2026年5月16日

H.C. Wainwright & Co.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5月15日、米国ニューヨークに本拠を置く投資銀行H.C. Wainwright & Co.のアナリストであるLander Egaña Gorroño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。

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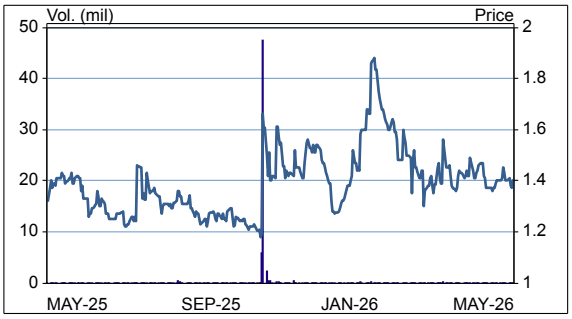
Important Clinical Inflection Points for Ibudilast and Tipelukast in The Year Ahead; 1Q26 Results

Stock Data	5/14/2026
Price	$1.40
Exchange	NASDAQ
Price Target	$10.00
52-Week High	$1.96
52-Week Low	$1.17
Enterprise Value (M)	$42
Market Cap (M)	$69
Shares Outstanding (M)	49.2
3 Month Avg Volume	47,288
Short Interest (M)	0.17
Balance Sheet Metrics	
Cash (M)	$27.3
Total Debt (M)	$0.0
Total Cash/Share	$0.55

EPS ($) Diluted			
Full Year - Dec	2025A	2026E	2027E
1Q	(0.06)	(0.05)A	--
2Q	(0.07)	(0.06)	--
3Q	(0.06)	(0.06)	--
4Q	(0.06)	(0.08)	--
FY	(0.24)	(0.26)	(0.43)

Revenue ($M)			
Full Year - Dec	2025A	2026E	2027E
1Q	0.0	0.2A	--
2Q	0.1	0.2	--
3Q	0.1	0.2	--
4Q	0.2	0.2	--
FY	0.4	0.7	0.8



Our perspective on 1Q26 results and next steps:

- Our primary focus is the clinical progress of ibudilast (MN-166) in ALS, and tipelukast (MN-001) in HTG/NAFLD due to T2D
- We contemplate upside potential based on: 1) tipelukast topline Phase 2 NATG-202 data in mid-2026; and 2) ibudilast Phase 2b/3 COMBAT-ALS data by YE26
- Ibudilast, potential to advance into registrational ALS studies and become the first genotype-agnostic, multi-target therapy for ALS

Corporate update. MediciNova entered 2026 fully focused on its core pipeline assets, including ibudilast (MN-166), currently in Phase 2b/3 studies for amyotrophic lateral sclerosis (ALS), and tipelukast (MN-001), under Phase 2 evaluation for the treatment of hypertriglyceridemia (HTG) and nonalcoholic fatty liver disease (NAFLD) in patients with type 2 diabetes (T2D). As a reminder, Ibudilast demonstrated stabilization or improvement in several functional ALS scores and prolonged survival in Phase 2 studies. The ongoing Phase 2b/3 COMBAT-ALS trial aims to validate ibudilast's longer-term efficacy in a larger ALS population, and inform next regulatory/clinical steps (topline data by YE26). For tipelukast, following preclinical data demonstrating significant anti-fibrotic effects, and clinically meaningful triglyceride reductions in NAFLD patients with HTG, which were greater in those with concomitant T2D, results from the ongoing Phase 2 NATG-202 trial (topline data in mid-2026) aim to support a registrational trial in T2D patients with HTG and NAFLD. Current cash position should provide runway through ibudilast (Phase 2b/3) and tipelukast (Phase 2) readouts and, if results are positive, the initiation of later-stage trials. See additional details from both programs below, and in our recent initiation report: *A Novo Approach to Multi-Target Medicine; Initiating at Buy and $10 PT*. We believe that ibudilast and tipelukast are well-positioned to achieve favorable data-driven clinical milestones and progress in their respective indications, and look forward to upcoming updates.

Financial update. MediciNova reported 1Q26 financial results, posting EPS of ($0.05), compared to our estimate and consensus of ($0.06). The company ended the quarter with $27.3 million in cash, which management believes provides runway to fund ongoing operations for at least the next 12 months.

Early functional and survival signals meet ibudilast's late-stage validation; Phase 2b/3 COMBAT-ALS data by YE26. MediciNova in-licensed ibudilast from Kyorin Pharmaceutical (TSE:4569; OTC:KYRNF; not rated) in 2004, following approval in Japan and South Korea for the treatment of asthma and post-stroke complications (i.e. dizziness) in the late 1980s. Ibudilast is a multi-target, oral small molecule inhibitor of phosphodiesterase (PDE), macrophage migration inhibitory factor (MIF), and toll-like receptor (TLR)-mediated pathways, that presents a multi-modal anti-inflammatory and neuroprotective MoA. The responder analysis from the Phase 2 ALS-1201 clinical trial evaluating ibudilast, in combination with riluzole SoC, in 49 ALS patients showed higher rates of stable or improved ALS Functional Rating Scale-Revised (ALSFRS-R), manual muscle testing (MMT), and five-item ALS Assessment Questionnaire (ALSAQ-5) scores at month six compared to the placebo + riluzole group. In addition, subjects who completed six or 12 months of treatment exhibited improved survival (p=0.0025) of up to 30 months following treatment. Ibudilast was generally safe and tolerable when administered with riluzole. While we acknowledge ALS-1201's single-site risk and the potential confounding effect of riluzole combination, our positive view is primarily driven by the favorable ALSFRS-R outcomes. Notably, prior late-stage ALS trials have shown that investigational therapies often struggle to sustain long-term functional ALSFRS-R improvements and meet clinical endpoints. We expect the ongoing Phase 2b/3 COMBAT-ALS trial to validate prior efficacy (functional and survival) and safety signals in a larger population in the longer-term (12 months), and inform next steps for ibudilast, including potential progression to regulatory filing or a confirmatory pivotal trial. Enrollment in COMBAT-ALS has been completed with a total of 234 randomized patients, and topline data are anticipated by YE26. While COMBAT-ALS does not incorporate prespecified biomarker endpoints, the ongoing NIH-supported SEANOBI Expanded Access Program (EAP) aims to generate meaningful neurofilament light chain (NfL) and clinical outcome (ALSFRS-R) data from the real-world ALS population. We believe that its broad, genotype-agnostic, and multi-modal approach, together with Phase 2 evidence of favorable safety and efficacy, support the clinical and regulatory advancement of ibudilast as a novel treatment to delay ALS disease progression.

Tipelukast set to reshape the HTG-NAFLD-T2D axis; Phase 2 NATG-202 data in mid-2026. 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 triglyceride (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. The Phase 2 NATG-202 trial is evaluating tipelukast in T2D patients with HTG and NAFLD over 24 weeks. Enrollment has been completed, and topline data are anticipated in mid-2026. We believe these results could mark a key inflection point supporting tipelukast's advancement into Phase 3 studies. Although multiple agents are in development for NAFLD, tipelukast is uniquely positioned in targeting both HTG and NAFLD driven by T2D, offering a more holistic therapeutic approach.

Broad indication optionality strengthens strategic collaboration prospects for ibudilast. MediciNova structures its pipeline around internally-funded core programs (strategic priority; ALS and HTG/NAFLD/T2D) and a capital-efficient, non-core portfolio characterized by a differentiated "platform-in-a-molecule" approach focused on ibudilast. The likelihood of ibudilast's multi-indication potential is reinforced by its multi-modal MoA and extensive human safety data pre- and post-approval in Japan and South Korea. This model enables focused investment in priority indications (ALS) while expanding the clinical reach of ibudilast through external collaborations. We view the non-core pipeline as a meaningful value driver for the company, offering: 1) capital-efficient development with minimal internal R&D spend; 2) diversified clinical risk for ibudilast beyond ALS; and 3) a strategic pathway to potential partnerships for late-stage development and commercialization. Collectively, this framework enhances both downside protection and long-term optionality across indications, in our belief. Non-core programs include clinical development in progressive multiple sclerosis (MS; Phase 2b completed), substance dependence (Phase 2 ongoing in methamphetamine dependence), chemotherapy-induced peripheral neuropathy (CPIN; Phase 2b ongoing), degenerative cervical myelopathy (DCM; Phase 3 ongoing), glioblastoma (Phase 1/2 completed), acute respiratory distress syndrome (ARDS; Phase 2 completed), and Long COVID (Phase 2/3 ongoing). On top of ALS, the FDA granted Fast Track designations to ibudilast for the treatment of progressive MS and methamphetamine dependence. With respect to the lead, non-core MS program, ibudilast showed ability to significantly reduce the rate of whole-brain atrophy (48% reduction) vs. placebo (p=0.04) in these patients. Ibudilast also demonstrated a 26% reduction (HR=0.74) in the risk of confirmed disability progression, with the greatest benefits observed in secondary progressive MS patients without relapse (46% risk reduction; HR=0.538). MediciNova finalized the design of a future registrational trial, and the progressive MS program is Phase 3-ready pending potential collaborators and/or partnerships.

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. Factors that could impede 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.

($ 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	0.7	0.8	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**	**0.7**	**0.8**	**61.2**	**188.5**	**310.5**
CoGS	0.0	0.0	0.0	0.0	0.2	0.4	5.2	7.9	11.3
Gross Profit	**0.0**	**1.0**	**0.0**	**0.4**	**0.5**	**0.4**	**56.0**	**180.6**	**299.2**
Gross margin	*0%*	*100%*	*0%*	*100%*	*71%*	*50%*	*92%*	*96%*	*96%*
G&A	5.5	5.2	5.5	6.2	6.8	10.8	19.0	34.1	41.0
R&D	9.1	5.7	7.2	7.2	8.5	15.8	20.5	25.6	30.7
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)**	**(14.8)**	**(26.2)**	**16.6**	**119.9**	**225.5**
EBIT margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*27%*	*64%*	*73%*
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)**	**(14.8)**	**(26.2)**	**16.6**	**119.9**	**225.5**
EBITDA margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*27%*	*64%*	*73%*
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)**	**(13.3)**	**(24.6)**	**18.3**	**121.8**	**227.7**
EBT margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*30%*	*65%*	*73%*
Provision for taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	27.3
Net Income	**(14.1)**	**(8.6)**	**(11.0)**	**(12.0)**	**(13.3)**	**(24.6)**	**18.3**	**121.8**	**227.7**
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)**	**(13.3)**	**(24.6)**	**18.3**	**122.8**	**202.3**
net margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*30%*	*65%*	*65%*
Number of shares - basic	49.0	49.0	49.0	49.1	50.9	56.9	60.0	61.0	63.6
Number of shares - diluted	49.0	49.0	49.0	49.1	50.9	56.9	62.5	64.6	66.9
EPS - basic	**(0.29)**	**(0.17)**	**(0.23)**	**(0.24)**	**(0.26)**	**(0.43)**	**0.30**	**2.01**	**3.18**
EPS - diluted	**(0.29)**	**(0.17)**	**(0.23)**	**(0.24)**	**(0.26)**	**(0.43)**	**0.29**	**1.90**	**3.02**

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	Q2'26E	H1'26E	Q3'26E	9M'26E	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	0.15	0.34	0.15	0.49	0.21	0.7
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**	**0.15**	**0.34**	**0.15**	**0.49**	**0.21**	**0.7**
CoGS	0.00	0.12	0.12	0.12	0.23	-0.23	0.0	0.17	0.12	0.29	0.12	0.40	-0.20	0.2
Gross Profit	**0.00**	**0.02**	**0.02**	**0.01**	**0.03**	**0.38**	**0.4**	**0.02**	**0.03**	**0.05**	**0.03**	**0.09**	**0.41**	**0.5**
Gross margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*100%*	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*71%*
G&A	1.36	1.44	2.80	1.81	4.61	1.55	6.2	1.59	1.66	3.25	1.72	4.97	1.80	6.8
R&D	1.84	2.19	4.03	1.58	5.61	1.54	7.2	1.26	1.85	3.11	2.07	5.18	3.33	8.5
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)**	**(3.5)**	**(6.3)**	**(3.8)**	**(10.1)**	**(4.7)**	**(14.8)**
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	0.33	0.58	0.42	1.00	0.50	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)**	**(3.1)**	**(5.7)**	**(3.3)**	**(9.1)**	**(4.2)**	**(13.3)**
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)**	**(3.1)**	**(5.7)**	**(3.3)**	**(9.1)**	**(4.2)**	**(13.3)**
net margin							*nm*							*nm*
NoSH basic	49.05	49.05	49.05	49.05	8.34	49.12	49.06	49.22	49.55	49.39	51.59	8.34	53.43	50.95
NoSH diluted	49.05	49.05	49.05	49.05	8.34	49.12	49.06	49.22	49.55	49.39	51.59	8.34	53.43	50.95
EPS - basic	**(0.06)**	**(0.07)**	**(0.13)**	**(0.06)**	**(1.10)**	**(0.06)**	**(0.24)**	**(0.05)**	**(0.06)**	**(0.12)**	**(0.06)**	**(1.09)**	**(0.08)**	**(0.26)**
EPS - diluted	**(0.06)**	**(0.07)**	**(0.13)**	**(0.06)**	**(1.10)**	**(0.06)**	**(0.24)**	**(0.05)**	**(0.06)**	**(0.12)**	**(0.06)**	**(1.09)**	**(0.08)**	**(0.26)**

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

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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.

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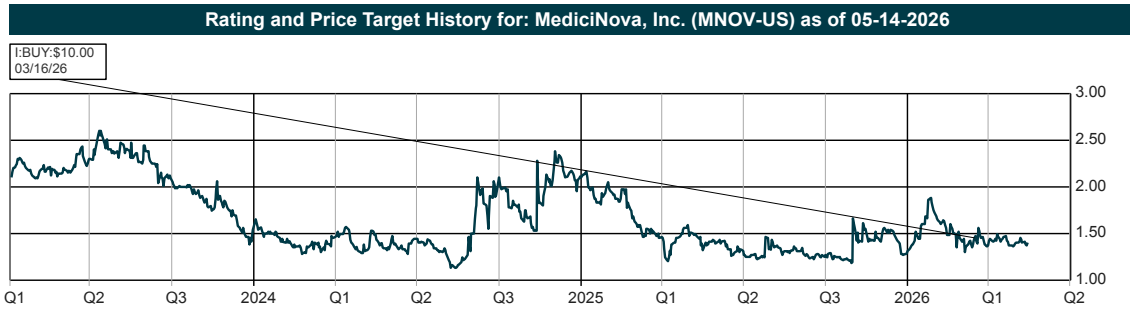

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Distribution of Ratings Table as of May 14, 2026

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	554	87.11%	164	29.60%
Neutral	47	7.39%	10	21.28%
Sell	2	0.31%	0	0.00%
Under Review	33	5.19%	14	42.42%

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