2025年2月21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2月21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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February 21, 2025

MedicNova Reports Full-Year Results: Focus on Clinical Progress and Financial Discipline

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. Cash and equivalents at year-end stood at $40.3M, providing a sufficient runway to advance its current programs through key inflection points. Management reiterated confidence in its financial position and ability to execute on upcoming milestones without immediate need for additional capital.

The interim analysis of the COMBAT-ALS trial revealed a strong correlation (0.71) between six- and twelve-month Combined Assessment of Function and Survival (CAFS) scores, reinforcing the trial's 12-month double-blind design. Functional measures, including bulbar, fine motor, and gross motor subscores, further validated MN-166's potential efficacy in ALS. The independent review by a Data Safety Monitoring Board (DSMB) affirmed these findings and supported the trial's continuation without modification. MediciNova's commitment to maintaining the current treatment regimen underscores its focus on generating high-quality clinical data for regulatory submission.

In parallel with the ongoing trial, MediciNova has expanded patient access to MN-166 through the FDA's Expanded Access Program (EAP), ensuring continued treatment for eligible participants post-trial. Additionally, preparations are underway for a large-scale, NIH-funded EAP trial set to launch next year. This dual-track strategy not only facilitates broader patient access but also enhances real-world evidence supporting MN-166's potential. By proactively advancing both clinical and access initiatives, MediciNova is positioning MN-166 as a pivotal treatment in ALS and broader neurodegenerative disease management.

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.

Jason Kolbert
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MARKET DATA

Rating	Buy
Price Target	$9.00
Price	$1.78
Average Daily Volume (000)	38
52-Week Range ($)	$1.12–$2.55
Market Cap (M)	$87
Enterprise Value (M)	$47
Book Value	$1.07
Dividend Yield	0.0%
Cash (M)	$40
Qrtly Burn Rate (M)	$(3)

ESTIMATES

		2023A	2024E	2025E
Revenue (M)		$1.0	$0.0	$0.0
Total Expenses (M)		$11	$13	$30
GAAP EPS		$(0.17)	$(0.23)	$(0.50)
	prev:	-	*$(0.21)*	-

One Year Performance Chart

Source: FactSet, 20 February 2025

This report is intended for lwaki@medicinova.com. Unauthorized distribution prohibited.

Please see analyst certification and important disclosures on page 4 of this report.

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

MEDICINOVA

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

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

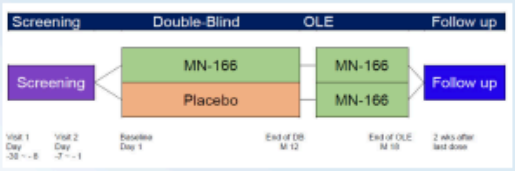
- To evaluate the efficacy of MN-166 (ibudilast) on ALSFRS-R score and survival in ALS patients.

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

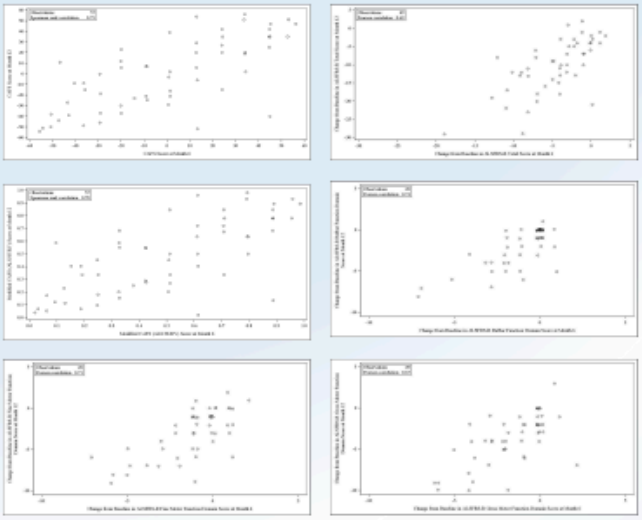
Modified CAFS scores at Month 6 and Month 12

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.																
Assets	2023A	1Q24A	2Q24A	3Q24A	4Q24A	2024A	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
Cash and Cash Equivilents	$50,999	$47,139	$44,338	$42,281	$40,360	$40,360	$27,924	$41,305	$7,848	($29,573)	($34,331)	$49,952	$415,579	$985,500	$1,612,451	$2,290,604
PrePaid Expenses	$175	$725	$1,168	$985	$715	$715	$715	$715	$715	$715	$715	$715	$715	$715	$715	$715
Total Current Assets	$51,174	$47,864	$45,506	$43,265	$41,074	$41,074	$28,638	$42,019	$8,563	($28,858)	($33,616)	$50,667	$416,293	$986,215	$1,613,166	$2,291,319
Goodwill	$9,600	$9,600	$9,600	$9,600	$9,600	$9,600	$9,600	$9,600	$9,600	$9,600	$9,600	$9,600	$9,600	$9,600	$9,600	$9,600
In-process research and development	$4,800	$4,800	$4,800	$4,800	$4,800	$4,800	$4,800	$4,800	$4,800	$4,800	$4,800	$4,800	$4,800	$4,800	$4,800	$4,800
Property and equipment, net	$46	$40	$36	$31	$26	$26	$26	$26	$26	$26	$26	$26	$26	$26	$26	$26
Right-of-use asset	$575	$519	$443	$404	$357	$357	$357	$357	$357	$357	$357	$357	$357	$357	$357	$357
Other non-current assets	$74	$70	$19	$19	$19	$19	$19	$19	$19	$19	$19	$19	$19	$19	$19	$19
Total Assets	$66,270	$62,894	$60,404	$58,119	$55,876	$55,876	$43,440	$56,821	$23,364	($14,057)	($18,815)	$65,469	$431,095	$1,001,016	$1,627,967	$2,306,120
Current Liabilities																
Accounts Payable	$1,004	$805	$668	$708	$1,102	$1,102	$1,102	$1,102	$1,102	$1,102	$1,102	$1,102	$1,102	$1,102	$1,102	$1,102
Accrued Expenses and other current liabilities	$2,059	$1,488	$1,637	$1,687	$1,663	$1,663	$1,663	$1,663	$1,663	$1,663	$1,663	$1,663	$1,663	$1,663	$1,663	$1,663
Operating Lease	$216	$218	$190	$202	$194	$194	$194	$194	$194	$194	$194	$194	$194	$194	$194	$194
Total Current Liabilities	$3,279	$2,510	$2,494	$2,597	$2,959	$2,959	$2,959	$2,959	$2,959	$2,959	$2,959	$2,959	$2,959	$2,959	$2,959	$2,959
Deferred tax liability	$202	$202	$202	$202	$202	$202	$202	$202	$202	$202	$202	$202	$202	$202	$202	$202
Other non-current liabilities	$411	$351	$302	$255	$211	$211	$211	$211	$211	$211	$211	$211	$211	$211	$211	$211
Total liabilities	$3,892	$3,063	$2,999	$3,054	$3,372	$3,372	$3,372	$3,372	$3,372	$3,372	$3,372	$3,372	$3,372	$3,372	$3,372	$3,372
Stockholders' equity:																
Common Stock	$49	$49	$49	$49	$49	$49	$49	$49	$49	$49	$49	$49	$49	$49	$49	$49
Addional Paid-In Capital	$478,149	$478,365	$478,572	$479,077	$479,341	$479,341	$496,273	$496,373	$496,516	$496,661	$496,806	$496,953	$497,102	$497,252	$497,403	$497,555
Accumulated Deficit	($415,702)	($418,456)	($421,084)	($423,937)	($426,751)	($426,751)	($456,120)	($442,838)	($476,438)	($514,004)	($518,907)	($434,771)	($69,293)	$500,478	$1,127,278	$1,805,279
Accumulated Other	($118)	($127)	($132)	($124)	($135)	($135)	($135)	($135)	($135)	($135)	($135)	($135)	($135)	($135)	($135)	($135)
Total Equity	$62,378	$59,830	$57,405	$55,066	$52,504	$52,504	$40,067	$53,449	$19,992	($17,429)	($22,187)	$62,096	$427,722	$997,644	$1,624,595	$2,302,748
Total Liab & Equity	$66,270	$62,894	$60,404	$58,119	$55,876	$55,876	$43,440	$56,821	$23,364	($14,057)	($18,815)	$65,469	$431,095	$1,001,016	$1,627,967	$2,306,120
Shares Iss'd (000)	49,046	8,145	49,046	49,046	49,046	$49,046	$59,243	$71,986	$84,806	$85,146	$85,487	$85,829	$86,173	$86,518	$86,865	$87,213
Shares Out (000)	49,046	8,145	49,046	49,046	49,046	$49,046	$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

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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	**53**	**98.15**	**14**	**26.42**
HOLD	**1**	**1.85**	**0**	**0.00**
SELL	**0**	**0.00**	**0**	**0.00**

MediciNova, Inc. Rating History as of 02/19/2025