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Medicinova Inc

(MNOV-NASDAQ)

MNOV: MN-166 Shows 26% Reduction in Disability Progression in Progressive MS Phase 2 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 $18/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 (02/07/18)	$10.75
Valuation	**$18.00**

OUTLOOK

On February 1, 2018, MedicNova, Inc. announced new results from the Phase 2b SPRINT-MS trial of MN-166 in patients with progressive multiple sclerosis (MS) in which treatment with MN-166 resulted in a 26% reduction in confirmed disability progression (hazard ratio = 0.74). Based upon these results, the company believes that a Phase 3 clinical trial with approximately 700 subjects will be properly powered to achieve statistical significance using confirmed disability progression as a primary endpoint. For comparison, Ocrevus® (ocrelizumab) was approved for the treatment of primary progressive MS based upon Phase 3 results that showed a 24% reduction in confirmed disability progression. Ocrevus® generated revenue of $935 million in 2017.

SUMMARY DATA

52-Week High	**$10.75**
52-Week Low	**$4.43**
One-Year Return (%)	**77.98**
Beta	**0.38**
Average Daily Volume (sh)	**147,896**
Shares Outstanding (mil)	**36**
Market Capitalization ($mil)	**$388**
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	**-31.6**
P/E using 2019 Estimate	**-28.3**

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)
2016	0 A	0 A	0 A	0 A	0 A
2017	0 A	0 A	0 A	0 E	0 E
2018					0 E
2019					0 E

Earnings per Share

	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	-$0.11 A	-$0.09 E	-$0.38 E
2018					-$0.37 E
2019					-$0.38 E

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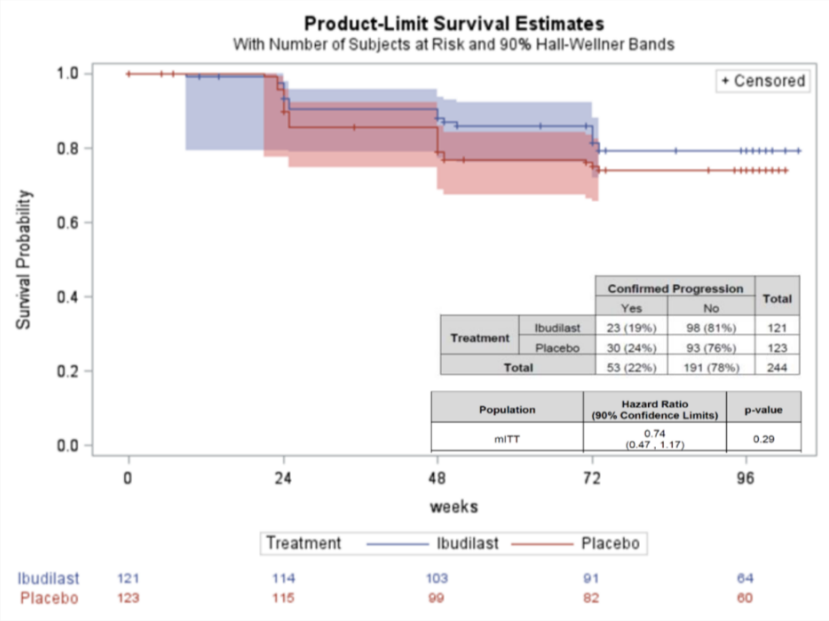
WHAT'S NEW

Additional Positive Data Presented for MN-166 in MS

On February 1, 2018, MediciNova, Inc. (MNOV) announced the presentation of additional positive data from the SPRINT-MS clinical trial of MN-166 (ibudilast) in patients with primary and secondary progressive multiple sclerosis (MS). The data showed that treatment with MN-166 resulted in a 26% reduction in confirmed disability progression, which was a secondary endpoint in the Phase 2 trial but which would be a primary endpoint in a Phase 3 trial. The company had previously announced positive topline data showing a statistically significant 48% reduction in the rate of progression of whole brain atrophy compared to placebo (P=0.04).

The following graph shows a Kaplan-Meier plot of confirmed EDSS progression along with the absolute numbers of patients with confirmed EDSS progression. The hazard ratio for progression in the MN-166 group compared to placebo was 0.74, representing a 26% reduction.



Source: Naismith *et al*., 2018

MN-166 was generally well tolerated during the study. Patients taking MN-166 experienced a higher rate of gastrointestinal side effects compared to those on placebo, however there were no increased serious adverse events (SAEs), no increased risk of infections, no cancer signal, no cardiovascular events and no deaths related to MN-166 treatment. In addition, there was no statistically significant difference in the number of discontinuations between the two groups.

To help put these data into context we believe a comparison to the Phase 3 data for Ocrevus® (ocrelizumab) is warranted since that study involved patients (n=732) with primary progressive MS and a primary endpoint of confirmed disability progression (Montalban *et al*., 2017). The following table shows confirmed disability progression at 12 weeks (primary endpoint) and 24 weeks (secondary endpoint) with a hazard ratio for those two endpoints of 0.76 (*P*=0.03) and 0.75 (*P*=0.04), respectively. Thus, a hazard ratio of 0.74 for MN-166 is right in line with data that resulted in the approval of Ocrevus® for the treatment of progressive MS.

End Point	Ocrelizumab (N=488)	Placebo (N=244)	Hazard Ratio or Relative Difference (95% CI)†	P Value
Confirmed disability progression for ≥12 wk: primary end point — no./total no. (%)‡	160/487 (32.9)	96/244 (39.3)	0.76 (0.59 to 0.98)	0.03
Secondary clinical end points				
Confirmed disability progression for ≥24 wk — no./total no. (%)‡	144/487 (29.6)	87/244 (35.7)	0.75 (0.58 to 0.98)	0.04

Source: Montalban *et al*., 2017

In addition, in 2016 Novartis announced positive Phase 3 results for BAF312 (siponimod), a selective sphingosine-1-phosphate (S1) receptor modulator, in patients with secondary progressive MS that showed treatment with BAF312 (siponimod) reduced the risk of three-month confirmed disability progression by 21% compared to placebo (*P*=0.013). We believe that the data for MN-166 compare quite favorably to both ocerlizumab and siponimod, potentially making MN-166 a best in disease treatment for patients with both primary and secondary MS, as shown in the following table.

Drug	Type of Progressive MS	Route of Administration	Phase / Study Size	Reduction in Brain Atrophy after 2 Years	Reduction in Disability Progression
ocrelizumab	PPMS	intravenous infusion	Phase 3 n=732	17.5%	24%
siponimod	SPMS	oral	Phase 3 n=1651	15%	21%
MN-166	**PPMS and SPMS**	**oral**	**Phase 2b n=255**	**48%**	**26%**

Source: MediciNova, Inc.

Lastly, MN-166 had a very favorable safety and tolerability profile as shown by no increases in serious adverse events or any safety signals. Treatment with ocrelizumab resulted in an increase in malignancies, infusion reactions, and infections, while treatment with some patients on siponimod experienced bradyarrhythmias, macular edema, lymphopenia, and liver function abnormalities. Interestingly, Novartis announced positive Phase 3 data in September 2016 but does not plan to file the NDA until the first half of 2018. It's possible Novartis had to delay the NDA filing in order to satisfy FDA requests for additional safety data regarding one or more of the potentially very serious side effects of siponimod.

Drug	Safety Issues	Most Common Adverse Reactions
ocrelizumab	• malignancies including breast cancer • serious infusion reactions • infections	• upper respiratory tract infections • infusion reactions • skin infections • lower respiratory tract infections
siponimod*	• bradyarrhythmias • macular edema • lymphopenia • liver function test elevation	• headache • nasopharyngitis • urinary tract infection • falls • hypertension
MN-166	• **None**	• **gastrointestinal side effects**

Source: MediciNova, Inc.

Phase 3 Trial for MN-166 in Progressive MS

MediciNova will meet with the FDA as quickly as possible to get formal feedback on the design of a Phase 3 trial. Based on the disability progression data from the Phase 2 trial, we estimate that the Phase 3 trial will be similarly sized to the Phase 3 Ocrevus® trial and enroll approximately 700 patients. We anticipate the trial beginning as soon as late 2018, however we will likely learn additional details about the trial once the company is able to meet with the FDA.

Confirmed Disability Progression

The Kurtzke Expanded Disability Status Scale (EDSS) is the 'gold standard' for assessing disability progression in patients with MS (Kurtzke, 1983). The EDSS consists of 19 disease steps on a scale between 0 and 10 and measures impairment or activity limitation in eight functional systems along with ambulation. The most commonly used method for determining disability progression is through repeat measurements of EDSS. An increase of 1.0 point on the EDSS above baseline confirmed three or six months later is a typical endpoint in a clinical trial. For example, in the Phase 3 clinical trial of Ocrevus® (ocrelizumab) in patients with primary progressive MS, the primary endpoint of the study was the percentage of patients with disability progression confirmed at 12 weeks, in which disability progression was defined as an increase in the EDSS of at least 1.0 point from baseline that was sustained for at least 12 weeks if the baseline score was 5.5 or less or an increase of at least 0.5 points that was sustained for at least 12 weeks if the baseline score was more than 5.5.

Conclusion

The Phase 2 SPRINT-MS trial was a resounding success for MediciNova as the trial achieved both primary endpoints, including a statistically significant 48% reduction in the rate of progression of whole brain atrophy while exhibiting a favorable safety and tolerability profile without any of the serious safety issues of other MS drugs. In addition, the demonstration of a 26% reduction in confirmed disability progression is very encouraging, as this is comparable to what was seen in the Phase 3 trial of Ocrevus® in patients with primary progressive MS that led to its approval. The company now has the data necessary to plan a Phase 3 clinical trial, which we anticipate will look very similar to the one conducted by Roche for Ocrevus®. Following its approval for the treatment of primary progressive MS in March 2017 (as well as for relapsing remitting MS), Ocrevus® has had a very strong launch with 2017 sales totaling $935 million, based on a 60/40 split between patients with relapsing MS and progressive MS. Sales of Ocrevus® are projected to reach $4 billion by 2022 (EvaluatePharma).

Based on the results of the SPRINT-MS trial we are raising our valuation from $13 to $18 per share, and we believe investors should take a close look at MediciNova as the company prepares to launch a Phase 3 program in MS.

PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2016 A	Q1 A	Q2 A	Q3 A	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	$1.268	$1.100	$4.166	$4.500	$4.700
General & Administrative	$7.363	$2.123	$1.908	$2.523	$2.000	$8.554	$8.300	$8.500
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($10.882)	($3.024)	($2.805)	($3.792)	($3.100)	($12.7)	($12.8)	($13.2)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.0	$0.01	$0.02	$0.04	($0.01)	($0.5)	($0.5)	($0.5)
Pre-Tax Income	($10.862)	($3.012)	($2.787)	($3.753)	($3.110)	($13.2)	($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)**	**($3.755)**	**($3.112)**	**($13.2)**	**($13.3)**	**($13.7)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.33)**	**($0.09)**	**($0.08)**	**($0.11)**	**($0.09)**	**($0.38)**	**($0.37)**	**($0.38)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	32.987	34.527	34.647	35.156	35.300	34.907	36.000	36.000

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

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