

2021年6月23日

Zacks Small-Cap Researchによる当社レポートの発表に関するお知らせ

現地時間の2021年6月22日、米国シカゴに本拠を置く投資家向け情報サービス企業Zacks Small-Cap ResearchのDavid Bautz氏による、アルコール使用障害に関する論文掲載のお知らせ（日本時間2021年6月21日公表）に基づくレポートが発表されましたので、参考情報としてお知らせいたします。

なお、当該レポートは、恐れ入りますが、権利の都合上、英文のままのご案内となりますので、ご了承ください。

【Zacks Small-Cap Research 公式 web サイト】

<https://scr.zacks.com/>

※当該レポートは、本書の下部にありますので、スクロールしてください。

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MediciNova, Inc.

(MNOV-NASDAQ)

MNOV: Positive Results for MN-166 in Phase 2 AUD Trial...

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 \$28.00/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 (06/22/21) **\$4.20**
Valuation **\$28.00**

OUTLOOK

On June 21, 2021, MediciNova, Inc. (MNOV) announced that positive results from a Phase 2 trial of MN-166 (ibudilast) in alcohol use disorder (AUD) were published in *Translational Psychiatry*. It was a randomized, double blind, placebo controlled trial to evaluate the effect of 14 days of ibudilast treatment on mood, heavy drinking, and neural reward signals in 52 individuals suffering from AUD. While ibudilast did not have a significant effect on negative mood, it reduced the odds of heavy drinking across time by 45%, attenuated alcohol cue-elicited activation in the ventral striatum compared to placebo ($P=0.01$), and reduced alcohol craving compared to placebo on non-drinking days ($P=0.02$). These results show that ibudilast has promising potential for aiding those with AUD.

SUMMARY DATA

52-Week High **\$11.00**
52-Week Low **\$3.76**
One-Year Return (%) **-24.19**
Beta **1.38**
Average Daily Volume (sh) **1,350,690**

Shares Outstanding (mil) **49**
Market Capitalization (\$mil) **\$205**
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

Type of Stock
Industry

Above Avg.
Small-Blend
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

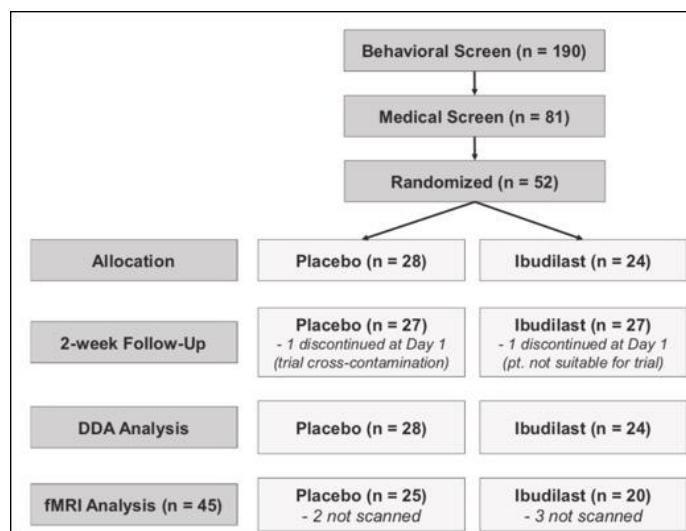
	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-\$0.06 A	-\$0.10 A	-\$0.08 A	-\$0.07 A	-\$0.31 A
2021	-\$0.00 A	-\$0.08 E	-\$0.09 E	-\$0.10 E	-\$0.27 E
2022					-\$0.37 E
2023					-\$0.39 E

WHAT'S NEW

Business Update

Positive Results for MN-166 in Phase 2 AUD Trial

On June 21, 2021, MediciNova, Inc. (MNOV) announced that positive results from a Phase 2 trial of MN-166 (ibudilast) in alcohol use disorder (AUD) were published in *Translational Psychiatry*, a *Nature* publication (Grodin *et al.*, 2021). The trial was a two-week randomized, double blind, placebo placebo-controlled study that tested the effect of ibudilast on mood, heavy drinking, and neural reward signals in individuals with AUD (NCT03489850). The following image gives an overview of the trial, in which a total of 52 individuals were randomized, 50 completed the study, and 45 provided usable neuroimaging data (ibudilast, n=20; placebo, n=25). There were no significant differences between groups on any baseline characteristic and overall medication compliance was high (98.7% via self-report and 97.1% via pill count).



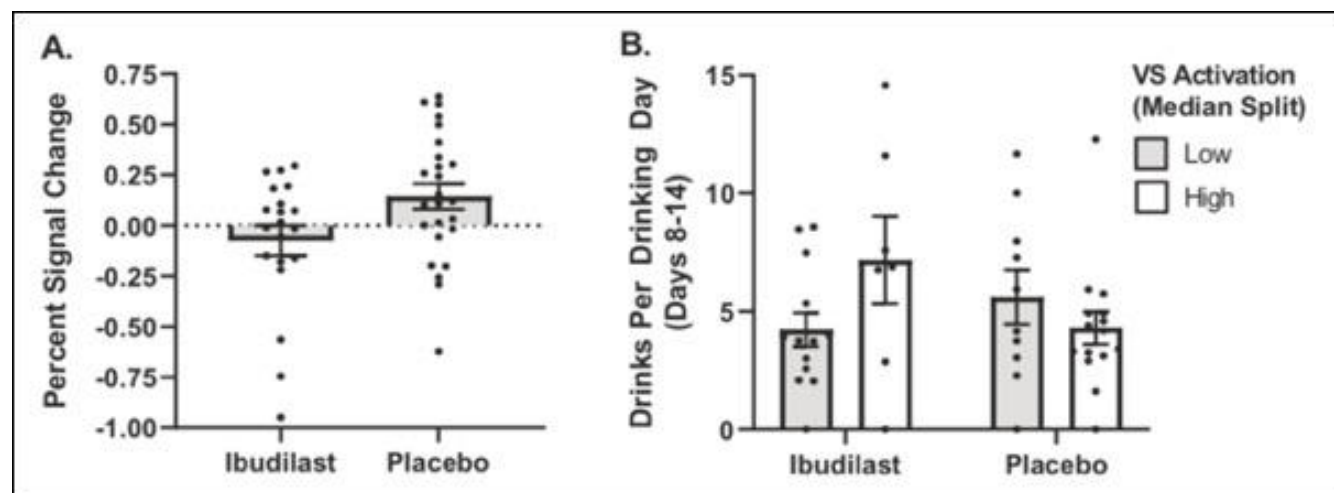
Source: Grodin *et al.*, 2021

The following table summarizes the statistical models and the effect of different predictor variables on mood, heavy drinking, and craving. While ibudilast did not have an effect on mood, it did significantly reduce the odds of heavy drinking days (HDD) compared to placebo by 45% ($P=0.04$). This was in spite of the fact that there was no significant difference in adverse events (AEs) between groups, indicating that the reduction was not due to an increased side effect, such as nausea, in the ibudilast group. In addition to reducing the odds of heavy drinking days, ibudilast reduced alcohol craving compared to placebo on non-drinking days ($P=0.02$).

Model and predictor variables	Parameter estimate	SE	95% confidence limits				Odds ratio	95% confidence limits	
			LL	UL	Z	P		LL	UL
Negative mood (POMS)									
Medication (IBUD)	0.34	0.69	-1.01	1.69	0.49	0.62			
Drinking day (no)	-0.13	0.18	-0.48	0.22	-0.74	0.46			
Med X drinking day	0.21	0.49	-0.76	-0.48	0.42	9.67			
Heavy drinking									
Medication (IBUD)	-0.60	0.30	-1.19	-0.02	-2.02	0.04	0.55	0.30	0.98
Time	0.003	0.02	-0.04	0.04	0.16	0.87	1.00	0.96	1.04
Smoking status (nonsmoker)	-0.87	0.32	-1.50	-0.24	-2.71	0.007	0.42	0.22	0.79
Baseline HDD	0.08	0.03	0.03	0.13	2.99	0.003	1.08	1.03	1.14
Craving (AUQ)									
Medication (IBUD)	-0.16	0.76	-1.62	1.30	-0.21	0.83			
Drinking day (no)	-1.06	0.28	-1.61	-0.50	-3.75	<0.001			
Med X Drinking Day	-0.90	0.49	-1.86	0.06	-1.84	0.07			

Source: Grodin *et al.*, 2021

For the brain imaging studies, alcohol induced the expected brain activation in all participants. The following figure on the left shows that ibudilast significantly attenuated bilateral ventral striatal (VS) activation to alcohol cues ($P=0.01$). There was also a significant effect of sex on percent signal change, with men having higher activation than women. The following image on the right shows that in individuals who had decreased activation of the VS to alcohol, ibudilast treatment resulted in a lower number of drinks per drinking day in the week following the scan.



Source: Grodin et al., 2021

Conclusion

The results showing ibudilast significantly reduced the probability of heavy drinking compared to placebo builds on previous research showing that ibudilast has a positive effect on AUD patients. In addition, the results showing VS activation to alcohol cues was predictive of drinking in the week following the neuroimaging scan suggests a biobehavioral mechanism that ibudilast acts through by reducing the reward response to alcohol cues in the brain and, in turn, resulting in a reduction in heavy drinking. Dr. Lara Ray, who conducted the aforementioned study, is currently conducting another clinical trial of ibudilast for the treatment of AUD that includes a 12-week treatment period with a primary outcome of percent heavy drinking days ([NCT03594435](https://clinicaltrials.gov/ct2/show/study/NCT03594435)) and we look forward to results from that study. The positive results from this study has led us to increase the probability of approval for MN-166 in AUD, which has increased our valuation from \$26.50 to \$28.

PROJECTED FINANCIALS

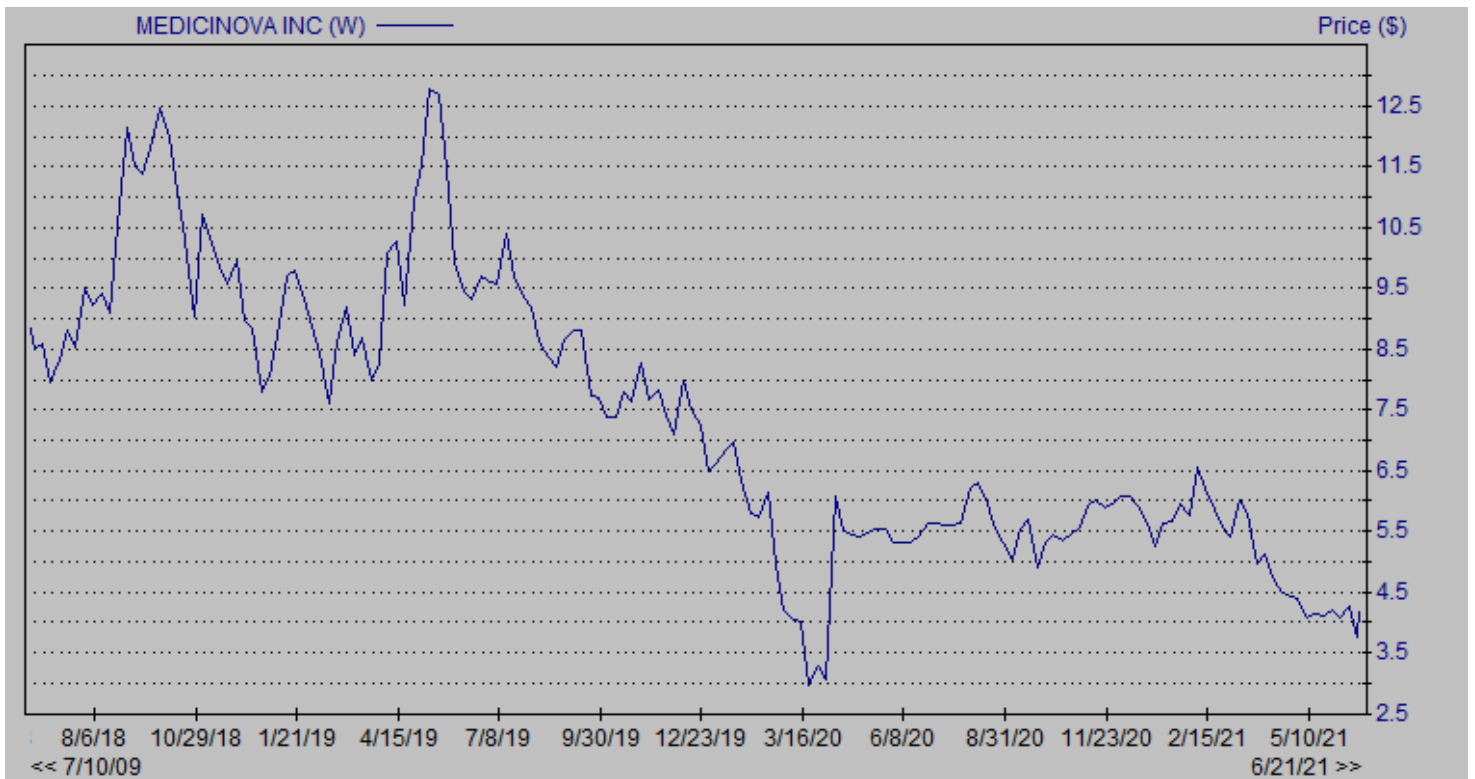
MediciNova Inc. Income Statement

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
<i>Product Gross Margin</i>	-	-	-	-	-	-	-	-
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)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
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
<i>Tax Rate</i>	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)
<i>Net Margin</i>	-	-	-	-	-	-	-	-
Reported EPS	(\$0.31)	(\$0.00)	(\$0.08)	(\$0.09)	(\$0.10)	(\$0.27)	(\$0.37)	(\$0.39)
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
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

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