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MediciNova, Inc. (MNOV-NASDAQ)

MNOV: Plans for Phase 2 Study of MN-001 (tipelukast) in NAFLD Patients with Type 2 Diabetes and Hypertriglyceridemia…

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 (05/25/22)	$2.38
Valuation	**$27.00**

OUTLOOK

In April 2022, MediciNova, Inc. (MNOV) announced plans for a Phase 2 clinical trial to evaluate MN-001 (tipelukast) in patients with non-alcoholic fatty liver disease (NAFLD), Type 2 diabetes and hypertriglyceridemia. The study builds on prior results from a Phase 2a study showing NASH/NAFLD patients with hypertriglyceridemia treated with MN-001 had reduced serum triglycerides, increased high-density lipoproteins (HDL), and reduced low-density lipoproteins (LDL). In this study, improvements in serum lipids were more significant in patients with Type 2 diabetes / prediabetes. The trial will include approximately 40 patients 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 at Week 24, and 2) change from baseline in fasting serum triglycerides at Week 24.

SUMMARY DATA

52-Week High	**$4.42**
52-Week Low	**$2.19**
One-Year Return (%)	**-40.50**
Beta	**1.16**
Average Daily Volume (sh)	**30,640**
Shares Outstanding (mil)	**49**
Market Capitalization ($mil)	**$117**
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	**Average**
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

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

In April 2022, MedicNova, Inc. (MNOV) announced plans for a Phase 2 clinical trial of MN-001 (tipelukast) in patients with non-alcoholic fatty liver disease (NAFLD), Type 2 diabetes mellitus (T2DM), and hypertriglyceridemia. It will be 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 14/15 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 that 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.

- Two separate studies in mouse models of NASH have shown MN-001 to have both anti-NASH and anti-fibrotic activity:

    - *Study #1*: MN-001 was administered orally once daily (10, 30, or 100 mg/kg) for three weeks in the STAM™ (NASH-HCC) mouse model of NASH. The model is created by a combination of chemical and dietary interventions in a standard laboratory mouse strain. Treatment with MN-001 resulted in a dose-dependent reduction in liver fibrosis as demonstrated by a reduction in liver hydroxyproline content (*P*<0.01). In addition, there was a significant improvement (*P*<0.01) in the NAFLD activity score (NAS), which is a summation of the separate scores for steatosis (0–3), hepatocellular ballooning (0–2) and lobular inflammation (0–3). Concurrently, MN-001 was shown to significantly down-regulate (*P*<0.01) the expression of MCP-1, CCR2, collagen type-1, and TIMP-1; all of which are genes associated with the formation of fibrosis.

- *Study #2*: In a second study, the same STAM™ (NASH-HCC) mouse model of NASH was utilized, however the mice were at a more advanced stage of NASH. MN-001 was administered orally once daily (10, 30, or 100 mg/kg) for four weeks. Once again, treatment with MN-001 resulted in a statistically significant decrease in NAS score (P<0.001), owing mostly to a decrease in hepatocyte ballooning score and lobular inflammation score. Fibrosis area was also significantly reduced in the MN-001 treated group (P<0.01). MN-001 was once again shown to decrease expression levels of the previously tested genes along with LOXL2, a gene shown to be upregulated in fibrotic livers (Barry-Hamilton *et al*., 2010). Importantly, treatment with MN-001 had no effect on body weight or general condition of the mice compared to placebo.

We believe the market opportunity for MN-001 in this indication is quite large, as there are approximately 5 million patients in the U.S. with the triple indication of NAFLD, T2DM, and hypertriglyceridemia. In addition, larger pharmaceutical companies have shown an interest in targeting this patient population. In October 2019, Pfizer Inc. (PFE) and Akcea Therapeutics Inc. (which was subsequently acquired by Ionis Pharmaceuticals Inc.) entered into a worldwide licensing agreement for AKCEA-ANGPTL3-LRx (vupanorsen), an antisense therapy targeting angiopoietin-like 3 (ANGPTL3) protein in the liver. The agreement included a $250 million upfront license fee, up to $1.3 billion in development, regulatory, and sales milestone payments, and double-digit royalties on sales. Pfizer projected peak revenues of $3 billion were possible, however in January 2022 the program was discontinued following results from a Phase 2b trial that showed the magnitude of reduction in non-HDL cholesterol and TG was not sufficient, there were dose-dependent increases in liver fat, and some patients experienced elevations in the liver enzyme alanine aminotransferase (ALT) and aspartate aminotransferase (AST). While we believe these issues were drug specific, the fact remains that this patient population represents a large market opportunity for a safe and effective drug.

Financial Update

On May 12, 2021, MediciNova (MNOV) filed form 10-Q with financial results for the first quarter of 2022. The company reported revenues of $0 million for the first quarter of 2022, compared to $4 million for the first quarter of 2021. The decrease was due to the receipt of two milestone payments under the company's agreement with Genzyme Corporation, a subsidiary of Sanofi, in 2021. R&D expenses in the first quarters of 2022 and 2021 were $2.1 million. The expense was relatively the same quarter over quarter, with changes primarily due to a decrease in stock-based compensation offset by an increase in MN-166 related expenses. G&A expenses in the first quarter of 2022 were $1.3 million, compared to $2.1 million for the first quarter of 2021. The decrease was primarily due to lower stock-based compensation.

MediciNova exited the first quarter of 2022 with approximately $67.7 million in cash and cash equivalents. As of May 12, 2022, MediciNova had approximately 49.0 million shares outstanding and, when factoring in stock options, a fully diluted share count of approximately 57.0 million shares.

Conclusion

We look forward to the Phase 2 trial in NAFLD, T2DM, and hypertriglyceridemia getting underway. This is an exciting opportunity for MediciNova both in terms of potential market size but also for the potential to get a Big Pharma partner, with the deal between Pizer and Akcea representing what is possible. In addition to initiating that trial, we are looking forward to topline results from the trial of MN-166 in hospitalized COVID-19 patients at risk for developing acute respiratory distress syndrome (ARDS), as the company announced completion of enrollment for that trial in April 2022. We have made no changes to our model, and our valuation remains at $27 per share.

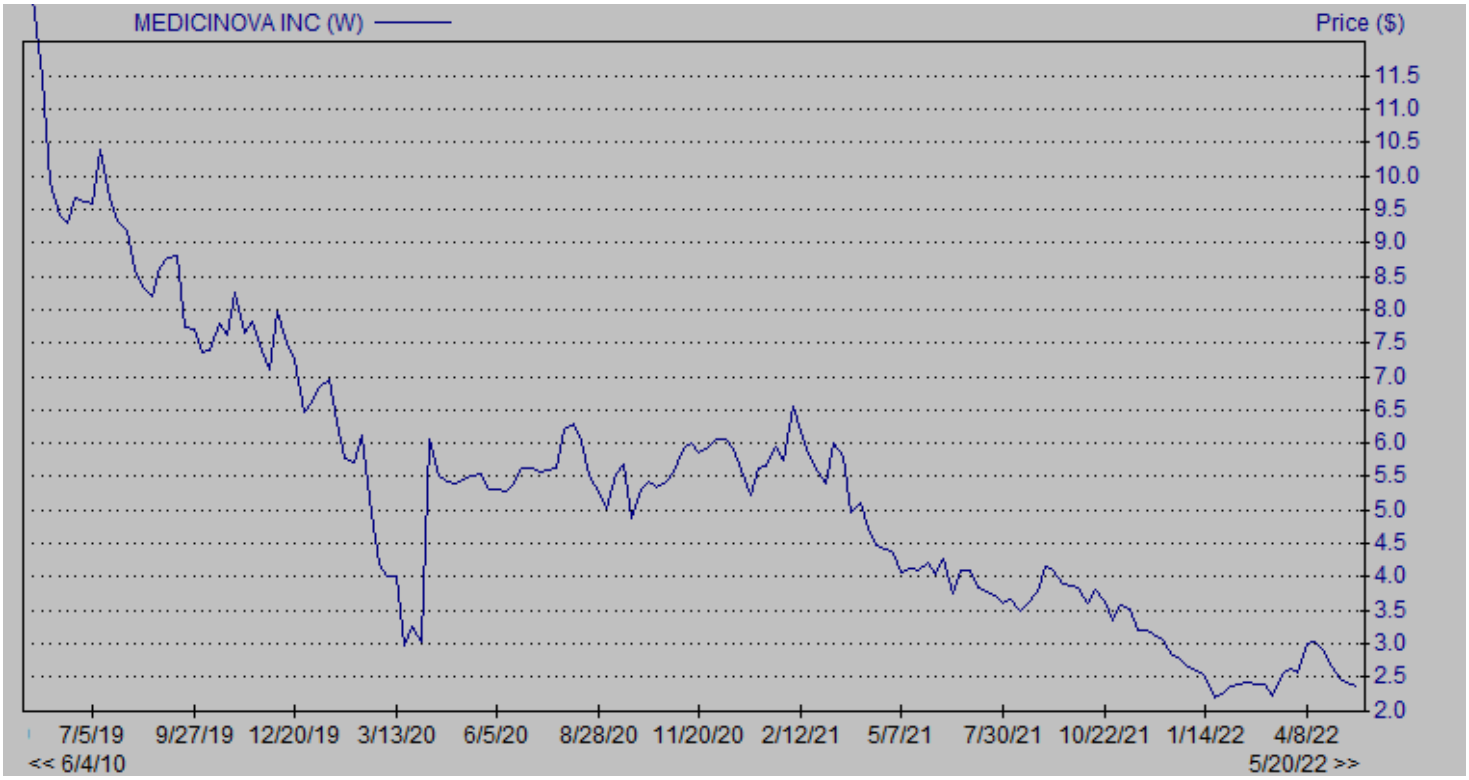
PROJECTED FINANCIALS

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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