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MediciNova, Inc. (MNOV-NASDAQ)

MNOV: Encouraging Data from Subgroup Analysis of ALS 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 $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 (07/12/18)	$8.75
Valuation	**$19.00**

OUTLOOK

MediciNova, Inc. (MNOV) recently announced encouraging data from an ad-hoc analysis of the completed Phase 2 study of MN-166 (ibudilast) in patients with amyotrophic lateral sclerosis (ALS). The company analyzed data from subjects with either bulbar onset or upper limb onset ALS with and without non-invasive ventilation (NIV) and found that there were a higher percentage of responders (defined as a patient that did not worsen at the end of the six-month double-blind treatment period) in those administered MN-166 compared to placebo. Most encouraging was the fact that 25% of subjects in this group treated with MN-166 improved at the end of the six-month treatment period. We expect the company to meet with the FDA to map out a Phase 3 registration program for MN-166 in ALS.

SUMMARY DATA

52-Week High	**$13.91**
52-Week Low	**$4.43**
One-Year Return (%)	**66.67**
Beta	**0.21**
Average Daily Volume (sh)	**162,464**
Shares Outstanding (mil)	**41**
Market Capitalization ($mil)	**$360**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**23**
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	**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)
2017	0 A	0 A	0 A	0 A	0 A
2018	0 A	0 E	0 E	0 E	0 E
2019					0 E
2020					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.09 A	-$0.08 A	-$0.11 A	-$0.04 A	-$0.32 A
2018	-$0.12 A	-$0.11 E	-$0.11 E	-$0.11 E	-$0.45 E
2019					-$0.43 E
2020					-$0.41 E

WHAT'S NEW

Business Update

Encouraging Subgroup Data from Phase 2 ALS Trial

On July 9, 2018, MediciNova, Inc. (MNOV) announced encouraging data from a subgroup analysis of the recently completed Phase 2 study of MN-166 (ibudilast) in patients with amyotrophic lateral sclerosis (ALS). For the analysis, the company examined data from patients with either bulbar onset or upper limb onset ALS that did not require non-invasive ventilation (NIV), which were defined as the "Early ALS subgroup". This group was comprised of 31 subjects out of a total of 49 subjects in the full analysis set. A second subgroup comprised of 39 subjects (out of a total of 67 subjects in the full analysis set) who had either bulbar onset or upper limb onset ALS with or without NIV (the "Early ALS + NIV subgroup"). Analyses were conducted for:

1) The ALS Functional Rating Scale Revised (ALSFRS-R) (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 score is utilized to keep track of the health of all ALS patients, and is a common outcome measure in ALS clinical trials.
2) The 5-item amyotrophic lateral sclerosis assessment questionnaire (ALSAQ-5) (Jenkinson *et al*., 2001). This is a shorter version of the ALSAQ-40, which is a 40-item questionnaire designed to evaluate five areas of subjective health status in ALS patients: physical mobility, activities of daily living and independence, eating and drinking, communication, and emotional reactions.
3) Manual muscle testing (MMT), which is used to evaluate any impairment in muscle function.

For this analysis, a responder was defined as a subject whose score either improved or did not change (i.e., the score did not worsen) following completion of the six-month double-blind treatment phase of the study.

ALSFRS-R

We believe the most important analysis performed was examining the ALSFRS-R score, as this is a validated measure of a patient's health and is typically used as an outcome in registration trials. In the Early ALS subgroup there was a higher percentage of responders in the MN-166 group (6/20 – 30%) than in the placebo group (1/11 – 9.1%). In addition, 25% (5/20) of subjects in the MN-166 group improved (their ALSFRS-R score increased) compared to 0% of placebo-treated subjects. This is very encouraging as improvement in ALS patients, particularly over a six-month timeframe is not very common. Similar results were seen in the Early ALS + NIV subgroup, in which 26.9% (7/26) of subjects in the MN-166 group were responders compared to 7.7% (1/13) in the placebo group. Just as with the Early ALS subgroup, 23.1% (6/26) patients improved in the MN-166 group compared to 0% (0/13) in the placebo group. It should be noted that none of the differences in percentage of responders between MN-166 and placebo groups was statistically significant (although the differences in percentage of improvers came close to significance with P=0.09 and P=0.07 for the two subgroups, respectively), however the trial was not powered to show statistical significance.

ALSAQ-5

In the Early ALS subgroup, there was a much higher percentage of responders in the MN-166 group (12/20 – 60%) than in the placebo group (1/11 – 9.1%), which was statistically significant (P=0.0071). In the Early ALS + NIV subgroup, 50% (13/26) of subjects treated with MN-166 were responders compared to 23.1% (3/13) in the placebo group (P=0.1017).

MMT

In the Early ALS subgroup, 35.0% (7/20) of subjects in the MN-166 group were responders compared to 18.2% (2/11) in the placebo group. Similarly, in the Early ALS + NIV subgroup, 34.6% (9/26) of subjects in the MN-166 group were responders compared to 23.1% (3/13) in the placebo group.

Putting the Data into Context

We believe the subgroup analysis for ALSFRS-R is very encouraging, particularly the data showing that 25% of subjects improved on MN-166! However, we also understand that ALS is a highly variable disease that can manifest itself quite differently from one patient to another, thus we were interested in how patients in other ALS trials fared and if sporadic responders (no change or improvement in ALSFRS-R score) are ever seen. To do this, we analyzed data from the Pro-Act Database, which has compiled over 8,500 ALS patient records from 18 Phase 2 and Phase 3 clinical trials that includes both placebo and treatment-arm data.

To perform this analysis, we first downloaded all available patient data, which yielded 1,681 records from placebo-treated patients with ALSFRS-R data and corresponding dates for that data. We then limited our analysis to patients who had data points at time 0 and a data point at approximately "6 months" (165-195 days). This reduced the number of patients to 1,493. Of those 1,493 patients, we found 37 (2.5%) that showed improvement at 6 months (the majority with a 1- or 2-point increase) and 74 (5.0%) that had the same ALSFRS-R score at 6 months for a combined responder rate of 7.4% (111/1,493).

While not a perfect comparison (for instance we did not control for riluzole use, although 82% of patients from the Pro-Act database were reported to have used riluzole vs. 100% of subjects in the MN-166 ALS trial), we believe this analysis gives a fairly good indication of what should be expected in terms of placebo responders at six months in an ALS trial based on ALSFRS-R score. The ALSFRS-R responder rate of 7.4% in placebo-treated patients from the Pro-Act database is very close to the 9.1% responder rate in the placebo group for the Phase 2 study of MN-166 in ALS and provides additional support that the 30% responder rate in the MN-166 group is a real signal.

Conclusion

The subgroup analysis for MN-166 is encouraging, although we note that the number of patients analyzed is small. However, we believe the data is supported by our analysis of the Pro-Act database, which shows a similar responder rate for placebo-treated patients when examining data from multiple Phase 2 and 3 ALS clinical trials. MediciNova's subgroup analysis was limited to patients with either bulbar or upper limb onset disease, however we believe this still includes approximately 60% of all ALS patients. Thus, even if the label for MN-166 was eventually limited to only those patients, the company would still be able to capture an appreciable size of the ALS market and there could be potential for additional off-label prescriptions. Based on this data we have slightly increased the probability for approval, which has increased our valuation from $18 to $19 per share.

PROJECTED FINANCIALS

MediciNova Inc.
Income Statement

MediciNova, Inc.	2017 A	Q1 A	Q2 E	Q3 E	Q4 E	2018 E	2019 E	2020 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	$4.224	$1.662	$1.600	$1.600	$1.600	$6.462	$6.800	$7.000
General & Administrative	$8.803	$3.005	$3.100	$2.900	$2.900	$11.905	$12.000	$12.400
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($13.0)	($4.7)	($4.7)	($4.5)	($4.5)	($18.4)	($18.8)	($19.4)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	$0.1	$0.0	$0.0	$0.0	$0.1	$0.0	$0.0
Pre-Tax Income	($12.9)	($4.5)	($4.7)	($4.5)	($4.5)	($18.2)	($18.8)	($19.4)
Income Taxes Paid	($2)	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($11.2)**	**($4.5)**	**($4.7)**	**($4.5)**	**($4.5)**	**($18.3)**	**($18.8)**	**($19.4)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.32)**	**($0.12)**	**($0.11)**	**($0.11)**	**($0.11)**	**($0.45)**	**($0.43)**	**($0.41)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	35.137	39.132	41.000	41.200	41.400	40.683	44.000	47.000

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

HISTORICAL STOCK PRICE

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