Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

May 28, 2021
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

MediciNova, Inc. (MNOV-NASDAQ)

MNOV: Phase 3 ALS Trial Ongoing…

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 $26.50/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 (05/28/21)	$4.12
Valuation	**$26.50**

OUTLOOK

On May 13, 2021, MediciNova, Inc. (MNOV) announced financial results for the first quarter of 2021 and provided a business update. The company's lead asset, MN-166 (ibudliast), is currently being evaluated in a Phase 3 clinical trial in amyotrophic lateral sclerosis (ALS), with the company having optimized the design of the Phase 3 trial based on results from the Phase 2 trial. Enrollment continues in that study and we anticipate future updates on the trial from the company. Additional milestones upcoming for the company include updates on progressive MS, initiation of a larger trial of MN-166 in glioblastoma (GBM), Phase 2 data for MN-001 (tipelukast) in idiopathic pulmonary fibrosis (IPF), and the initiation of a Phase 2 study of MN-001 in non-alcoholic steatohepatitis (NASH).

SUMMARY DATA

52-Week High	**$11.00**
52-Week Low	**$3.93**
One-Year Return (%)	**-22.85**
Beta	**1.37**
Average Daily Volume (sh)	**262,586**
Shares Outstanding (mil)	**49**
Market Capitalization ($mil)	**$201**
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	**High**
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 E	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	-$0.08 E	-$0.09 E	-$0.10 E	-$0.27 E
2022					-$0.37 E
2023					-$0.39 E

WHAT'S NEW

Business Update

Phase 3 ALS Trial Ongoing

MediciNova, Inc. (MNOV) is currently conducting a Phase 3 clinical trial of MN-166 (ibudilast) in patients with amyotrophic lateral sclerosis (ALS). The clinical trial is a multi-center, two-arm, randomized, double blind, placebo-controlled trial that will compare MN-166 to placebo in approximately 230 patients with ALS (NCT04057898). Participants in the trial will be randomized 1:1 between placebo and 100 mg/day of MN-166 for 12 months of treatment. The primary endpoint of the trial is the mean change from baseline in ALS functional rating scale-revised (ALSFRS-R) (Cedarbaum *et al*., 1999) at month 12 and survival time. The ALSFRS-R consists of a series of 12 questions on basic tasks (speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, and respiratory insufficiency) that are rated on a five-point scale where 0 = can't do and 4 = normal ability. The individual items are summed to produce a score of between 0 = death and 48 = best. The ALSFRS-R score is utilized to keep track of the health of all ALS patients, and is a common outcome measure in ALS clinical trials as well as an established FDA-approvable endpoint. Secondary endpoints in the trial include the mean change from baseline in muscle strength and quality of life, responders, time to survival, and safety and tolerability.

Important inclusion criteria include onset of ALS no more than 18 months prior to screening, the use of riluzole for at least 30 days prior to initiation of the study drug, slow vital capacity or forced vital capacity of at least 70% of predicted, and an ALSFRS-R score of at least 35 at screening. Patients currently taking Nuedexta® (dextromethorphan/quinidine) may be eligible as long as they cease taking it three months prior to entering the trial.

The company has optimized the design of the Phase 3 trial to improve the chances for success based on the results of the Phase 2 trial, including:

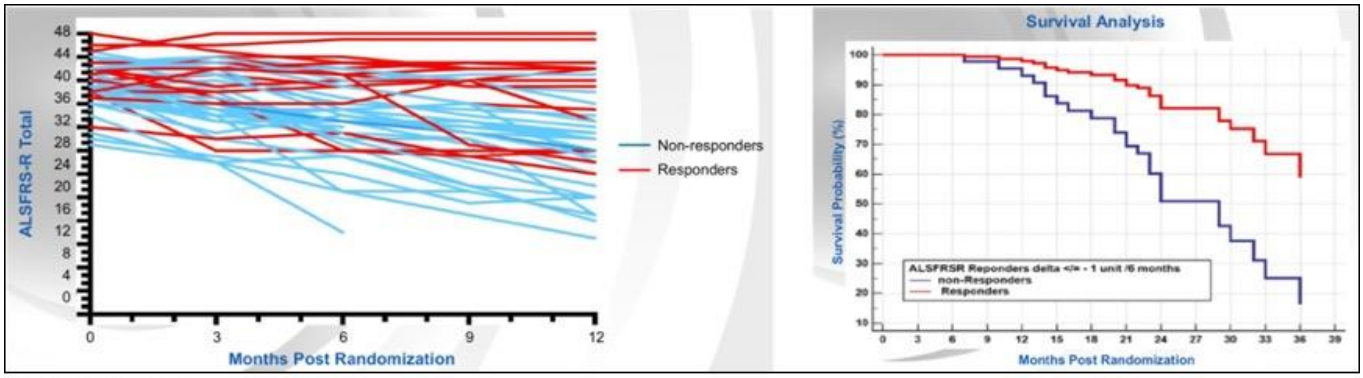
- A Higher Dose of MN-166: The company previously completed a Phase 2 trial using 60 mg/day of MN-166 in ALS patients. The dose for the Phase 3 trial has been increased to 100 mg/day based on the safety of 100 mg/day being established in other clinical trials, including the company's successful Phase 2b trial of MN-166 in patients with progressive MS. Based on the clear dose-dependent response of MN-166 observed in other studies, we anticipate a higher dose leading to greater efficacy than was seen in the Phase 2 trial.

- A Longer Treatment Period: The Phase 2 trial utilized a six-month double-blind treatment period while the Phase 3 trial has a 12-month double-blind treatment period. Given the variability that is typically seen with the progression of ALS and the fact that the disease progresses over time, a longer treatment period will likely make it easier to achieve a statistically significant treatment effect.

- Enrolling Patients in the Early Stage of Disease: A subgroup analysis of the Phase 2 trial showed that patients who were more recently diagnosed fared better on MN-166 than those that were farther along in their disease, thus the Phase 3 trial will only enroll patients ≤18 months from ALS onset.

- Excluding Slow Progressors: ALS patients whose disease is progressing at a slower rate are excluded from the Phase 3 trial as it is harder to show a treatment effect with those patients included in the data set.

An example of the data seen in the Phase 2 ALS trial is shown in the following graphs, which depict the difference between 'responders' and 'non-responders'. The graph on the left shows the change in ALSFRS-R score over 12 months. A responder was defined as a subject that had a decline of 1 point, no change, or improved on the ALSFRS-R score over six months. Interestingly, there are even a few patients whose ALSFRS-R score increased over six months of treatment with MN-166. The graph on the right shows that responders survived longer than non-responders, showing the importance of slowing the decrease in the ALSFRS-R score.



Source: MediciNova, Inc.

Financial Update

On May 13, 2021, MediciNova (MNOV) announced financial results for the first quarter of 2021. The company reported revenues of $4 million for the first quarter of 2021, compared to $0 million for the first quarter of 2020. The increase was due to the receipt of two milestone payments under the company's agreement with Genzyme Corporation, a subsidiary of Sanofi. R&D expenses in the first quarter of 2021 were $2.1 million, compared to $1.3 million for the first quarter of 2020. The increase was primarily due to higher clinical trial expenses for MN-166 in ALS along with higher stock-based compensation. G&A expenses in the first quarter of 2021 were $2.1 million, compared to $1.7 million for the first quarter of 2020. The increase was primarily due to higher stock-based compensation.

MediciNova exited the first quarter of 2021 with approximately $76.3 million in cash and cash equivalents. This was due in part to a $20 million private placement of common stock sold to 3D Opportunity Master Fund which closed in January 2021. We estimate the company has sufficient capital to fund operations at least through the end of 2022. As of May 11, 2021, MediciNova had approximately 48.8 million shares outstanding and, when factoring in stock options, a fully diluted share count of approximately 57.0 million shares.

Conclusion

Upcoming milestones for MediciNova include providing updates on the ongoing Phase 3 trials in ALS and degenerative cervical myelopathy (DCM), an update on plans for MN-166 in progressive MS, to initiate a larger trial in glioblastoma (GBM) for MN-166, updates on the acute respiratory distress syndrome (ARDS) program (both in COVID-19 and the BARDA contract), Phase 2 data for MN-001 (tipelukast) in idiopathic pulmonary fibrosis (IPF), and to initiate a Phase 2 trial of MN-001 in non-alcoholic steatohepatitis (NASH). The company has a strong balance sheet and low cash burn to see it through those important milestones. With no changes to our model our valuation remains at $26.50.

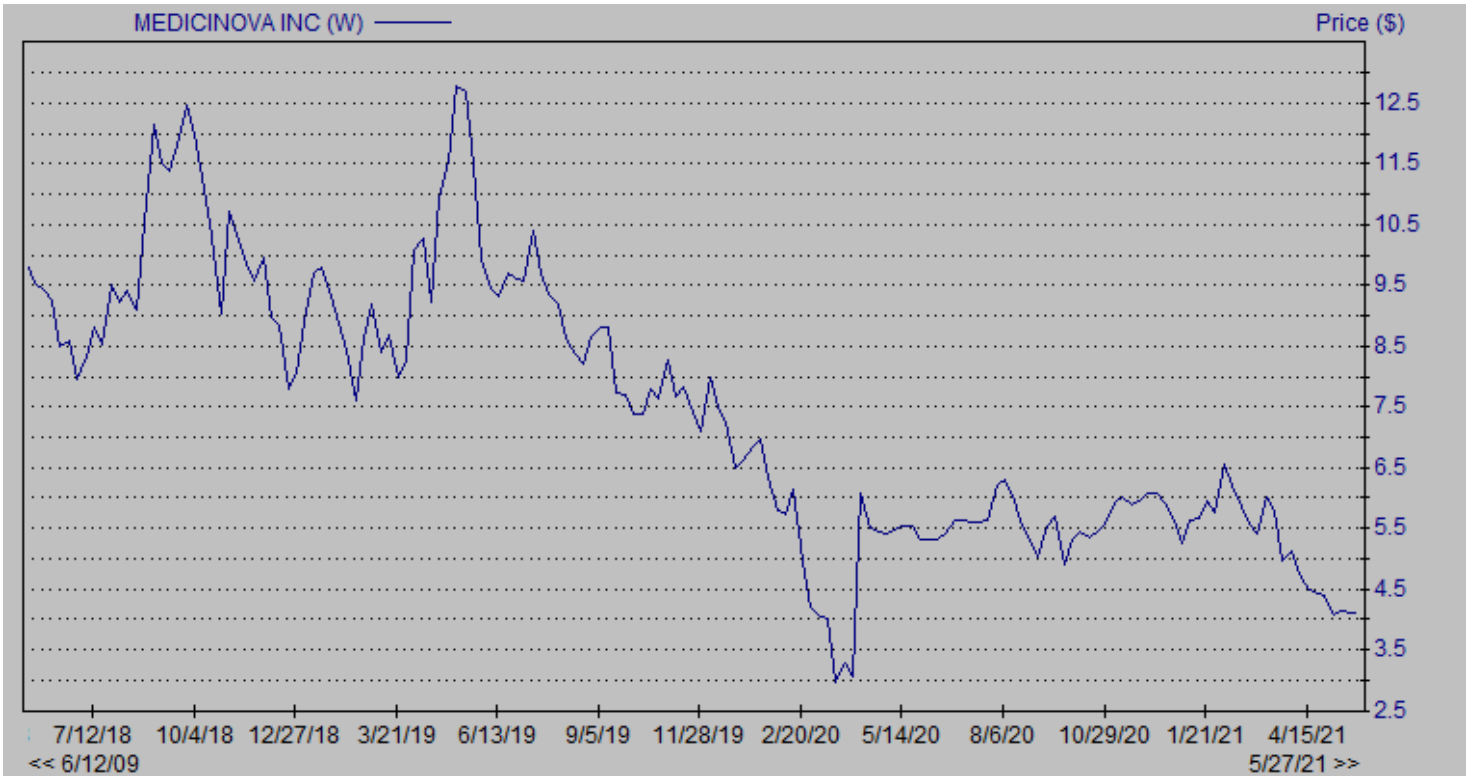
PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2020 A	Q1 A	Q2 E	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	$2.3	$2.5	$2.8	$9.7	$11.0	$13.0
General & Administrative	$6.7	$2.1	$1.8	$1.9	$2.0	$7.8	$8.0	$9.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($14.2)	($0.2)	($4.1)	($4.4)	($4.8)	($13.5)	($19.0)	($22.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.3	$0.0	$0.1	$0.1	$0.1	$0.3	$0.4	$0.4
Pre-Tax Income	($13.9)	($0.2)	($4.0)	($4.3)	($4.7)	($13.2)	($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)**	**($4.0)**	**($4.3)**	**($4.7)**	**($13.2)**	**($18.6)**	**($21.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.31)**	**($0.00)**	**($0.08)**	**($0.09)**	**($0.10)**	**($0.27)**	**($0.37)**	**($0.39)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	44.413	47.535	48.800	49.000	49.200	48.634	50.000	55.000

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.