2025年4月9日

D. Boral Capitalによる当社レポートの発表に関するお知らせ

現地時間の4月9日、米国ニューヨークに本拠を置く投資銀行D. Boral Capitalのアナリストである Jason Kolbert 氏による、当社レポートが発表されましたので、参考情報としてお知らせいたします。

なお、当該レポートは、恐れ入りますが、権利の都合上、英文のままでのご案内となりますので、ご了承ください。

【D. Boral Capital 公式 web サイト】
https://dboralcapital.com/

※当該レポートは、本書の下部にございますので、スクロールしてご確認ください。

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April 9, 2025

MediciNova Initiates NIH-Funded Expanded Access Program for ALS Treatment

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MediciNova has enrolled the first patient in its NIH-funded Expanded Access Program (EAP) trial to evaluate MN-166 (ibudilast) in individuals with Amyotrophic Lateral Sclerosis (ALS). This trial aims to provide access to MN-166 for approximately 200 ALS patients who are ineligible for the ongoing Phase 2/3 COMBAT-ALS trial. The EAP is supported by the National Institutes of Health's National Institute of Neurological Disorders and Stroke (NINDS).

MN-166 (ibudilast) is an orally administered small molecule that inhibits phosphodiesterase type-4 (PDE4) and inflammatory cytokines, including macrophage migration inhibitory factor (MIF). It is currently in late-stage clinical development for neurodegenerative diseases such as ALS, progressive multiple sclerosis, and degenerative cervical myelopathy. Additionally, MN-166 is being investigated for glioblastoma, Long COVID, chemotherapy-induced peripheral neuropathy, and substance use disorder. MediciNova holds Orphan Drug Designation for MN-166 in ALS from both the U.S. FDA and the European Medicines Agency, along with Fast Track Designation from the FDA.

Catalysts Ahead: The initiation of the EAP trial represents a significant milestone for MediciNova. It potentially broadens the patient population that can access MN-166 and accelerates the collection of safety and efficacy data. Successful outcomes from this trial could enhance the therapeutic profile of MN-166 and support regulatory approval efforts. Investors should monitor enrollment progress and subsequent data releases as these will be critical indicators of the program's impact on MediciNova's clinical development trajectory and market position.

How does Ibudilast's work? The drug's mechanism of action in ALS is through its ability to inhibits phosphodiesterases (PDE-4 and PDE-10), increasing cyclic AMP levels, which helps suppress neuroinflammation. It also reduces activation of microglia and astrocytes, the CNS's immune cells, thereby lowering the production of pro-inflammatory cytokines like TNF-α and mitigating neurotoxicity. Additionally, Ibudilast promotes neurotrophic factors, supporting neuronal survival and reducing oxidative stress, which collectively contribute to its potential to slow ALS progression.

Valuation: For the purpose of our model we value MN-166 in ALS. We apply a probability of success factor of 30% based on the fact that its in pivotal trial. In addition, we have selected a 30% discount rate (r) for our forecasting models. We assume additional capital will be raised in our final share count. We then apply these projections to our Free Cash Flow to the firm, or FCFF discounted EPS or dEPS, and sum-of-the-parts or SOP models, which are equal-weighted, averaged, and rounded to the nearest whole number to derive our 12-month price target of $9.00.

Risk Factors: These include Clinical/Regulatory Risk, Partnership and Financial Risk, Commercial Risk, Legal and Intellectual Property Risk, and Market Share Risk.

MARKET DATA

Rating	Buy
Price Target	$9.00
Price	$1.20
Average Daily Volume (000)	17
52-Week Range ($)	$1.12–$2.55
Market Cap (M)	$59
Enterprise Value (M)	$19
Book Value	$1.07
Dividend Yield	0.0%
Cash (M)	$40
Qrtly Burn Rate (M)	$(3)

ESTIMATES

	2024A	2025E	2026E
Revenue (M)	$0.0	$0.0	$0.0
Total Expenses (M)	$13	$30	$30
GAAP EPS	$(0.23)	$(0.50)	$(0.38)

One Year Performance Chart

Source: FactSet, 08 April 2025

Please see analyst certification and important disclosures on page 5 of this report.

MediciNova (December 2024) announced an interim analysis update from its COMBAT-ALS Phase 2b/3 clinical trial evaluating MN-166 (ibudilast) in amyotrophic lateral sclerosis (ALS). Presented at the 35th International Symposium on ALS/MND, the analysis revealed positive correlations between six- and twelve-month functional and survival metrics, supporting the robustness of the trial design. With over 200 patients enrolled, MediciNova anticipates completing assignments by mid-2025, with final results projected for 2026. This progress underscores MN-166's potential as a treatment for ALS and its broader implications for other neurodegenerative diseases. See the actual poster—next page.

COMBAT Trial: The interim analysis of the COMBAT-ALS trial demonstrated a strong correlation (0.71) between six- and twelve-month Combined Assessment of Function and Survival (CAFS) scores, reinforcing the trial's robust 12-month double-blind design. Functional assessments, including bulbar, fine motor, and gross motor subscores, further supported MN-166's therapeutic potential in ALS. An independent review by the Data Safety Monitoring Board (DSMB) affirmed these findings, allowing the trial to proceed without modification. MediciNova's decision to maintain the current treatment regimen reflects its commitment to generating high-quality clinical data for regulatory submission.

Alongside the trial, MediciNova has expanded patient access to MN-166 through the FDA's Expanded Access Program (EAP), ensuring that eligible participants can continue treatment post-study. Preparations are also underway for a large-scale, NIH-funded EAP trial set to launch next year. This parallel approach not only broadens patient access but also strengthens the real-world evidence base supporting MN-166. By advancing both clinical development and expanded access initiatives, MediciNova is positioning MN-166 as a critical treatment for ALS and a potential breakthrough in neurodegenerative disease management.

Recent Quarter- Full Year Results: MedicNova released its full-year 10-K report, highlighting both financial and operational progress over the past year. The company reported total operating expenses of $12.7M for the year, reflecting its ongoing investments in research and development, as well as general and administrative costs. Net loss for the year came in at $11.05M, consistent with expectations given the company's stage of development. As noyes on page one, cash and equivalents at year-end stood at $40.3M, providing a sufficient runway to advance its current programs through key inflection points. As such the settlement represents upside to us. Management reiterated confidence in its financial position and ability to execute on upcoming milestones without immediate need for additional capital.

Exhibit 1. MedicNova's Poster Presented at the 35th International Symposium on ALS/MND held December 6-8, 2024 in Montreal, Canada.

MEDICINOVA

COMBAT-ALS Phase 2b/3 Trial of MN-166 (Ibudilast) in ALS: Trial Update and Interim Analysis Results (NCT04057898)

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Oskarsson B, Bedlack R, Bodkins C, Dionne A, Elliott M, Genge A, Gosselin S, Goyal N, Johnston W, Maiser S, Maragakis N, Meyer JA , Rivner M, Schellenberg K, Turnbull J, Walsh A, Zinman L, Matsuda K

Mayo clinic Florida, Duke University, Indiana University, CHU de Québec-Université Laval, Montreal Neurological Institute, Université de Sherbrooke, University California Irvine, University of Alberta, Hennepin Healthcare, John Hopkins University, SUNY Upstate, University of Augusta, University of Saskatchewan, McMaster University, Lehigh Valley Health Network, Sunnybrook University and MedicNova Inc.

Background

MN-166 is an orally available small molecule that penetrates the CNS well. It inhibits macrophage migration inhibitory factor and phosphodiesterases 3,4, and 10 with demonstrated neuroprotective action and glial cell attenuation in multiple in vitro and in vivo models. Preclinical studies have suggested that ibudilast may also act by inducing autophagy via mammalian target of rapamycin complex 1 (mTORC1)–transcription factor EB signaling in vitro, resulting in clearance of SOD1 and TAR DNA-binding protein 43 (TDP-43) aggregates. (Chen et al 2020). MN-166 has been exposed to > 900 subjects with favorable safety profile.

Based on findings from a completed Phase 1b/2a trial in ALS subjects (Oskarsson et al, NCT 02238626) we hypothesize MN-166 can slow disease progression.

Study Objectives

Primary objective

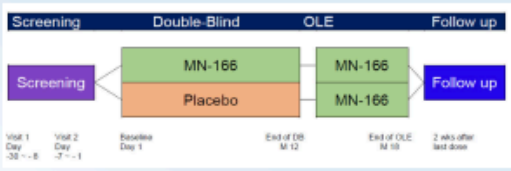
- To evaluate the efficacy of MN-166 (ibudilast) on ALSFRS-R score and survival in ALS patients.

Major Secondary objectives

- To evaluate the efficacy on muscle strength measured by hand-held dynamometry (HHD)
- To evaluate the efficacy of MN-166 on quality of life measured by ALSAQ-5
- To evaluate the efficacy of safety and tolerability

Study Design / Method

This is a Phase 2b/3, multicenter, randomized, double-blind (12 months) placebo-controlled study followed by open-label extension phase (6 months) in ALS patients on riluzole. Patients who meet entry-criteria are randomly assigned 1 of treatment groups, MN-166 or placebo.



Study Design

Major Inclusion Criteria

- Diagnosis of familial or sporadic ALS as defined by the El Escorial-Revised (2000) research diagnostic criteria for ALS [clinically definite, clinically probable, probable-laboratory-supported];
- ALS onset of ≤ 18 months from first clinical symptoms of weakness prior to screening;
- If currently using edaravone, subject should have completed the first 14 days of their initial treatment cycle prior to initiating study drug;
- A total ALSFRS-R score of at least 35 overall at screening and:
  - a. No more than one of the 12 ALSFRS-R individual component items has a score of 1 or less at screening;
  - For limb onset subjects, ALSFRS-R score of ≥ 3 on item #1 (speech), #2 (salivation) and #3 (swallowing);
- ALSFRS-R progression rate from onset of first symptom of weakness to the ALSFRS-R score at Screening of ≥ 0.3 points and ≤ 1 point per month calculated as: a. ALSFRS-R score at onset of first symptom of weakness (assume 48) minus ALSFRS-R score at Screening divided by number of months since onset of first symptom of weakness.
- Documented pulmonary function test (PFT) result within the last 6 months (i.e., slow vital capacity or forced vital capacity) must be ≥70% of predicted

Study Status

Currently we are enrolling in US and Canada at 17 sites. Referrals are requested. As of 15 Nov 2024, a total of 217 subjects were enrolled and 183 participants have been randomized.

Interim Analysis

Interim Analysis was conducted as pre-defined in the study protocol.

Purpose

To evaluate the correlation between Month-6 data and Month-12 data to assess the 12-month DB phase duration study design.

Analysis Population

The primary correlation analysis will be conducted on the subset of patients with both Month 6 and at least one post-Month 6 ALSFRS-R data of the full analysis set, excluding ongoing patients

Primary Analysis

Correlation analysis between Combined Assessment of Function and Survival (CAFS) scores at Month 6 and Month 12 was performed.

Sensitivity Analysis I

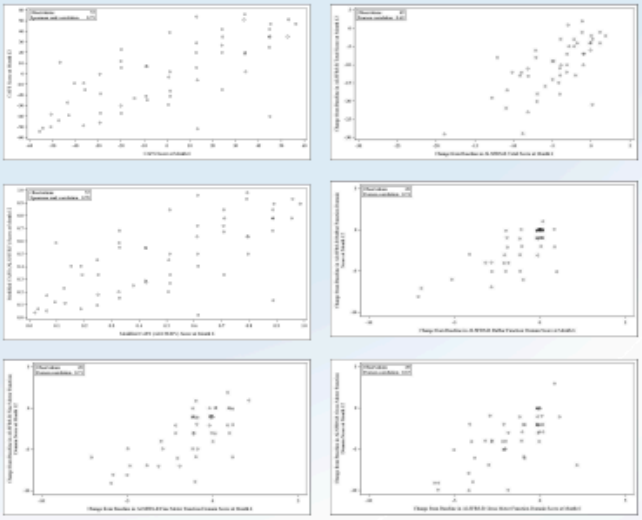
Modified CAFS scores at Month 6 and Month 12

Sensitivity Analysis II

Correlation analysis between change from baseline in ALSFRS-R total scores at Month 6 and Month 12 was performed

Interim Analysis Results

A positive correlation were observed between the Month 6 and Month 12 assessments of CAFS, modified CAFS and ALSFRS-R total scores.
With sub-group analysis, positive correlation were identified in bulbar, score, fine motor score and gross motor score, but not in respiratory score. These observations support the measurement tools used in the clinical trial between timepoints.



Conclusion

Ongoing Phase 2/3 COMBAT-ALS study update and interim analysis results were presented.

Interim Analysis was conducted as pre-defined in the study protocol, positive correlation were observed between Month-6 and Month -12 data. These observations support the measurement tools used in the clinical trial between timepoints.

Changing the DB phase to 6 month will enhance recruitment and accelerate acquisition of results, however, it will diminish statistical power, compromise face validity, and potentially decrease probability of regulatory approval in the event of positive outcomes.

External DSMB (Data and Safety Monitoring Board) reviewed the results and made the recommendation that the trial should continue as planned and this recommendation was accepted.

Ref: Oskarsson B, Maragakis N, Bedlack RS, Goyal N, Meyer JA, Genge A, Bodkin C, Maiser S, Staff N, Zinman L, Olney N, Turnbull J, Brooks BR, Klonowski E, Makhay M, Yasui S, Matsuda K. MN-166 (ibudilast) in amyotrophic lateral sclerosis in a Phase IIb/III study: COMBAT-ALS study design. Neurodegener Dis Manag. 2021 Dec;11(6):431-443. doi: 10.2217/nmt-2021-0042. Epub 2021 Nov 24. PMID: 34816762.

Source: MedicNova

MedicNova, Inc.																
Product Revenues	**2023A**	**2024A**	**1Q25E**	**2Q25E**	**3Q25E**	**4Q25E**	**2025E**	**2026E**	**2027E**	**2028E**	**2029E**	**2030E**	**2031E**	**2032E**	**2033E**	**2034E**
US ALS									-	-	40,542	83,532	172,110	265,962	296,827	305,791
EU ALS									-	-	-	33,622	171,490	279,899	356,906	396,522
Japan ALS									-	-	-	44,275	159,613	305,317	338,667	352,315
ROW ALS									-	-	-	-	47,489	96,888	123,544	149,736
Total Product Revenues								**-**	**-**	**-**	**40,542**	**161,430**	**550,702**	**948,065**	**1,115,944**	**1,204,364**
Grant Revenue		-														
Milestone and Royalty Revenue																
Total Revenues ($000)	**1,000**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**40,542**	**161,430**	**550,702**	**948,065**	**1,115,944**	**1,204,364**
Expenses																
COGS		-					-	-	-	-	8,108	24,215	55,070	94,807	111,594	120,436
% COGS											20%	15%	10%	10%	10%	10%
Research and Development	5,658	7,195	3,010	2,868	3,000	3,000	24,000	20,000	20,000	20,000	20,200	20,402	20,810	21,226	21,651	22,084
Selling, General and Administrative	5,242	5,481	4,997	4,363	4,200	4,200	10,000	10,100	14,000	18,000	18,180	18,362	18,545	18,731	19,105	19,488
Operating expenses	**10,900**	**12,675**	**8,007**	**7,231**	**7,200**	**7,200**	**29,638**	**30,100**	**34,000**	**38,000**	**46,488**	**62,978**	**94,426**	**134,764**	**152,351**	**162,008**
Oper. Inc. (Loss)	9,900	(12,675)	(8,007)	(7,231)	(7,200)	(7,200)	(29,638)	(30,100)	(34,000)	(38,000)	(5,947)	98,452	456,277	813,302	963,593	1,042,356
Other Income (net)	1,835	1,670	(5)	(10)	(10)	(10)	500	(40)	(40)	(10)						
Interest Income	(503)	(39)					-									
Interest Expense		(0)					-									
Financial Expenses, Net	**1,332**	**1,630**	**(5)**	**(10)**	**(10)**	**(10)**	**(35)**	**(40)**	**(40)**	**(10)**	**-**	**-**	**-**	**-**	**-**	**-**
Pretax Income	**(8,568)**	**(11,045)**	**(8,012)**	**(7,241)**	**(7,210)**	**(7,210)**	**(29,673)**	**(30,140)**	**(34,040)**	**(38,010)**	**(5,947)**	**98,452**	**456,277**	**813,302**	**963,593**	**1,042,356**
Pretax Margin																
Income Tax Benefit (Provision)	(3)	(6)	-	-			-	-	-	-	(595)	14,768	91,255	243,990	337,258	364,825
Tax Rate		0%	0%	0%	0%	0%	0%	0%	0%	0%	10%	15%	20%	30%	35%	35%
GAAP Net Income (loss)	**(8,571)**	**(11,050)**	**(8,012)**	**(7,241)**	**(7,210)**	**(7,210)**	**(29,673)**	**(30,140)**	**(34,040)**	**(38,010)**	**(5,352)**	**83,684**	**365,021**	**569,311**	**626,335**	**677,531**
Net Margin	NM		NM					NM	NM	NM	NM	0.52	0.66	0.60	0.56	0.56
Net loss attributable to non controlling interests	-	-					-									
GAAP-EPS	**(0.17)**	**(0.23)**	**(0.14)**	**(0.12)**	**(0.12)**	**(0.12)**	**(0.50)**	**(0.38)**	**(0.40)**	**(0.44)**	**(0.06)**	**0.97**	**4.21**	**6.54**	**7.16**	**7.72**
Non GAAP EPS (dil)	(0.17)	(0.23)	(0.14)	(0.12)	(0.12)	(0.12)	(0.50)	(0.38)	(0.40)	(0.44)	(0.06)	0.97	4.21	6.54	7.16	7.72
Wgtd Avg Shrs (Bas)	49,046	49,046	59,154	59,213	59,272	59,332	59,243	71,986	84,806	85,146	85,487	85,829	86,173	86,518	86,865	87,213
Wgtd Avg Shrs (Dil)	49,046	49,046	59,154	59,213	59,805	60,403	59,644	85,008	85,380	85,722	86,066	86,410	86,757	87,104	87,453	87,803

Source: DBoralCapital & Company reports

Important Disclosures

Analyst Certification

I, Jason Kolbert, certify that all of the views expressed in this research report accurately reflect my personal views about the subject security(ies) and subject company(ies). I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed in this research report.

Company-Specific Disclosures

General Disclosures

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BUY (B) - Total return expected to exceed S&P 500 by at least 10%

HOLD (H) - Total return expected to be in-line with S&P 500

SELL (S) - Total return expected to underperform S&P 500 by at least 10%

Distribution of Ratings/IB Services

	D. Boral		IB Serv./Past 12 Mos.	
Rating	**Count**	**Percent**	**Count**	**Percent**
BUY	**60**	**98.36**	**16**	**26.67**
HOLD	**1**	**1.64**	**0**	**0.00**
SELL	**0**	**0.00**	**0**	**0.00**

MediciNova, Inc. Rating History as of 04/07/2025