2025年9月23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9月22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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September 22, 2025

MediciNova Completes Enrollment in COMBAT-ALS Phase 2b/3 Trial

MediciNova has achieved full patient enrollment in its COMBAT-ALS Phase 2b/3 trial for MN-166 (ibudilast), closing recruitment at 234 ALS patients across two treatment arms in the US and Canada. The study will run a 12-month blinded treatment period followed by six months of open-label treatment and has endpoints including the Combined Assessment of Function and Survival (CAFS), ALSFRS-R progression, muscle strength measures, and quality of life assessments. Top-line data are expected by end of 2026.

This enrollment milestone is significant because it allows the trial to move forward without delay, preserving timelines for efficacy and safety evaluation. MN-166 has previously shown promising results in earlier trials and has garnered regulatory interest, having received Orphan Drug Designation and Fast Track status from the FDA and Orphan Designation from the EMA. The study design's robustness with both primary and multiple secondary endpoints should provide meaningful readouts for various aspects of disease impact.

MediciNova's accrual of 234 patients completes the recruitment phase for the COMBAT-ALS study, meaning the company can now transition fully into the treatment phases without further delays from enrollment challenges. Since patient recruitment is officially closed, resources can shift toward treatment monitoring, data collection, and compliance. The 12-month double-blind period followed by 6-month open label ensures that both short- and longer-term effects (including durability of response and safety) can be assessed.

Beyond enrollment, the clinical development context continues to favor MN-166. The earlier Phase 1/2 and Phase 2 trials reported a favorable safety profile and higher proportions of responders versus placebo or baseline. Regulatory recognitions (Orphan Drug, Fast Track, etc.) support expedited pathways if results are compelling. The multiple secondary endpoints (ALSFRS-R, muscle strength, quality of life) provide multiple lenses through which efficacy can be judged, reducing the risk that a narrow failure in one measure condemns the program entirely.

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.

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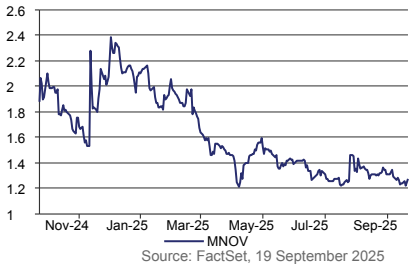
MARKET DATA

Rating	Buy
Price Target	$9.00
Price	$1.27
Average Daily Volume (000)	32
52-Week Range ($)	$1.12–$2.55
Market Cap (M)	$62
Enterprise Value (M)	$28
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, 19 September 2025

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

How Does MN-166 Work? ALS remains a devastating neurodegenerative disease with limited treatment options and a high unmet medical need, as most approved therapies offer only modest benefits in slowing progression or extending survival. MN-166 (ibudilast) represents a differentiated approach by targeting multiple inflammatory and neurodegenerative pathways implicated in ALS. Its mechanism of action includes inhibition of phosphodiesterases (PDE-4 and PDE-10), which elevates cyclic AMP levels and suppresses neuroinflammation. Ibudilast also inhibits macrophage migration inhibitory factor (MIF) and reduces the activation of glial cells such as microglia and astrocytes, thereby limiting the release of pro-inflammatory cytokines like TNF-alpha and mitigating neurotoxicity. In addition, the compound promotes the expression of neurotrophic factors and helps reduce oxidative stress, supporting neuronal survival. This multi-modal activity sets MN-166 apart from existing treatments and may offer broader and more durable clinical benefits in slowing ALS progression across a diverse patient population.

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.

In the competitive ALS treatment landscape, MN-166 (ibudilast) holds a unique position as a late-stage, small-molecule therapy with broad applicability across the ALS population. Unlike gene-targeted therapies and antisense oligonucleotides that focus on rare genetic subtypes such as SOD1-ALS, MN-166 is designed to modulate neuroinflammation and glial cell activation, mechanisms implicated in both familial and sporadic forms of the disease. This positions it as a potentially disease-modifying option for a wider patient base.

Several other approaches in the pipeline have faced challenges or are limited in scope. For example, some gene therapies have been discontinued following the release of lackluster mid-stage data. At the same time, certain marketed treatments have been withdrawn after failing to confirm efficacy in larger studies. At the same time, other experimental therapies remain in earlier stages or target niche mechanisms such as mitochondrial support or cell-based repair.

MN-166, as noted above, distinguishes itself through its multi-modal mechanism of action, including PDE-4 and PDE-10 inhibition, suppression of pro-inflammatory cytokines, and support for neurotrophic signaling. Combined with regulatory designations such as Fast Track and Orphan Drug status, MN-166 is well-positioned as a differentiated, potentially disease-modifying therapy in a late-stage setting where few alternatives offer broad utility or durable benefit.

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.

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.

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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

Rating	Count	Percent	IB Serv./Past 12 Mos. Count	IB Serv./Past 12 Mos. Percent