Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

September 28, 2018
David Bautz, PhD
312-265-9471
dbautz@zacks.com

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

MediciNova, Inc. (MNOV-NASDAQ)

MNOV: Positive FDA Feedback on ALS Phase 3 Plan…

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 $19/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 (09/28/18)	$11.97
Valuation	**$19.00**

OUTLOOK

MediciNova, Inc. (MNOV) recently announced that the FDA provided positive feedback regarding the company's Phase 3 development plan for MN-166 (ibudilast) in amyotrophic lateral sclerosis (ALS). The key takeaways are that only a single trial may be necessary if there is a statistically significant benefit provided by MN-166 compared to placebo in a functional outcome (most likely ALSFRS-R), the FDA has no safety concerns with MN-166, and the agency would like to see a broad range of ALS patients with randomization stratified by baseline disease severity. The company is currently working on the study design based on this feedback and we expect additional details on the program in the first half of 2019.

SUMMARY DATA

52-Week High	**$13.91**
52-Week Low	**$5.89**
One-Year Return (%)	**87.03**
Beta	**0.32**
Average Daily Volume (sh)	**72,658**
Shares Outstanding (mil)	**42**
Market Capitalization ($mil)	**$501**
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 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**

Risk Level	**High**
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 A	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	-$0.08 A	-$0.11 E	-$0.11 E	-$0.41 E
2019					-$0.44 E
2020					-$0.42 E

© Copyright 2018, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

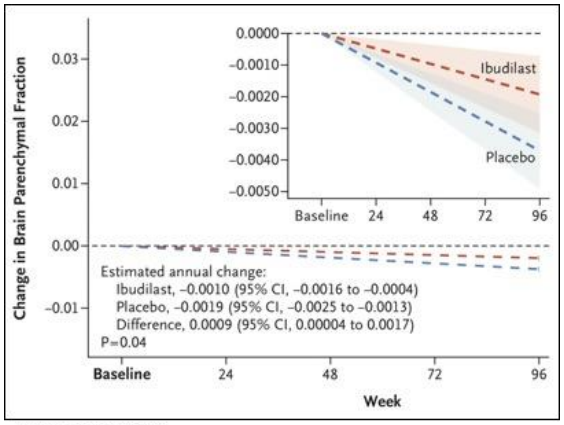
Business Update

Positive FDA Feedback Regarding Phase 3 ALS Development Plan

On September 25, 2018, MediciNova, Inc. (MNOV) announced that the FDA provided positive feedback in regards to the company's development plan for MN-166 (ibudilast) in amyotrophic lateral sclerosis (ALS). The FDA did not raise any concerns with the safety of MN-166, only a single trial may be necessary if there is a statistically significant result when comparing MN-166 to placebo in a functional outcome (such as ALSFRS-R), and the agency would like to see a broad range of ALS patients with randomization stratified by baseline disease severity. The company will now finalize the design of a Phase 3 trial based on these suggestions and we anticipate learning additional details in the first half of 2019.

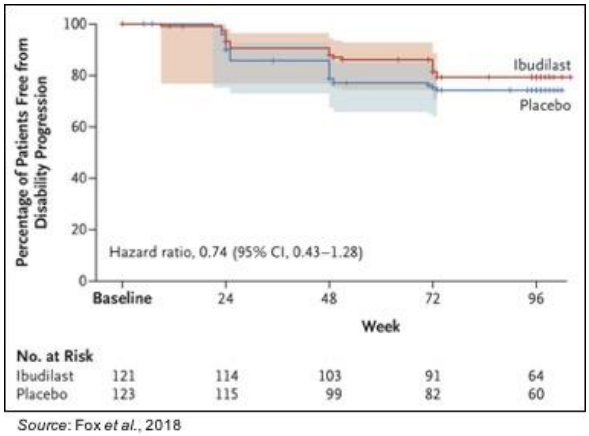
SPRINT-MS Data Published in the New England Journal of Medicine

In August 2018, MediciNova announced the publication of the results of the Phase 2 SPRINT-MS trial of MN-166 in patients with progressive multiple sclerosis (MS) in the New England Journal of Medicine (Fox *et al*., 2018). The company had previously announced positive topline results from the study that showed a statistically significant 48% reduction in the rate of progression of whole brain atrophy compared to placebo (*P*=0.04). The following graph shows the estimated rate of change in the brain parenchymal fraction, which was -0.0010 per year for those on MN-166 compared to -0.0019 per year for those on placebo. This represented approximately 2.5 mL less brain-tissue loss with MN-166 compared to placebo over the 96 weeks of the study.



Source: Fox *et al*., 2018

While not powered to show statistical significance, a key secondary endpoint of the trial was confirmed disability progression. The following graph shows a Kaplan-Meier plot of confirmed disability progression as measured by EDSS (Expanded Disability Status Scale). The hazard ratio for progression in the MN-166 group compared to placebo was 0.74, representing a 26% reduction in confirmed disability progression in the MN-166 group.



Source: Fox *et al*., 2018

To help put these data into context we believe a comparison to the Phase 3 data for Ocrevus® (ocrelizumab) is warranted since that study involved patients (n=732) with primary progressive MS and a primary endpoint of confirmed disability progression (Montalban *et al*., 2017). The following table shows confirmed disability progression at 12 weeks (primary endpoint) and 24 weeks (secondary endpoint) with a hazard ratio for those two endpoints of 0.76 (*P*=0.03) and 0.75 (*P*=0.04), respectively. Thus, a hazard ratio of 0.74 for MN-166 is right in line with data that resulted in the approval of Ocrevus® for the treatment of progressive MS.

End Point	Ocrelizumab (N=488)	Placebo (N=244)	Hazard Ratio or Relative Difference (95% CI)†	P Value
Confirmed disability progression for ≥12 wk: primary end point — no./total no. (%)‡	160/487 (32.9)	96/244 (39.3)	0.76 (0.59 to 0.98)	0.03
Secondary clinical end points				
Confirmed disability progression for ≥24 wk — no./total no. (%)‡	144/487 (29.6)	87/244 (35.7)	0.75 (0.58 to 0.98)	0.04

Source: Montalban *et al*., 2017

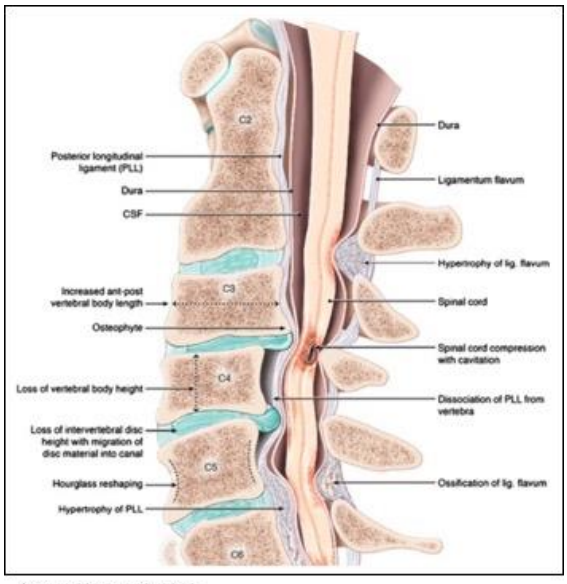
MN-166 was generally well tolerated during the study. Patients taking MN-166 experienced a higher rate of gastrointestinal side effects compared to those on placebo, however there were no increased serious adverse events (SAEs), no increased risk of infections, no cancer signal, no cardiovascular events, and no deaths related to MN-166 treatment. In addition, there was no statistically significant difference in the number of discontinuations between the two groups. In comparison, the first page of the Ocrevus® (ocrelizumab) label contains a number of warnings about potentially serious safety issues including malignancies, infusion reactions, and infections. We believe this is an important distinction as safety is a major driver of market share in MS. For example, Copaxone achieved the highest market share in the relapsing MS market, with annual sales in excess of $4.0 billion, due to its superior safety profile and despite the fact that it did not have the best efficacy. The data available so far indicates that MN-166 would likely have the best safety profile in the progressive MS market.

MediciNova is currently preparing for an "end-of-Phase 2" meeting with the FDA after which a Phase 3 program can begin.

Potential New Indication for MN-166

In August 2018, MediciNova announced plans to conduct a Phase 2/3 trial of MN-166 in degenerative cervical myelopathy (DCM) through an agreement with the University of Cambridge and Cambridge University Hospitals NHS Foundation Trust. The Principal Investigator is Dr. Mark Kotter and the trial is being funded by a grant from the National Institute for Health Research (NIHR) in the United Kingdom. MediciNova is not funding the trial but will provide the study drug supply, regulatory support, and safety monitoring support.

DCM is the leading cause of spinal cord dysfunction (Fehlings *et al*., 2013). It is typically caused by degeneration of the vertebral column, which can include changes to the vertebrae or the ligamentum flavum and/or posterior longitudinal ligament, as shown in the following figure.



Source: Kato *et al*., 2016

Symptoms of DCM include pain and numbness in the limbs, poor coordination, vertigo, and bladder/bowel problems. The most commonly reported symptoms in a 2004 study of 79 DCM patients were numb arms or hands, numb legs or feet, clumsy hands, and neck pain (King *et al*., 2004). Additional symptoms include muscle weakness, stiff muscles, and overactive reflexes. There are over 200,000 procedures performed each year in the U.S. to relieve compression on the spinal cord or nerve roots. The condition is uncommon in those younger than 40 and incidence increases with age. Treatment for DCM includes both surgery and non-surgical options such as physical therapy, muscle relaxants, and neck collars. There are no approved medications for DCM.

The Phase 2/3 clinical trial is titled "Regeneration in Cervical Degenerative Myelopathy – a multi-centre, double-blind, randomized, placebo-controlled trial assessing the efficacy of ibudilast as an adjuvant treatment to decompressive surgery for degenerative cervical myelopathy". This is a two-part trial; the plan is to enroll 25-80 subjects in part 1 and 220-325 subjects in part 2 with a total of 300-350 subjects enrolled in the study. Patients will be administered MN-166 (up to 100 mg/day) for two to three months prior to decompression surgery and then MN-166 treatment will continue for six months following surgery. The primary endpoint is the modified Japanese Orthopaedic Association (mJOA) Score, which assesses neurological function through evaluating motor function in upper and lower extremities, sensation, and micturition.

Conclusion

MediciNova's lead programs are in progressive MS and ALS, and both of those programs have received a positive boost in the past month between the publication of the SPRINT-MS results in the NEJM and the positive feedback from the FDA regarding the Phase 3 program for ALS. We look forward to hearing additional details about each of these programs in the coming months. While the focus is on those two programs, the study of MN-166 in DCM represents additional upside as the company is not funding that trial and the approximately 200,000 patients affected by the disorder each year represents a sizeable potential market. Our current valuation is $19 per share.

PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2017 A	Q1 A	Q2 A	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	$1.379	$1.900	$2.200	$7.141	$7.200	$7.400
General & Administrative	$8.803	$3.005	$2.021	$2.900	$3.200	$11.126	$12.000	$12.400
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($13.0)	($4.7)	($3.4)	($4.8)	($5.4)	($18.3)	($19.2)	($19.8)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	$0.1	$0.3	$0.0	$0.0	$0.4	$0.0	$0.0
Pre-Tax Income	($12.9)	($4.5)	($3.1)	($4.8)	($5.4)	($17.9)	($19.2)	($19.8)
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)**	**($3.1)**	**($4.8)**	**($5.4)**	**($17.9)**	**($19.2)**	**($19.8)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.32)**	**($0.12)**	**($0.08)**	**($0.11)**	**($0.13)**	**($0.44)**	**($0.44)**	**($0.42)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	35.137	39.132	41.558	41.800	42.000	41.122	44.000	47.000

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

© Copyright 2018, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2018, Zacks Investment Research. All Rights Reserved.

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 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.