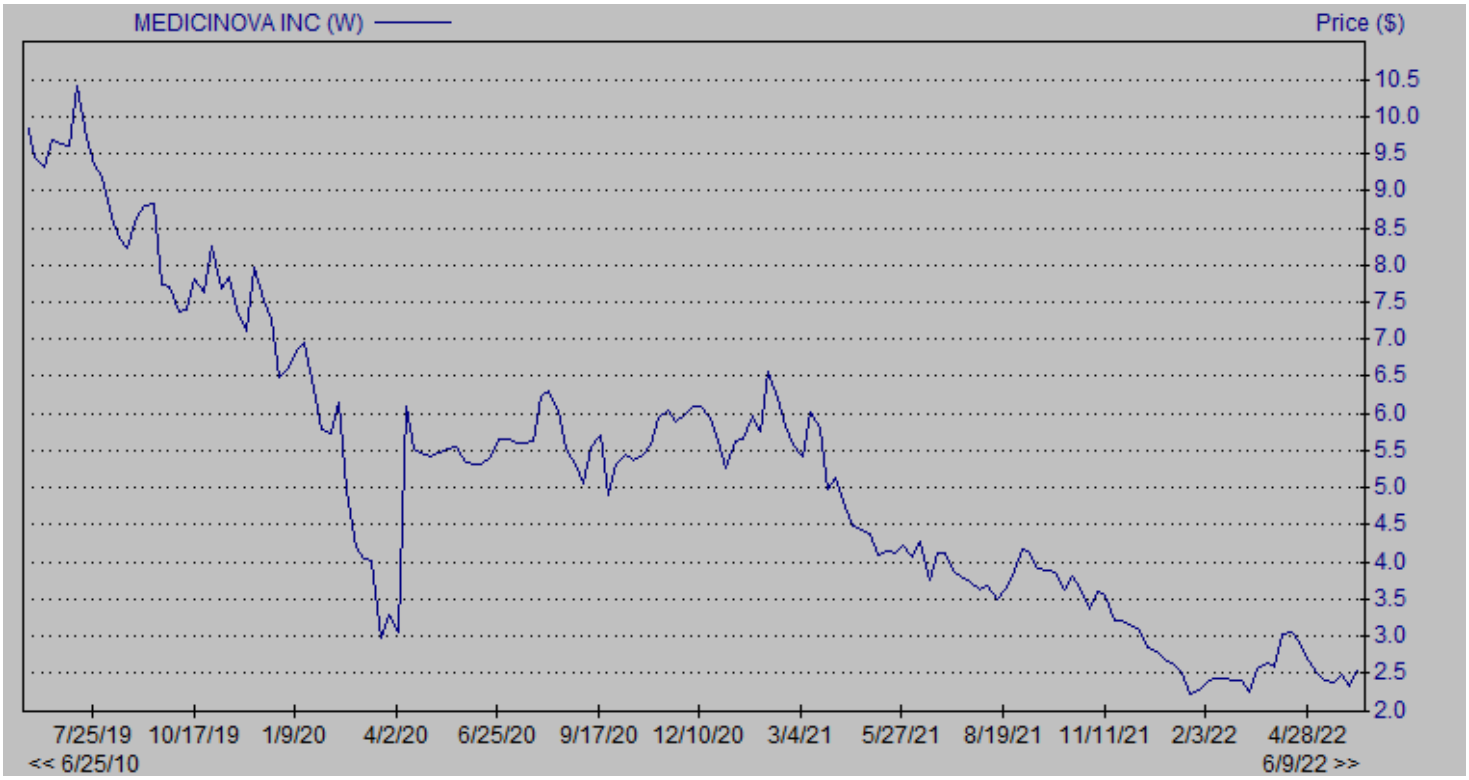
PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2021 A	Q1 A	Q2 E	Q3 E	Q4 E	2022 E	2023 E	2024 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-166 (DCM)	$0	$0	$0	$0	$0	$0	$0	$0
MN-001 (NASH)	$0	$0	$0	$0	$0	$0	$0	$0
Grants & Collaborative Revenue	$4.0	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$4**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$8.5	$2.1	$2.3	$2.3	$2.4	$9.1	$10.0	$12.0
General & Administrative	$5.7	$1.3	$1.8	$1.9	$2.0	$7.0	$8.0	$9.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($10.2)	($3.4)	($4.1)	($4.2)	($4.4)	($16.1)	($18.0)	($21.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($10.1)	($3.4)	($4.1)	($4.2)	($4.4)	($16.0)	($17.9)	($20.9)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($10.1)**	**($3.4)**	**($4.1)**	**($4.2)**	**($4.4)**	**($16.0)**	**($17.9)**	**($20.9)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.21)**	**($0.07)**	**($0.08)**	**($0.09)**	**($0.09)**	**($0.33)**	**($0.36)**	**($0.40)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	48.596	49.043	48.800	49.000	49.200	49.011	50.000	52.000

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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