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MediciNova, Inc. (MNOV-NASDAQ)

MNOV: Additional Data Presented for MN-166 in MS and ALS…

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 $18/share. This model is highly dependent upon continued clinical success of both MN-166 and MN-001 and will be adjusted accordingly based upon future clinical results.

Current Price (05/01/18)	$11.27
Valuation	**$18.00**

OUTLOOK

MediciNova, Inc. (MNOV) recently had data presented on one of its lead compounds in two different indications at the American Academy of Neurology (AAN) 70th Annual Meeting. Dr. Robert Fox, the principal investigator of the Phase 2 SPRINT-MS study of ibudilast in patients with progressive multiple sclerosis (MS), presented additional data from the study showing that the previously announced results of a statistically significant reduction in whole brain atrophy by MN-166 were not driven by outliers and the data were still consistent even when adjusting for baseline age. Final data for the Phase 2 clinical trial of MN-166 in patients with amyotrophic lateral sclerosis (ALS) were presented by Dr. Benjamin Brooks, which showed a higher rate of responders in the ibudilast-treated group along with increased overall survival in the responders group.

SUMMARY DATA

52-Week High	**$13.91**
52-Week Low	**$4.43**
One-Year Return (%)	**97.72**
Beta	**0.31**
Average Daily Volume (sh)	**249,493**
Shares Outstanding (mil)	**41**
Market Capitalization ($mil)	**$464**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**19**
Insider Ownership (%)	**15**
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	**Above Avg.**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	0 A	0 A	0 A	0 A	0 A
2018	0 A	0 E	0 E	0 E	0 E
2019					0 E
2020					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.09 A	-$0.08 A	-$0.11 A	-$0.04 A	-$0.32 A
2018	-$0.12 A	-$0.11 E	-$0.11 E	-$0.11 E	-$0.45 E
2019					-$0.43 E
2020					-$0.41 E

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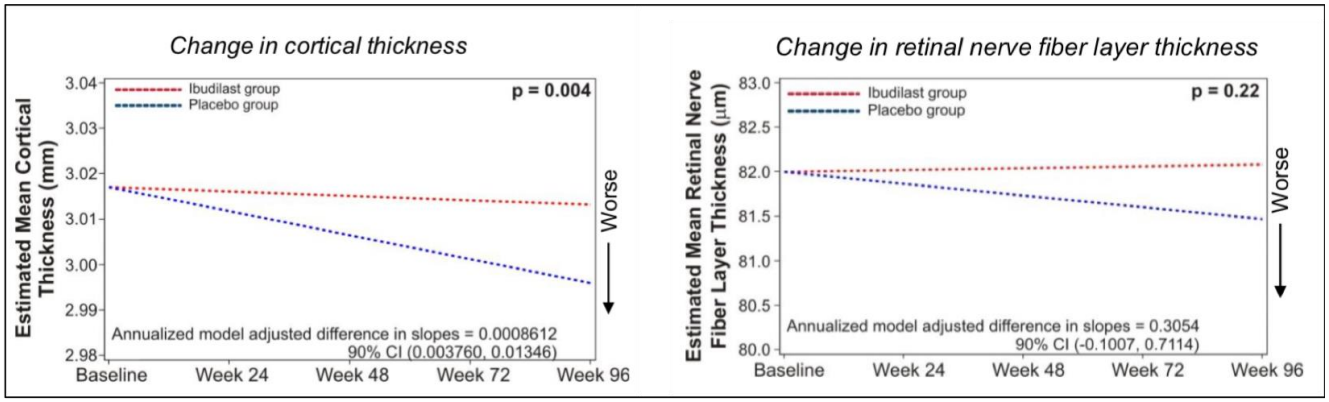
WHAT'S NEW

Additional Data Presented on MN-166 in MS and ALS

MediciNova, Inc. (MNOV) recently had additional data presented on one of its lead compounds, MN-166 (ibudilast), in two different indications at the American Academy of Neurology (AAN) 70th Annual Meeting.

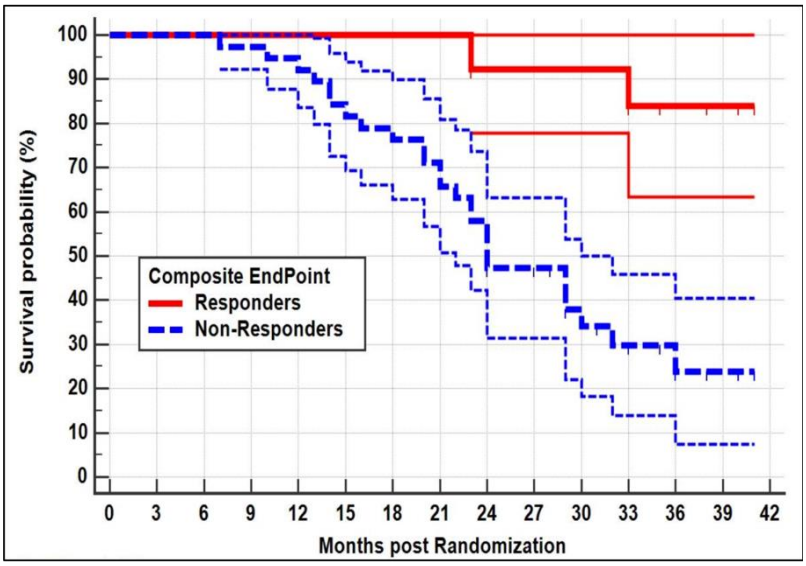
Progressive Multiple Sclerosis (MS): Dr. Robert Fox, the principal investigator of the completed Phase 2 SPRINT-MS trial, gave a presentation titled "A Phase II Trial of Ibudilast in Progressive Multiple Sclerosis". Included in the presentation was the previously announced data showing that treatment with MN-166 resulted in a 48% reduction in the rate of whole brain atrophy progression. In addition, Dr. Fox presented data showing that the results were not due to any outliers, a modified per-protocol sensitivity analysis resulted in findings consistent with the primary analysis (*P*=0.02), and an analysis to adjust for baseline age was also consistent with the earlier findings (*P*=0.03).

New data presented by Dr. Fox concerned secondary endpoints derived from novel imaging techniques. The purpose of these outcomes was simply to gather data as the clinical relevance for any of them is currently unknown. The following graphs show the changes in cortical thickness and retinal nerve fiber layer thickness. There was an 80% slowing in the progression of cortical atrophy, which was statistically significant (*P*=0.004). While the difference in retinal nerve fiber layer thickness was not statistically significant (*P*=0.22), we are still intrigued by the way that MN-166-treated patients actually showed a slight increase in thickness while those on placebo had a substantial decrease. We believe the new data presented at AAN is encouraging because ibudilast's effect compared to placebo is moving in the right direction for all of these endpoints. MediciNova is planning to move forward into Phase 3 in progressive MS and is currently preparing for an end-of-Phase 2 meeting with FDA.



Source: Fox *et al.*, 2018

Amyotrophic Lateral Sclerosis (ALS): Dr. Benjamin Brooks, principal investigator of the Phase 2 clinical trial of MN-166 in patients with ALS, presented additional data from this recently completed clinical trial. A novel composite endpoint was established whereby a responder was defined as someone who 1) had < 12 unit drop in ALSFRS-R total score at the end of the open-label extension phase (< 1 unit drop per month over 12 months) and/or 2) had < 1 MMT unit decline in neck and/or leg muscles at the end of the open-label extension phase. There was a higher rate of responders in the MN-166 group (11/34) than in the placebo group (2/17). In addition, the following graph shows that responders had increased survival compared to non-responders (*P*=0.001). MediciNova is planning to discuss the next steps in its development plan for ALS with FDA.



Source: Brooks *et al.*, 2018

MN-001 Reduces Serum Triglycerides in NASH Patients

On April 13, 2018, MediciNova announced the presentation of positive results from the company's Phase 2 clinical trial of MN-001 (tipelukast) in patients with non-alcoholic steatohepatitis (NASH) and non-alcoholic fatty liver disease (NAFLD) at the 53rd annual meeting of the European Association for the Study of the Liver (EASL).

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), and MN-001 reduced serum triglyceride levels in 14/15 subjects. The average pre-treatment serum triglyceride 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 triglyceride level of 1288 mg/dL prior to treatment that was reduced to 300 mg/dL after treatment. That analysis showed 13/14 subjects with a reduction in serum triglycerides, 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.

MediciNova has ceased enrolling additional patients and is stopping the study early due to achieving the primary endpoint, a reduction in average serum triglyceride level. Data will continue to be collected on patients that are already enrolled in the study, including a number of secondary endpoints at the 12-week timepoint. Based on the positive data in reducing triglycerides, we believe MediciNova may pursue a partnership for development of MN-001 to lower triglycerides in all patients, not limited to NASH and NAFLD.

MN-166 does not Meet Primary Endpoint in Phase 2 Study of Methamphetamine Dependence

On March 29, 2018, MediciNova announced that the Phase 2 study of MN-166 (ibudilast) in methamphetamine dependence did not meet the primary endpoint of methamphetamine abstinence during the final two weeks of treatment. The study was a randomized, double-bind, placebo-controlled, outpatient study of treatment-seeking individuals with methamphetamine dependence at a UCLA research clinic. Study subjects were randomized to MN-166 (100 mg/day) or placebo for 12 weeks with twice-weekly clinic visits for counseling, urine drug tests, and safety/medication adherence monitoring. While disappointing, we always viewed this indication as secondary to the primary focus for MN-166 in progressive multiple sclerosis (MS) and amyotrophic lateral sclerosis (ALS). The use of MN-166 in methamphetamine dependence was not factored into our valuation model, thus these results will not alter our fair value of the company.

Financial Update

On April 25, 2018, MediciNova filed form 10-Q with financial results for the first quarter of 2018. As expected, the company did not report any revenues. Net loss for the first quarter of 2018 was $4.5 million, or $0.12 per share, and was comprised of $1.7 million in R&D expenses and $3.0 million in G&A expenses. This compares with $0.9 million in R&D expenses and $2.1 million in G&A expenses for the first quarter of 2017. The increase in R&D expenses

was due to higher stock-based compensation and an increase in clinical trial activities related to MN-166. The increase in G&A expenses was due primarily to higher stock-based compensation.

Total operating burn for the first quarter of 2018 was $4.1 million and the company exited the first quarter of 2018 with approximately $62.9 million in cash and cash equivalents. On February 12, 2018, the company completed an underwritten public offering of approximately 4.4 million shares of common stock at a price of $9.05 per share that resulted in net proceeds of $37.4 million. An additional 126,038 shares were sold pursuant to the partial exercise by the underwriters of their over-allotment option. We believe the company has sufficient capital to fund operations through the end of 2019.

As of April 24, 2018, MediciNova had approximately 41.1 million shares of common stock outstanding. When factoring in the approximately 6.6 million outstanding stock options and the 0.75 million warrants (which expire on May 9, 2018) the company has a fully diluted share count of approximately 48.4 million.

Conclusion

We are encouraged by both sets of data presented on MN-166 at AAN and we look forward to hearing additional details about future clinical trials for the drug in both MS and ALS, indications for which we believe MN-166 has blockbuster potential. The Phase 2 NASH data showing a robust decrease in triglycerides is encouraging and could allow for the company to target a broad population of patients with hypertriglyceridemia, however we will have to wait to see data on the decrease in liver fat in order to make a better comparison to other NASH compounds currently in development. The company is in strong financial shape and our probability adjusted discounted cash flow model results in a current valuation of $18.

PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2017 A	Q1 A	Q2 E	Q3 E	Q4 E	2018 E	2019 E	2020 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	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$4.224	$1.662	$1.600	$1.600	$1.600	$6.462	$6.800	$7.000
General & Administrative	$8.803	$3.005	$3.100	$2.900	$2.900	$11.905	$12.000	$12.400
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($13.0)	($4.7)	($4.7)	($4.5)	($4.5)	($18.4)	($18.8)	($19.4)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	$0.1	$0.0	$0.0	$0.0	$0.1	$0.0	$0.0
Pre-Tax Income	($12.9)	($4.5)	($4.7)	($4.5)	($4.5)	($18.2)	($18.8)	($19.4)
Income Taxes Paid	($2)	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($11.2)**	**($4.5)**	**($4.7)**	**($4.5)**	**($4.5)**	**($18.3)**	**($18.8)**	**($19.4)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.32)**	**($0.12)**	**($0.11)**	**($0.11)**	**($0.11)**	**($0.45)**	**($0.43)**	**($0.41)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	35.137	39.132	41.000	41.200	41.400	40.683	44.000	47.000

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

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