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MediciNova, Inc. (MNOV-NASDAQ)

MNOV: Phase 2 Trial of MN-001 in NAFLD Patients with Type 2 Diabetes and Hypertriglyceridemia Underway…

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 (08/19/22)	$2.40
Valuation	**$27.00**

OUTLOOK

In July 2022, MediciNova, Inc. (MNOV) announced the initiation of a Phase 2 clinical trial of MN-001 (tipelukast) in patients with non-alcoholic fatty liver disease (NAFLD) with Type 2 diabetes mellitus and hypertriglyceridemia. The trial is anticipated to enroll approximately 40 patients that will be randomized 1:1 to receive either 500 mg/day of MN-001 or placebo for 24 weeks. The co-primary endpoints are 1) change from baseline in liver fat content as measured by MRI-PDFF; and 2) change from baseline in fasting serum triglycerides.

MediciNova also recently announced the initiation of a clinical study of a new parenteral (injectable) formulation of MN-166. This new formulation could be utilized in acute care settings as well as indications that require precise injections such as intra-ocular and intrathecal routes.

MediciNova announced that MN-166 will also be evaluated in a grant-funded study as a treatment for Long COVID, pending protocol finalization and regulatory review.

SUMMARY DATA

52-Week High	**$4.42**
52-Week Low	**$2.19**
One-Year Return (%)	**-32.58**
Beta	**0.96**
Average Daily Volume (sh)	**16,048**
Shares Outstanding (mil)	**49**
Market Capitalization ($mil)	**$118**
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 A	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 A	-$0.09 E	-$0.09 E	-$0.33 E
2023					-$0.36 E
2024					-$0.40 E

WHAT'S NEW

Business Update

Phase 2 Trial of MN-001 in Patients with NAFLD, Type 2 Diabetes, and Hypertriglyceridemia Underway

On July 26, 2022, MediciNova, Inc. (MNOV) announced the initiation of a Phase 2 trial to evaluate MN-166 in patients with non-alcoholic fatty liver disease (NAFLD), type 2 diabetes mellitus (T2DM), and hypertriglyceridemia. It is a multi-center, two-arm, double blind, placebo controlled trial in approximately 40 patients in the U.S. Patients will be randomized 1:1 to receive 500 mg/day of MN-001 or placebo for a total of 24 weeks. The co-primary endpoints will be 1) change from baseline in liver fat content as measured by MRI-PDFF; and 2) change from baseline in fasting serum triglycerides (TGs) at Week 24. Secondary endpoints will include changes in liver profiles, safety, and tolerability.

The Phase 2 trial builds upon multiple previous studies examining the effect of MN-001 on TGs in NASH/NAFLD patients, preclinical studies in mice, and *in vitro* studies examining the mechanism of action of MN-001 in lowering TGs.

- MediciNova previously reported positive results from a Phase 2 clinical trial of MN-001 in patients with NASH and NAFLD with hypertriglyceridemia. A total of 15 patients completed eight weeks of treatment with MN-001 (four weeks at 250 mg/day and four weeks at 500 mg/day), with MN-001 reducing serum TG levels in 14 out of 15 subjects. The average pre-treatment serum TG 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 also analyzed the data excluding an outlier subject that had an extremely high serum TG level of 1288 mg/dL prior to treatment that was reduced to 300 mg/dL after treatment. That analysis showed 13 out of 14 subjects had a reduction in serum TGs, from an average 260.1 mg/dL prior to treatment to an average 185.2 mg/dL following treatment (-28.8%, *P*=0.00006). Importantly, there were no clinically significant safety or tolerability issues during the study.

- In November 2021, MediciNova announced the presentation of results from a study investigating the mechanism by which MN-001 (tipelukast) alters 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.

On August 9, 2022, MediciNova announced an abstract on additional findings from the completed Phase 2 study of MN-001 in patients with NASH and NAFLD with hypertriglyceridemia will be presented at the International Diabetes Federation (IDF) 2022 Congress in December 2022. While full details of the presentation will be disclosed at a later date, one of the findings showed that MN-001 improved serum lipid profiles in the NAFLD participants with T2DM more significantly than in the NAFLD participants without T2DM.

New Parenteral Formulation for MN-166

On July 21, 2022, MediciNova announced a first-in-human clinical trial was underway to evaluate the pharmacokinetics and bioavailability of a new parenteral (injectable) formulation of MN-166. This new formulation will provide health care providers another option for administering MN-166, such as in acute care settings to achieve a rapid effect or when a patient is unable to take an oral dose, along with indications that require injections in precise locations, such as intra-ocular, intra-articular, and intrathecal routes. Lastly, a

parenteral formulation will allow MN-166 to be evaluated in additional target indications that aren't currently feasible with an oral formulation.

MN-166 to be Studied in Long COVID

On August 16, 2022, MediciNova announced that it plans to participate in RECLAIM (Recovering from COVID-19 Lingering Symptoms Adaptive Integrative Medicine Trial), which is a grant-funded, multi-center, randomized clinical trial to evaluate MN-166 and other therapies for the treatment of Long COVID. The University Health Network will conduct the trial, which is being funded by the Canadian government through the Canadian Institutes of Health Research. The initiation of the trial is contingent on protocol finalization and regulatory review.

This study is an excellent opportunity for MediciNova. Since it is a grant funded study the company will not have to expend any financial resources. Grant funding is incredibly competitive, thus the fact that a study involving MN-166 got selected for funding is very encouraging. Lastly, Long COVID could represent a tremendous market opportunity given the number of patients that could be affected by the condition and the limited drug development competition.

Following an infection with SARS-CoV-2, the virus that causes COVID-19, approximately 30% of patients will experience symptoms that last for weeks or months or years, which is referred to as Long COVID. The range of symptoms varies from patient to patient, however the most commonly reported (from a recent meta analysis) were fatigue (58%), headache (44%), attention disorder (27%), hair loss (25%), and dyspnea (24%) (Lopez-Leon *et al*., 2021). With approximately 200 million individuals already having been infected with SARS-CoV-2 in the U.S., and greater than one billion around the world, there are a very large number of potential Long COVID patients. There are currently no treatment options available for Long COVID.

Extension of BARDA Contract

In June 2022, MediciNova announced that its contract with the Biomedical Advanced Research and Development Authority (BARDA) was amended to extend the period of performance until March 2023. The purpose of the contract is to evaluate MN-166 as a potential medical countermeasure (MCM) against chlorine gas-induced lung damage such as acute respiratory distress syndrome (ARDS) and acute lung injury (ALI). Please see our previous report that discusses the BARDA contract and preclinical data to support the use of MN-166 in the treatment of ARDS and ALI in greater detail.

Financial Update

On August 11, 2022, MediciNova (MNOV) filed form 10-Q with financial results for the second quarter of 2022. As expected, the company did not report any revenues in the second quarter of 2022. R&D expenses in the second quarters of 2022 and 2021 were $2.6 million and $2.5 million, respectively. The increase was primarily due to an increase in MN-221 related expenses partially offset by decreases in MN-166 related expenses and stock option expenses. G&A expenses in the second quarter of 2022 were $1.5 million, compared to $1.8 million for the second quarter of 2021. The decrease was primarily due to lower stock-based compensation.

MediciNova exited the second quarter of 2022 with approximately $65.2 million in cash and cash equivalents. As of August 9, 2022, 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

MediciNova continues to advance its pipeline with the start of the Phase 2 study of MN-001 in patients with NAFLD, T2DM, and hypertriglyceridemia and a new agreement to participate in a grant-funded trial for Long COVID. The new parenteral formulation of MN-166 could be utilized for current indications the company is pursuing, such as ALS and ARDS, and could eventually be applied to new indications to help expand the drug's potential applications. MediciNova is well capitalized with approximately five year's worth of cash. We have made no changes to our model and our valuation remains at $27.

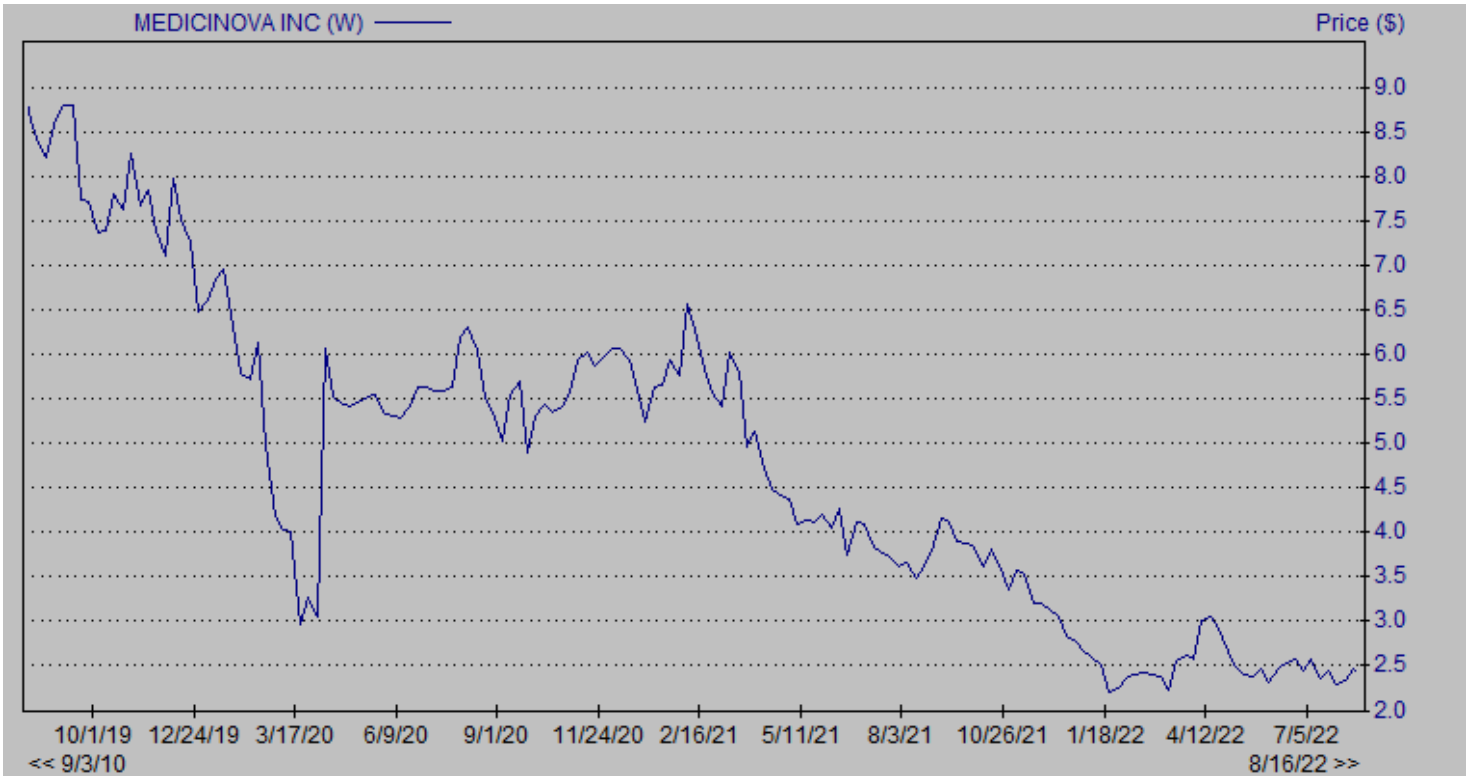
PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2021 A	Q1 A	Q2 A	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	$2.6	$2.3	$2.4	$9.4	$10.0	$12.0
General & Administrative	$5.7	$1.3	$1.5	$1.9	$2.0	$6.7	$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	$0.1	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($10.1)	($3.4)	($4.0)	($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)**	**($4.0)**	**($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	49.046	49.050	49.100	49.060	50.000	52.000

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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