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MediciNova, Inc. (MNOV-NASDAQ)

MNOV: Continuing to Plan for Phase 3 Studies in Progressive 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 $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 (02/20/19)	$8.90
Valuation	**$19.00**

OUTLOOK

MediciNova, Inc. (MNOV) is developing MN-166 (ibudilast) for the treatment of progressive multiple sclerosis (MS) and amyotrophic lateral sclerosis (ALS). The company has announced positive Phase 2 data and is currently in the planning stages for Phase 3 programs for each of those indications. The company previously announced positive FDA feedback regarding the Phase 3 study design in ALS and is planning to get FDA feedback regarding the Phase 3 program in progressive MS. In addition to ALS and progressive MS, MN-166 is also being tested in clinical trials for glioblastoma and chemotherapy-induced peripheral neuropathy, with a clinical trial anticipated to begin enrollment in mid-2019 for degenerative cervical myelopathy.

SUMMARY DATA

52-Week High	**$13.91**
52-Week Low	**$6.82**
One-Year Return (%)	**-19.16**
Beta	**1.11**
Average Daily Volume (sh)	**49,964**
Shares Outstanding (mil)	**42**
Market Capitalization ($mil)	**$375**
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	**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)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 E	0 E	0 E	0 E	0 E
2020					0 E
2021					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.12 A	-$0.08 A	-$0.16 A	-$0.00 A	-$0.36 A
2019	-$0.14 E	-$0.14 E	-$0.15 E	-$0.15 E	-$0.59 E
2020					-$0.56 E
2021					-$0.56 E

WHAT'S NEW

Business Update

Advancing MN-166 to Phase 3 for Progressive MS and ALS

MediciNova, Inc. (MNOV) is currently developing MN-166 (ibudilast) for a number of indications, with the lead programs being in progressive multiple sclerosis (MS) and amyotrophic lateral sclerosis (ALS). The company has completed Phase 2 clinical trials with positive results from both trial trials.

Progressive MS: Previously, the company had reported positive results from the SPRINT-MS Phase 2b clinical trial of MN-166 in patients with progressive MS. Not only did the trial achieve both primary endpoints (a statistically significant 48% reduction in the rate of progression of whole brain atrophy along with being safe and tolerable) but also demonstrated effects on important secondary endpoints including a positive trend of a 26% reduction in confirmed disability progression, which would be a primary endpoint in a Phase 3 trial. Currently, the company is compiling the data package in order to get FDA feedback on the Phase 3 plan.

ALS: In September 2018, the company announced that the FDA provided positive feedback in regards to the company's development plan for a Phase 3 clinical trial. 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 encouraged including a broad range of ALS patients with randomization stratified by baseline disease severity. The company is working to finalize the protocol for the pivotal Phase 3 trial.

New Patent Aligns IP Coverage for ALS and Progressive MS Indications

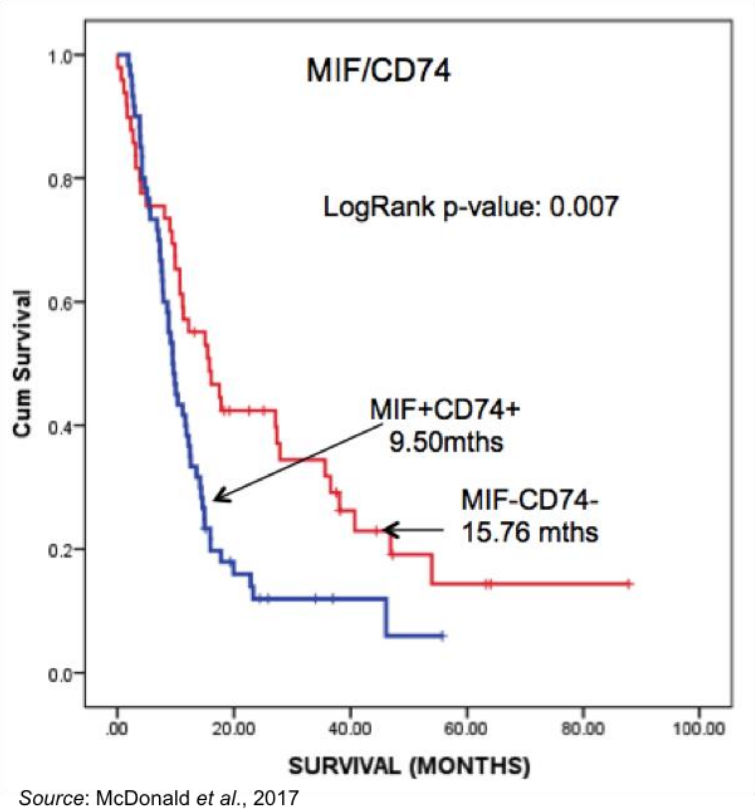
On January 21, 2019, MediciNova announced it received a Notice of Allowance from the U.S. Patent and Trademark Office for a pending patent application that covers the use of MN-166 in combination with riluzole for the treatment of ALS. The new patent would expire no earlier than November 2035 and includes claims that cover treating a patient diagnosed with ALS as well as a number of other neurodegenerative diseases using the combination of MN-166 and riluzole, including Alzheimer's disease, Parkinson's disease, MS, Huntington's disease, and many others. Previously, the company was granted three U.S. patents covering the use of MN-166 as a monotherapy for the treatment of progressive MS, with the first of those patents expiring no earlier than November 2029. Were MN-166 approved for the treatment of progressive MS, patent term restoration would add an additional five years to the life of that patent leading to an expiration no earlier than November 2034, which is very close to the expiration for the newly issued patent covering the treatment of ALS with MN-166 and riluzole. Having patents that cover the use of MN-166 in progressive MS and ALS with similar expiration dates should help facilitate partnering discussions and potentially increase the value of the drug.

GBM Study is Underway

On January 8, 2019, MediciNova announced that the first patient has been enrolled in the clinical trial of MN-166 in combination with temozolomide for the treatment of glioblastoma (GBM). The principal investigators for the study are Dr. Patrick Y. Wen, Professor of Neurology, Harvard Medical School and Director, Neuro-Oncology Division at the Dana-Farber Cancer Institute in Boston, and Dr. Kerrie McDonald, Associate Professor and Head of Biomarkers and Translational Research at the Lowy Cancer Research Centre, University of New South Wales, Australia.

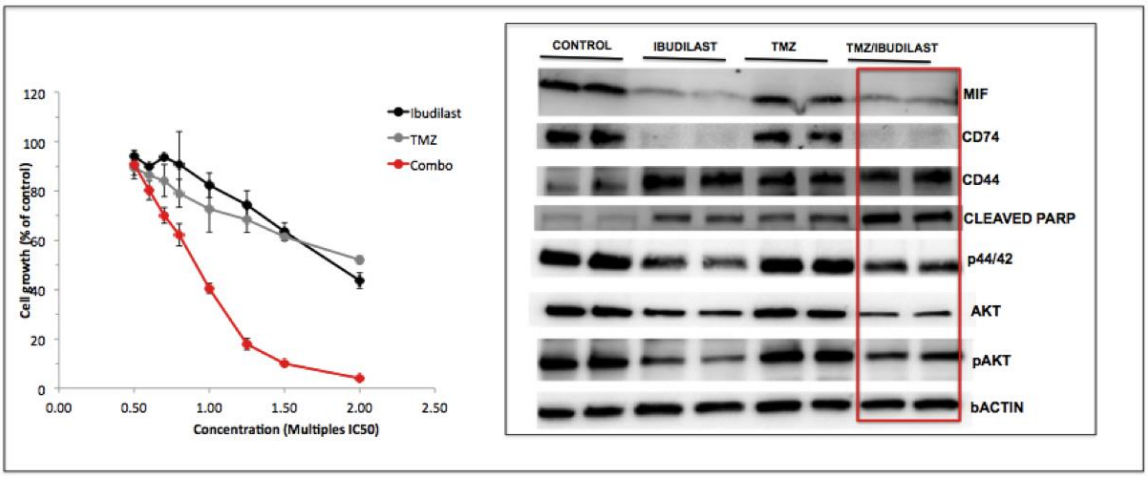
Dr. McDonald presented results from a preclinical study of MN-166 in the treatment of GBM at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting. The aims of the study were to compare proteomic profiles of tumors from two groups of patients with GBM (grouped according to survival, ± 1 year) such that novel biomarkers could be identified and explored as potential therapeutic targets.

Proteomic profiling of samples from 30 GBM patients revealed macrophage inhibitory factor (MIF) as a protein that was expressed in "poor responders" (e.g., those that lived < 1 year). MIF is an inflammatory-related cytokine that is secreted by cancer stem cells. The researchers then examined an additional 168 GBM samples and found co-expression of MIF and its receptor CD74 in 57% of the samples. In addition, co-expression of MIF and CD74 was significantly associated with poor survival, as shown in the following graph. These results point to MIF being a suitable target for GBM treatment.



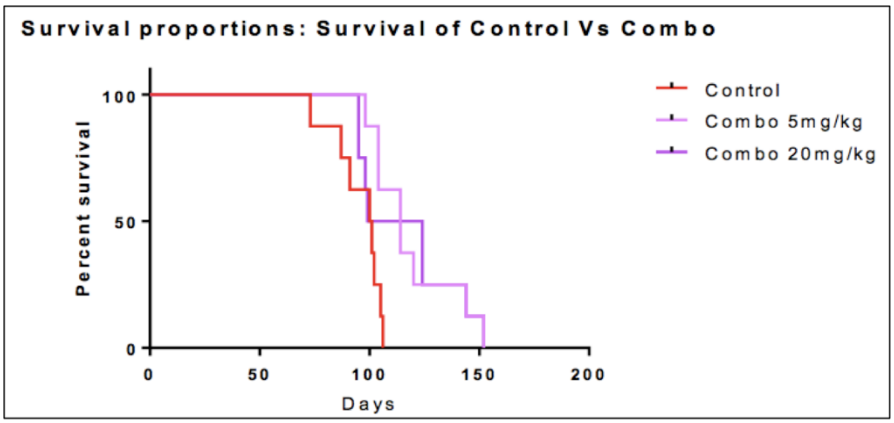
Source: McDonald *et al*., 2017

MN-166 is an inhibitor of MIF (Cho *et al*., 2010). To determine if MN-166 could show an effect in GBM, the researchers first treated patient derived GBM cell lines with MN-166, TMZ, or a combination of the two and evaluated the effect on cell growth and protein expression. Results showed that in all cell lines tested, the combination of MN-166 and TMZ resulted in significant synergy in inhibiting cell growth, as well as decreases in MIF, CD74, and AKT expression.



Source: McDonald *et al*., 2017

An *in vivo* study was performed using RN1 GBM cells, which were intracranially injected into the brains of mice followed by no treatment or a combination of TMZ and MN-166 at two different concentrations. Results showed that mice treated with the combination of TMZ and MN-166 had significantly enhanced survival (median overall survival 114 days vs. 100.5 days, *P*=0.005) with suppression of MIF and CD74 expression also noted.



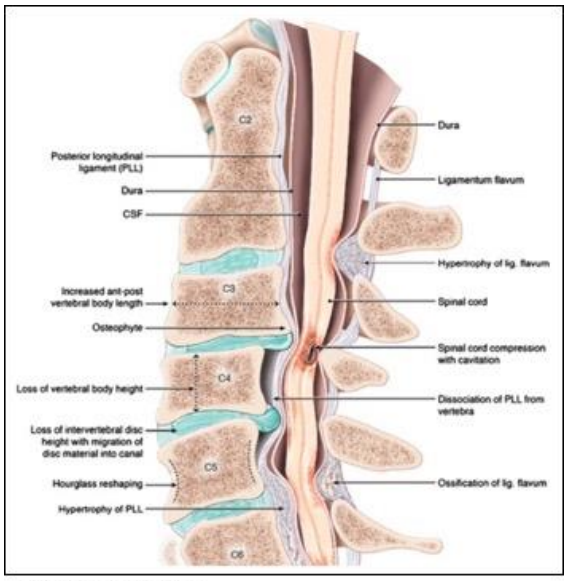
Source: McDonald *et al*., 2017

The company had previously announced that the FDA granted MN-166 orphan drug designation (ODD) to MN-166 for the treatment of GBM. ODD carries a number of incentives for the company, including seven years of market exclusivity following approval for the treatment of GBM, tax credits, and a waiver of PDUFA fees.

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. We anticipate enrollment starting in mid-2019.

Amarin Data Shows Potential for Triglyceride Lowering Compounds

In 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.

Earlier in 2018, Amarin Corporation plc (AMRN) announced positive results from the REDUCE-IT trial, a cardiovascular (CV) outcomes trial of 8,179 patients with elevated CV risk who were treated with either Vascepa 4 g/day or placebo. Vascepa (an ethyl ester of eicosapentaenoic acid [EPA]) is an FDA approved treatment for the reduction of triglycerides in adults with severe hypertriglyceridemia (≥ 500 mg/dL). The REDUCE-IT trial results showed that treatment with Vascepa resulted in an approximately 25% relative risk reduction in major CV events (MACE) (*P*<0.001). Thus, these data show the positive effects that lowering triglyceride levels can have on CV outcomes.

MediciNova is currently evaluating next steps for MN-001, which could include a Phase 2b clinical trial funded by MediciNova or a partnership to develop the drug to lower triglycerides in all patients, not just in those with NASH and NAFLD. We believe the data presented by Amarin could increase the potential value of MN-001 in a partnership deal.

Financial Update

On February 13, 2019, MediciNova filed Form 10-K with financial results for the full year 2018. As expected, the company did not report any revenues. Net loss for 2018 was $14.7 million, or $0.36 per share, compared to a net loss of $11.2 million, or $0.32 per share, in 2017. The $14.7 million net loss in 2018 consisted of $5.6 million in R&D expenses, $10.0 million in G&A expenses, and $0.9 million in interest income. Operating cash burn for 2018 was approximately $9.1 million, which was considerably lower than the operating loss primarily due to approximately $6.3 million in non-cash share-based compensation.

MediciNova exited 2018 with approximately $62.3 million in cash and cash equivalents. As of Feb. 12, 2019, the company had approximately 42.2 million shares outstanding along with approximately 6.6 million stock options for a fully diluted share count of approximately 48.8 million.

Conclusion

MediciNova's focus is clearly on the advancement of MN-166 in the two lead indications, progressive MS and ALS. The company has already had a successful meeting regarding design of the Phase 3 study in ALS and is currently preparing to get FDA feedback for the Phase 3 design in progressive MS. We look forward to additional updates from the company as the year progresses regarding those two programs. The principal investigator is working on the start-up phase of the study of MN-166 in DCM, which we expect to begin enrollment in mid-2019. We believe this opportunity is currently underappreciated by investors and with approximately 200,000 patients surgically treated for the disorder each year it represents a sizeable potential market. With multiple programs advancing in the clinic we remain positive on MediciNova and our current valuation is $19 per share.

PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2018 A	Q1 E	Q2 E	Q3 E	Q4 E	2019 E	2020 E	2021 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	$5.626	$3.500	$3.800	$3.900	$4.000	$15.200	$15.500	$17.000
General & Administrative	$9.961	$2.500	$2.600	$2.800	$3.000	$10.900	$11.000	$11.500
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($15.6)	($6.0)	($6.4)	($6.7)	($7.0)	($26.1)	($26.5)	($28.5)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.9	$0.1	$0.1	$0.1	$0.1	$0.4	$0.4	$0.4
Pre-Tax Income	($14.7)	($5.9)	($6.3)	($6.6)	($6.9)	($25.7)	($26.1)	($28.1)
Income Taxes Paid	($0)	$0	$0	$0	($0)	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($14.7)**	**($5.9)**	**($6.3)**	**($6.6)**	**($6.9)**	**($25.7)**	**($26.1)**	**($28.1)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.36)**	**($0.14)**	**($0.15)**	**($0.15)**	**($0.15)**	**($0.59)**	**($0.56)**	**($0.56)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	41.125	42.000	43.000	44.000	46.000	43.750	47.000	50.000

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

HISTORICAL STOCK PRICE

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