Zacks Small-Cap Research

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MediciNova, Inc.

(MNOV - Nasdaq)

MNOV: Positive Topline Results for MN-166 in P2 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 $13/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 (12/13/17)	$6.19
Valuation	**$13.00**

OUTLOOK

On December 7, 2017, MediciNova, Inc. (MNOV) announced positive topline results from a Phase 2 study of MN-166 (ibudilast) in patients with amyotrophic lateral sclerosis (ALS). The primary endpoint of safety and tolerability was achieved along with efficacy trends in key secondary endpoints. A total of seven serious adverse events were reported, however none were related to treatment. All treatment related adverse events were mild or moderate with none being severe or life-threatening. The trial was not statistically powered to show efficacy in functional endpoints, however there were a higher rate of responders in the MN-166 treatment group when evaluating the amyotrophic lateral sclerosis functional rating scale-revised (ALSFRS-R). The company is planning to meet with the FDA to discuss a regulatory path forward for MN-166 in ALS.

SUMMARY DATA

52-Week High	**$7.36**
52-Week Low	**$4.43**
One-Year Return (%)	**-12.45**
Beta	**0.04**
Average Daily Volume (sh)	**76,218**
Shares Outstanding (mil)	**36**
Market Capitalization ($mil)	**$223**
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 A	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	-$0.11 A	-$0.09 E	-$0.38 E
2018					-$0.37 E
2019					-$0.38 E

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WHAT'S NEW

Business Update

Positive Topline Results for MN-166 in ALS

On December 7, 2017, MediciNova, Inc. (MNOV) announced positive topline results from a Phase 2 study of MN-166 (ibudilast) in patients with amyotrophic lateral sclerosis (ALS). The primary endpoint of the study (safety and tolerability) was achieved and there were efficacy trends in key functional secondary endpoints that favored MN-166. The data was presented by PI Dr. Benjamin Brooks at the 28th International Symposium on ALS/MND on Dec. 8, 2017.

This was a single center, double blind, placebo controlled six-month study with patients randomized 2:1 to receive riluzole (100 mg/day) plus either MN-166 (60 mg/day) or placebo. The six-month double blind portion was followed by a six-month open label extension phase during which all patients received MN-166. The intent-to-treat (ITT) population consisted of 51 patients who were randomized to placebo (n=17) or MN-166 (n=34) for the double-blind portion of the study. The per protocol (PP) population consisted of 44 patients that completed the double-blind portion of the study (n=15 for placebo; n=29 for MN-166) and 35 patients that completed the open label extension (n=12 for placebo; n= 23 for MN-166).

Safety and Tolerability

Since this was the first time MN-166 was tested in ALS patients the primary outcome of the study was safety and tolerability of the drug when administered along with riluzole (100 mg/day), the standard of care for ALS patients. The study achieved the primary outcome with no serious or life-threatening treatment-related adverse events (TEAEs). There were six subjects that had a total of seven serious adverse events (five for MN-166 group and one for placebo group), however none of them were related to treatment.

	# of Subjects or # of Events	
	Placebo N=17	Ibudilast N=34
# of Subject with at Least one TRAEs	n= 3	n= 4
Total events # of TRAEs	5	8
Severe or Life-threatening TRAEs	0	0
Serious TRAEs	0	0
	# of Subjects	
	Placebo N = 17	Ibudilast N = 34
At Least one TEAEs	n = 17	n = 34
Severe or Life threatening TEAEs	n = 2	n = 4
Serious Adverse Events	n = 1	n = 5
Treatment Related Adverse Events	n = 10	n = 13

Source: Brooks *et al*., 2017

Secondary Efficacy Endpoints

In addition to the primary endpoint of safety and tolerability, the study also evaluated secondary efficacy endpoints. These secondary endpoints were not powered for significance but were evaluated to look for positive trends that could help guide the design of future clinical trials. Perhaps the most important secondary endpoint evaluated was 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.

For this study, a responder was defined as someone who had ≤1 point decline in the ALSFRS-R during the six-month double blind period while a non-responder was defined as someone who had >1 point decline in ASLFRS-R. For the ITT population, the following table shows that 29.4% (10/34) of MN-166-treated patients were responders, compared to 17.6% (3/17) of placebo-treated patients. The third and fourth columns in the table show the percentage of patients who were responders in the open-label six-month extension phase during which all patients received MN-166. In the open-label extension, 35.3% (6/17) of the patients who had received placebo during the double blind portion of the study were responders when taking MN-166. This compares quite favorably with the 29.4% of patients were responders with MN-166 during the double blind portion of the study.

Double-Blind Phase		Open Label Phase		Overall
Placebo (N = 17)	Ibudilast (N = 34)	Ibudilast 0-6 mon treatment (N = 17)	Ibudilast 6-12 mon treatment (N = 34)	Ibudilast 0-12 mon treatment combined (N = 51)
3 / 17 (17.6 %)	10 / 34 (29.4 %)	6 / 17 (35.3 %)	3 * / 34 (8.8 %)	19 * / 51 (37.3 %)

Source: Brooks *et al.*, 2017

For the PP population, the following table shows that 34.5% (10/29) of MN-166-treated patients were responders, compared to 20.0% (3/15) of placebo-treated patients. Again, the open-label extension results showing 50.0% (6/12) of patients who had received placebo during the double blind portion of the study were responders when taking MN-166 compared well with the 34.5% of patients that were responders when taking MN-166 in the double blind portion of the study.

Double-Blind Phase		Open Label Phase		Overall
Placebo (N = 15)	Ibudilast (N = 29)	Ibudilast 0-6 mon treatment (N = 12)	Ibudilast 6-12 mon treatment (N = 23)	Ibudilast 0-12 mon treatment combined (N = 35)
3 / 15 (20.0 %)	10 / 29 (34.5 %)	6 / 12 (50.0 %)	3 * / 23 (13.0 %)	19 * / 35 (54.3 %)

Source: Brooks *et al.*, 2017

Conclusion

This was a successful trial for MediciNova because it achieved the following objectives: 1) it showed that MN-166 can be safely administered to ALS patients who are also taking riluzole, and 2) there were positive efficacy trends in favor of MN-166 for ALSFRS-R, which would be the most likely primary outcome for a Phase 3 pivotal study. The subjects in this study were administered 60 mg/day MN-166, and now that it is shown to be safe the company will move to a higher dose of 100 mg/day in future trials. We are confident that this higher dose will also be safe and well tolerated based on the fact that the company demonstrated the safety of 100 mg/day in the recently completed progressive multiple sclerosis (MS) Phase 2b study and is currently using that dose in the ongoing ALS biomarker study. In addition, just as was seen in the progressive MS study, we anticipate that the higher dose of MN-166 will likely lead to an increase in efficacy. Lastly, the bar for approval of an ALS drug is not that high as there are only two treatments currently approved for use in this fatal disease: riluzole and edaravone (Radicava®). The FDA

approved edaravone in May 2017 based on the results of a clinical trial conducted in Japan with only 137 patients, which used the change in the ALSFRS-R score as the primary endpoint. More than 90% of patients in that trial were also administered riluzole.

MN-166 has Fast Track designation in ALS and the Phase 2 data certainly warrant its continued development in this indication. We believe the company will move directly to a pivotal Phase 3 trial and will meet with the FDA to receive guidance on the trial design (e.g., number of patients, primary outcome, etc.). An efficacious ALS treatment would likely become a blockbuster drug, and we have increased the probability of approval of MN-166 in ALS to 40%, which increases our valuation of MediciNova to $13 per share.

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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