Zacks Small-Cap Research

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MediciNova, Inc. (MNOV - Nasdaq)

MNOV: Multiple Catalysts Ahead in 2016…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	05/12/2015
Current Price (03/09/16)	$6.09
Target Price	**$10.00**

UPDATE

MediciNova, Inc. (MNOV) is a biopharmaceutical company focused on the development of small molecule therapies to treat serious diseases with few treatment options. MN-166 (ibudilast) is currently being evaluated in clinical trials for progressive multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), and substance dependence. MN-001 (tipelukast) is currently being evaluated in clinical trials for the treatment of fibrotic diseases such as nonalcoholic steatohepatitis (NASH) and idiopathic pulmonary fibrosis (IPF). We anticipate an interim analysis of the ongoing Phase2b MS clinical trial occurring in the second half of 2016 along with data from the ALS study. We have made slight modifications to our model and have increased our target price to $10, noting that positive data from the MS and/or ALS trial would cause a significant revaluation of the shares.

SUMMARY DATA

52-Week High	**$6.42**
52-Week Low	**$2.79**
One-Year Return (%)	**80.71**
Beta	**0.88**
Average Daily Volume (sh)	**329,741**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$183**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**22**
Insider Ownership (%)	**27**
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 E	0 E	0 E	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	-$0.08 E	-$0.08 E	-$0.08 E	-$0.08 E	-$0.32 E
2017					-$0.34 E
2018					-$0.35 E

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WHAT'S NEW

Financial Update

On February 25, 2016, MediciNova, Inc. (MNOV) filed form 10-K with financial results for the fourth quarter and full year ending December 31, 2015. As expected, the company did not report any revenues in the fourth quarter or for the full year. Net loss in the fourth quarter of 2015 was $2.7 million, or $0.09 per share, and consisted of $0.9 million in R&D expenses and $1.8 million in G&A expenses. For the full year, net loss was $8.8 million, or $0.33 per share, and consisted of $3.0 million in R&D expenses and $5.8 million in G&A expenses. Operating cash burn for 2015 was $7.2 million. For 2016, we forecast a similar level of G&A expenses ($6.0 million) and slightly increased R&D expenses ($4.3 million) to account for increased clinical trial activity.

MediciNova exited 2015 with $22.1 million in cash and cash equivalents. In August 2015, the company raised gross proceeds of $17.5 million (net proceeds of $16.0 million) through the sale of 5 million shares of common stock at $3.50 per share. Fidelity Investments (FMR LLC) acquired 3.5 million of those shares and now owns approximately 11% of the outstanding shares. We estimate the company currently has sufficient cash to fund operations at least through the end of 2017.

MN-166 Update

MediciNova is developing MN-166 (ibudilast) for the treatment of primary and secondary progressive multiple sclerosis (PPMS and SPMS), amyotrophic lateral sclerosis (ALS), methamphetamine (MA) addiction, opioid dependence, and alcohol dependence. The drug is currently being tested in three separate clinical trials in the aforementioned indications with two trials recently completed in alcohol dependence and opioid dependence.

MN-166 is an anti-inflammatory drug that has been utilized for over 20 years in Japan to treat asthma (Rolan *et al*., 2009). It acts as a phophodiesterase (PDE) inhibitor (Suzumura *et al*., 1999) and preferentially inhibits PDE-4 (Huang *et al*., 2006). The drug has shown anti-inflammatory activity in both the peripheral immune system and in the CNS via attenuation of glial cells, which play a role in certain neurological conditions. In addition, delivery of a PDE-4 inhibitor lead to enhanced differentiation of oligodendrocyte progenitor cells within areas of demyelination and a consequent acceleration of remyelination (Syed *et al*., 2013).

Preclinical work performed with MN-166 showed that the compound can suppress neuronal cell death induced by activated microglia (Mizuno *et al*., 2004). MN-166 was shown to suppress the production of TNF-α and IL-6 by microglia as well as enhance the production of the anti-inflammatory cytokine IL-10 and neurotrophic factors such as NGF, GDNF, and NT-4. These data are in agreement with an earlier study of MN-166 in a chronic cerebral hypoperfusion model that showed it could inhibit the activation of microglia cells and prevent the formation of white matter lesions (Wakita *et al*., 2003). This inhibitory effect was shown to be dose dependent and involve the suppression of TNF-α production.

MN-166 for the Treatment of Multiple Sclerosis

Multiple sclerosis (MS) is a chronic autoimmune, inflammatory disease that affects axons in the central nervous system (CNS). There is no single diagnostic test for MS, with diagnosis based on the following criteria: 1) at least two different lesions in the white matter of the CNS, 2) at least two different episodes in the disease course, and 3) chronic inflammation of the CNS as determined by analysis of the cerebrospinal fluid (CSF). Having one or more of these criteria allows a general diagnosis of MS.

The pattern and course of the disease is characterized by the following patterns:

- Primary progressive (PPMS): Characterized by disease progression from the onset with occasional plateaus and temporary minor improvements. It makes up approximately 10 percent of cases at onset. Patients typically experience a steady decline in function from the beginning and never have acute attacks. There are no currently approved medications for treating primary progressive MS.

- Relapsing remitting (RRMS): Characterized by clearly defined relapses with full recovery. There is no disease progression during the periods between relapses. This type of MS accounts for approximately 85 to 90 percent

of MS cases at onset. However, most patients will then progress into secondary progressive phase.

- ⇨ Secondary progressive (SPMS): Characterized by progression with or without occasional relapses, minor remissions, and plateaus. Studies suggest that approximately 50% of patients with relapsing-remitting MS will go on to develop secondary progressive MS.

- ⇨ Progressive relapsing (PRMS): Characterized by progressive disease from the onset, with clear acute relapses, with or without full recovery. Disease progression continues to occur during the periods between disease relapses.

MN-166 was previously tested in a randomized, double blind, placebo controlled Phase 2a clinical trial to evaluate its safety and effectiveness in MS patients. The primary outcome of the study was the cumulative number of newly active lesions seen on bimonthly MRI scans over the first 12 months of treatment. Secondary outcomes included the time to first exacerbation, number of relapses, and annualized relapse rate over 12 months, and the cumulative volume of Gd-enhancing lesions over 12 months. The results showed that there was no difference in the number of newly active lesions or in the cumulative volume of Gd-enhancing lesions between treatment arms. Thus, MN-166 did not appear to have an effect on overt inflammation leading to a suppression of disease activity. However, MN-166 may exert a neuroprotective effect. 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.

Based on the results of the Phase 2a study, investigators from NeuroNEXT, an NIH funded clinical trial network that conducts studies of treatments for neurological diseases, have initiated the SPRINT-MS trial; a Phase 2b trial evaluating MN-166 in PPMS and 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).

In June 2015, the company announced the ongoing clinical trial of MN-166 in progressive MS had completed randomization of 255 patients. 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. There is a planned interim efficacy analysis after half the subjects complete the 96-week treatment period. As of September 15, 2014, the clinical trial had enrolled 150 patients. Ninety-six weeks from that date is approximately the middle of July 2016, thus we would anticipate interim results being released sometime in the fall of 2016. The primary outcome of the study is the rate of change in brain atrophy over 96 weeks as measured by brain parenchymal fraction (BPF) using MRI.

Roche's Ocrelizumab Shows Efficacy in Primary Progressive MS

Currently, there are no approved medications for treating PPMS, however in September 2015, Roche announced positive clinical trial results for ocrelizumab (an anti-CD20 monoclonal antibody) in a Phase 3 study of patients with PPMS. The ORATORIO study (NCT01194570) enrolled 732 patients who had an elevated cerebrospinal fluid IgG index or one or more oligoclonal bands. The mean duration since PPMS diagnosis was 2.8 years. The patients were randomly assigned in a 2:1 fashion to receive either ocrelizumab (600 mg intravenous infusion every 24 weeks) or placebo. The primary endpoint of progression of clinical disability (on the Expanded Disability Status Scale) sustained for at least 12 weeks was reduced by 24% in the ocrelizumab group (P=0.0321). In addition, the rate of brain volume loss was significantly less in the ocrelizumab group (0.9%) compared to the placebo group (1.1%) (P=0.02). In February 2016, Roche announced that ocrelizumab was granted Breakthrough Therapy Designation by the FDA for the treatment of PPMS. The company is planning to file for approval of ocrelizumab in PPMS in the first half of 2016. However, we are uncertain as to the ultimate safety profile of ocrelizumab given its history including FDA clinical holds for Roche's prior clinical studies of ocrelizumab in lupus and rheumatoid arthritis. There were serious and opportunistic infections including fatalities in these studies that led to the clinical holds and Roche's termination of these programs.

Market Opportunity in MS

MS affects approximately 400,000 people in the U.S. (Tullman, 2013) and 700,000 people in the EU (European MS Platform). Approximately 10% of MS patients have the primary progressive form while approximately 85-90% are initially diagnosed with the relapse-remitting form (RRMS). Approximately 50% of those diagnosed with RRMS will go on to develop SPMS, although they still may suffer from relapses.

Although they are not approved for SPMS (except for mitoxantrone), all of the medications approved to treat RRMS may be used off label in patients who have progressed to SPMS. For example, if a RRMS patient is taking a beta interferon they are likely to stay on treatment even after they have progressed to SPMS. At that time, the patient may transition to Merck-KGa's Novantrone® (mitoxantrone), the only FDA approved medication specifically for the treatment of SPMS. However, as per the label, the cumulative lifetime dose is limited to 2-3 years of treatment. In practice, very few patients actually take this medication due to its potential for cardiotoxicity.

In the following figure we have compiled a list of the top selling MS medications and their total sales for 2014. Each of these medications is approved for treating RRMS, and given the fact that half of RRMS patients go on to develop SPMS, there is an enormous market opportunity for an effective SPMS drug to become a blockbuster medication.

Company	Product	WW 2014 Sales (Millions)	YoY Growth
Biogen	Tecfidera	$2,909	232%
Biogen	Tysabri	$1,960	39%
Biogen	Avonex	$3,013	0%
Novartis	Gilenya	$2,477	28%
Merck Serono	Rebif	$2,445	-3%
Sanofi	Aubagio	$575	160%
Bayer	Betaseron	$1,088	-21%
Copaxone	Teva	$4,237	-2%
	TOTAL	$18,704	

Source: Company reports / Zacks SCR (Bautz)

MN-166 for the Treatment of ALS

Amyotrophic lateral sclerosis (ALS) is a rapidly progressing neurodegenerative disease whereby the nerve cells in the brain and spinal cord that control muscle movement degenerate. This rapid degeneration of the motor neurons eventually leads to death, typically in three to five years after patients are first diagnosed. As the motor neurons cease to function properly, they can no longer send signals to the muscle fibers, and thus voluntary muscle action is progressively affected. Eventually, patients in later stages of the disease may become completely paralyzed which includes losing the ability to control their breathing. In the U.S., approximately 30,000 people are currently living with ALS.

The rate at which the disease progresses varies from patient to patient and is measured utilizing a scoring system called the "ALS Functional Rating Scale Revised" (ALSFRS-R) (Cedarbaum *et al*., 1999). This scoring system 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.

There is only one drug approved by the FDA for the treatment of ALS. Sanofi's Riluzole® (rilutek) has been shown to improve survival, but only for two to three months. The compound works by preferentially blocking tetrodotoxin (TTX)-sensitive sodium channels that are associated with damaged neurons (Song *et al*., 1997). Rilutek does not reverse damage already done to motor neurons, and people taking it must be monitored for liver damage (approximately 10% incidence). It is now available as a generic.

The remaining treatments for ALS are designed to relieve symptoms and improve quality of life. This supportive care includes a multidisciplinary approach that may include medications to reduce fatigue, control spasticity, reduce excess saliva and phlegm, limit sleep disturbances, reduce depression, and limit constipation. However, none of these treatments reduces disease progression or addresses the underlying cause of the disease.

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 60 subjects with ALS. Patients in the study will be randomized 2:1 to receive either MN-166 or placebo. The study will consist of a three month screening phase, a six-month double blind treatment phase, and an open label six-month phase and is taking place at the Carolinas Healthcare System 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 change in ALSFRS-R, respiratory function, muscle strength, and non-invasive ventilation utilization.

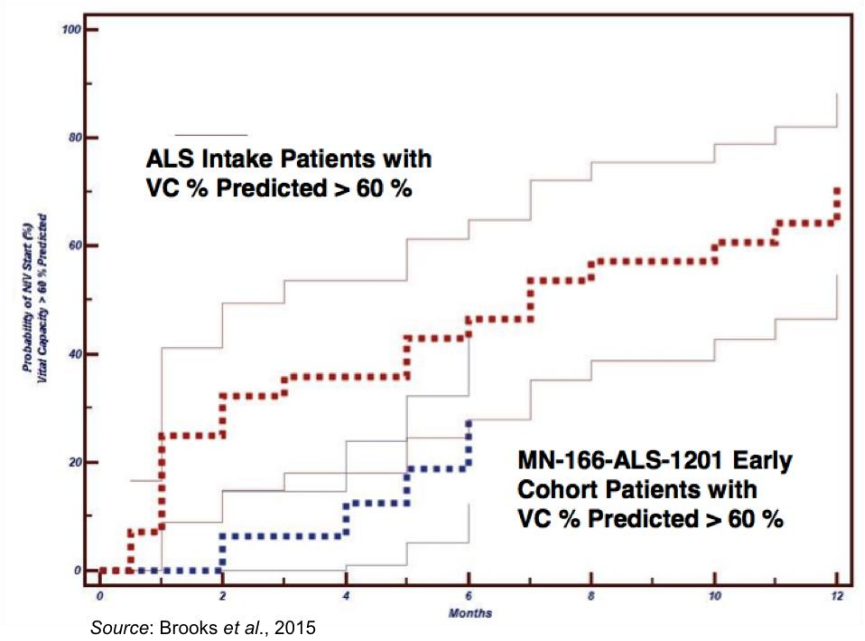
On April 21, 2015, MediciNova announced positive interim safety data from the study that showed no difference in safety or tolerability between MN-166 and placebo in the first 21 subjects enrolled in the study following three months of treatment. Importantly, the independent safety medical monitor recommended that the study continue as planned. In February 2015 the company announced the enrollment of 30 of the 60 patients for the trial.

On September 2, 2015, MediciNova announced that the first ALS patient using non-invasive ventilation (NIV) was enrolled in the company's ongoing Phase 2 clinical trial of MN-166 (NCT02238626). 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 utilized 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 60 patients with advanced ALS using NIV in addition to the already planned recruitment of 60 patients with ALS that are not using NIV. Since the trial is now enrolling both NIV and non-NIV patients, we are not sure when enrollment will be completed. We do anticipate that the two sets of patients (non-NIV and NIV) will be evaluated separately, thus depending upon the rate of enrollment, we are hopeful that the data for the non-NIV patients will be available in 2016, with the data for the NIV patients available later.

On December 14, 2015, MediciNova, Inc. (MNOV) announced the presentation of positive interim safety and clinical data from the company's ongoing Phase 2 clinical trial of MN-166 in patients with amyotrophic lateral sclerosis (ALS). The blinded data was presented at the 26th International Symposium on ALS/MND and included a total of 36 subjects, 33 of which had completed six months of treatment on study drug (MN-166 or placebo in a 2:1 ratio). It is important to keep in mind that the interim analysis is reporting data that is still blinded, thus there is no way at this point to compare MN-166 and placebo treated patients; they are only looked at as a pooled group. Thus far, MN-166 has been safe and well-tolerated as there has been no differential cluster of adverse events in placebo and active treatment subjects.

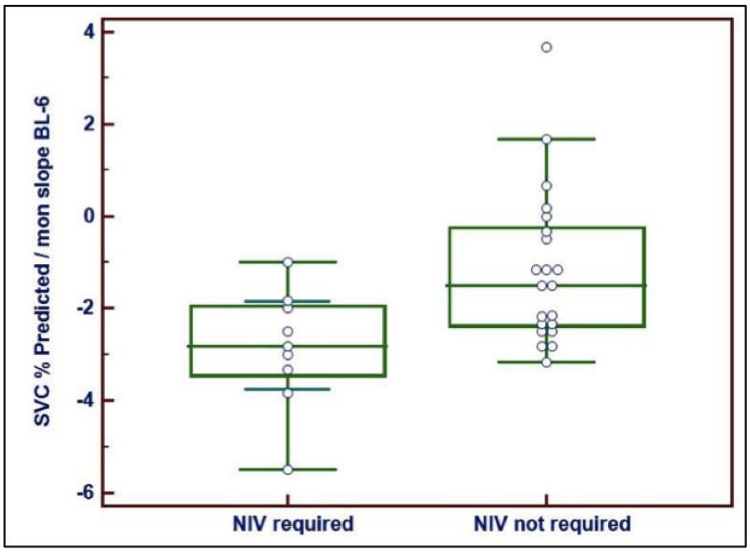
Perhaps the most interesting bit of data to emerge from this trial involves the need for NIV due to progression of respiratory failure. Thus far, nine of 32 patients required NIV, and as the following graph shows, NIV utilization is lower in patients from the ongoing clinical trial when compared with the deployment of NIV in a sample of patients referred to the ALS Multidisciplinary Clinic with vital capacity greater than 60% predicted. The difference was close to being statistically significant (*P*=0.071). Whether this effect is due to treatment with MN-166 is unknown at this time.



Source: Brooks *et al.*, 2015

Even though the data is still blinded, there are still a couple of other data points that are intriguing given their difference from historical controls. The first has to do with the decline in slow vital capacity (SVC) percentage

predicted. SVC is a test of lung function that measures how much air the patient can slowly exhale after inhaling as deep a breath as possible. It is typically reported as a percentage of a predicted value based on a patient's age, gender, height, and weight. Values above 80% often considered close to normal. The following chart shows that for patients who did not require NIV, the average % predicted SVC declined at a much lower rate (1.5% per month) than for those patients requiring NIV. In addition, the decline in % predicted SVC for those patients not requiring NIV was lower than what has been seen in previous clinical studies. In particular, the Pro-Act database, the largest ALS clinical trials dataset ever created, showed the average rate of decline of patients in prior ALS studies was 2.2% per month with n=8,404 patients.

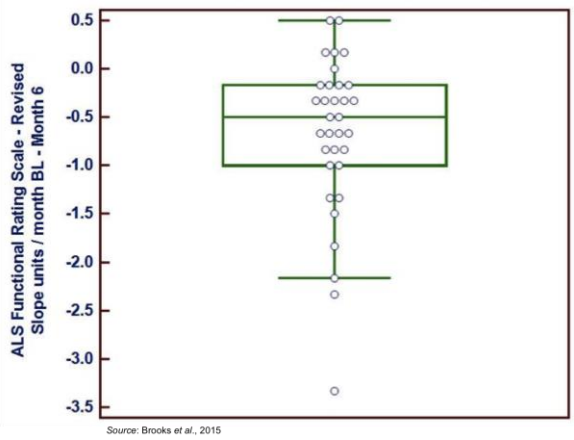


Source: Brooks *et al.*, 2015

Treatment	N	VC % Predicted ± SD	VC % Predicted / month ± SD
Philadelphia Cohort Before NIV	122	85 ± 20	- 4.6 ± 2.9
Philadelphia Cohort On NIV > 4 hr / d Group 1	38	83 ± 18	- 3.5 ± 5.3
Philadelphia Cohort On NIV < 4 hr / d Group 2	32	87 ± 24	- 5.9 ± 4.8
Philadelphia Cohort NIV not used Group 3	52	85 ± 13	- 8.3 ± 5.0
Pro-Act Cohort Before NIV	8404	86 ± 24	- 2.2 ± 6.9
Brisbane Cohort Before NIV	34	95 ± 19	- 3.1 ± 3.7
Penn State Cohort Before NIV	139	93 ± 16	- 2.4 ± 4.1
BCAA Cohort Before NIV	85	75 ± 21	- 3.1 ± 18.3
Memantine Cohort Before NIV	63	93 ± 16	- 2.6 ± 21.4
Charlotte Cohort Before Trilogy NIV	31	89 ± 22	- 2.8 ± 13.2
Charlotte CHS Cohort On Trilogy NIV > 4 hr / d	55	77 ± 18	- 1.2 ± 20.5
Charlotte CHS Ibudilast Safety Cohort Before Trilogy NIV	33	88 ± 15	- 1.3 ± 7.7

Source: Brooks *et al.*, 2015

The last data point examined for the interim analysis was the rate in decline of the ALSFRS-R The following figure shows that the overall rate of decline for patients in the Phase 2 study (both on MN-166 and placebo) was approximately -0.5 points/month, which is lower than has been observed in previous clinical trials (-1.2 points/month when looking at the totality of data from the Pro-Act Database).



On December 16, 2015, the company announced that the FDA granted Fast Track designation to MN-166 for the treatment of ALS. In addition, an abstract regarding MN-166 has been selected for dual presentation at the 2016 American Academy of Neurology (AAN) on April 20, 2016. We anticipate additional data being presented for the ongoing ALS study.

On November 9, 2015, the company announced a new clinical trial in ALS will be undertaken in collaboration with Massachusetts General Hospital to measure the effect of MN-166 on reducing brain microglial activation utilizing a biomarker. This will be an open label, proof-of-mechanism, Phase 2a clinical trial in approximately 15 ALS patients. The primary objective is to measure the effects of MN-166 on reducing brain microglial activation as measured by [^{11}C]-PBR28-PET. Secondary outcome measurements include evaluation of the safety and tolerability of MN-166 and different clinical outcomes (ALSFRS-R), SVC, and muscle strength over 36 weeks.

MN-166 for the Treatment of Substance Dependence

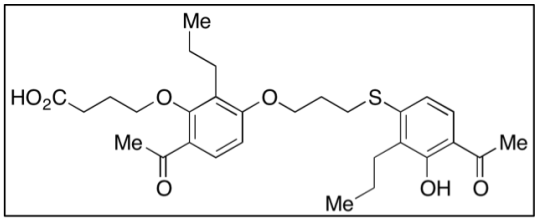
The company has announced that two different presentations took place at the Behavior, Biology and Chemistry Annual Meeting and Symposium in San Antonio, TX on March 5, 2016.

- Dr. Sandra Comer presented results from the completed Phase 2 clinical trial that evaluated MN-166 in patients with opioid dependence. The results showed that MN-166 significantly decreased the reinforcing effects of oxycodone and significantly decreased craving for heroin, cocaine, and tobacco. As a reminder, the trial was a randomized, placebo controlled, double blind, inpatient study in opioid-dependent abusers. Subjects were maintained on either MN-166 or placebo for two to three consecutive weeks (one week stabilization and 1.5 week testing). During test weeks, participants received oxycodone (0, 15, or 30 mg) in random order on separate days and were then offered a choice session that involved a drug versus money self-administration paradigm.

- Dr. Keith Heinzerling will discuss MN-166 and methamphetamine dependence. The study is a randomized, double blind, placebo controlled Phase 2 trial taking place over 12 weeks in treatment-seeking methamphetamine-dependent subjects (n=140). It is designed to detect a statistically significant benefit of MN-166 over placebo on the primary outcome of methamphetamine abstinence during the final two weeks of treatment.

MN-001 Update

MN-001 is a novel, orally available small molecule compound that works through several mechanisms to produce anti-fibrotic and anti-inflammatory effects in preclinical models. The compound is a leukotriene (LT) receptor antagonist, a PDE inhibitor (mainly 3 and 4), and also inhibits 5-lipoxygenase (5-LO). The 5-LO/LT pathway is though to be a pathogenic factor in fibrosis development (Zeldin *et al*., 2002). Previously, the company had tested MN-001 as a treatment for asthma and completed a Phase 2 study with positive results. The compound has been tested in over 600 subjects and was considered generally safe and well tolerated.



Source: trc-canada.com

Medicinova has recently announced clinical trial details for MN-001 in the treatment of both idiopathic pulmonary fibrosis (IPF) and nonalcoholic steatohepatitis (NASH).

Details of Phase 2 Clinical Trial of MN-001 in IPF

On October 9, 2015, MediciNova announced the company had come to an agreement with Penn State University to conduct a Phase 2 clinical trial of MN-001 in patients with moderate to severe IPF. The study will be a randomized, placebo controlled, double blind 6-month study followed by a 6-month open-label extension phase (NCT02503657). The drug will be administered twice daily at 750 mg per dose over a 26-week period. The study is expected to enroll 15 patients that will be randomized 2:1 to receive MN-001 or placebo. After the 26-week double-blind period, there will be a 26-week open label extension phase where patients who received placebo will be administered drug and those who previously received drug will be allowed to stay on treatment. The primary outcome of the study is change from baseline in forced vital capacity (FVC) at 26 weeks, a measure of lung function. There are a number of secondary outcomes including safety and tolerability of MN-001 and various measures of the rate of decline in disease activity.

As a reminder, FDA has granted Fast Track Designation and Orphan Drug Designation to MN-001 for the treatment of IPF.

Details of Phase 2 Clinical Trial of MN-001 in NASH

On November 19, 2015, MediciNova announced the plan for a Phase 2 clinical trial of MN-001 for the treatment of hypertriglyceridemia in NASH patients (NCT02681055). This will be a multi-center, proof-of-principle, open label study in males and females age 21-65 who have a histologically confirmed diagnosis of NASH and an elevated serum triglyceride level (>150 mg/dL). Approximately 20 subjects are expected to enroll and will be given once-daily MN-001 (250 mg) for the first four weeks followed by twice daily dosing for an additional eight weeks. The study will consist of a screening phase (up to four months), a treatment phase (12 weeks), and a follow-up visit (within one week after the last dose). The primary efficacy endpoints are to evaluate the effect of MN-001 on triglyceride levels and cholesterol efflux capacity in NASH patients with hypertriglyceridemia. Secondary endpoints include the safety and tolerability of MN-001, the pharmacokinetics of the drug, the effect of MN-001 on cholesterol levels, and effects of MN-001 on liver enzymes and percent fat in the liver.

As a reminder, in April 2015 the company announced the FDA had granted Fast Track Designation for MN-001 for the treatment of NASH patients with fibrosis.

Conclusion

There are a number of potential catalysts for MediciNova's stock this year as we expect the initiation of the ALS biomarker study with Mass General, continued updates from the Phase 2 study of MN-166 in ALS, as well as an interim analysis for the ongoing Phase 2b study of MN-166 in progressive MS to take place in the fall of 2016. The data that has been presented thus far from the ALS trial has been quite encouraging, and we are looking forward to the additional data that will be presented at the 2016 AAN annual meeting on April 20, 2016. While potentially less lucrative than the other indications in development, the development of MN-166 for treatment of substance dependence is another meaningful opportunity with additional updates from those programs expected in 2016.

The treatment of ALS is a potential blockbuster opportunity. As there has only ever been one drug approved for treating ALS, there is a huge unmet medical need for better treatment options for these patients. The FDA recently granted MN-166 Fast Track designation for the treatment of ALS, which includes a number of incentives for the company including increased interactions with the FDA to discuss the drug's development plan and the opportunity for priority review and accelerated approval.

While ocrelizumab could be approved for the treatment of PPMS, we question its safety and we believe there is plenty of room in the market for additional therapies, particularly for a compound like MN-166 that has a completely different mechanism of action. The MS market is enormous (currently $18.7 billion), and as shown by the chart earlier for treatments of RRMS, there is room for multiple blockbuster therapies for the treatment of progressive MS.

We have made slight modifications to our model that include slightly reducing the discount rate we apply to future revenues and reducing the expected cash burn for the next few years. As a result, we are increasing our price target to $10 and maintaining a 'Buy' rating on the shares.

PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2015 A	Q1 E	Q2 E	Q3 E	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	$0.950	$1.050	$1.100	$1.150	$4.250	$5.500	$7.000
General & Administrative	$5.805	$1.500	$1.500	$1.500	$1.500	$6.000	$6.100	$6.300
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($8.822)	($2.450)	($2.550)	($2.600)	($2.650)	($10.3)	($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)	($2.460)	($2.558)	($2.612)	($2.660)	($10.3)	($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)**	**($2.462)**	**($2.560)**	**($2.614)**	**($2.662)**	**($10.3)**	**($12.1)**	**($13.8)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.33)**	**($0.08)**	**($0.08)**	**($0.08)**	**($0.08)**	**($0.32)**	**($0.34)**	**($0.35)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	26.579	31.000	32.500	33.000	33.500	32.500	36.000	40.000

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

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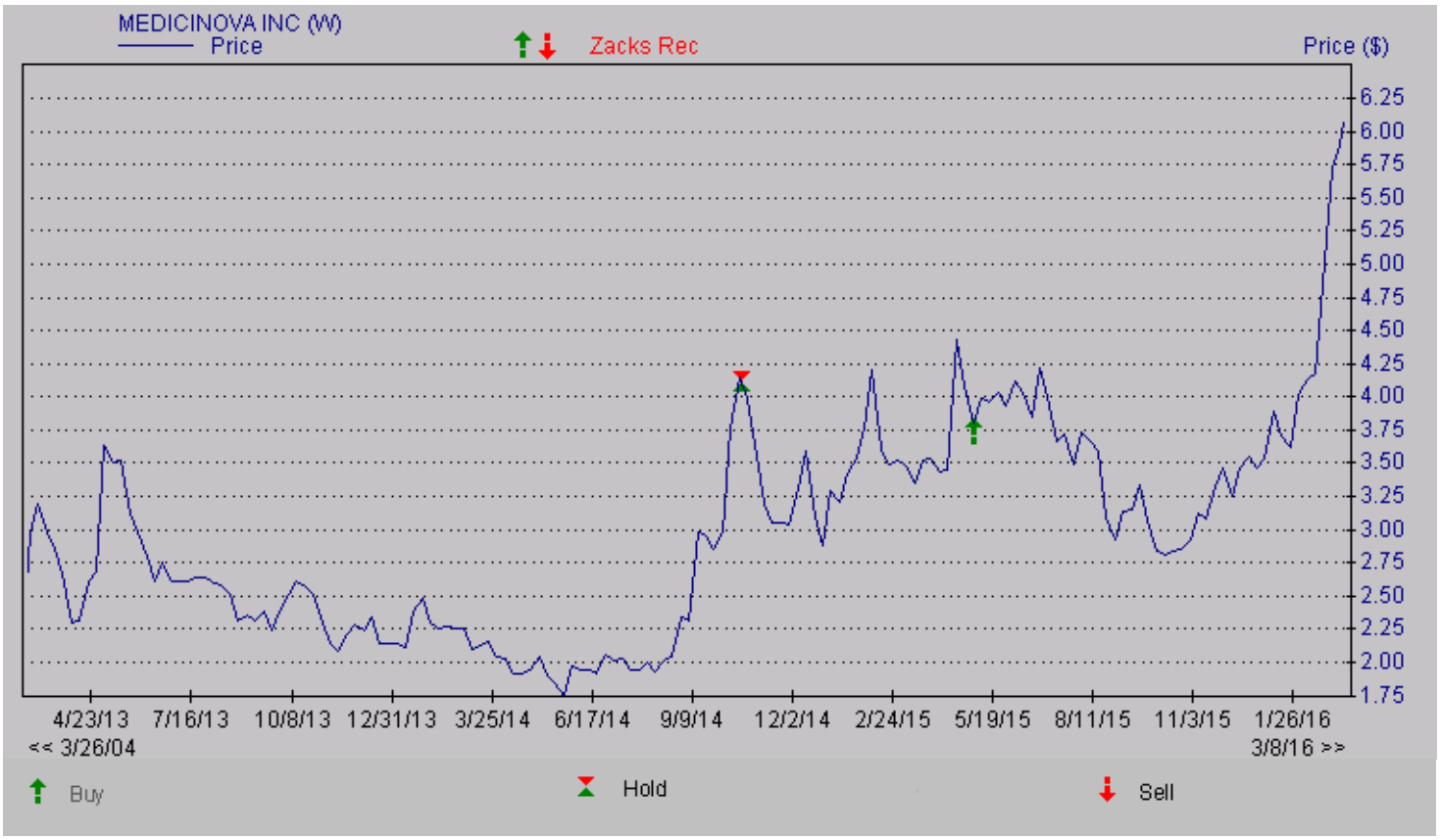

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