

2026 年 10 月 6 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 10 月 5 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 Joseph Pantginis 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、英文のままのご案内となりますので、ご了承ください。

【H.C. Wainwright & Co. 公式 web サイト】

<https://www.hcwco.com/>

※当該レポートは、本書の下部にありますので、スクロールしてご確認ください。

MediciNova, Inc. (メディシノバ・インク)

東京事務所 IR 担当

E-mail infojapan@medicinova.com

URL <https://medicinova.jp/>

Our Universe 4Q26 Catalyst Movers and Shakers

We take this opportunity to highlight key catalysts, for the remainder of the year, in our universe that span from primarily important data updates to regulatory and legal. These events are particularly highlighted based on their projected stock moving capabilities that require investor attention.

The table below provides a snapshot of these catalysts; further below, we provide more discussion around each catalyst as well as provide our projections as to stock moves based on scenarios/outcomes around the event.

Joseph Pantginis, Ph.D.
jpantginis@hcwresearch.com

Matthew Keller, Ph.D.
mkeller@hcwresearch.com

Sara Nik, Ph.D.
snik@hcwresearch.com

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

Joshua Korsen, Ph.D.
jkorsen@hcwresearch.com

4Q26 Catalysts to Pay Attention To (alphabetical order)

Name	Ticker	Analyst	Rating	PT \$	Event - Focus
AnaptysBio	ANAB	Pantginis	Buy	95	GSK/Tesaro litigation judgment
Actinium	ATNM	Pantginis	Buy	4	ATNM-400 target disclosure
Capricor	CAPR	Pantginis	Neutral	NA	November 22 PDUFA date for deramioceel
Celldex	CLDX	Pantginis	Buy	64	Phase 2 atopic derm data
Cytokinetics	CYTK	Pantginis	Buy	140	November 14 PDUFA date for MYQORZO's oHCM label expansion based on Phase 3 MAPLE-HCM data
Fractyl	GUTS	Pantginis	Buy	8	Topline 6-month REMAIN-1 pivotal cohort data for Revita (weight change vs. sham)
Gyre	GYRE	Keller	Buy	18	NMPA approval for CHB liver fibrosis
Iovance	IOVA	Pantginis	Buy	20	Phase 2 NSCLC update
Kyntra	KYNB	Keller	Buy	43	Phase 2 FG-3246 mono interim update
MediciNova	MNOV	Egana-Gorrono	Buy	10	Topline Phase 2b/3 COMBAT-ALS data for ibudilast (MN-166) in ALS
NewAmsterdam	NAMS	Egana-Gorrono	Buy	52	Topline Phase 3 RUBENS data of obicetrapib in T2D/metabolic syndrome patients
Pasithea	KTAA	Nik	Buy	3	First Part A PAS-004 data in adult NF1 (cNF and PN, 6-month efficacy, safety/PK)
Rigel	RIGL	Pantginis	Buy	85	R289 Phase 1b dose-expansion data
Tenaya	TNYA	Pantginis	Buy	3	Additional interim data from MyPEAK-1 (TN-201, MYBPC3-associated HCM) and RIDGE-1 (TN-401, PKP2-associated ARVC)
Tvardi	TVRD	Nik	Buy	9	REVERT LIVER CANCER Phase 1b/2 topline (TTI-101 in HCC)

Source: H.C. Wainwright estimates and company documents.



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AnaptysBio

Jemperli litigation remains an important potential catalyst for Anaptys' royalty thesis. The July trial focused on two main issues: what Anaptys and Tesaro/GSK (GSK; not rated) actually agreed to when they amended the collaboration agreement in 2020, and whether Tesaro/GSK continued to satisfy its commercially reasonable efforts (CRE) obligations when developing and commercializing Jemperli. Anaptys is seeking reversion of Jemperli rights. We continue to believe Anaptys has a credible case, although the trial transcripts provided greater clarity that the 2020 amendment gave GSK more operating flexibility than a simple Zejula-only carveout would suggest, while the written record still supports Anaptys' view that this flexibility had limits. Anaptys' updated post-trial brief also disclosed internal GSK projections suggesting several billion dollars of potential Jemperli sales tied to disputed opportunities. Post-trial argument is scheduled for October 20, with a court decision potentially in 4Q26 or 1Q27. Importantly, the existing royalty and milestone economics remain in place while the litigation is pending.

Recent notes:

Jemperli Momentum Continues With Multiple PDUFA and Data Catalysts Ahead; 2Q26 Results

Jemperli Litigation; Trial Transcripts Add More Color to the Debate, We Think Helping Anaptys

AnaptysBio Scenario Projections

AnaptysBio				
Event	Scenario		Upside	Downside
GSK/Tesaro litigation judgment	1	Court rules in Anaptys' favor on the key claims and orders reversion of Jemperli rights.	50-80%	0%
	2	Court finds a breach but does not grant full reversion, resulting in a more limited remedy.	15%	(-20%)
	3	Court rules in favor of Tesaro/GSK on the remaining claims, with the collaboration continuing under the existing royalty and milestone economics.	0%	(20-30%)

Source: H.C. Wainwright projections.

Valuation and Risks. We reiterate our Buy rating and \$95 price target. Our price target is based on a sum-of-the-parts analysis including:

- Royalty NPV of current royalties from Jemperli – \$60 contribution
- Clinical NPV of the Jemperli CRC and imsidolimab clinical programs – \$35 contribution

Our clinical NPV model allows us to flex multiple assumptions affecting a drug's potential commercial profile.

Risk factors that could impede the stock from reaching our price target include: (1) failed or inconclusive clinical trials from Jemperli's clinical development indications led by CRC; (2) ongoing litigation with GSK; (3) regulatory risk surrounding both Jemperli adding new indications and the currently submitted BLA for imsidolimab. We currently do not project that Anaptys will need to raise additional capital, but based on any of these risks, this could be needed.

Actinium

ATNM-400 has become an important emerging value driver for Actinium ahead of its 4Q26 target reveal. The first-in-class Ac-225 antibody radiocjugate is directed against an undisclosed, non-PSMA antigen that Actinium says is broadly expressed across prostate cancer, NSCLC and breast cancer and upregulated in treatment-resistant tumors. Preclinical work has supported a differentiated pan-cancer profile, but investor visibility remains limited while the target is undisclosed. We expect the initial stock reaction to depend on whether the revealed antigen is viewed as biologically validated, broadly druggable and differentiated from crowded radiopharma targets; initial human biodistribution and safety data later in 4Q26 should provide the next clinical validation step.

Recent note:

[ATNM-400 Nears Target Reveal and Clinical Debut in 4Q26; 2Q26 Results](#)

Actinium Scenario Projections

Actinium				
Event	Scenario		Upside	Downside
ATNM-400 target disclosure	1	Target is viewed as well validated and clearly differentiated from other radiopharma targets.	35-45%	0%
	2	Target is credible but has more competition or less differentiation than hoped.	10-20%	(10-20%)
	3	Target is viewed as poorly differentiated or less compelling than expected.	0%	(20-50%)

Source: H.C. Wainwright projections.

Valuation and Risks. We reiterate our Buy rating and \$4 price target. Our current valuation includes only Actimab-A for AML (82% contribution) and lomab-ACT, which recently had its IND approved (18% contribution). Our valuation is based on our clinical net present value (NPV) model, which allows us to flex multiple assumptions affecting a drug's potential commercial profile. Factors that could impede the stock from reaching our price target include failed or inconclusive clinical trials or inability of the company to secure adequate funding to progress its drugs through the development pathway.

Capricor

The OLE strengthens the efficacy story but does not resolve the regulatory uncertainty. Capricor presented new 24-month HOPE-3 OLE data at WMS 2026 showing slower modeled PUL 2.0 decline after placebo patients crossed over to deramiocele. Key findings include:

- In the delayed-start cohort, the cross-phase MMRM estimated a 2.05-point decline during Year 1 on placebo vs. a 0.49-point decline during Year 2 on deramiocele.
- Patients treated continuously with deramiocele showed similar modeled declines in Years 1 and 2, while external natural-history comparisons were also directionally consistent with slower decline on treatment.

The 24-month OLE data are encouraging, with slower modeled PUL 2.0 decline after placebo patients crossed over to deramiocele. These data formed the major amendment submitted to the BLA, but the OLE stat plan was not discussed prior to the submission.

We believe the OLE data do not change the statistical uncertainty from the randomized portion of HOPE-3, where the PUL result was subject to differing FDA and management analyses depending on the SAP version and statistical assumptions.

We continue to view a CRL as the more likely outcome and remain Neutral ahead of the November 22 PDUFA. We see a small chance of approval, potentially with a narrower label focused on upper-limb function.

Recent notes:

[FDA Extends Deramiocele PDUFA to November; Regulatory Risk Remains High](#)

[Regulatory Pieces Continue to Shift Around for Deramiocele; 2Q26 Results](#)

Capricor Scenario Projections

Capricor				
Event	Scenario		Upside	Downside
November 22 PDUFA date for deramiocele	1	Approval with no confirmatory study	200-300%	5%
	2	Approval with confirmatory study	90-100%	5%
	3	CRL	0%	90%

Source: H.C. Wainwright projections.

Valuation and Risks.

Valuation and potential impediments to achieving our price target. We maintain our Neutral rating. We look to reassess our view of Capricor following the FDA's decision on the deramioceel BLA, with the PDUFA date set for November 22. Risk factors that could impede the overall valuation of the company include an unfavorable regulatory outcome for deramioceel, failed or inconclusive clinical trials, the inability of the company to secure adequate funding to progress its drugs through the development pathway, the occurrence of dilutive capital raises, and lack of commercial success.

Celldex

Celldex recently readout positive data from its Phase 3 CSU program. However, in 4Q26 we direct investors to another upcoming catalyst on the horizon: a topline readout from a Phase 2 trial assessing barzo in atopic dermatitis (AD). Recall, this Phase 2 study is a randomized, double-blind, placebo-controlled, parallel-group study evaluating subcutaneous barzo in 131 adults with moderate-to-severe AD that are not responding to topical medications, or for those where available treatments are medically inadvisable. Patients were randomized 1:1:1 to 150 mg barzo every four weeks, 300 mg every four weeks, or placebo for 16 weeks (both active arms receive an initial 450 mg loading dose). At week 16, placebo recipients are re-randomized equally to the two active regimens, with a 450 mg loading dose, while patients initially assigned barzo cohort continue their original regimen. The study includes 32 weeks of treatment followed by 16 weeks of follow-up. The primary endpoint is percentage change from baseline in the weekly average daily PP-NRS score at week 16, measuring worst itch on a 0 to 10 scale. Key secondary endpoints are percentage change in EASI and the proportion achieving an IGA score of 0 or 1 (clear or almost-clear skin) at week 16.

Recent notes:

Barzo Bears Keep Finding New Flaws; Physician Survey Suggests They Don't Hold Up

EMBARQ Executes; Both Phase 3 Trials Achieve Primary Endpoint; PT Increased to \$64

Celldex Scenario Projections

Celldex				
Event	Scenario		Upside	Downside
Topline Phase 2 data in trial assessing barzo in atopic dermatitis (AD)	1	Barzo exhibits a clear treatment effect (improves metrics in both itch and EASI), and is safe and well tolerated.	25%	0%
	2	Barzo demonstrates only marginal clinical benefit	0-5%	(0-5%)
	3	Barzo fails to improve signs and symptoms of AD, and/or safety new safety signal emerges	0%	-15%

Source: H.C. Wainwright projections.

Valuation and risks to price target achievement. We reiterate our Buy rating and \$64 price target. Our price target is based on our clinical net present value (NPV) model, which currently derives its value from barzolvolimab (CDX-0159) in its three lead indications: CSU/CIndU, SD, and atopic dermatitis. Further, we also do not include additional assets from the pipeline and further expansion, each of which could provide further upside as they progress into the clinic. This model allows us to flex multiple assumptions affecting a drug's potential commercial profile. Risk factors that could impede the stock from reaching our price target include failed or inconclusive clinical trials or inability of the company to secure adequate funding to progress its drugs through the development pathway.

Cytokinetics

The FDA decision (PDUFA set for November 14) could mark an important commercial catalyst for MYQORZO by potentially strengthening its positioning for earlier use in symptomatic oHCM patients. MAPLE-HCM demonstrated superior improvements with aficamten vs. metoprolol SoC in exercise capacity and multiple secondary measures, providing clinical evidence that could support the use of MYQORZO earlier in the treatment pathway, including potentially as a first-line option for appropriate patients rather than requiring prolonged treatment with beta blockers or calcium-channel blockers first. We are bullish on a favorable label update without meaningful new restrictions on the treatment sequence or eligible patient subsets. The preferred outcome, in our view, would be a broad symptomatic oHCM label that incorporates the MAPLE-HCM evidence while avoiding a requirement to first fail or inadequately respond to SoC. Such an outcome could both expand the treated population and strengthen the preference for MYQORZO within the CMI category, consistent with management's expectations that MAPLE-

HCM could broaden physicians' adoption and market growth. A more limited label update could still be constructive, in our opinion, but would offer less leverage to accelerate earlier-line adoption. We view a CRL as unlikely given the strength and consistency of the MAPLE-HCM efficacy results, although this could leave the current MYQORZO treatment positioning largely unchanged.

Recent notes:

ACC.26 Strengthens MYQORZO's First-Line Potential in oHCM; sNDA Approval Anticipated in 4Q26

Building on MYQORZO's Launch Momentum Across Geographies and New Indications; 2Q26 Results

Cytokinetics Scenario Projections

Cytokinetics				
Event	Scenario		Upside	Downside
November 14 PDUFA date for MYQORZO's oHCM label expansion based on Phase 3 MAPLE-HCM data	1	Label expansion approved	20-25%	0%
	2	Narrower label approved	0-10%	(0-5%)
	3	CRL	0%	(15-20%)

Source: H.C. Wainwright projections.

Valuation and Risks. We reiterate our Buy rating and \$140 price target. Our valuation is based on our clinical net present value (NPV) model. We believe this method is appropriate for capturing the value of the clinical stage pipeline by allowing us to flex multiple assumptions, including the chance of success, peak sales estimates, and year of commercial launch. Aficamten represents 76% of our valuation (52% oHCM and 19% nHCM); omecamtiv mecarbil contributes 25%, and ulacamten contributes 4%. As it stands, we have Cytokinetics maintaining rights of its drugs in the U.S. and E.U., with an average 16% royalty from Sanofi (SNY; not rated) coming from sales in China. Risk factors that could impede the stock from reaching our price target include failed or inconclusive clinical trials, lack of regulatory and commercial success, or inability of the company to secure adequate funding to progress its drugs through the development pathway.

Fractyl

The 6-month REMAIN-1 Pivotal Cohort readout (n~315) is the key test of whether Revita can reproduce the durable weight-maintenance benefit observed in the REMAIN-1 Midpoint Cohort, where Revita-treated patients (n=24) demonstrated improved weight maintenance (4.5% weight regain) vs. sham (n=16; 7.5% weight regain) at six months post-procedure, and 7.8% weight regain (n=29) vs. 13% weight regain with sham (n=16) at one year. Recall, benefits were particularly pronounced in patients with complete duodenal ablation (>14 cm) and higher GLP-1 run-in weight loss (≥17.5%). For the pivotal analysis, the first efficacy requirement is the percent total body weight regain (Revita vs sham; p<0.05) at six months post-randomization. We expect a positive outcome, with a statistically significant and clinically meaningful reduction in weight regain in the overall modified intention-to-treat population, supported by: 1) the midpoint cohort efficacy signal; 2) the REVEAL-1 OLE data; and 3) the pivotal cohort's more complete ablation and substantial run-in weight loss. This outcome would strengthen the case for Revita as a potentially durable, drug-free maintenance option and support Fractyl's planned De Novo submission in late 4Q26, although the responder rate analysis of percent of Revita participants (≥50%) maintaining ≥5% total body weight loss at 12 months post-randomization remains a separate additional requirement for potential approval. A mixed outcome would comprise an overall endpoint miss with significant benefit confined to the "optimized population" of participants receiving complete duodenal ablation with higher run-in weight loss, preserving evidence of activity but raising questions about the breadth of applicability and the regulatory path. Conversely, numerical benefit without statistical significance would challenge the efficacy thesis and potentially delay further clinical development.

Recent notes:

Building an Optimal Commercial Framework for Revita Ahead of Potential 2027 Approval; Reiterate Top Pick

Revita Enters Final Stretch Toward Potential Registration; Pivotal Data in 4Q26; 2Q26 Results; Reiterate Top Pick

Fractyl Scenario Projections

Fractyl				
Event	Scenario		Upside	Downside
Topline 6-month REMAIN-1 pivotal cohort data for Revita (weight change vs. sham)	1	Statistically significant benefit with meaningful less weight-regain vs. sham in overall population	40-65%	0%
	2	Significant benefit (less weight-regain vs. sham) in optimized population	5-15%	(10-20%)
	3	Numerical benefit, but not statistically significant	0%	(30-45%)

Source: H.C. Wainwright projections.

Valuation and Risks. We maintain our Buy rating and \$8 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 Fractyl based on the contribution of Revita program for weight maintenance after GLP-RA discontinuation (60% PoS; 100% contribution) in Moving forward, we believe significant upside potential exists based on: (1) attaining higher market penetration than currently projected for Revita; (2) adding additional commercial geographies for Revita; (3) obtaining visibility on pricing structure/bundling of the overall procedure; (4) the addition of Rejuva (RJVA-001) following Phase1/2 trial initiation; (5) augmenting projected chances of success based on the progress of the clinical candidates; and (6) addition of new assets emerging from Fractyl's platforms (i.e. RJVA-002). 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, the occurrence of dilutive capital raises, or the potential risk of delisting due to noncompliance with exchange requirements.

Gyre

Ahead of the NMPA approval, the stock has continued to largely traded flat over the last 12 months. We believe this is likely due to many investors not assigning value to a product approval in China. However, we think it's important to point out commercialization in that geography could provide: 1) a significant revenue stream to the company to fund current and future programs; 2) some measure of regulatory de-risking of subsequent U.S. trials; and 3) potential acceleration of clinical timeline.

Recent note:

Hydronidone Approaching the Finish Line in China: 1Q26 Results

Gyre Scenario Projections

Gyre				
Event	Scenario		Upside	Downside
Potential NMPA approval decision for hydronidone in CHB-induced liver fibrosis	1	Hydronidone is approved in China for CHB-induced liver fibrosis	15%	0%
	2	Hydronidone's application in this geography is denied	0%	(10-15%)

Source: H.C. Wainwright projections.

Valuation and risks. We reiterate our Buy rating and \$18 price target. Our price target is based on our clinical net present value (NPV) model, which derives its value from Gyre's lead asset, hydronidone in MASH and associated fibrosis (100% contribution; 20% PoS) in the U.S. Key areas of future potential upside are based on four main factors: 1) securing further partnership agreements to develop pipeline in both U.S. and ex-U.S. markets; 2) identification of additional indications being targeted for approval; 3) adjustment to projections factors, including chance of success and peak sales; 4) visibility on commercial success of recently acquired assets; and 5) entrance of preclinical assets into clinical development. The three primary risks for companies that are developing new therapeutic agents that could impede price target achievement are: 1) regulatory risk including how the clinical data will be assessed by the FDA and ex.-U.S. regulatory agencies; 2) potential peers' competition; and 3) the risk of clinical trial failure of assets in development.

lovance

We are quickly approaching an addition inflection points for lovance as AMTAGVI's launch traction continues to improve. While we believe investors are paying attention to the data showing initiatives to improve margins are working, focus remains on growing revenue streams. Keys part of our long-term thesis are looking toward an sBLA filing for a tumor indication beyond melanoma and in combination with expansions into ex.-U.S. geographies. We view each of these catalysts/milestones as a potentially major validating event, if approved, for TIL technology and differentiates it against other CAR-T assets in the space which continue to have efficacy and/or safety issues. Of note, following positive feedback from the FDA, an sBLA is expected to be filed in 2027 for NSCLC with a projected launch soon after. An sBLA will be based on data from the IOV-LUN-202 study that has a planned update in 4Q26. In tandem, the company continues to make regulatory progress. Following recent approvals in both Canada and Australia, an approval decision is expected in the U.K. by year-end.

Recent note:

Getting Credit for Solidifying Commercial Traction; Pipeline Value Needs More Attention; Target Upped to \$20

lovance Scenario Projections

lovance				
Event	Scenario		Upside	Downside
IOV-LUN-202 Phase 2 trial update	1	Lifileucel exhibits clear and durable response (ORR > 30%) in NSCLC	25%	0%
	2	Lifileucel exhibits a more modest response (ORR = 20%, for example) and/or new issues arising from safety metrics	0-10%	(0-5%)
	3	Lifileucel treatment shows low to no responses with little durability	0%	(10-20%)
Potential U.K. AMTAGVI decision in advanced melanoma	1	AMTAGVI's MAA is granted by the MHRA	10%	0%
	2	AMTAGVI's MAA is denied by the MHRA	0%	-5%

Source: H.C. Wainwright projections.

Valuation and impediments to achieving price target. We reiterate our Buy rating and price target of \$20. Our price target is based on our clinical net present value (NPV) model, which derives its primary value from AMTAGVI for metastatic melanoma (47% contribution) and lifileucel for endometrial cancer (9% contribution), NSCLC (19% contribution), sarcoma (5% contribution) and for 1L advanced melanoma (20% contribution). This model allows us to flex multiple assumptions affecting a drug's potential commercial profile. Risk factors that could impede the stock from reaching our price target include failed or inconclusive clinical trials or inability of the company to secure adequate funding to progress its drugs through the development pathway.

Kyntra

Recall, earlier in the year, the company reported encouraging data from an IST combo study investigating FG-3246 in mCRPC. These positive results nicely set the stage for a Phase 2 monotherapy trial interim readout that is still expected in 4Q26, in our opinion. This interim trial readout is expected to report a futility analysis based on a composite response rate of PSA50/ORR. We underscore with investors the company is including their PET imaging molecule, FG-3180, in this study and recruiting a patient population that is most likely to benefit from FG-3246 (i.e., at earlier stages of treatment). We think smart study design and the incorporation of a PET molecule are underappreciated aspects of trial design that de-risk and also set the stage to for the therapy to exhibit best-in-class properties in the mCRPC space.

The FG-3246 Phase 2 monotherapy trial is a dose optimization Phase 2 trial designed to evaluate the safety, efficacy, tolerability, and pharmacokinetics (PK) of FG-3246 for mCRPC patients who have progressed following ARSI treatment and who have not received chemotherapy. The trial plans to enroll 75 patients who will be randomized 1:1:1 to receive either 1.8, 2.4 or 2.7 mg/kg AJBW FG-3246. The study's primary endpoint is determining the optimal dose for the Phase 3 trial. Secondary endpoints include: 1) radiographic PFS, 2) PSA50 response, and 3) PSA90 response. An interim analysis is planned once 12 patients are enrolled in each of the three dose arms have completed 12 weeks on study or discontinued. It is also important to highlight,

in our opinion, an exploratory sub-study is incorporated to evaluate FG-3180, (a CD46 PET imaging agent) as a diagnostic radiopharmaceutical.

Recent notes:

[More Balance Sheet Clean-Up Paves the Way for Clinical Execution](#)

['3246 Phase 2 Readout Quickly Approaches; Roxa Readies for Phase 3; 2Q26 Results](#)

Kyntra Scenario Projections

Kyntra				
Event	Scenario		Upside	Downside
Phase 2 FG-3246 monotherapy interim analysis	1	FG-3246 exhibits a superior composite response rate of PSA50/ORR	10-20%	0%
	2	Achieves statistically non-futility, but FG-3246 demonstrates clinical benefit on par with approved products in mCRPC	0-5%	(0-15%)
	3	Based on interim results, program lacks a treatment effect worth pursuing	0%	(20%)

Source: H.C. Wainwright projections.

Valuation and risks. We reiterate our Buy rating and our \$43 PT. Our valuation is based on our clinical net present value (NPV) model, which allows us to flex multiple assumptions affecting a drug's profile. Our NPV model currently derives its value from: 1) FG-3246 in mCRPC (57% contribution; 15% PoS) in the U.S. only and 2) potential future sales of roxadustat in MDSanemia (43% contribution; 25% PoS). Key areas of future potential upside are based on four main factors: 1) securing further partnership agreements to develop pipeline in both U.S. and ex-U.S. markets; 2) identification of additional indications being targeted for approval; and 3) adjustment to projections factors, including chance of success and peak sales. Factors that could impede reaching our price target include failed or inconclusive clinical trials, the inability of the company to secure adequate funding to progress its products through the development pathway or the occurrence of dilutive capital raises, lack of commercial success, and delisting risk.

MediciNova

Following completion of the last patient-last visit in the 12-month double-blind treatment period (n=234), MediciNova expects to report topline results from the Phase 2b/3 COMBAT-ALS trial of ibudilast in December 2026. 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). 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.

Recent notes:

[A Novo Approach to Multi-Target Medicine: Initiating at Buy and \\$10 PT](#)

[Advancing Dual-Asset Pipeline with Two Key Readouts on the Horizon: 2Q26 Results](#)

MediciNova Scenario Projections

MediciNova				
Event	Scenario		Upside	Downside
Topline Phase 2b/3 COMBAT-ALS data for ibudilast (MN-166) in ALS	1	Significant CAFS benefit vs. placebo	15-20%	0%
	2	CAFS not significant, but significant benefit on ALSFRS-R, survival, and/or key secondary endpoint(s)	0%	(5-10%)
	3	CAFS, ALSFRS-R, survival, and key secondary endpoints not significant	0%	(10-20%)

Source: H.C. Wainwright projections.

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 abovementioned 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.

NewAmsterdam

Phase 3 RUBENS readout by YE26 is expected to provide another important validation of obicetrapib's LDL-C-lowering efficacy, this time in patients with T2D or metabolic syndrome who require additional LDL-C lowering despite available therapy (n~100 per arm; FDC/obi 10 mg/placebo for 12 weeks). RUBENS is primarily a differentiation and future label-expansion study. We expect both obi monotherapy and the FDC to meet the primary endpoint of percent change in LDL-C vs. placebo at day 84, given the positive LDL-C results from the Phase 3 BROADWAY, BROOKLYN, and TANDEM trials, which included approximately 38%, 21%, and 49% T2D representation, respectively. We view the key question as whether obi can reproduce the robust magnitude of LDL-C lowering observed previously (~35% as monotherapy; ~50% as FDC) in this target population. A result broadly consistent with the prior Phase 3 experience would further strengthen the clinical package and support potential expansion of obi into a broader dyslipidemia population, while a statistically significant but more modest LDL-C reduction would temper expectations for obi's incremental value. We expect the stock move from RUBENS to be relatively modest, since PREVAIL CVOT is the main valuation driver.

Recent notes:

[First Global Approval for Ubeslo and Evlarco; CVOT Catalyst Ahead](#)

[Breaking Bad Cholesterol With Optimized CETPi Approach; Assuming Coverage at Buy and \\$52 PT](#)

NewAmsterdam Scenario Projections

NewAmsterdam				
Event	Scenario		Upside	Downside
Topline Phase 3 RUBENS data of obicetrapib in T2D/metabolic syndrome patients	1	Robust LDL-C lowering consistent with prior Phase 3 data	5-10%	0%
	2	Significant LDL-C lowering, but below expectations	0-5%	(0-5%)

Source: H.C. Wainwright projections.

Valuation and Risks. We reiterate our Buy rating and \$52 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 NewAmsterdam based on the contribution of its late stage asset, obicetrapib, for LDL-C lowering (100% PoS) and CV risk reduction (75% PoS); in the U.S. 27% and 53% contribution, respectively, and currently split 10% each contribution for ex-U.S., which we believe higher market penetration based on the size of the addressable markets represents a conservative component in our model. 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 ongoing trials; (3) including additional commercial geographies (i.e. Japan and China); and (4) addition of new programs evaluating the obicetrapib's potential for new indications (i.e. AD), or new assets emerging from NewAmsterdam's platform. Factors that could impede PT achievement 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.

Pasithea

Pasithea is approaching its first public disclosure of clinical data in NF1, which we see as the key inflection point for the thesis. Initial Part A data from the ongoing Phase 1/1b trial of PAS-004, a next-generation oral macrocyclic MEK inhibitor, in adults with NF1-associated neurofibromas will be presented at the European Neurofibromatosis Conference in Vienna with: (1) a poster on plexiform neurofibromas (PN) on November 1, and (2) an oral presentation on cutaneous neurofibromas (CN) on November 13. Recall, Part A enrolled 12 patients across the first four dose cohorts (4, 8, 12 and 18 mg tablets), and the data are expected to include efficacy through the six-month timepoint in both PN and cNF, along with safety, tolerability and PK. With selumetinib and mirdametinib approved in NF1-PN, we believe the bar for PAS-004 is differentiation on tolerability, given that class-related toxicities (rash, CPK elevation, GI and ocular events) can limit chronic dosing in a disease that requires long-term treatment. We see CN as a particularly meaningful opportunity given the absence of approved systemic therapies and the significant quality-of-life burden for patients. Encouragingly, the advanced cancer study previously showed early activity, including a partial response and a 71.4% disease control rate among efficacy-evaluable, MEK inhibitor-pretreated patients with BRAF-mutated tumors, alongside a favorable tolerability profile.

Recent notes:

[PAS-004 Dose Escalation Broadens Ahead of 4Q26 NF1 Interim; 2Q26 Results](#)

[Differentiated Profile and Early NF1 Safety Underpin the PAS-004 Thesis](#)

Pasithea Scenario Projections

Pasithea				
Event	Scenario		Upside	Downside
First Part A data from the Phase 1/1b trial of PAS-004 in adults with NF1-associated neurofibromas	1	Clear activity in cNF and/or PN at 6 months with differentiated MEK tolerability	80-120%	0%
	2	Clean tolerability but modest or early activity, mostly stable disease	0-15%	(25%)
	3	No meaningful activity or class-typical MEK toxicity	0%	(60%)

Source: H.C. Wainwright projections.

Valuation and Risks. We reiterate our Buy rating and \$3 price target. Our price target is based on our clinical net present value (NPV) model, which allows us to flex multiple assumptions affecting a drug's profile. We consider three key factors when considering our valuation of Pasithea using our NPV approach: • We currently only value PAS-004 for NF1-PN for the U.S. market (15% PoS; 100% contribution). We feel we are being conservative in our market model approach of PAS-004 by only attaining 30-35% market penetration and ~\$900 million peak sales, while still representing an unmet medical need. • We purposely omit PAS-004 for RAS/RAF/NF1-mutated advanced solid tumors, which is already in the clinic, and will reassess the potential upside pending further visibility on the program. This represents not only an additional layer of conservatism but, in our view, meaningful long-term upside potential, as multiple shots on goal increase the overall probability of success. • Consistent with our approach on advanced solid tumors, we currently ascribe no value to NF1-CN, valuing PAS-004 on NF1-PN alone. Given management sized the U.S. CN population at more than double NF1-PN with no approved systemic therapy, we regard it as a meaningful source of potential upside to our price target once the endpoint framework and regulatory path are clearer. Risk factors that could impede the stock from reaching our price target include failed or inconclusive clinical trials, the inability of the company to secure adequate funding to progress its drug through the development pathway or the occurrence of dilutive capital raises.

Rigel

R289's YE26 Phase 1b update will provide a broader look at whether the encouraging dose-escalation signal in heavily pretreated, transfusion-dependent lower-risk MDS is reproducible in the expansion cohort. Prior data showed RBC transfusion independence in 33% (6/18) of evaluable patients treated at doses of 500 mg QD or higher, including 40% (2/5) at 500 mg BID, with three responses lasting more than 24 weeks. For a closer look at these data, please see [HERE](#). The ongoing expansion

randomizes patients to 500 mg QD vs. 500 mg BID and is intended to select the recommended Phase 2 dose. We expect the stock reaction to be driven by the RBC-TI rate, durability, safety and whether one regimen emerges with a favorable profile to support further development.

Recent note:

Veppanu Opportunity Remains Intact as Etcamah Receives Accelerated Approval

Rigel Scenario Projections

Rigel				
Event	Scenario		Upside	Downside
R289 Phase 1b dose-expansion data	1	Dose expansion reproduces or improves on the prior ~33% RBC-TI signal, with durable responses, favorable safety, and a clear RP2D.	20-30%	0%
	2	Activity is lower or more variable than prior data, but safety remains manageable and an RP2D can still be selected.	5-15%	(5-15%)
	3	RBC-TI is well below the prior signal, responses are less durable and/or safety limits RP2D selection.	0%	(15-25%)

Source: H.C. Wainwright projections.

Valuation and Risks. We reiterate our Buy rating and \$85 price target. Given Rigel's evolution into a multi-product commercial-stage company, our valuation is based on a sum-of-the-parts analysis that separately captures the value of its commercial portfolio and clinical-stage pipeline, including:

- rNPV of Tavalisse, Gavreto, Rezlidhia, and Veppanu - \$81.90/share contribution
- Clinical NPV of R289 in LR-MDS - \$3.41/share contribution

Our commercial valuation is based on a risk-adjusted net present value (rNPV) analysis of projected future revenues from Tavalisse, Gavreto, Rezlidhia, and Veppanu; we assume an 8% discount rate and 0% terminal growth in our model. Our rNPV is based on approximately \$1.62B and added net cash of approximately \$56.1M, resulting in an \$81.90/share contribution to our valuation. Separately, our clinical NPV for R289 assumes \$250M in peak U.S. sales and a 20% probability of success, along with a 2031 U.S. launch, resulting in a \$3.41/share contribution. Together, the two components support our \$85 price target. Risk factors that could impede Rigel from reaching our price target include weaker-than-expected commercial performance across Tavalisse, Gavreto, Rezlidhia, and Veppanu, as well as failed or inconclusive clinical trials or regulatory setbacks for R289.

Tenaya

We see 4Q26 as an important period for Tenaya, with additional interim data expected from both of its lead cardiac gene therapy programs: (1) MyPEAK-1, evaluating TN-201 in MYBPC3-associated hypertrophic cardiomyopathy (HCM), and (2) RIDGE-1, evaluating TN-401 in PKP2-associated arrhythmogenic right ventricular cardiomyopathy (ARVC). Recall that the June MyPEAK-1 update included 78–104 weeks of follow-up for Cohort 1 (3E13 vg/kg, n=3) and 26–52 weeks for Cohort 2 (6E13 vg/kg, n=4). All six evaluable patients showed reductions in one or more echocardiographic measures of hypertrophy, suggestive of cardiac remodeling, and all six improved in one or more measures of symptom burden (NYHA class or KCCQ). TN-201 was generally well tolerated across both dose cohorts, with no dose-limiting toxicities, and all patients have tapered off immunosuppression. Because continuation of these trends is largely expected by investors, we believe the key focus of the upcoming update is Cohort 2 durability at ~1 year and whether a clear dose response emerges to inform late-stage dose selection. For TN-401, we look for durable reductions in arrhythmia burden alongside consistency between early Cohort 2 data and Cohort 1. We note TN-201 recently received PRIME designation from the EMA.

Recent notes:

Positioning for the Next Development Phase: Multiple Regulatory and Clinical Updates in 4Q26; 2Q26 Results A Singular Focus on the Heart, But Not a Single Path to Value; Year-End Updates Should Sharpen the Picture

Tenaya Scenario Projections

Tenaya				
Event	Scenario		Upside	Downside
Additional interim data from MyPEAK-1 (TN-201) data	1	Deepening, durable remodeling with clear dose response favoring Cohort 2	60-70%	0%
	2	Benefit maintained but not deepening; dose response unclear	0-10%	(20%)
	3	Waning effect in some patients or new safety signal	0%	(45-50%)
Additional interim RIDGE-1 (TN-401) data	1	Durable reductions in arrhythmia burden (PVCs, NSVT) with PKP2 expression, and early Cohort 2 data consistent with Cohort 1	30-50%	0%
	2	Directionally positive but variable arrhythmia response; modest expression	0-10%	(15%)
	3	No consistent arrhythmia benefit or new safety signal	0%	(25%)

Source: H.C. Wainwright projections.

Valuation and Risks. We maintain our Buy and \$3 PT. Our valuation is based on our clinical net present value (NPV) model, which allows us to flex multiple assumptions affecting a drug's potential commercial profile. Pipeline assets' contribution to our valuation are as follows: (1) TN-201 at 54%; and (2) TN-401 at 46%. Risk factors that could impede the stock from reaching our price target 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.

Tvardi

We view topline data from the REVERT LIVER CANCER Phase 1b/2 trial of TTI-101, Tvardi's oral small-molecule STAT3 inhibitor, in hepatocellular carcinoma (HCC), expected in 2H26, as the defining event for the thesis. At current levels, we believe the market is assigning little to no value to TTI-101 in HCC. STAT3 is, in our opinion, a well-validated driver of HCC progression and immune evasion that has historically been difficult to drug. While the REVERT IPF Phase 2 trial did not meet its primary endpoint, additional analyses showed a 9.4% baseline-weighted reduction in fibrosis score vs. 2.4% for placebo, alongside a 4.5-fold greater decline in IL-6, a central STAT3-driven cytokine, which we believe supports TTI-101's biological activity on the pathway. Our valuation is anchored on TTI-101 in 2L/3L HCC in the U.S. (20% PoS, 2029 launch). A clean efficacy signal supporting a registrational path would, in our view, warrant a meaningful move toward that value, though we would expect a Phase 3 financing to follow. TTI-109, the company's next-generation STAT3 prodrug, is being developed in ulcerative colitis (UC) following indication selection in July, is currently excluded from our valuation, and represents additional upside.

Recent notes:

STAT3 Goes to the Gut; KOL Event Makes Mechanistic Case for TTI-109 in UC

Underrated STAT3 Play at a Pivotal Moment; Initiating at Buy and \$9 PT

Tvardi Scenario Projections

Tvardi				
Event	Scenario		Upside	Downside
TTI-101 Phase 1b/2 topline in HCC	1	Clear efficacy signal with acceptable tolerability, supporting a registrational path	100-150%	0%
	2	Modest or ambiguous activity; tolerability acceptable	0-10%	(30%)
	3	No efficacy signal or tolerability limits dosing	0%	(50%)

Source: H.C. Wainwright projections.

Valuation and Risks. We maintain our Buy rating and \$9 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 Tvardi Therapeutics based on only the U.S. opportunity of the company's lead asset, TTI-101, in 2L/3L HCC (20% PoS, 100% contribution). We continue to ascribe no value to TTI-109. An indication has now been selected, but the program remains pre-IND, unfunded, and guided to a 2027 study start. We believe additional upside exists to our valuation based on: (1) positive clinical data demonstrating durability of response and supporting differentiation vs. existing SoC; (2) securing partnership agreements to develop TTI-101 in ex-U.S. markets; (3) identification of additional indications being targeted for approval with TTI-101; (4) addition of new assets from the company's pipeline; and (5) adjustments to projection factors, including peak sales and pricing assumptions, none of which are currently included in our valuation. 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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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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Related Companies Mentioned in this Report as of October/2/2026					
Company	Ticker	H.C. Wainwright Rating	12 Month Price Target	Price	Market Cap
AnaptysBio, Inc.	ANAB-US	Buy	\$95.00	\$48.53	\$1451
Actinium Pharmaceuticals, Inc.	ATNM-US	Buy	\$4.00	\$1.17	\$37
Capricor Therapeutics, Inc.	CAPR-US	Neutral	\$NA	\$8.95	\$520
Celldex Therapeutics, Inc.	CLDX-US	Buy	\$64.00	\$31.65	\$2485
Cytokinetics, Inc.	CYTK-US	Buy	\$140.00	\$65.60	\$9120
Fractyl Health, Inc.	GUTS-US	Buy	\$8.00	\$0.41	\$65
Gyre Therapeutics, Inc.	GYRE-US	Buy	\$18.00	\$7.11	\$754
Iovance Biotherapeutics, Inc.	IOVA-US	Buy	\$20.00	\$14.22	\$6439
Kyntra Bio, Inc.	KYNB-US	Buy	\$43.00	\$6.31	\$26
MediciNova, Inc.	MNOV-US	Buy	\$10.00	\$1.78	\$88
NewAmsterdam Pharma Company N.V.	NAMS-US	Buy	\$52.00	\$23.20	\$2773
Pasithea Therapeutics Corp.	KTTA-US	Buy	\$3.00	\$0.48	\$16
Rigel Pharmaceuticals, Inc.	RIGL	Buy	\$85.00	\$47.15	\$881
Tenaya Therapeutics, Inc.	TNYA-US	Buy	\$3.00	\$0.56	\$126
Tvardi Therapeutics, Inc.	TVRD-US	Buy	\$9.00	\$1.15	\$15

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Ratings	Count	Percent	IB Service/Past 12 Months		
			Count	Percent	
Buy	545	84.63%	160	29.36%	
Neutral	49	7.61%	12	24.49%	
Sell	2	0.31%	0	0.00%	
Under Review	48	7.45%	18	37.50%	

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