Zacks Small-Cap Research

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MediciNova, Inc.

(MNOV - Nasdaq)

MNOV: MN-166 Shows Activity in Preclinical Brain Cancer Study…

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 $10/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 (08/01/17)	$5.21
Valuation	**$10.00**

OUTLOOK

During the quarter, MediciNova announced encouraging results from a preclinical study of MN-166 (ibudilast) in a mouse model of glioblastoma. The results were presented at the 2017 ASCO Annual Meeting, and showed increased survival in mice treated with MN-166 (ibudilast) plus standard of care treatment compared to standard of care alone.

On July 26, 2017, MediciNova filed form 10-Q with financial results for the second quarter of 2017. The company reported a net loss of $2.8 million, or $0.08 per share. The company's operating cash burn was $4.0 million for the first six months of 2017 and the company exited the quarter with approximately $22.9 million in cash and cash equivalents.

SUMMARY DATA

52-Week High	**$7.77**
52-Week Low	**$4.91**
One-Year Return (%)	**-16.91**
Beta	**0.03**
Average Daily Volume (sh)	**24,567**
Shares Outstanding (mil)	**35**
Market Capitalization ($mil)	**$183**
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 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)
2016	0 A	0 A	0 A	0 A	0 A
2017	0 A	0 A	0 E	0 E	0 E
2018					0 E
2019					0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.11 A	-$0.10 A	-$0.08 A	-$0.04 A	-$0.33 A
2017	-$0.09 A	-$0.08 A	-$0.09 E	-$0.09 E	-$0.36 E
2018					-$0.37 E
2019					-$0.38 E

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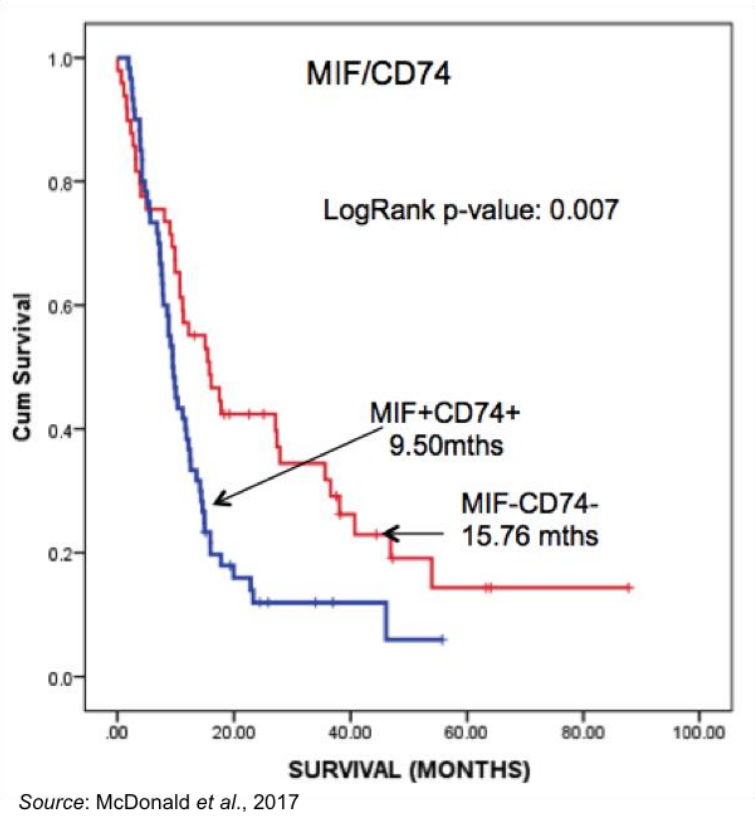
WHAT'S NEW

Business Update

MN-166 in Glioblastoma

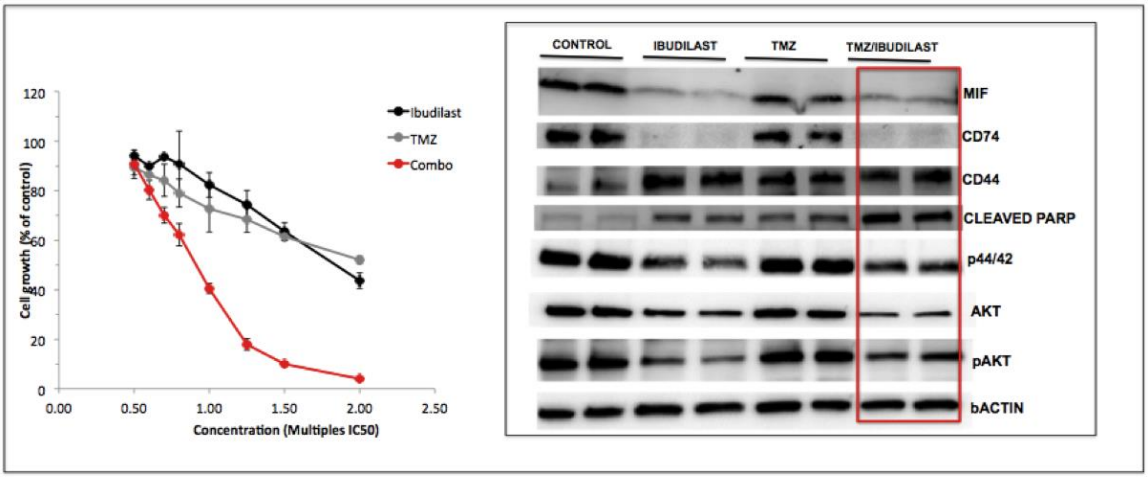
On June 5, 2017, MediciNova announced that Professor Kerrie McDonald presented results from a preclinical study of MN-166 (ibudilast) in the treatment of glioblastoma (GBM) at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting. The aims of the study were to compare proteomic profiles 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.



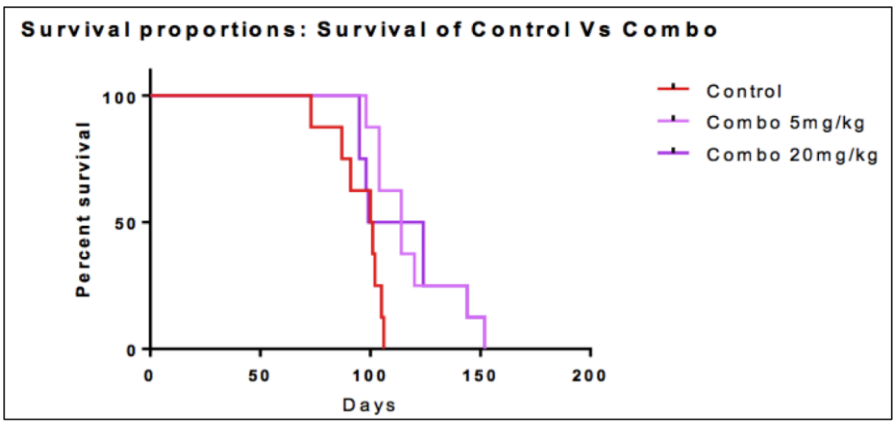
Source: McDonald *et al*., 2017

MN-166 (ibudilast) is an inhibitor of MIF (Cho *et al*., 2010). To determine if MN-166 (ibudilast) could show an effect in GBM, the researchers first treated patient derived GBM cell lines with MN-166 (ibudilast), 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 (ibudilast) 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 (ibudilast) at two different concentrations. Results showed that mice treated with the combination of TMZ and MN-166 (ibudilast) 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

MediciNova is planning on following up on these results by initiating a Phase 2 clinical trial of MN-166 (ibudilast) in patients with recurrent GBM at the University of Sydney Royal North Shore Hospital.

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 (SOC) 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).

MN-166 in Progressive MS

On December 19, 2016, MediciNova, announced that the Data and Safety Monitoring Board (DSMB) for the ongoing Phase 2b clinical trial of MN-166 (ibudilast) in progressive multiple sclerosis (MS) reviewed the results of the interim efficacy analysis and recommended to the National Institute of Neurological Diseases and Stroke (NINDS) that the trial should continue as planned, to which the NINDS has agreed.

We view this as a positive outcome, as there were three potential consequences to the interim analysis: 1) the trial could be stopped for futility; 2) the trial could continue as planned; or 3) the trial could be stopped for overwhelming efficacy. We viewed the trial being stopped early for overwhelming efficacy as a highly unlikely outcome, as the trial was powered for 250 patients and the interim analysis was performed using data from only half of the patients enrolled (127 out of 255 enrolled). Thus, the fact that the DSMB recommended that the trial continue as planned is indicative that there is at least a positive trend in the direction of efficacy for MN-166. If there were no trend in favor of MN-166, the trial would have been stopped for futility. We look forward to the release of the final data analysis, which we anticipate will be in the second half of 2017 or the first half of 2018, depending on which medical conference the data is presented at (e.g., ECTRIMS, ACTRIMS, or AAN).

Phase 2b Trial
NeuroNEXT, an NIH funded clinical trial network that conducts studies of treatments for neurological diseases, is conducting the SPRINT-MS trial, a Phase 2b trial evaluating MN-166 in primary progressive MS (PPMS) and secondary progressive MS (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).

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. In June 2015, the company announced the trial had completed randomization of 255 patients and we would anticipate final results sometime in the second half of 2017 or the first half of 2018.

The primary outcome of the ongoing study is the rate of change in brain atrophy over 96 weeks as measured by brain parenchymal fraction (BPF) using MRI. MN-166 was previously tested in a randomized, double blind, placebo controlled Phase 2a clinical trial of 297 patients with relapsing-remitting MS (RRMS) or SPMS with continued relapses. Patients were treated for 12 months with 30 mg/day MN-166, 60 mg/day MN-166, or placebo. While the study did not hit the primary outcome on the cumulative number of newly active lesions seen on bimonthly MRI scans over the first 12 months of treatment, 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. We believe that due to the fact the ongoing study is testing a higher dose of MN-166 than the earlier study (100 mg/day vs. 60 mg/day) and the treatment period is longer (96 weeks vs. 52 weeks), there is a high likelihood that the ongoing study will achieve the primary endpoint of reducing brain volume loss. Also, there is published research that indicates that the rate of brain volume loss is higher in progressive MS patients than in relapsing MS patients, which should make it easier to show a statistically significant reduction in brain volume loss in the progressive MS population (Ge *et al*., 2000).

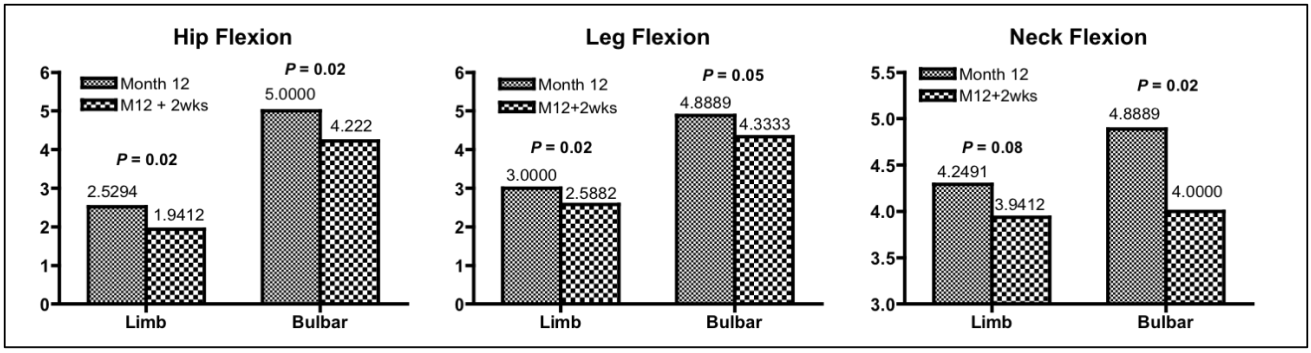
MN-166 in ALS

On April 25, 2017, MediciNova, Inc. (MNOV) announced exploratory interim clinical outcomes data were presented by Dr. Benjamin Rix Brooks at the American Academy of Neurology 69th Annual Meeting. Dr. Brooks is the principal investigator of the ongoing Phase 1b/2a clinical trial of MN-166 (ibudilast) in patients with amyotrophic lateral sclerosis (ALS).

An exploratory interim analysis of survival rate was conducted on 47 randomized ALS patients without non-invasive ventilator support who completed the per-protocol treatment compared to those who withdrew from the study before the open-label period. Per protocol treatment consisted of a 6-month double-blind treatment period followed by a 6-month open-label extension period. The survival rate after the open-label period was significantly higher in the group of patients that completed the entire treatment (n= 31) than in the in the group of subjects who withdrew prior

to the open-label period (n=16; *P*=0.007). While encouraging, these data may just represent the loss of rapidly progressing patients.

In addition, Dr. Brooks presented data from a sub-group analysis sorted by the type of onset of ALS. ALS patients were classified as either bulbar-onset or limb-onset, depending upon what area of the body the patient first started experiencing symptoms. Bulbar-onset patients experience difficulties with speech, salivation, and swallowing first, while limb-onset patients experience difficulties with arm or leg strength first. The data showed there were significant decreases in muscle strength two weeks after stopping MN-166 for hip, leg, and neck flexion as measured by Manual Muscle Testing.



Source: Brooks 2017 / Zacks SCR

Were these trends to continue, it would likely result in a significant decline in the patient's health in a short period of time, as decreases in muscle strength as measured for hip flexion (Santos *et a*l., 2016), leg flexion (Slavin *et al*., 1998), and neck flexion (Nakamura *et al*., 2013) are correlated with function and survival.

Lastly, lower motor neuron (LMN) ALS burden significantly deteriorated in limb-onset patients during the study, however there was no significant change in LMN burden in bulbar-onset patients between baseline and Month 12 as measured by the Brisbane-Sydney UMN-LMN ALS burden scale (arm-onset patients P=00001; leg-onset patients P=0.0004). This may indicate that bulbar-onset patients should be a targeted population for treatment in future trials, as LMN burden is associated with survival in ALS patients (Devine *et al*., 2016).

Phase 2 Clinical Trial

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 up to 60 subjects with ALS. Patients in the study were randomized 2:1 to receive either MN-166 or placebo. The study includes a three month screening phase, a six-month double blind treatment phase, and a six-month open-label extension phase and is taking place at the Carolinas Healthcare System's Neuromuscular/ALS-MDA Center 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 the change in ALS Functional Rating Scale Revised (ALSFRS-R), respiratory function, muscle strength, and non-invasive ventilation.

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.

On September 2, 2015, MediciNova announced that the first ALS patient using non-invasive ventilation (NIV) was enrolled in the ongoing Phase 2 clinical trial. 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 used 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 up to 60 patients with advanced ALS using NIV in addition to the already planned recruitment of up to 60 patients with ALS that are not using NIV. We anticipate that the two sets of patients (non-NIV and NIV) will be evaluated separately and we expect data from the six-month double-blind portion of the study later this year.

On April 20, 2016, MediciNova announced interim data from the ongoing clinical trial of MN-166 (ibudilast) in amyotrophic lateral sclerosis (ALS) at the American Academy of Neurology (AAN) 68th Annual Meeting. The interim analysis included a total of 25 subjects without non-invasive ventilator support who completed the 6-month double-blind treatment period with complete spirometry (respiratory function test) data. The mean decline in the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R) total score (the higher the score the more function is retained) from Baseline to Month 6 was 4.55 (0.76 per month) in the MN-166 group compared to 5.80 (0.97 per month) in the placebo group (a higher rate of decline indicates a greater worsening of disability). The mean decline in slow vital capacity (SVC), a measure of respiratory function, from Baseline to Month 6 was 10.93% (1.82% per month) in the MN-166 group compared to 12.71% (2.12% per month) in the placebo group. No cluster of adverse events was differentially present in MN-166 treatment and placebo treatment subjects.

ALS Biomarker Study Underway

MediciNova had previously announced a biomarker study in ALS patients would take place in collaboration with Massachusetts General Hospital. The trial is now open and is expected to enroll 15 ALS patients and will investigate the effects of MN-166 on reducing brain microglial activation (NCT02714036). In this open-label trial, ALS patients will be administered 100 mg MN-166 daily (50 mg in the morning and 50 mg at night) for 36 weeks and the primary outcome is to measure the effects of MN-166 on brain microglial activation as measured through the uptake of [11C]-PBR28, which is a ligand that is preferentially taken up by peripheral benzodiazepine receptors (PBRs) and can be tracked by positron emission tomography (PET) imaging. PBRs are known to be upregulated on activated microglia (Imalzumi *et al*., 2007). Secondary outcome measurements include changes in ALSFRS-R, SVC (slow vital capacity, a measure of respiratory function), and muscle strength from baseline. This study will provide important safety and efficacy data in regards to an increased daily dose of MN-166 as the company begins preparations for planning future studies in ALS. Importantly, this biomarker could potentially be used as a screening tool for recruitment in future studies.

MN-166 in Methamphetamine Dependence

On February 6, 2017, MediciNova announced that results from the completed Phase 1b clinical trial of MN-166 in methamphetamine dependence were presented at the 50th Winter Conference on Brain Research. The trial was a randomized, double blind, placebo-controlled, within-subject study of MN-166 in methamphetamine-dependent, non-treatment seeking abusers. Each subject was treated with one of two medication sequences: 1) placebo – 20 mg MN-166 – 50 mg MN-166 twice/day or 2) 20 mg MN-166 – 50 mg MN-166 – placebo twice/day. Methamphetamine infusions (0 mg, 15 mg, 30 mg) were given while subjects were taking MN-166 or placebo and were followed by cardiovascular assessments, subjective effects ratings, and pharmacokinetic (PK) assessments.

Results showed that MN-166 increased the levels of brain-derived neurotrophic factor (BDNF) compared to placebo, decreased levels of tumor necrosis factor alpha (TNF-α) compared to placebo (P=0.027), decreased levels of vascular cell adhesion molecule (VCAM1) compared to placebo (P=0.035), and was safe and well tolerated during the methamphetamine infusions. We believe these results demonstrate MN-166's neuroprotective and anti-neuroinflammatory effects.

MN-166 is being studied in an ongoing methamphetamine Phase 2 study that is expected to enroll up to 140 treatment-seeking methamphetamine dependent subjects. Subjects will be randomized and stratified by HIV serostatus to receive either 50 mg of MN-166 twice a day or placebo for 12 weeks. There will be twice weekly clinic visits for counseling, drug tests, and safety/medication adherence monitoring. The primary outcome is methamphetamine abstinence during the final two weeks of treatment. We expect this study will be completed by the end of 2017 with results in the first half of 2018.

Financial Update

On July 26, 2017, MediciNova, Inc. (MNOV) filed form 10-Q with financial results for the second quarter of 2017. As expected, the company did not report any revenues. Net loss for the second quarter of 2017 was $2.8 million, or $0.08 per share, and was comprised of $0.9 million in R&D expenses and $1.9 million in G&A expenses. This compares to $1.0 million in R&D expenses and $2.2 million in G&A expenses for the second quarter of 2016. The

decreases in R&D and G&A expenses were both due to lower stock compensation expense for performance-based stock options.

Total operating cash burn for the second quarter of 2017 was $1.4 million. As of June 30, 2017, the company had approximately $22.9 million in cash and cash equivalents. We believe the company has sufficient capital to fund operations through the end of 2019.

Conclusion

The data on MN-166 in GBM is encouraging and certainly warrants following-up with a clinical trial to test its effectiveness in patients. We anticipate learning more about the Phase 2 GBM trial in the coming months. There are few treatment options available for GBM patients, thus a successful GBM therapy would likely generate greater than $500 million in peak revenues.

The biggest catalyst for MediciNova during the next 12 months will be the final results from the Phase 2b study of MN-166 in Progressive MS, which we expect in the second half of this year or first half of next year. The progressive MS market opportunity is estimated to be in excess of $20 billion (based on current sales of relapsing MS drugs), thus positive results from MediciNova's Phase 2b trial in progressive MS would likely result in a significant readjustment to the company's valuation.

MediciNova is in strong financial shape, as it currently has sufficient funding to last through the end of 2019. This is an enviable position to be in and allows the company flexibility in pursuing the various different projects in its pipeline. We have constructed a probability adjusted discounted cash flow model that takes into account potential future revenues from the company's pipeline, and our current valuation stands at $10 per share.

PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2016 A	Q1 A	Q2 A	Q3 E	Q4 E	2017 E	2018 E	2019 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	$3.519	$0.901	$0.897	$1.100	$1.100	$3.998	$4.500	$4.700
General & Administrative	$7.363	$2.123	$1.908	$2.000	$2.000	$8.031	$8.300	$8.500
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($10.882)	($3.024)	($2.805)	($3.100)	($3.100)	($12.0)	($12.8)	($13.2)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.0	$0.01	$0.02	$0.01	($0.01)	($0.5)	($0.5)	($0.5)
Pre-Tax Income	($10.862)	($3.012)	($2.787)	($3.089)	($3.110)	($12.5)	($13.3)	($13.7)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($10.9)**	**($3.017)**	**($2.789)**	**($3.091)**	**($3.112)**	**($12.5)**	**($13.3)**	**($13.7)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.33)**	**($0.09)**	**($0.08)**	**($0.09)**	**($0.09)**	**($0.36)**	**($0.37)**	**($0.38)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	32.987	34.527	34.647	35.000	35.300	34.868	36.000	36.000

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

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