Zacks Small-Cap Research
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February 25, 2020
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MediciNova, Inc.

(MNOV-NASDAQ)

MNOV: Multiple Trials of MN-166 Ongoing; Recent Price Move Creates Buying Opportunity

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 $24/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 (02/25/20)	$4.76
Valuation	**$24.00**

OUTLOOK

MediciNova, Inc. (MNOV) is currently conducting seven clinical trials with MN-166 (ibudilast):

1) A Phase 3 clinical trial in patients with amyotrophic lateral sclerosis (ALS);
2) A Phase 2 clinical trial in patients with glioblastoma;
3) A Phase 3 clinical trial in patients with degenerative cervical myelopathy (DCM);
4) A Phase 2 clinical trial in patients with chemotherapy-induced peripheral neuropathy (CIPN);
5) Three clinical trials in substance dependence: Two Phase 2 clinical trials in patients with alcohol use disorder and a Phase 2 clinical trial in patients with methamphetamine dependence

We anticipate updates on each of these trials. The company exited 2019 with approximately $63.8 million in cash and cash equivalents, which we estimate is sufficient to fund operations for at least the next 24 months. We believe irrational selling in the Japanese stock market has created a buying opportunity for MNOV.

SUMMARY DATA

52-Week High	**$13.22**
52-Week Low	**$4.76**
One-Year Return (%)	**-44.00**
Beta	**1.34**
Average Daily Volume (sh)	**72,540**
Shares Outstanding (mil)	**44**
Market Capitalization ($mil)	**$209**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**22**
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-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 E	0 E	0 E	0 E	0 E
2021					0 E
2022					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.11 A	-$0.09 A	-$0.05 A	-$0.04 A	-$0.30 A
2020	-$0.08 E	-$0.08 E	-$0.09 E	-$0.09 E	-$0.34 E
2021					-$0.34 E
2022					-$0.35 E

WHAT'S NEW

Financial Update

On February 13, 2020, MediciNova filed Form 10-K with financial results for the full year 2019. As expected, the company did not report any revenues. Net loss for 2019 was $12.9 million, or $0.30 per share, compared to a net loss of $14.7 million, or $0.36 per share, in 2018. The $12.9 million net loss in 2019 consisted of $6.1 million in R&D expenses, $8.0 million in G&A expenses, and $1.1 million in interest income. Operating cash burn for 2019 was approximately $9.1 million, which was considerably lower than the operating loss primarily due to approximately $4.1 million in non-cash share-based compensation.

MediciNova exited 2019 with approximately $63.8 million in cash and cash equivalents. As of Feb. 12, 2020, the company had approximately 44.0 million shares outstanding along with approximately 6.8 million stock options for a fully diluted share count of approximately 50.8 million.

Business Update

ALS Trial of MN-166 Underway

In June 2019, MediciNova, Inc. (MNOV) announced the kick-off meeting to officially launch the Phase 3 trial of MN-166 (ibudilast) in amyotrophic lateral sclerosis (ALS). The Phase 2b/3 clinical trial is a multi-center, two-arm, randomized, double blind, placebo controlled trial that will compare MN-166 to placebo in approximately 230 patients with ALS (NCT04057898). Participants in the trial will be randomized 1:1 between placebo and 100 mg/day of MN-166 for 12 months of treatment. The primary endpoint of the trial is the change from baseline in ALS functional rating scale-revised (ALSFRS-R) score at Month 12 (or last measurement before death in case of censoring) and survival time (Cedarbaum *et al*., 1999). The ALSFRS-R consists of a series of 12 questions on basic tasks (speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, and respiratory insufficiency) that are rated on a five-point scale where 0 = can't do and 4 = normal ability. The individual items are summed to produce a score of between 0 = death and 48 = best. The ALSFRS-R score is utilized to keep track of the health of all ALS patients, and is a common outcome measure in ALS clinical trials as well as an established FDA-approvable endpoint. Secondary endpoints in the trial include the mean change from baseline in muscle strength and quality of life, time to survival, and safety and tolerability.

Important inclusion criteria include onset of ALS no more than 18 months prior to screening, the use of riluzole for at least 30 days prior to initiation of the study drug, slow vital capacity at least 70% of predicted, and an ALSFRS-R score of at least 35 at screening. Patients currently taking Radicava® (edaravone) or Nuedexta® (dextromethorphan/quinidine) may be eligible as long as they cease taking those treatments three months prior to entering the trial.

Additional Analyses on MN-166 in ALS

On Dec 4, 2019, MediciNova announced that additional analyses from the company's completed clinical trial of MN-166 in ALS were presented at the 30th International Symposium on ALS/MND. The presentation, entitled "Interaction (nonuniformity) of ALS Progression and the Efficacy of MN-166 (ibudilast)", showed that ALS history was a statistically significant factor affecting treatment effect (P=0.015) and that a significant positive correlation (0.63, P<0.05) was observed between ALS history and ALS disease progression in the placebo group while no such correlation was observed between ALS history and ALS disease progression in the MN-166 group. This was attributed to the treatment effect in short ALS history patients, thus the efficacy of MN-166 is expected to be more robust in patients with a short ALS history. The ongoing Phase 2b/3 is only including ALS patients who had onset of disease ≤ 18 months from the first clinical sign of weakness prior to screening.

Radicava® Most Recently Approved ALS Treatment

Radicava (edaravone) was approved for the treatment of ALS by the FDA in May 2017. Edaravone is a potent scavenger of oxygen radicals. While the underlying mechanisms responsible for causing ALS are unknown, it is believed that oxidative stress plays some role in the development of the disease. This is supported by the fact that

mutations in superoxide dismutase 1 (SOD1) cause familial ALS. SOD1 is responsible for converting superoxide radicals to oxygen and hydrogen peroxide.

In an ALS mouse model that involves a mutation in SOD1, administration of edaravone resulted in reduced motor decline and preserved motor neurons in the spinal cord (Ito *et al*., 2008). Similar results were seen in a rat model of ALS (Aoki *et al*., 2011). Based on these results, edaravone was tested in ALS patients in three different clinical trials.

Edaravone Clinical Trials

Edaravone was originally tested in a Phase 2 clinical trial involving 20 ALS patients (Yoshino *et al*., 2006). The study was an open-label comparison study that evaluated patients before and after treatment with edaravone. Results showed a statistically significant difference in the change in ALSFRS-R before treatment (4.7 points) compared to during the treatment period (2.3 points; *P*=0.036).

The first Phase 3 clinical trial of edaravone was conducted in 205 patients randomized to receive edaravone (n=101) or placebo (n=104) (Abe *et al*., 2014). Treatment consisted of intravenous infusions given over 60 min for the first 14 days of cycle 1 (followed by 14 days off drug), and then 10 of the first 14 days during cycles two through six, with 14 days off drug following treatment in each cycle. The primary endpoint was the change in ALSFRS-R during the 24-week treatment period. Results showed that the change in ALSFRS-R scores were -5.70 and -6.35 in the edaravone and placebo groups, respectively, which did not represent a statistically significant difference (*P*=0.411). No serious adverse events were reported and the level and frequency of adverse events were similar between the two treatment groups. A post-hoc analysis suggested that edaravone could be efficacious in a restricted subgroup that includes recently diagnosed patients with milder disease symptoms.

Based on the post-hoc analysis, a second Phase 3 clinical trial was conducted that was restricted to patients with a disease duration of <2 years and independent activity of daily living (Tanaka *et al*., 2015). A total of 134 patients were randomized to receive edaravone (n=68) or placebo (n=66) for six months, with treatment given the same as in the first Phase 3 clinical trial. The change in ALSFRS-R score from baseline at six months was -5.01 in the edaravone group and -7.50 in the placebo group (*P*=0.001). Once again, adverse events were similar between the edaravone and the placebo groups.

Positive Results from Phase 2 Trial of MN-166 in ALS

MediciNova previously studied MN-166 in a Phase 2 trial in ALS. This was a single center, double blind, placebo controlled six-month study with patients randomized 2:1 to receive riluzole (100 mg/day) plus either MN-166 (60 mg/day) or placebo. The six-month double blind portion was followed by a six-month open label extension phase during which all patients received MN-166. The intent-to-treat (ITT) population consisted of 51 patients who were randomized to placebo (n=17) or MN-166 (n=34) for the double-blind portion of the study. The per protocol (PP) population consisted of 44 patients that completed the double-blind portion of the study (n=15 for placebo; n=29 for MN-166) and 35 patients that completed the open label extension (n=12 for placebo; n= 23 for MN-166). The results shown below were presented at the 28th International Symposium on ALS/MND in Dec. 2017.

Since this was the first time MN-166 was tested in ALS patients the primary outcome of the study was safety and tolerability of the drug when administered along with riluzole (100 mg/day), the standard of care for ALS patients. The study achieved the primary outcome with no serious or life-threatening treatment-related adverse events (TRAEs). There were six subjects that had a total of seven serious adverse events (five for MN-166 group and one for placebo group), however none of them were related to treatment.

	# of Subjects or # of Events	
	Placebo N=17	Ibudilast N=34
# of Subject with at Least one TRAEs	n= 3	n= 4
Total events # of TRAEs	5	8
Severe or Life-threatening TRAEs	0	0
Serious TRAEs	0	0
	# of Subjects	
	Placebo N = 17	Ibudilast N = 34
At Least one TEAEs	n = 17	n = 34
Severe or Life threatening TEAEs	n = 2	n = 4
Serious Adverse Events	n = 1	n = 5
Treatment Related Adverse Events	n = 10	n = 13

Source: Brooks *et al*., 2017

In addition to the primary endpoint of safety and tolerability, the study also evaluated secondary efficacy endpoints. These secondary endpoints, which included an analysis of ALSFRS-R, were not powered for statistical significance but were evaluated to look for positive trends that could help guide the design of future clinical trials. For this study, a responder was defined as someone who had a ≤1 point decline in the ALSFRS-R during the six-month double blind period while a non-responder was defined as someone who had >1 point decline in ASLFRS-R. For the ITT population, the following table shows that 29.4% (10/34) of MN-166-treated patients were responders, compared to 17.6% (3/17) of placebo-treated patients. The third and fourth columns in the table show the percentage of patients who were responders in the open-label six-month extension phase during which all patients received MN-166. In the open-label extension, 35.3% (6/17) of the patients who had received placebo during the double blind portion of the study were responders when taking MN-166. This compares quite favorably with the 29.4% of patients who were responders with MN-166 during the double blind portion of the study.

Double-Blind Phase		Open Label Phase		Overall
Placebo (N = 17)	Ibudilast (N = 34)	Ibudilast 0-6 mon treatment (N = 17)	Ibudilast 6-12 mon treatment (N = 34)	Ibudilast 0-12 mon treatment combined (N = 51)
3 / 17 (17.6 %)	10 / 34 (29.4 %)	6 / 17 (35.3 %)	3 * / 34 (8.8 %)	19 * / 51 (37.3 %)

Source: Brooks *et al*., 2017

For the PP population, the following table shows that 34.5% (10/29) of MN-166-treated patients were responders, compared to 20.0% (3/15) of placebo-treated patients. Again, the open-label extension results showing 50.0% (6/12) of patients who had received placebo during the double blind portion of the study were responders when taking MN-166 compared well with the 34.5% of patients that were responders when taking MN-166 in the double blind portion of the study.

Double-Blind Phase		Open Label Phase		Overall
Placebo (N = 15)	Ibudilast (N = 29)	Ibudilast 0-6 mon treatment (N = 12)	Ibudilast 6-12 mon treatment (N = 23)	Ibudilast 0-12 mon treatment combined (N = 35)
3 / 15 (20.0 %)	10 / 29 (34.5 %)	6 / 12 (50.0 %)	3 * / 23 (13.0 %)	19 * / 35 (54.3 %)

Source: Brooks *et al*., 2017

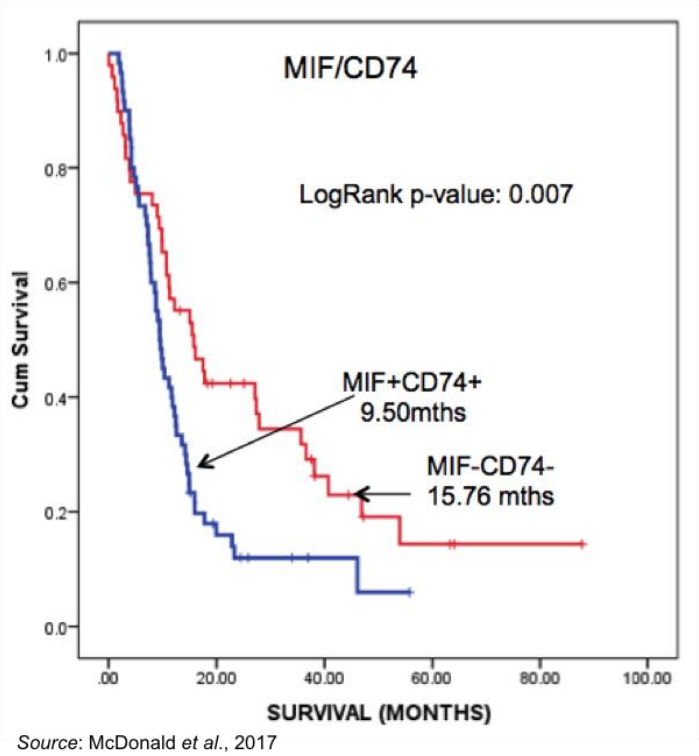
We believe these results show that MN-166 was having a positive effect on ALSFRS-R and that this effect is likely to increase in the Phase 3 trial, as the company will be testing a 100 mg/day dose, compared to the 60 mg/day dose that was utilized in the Phase 2 trial.

Glioblastoma Trial Ongoing

In January 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 recurrent glioblastoma. 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.

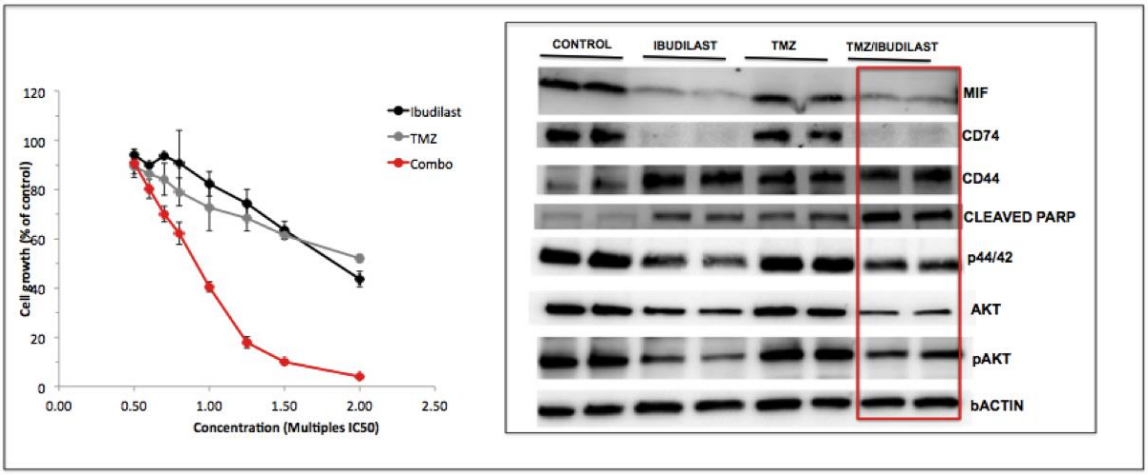
Dr. McDonald presented results from a preclinical study of MN-166 in the treatment of GBM at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting. The aims of the study were to compare proteomic profiles of tumors from two groups of patients with GBM (grouped according to survival, ± 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 migration 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.



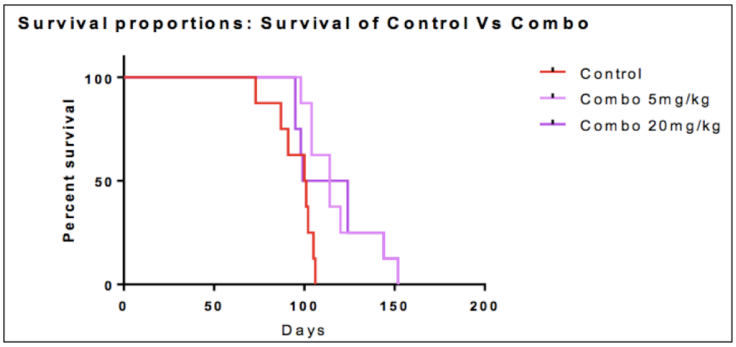
Source: McDonald *et al*., 2017

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, temozolomide (TMZ, the standard of care chemotherapeutic for GBM) 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.



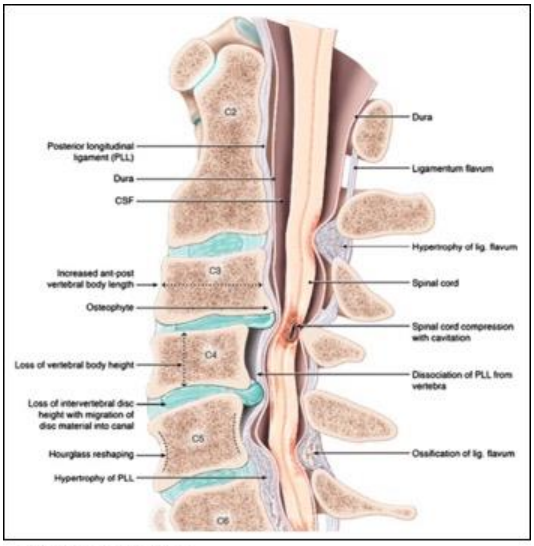
Source: McDonald *et al*., 2017

The company had previously announced that the FDA granted MN-166 orphan drug designation (ODD) as adjunctive therapy to TMZ 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.

Phase 3 Trial in Degenerative Cervical Myelopathy Ongoing

In May 2019, MediciNova announced the company's participation in the kick-off meeting for the Phase 3 RECEDE Myelopathy clinical trial of MN-166 in degenerative cervical myelopathy (DCM). The trial is titled "**Re**generation in **Ce**rvical **De**generative **Myelopathy** – a multi-center, 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 targeted enrollment of 362 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 endpoints assess changes in pain and function 6 months after surgery using the visual analog scale (VAS) for monitoring neck pain and the modified Japanese Orthopaedic Association (mJOA) Score, which assesses neurological function through evaluating motor function in upper and lower extremities, sensation, and micturition.

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 (Kato *et al*., 2016).



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.

Patent Portfolio Expands

In the first quarter of 2020, MediciNova continued to expand its intellectual property portfolio for MN-001 (tipelukast) through the following:

- On Jan. 27, 2020, the company received a notice of intention to grant from the European Patent Office for a pending patent application that covers MN-001 for the treatment of idiopathic pulmonary fibrosis (IPF). The patent is expected to have an expiration date no earlier than May 2035. This follows previous patents granted covering IPF in Japan and China.

- On Feb. 17, 2020, the company received a notice of allowance from the Japan Patent Office for a pending patent application that covers MN-001 and MN-002 (a major metabolite of MN-001) for the treatment of advanced NASH. The patent is expected to expire no earlier than May 2035.

Valuation and Conclusion

We look forward to updates from the company on the ongoing clinical trials of MN-166 and the potential for clinical data later in 2020. Our valuation for MediciNova has increased slightly to $24 per share from $22 per share based on moving our DCF model ahead one year, and investors could use the recent weakness in the stock price as an opportunity to initiate or add to a position. The stock has not traded this low since 2017, yet the company has steadily added value through positive clinical data, non-dilutive financing of multiple clinical trials (e.g., grants), additional indications in development, and continued expansion of the patent portfolio. Investors may not have another opportunity to buy MNOV at this price level.

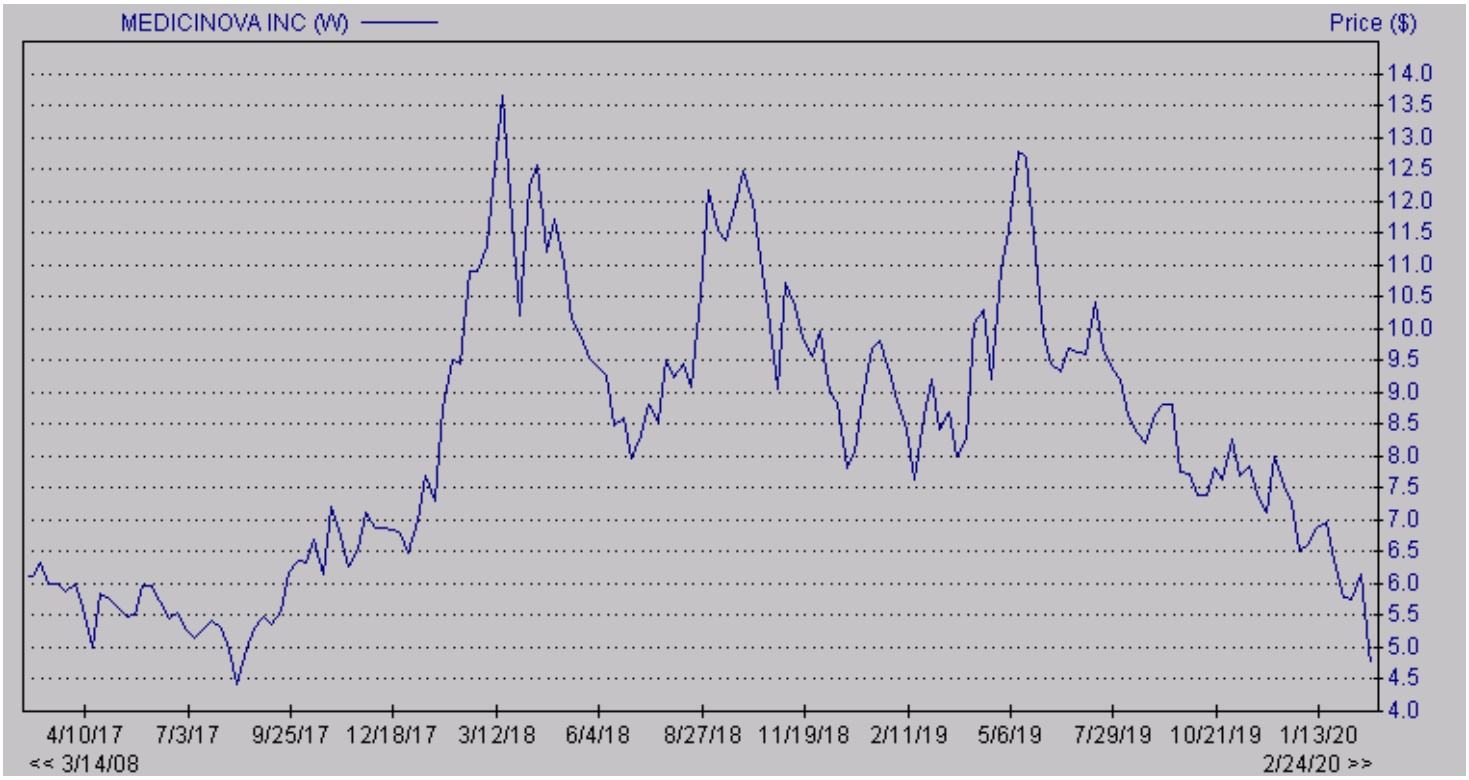
PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2019 A	Q1 E	Q2 E	Q3 E	Q4 E	2020 E	2021 E	2022 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	$6.079	$1.800	$1.800	$1.800	$1.800	$7.200	$9.000	$10.000
General & Administrative	$7.952	$1.800	$2.000	$2.200	$2.400	$8.400	$8.500	$9.000
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($14.0)	($3.6)	($3.8)	($4.0)	($4.2)	($15.6)	($17.5)	($19.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$1.1	$0.1	$0.1	$0.1	$0.1	$0.4	$0.4	$0.4
Pre-Tax Income	($12.9)	($3.5)	($3.7)	($3.9)	($4.1)	($15.2)	($17.1)	($18.6)
Income Taxes Paid	($0)	$0	$0	$0	($0)	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($12.9)**	**($3.5)**	**($3.7)**	**($3.9)**	**($4.1)**	**($15.2)**	**($17.1)**	**($18.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.30)**	**($0.08)**	**($0.08)**	**($0.09)**	**($0.09)**	**($0.34)**	**($0.34)**	**($0.35)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	43.159	43.900	44.000	44.200	44.400	44.125	50.000	53.000

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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