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MediciNova, Inc. (MNOV-NASDAQ)

MNOV: New Analysis Shows Efficacy of MN-166 in Non-Relapsing SPMS…

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 (04/08/19)	$10.09
Valuation	**$19.00**

OUTLOOK

MediciNova, Inc. (MNOV) recently completed a subgroup analysis of the SPRINT-MS Phase 2b trial of MN-166 (ibudilast) in progressive multiple sclerosis (MS). Results showed that treatment with MN-166 resulted in a 46% risk reduction in confirmed disability progression compared to placebo (HR=0.538) in secondary progressive MS (SPMS) patients without relapse, while in SPMS patients with relapse there was no treatment effect. The FDA recently approved two new therapies for patients with SPMS with relapse, and there are currently no approved long-term therapies for SPMS without relapse, thus representing a large market opportunity. The company is planning a meeting with the FDA to discuss plans for the Phase 3 trial in progressive MS.

SUMMARY DATA

52-Week High	**$13.23**
52-Week Low	**$6.82**
One-Year Return (%)	**-17.57**
Beta	**1.12**
Average Daily Volume (sh)	**61,749**
Shares Outstanding (mil)	**42**
Market Capitalization ($mil)	**$426**
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	**High**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 E	0 E	0 E	0 E	0 E
2020					0 E
2021					0 E

Earnings per Share

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

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WHAT'S NEW

Business Update

New Analysis Shows MN-166 Efficacy in Non-Relapsing SPMS

On April 1, 2019, MediciNova, Inc. (MNOV) announced results from a subgroup analysis of the SPRINT-MS Phase 2b trial of MN-166 (ibudilast) in progressive multiple sclerosis (MS). The SPRINT-MS trial was a Phase 2b clinical trial of patients with either secondary progressive MS (SPMS) or primary progressive MS (PPMS) in which participants received either MN-166 (100 mg/day) or placebo twice a day for a total of 96 weeks of treatment. The company has previously reported positive results from the SPRINT-MS trial, as it achieved both primary endpoints (a statistically significant 48% reduction in the rate of progression of whole brain atrophy along with safety and tolerability) and also demonstrated effects on important secondary endpoints including a positive trend of a 26% reduction in confirmed disability progression, which would be a primary endpoint in a Phase 3 trial.

The subgroup analysis was performed based on feedback the company received from the FDA that relapsing SPMS is different from non-relapsing SPMS. Non-relapsing SPMS is the only type of SPMS without available therapy, however there were two recent FDA approvals for therapies to treat SPMS with relapse (discussed below). The subgroup analysis performed by MediciNova was done to better understand which type of progressive MS responds best to treatment with MN-166 in regards to confirmed disability progression as measured by EDSS. The following table shows that the greatest treatment effect for MN-166 occurred in patients with SPMS without relapse, as demonstrated by a 46% risk reduction and a hazard ratio of 0.538.

Subgroup	# subjects		Hazard Ratio	Risk Reduction
	MN-166	Placebo		
PPMS	68	66	0.707	29%
SPMS with relapse	9	6	1.153	-15%
SPMS without relapse	52	54	0.538	46%

Source : MediciNova, Zacks SCR

The market opportunity for treating SPMS without relapse appears to be much larger than for treating SPMS with relapse. During the 96-week SPRINT-MS trial only 12% of SPMS patients experienced relapse, and as the table above shows treatment with MN-166 was not effective for that group of patients. Thus, we would anticipate at least 80% of SPMS patients do not have relapse, creating a potentially large market opportunity.

New FDA Approved Therapies to Treat SPMS with Relapse

On Mar. 26, 2019 and Mar. 29, 2019, the FDA approved Mayzent® (siponimod) and Mavenclad® (cladribine), respectively, for the treatment of relapsing-remitting MS (RRMS) and active SPMS (i.e., SPMS with relapse).

- Mayzent® is a sphingosine 1-phosphate receptor (S1PR) modulator that binds to S1PR on lymphocytes and prevents their entry into the central nervous system. The drug was approved based on the results of the EXPAND Phase 3 clinical trial, a randomized, double blind, placebo controlled study that included 1651 patients with SPMS (Kappos *et al*., 2018). Results showed that compared to placebo, Mayzent® decreased the risk of confirmed disability progression by 21% (HR=0.79; *P*=0.0134). While Mayzent® had a significant effect on disability progression in patients with active SPMS (defined as a relapse in the two years prior to the study), the effect of Mayzent® in patients with non-active SPMS (no relapses in the two years prior to the study) was not significant as the reduction in disability was only 13% (HR=0.87). Approximately 19% of placebo patients had a relapse during the EXPAND trial, further demonstrating that the total patient population for active SPMS patients is small. Lastly, Mayzent® has seven safety warnings on page 1 of its prescribing information, including warnings about infections, macular edema, bradyarrhythmia, respiratory effects, liver injury, increased blood pressure, and fetal risks (Mayzent® prescribing information). Because of the safety issues, the patient must complete seven assessments prior to the first dose of Mayzent® including one that is not FDA-approved (CYP2C9 genotype determination). Due to the high number of warnings and the burdensome assessment process before initiation of treatment, we are not optimistic about the market uptake of Mayzent® in the limited active SPMS population.

- Mavenclad® is a purine antimetabolite that selectively targets the depletion of B cells and T cells. It is administered over two annual courses given for a maximum of 20 days over two years, with no additional treatment allowed for the next two years due to the risk of malignancy. The drug was approved with a 'black-box' warning for increased risk of cancer and teratogenicity, thus it is not utilized as a first-line treatment but is instead recommended for patients with an inadequate response to alternate MS treatments. In addition to the 'black-box' warning, Mavenclad® has five other warnings on page 1 of its prescribing information. Although Mavenclad® was approved in Europe in 2017, it only generated sales of 90 million euros in 2018, which is 2% of the $4.3 billion in sales generated by MS market-leader Tecfidera in 2018. This demonstrates the value of safety in the MS market as Tecfidera only has one warning on page 1 of its prescribing information and no 'black-box' warnings.

Conclusion

Based upon the approval of Mayzent® and Mavenclad® for active SPMS (and not for SPMS without relapse), the fact that the vast majority of SPMS patients do not have relapses, and the robust risk reduction for disability progression in SPMS patients without relapse resulting from treatment with MN-166, we believe MN-166 has enormous potential in treating progressive MS. MN-166 could end up being the only drug approved for the large patient population of SPMS patients without relapse. With positive Phase 3 results, we believe MN-166 could go on to have peak revenues of $3 billion in progressive MS.

Ocrevus® (ocrelizumab), which was approved for the treatment of PPMS and RRMS in 2017 (but not for SPMS), generated revenues of approximately $2.4 billion in 2018 and is currently forecasted to generate $5.8 billion in revenues in 2024 (EvaluatePharma). We believe this shows the potential for a successful treatment for progressive MS.

In addition to progressive MS, MediciNova is continuing to plan for a Phase 3 trial in ALS, recently initiated a trial in glioblastoma (GBM) and expects enrollment to begin in mid-2019 for a trial in degenerative cervical myelopathy (DCM). With multiple clinical programs advancing and two potential blockbuster indications in MS and ALS, we remain positive on MediciNova and our current valuation is $19 per share.

PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2018 A	Q1 E	Q2 E	Q3 E	Q4 E	2019 E	2020 E	2021 E
MN-166 (Multiple Sclerosis)	$0	$0	$0	$0	$0	$0	$0	$0
MN-166 (ALS)	$0	$0	$0	$0	$0	$0	$0	$0
MN-166 (Addiction)	$0	$0	$0	$0	$0	$0	$0	$0
MN-001 (NASH)	$0	$0	$0	$0	$0	$0	$0	$0
MN-001 (IPF)	$0	$0	$0	$0	$0	$0	$0	$0
Grants & Collaborative Revenue	$0	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$5.626	$3.500	$3.800	$3.900	$4.000	$15.200	$15.500	$17.000
General & Administrative	$9.961	$2.500	$2.600	$2.800	$3.000	$10.900	$11.000	$11.500
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($15.6)	($6.0)	($6.4)	($6.7)	($7.0)	($26.1)	($26.5)	($28.5)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.9	$0.1	$0.1	$0.1	$0.1	$0.4	$0.4	$0.4
Pre-Tax Income	($14.7)	($5.9)	($6.3)	($6.6)	($6.9)	($25.7)	($26.1)	($28.1)
Income Taxes Paid	($0)	$0	$0	$0	($0)	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($14.7)**	**($5.9)**	**($6.3)**	**($6.6)**	**($6.9)**	**($25.7)**	**($26.1)**	**($28.1)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.36)**	**($0.14)**	**($0.15)**	**($0.15)**	**($0.15)**	**($0.59)**	**($0.56)**	**($0.56)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	41.125	42.000	43.000	44.000	46.000	43.750	47.000	50.000

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

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