Zacks Small-Cap Research

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MediciNova, Inc. (MNOV - Nasdaq)

MNOV: Phase 2b Trial of MN-166 in Progressive MS Will Continue to Conclusion…

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 $10/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 (12/22/16)	$6.90
Valuation	**$10.00**

OUTLOOK

On December 19, 2016, MediciNova, Inc. (MNOV) announced that the Data and Safety Monitoring Board (DSMB) for the ongoing Phase 2b clinical trial of MN-166 (ibudilast) in progressive multiple sclerosis recommended that the trial should continue as planned. This was a positive outcome, as the trial could have been stopped early for futility. We did not view the trial stopping early for overwhelming efficacy as being a likely outcome since the study was powered for 250 patients, and the interim efficacy analysis was performed using data from only half of the subjects. The trial will continue as planned, with final results expected in the second half of 2017.

SUMMARY DATA

52-Week High	**$9.39**
52-Week Low	**$3.47**
One-Year Return (%)	**96.58**
Beta	**0.80**
Average Daily Volume (sh)	**138,226**
Shares Outstanding (mil)	**35**
Market Capitalization ($mil)	**$238**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**22**
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 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**

Risk Level	**Above Average**
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)
2015	0 A	0 A	0 A	0 A	0 A
2016	0 A	0 A	0 A	0 E	0 E
2017					0 E
2018					0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.09 A	-$0.09 A	-$0.06 A	-$0.09 A	-$0.33 A
2016	-$0.11 A	-$0.10 A	-$0.08 A	-$0.05 E	-$0.34 E
2017					-$0.34 E
2018					-$0.35 E

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WHAT'S NEW

Phase 2b Trial of MN-166 to Continue as Planned

On December 19, 2016, MediciNova, Inc. (MNOV) announced that the Data and Safety Monitoring Board (DSMB) for the ongoing Phase 2b clinical trial of MN-166 (ibudilast) in progressive multiple sclerosis (MS) reviewed the results of the interim efficacy analysis and recommended to the National Institute of Neurological Diseases and Stroke (NINDS) that the trial should continue as planned, to which the NINDS has agreed.

We view this as a positive outcome, as there were three potential consequences to the interim analysis: 1) the trial could be stopped for futility; 2) the trial could continue as planned; or 3) the trial could be stopped for overwhelming efficacy. We viewed the trial being stopped early for overwhelming efficacy as a highly unlikely outcome, as the trial was powered for 250 patients and the interim analysis was only performed using data from half of the patients enrolled (127 out of 255 enrolled). Thus, the fact that the DSMB recommended that the trial continue as planned is indicative that there is at least a positive trend in the direction of efficacy for MN-166. If there was no trend in favor of MN-166, the trial would have been stopped for futility. We look forward to the release of the final data analysis, which we anticipate will be in the second half of 2017, since the final patient was enrolled in the study in June 2015.

Phase 2b Trial of MN-166 in Progressive MS

NeuroNEXT, an NIH funded clinical trial network that conducts studies of treatments for neurological diseases, is conducting the SPRINT-MS trial, a Phase 2b trial evaluating MN-166 in primary progressive MS (PPMS) and secondary progressive MS (SPMS) patients titled **"**A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability and Activity of Ibudilast (MN-166) in Subjects with Progressive Multiple Sclerosis" (NCT01982942).

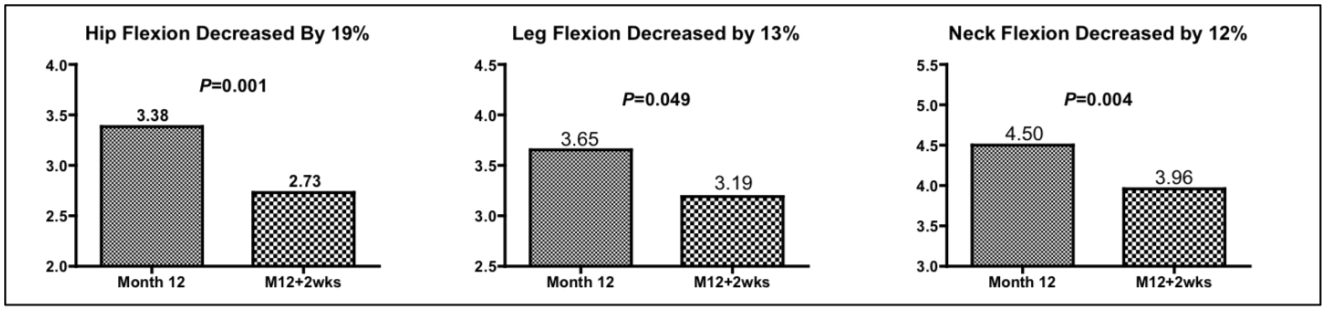
Participants are receiving either MN-166 (100 mg/day) or placebo twice a day (e.g., MN-166 50 mg or placebo taken once in the morning and once at night) for a total of 96 weeks of treatment with a follow up visit one month after the week 96 visit. In June 2015, the company announced the trial had completed randomization of 255 patients. Ninety-six weeks from that date is approximately the middle of April 2017, thus we would anticipate final results sometime in the second half of 2017.

The primary outcome of the ongoing study is the rate of change in brain atrophy over 96 weeks as measured by brain parenchymal fraction (BPF) using MRI. MN-166 was previously tested in a randomized, double blind, placebo controlled Phase 2a clinical trial of 297 patients with relapsing-remitting MS (RRMS) or SPMS with continued relapses. Patients were treated for 12 months with 30 mg/day MN-166, 60 mg/day MN-166, or placebo. While the study did not hit the primary outcome on the cumulative number of newly active lesions seen on bimonthly MRI scans over the first 12 months of treatment, a preplanned evaluation of brain atrophy showed a statistically significant dose-dependent decrease in atrophy progression in the 60-mg MN-166 group (mean -0.79) compared to placebo (mean -1.20, $P = 0.04$) after only one year of treatment. We believe that due to the fact the ongoing study is testing a higher dose of MN-166 than the earlier study (100 mg/day vs. 60 mg/day) and the treatment period is longer (96 weeks vs. 52 weeks), there is a high likelihood that the ongoing study will achieve the primary endpoint of reducing brain volume loss. Also, there is published research that indicates that the rate of brain volume loss is higher in progressive MS patients than in relapsing MS patients, which should make it easier to show a statistically significant reduction in brain volume loss in the progressive MS population (Ge *et al*., 2000).

Additional Data Presented From Phase 2 Trial of MN-166 in ALS

On December 9, 2016, MediciNova announced that Dr. Benjamin Brooks, the principal investigator of the ongoing Phase 2 clinical trial of MN-166 in patients with amyotrophic lateral sclerosis (ALS), presented exploratory interim data at the 27th International Symposium on ALS/MND in Dublin, Ireland. The exploratory analysis included a total of 26 subjects with ALS who completed the 6-month open-label extension (OLE) period of the trial that followed the 6-month double-blind treatment period. All 26 subjects were treated with MN-166 during the 6-month OLE and then stopped taking MN-166 at the end of Month 12 (following the 6-month double-blind treatment portion and the 6-month OLE). Patients were evaluated at the end of Month 12 and then again two weeks later (the patients did not take MN-166 during those two weeks) in order to evaluate the effect of stopping MN-166 treatment.

The data showed that only two weeks following the end of MN-166 treatment, there were statistically significant decreases in muscle strength as measured for hip flexion, leg flexion, and neck flexion. Were these trends to continue, it would likely result in a significant decline in the patient's health in a short period of time, as decreases in muscle strength as measured for hip flexion (Santos *et al*., 2016), leg flexion (Slavin *et al*., 1998), and neck flexion (Nakamura *et al*., 2013) are correlated with function and survival. The following graphs show the decrease in each of those measurements at the conclusion of MN-166 dosing (Month 12) and two weeks after treatment with MN-166 finished (M12+2wks).



Source: Brooks *et al*., 2016; Zacks SCR

Phase 2 Study of MN-166 in ALS

In September 2014, MediciNova initiated a Phase 2 study of MN-166 in patients with ALS (NCT02238626). This is a single center, randomized, double blind, placebo controlled six-month study to evaluate the safety, tolerability, and clinical responsiveness of MN-166 (60 mg/day) when administered as an adjunct to riluzole (100 mg/day) in up to 60 subjects with ALS. Patients in the study are randomized 2:1 to receive either MN-166 or placebo. The study includes a three month screening phase, a six-month double blind treatment phase, and a six-month open-label extension phase and is taking place at the Carolinas Healthcare System's Neuromuscular/ALS-MDA Center in Charlotte, NC. The primary endpoint of the study is the safety and tolerability of MN-166 when administered with riluzole in ALS patients. A number of secondary endpoints are being evaluated including the change in ALS Functional Rating Scale Revised (ALSFRS-R), respiratory function, muscle strength, and non-invasive ventilation.

On April 21, 2015, MediciNova announced positive interim safety data from the study that showed no difference in safety or tolerability between MN-166 and placebo in the first 21 subjects enrolled in the study following three months of treatment. Importantly, the independent safety medical monitor recommended that the study continue as planned.

On September 2, 2015, MediciNova announced that the first ALS patient using non-invasive ventilation (NIV) was enrolled in the ongoing Phase 2 clinical trial. As ALS progresses, the muscles that control breathing become weaker, which leads to impairment of breathing function and an increased susceptibility for lung infections. In addition, patients may experience shortness of breath, fatigue, sleep apnea, and weakened cough. NIV is administered through a removable face mask that is placed around the nose and mouth and is used by ALS patients that can still breathe on their own but are beginning to experience the aforementioned effects of decreased breathing capabilities. The use of NIV typically signifies that a patient is more advanced in the course of the disease than a patient not using NIV. MediciNova amended the clinical protocol to allow for the recruitment of up to 60 patients with advanced ALS using NIV in addition to the already planned recruitment of up to 60 patients with ALS that are not using NIV. We anticipate that the two sets of patients (non-NIV and NIV) will be evaluated separately.

On April 20, 2016, Dr. Benjamin Brooks presented interim data at the American Academy of Neurology (AAN) 2016 Annual Meeting. The preliminary data analysis was conducted on 25 patients (20 on MN-166, 5 on placebo) that had completed the six-month double blind portion of the study. The average decline in ALSFRS-R score from baseline to month six was 4.55 (0.76 per month) in the MN-166 group compared to 5.80 (0.97 per month) in the placebo group. Additional positive trends were seen in some of the subscores of the ALSFRS-R. Two of the subscores, for bulbar function (which measures speech, salivation, and swallowing) and arm function, showed positive trends in slowing decline in the MN-166 treated group. The mean decline in the bulbar score from baseline to month six was 0.90 (0.15 per month) in the MN-166 group compared to 1.80 (0.30 per month) in the placebo group. The mean decline in the arm score from baseline to month six was 1.50 (0.25 per month) in the MN-166 group compared to 2.40 (0.40 per month) in the placebo group.

We anticipate final results from the 6-month double-blind portion of the study in 2017.

ALS Biomarker Study Underway

MediciNova had previously announced a biomarker study in ALS patients would take place in collaboration with Massachusetts General Hospital. The trial is now enrolling and is expected to enroll 15 ALS patients and will investigate the effects of MN-166 on reducing brain microglial activation (NCT02714036). In this open-label trial, ALS patients will be administered 100 mg MN-166 daily (50 mg in the morning and 50 mg at night) for 36 weeks and the primary outcome is to measure the effects of MN-166 on brain microglial activation as measured through the uptake of [11C]-PBR28, which is a ligand that is preferentially taken up by peripheral benzodiazepine receptors (PBRs) and can be tracked by positron emission tomography (PET) imaging. PBRs are known to be upregulated on activated microglia (Imalzumi *et al*., 2007). Secondary outcome measurements include changes in ALSFRS-R, SVC, and muscle strength from baseline. This study will provide important safety and efficacy data in regards to a higher daily dose of MN-166 as the company begins preparations for planning future studies in ALS. Importantly, this biomarker could potentially be used as a screening tool for recruitment in future studies.

MN-166 Granted Orphan Drug Designation in U.S. and Orphan Medicinal Product Designation in E.U.

On October 11, 2016, MediciNova announced that the Food and Drug Administration (FDA) has granted MN-166 (ibudilast) Orphan Drug Designation (ODD) for the treatment of ALS. Orphan drug designation carries a number of incentives for the company including seven years of market exclusivity following approval for the treatment of ALS, tax credits, and a waiver of PDUFA fees.

On December 20, 2016, MediciNova announced that the European Commission has granted Orphan Medicinal Product Designation (OMPD) for MN-166 for the treatment of ALS. Similar to ODD in the U.S., OMPD carries a number of potential benefits including protocol assistance, fee reductions, and 10-year market exclusivity following approval in Europe.

Conclusion

The continuation of the Phase 2b trial of MN-166 in progressive MS is positive news for the company, as the trial could have been stopped early for futility. The fact that it is continuing means that the data is at least trending in a positive direction in favor of MN-166. We anticipate the topline results from the trial being reported in the second half of 2017. The progressive MS market opportunity is estimated to be in excess of $19 billion (based on current sales of relapsing MS drugs), thus positive results from MediciNova's Phase 2b trial in progressive MS are likely to result in a significant readjustment to the company's valuation.

The new data presented by Dr. Brooks regarding the decline in muscle strength following conclusion of treatment with MN-166 in ALS patients is intriguing, as such a rapid decline in muscle strength could portend an acceleration of the disease after stopping MN-166 treatment. The data likely warrant further investigation in a separate clinical trial designed to examine the effect of stopping MN-166 treatment.

We anticipate the final results from the double-blind portion of the ALS study in 2017. As a reminder, this trial was not designed to show statistical significance, but was instead set up to look for positive trends in clinical endpoints including ALSFRS-R, respiratory function, muscle strength, and non-invasive ventilation utilization.

We believe that the treatment of progressive MS is a potential blockbuster opportunity. As there is currently no drug approved for long-term treatment of progressive MS patients, with a market opportunity of more than $19 billion, peak sales of MN-166 could be at least several billion dollars per year if approved. As there has only ever been one drug approved for treating ALS, Sanofi's Rilutek® (riluzole) (which is not very effective), there is a huge unmet medical need for better treatment options for these patients. If effective, MN-166 would likely generate peak revenues for treating ALS of $1 billion, although we only assign a 33% chance of approval at this point based on the fact that only one drug has ever been approved for treating ALS.

Based on our probability adjusted discounted cash flow model we believe MediciNova is currently worth $10 per share.

PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2015 A	Q1 A	Q2 A	Q3 A	Q4 E	2016 E	2017 E	2018 E
MN-166 (Multiple Sclerosis)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
MN-166 (ALS)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
MN-166 (Addiction)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
MN-001 (NASH)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
MN-001 (IPF)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Grants & Collaborative Revenue	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$3.017	$1.075	$0.963	$0.890	$0.900	$3.828	$5.500	$7.000
General & Administrative	$5.805	$2.316	$2.242	$1.955	$0.900	$7.413	$6.100	$6.300
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($8.822)	($3.392)	($3.205)	($2.845)	($1.800)	($11.2)	($11.6)	($13.3)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($0.02)	$0.01	$0.01	$0.01	($0.01)	$0.0	($0.5)	($0.5)
Pre-Tax Income	($8.838)	($3.380)	($3.198)	($2.834)	($1.810)	($11.2)	($12.1)	($13.8)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($8.845)**	**($3.382)**	**($3.199)**	**($2.836)**	**($1.812)**	**($11.2)**	**($12.1)**	**($13.8)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.33)**	**($0.11)**	**($0.10)**	**($0.08)**	**($0.05)**	**($0.34)**	**($0.34)**	**($0.35)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	26.579	30.357	32.576	34.476	34.500	32.977	36.000	40.000

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

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