December 8, 2025

MediciNova Provides COMBAT-ALS Enrollment Update

MediciNova announced updated baseline characteristics from its Phase 2b/3 COMBAT-ALS clinical trial of MN-166 in ALS, confirming enrollment of 234 randomized participants and completion of recruitment in September 2025. The dataset presented at the International Symposium on ALS/MND indicates that the study population reflects the demographic and clinical composition seen across other late stage ALS trials, supporting the generalizability of eventual top-line results expected by the end of 2026. The company reiterated its continued commitment to patients through expanded access programs and emphasized the importance of MN-166's orphan and fast track designations as it advances development.

The update reinforces that COMBAT-ALS achieved its enrollment goal despite COVID-era disruptions that affected site availability and slowed recruitment. The baseline population has a mean age of roughly sixty and shows a balanced distribution of onset type with nearly half presenting with upper limb involvement. The mean ALSFRS-R score of approximately forty at screening and disease duration near one year are aligned with contemporary ALS studies, suggesting a representative cohort. MediciNova underscored that the completion of randomization enables the program to stay on track for next year's data readout while expanded access efforts continue to support patients who wish to remain on therapy.

Catalysts Ahead: Top-line results from COMBAT-ALS remain targeted for the end of 2026, positioning MN-166 as one of the more advanced late-stage assets in the ALS landscape. Ongoing regulatory interactions, including work with U.S. and EU authorities under orphan and fast-track designations, are expected to shape the next clinical and regulatory steps. Continued progress in parallel late-stage programs for progressive MS and degenerative cervical myelopathy or DCM may further enhance visibility as multiple MN-166 indications advance through development.

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 it's in a 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	$1.55
Average Daily Volume (000)	104
52-Week Range ($)	$1.12–$2.55
Market Cap (M)	$76
Enterprise Value (M)	$44
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, 05 December 2025

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Why COMBAT-ALS baseline characteristics matter, versus to prior ALS trials:

1. The population mirrors prior pivotal ALS trials

COMBAT-ALS enrolled 234 patients with a mean age around sixty, roughly two-thirds male, and predominantly Caucasian. This demographic mix is essentially identical to CENTAUR (the PB-TURSO/AMX0035 trial) and very similar to the edaravone dataset. ALS trials for decades have centered on populations within this age and sex distribution, so COMBAT-ALS looks like a standard, interpretable ALS cohort. That matters because regulators and clinicians expect late-stage ALS trials to broadly resemble the "typical" ALS epidemiologic profile.

2. The onset distribution is almost a textbook match

COMBAT-ALS shows about seventy-nine percent limb-onset and about twenty-one percent bulbar-onset when combining upper- and lower-limb categories. Real-world ALS is roughly seventy to seventy-five percent limb-onset and twenty-five percent bulbar. That near-perfect match eliminates concerns that the study over-enrolled slower or faster progressors, which can distort placebo decline rates. A balanced onset mix makes the eventual ALSFRS-R outcomes easier to compare with historical standards.

3. The cohort's disease stage resembles other successful ALS trials

With a mean ALSFRS-R score of about forty and disease duration around twelve months, COMBAT-ALS enrolled patients who are relatively early in their disease course. This places the trial's population closer to the early-stage enrichment used in the edaravone trial, while still sitting comfortably within the same functional window targeted by CENTAUR. Patients who enter trials earlier generally decline a bit more slowly on placebo, which can shrink absolute point differences on ALSFRS-R. At the same time, early-stage cohorts are where prior disease-modifying signals have been most detectable. That makes the COMBAT-ALS profile strategically favorable: early enough to detect a neuroprotective signal, but not so early that the population becomes unrepresentative.

4. Generalizability and regulatory implications

Because COMBAT-ALS aligns so closely with the demographic, onset, and functional profiles of prior large ALS studies, regulators will be able to compare results directly to historical benchmarks without needing to adjust for unusual enrollment patterns. This strengthens the interpretability of top-line data when it arrives. A trial that looks "normal" is much easier to evaluate: if MN-166 works, the result will be seen as credible; if it fails, the explanation cannot easily be blamed on a skewed population.

Bottom line

Baseline characteristics matter because they set the stage for how meaningful, comparable, and regulatory-ready the final data will be. COMBAT-ALS essentially recruited a classic ALS trial population, eliminating noise and reducing variables that could obscure a treatment effect.

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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

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MediciNova, Inc. Rating History as of 12/05/2025

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