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MediciNova, Inc. (MNOV-NASDAQ)

MNOV: MN-166 to be Studied in Degenerative Cervical Myelopathy…

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 (10/31/18)	$9.27
Valuation	**$19.00**

OUTLOOK

MediciNova, Inc. (MNOV) recently announced that the company will be testing MN-166 (ibudilast) in patients with degenerative cervical myelopathy (DCM). DCM is the leading cause of spinal cord dysfunction in the U.S. and there are over 200,000 procedures performed each year to relieve compression on the spinal cord or nerve roots. The planned Phase 2/3 trial will enroll 25-80 subjects in part 1 and 220-325 subjects in part 2. 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 change in neurological function. Importantly, the trial is fully funded by a grant from the National Institute for Health Research (NIHR) in the United Kingdom.

SUMMARY DATA

52-Week High	**$13.91**
52-Week Low	**$5.89**
One-Year Return (%)	**30.38**
Beta	**0.31**
Average Daily Volume (sh)	**107,752**
Shares Outstanding (mil)	**42**
Market Capitalization ($mil)	**$388**
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)
2017	0 A	0 A	0 A	0 A	0 A
2018	0 A	0 A	0 A	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	-$0.16 A	-$0.08 E	-$0.43 E
2019					-$0.44 E
2020					-$0.42 E

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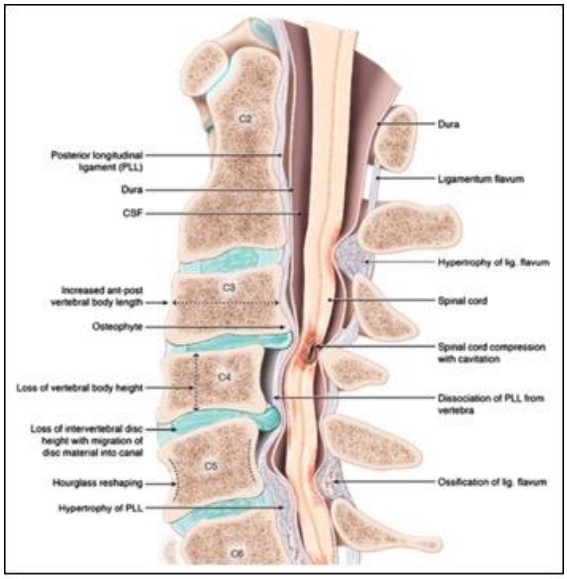
WHAT'S NEW

Business Update

Potential New Indication for MN-166

In August 2018, MediciNova, Inc. (MNOV) 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.

Positive FDA Feedback Regarding Phase 3 ALS Development Plan

On September 25, 2018, MediciNova 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.

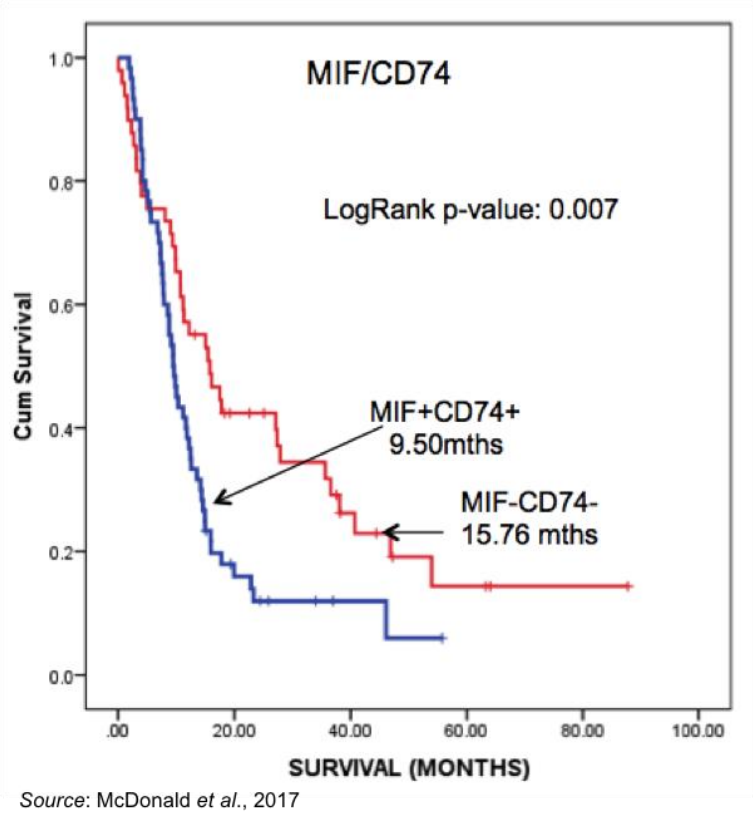
FDA Grants Orphan Drug Designation to MN-166 for GBM

On October 4, 2018, MediciNova announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to MN-166 (ibudilast) for the treatment of glioblastoma (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.

Earlier in 2018, the company announced the opening of an IND with the FDA for MN-166 for the treatment of GBM indicating that clinical trials testing of MN-166 in combination with the standard-of-care chemotherapy agent temozolomide (TMZ) may proceed.

In 2017, MediciNova announced that Associate Professor Kerrie 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.

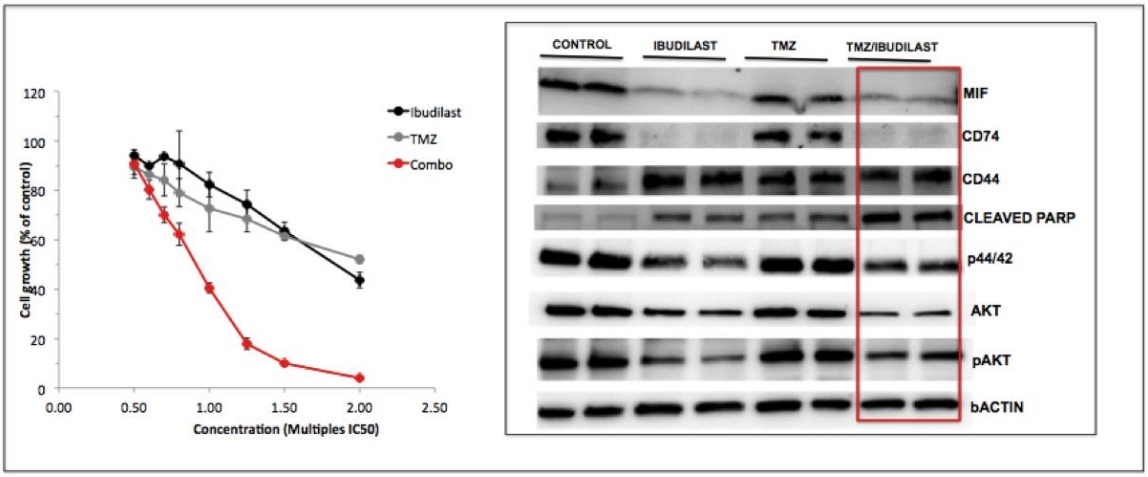
Proteomic profiling of samples from 30 GBM patients revealed macrophage inhibitory factor (MIF) as a protein that was expressed in “poor responders” (e.g., those that lived < 1 year). MIF is an inflammatory-related cytokine that is secreted by cancer stem cells. The researchers then examined an additional 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

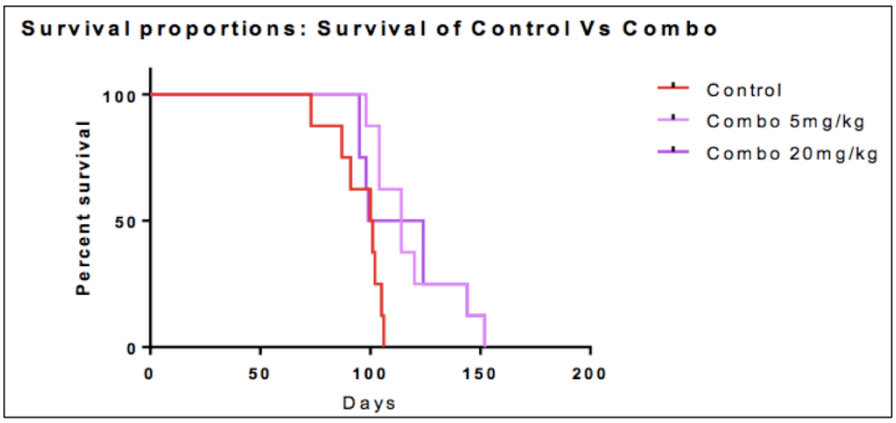
MN-166 is an inhibitor of MIF (Cho *et al*., 2010). To determine if MN-166 could show an effect in GBM, the researchers first treated patient derived GBM cell lines with MN-166, TMZ, or a combination of the two and evaluated the effect on cell growth and protein expression. Results showed that in all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

GBM Background

GBM is the most aggressive of the category of tumors known as gliomas, which all arise from glia cells within the central nervous system. There are four grades of gliomas, with the highest grade, Grade 4 or GBM, being the most aggressive and the most common form in humans. Unfortunately, most patients with GBM don't live much longer than one or two years, and this has not changed appreciably over the years. The reason these tumors are so difficult to treat is multi-dimensional and has to do with both the genetic make-up of the tumor (most GBM cells have multiple activating mutations and other genetic anomalies) as well as the way the tumors grow (they are highly infiltrative and arise in many different regions of the brain).

Current standard-of-care treatment for GBM consists of surgery to resect as much of the tumor as possible followed by radiation and chemotherapy (TMZ) to kill any tumor cells that were not removed through surgery. While some types of solid tumors can be cured surgically, this is very rare in GBM due to the diffuse nature of the tumor.

Gliomas are the most common type of intracranial cancer, accounting for 81% of all malignant brain cancers, and GBM accounts for 45% of all gliomas (Ostrom *et al*., 2014). There are approximately 25,000 people diagnosed with malignant brain cancer each year in the U.S. Since GBM is mostly diagnosed in older individuals (median age = 65 years), the aging demographics of the Western world has resulted in the incidence of GBM increasing from 5.1 per 100,000 in the 1970's to 10.6 per 100,000 in the 1990's (Chakrabarti *et al*., 2005). Those diagnosed with the

disease have a very grim prognosis, with the median survival time of untreated patients being only 4.5 months. Current standard of care treatment only provides a 12-14 month median overall survival after diagnosis (Johnson *et al*., 2012).

Financial Update

On October 25, 2018, MediciNova filed form 10-Q with financial results for the third quarter of 2018. As expected, the company did not report any revenues. Net loss for the third quarter of 2018 was $6.8 million, or $0.16 per share, and was comprised of $2.4 million in R&D expenses and $4.7 million in G&A expenses. This compares with $1.3 million in R&D expenses and $2.5 million in G&A expenses for the third quarter of 2017. The increase in R&D expenses was primarily due to increased clinical trial costs for MN-166 along with increased stock-based compensation. The increase in G&A expenses was driven by increased stock-based compensation due to an increase in the stock price.

Total operating burn for the second quarter of 2018 was $1.7 million and the company exited the third quarter of 2018 with approximately $62.4 million in cash and cash equivalents. During the first half of 2018 the remaining 750,000 warrants were exercised that resulted in gross proceeds of $2.4 million. There are currently no warrants outstanding. We believe the company has sufficient capital to fund operations at least through the end of 2019.

As of October 24, 2018, the company had approximately 41.9 million shares of common stock outstanding. When factoring in the approximately 6.6 million stock options the company has a fully diluted share count of approximately 48.5 million.

Conclusion

MediciNova continues to focus on the company's lead programs in progressive MS and ALS. The company has already received positive feedback from the FDA regarding the Phase 3 program for ALS and trial design is currently ongoing. We expect to hear additional details regarding the Phase 3 trial for MN-166 in MS once the company is able to meet with the FDA regarding that program. 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 treated for the disorder each year represents a sizeable potential market. The preclinical data for MN-166 in GBM is interesting and we look forward to additional details about that program as it advances. Our current valuation is $19 per share.

PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2017 A	Q1 A	Q2 A	Q3 A	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	$2.370	$1.200	$6.611	$7.200	$7.400
General & Administrative	$8.803	$3.005	$2.021	$4.658	$2.000	$11.683	$12.000	$12.400
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($13.0)	($4.7)	($3.4)	($7.0)	($3.2)	($18.3)	($19.2)	($19.8)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	$0.1	$0.3	$0.2	$0.0	$0.6	$0.0	$0.0
Pre-Tax Income	($12.9)	($4.5)	($3.1)	($6.8)	($3.2)	($17.7)	($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)**	**($6.8)**	**($3.2)**	**($17.7)**	**($19.2)**	**($19.8)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.32)**	**($0.12)**	**($0.08)**	**($0.16)**	**($0.08)**	**($0.43)**	**($0.44)**	**($0.42)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	35.137	39.132	41.558	41.879	42.000	41.142	44.000	47.000

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

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