MediciNova, Inc. (MNOV)
Rating: Buy

Lander Egaña Gorroño, Ph.D.
212-916-3977
legana@hcwresearch.com

COMBAT-ALS Approaching; Additional Tipelukast Analyses to Guide Next Steps; 3Q26 Results

Stock Data	11/13/2026
Price	$1.40
Exchange	NASDAQ
Price Target	$10.00
52-Week High	$3.90
52-Week Low	$1.22
Enterprise Value (M)	$42
Market Cap (M)	$71
Shares Outstanding (M)	49.2
3 Month Avg Volume	323,512
Short Interest (M)	0.31
Balance Sheet Metrics	
Cash (M)	$29.3
Total Debt (M)	$0.0
Total Cash/Share	$0.59

EPS ($) Diluted			
Full Year - Dec	2025A	2026E	2027E
1Q	(0.06)	(0.05)A	--
2Q	(0.07)	(0.05)A	--
3Q	(0.06)	(0.06)A	--
4Q	(0.06)	(0.06)	--
FY	(0.24)	(0.21)	(0.35)

Revenue ($M)			
Full Year - Dec	2025A	2026E	2027E
1Q	0.0	0.2A	--
2Q	0.1	0.5A	--
3Q	0.1	0.1A	--
4Q	0.2	0.2	--
FY	0.4	1.0	1.0



Our perspective on 3Q26 results and next steps:

- COMBAT-ALS remains the key near-term catalyst with topline data expected by YE26; potential longer-term efficacy should inform ibudilast's path toward registrational development in ALS
- Additional tipelukast analyses underway; secondary metabolic signals in NATG-202 despite missing co-primary endpoints

Corporate update. MediciNova continues to advance its two core programs, ibudilast (MN-166) for ALS and tipelukast (MN-001) for TG/lipid management in the context of metabolic disease. Following completion of LPLV in the double-blind portion of the Phase 2b/3 COMBAT-ALS trial, management remains on track to report topline results by YE26 (see our thoughts and expectations below). We view the evaluation of ibudilast's longer-term efficacy in a larger ALS population as the company's most important near-term catalyst, with positive findings potentially supporting further registrational development and regulatory discussions with the FDA. In parallel, the NIH-supported SEANOBI EAP has completed its target enrollment, with final follow-ups expected to conclude in early 2027 (details below). Separately, the company recently announced topline results from the Phase 2 NATG-202 trial of tipelukast in patients with HTG and NAFLD associated with T2D. Although the study did not meet the co-primary endpoints of change from baseline in liver fat content and fasting serum TG levels at week 24, statistically significant improvements in HDL-C and HDL-P concentrations, as well as an early reduction in TG levels, provide preliminary secondary metabolic signals. Management is conducting additional analyses to better understand the results and determine potential next steps for the program. As discussed, we remain focused on COMBAT-ALS, which we expect to provide important clarity on ibudilast's clinical efficacy and potential path toward registrational development in ALS.

Continued support for ibudilast's EAP. This month, the ACT for ALS Reauthorization Act was signed into law, extending research and treatment access programs established under the original 2021 legislation through 2031. Importantly, the legislation supports the continued availability of the NIH-funded SEANOBI EAP, which provides access to ibudilast for ALS patients who are not eligible for clinical trials. We view this as a positive development for MediciNova, potentially supporting continued patient access to ibudilast and the generation of complementary real-world biomarker (NfL) and functional outcome (ALSFRS-R) data alongside the randomized COMBAT-ALS study.

Financial update. MediciNova reported 3Q26 financial results, posting EPS of ($0.06), in line with our estimate and consensus. The company ended the quarter with $29.26 million in cash, which management believes provides runway to fund ongoing operations for at least the next 12 months.

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A key inflection point for ibudilast by YE26; CAFS endpoint to inform its path forward. Topline results from the Phase 2b/3 COMBAT-ALS trial of ibudilast are expected in December 2026 (n=234 randomized). The key focus is the primary endpoint of Combined Assessment of Function and Survival (CAFS), which integrates functional decline and survival, with supportive data from ALSFRS-R, muscle strength, and QoL measures. We view the use of CAFS as potentially advantageous because it captures two major dimensions of ALS disease progression within a single endpoint, allowing treatment effects on either function or survival to contribute to the overall assessment rather than requiring both measures to independently achieve statistical significance. This integrated approach may provide a more comprehensive assessment of clinical benefit, particularly in a disease where preservation of function and prolongation of survival are both highly meaningful outcomes. A statistically significant improvement in CAFS would provide the clearest evidence of efficacy, while a favorable but non-significant CAFS result accompanied by positive findings on secondary measures could represent a more mixed outcome, providing important information to guide patient selection, endpoint strategy, and the design of subsequent studies, albeit with less compelling evidence of efficacy. Our bullish view is primarily driven by the favorable ALSFRS-R outcomes and improved survival observed in the Phase 2 ALS-1201 trial of ibudilast in combination with riluzole SoC (n=49) (see additional details in: *A Novo Approach to Multi-Target Medicine; Initiating at Buy and $10 PT*). We believe COMBAT-ALS represents a critical inflection point for ibudilast, potentially informing the next clinical and regulatory steps, including progression toward a regulatory filing or the need for an additional confirmatory pivotal trial. As a reminder, while COMBAT-ALS does not incorporate prespecified biomarker endpoints, the ongoing NIH-supported SEANOBI EAP (n=200; enrollment completed) is expected to generate complementary real-world data on NfL and clinical outcomes. The two programs could provide complementary efficacy and biomarker datasets as MediciNova approaches an important clinical and regulatory period for ibudilast.

Ibudilast completes double-blind COMBAT-ALS portion. Recently, MediciNova announced the completion of the last patient last visit (LPLV) in the double-blind portion of the Phase 2b/3 COMBAT-ALS trial evaluating ibudilast in ALS. A total of 234 participants were randomized across clinical sites in the U.S. and Canada and have now completed the 12-month double-blind treatment period, with patients remaining in the study continuing active treatment in the six-month open-label extension (OLE). Recall, the trial's primary endpoint is the Combined Assessment of Function and Survival (CAFS), with secondary endpoints including change in the ALS Functional Rating Scale–Revised (ALSFRS-R), muscle strength (hand-held dynamometry), and QoL, which could provide additional support for the treatment effect. With enrollment and dosing complete, the company's next step is database lock and analysis, with topline results from the double-blind portion expected by YE26, most likely in December. LPLV for the full study, including the OLE, is anticipated in March 2027. As a reminder, the company recently announced that target enrollment (n=200) was completed in ibudilast's SEANOBI EAP (see next). With the two programs expected to provide complementary datasets, we see ibudilast well positioned for a pivotal period and look forward to upcoming clinical and regulatory updates.

SEANOBI EAP fully enrolled and on track to complement COMBAT-ALS. Recently, MediciNova announced that the target enrollment of 200 patients has been achieved in the SEANOBI Expanded Access Program (EAP) evaluating ibudilast in ALS patients. With funding from the National Institute of Neurological Disorders and Stroke (NINDS/NIH), the multicenter, open-label EAP offers access to ibudilast treatment to ALS patients who are not eligible to participate in the COMBAT-ALS randomized clinical trial, while also generating important biomarker (NfL) and clinical outcome (ALSFRS-R) data from a real-world ALS population (NCT06743776). Active participants in SEANOBI remain on track with treatment and protocol-specified follow-ups. Final patient follow-ups are projected to conclude in early 2027, triggering the data analysis phase. We believe this enrollment milestone underscores strong interest from the ALS community in ibudilast and its potential as a novel therapeutic option for ALS. Together with Orphan Drug Designations from the FDA and EMA, and Fast Track Designation from the FDA, ibudilast continues to advance toward potential approval for the treatment of ALS.

Mixed week-24 results; missing on TG and liver fat, but offering broader metabolic insight. In September, MediciNova announced topline results from the Phase 2 NATG-202 study evaluating tipelukast (MN-001) for the treatment of hypertriglyceridemia (HTG) and nonalcoholic fatty liver disease (NAFLD) associated with type 2 diabetes (T2D). As a reminder, NATG-202 was a multi-center (U.S.), randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of tipelukast in 40 T2D patients with HTG and NAFLD (NCT05464784). Participants (FibroScan score ≥ 248 dB/m, HbA1c >6.5 and ≤10% at screening, oral anti-diabetic therapy for ≥3 months, fasting TG levels >150 mg/dL at screening) were randomized to receive either 500 mg/day of tipelukast or placebo for 24 weeks. The co-primary endpoints were change from baseline in liver fat content (FibroScan; controlled attenuation parameter (CAP) score) and change from baseline in fasting serum TG levels at week 24. Secondary endpoints included safety and tolerability, and changes in lipid profile. Results showed:

- At week 4, mean serum TG decreased from baseline by 54.7 mg/dL (26.05%) in the tipelukast arm vs. 23.8 mg/dL (11.54%) in the placebo group, representing a 30.96 mg/dL greater reduction with tipelukast vs. placebo (p=0.015).
- At week 24, mean serum TG decreased from baseline by 45.8 mg/dL (21.78%) in the tipelukast arm vs. 14.4 mg/dL (6.97%) in the placebo group, representing a 31.4 mg/dL greater reduction with tipelukast vs. placebo (p=0.113).
- At week 24, CAP score decreased from baseline by 14.1 dB/m (4.24%) in the tipelukast group vs. 4.3 dB/m (1.27%) with placebo, representing a 9.7 dB/m greater reduction with tipelukast vs. placebo (p=0.2438).

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- At week 24, mean HDL-C increased by 3.3 mg/dL (8.39%) with tipelukast vs. a 2.4 mg/dL (6.23%) decline with placebo, corresponding to a 5.7 mg/dL treatment difference (p=0.0048).
- At week 24, HDL particle (HDL-P) concentration increased by 3.62 µmol/L (11.80%) with tipelukast vs. a 0.9 µmol/L (3.00%) decline with placebo, representing a 4.52 µmol/L treatment difference (p=0.018).
- Body weight tended to favor tipelukast, with a decrease of 4.91 lb (2.28%) vs. 0.55 lb (0.25%) with placebo at the end of the study (p=0.082).
- Tipelukast was generally safe and well tolerated, with mild to moderate TRAEs and no drug-related SAEs.

Overall, we view NATG-202 as providing a mixed efficacy signal for tipelukast in this small, PoC, exploratory study. While the numerical magnitude of the TG treatment difference was broadly maintained through week 24, the study did not demonstrate a statistically significant between-group difference at the prespecified co-primary endpoints of change in TG and liver fat content. The week 4 TG result provides evidence of an early lipid-lowering effect, but the lack of statistical significance at week 24 may limit the strength of the evidence for a sustained treatment effect. Similarly, while CAP score decreased numerically more with tipelukast vs. placebo, the difference did not reach statistical significance. The more notable findings came from the broader lipid profile. The statistically significant increases in HDL-C and HDL-P, together with the numerical reduction in body weight, suggest broader metabolic effects that may warrant further investigation in a larger study with an appropriately selected patient population, endpoints, time points, and sample size. Mechanistically, we believe these findings are directionally consistent with tipelukast's proposed multimodal MoA (see below). The company expects to conduct further detailed analyses of the study data and use these findings to inform the design and target population of a potential follow-on study.

Tipelukast aims to reshape the HTG-NAFLD-T2D axis. Tipelukast was in-licensed from Kyorin in 2002 as an orally bioavailable small molecule with multiple MoA targeting inflammation (5-lipoxygenase (5-LO)/ leukotriene (LTs), PDE, and CD36 pathways), fibrosis, and lipid metabolism. Preclinical studies demonstrated anti-fibrotic effects in livers from NAFLD animal models, and inhibition of TG biosynthesis and lipid-modifying activity in hepatotoxic and monocytic human cell lines, respectively. Of note, HTG, NAFLD, and T2D are pathophysiologically interconnected through systemic insulin resistance, dysregulated lipid metabolism, and chronic inflammation, forming a self-reinforcing metabolic axis. An open-label Phase 2 trial in patients with NAFLD and HTG (n=14) showed that tipelukast treatment led to early serum TG reductions (28.8%; p=0.00006) at week eight. Interestingly, subgroup analyses demonstrated that compared to participants without T2D (n=9), T2D patients (n=10) showed greater TG reductions at week eight (50.8% vs. 17.8% reduction in non-T2D), and a greater high-density lipoprotein cholesterol (HDL-C) increases (15.8% vs. 1.0% in non-T2D; p<0.0002), strengthening the case for prioritizing T2D patients in further clinical evaluation. There were no clinically significant safety and tolerability issues related to tipelukast. Details on tipelukast's MoA, preclinical data demonstrating significant anti-fibrotic effects, and clinically meaningful TG reductions in NAFLD patients with HTG can be found in: *A Novo Approach to Multi-Target Medicine; Initiating at Buy and $10 PT*.

Valuation and Risks. We maintain our Buy rating and $10 price target. Our valuation is based on our clinical net present value (NPV) model, which allows us to flex multiple assumptions affecting a drug's profile. We currently value MediciNova based on the contribution of its core clinical-stage assets, ibudilast (MN-166) in ALS (15% PoS; 33% contribution) and tipelukast (MN-001) for the treatment of HTG and NAFLD due to T2D (20% PoS; 67% contribution) in the U.S. Moving forward, we believe significant upside potential exists based on: (1) attaining higher market penetration than currently projected in the above-mentioned indications; (2) augmenting projected chances of success based on the progress of the clinical candidates; (3) adding additional commercial geographies; and (4) progress of non-core programs through licensing deals and/or collaboration agreements. Risk factors that could impede the stock from reaching our PT include failed or inconclusive clinical trials, the inability of the company to secure adequate funding to progress its drugs through the development pathway or the occurrence of dilutive capital raises.

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($ in millions except per share data)

Profit & Loss	2022A	2023A	2024A	2025A	2026E	2027E	2028E	2029	2030
Licensing and R&D revenue	0.0	0.0	0.0	0.4	1.0	1.0	1.2	1.5	1.5
Milestone revenue	0.0	1.0	0.0	0.0	0.0	0.0	0.0	1.0	2.0
Product and Royalties	0.0	0.0	0.0	0.0	0.0	0.0	60.0	185.0	305.0
Other revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	2.0
Revenues	**0.0**	**1.0**	**0.0**	**0.4**	**1.0**	**1.0**	**61.2**	**188.5**	**310.5**
CoGS	0.0	0.0	0.0	0.0	0.5	0.9	5.2	7.9	11.3
Gross Profit	**0.0**	**1.0**	**0.0**	**0.4**	**0.4**	**0.2**	**56.0**	**180.6**	**299.2**
Gross margin	*0%*	*100%*	*0%*	*100%*	*46%*	*15%*	*92%*	*96%*	*96%*
G&A	5.5	5.2	5.5	6.2	6.7	10.6	18.6	33.5	40.2
R&D	9.1	5.7	7.2	7.2	6.1	11.3	14.6	18.3	21.9
Other op ex	0.0	0.0	0.0	0.4	0.0	0.0	0.0	1.0	2.0
EBIT	**(14.6)**	**(9.9)**	**(12.7)**	**(13.3)**	**(12.3)**	**(21.7)**	**22.7**	**127.8**	**235.0**
EBIT margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*37%*	*68%*	*76%*
Depreciation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Amortization Intangibles	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA	**(14.6)**	**(9.9)**	**(12.7)**	**(13.3)**	**(12.3)**	**(21.7)**	**22.7**	**127.8**	**235.0**
EBITDA margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*37%*	*68%*	*76%*
Non operating expenses	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Interest Income/Other	0.6	1.3	1.6	1.3	1.5	1.6	1.7	2.1	2.4
Interest expense	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.3
EBT	**(14.1)**	**(8.6)**	**(11.0)**	**(12.0)**	**(10.8)**	**(20.1)**	**24.4**	**129.7**	**237.2**
EBT margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*40%*	*69%*	*76%*
Provision for taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	28.5
Net Income	**(14.1)**	**(8.6)**	**(11.0)**	**(12.0)**	**(10.8)**	**(20.1)**	**24.4**	**129.7**	**237.2**
Participation of preferred stock	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	2.0
Net Income to common	**(14.1)**	**(8.6)**	**(11.0)**	**(12.0)**	**(10.8)**	**(20.1)**	**24.4**	**130.7**	**210.7**
net margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*40%*	*69%*	*68%*
Number of shares - basic	49.0	49.0	49.0	49.1	50.3	56.9	60.0	61.0	63.6
Number of shares - diluted	49.0	49.0	49.0	49.1	50.3	56.9	62.5	64.6	66.9
EPS - basic	**(0.29)**	**(0.17)**	**(0.23)**	**(0.24)**	**(0.21)**	**(0.35)**	**0.41**	**2.14**	**3.31**
EPS - diluted	**(0.29)**	**(0.17)**	**(0.23)**	**(0.24)**	**(0.21)**	**(0.35)**	**0.39**	**2.02**	**3.15**

Source: SEC filings and H.C. Wainwright estimates.

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Quarterly P&L

	Q1'25A	Q2'25A	H1'25A	Q3'25A	9M'25A	Q4'25A	FY'25A	Q1'26A	Q2'26A	H1'26A	Q3'26A	9M'26A	Q4'26E	FY'26E
Licensing and R&D revenue	0.00	0.13	0.13	0.12	0.26	0.15	0.4	0.19	0.46	0.65	0.14	0.78	0.17	1.0
Milestone revenue	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Product and Royalties	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Other revenues	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Revenues	**0.00**	**0.13**	**0.13**	**0.12**	**0.26**	**0.15**	**0.4**	**0.19**	**0.46**	**0.65**	**0.14**	**0.78**	**0.17**	**1.0**
CoGS	0.00	0.12	0.12	0.12	0.23	-0.23	0.0	0.17	0.14	0.31	0.08	0.39	0.12	0.5
Gross Profit	**0.00**	**0.02**	**0.02**	**0.01**	**0.03**	**0.38**	**0.4**	**0.02**	**0.32**	**0.33**	**0.06**	**0.39**	**0.05**	**0.4**
Gross margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*100%*	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*46%*
G&A	1.36	1.44	2.80	1.81	4.61	1.55	6.2	1.59	1.83	3.42	1.25	4.67	1.98	6.7
R&D	1.84	2.19	4.03	1.58	5.61	1.54	7.2	1.26	1.03	2.29	1.87	4.16	1.92	6.1
Other op ex	0.00	0.00	0.00	0.00	0.00	0.38	0.4	0.00	0.00	0.00	0.00	0.00	0.00	0.0
EBITDA	**(3.2)**	**(3.6)**	**(6.8)**	**(3.4)**	**(10.2)**	**(3.1)**	**(13.3)**	**(2.8)**	**(2.5)**	**(5.4)**	**(3.1)**	**(8.4)**	**(3.9)**	**(12.3)**
EBITDA margin							*nm*							*nm*
Non operating expenses	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Net Interest Income/Other	0.34	0.33	0.66	0.33	0.99	0.30	1.3	0.25	0.23	0.48	0.22	0.69	0.81	1.5
Interest expense	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
EBT	**(2.9)**	**(3.3)**	**(6.1)**	**(3.1)**	**(9.2)**	**(2.8)**	**(12.0)**	**(2.6)**	**(2.3)**	**(4.9)**	**(2.8)**	**(7.7)**	**(3.1)**	**(10.8)**
EBT margin							*nm*							*nm*
Provision for taxes	0.00	0.00	0.00	0.00	0.00	0.01	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Participation of preferred stock							0.0							0.0
Net Income to common	**(2.86)**	**(3.3)**	**(6.1)**	**(3.1)**	**(9.2)**	**(2.8)**	**(12.0)**	**(2.59)**	**(2.3)**	**(4.9)**	**(2.8)**	**(7.7)**	**(3.1)**	**(10.8)**
net margin							*nm*							*nm*
NoSH basic	49.05	49.05	49.05	49.05	98.09	49.12	49.06	49.22	49.22	49.22	51.23	100.45	51.68	50.34
NoSH diluted	49.05	49.05	49.05	49.05	98.09	49.12	49.06	49.22	49.22	49.22	51.23	100.45	51.68	50.34
EPS - basic	**(0.06)**	**(0.07)**	**(0.13)**	**(0.06)**	**(0.09)**	**(0.06)**	**(0.24)**	**(0.05)**	**(0.05)**	**(0.10)**	**(0.06)**	**(0.08)**	**(0.06)**	**(0.21)**
EPS - diluted	**(0.06)**	**(0.07)**	**(0.13)**	**(0.06)**	**(0.09)**	**(0.06)**	**(0.24)**	**(0.05)**	**(0.05)**	**(0.10)**	**(0.06)**	**(0.08)**	**(0.06)**	**(0.21)**

Source: SEC filings and H.C. Wainwright estimates.

Lander Egaña Gorroño, Ph.D. legana@hcwco.com

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RETURN ASSESSMENT

Market Outperform (Buy): The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

Market Perform (Neutral): The common stock of the company is expected to mimic the performance of a passive index comprised of all the common stock of companies within the same sector.

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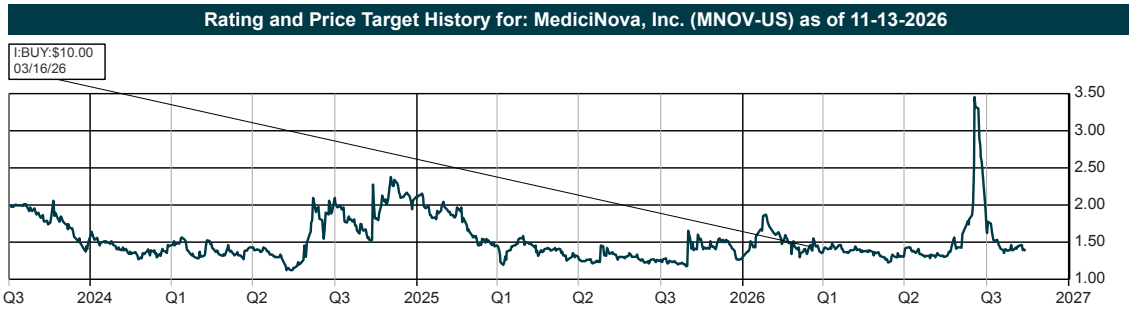

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Distribution of Ratings Table as of November 13, 2026

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	535	81.55%	146	27.29%
Neutral	53	8.08%	14	26.42%
Sell	2	0.30%	0	0.00%
Under Review	66	10.06%	21	31.82%

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As of October 31, 2026 neither the Firm nor its affiliates beneficially own 1% or more of any class of common equity securities of MediciNova, Inc..

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