BofA SECURITIES

US Biopharmaceuticals

What to expect from our coverage universe in 2024

Industry Overview

Lingering macro concerns aside, Biotech outlook still +ve

Even after benefiting from a late rally, 2023 was challenging for SMid-Cap Biopharma (NBI +4%; XBI +8%; S&P 500: +24%) largely given macro uncertainties. Beyond the recent momentum, dynamics look favorable heading into 2024, but we wouldn't be surprised if lingering uncertainties over the broader economy remain an overhang near-term, especially on generalist investor interest. Regardless, we still see reasons for optimism in the space, including opportunities for value creation driven by the usual drivers (solid science; differentiated platforms; novel/ value-add products, etc.). In this note, we provide our outlook for 2024, reviewing major catalysts, key events, and ongoing debates, while highlighting our names with especially favorable set-ups below:

INSM: Catalyst rich '24 offers upside to 2023's momentum

Insmed was one of our top performers in 2023, with both solid commercial and clinical execution (see reports on our takes on the ARISE and TPIP updates) driving outperformance (+55% vs. +4% NBI). That said, we'd argue the set-up looks at least as favorable in 2024 with Arikayce gaining traction and several underappreciated/ undervalued catalysts set to read-out: 1) brenoscatib's ASPEN topline in NCFB, 2) TPIP phase 2 safety/ tolerability update in PH-ILD, and 3) preliminary insights from the early-stage pipeline (DMD). Especially given brenoscatib's potential in other pulmonary/ neutrophil-driven diseases (CF, CRSsNP, HS), many with blockbuster potential, we look for the company to build on last year's momentum towards further outperformance. Maintain Buy and $37 PO.

KURA: Upside opportunities as landscape clarifies

KURA shares rebounded in 2023, ending the year above (+16% vs. +4% NBI). In our view, much of this had to do with the improving outlook for the menin inhibitor class, with updates from Kura and rivals Syndax and J&J (Geoff Meacham) helping address lingering skepticism. Looking to 2024, we see opportunities for further share upside as the competitive picture begins to clarify, beginning with a Jan/ Feb update from KOMET-007 that should provide the first combination data of ziftomenib with SoCs "7+3" and ven + aza in *KMT2A*r and *NPM1*m AML. In our view, solid efficacy with limited DS, QTc prolongation, and/or myelosuppression could go a long way towards reassuring investors about ziftomenib's longer-term potential as the ongoing monotherapy '001 study in R/R *NPM1*m provides a path to initial approval/ commercialization. Maintain Buy and $31 PO.

HOWL: Novel platform emerging from the "shadows"

Werewolf had a solid 2023 (+88% vs. +4% NBI)—investors clearly starting to take note of its intriguing (in our view) oncology platform that masks effective but toxic native cytokines until activated in the TME. In our opinion, while the early efficacy updates for '124 (IL-2) were encouraging, it was the positive safety data that impressed (see our SITC data takes). Positive updates from higher dose cohorts of the '124 phase 1/1b should build on '23's momentum in our view, especially as the name emerges from the shadow of other cytokine developers. That said, similarly positive safety data from the '330 phase 1 could be key in driving a potential re-rating—with previous attempts to administer IL-12, a potent T-cell/ macrophage activator, derailed by high toxicities. Maintain Buy, $10 PO.

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Abbreviations

1L: frontline
AML: acute myeloid leukemia
ASH: American Society of Hematology
CF: cystic fibrosis
CVR: Conversion rate
CRSsNP: Chronic rhinosinusitis without nasal polyps
DMD: Duchenne muscular dystrophy
HS: Hidradenitis suppurativa
IL-12: interleukin 12
KOLs: key opinion leaders
MoA: mechanism of action
Mos: months
NCFB: non-cystic fibrosis bronchiectasis
***NPM1*m/*KMT2A*r:** mutational subtypes in leukemia
NTM-PD: non-tuberculosis mycobacteria pulmonary disease
PH-ILD: pulmonary hypertension with interstitial lung disease
QTc: corrected QT interval
SoC: standard of care
TME: tumor microenvironment
TPIP: treprostinil palmitil inhalation powder

2024 Catalysts

1Q24

Insmed: Will Arikayce 2024 guidance trend conservative again? (early Jan): Last year Insmed pre-announced full year '23 Arikayce sales and provided FY guidance in conjunction with the San Francisco healthcare conference (Jan 8-11), and we look for the company do the same in 2024. Even after accounting for pricing/ reimbursement headwinds in France and Japan, we thought last year's update was conservative, and we wouldn't be surprised if initial guidance comes in similarly below. Still—while not the primary driver of our positive thesis—we'd argue Arikayce has additional near-term upside in refractory disease, especially with pandemic-related headwinds declining, side-effect mitigation strategies catching on, and positive "buzz" from ARISE (see note on our takes on the topline). For these reasons, we are above for 4Q23 (BofA $88M vs. cons $82M) and FY24 ($386M vs. $366M, respectively); given management's historically cautious approach though, we see any update weighed to the downside: +5% /-10%.

Esperion: Can 12(c) end the litigation overhang? (early Jan): Our legal experts were divided on the Court's decision to allow a motion for judgement under 12(c). While there was consensus the ruling favored Esperion given implications the judge saw at least some merit to its arguments, most of our legal experts warned a positive outcome represented a high bar—the Court essentially needing to find a complete lack of ambiguity in the contract. Rather, with the trial scheduled for April 15, many thought the judge would likely delay a final ruling in order to hear from both sides' experts. Ultimately, handicapping outcomes here is challenging: inasmuch as a positive decision could drive shares meaningfully up (>50%), we think the likelihood is rather low (~20%). And while we suspect much of the Street is similarly cautious, given the recent move in shares (Dec '23: +125% vs. NBI +13%), we see the risk/ reward here as skewed to the downside—even as we are ultimately positive on a favorable resolution.

Arcus: Is the SKY-01 the limit? (Jan): Although we think acute focus remains on Roche's (covered by Jain/ Parry) SKYSCRAPER-01 OS topline, we wouldn't be surprised if some of the initial interest has waned following the leak of the update (our takes on the SKY-01 leak). Admittedly, while the phase 3 of TIGIT tiragolumab + PD-L1 atezolizumab in 1L NSCLC is still likely to provide the first definitive insights into the value of the next-gen I/O agent, we think investors have soured somewhat on its potential—which looks far removed from the benefit observed in Roche's phase 2 CITYSCAPE.

In investor meetings, Arcus has framed the SKY-01 data as win/ win, with a positive outcome confirming TIGIT's efficacy and a negative ruling more likely to be attributed to the statistical powering and/or atezo than the class itself. We see potential downside to both scenarios though, a win giving Roche first mover advantage in NSCLC and a miss likely resulting in negative broader read-throughs about the class. Somewhat overlooked, SKY-01's OS HR was trending towards 0.81, an outcome we think would be unlikely to renew enthusiasm amongst prescribers (see our Arcus profile for a deeper discussion). For these reasons, despite some potential initial volatility, we think the risk/reward for shares is weighed to the downside: +5-10%/-15%.

Arcus: Is HIF-2α NIC... or BIC? (Jan 18-20 / ASCO GI): Arcus plans to share initial dose escalation data, along with activity in RCC, early 2024 from its phase 1/1b of AB521. The company remains optimistic it can drive quicker and deeper responses vs. Lilly's (covered by Geoff Meacham) Welireg—although our KOLs have warned safety could be an issue, given on-target rates of anemia and hypoxia could lead to meaningful rates of discontinuation (see our post-ESMO call transcript). Just as critical, it remains unclear whether hitting the target "harder"—or with better kinetics—can indeed drive improved outcomes. Management has cautioned the update reflects a small sample size (~12), complicating cross-trial comparisons of any responses, an outlook we agree with. That said, a more favorable onset of action vs. Welireg, where it can reportedly take 4-6 months to see tumor shrinkage, could spark interest. Ultimately, we expect few have

included meaningful contributions from AB521 in their models given its relatively early-stage. But while that certainly suggests the risk/ reward should skew positively, we suspect the preliminary nature of the data, along with longer-term questions over competing with Lilly, could cap any upside: +5%/ <-5%.

Reneo: Where to from here? (~Jan) STRIDE's failure was a major setback for Reneo and its development strategy/ approach, with the lack of benefit in any major subgroup raising critical questions about a potential role for PPARδ agonists in mitochondrial myopathies (see our STRIDE readout takes). That said, the team had planned well for the LT (i.e., IRA), assembling a library of compounds that, together with >$100M remaining in cash, leave it well-positioned to regroup—an option often unavailable to developers in similar circumstances. Certainly, the class has been validated in other indications, notably PBC, but while this provides a path forward developmentally, it also suggests returns may be greater should the board opt to pursue other strategic alternatives. Ultimately, we wouldn't be surprised if the company is weighing multiple options, including an offer it disclosed to be acquired for $1.80/sh plus a CVR. But while it's challenging for us to handicap what happens next, we expect a decision sooner vs. later.

Arcus: New life for CD73 inhibitor quemliclustat? ("early '24"): The report of positive OS trends in ARC-8 surprised many, including us (see our 2Q earnings review). For starters, the ORR/ PFS interim had underwhelmed in 2022. At the same time, PDAC is one of the more refractory indications, with the CD73 class disappointing as of yet (e.g., Incyte/ covered by Tazeen Ahmad). Management has said the data compare well to historical values, but with the phase 1/1b uncontrolled, our KOLs admittedly think much more is needed to account for the typical attenuation in these early trials. Indeed, to be meaningful, our experts are looking for a PFS of 9-10 mos; OS >13 mos; and an of ORR >50%. Arcus has pointed to differentiating characteristics for quemli—including its formulation (small-molecule) and its ability to block both the membrane-bound and soluble forms of CD73—which could well result in improved efficacy vs. competitors. That said, given likely significant skepticism for all the above reasons, we think investors are going to want more before assigning more credit to the asset: +5%/ <-5%.

Arcus: Is Bristol's Opdualag another TIGIT headwind? ("early '24"): Likely somewhat underappreciated as a potential threat by the Street, our KOLs have long warned about Bristol's (covered by Geoff Meacham) Opdualag. Unlike Roche's or Arcus' PD-(L)1, Bristol's is well-established in NSCLC, and, with the community becoming increasingly comfortable with LAG3 in melanoma, we see the fixed-dose combo posing a potential commercial threat. While admittedly behind developmentally vs. both TIGIT rivals, we wouldn't be surprised if it's able to move quickly should the 1L NSCLC phase 2 prove positive—where its commercial advantages and Bristol's strong footprint should be able to overcome a second/ third to market entry. Overall, we see challenges trying to displace Merck's (Geoff Meacham) dominant position, but we could still see Opdualag becoming the *defacto* I/O-I/O combination. And, with Opdualag unlikely on many Arcus investors' radars, we see the risk/reward as weighed to the downside: +<5% / -5-10%.

Kura: How does ziftomenib compare to Syndax's revumenib? (Jan/Feb): 2023 proved to be a solid year for the menin inhibitor class, with overall sentiment on the MoA improving on the back of de-risking data, momentum we expect to continue into 2024 starting with insights from ~20 patients in Kura's KOMET-007 (see our San Diego Bus Tour update). We think the update should provide an early glimpse into ziftomenib's safety/ efficacy when combined with chemo 7+3 regimen frontline and ven + aza in R/R disease in both *KMT2Ar* and *NPM1*m AML. As we noted (see below for our Kura company profile), rates of DS are likely to be a key focal point especially after cases of grade 5 DS derailed monotherapy development in *KMT2Ar* patients. Indeed, while admittedly slightly behind Syndax in the R/R space, we see solid upside longer-term in combinations with our KOLs noting a potentially improved safety profile (see our Kura initiation). Based on management's feedback, we think a win on safety would include DS largely limited to grade 1-2 DS, low rates of dose-reductions/ interruptions, and minimal/ lack of additive

myelosuppression related AEs beyond that associated with SoC. Ultimately, KURA shares ended the year up (Dec: +49% vs. NBI 13%), largely we think due to positive readthroughs from Syndax's solid ASH conference. That said, we still see room for meaningful upside if the results are encouraging, even as we see greater downside risk: +15%/-20%.

AlloVir: Where to from here? (1Q24): The decision to discontinue the three posoleucel phase 3s was a surprise to us, not the least of which was the timing, i.e., relatively early in the study given the solid phase 2 results (see our posoleucel update takes). As we noted, though, the studies are complex, and while there could be an issue with the underlying MoA, other potential contributors could easily include the unusual manufacturing process or an unforeseen issue with the trial design/ sites. AlloVir is currently analyzing the data, and with ~$200M in cash reserves, management may well be able to get the program back on track in short order. But inasmuch as insights into what went wrong—and more importantly, the timing needed to fix it—remain opaque, we look for major updates sometime ~1Q.

Syndax: Are the regulatory submissions on track? (1Q24): With the story pivoting to the commercial front, we think investor focus has moved to execution. Recall at ASH the team reiterated guidance for YE submissions of 1) menin inhibitor revumenib's NDA, (RTOR and Breakthrough designation), and 2) a BLA for Incyte (covered by Tazeen Ahmad) partnered CSF-1R inhibitor axatilimab (Orphan Drug designation). Given solid data from both pivotals (see our takes on the AUGMENT topline and our initiation), we think few are expecting any FDA pushback or delays over the application acceptances/ PDUFA date assignments: +5%/ ->10%.

Esperion: Label update looks on track, but will it matter? (Mar 31st): Though overshadowed by the milestone dispute, the long-term Esperion story remains driven by bempedoic acid's (BA) relaunch. Inasmuch as CLEAR arguably underwhelmed (see our takes on the CLEAR presentation), the study was still positive, and we think most see the label update as all but assured (FDA PDUFA Mar 31st; EMA 1H24). Indeed, if there was any lingering doubt, much of it was likely addressed following FDA's unexpected decision mid-Dec to expand the label. Rather we'd argue removal of the qualifier "maximally tolerated" statin use may indicate the agency could similarly exclude "history of statin intolerance", even as it was an entry requirement for CLEAR—potentially helping uptake.

The recent strength in ESPR shares (concordant with the label update; see above for our 12(c) comments) certainly speaks to investor interest in BA, although for all the reasons described above, we are cautious. We don't disagree the drug may play a role in the treatment paradigm, but with 1) primary prevention challenging to access (see *Kim CJ, Annals of Internal Medicine, Dec '23* for a recent analysis); 2) access to PCSK9s expanding; 3) a limited sales force; and 4) multiple competitors advancing late-stage assets, it's not clear to us how much share BA can ultimately capture.

Cytokinetics: How does Bristol's next-gen CMI compare to afi? (1Q24): Beyond our questions over aficamten's differentiated profile vs Bristol's (covered by Geoff Meacham) Camzyos, our cautious outlook on Cytokinetics includes concerns over the former's competitive response (see our takes on the SEQUOIA data). Likely overlooked, Bristol is advancing its own next-gen CMI, MYK-224, that could ultimately compete with aficamten. Indeed, similarly to aficamten, MYK-224, was developed to have an improved PK/PD, with initial insights likely to come from the open-label MERCUTIO phase 2 in oHCM sometime 1Q24. We recognize the asset is still early, and may ultimately be a better target for other indications (i.e. HFpEF); that said, we think it's possible should aficamten prove differentiated over Camzyos, the advantage may not last: <+5%/ -<5%.

2Q24

Cytokinetics: How does aficamten compare to Bristol's Camzyos? (2Q/ April 6-8): While not a surprise to us, SEQUOIA's success was a win for Cytokinetics—with aficamten's impact on pVO2 (+1.74 mg/kg/min) and LVEF<50% (3.5%) comparing

favorably to Bristol's (covered by Geoff Meacham) Camzyos' EXPLORER (+1.4 and 5.7%; see our thoughts on the SEQUOIA readout). All that said, it's still unclear how the two molecules stack up—a key focus of current investor debate. Here, inasmuch as bulls have pointed to aficamten's improved PK/PD as capable of producing a commercial edge, our clinical, regulatory, and commercial KOLs all see the molecule as more similar to Camzyos than not (see our FIC vs. BIC analysis).

For this reason, we look for additional updates from SEQUOIA, especially more functional endpoints like NYHA class improvement. Even as all were reportedly stat sig, according to our experts, prescribers see these as more clinically relevant and thus are more likely to use to make cross-trial comparisons (EXPLORER: +34%; see our SEQUOIA preview for a table). Aficamten may well be clinically advantaged (safety is another story: see below for our Cytokinetics profile), but with it still unclear as to whether the relative difference in pVO2 correlates to better performance in these endpoints, we see the readout—likely at ACC (April 6-8, Atlanta GA)—as weighed to the downside, especially with expectations currently as high as they are: +>10%/-25%.

Insmed: Can brenso drive the next leg of growth? (2Q24): Easily one of the biggest catalysts in our universe—and certainly potentially transformative for Insmed—is DPP-1 inhibitor brensocatib's phase 3 ASPEN for non-cystic fibrosis bronchiectasis. While we think investors have warmed some to the asset, we wouldn't be surprised if there's lingering skepticism stemming from the WILLOW phase 2 (discussed below in our Insmed profile).

In contrast, we see more reasons be optimistic. Early blinded data suggest ASPEN is tracking similarly to WILLOW, which given the former's powering (90% to detect a 30% reduction in PE) arguably augurs well for success. Insmed also reported a blended PE rate of 1.12-1.15 events/ patient/ year, in line with expectations and well below the 1.37 rate observed in the WILLOW's placebo arm (recall ASPEN assumes a more conservative 1.2 PE per patient/ year placebo rate). Regulatory support also looks favorable, with FDA reportedly willing to accept WILLOW as part of a submission package should ASPEN succeed but fail to reach the P<0.01 threshold. At the same time, we see upside to brensocatib's current forecasts given strong feedback from prescribers, supporting our above forecast expectations (2028e unadjusted BofA $1.8B vs. cons $1.5B). Thus, we continue to view brensocatib as underappreciated, with risk/ reward weighed to the upside: +>25-30%/->15-20%.

Insmed: Will an update from PH-ILD build on TPIP's momentum? (2Q24): In our view, TPIP was largely overlooked until recently, even as we've long-seen meaningful upside potential from Insmed's treprostinil pro-drug. Indeed, inasmuch as United Therapeutics' (covered by Greg Harrison) franchise now anchors SoC for advanced PAH patients—with PH-ILD rapidly following—side effects remain an impediment to use, with clear need for alternatives. In our view, the initial update in PAH was robust, with an average 47% reduction in PVR among those likely on TPIP comparing favorably to Tyvaso (challenges of identifying comps aside). Just as impressive was the proportion of patients achieving the top 640µg dose (83% PAH and 80% PH-ILD participants)—60% above Tyvaso's max dose (see our 3Q INSM takes).

The next update from the program is likely to be from the ongoing phase 2 in PH-ILD. Management recently narrowed the timing to 2Q (vs. 1H24 prior), but less clear at this point is what efficacy details will be included (potentially 6MWD, FVC). That said, similarly positive safety insights—especially after QD administration (vs. United's QID)—could help further de-risk the molecule in the minds of investors, offering another shot on goal for share outperformance in 2024. For these reasons, we see the readout as weighed to the upside: +10%/-5%.

1H24

Insmed: Can Pillar 4 provide long-term upside? (1H24): While we think investors have been warming to Insmed's commercial story (Arikayce) and the late-stage portfolio

(brenso, TPIP), there's easily more skepticism for the early-stage pipeline. Indeed, insofar as we think the company has assembled an impressive suite of technologies/ platforms, its long-term goals are arguably quite advanced, leaving, in our view, legitimate concerns the so-called Pillar 4 may become a distraction and a resource sink. We thus wouldn't be surprised if there's greater interest than normal for an early-stage update—specifically biopsy data following intrathecal delivery—from its DMD program in 1H24 (see our notes from the R&D Day). We recognize the competitive landscape has become more challenging given Sarepta's (covered by Tazeen Ahmad) recent regulatory success with quite a bit of additional de-risking still ahead. That said, given the lack of credit for the program, we could see potential upside, albeit modestly so: +2-3%/-1-2%.

Werewolf: Will positive safety and efficacy trends in '124 continue at higher doses? (1H24): While there was much discussion over Werewolf's IL-2 INDUKINE '124's hints of efficacy in the phase 1/1b update at SITC, we thought the bigger takeaway was the encouraging safety updates—a clear sign the molecular "mask" is limiting off-target activation (see our takes from the '124 presentation and our initial review of the safety data). In our view, sentiment on the name has been weighed by negative readthroughs from other cytokine developers, even as rivals have used different approaches (see our takes on the Nektar setback). That said, we wouldn't be surprised if there's renewed interest in the story—which could continue to build with additional data (guidance: 1H24). Admittedly, we're unlikely to get a greater sense of the total picture, with critical details more likely to come from the subsequent mono/ Keytruda combo expansion arms. Still, if the efficacy and safety trends from the 18mg dose cohort follow the trajectory from the 12mg arm (3/5 had their tumors shrink), we could see greater declines in skepticism towards a potential re-rating: +10-15%/ -5-10%.

2H24/ 2024

Kura: Can updates from the early-stage FTI program engage investors? (mid-24): While few, in our view, attribute much value to Kura's earlier-stage FTI program, the preliminary updates have been positive—and we could well see investor interest grow in 2024 on the basis of several incremental updates (expected mid-2024), namely: 1) insights from the phase 1/2 of Novartis' (covered by Parry and Jain) alpelisib + tipifarnib in PIK3CA HNSCC (KURRENT-HN), including the OBAD, and 2) initiation of the phase 1 FIT-001 of next-gen '2806 in combination with i) Bristol/ Mirati's adagrasib in KRAS mutant NSCLC, and ii) Exelixis' cabozantinib in ccRCC (covered by Jason Gerberry). On the back of positive updates at ESMO (see our takes on the tipi presentation), we remain cautiously optimistic on the progress even as we recognize much more de-risking is necessary. Still, with few ascribing much value to the early-stage platform, we see risk/reward skewing to the upside: +5%/ -2-5%.

Werewolf: What does the rest of the platform look like? (2024): Arguably somewhat overlooked with investors only recently engaging with the story—and then focusing primarily on IL-2 INDUKINE '124—Werewolf has a second asset in the clinic, IL-12 INDUKINE '330. While management hasn't provided guidance, we expect initial data from the ongoing phase 1 ~2H24. While there's long been clinical interest in the potent T-cell and macrophage activator, attempts to use IL-12 have been stymied by meaningful tolerability issues. It's thus challenging to benchmark what a positive outcome looks like for '330, even if the safety update is in-line with '124's. Indeed, while we're optimistic for efficacy, even if properly "masked", IL-12 may ultimately not have much/ any therapeutic value. Still, positive data would easily go a long-way towards validating the potential of the platform as the company advances other cytokines, including IL-21 and IL-18. With expectations low, we see risk/ reward as weighed to the upside, although estimating the extent is more challenging: >5%/ -<5%.

Syndax: How does revumenib look in *NPM1*m disease? (4Q24): Positive clinical updates have established revumenib's clear monotherapy potential in R/R *KMT2Ar* acute leukemias, with Syndax guiding towards a YE23 NDA filing (see our takes on AUGMENT-101 and the Investor Presentation). Less clear, though, is its activity in *NPM1*m disease

where early data suggested rival Kura (ziftomenib) had the advantage. Overall, the broader competitive picture should clarify in 2024, where beyond Kura's early combo data, Syndax currently expects topline AUGMENT-101 data in R/R *NPM1*m patients 4Q24e. We won't have Kura's pivotal data at that point, but given the rival's 35% CR/CRh benchmark, we should have a better sense of how the two are likely to compete in the same indication: +15%/ -<15%.

AlloVir, Inc.

ALVR US – Rating: UNDERPERFORM (C-3-9) | PO: 1.00 USD | Price: 0.68 USD

What we expect in 2024: Setbacks cloud outlook, with acute focus now on potential questions over the path forward

AlloVir ended the year in transition, with much uncertainty weighing heading into 2024. Admittedly, '23 was challenging, with shares trading well below Jan/Feb levels. We suspect much of this was driven by the challenging macro backdrop and accompanying decline in risk appetite; not helping matters, though, there were capital concerns with key catalysts not expected until mid-2024. Admittedly, the company's strategy—using pooled donor T-cells as an off-the-shelf option for prophylaxis or acute treatment of viruses in immune-compromised patients—seems quite novel. However, the approach had proven successful in several (albeit small) mostly academic-based studies going back ~30 years. And this, along with the positive phase 2 data, had been a major driver of our positive thesis (see our AlloVir initiation).

For precisely these reasons, the failure of all three ongoing phase 3s of posoleucel (prevention, treatment of AdV or vHC) in Dec—especially this early in the study—came as a major surprise, raising critical questions about posoleucel and AlloVir's fundamental approach (see our discussion of the trial discontinuations).

To be fair, much remains unresolved, with the data still to be analyzed, and we can certainly see several potential favorable outcomes. Indeed, the trials are complex, with allo-HCT recipients very sick and patient care/ protocols heterogeneous between transplant centers. It thus remains possible there was a clear confounding issue that just didn't emerge in the smaller phase 2s. At the same time, AlloVir also has a relatively strong balance sheet, including ~$200M, which could provide enough support to regroup—at least to a point where there's clear evidence of progress for investors. And certainly, the backdrop remains favorable given the limited number of treatment options, with AlloVir's platform easily among the most advanced.

Ultimately though, until there's much more clarity, we look for sentiment to continue to weigh. With the next update likely sometime 1Q, in our view, the Street may not have long to wait. But assuming the board opts to continue development, we suspect it will take longer to reassure investors about next steps—with 2024 still shaping up to be a pivotal year for the company.

Abbreviations
vHC: virus-associated hemorrhagic cystitis
AdV: adenovirus
allo-HCT: allogeneic hematopoietic cell transplant

Arcus Biosciences, Inc.

RCUS US – Rating: NEUTRAL (C-2-9) | PO: 23.00 USD | Price: 19.10 USD

2023: Skepticism overshadows favorable TIGIT updates

2023 was a challenging year for Arcus (-8% vs. NBI +4%), with investors still cautious on TIGIT. Indeed, going back to Dec '22, when the company presented ARC-7's top-line, its phase 2 of domvanalimab + PD-1 zimberelimab in 1L NSCLC, the company has seen its market cap decline $1.1B. Admittedly expectations on the next-gen I/O had already fallen given little evidence of efficacy in refractory patients or low PD-L1 expressors. Still, even after admittedly favorable ARC-7 (see our takes on the ASCO presentation) and EDGE-Gastric updates (see our takes on the gastric data) as well as competitor outcomes in HCC (see our takes on MORPHEUS) and NSCLC (see our takes on the SKY-01 leak), we'd argue the Street remains unconvinced about the class's overall potential.

We're not entirely surprised, our KOLs long skeptical on TIGIT's broad upside. And while conceding the mechanism may have niche applications, an outlook the ARC-7 presenter admitted at ASCO, it's not clear to our experts this includes NSCLC, HCC, or even gastric, especially when also factoring in the competitive dynamics, supporting our more cautious near-term view on the story.

What we see in 2024: With TIGIT updates unlikely before 2025…

Looking ahead in 2024, we see opportunities for the Arcus story to get back on track—but we suspect this is more likely to come from the early pipeline vs. TIGIT.

Easily the biggest catalyst is competitor Roche's (covered by Jain/ Parry) SKY-01 OS readout, its pivotal of TIGIT tiragolumab and PD-L1 atezolizumab, expected Jan. As we noted, initial enthusiasm for developers after the leak eroded quickly. Despite early separation of the survival curves, the ~0.81 HR is underwhelming. For one, the value falls just above the 0.80 level needed for clinical relevance. We also think clinicians are likely to see this as more the result of atezo underperformance. Indeed, in Bristol's (Geoff Meacham) CM-227, the HR between Opdivo vs. Opdivo/Yervoy (another I/O vs. I/O-I/O) was 0.87 in the same population (*Hellman MD*, 2019), far less of a benefit despite CTLA-4's seemingly greater potency (e.g., unlike TIGIT, it has monotherapy activity).

In terms of internal catalysts, management has pledged to clarify timelines for pivotals ARC-10 and STAR-121 in lung and STAR-221 in gastric, but we suspect readouts are more likely 2025. And with phase 2s ARC-7 and EDGE-GASTRIC already failing to move the needle much, we suspect data follow-ups may not re-engage investors.

…2024 likely to revolve around insights into the early-pipeline

Rather, we look for greater focus on earlier assets, with presentations for both CD73 quemliclustat and HIF-2α AB521 expected early 2024.

As we previously noted, the report of positive OS trends in ARC-8 was a surprise, especially after the ORR/ PFS interim underwhelmed (see our 2Q earnings review). At the same time, 1) PDAC has been one of the most refractory indications, and 2) the anti-CD73 class has disappointed (e.g., Incyte)—likely leaving investors skeptical. With the phase 1/1b uncontrolled, our KOLs are looking for a PFS of 9-10 mos, OS >13 mos, and an of ORR >50% not only to account for attenuation in more advanced studies but also because PDAC grows quickly, with need to control the primary site rapidly.

Arcus also plans to share initial dose escalation data (including activity in RCC) early 2024 for the AB521 phase 1/1b. The company remains optimistic it can driver quicker and deeper responses vs. Lilly's (Geoff Meacham) Welireg—although our KOLs have warned safety could be an issue, given on-target rates of anemia and hypoxia can lead to high discontinuation rates (see our post-ESMO call transcript).

Abbreviations

TIGIT: T-cell immunoreceptor with Ig and ITIM domains
PD-1/L1: programmed cell death protein (ligand) 1
NSCLC: non-small cell lung cancer
I/O: immuno-oncology
ASCO: American Society of Clinical Oncology conference
HCC: hepatocellular carcinoma
OS: overall survival
ORR: objective/ overall response rate
HR: hazard ratio
CM-227: CheckMate-227, a clinical trial in NSCLC
CTLA-4: cytotoxic T-lymphocyte associated protein 4
PDAC: pancreatic ductal adenocarcinoma
MoA: mechanism of action
KOL: key opinion leader
HIF-2a: hypoxia inducible factor-two alpha
RCC: renal cell carcinoma

Cytokinetics, Inc.

CYTK US – Rating: NEUTRAL (C-2-9) | PO: 85.00 USD | Price: 83.49 USD

What we see in '24: Focus shifting to afi's potential differentiation

Cytokinetics ended the year on a very high note (YTD +82% vs. NBI +4%), although 2023 was not without challenges that included FDA's CRL for OM (see our takes on the CRL) and the discontinuation of reldesemtiv (see our thoughts COURAGE-ALS). Still, the narrative was acutely focused on cardiac myosin inhibitor aficamten, and despite some concerns over its profile following phase 2 updates (see takes and follow-ups on CYTK's ACC and ESC HF presentations), the positive SEQUIOA topline confirmed its efficacy in oHCM, likely providing a clear path to approval (see our SEQUIOA results discussion).

That SEQUOIA succeeded wasn't a surprise to us even as the selection of pVO2 as the sole primary added some uncertainty (see our SEQUIOA preview and Dec catalyst update). Indeed, our thesis has been aficamten is more similar than not to Bristol's (Geoff Meacham) Camzyos—the latter's success certainly supportive of the former's in oHCM. But, for the same reason we have struggled to see aficamten as commercially differentiated, at least to the extent where it can capture meaningful share from Camzyos and expand the overall market (see our FIC vs. BIC analysis). We don't disagree SEQUIOA's pVO2 (+1.74 mg/kg/min) and LVEF<50% (3.5%) compare favorably to Camzyos' EXPLORER (+1.4 and 5.7%), but cross-trial comparisons aside (see our Analyst Day takes) both metrics seemingly fell short of thresholds investors/ KOLs felt needed to establish clear clinical separation (1.8-2.0; 1-2%).

For these reasons, while we see potential for further share upside, we look for greater clarity into aficamten's market potential before becoming more comfortable with the story—insights that should start to materialize starting with the full SEQUOIA data presentation, likely at ACC (April 6-8; Atlanta). Among key questions for us is whether the relative improvement in pVO2 produced meaningful increases over Camzyos on NYHA class improvement (EXPLORER: +34%) as well as KCCQ (+9.1; see our SEQUIOA preview). Even as these were reportedly stat sig in SEQUOIA, according to our KOLs, prescribers see these functional endpoints as more clinically relevant and useful, caveats aside, in making cross-trial comparisons—at least on the efficacy front.

That said, we see fewer insights into safety/ tolerability dynamics, which arguably will have the greater impact on sales and remain an ongoing focus of debate. Indeed, despite management's optimism at the start of '23, our experts believe aficamten is unlikely to escape Camzyos' REMS, which has been a major impediment to uptake. It's challenging, though, to project what a label could look like, with uncertainty over how FDA will weigh the 3.5% incidence of LVEF<50%—as well the greater monitoring in SEQUOIA—vs. the drug's admittedly improved PK/PD. Our FDA KOLs also warned real-world and trial data from Camzyos (esp the death in VALOR) could also factor into the decision. Two vs. 4 echos/year may well advantage afi over Camzyos, but we are concerned regulators may err on the side of caution given the potential for fatal outcomes (see our FDA call takes). But absent clear, supportive feedback from regulators, with submissions not planned until 2H24, a definitive answer may not come until 2025.

Abbreviations

OM: omecamtiv mecarbil

CRL: Complete Response Letter

ACC: American College of Cardiology conference

ESC HF: European Society of Cardiology Heart Failure conference

pVO2: peak oxygen uptake

KOLs: key opinion leaders

oHCM: obstructive hypertrophic cardiomyopathy

BIC/ FIC: best-in-class/first-in-class

NYHA: New York Heart Association

KCCQ: Kansas City Cardiomyopathy Questionnaire

LVEF: left ventricular ejection fraction

Esperion Therapeutics, Inc.

ESPR US – Rating: BUY (C-1-9) | PO: 4.00 USD | Price: 2.99 USD

Despite regulatory progress, 2023 dominated by milestone dispute

Esperion entered 2023 on a high note, having just announced its CV outcomes study for bempedoic acid (BA), CLEAR, was positive, providing a path towards label expansion—the next step towards completing a turn-around for the lipid lowering franchise. Admittedly, the results, presented at ACC arguably underwhelmed, the 13% relative risk reduction falling short of the 15% investors were looking for (see our CLEAR takes). That said, it was EU partner DSE's unwillingness to pay a $300M milestone, and Esperion's following civil suit, that dominated the story, contributing to significant Cytokinetics, Inc (CYTK) share underperformance (YTD -52% vs. NBI +4%). Heading into the dispute, we were cautious on BA, where even prior to ACC, our KOLs were skeptical it could capture meaningful share occupying a place in the paradigm after established, generic statins but ahead of the PCSK9s—an outlook confirmed by our prescriber survey (see our survey results). That said, following discussions with our legal experts (see their feedback on the trial) and our financial analysis (see our scenario review), we saw strong likelihood of a settlement, supporting our near-term positive outlook.

Civil case heads towards inflection, though settlement still looks likely

Not surprisingly, 2024 looks to be a pivotal year for Esperion given the need to address the Balance Sheet, the capital critical for its re-launch plans and the Oberland RIPA (as of 3Q, the remaining redemption amount stands at $377M). We'd argue the lawsuit is headed towards a near-term inflection. Admittedly, our legal experts were divided on the Court's decision to allow a motion for judgement under 12(c). While most felt the ruling was positive for Esperion given how infrequently these are granted, suggestive the judge sees at least some merit to its arguments. That said, many cautioned the Court needs to find a complete lack of contractual ambiguity to rule for the plaintiff—a high bar, in their view. Rather, these KOLs expect the Court to wait for the expert testimony during the trial (April 15). Still, they conceded the judge could signal his concerns, which would give Esperion's team time to address the uncertainties during the proceedings.

Ultimately though, while handicapping the outcomes of litigation is challenging, with DSE's goals somewhat unclear (the company has publicly highlighted BA's potential and made clear commercial inroads), should signals favoring Esperion continue to build, we wouldn't be surprised if support for a settlement also grows.

Overlooked, re-launch set to start—even as we question upside

While somewhat obscured by the trial, Esperion remains focused on BA's relaunch. ESPR shares have meaningfully traded up since Dec (+125% vs. NBI +13%) following FDA's unexpected decision to expand the labels, though the update does little to open access. But while we think few on the Street expected regulatory pushback to CLEAR, removal of the qualifier "maximally tolerated" for statin use may indicate the agency will similarly exclude "history of statin intolerance", even as it was an entry requirement for CLEAR.

The recent strength certainly speaks to investor interest in BA, although for all the reasons described above, we are cautious. We don't disagree the drug may play an important role in the treatment paradigm, but with 1) the primary prevention market challenging to access (see *Kim CJ, Annals of Internal Medicine, Dec '23* for a recent analysis); 2) access to PCSK9s expanding; 3) a limited sales force; and 4) multiple competitors advancing late-stage assets, it's not clear to us how much share BA can ultimately capture.

Abbreviations
BA: bempedoic acid
CV: cardiovascular
ACC: American College of Cardiology conference
DSE: Daiichi Sankyo Europe
KOLs: key opinion leaders
PCSK9s: proprotein convertase subtilisin/kexin type 9s
RIPA: Revenue Interest Purchase Agreement

Insmed, Inc.

INSM US – Rating: BUY (C-1-9) | PO: 37.00 USD | Price: 30.99 USD

What we expect in 2024: Arikayce outlook remains positive

Despite a tough macro environment, INSM shares outperformed in 2023 (INSM +55% vs. +4% NBI), with investors largely warming to the story. In our view, much of this was driven by sole commercial asset Arikayce. Although initial '23 guidance underwhelmed, sales impressed—in-line with our positive outlook—and are on pace to achieve Y/Y growth of +24% cons/ +26% BofA, a signal we'd argue, pandemic-related headwinds are abating while side-effect mitigation strategies have proven effective. That said, easily the biggest catalyst was the success of phase 3b ARISE, conducted to identify a PRO—a necessary regulatory step for 1L expansion (see our takes on ARISE). Despite the drug's clear efficacy, there was evidently uncertainty over whether it would translate into patients "feeling better," an overhang definitively addressed given the strength of the data, providing, in our view, a straightforward regulatory path to 1L (see our thoughts on 1L).

Looking to 2024, we expect Arikayce's growth to again outpace expectations (BofA: $386M vs. $378M cons). Indeed, as COVID-19 related issues further decline, we see opportunities for growth, especially in Japan where 1) incidence of R/R NTM-PD is ~20% higher; 2) the population is older; and 3) pricing issues have been resolved. We wouldn't be surprised if management guides conservatively again (we expect '24 outlook later this week), but supported by our positive channel checks, we remain positive.

Key readouts for brensocatib and TPIP capable of driving a re-rating

While Arikayce should anchor the near-term commercial story, the bigger drivers of our positive thesis are brensocatib and TPIP, both of which, in our view, offer compelling, underappreciated upside—with 2024's readouts capable of driving significant share performance.

Arguably ASPEN, brensocatib for NCFB (2Q24), is top of mind for most. Admittedly, there is uncertainty given 1) the lack of a consistent dose dependent response in the phase 2 WILLOW: though 10mg lowered the incidence-rate ratio to 0.64 (P=0.04), the 25mg arm missed (0.75; P=0.17); 2) the unpredictability of PEs, with timing non-linear; and 3) concerns of reaching the P=0.01 needed in lieu of running two phase 3s.

That said, we and our KOLs, see reasons to be encouraged, namely: 1) brenso reduced 3 different NSPs in the CF phase 2 in a dose-dependent manner; 2) the switch to rate of PE over 52 weeks as the primary endpoint vs. time to first PE in WILLOW offers a more real-world endpoint, in our view; 3) Insmed's powering assumptions, which included enrolling 1.7k participants; and 4) a thus far blended PE rate of 1.12-1.15 events/ patient/ year—in line with expectations/ what was observed in WILLOW and well below the 1.37 rate observed in the phase 2's placebo arm.

We also look for updates from TPIP's phase 2/3 in PH-ILD 2Q24. Initially overlooked, we suspect there's growing interest after Insmed reported solid preliminary safety/ efficacy data, with >80% reaching the top 640µg dose (see our takes on TPIP). While it's too early to judge whether the treprostinil pro-drug is indeed the "category killer" management maintains, we see potential for differentiation from United's Tyvaso/DPI (Greg Harrison).

In addition, Insmed also expects to present data from the first patient from its DMD gene therapy in 1H24, which should offer early insights into its new platform. Given the early stage of the program, with the landscape arguably becoming increasingly competitive, we don't think this by itself will calm investor concerns about the so-called Pillar 4 becoming a distraction. Still, it could help support management's claims about the technological capabilities of its new platforms ahead of further de-risking.

Abbreviations
R/R: relapsed/ refractory
MAC: mycobacterium avium complex
NTM-PD: non-tuberculosis mycobacteria pulmonary disease
1L: frontline
OUS: outside of the US
DPP-1: dipeptidyl peptidase 1 inhibitor
CF: cystic fibrosis
PRO: patient reported outcome
NCFB: non-cystic fibrosis bronchiectasis
TPIP: treprostinil palmitil inhalation powder
PAH: pulmonary arterial hypertension
PH-ILD: pulmonary hypertension with interstitial lung disease
QoL-B: quality of life bronchiectasis score
FDA: Food and Drug Administration
PE: pulmonary exacerbations
DPI: dry powder inhaler
NSP: neutrophil serine proteases
DMD: Duchenne muscular dystrophy

Kura Oncology, Inc.

INSM US – Rating: BUY (C-1-9) | PO: 37.00 USD | Price: 30.99 USD

What we expect in 2024: progress on combinations likely key focus

Kura outperformed in 2023 (+16% vs. +4% NBI). Admittedly, while sentiment at the year's start was weighed by a mixed 2022 ASH, we thought management executed well—with investors clearly re-engaging. In our view, data at EHA impressed, with lead asset menin inhibitor ziftomenib achieving a robust CR of 35% in *mNPM1* R/R AML; this together with positive readthroughs from rival Syndax (see our Syndax company profile below) arguably renewed confidence in the MoA after some early questions and safety issues gave some pause.

In our view, the outlook for ziftomenib—as well as Syndax's revumenib—look favorable, with opportunities for both, at least near-term in R/R disease; that said, based on early readouts, our KOLs have signaled ziftomenib's tolerability may advantage it in combos with established agents—likely required to expand into 1L/ maintenance (see our Kura initiation). In 2024, we look for greater insights not only clinically but commercially with Syndax potentially able to launch in *KMT2Ar* R/R disease; and while it may not completely clarify dynamics, it could well drive a re-rating of either or both companies.

Updates should come early, beginning with the first combination insights from Kura's KOMET-007 in AML, with the company guiding to data on the first ~20 patients Jan/ Feb (see our San Diego Bus Tour update). The trial, which pairs zifto with 7+3 chemotherapy regimen 1L and ven + aza in R/R disease for both *KMT2Ar* and *NPM1*m AML, should provide a peak into both efficacy and safety. For the latter, we expect acute focus on levels of DS. Recall a patient death in *KMT2Ar* AML resulted in FDA leveling a temporary clinical hold in 2021—and Kura ceasing development as a monotherapy in this subtype. DS is admittedly a two-sided issue, while a clear and potentially fatal AE, it's also a common sign of efficacy and generally well-managed at low levels. If a zifto combo is better tolerated in R/R *KMT2Ar* AML, where SoC can theoretically de-bulk the tumor and limit DS, we think it could go a long way towards reassuring investors over the longer-term potential of Kura's program. Based on management feedback, we think a win here would include DS largely limited to grade 1-2, low rates of dose-reductions and/ or interruptions, and minimal/ a lack additive myelosuppression related AEs beyond that associated with SoC options.

Beyond '007, Kura also plans to initiate KOMET-008, its zifto combo study of FLAG-IDA, LDAC, and gilteritinib, in *NPM1*m and *KMT2Ar* R/R AML as well as its post-transplant maintenance program in 1Q24.

FTI program offers potential downside support, with intriguing upside

Somewhat overlooked, we see underappreciated downside support from Kura's FTI platform, which includes tipifarnib and next-gen KO-2806. Admittedly, we're somewhat cautious given the checkered history of the class. Still, early updates from AACR-NCI-EORTC and ESMO (see our ESMO data takes) encouraged, with collaborations with Mirati/ Bristol's (covered by Geoff Meacham) adagrasib in NSCLC (initiation planned mid-24) and Exelixis' (Jason Gerberry) cabozantinib in ccRCC (FIT-001 phase 1 ongoing) offering a clear path forward. We recognize concerns over the potential for the FTIs to become a distraction, as well as broader questions over the MoA, (our KOLs believe it to be disadvantaged vs. kinase inhibitors); still, given high unmet need across a number of indications, the program could well become a solid P&L contributor, albeit likely less extensive vs. the menin inhibitor platform.

Abbreviations
AML: acute myeloid leukemia
CR/CRh: complete remission/ CR with partial hematologic recovery
***KMT2Ar*/ *NPM1*m**: genotypic subclasses
R/R: relapsed/ refractory
MoA: mechanism of action
DS: differentiation syndrome
AEs: adverse events
SoC: standard of care
FLAG-IDA: fludarabine, cytarabine, idarubicin and G-CSF
LDAC: low-dose cytarabine
FTI: farnesyl transferase inhibitor
PK/ PD: pharmacokinetic/ pharmacodynamic
KOLs: key opinion leaders
NSCLC: non-small cell lung cancer
ccRCC: clear cell renal cell carcinoma
ESMO: European Society for Medical Oncology
1L: frontline
AACR-NCI-EORTC: American Association for Cancer Research, the National Cancer Institute, and the European Organization for Research and Treatment of Cancer

Reneo Pharmaceuticals, Inc.

RPHM US – Rating: UNDERPERFORM (C-3-9) | PO: 1.45 USD | Price: 1.60 USD

What we expect in 2024: Despite promise, pivotal fails, leaving path ahead uncertain

Reneo ended 2023 on a clear down note, leaving the outlook for this year uncertain. Though admittedly a higher risk program, we thought there were more reasons than not to be optimistic heading into the STRIDE topline, where beyond the mechanistic rationale, there was good clinical support from earlier phase studies; positive KOL feedback; the thoughtful pivotal design (see our STRIDE readout takes); and interest from other developers working on the same mechanism (Astellas). Absent further analyses, it's challenging to speculate on potential explanations for the trial's failure. More importantly though, the seeming lack of positive numerical trends, including across different major subgroups (including geography, subgroup, disease severity), raises substantive questions over Reneo's underlying premise: i.e., using PPARδ agonists to increase fatty-acid metabolism to provide clinical benefit to those with PMM.

Reneo is undertaking a complete analysis of STRIDE before meeting with the board to decide next steps, which we certainly think prudent given the situation/ circumstances. To be fair, the company has several options to weigh. Indeed, despite the setback in PMM, mavodelpar has physiological activity and, just as importantly, appears safe having seemingly passed FDA's required two-year rodent carcinogenicity test. Moreover, the company has a library of early-stage PPARδ agonists, which it intended to advance had mavodelpar established PoC in other indications (e.g., LC-FAOD). The class has also been investigated in other metabolic diseases (e.g., type 2 diabetes), and we similarly note developers like CymaBay (CBAY; not covered) have recently established efficacy in PBC.

But while other exploration is certainly conceivable given ~$100M remaining on the balance sheet, other strategic options may well include a divesture of the portfolio. Ultimately, we look for greater insights during the first part of the year as the company regroups and completes a complete analysis of STRIDE.

Abbreviations
KOL: key opinion leader
PPARδ: peroxisome proliferator-activated receptors-delta
PMM: Primary Mitochondrial Myopathy
LC-FAOD: long chain fatty acid oxidation disorder
PoC: proof-of-concept
PBC: primary biliary cholangitis

Syndax Pharmaceuticals, Inc.

SNDX US – Rating: BUY (C-1-9) | PO: 29.00 USD | Price: 21.61 USD

2024: revumenib, axatilimab commercialization likely to drive upside

2023 was not without its challenges for Syndax, which saw its shares largely trailing (YTD -15% vs. +4% NBI). While some of this was no doubt driven by macro issues and broader concerns over risk, in our view questions over the menin inhibitor class easily weighed (see our Syndax initiation). That said, we thought the company ended '23 on a high-note, with momentum building after a successful ASH conference that saw shares bounce back after the AUGMENT-101 Oct update somewhat disappointed.

Looking ahead though, we see opportunities for meaningful upside in 2024 as Syndax transitions to a commercial entity with likely approvals for 1) revumenib for R/R *KMT2Ar* acute leukemias (Breakthrough designation, ROTR) and 2) axatilimab, partnered with Incyte (covered by Tazeen Ahmad), for cGvHD (Orphan Drug designation). Indeed, especially for revumenib, we see strong near-term upside given the lack of available treatment options; challenges addressing the *KMT2Ar* subtype; and strong prescriber interest—the basis of our positive outlook on the name (2025e unadjusted: $129M BofA vs. $75M cons). Admittedly, uptake for CSF-1R inhibitor axatilimab may not be as robust given its likely position in the treatment paradigm (i.e., refractory patients), with its formulation (non-oral) possibly limiting use, at least initially, in the community setting. Still, leveraging Incyte's infrastructure, we look for solid performance that should offer meaningful longer-term downside protection (2025e revs: $37M BofA vs. $27M cons).

Clinical updates likely to clarify long-term revumenib picture

At the same time, clinical updates on the menin front should start to clarify the competitive position of revumenib relative to Kura's ziftomenib—which we'd argue is increasingly becoming the focal point of investor debate. Among key readouts:

Efficacy in R/R NPM1m leukemia: While early data suggested ziftomenib had greater monotherapy activity for R/R *NPM1m* leukemias (CR/CRh 35%), recent updates from Syndax suggest revumenib's efficacy may be closer to 27%—based on a more conservative assessment of the denominator—vs. 21% prior. Regardless, registrational data from Syndax's AUGMENT-101 in this population is likely to read-out 4Q24, more or less in-line to slightly earlier than rival Kura's KOMET-001, where we expect the topline likely early 2025 based on management's 1H24 enrollment completion guidance—with potential implications for the near-term commercial picture if these rates hold.

What do the relative combinations look like? Easily of greater focus, though, is how each agent combines with available therapies, key to expanding into 1L/ maintenance while bolstering R/R efficacy (see our ASH preview). Based on early data, our KOLs felt zifto may be advantaged. Indeed, while SAVE and BEAT AML both impressed at ASH, rates of myelosuppression and QTc prolongation may pose challenges if ziftomenib ultimately proves to be relatively more tolerable (see our takes from SAVE and our investor presentation takes). Here we look for greater clarity in 2024, starting with preliminary data 1Q from ~20 participants from Kura's KOMET-007 for ven + aza and 7+3 (see our KURA company profile above).

Abbreviations
SoC: standard of care
ASH: American Society of Hematology
KMT2Ar*/ *NPM1m: genotypic subclasses
1L: frontline
CSF-1R: colony stimulating factor-1 receptor
cGvHD: chronic graft vs host disease
AML: acute myeloid leukemia
ALL: acute lymphoblastic leukemia
MPAL: mixed phenotype acute leukemia
QTc: corrected QT interval
FIC: first in class
BLA: Biologics License Application
IPF: idiopathic pulmonary fibrosis
CR/CRh: complete remission/ CR with partial hematologic recovery
FLA: fludarabine-cytarabine
ROTR: Real-Time Oncology Review

Werewolf Therapeutics, Inc.

HOWL US – Rating: BUY (C-1-9) | PO: 10.00 USD | Price: 3.86 USD

2023: Despite early skepticism, Werewolf executes to outperformance

In contrast to 2022, Werewolf was one of the stronger performers of 2023, concluding the year well above peers (+88% vs. NBI +4%). Admittedly sentiment at the end of '21 was weighed—unfairly in our view—by negative read-throughs from other cytokine-focused programs (e.g., Nektar, Sanofi). That said, Werewolf arguably did a solid job executing over the past 12 months, with investors starting to take note of the company's intriguing—in our opinion—platform that we have long viewed as having underappreciated upside. Key '23 highlights include: 1) presenting initial dose-escalation phase 1/1b data from IL-2 INDUKINE '124; 2) moving IL-12 INDUKINE '330 into the clinic; and 3) advancing new assets, IL-21 ('712) and IL-18 ('518) INDUKINEs into pre-clinical development—all while maintaining good fiscal discipline (sufficient runway remains through at least 4Q24). In addition, partner Jazz (Jason Gerberry) also initiated a phase 1 of IFN-a INDUKINE JZP898, further evidence regulators are comfortable with the company's proprietary conditional active "masking" technology.

What we expect in 2024: early momentum positions name favorably

Pivoting to 2024, we look for Werewolf to build on its momentum towards a potential re-rating. Indeed, inasmuch as the SITC presentation provided hints of activity—especially impressive in I/O refractory patients (see our takes from the '124 presentation)—we think the bigger takeaway was good safety, including notably no cases of vascular leak syndrome or DLTs (our initial review of the safety data), issues limiting broad use of native IL-2 and a very encouraging sign the "mask" is limiting off-target activation.

Management has guided to additional data 1H24, with the update to include the RDE and the opening of the expansion arms (monotherapy and Keytruda combos). While additional positive safety signals should give investors greater comfort, we think good efficacy insights could be appreciably stock moving, especially if responses increase and deepen in the 18mg cohort (3/5 at 12mg saw their tumors shrink). Indeed, even in more sensitive tumors, I/O refractory patients remain challenging to treat, representing an attractive opportunity, should '124's durability similarly prove solid.

We also look for initial data on the '330 dose-escalation phase 1 sometime in 2024. In our view, the molecule could be a game-changer, where despite high expectations for the potent T-cell and macrophage activator, significant toxicities have derailed use of the native IL-12. Should the early signals resemble what was seen for '124, we could see further meaningful upside to share performance.

With development plan critical, rationale may also be de-risking

Possibly just as reassuring as positive data are insights into the company's next development steps. Indeed, we'd argue one the more challenging decisions ahead for Werewolf is selecting the right/ optimal tumors to investigate, at least initially. Fair or not, given the novelty of the platform and the history of the modality, we suspect skepticism on the Street will persist until the company establishes both clinical evidence and regulatory support—placing high importance on the design of its first pivotal studies. And while focusing on RCC and melanoma for '124 certainly makes sense given IL-2's established efficacy, the path for other cytokines is less clear. For these reasons, we wouldn't overlook the upside potential of cogent rationale from management on its nearer-term strategy.

Abbreviations

IL-2: interleukin 2
IL-12: interleukin 12
IL-21: interleukin 21
IL-18: interleukin 18
IFN-a: interferon-alpha
I/O: immuno-oncology
SITC: Society for Immunotherapy of Cancer
DLTs: dose-limiting toxicities
RDE: recommended dose for expansion
MTD: maximally tolerated dose
RRC: renal cell carcinoma

Abbreviations:

1L: frontline

6MWD: 6-minute walk distance

AACR-NCI-EORTC: American Association for Cancer Research, the National Cancer Institute, and the European Organization for Research and Treatment of Cancer

ACC: American College of Cardiology

AdV: adenovirus

AEs: adverse events

ALL: acute lymphoblastic leukemia

allo-HCT: allogeneic hematopoietic cell transplant

AML: acute myeloid leukemia

ASCO GI: American Society of Clinical Oncology Gastrointestinal Cancers Symposium

ASH: American Society of Hematology conference

BA: bempedoic acid

BIC: best-in-class

BLA: biologics license application

ccRCC: clear cell renal cell carcinoma

CD73: Cluster of Differentiation 73

CF: cystic fibrosis

cGvHD: chronic graft vs host disease

CMI: cardiac myosin inhibitor

CR/CRh: complete remission/ CR with partial hematologic recovery

CRL: Complete Response Letter

CSF-1R: colony stimulating factor-1 receptor

CTLA-4: cytotoxic T-lymphocyte associated protein 4

CV: cardiovascular

CVR: contingent value right

DLTs: dose-limiting toxicities

DMD: Duchenne muscular dystrophy

DPI: dry powder inhaler

DPP-1: dipeptidyl peptidase-1

DS: differentiation syndrome

DSE: Daiichi Sankyo Europe

EMA: European Medicines Agency

ESC HF: European Society of Cardiology Heart Failure conference

ESMO: European Society for Medical Oncology conference

FDA: Food and Drug Administration

FLA: fludarabine-cytarabine

FLAG-IDA: fludarabine, cytarabine, idarubicin and G-CSF

FIC: first-in-class

FTIs: farnesyltransferase inhibitors

FVC: forced vital capacity

HCC: hepatocellular carcinoma

HFpEF: heart failure with preserved ejection fraction

HIF-2a: hypoxia inducible factor-two alpha

HNSCC: head and neck squamous cell carcinomas

HR: hazard ratio

IL: interleukin

I/O: immuno-oncology

IPF: idiopathic pulmonary fibrosis

IRA: Inflation Reduction Act

KCCQ: Kansas City Cardiomyopathy Questionnaire

KRAS: Kristen Rat Sarcoma Viral oncogene homolog

KOL: key opinion leader

LAG3: Lymphocyte-Activation Gene 3

LC-FAOD: long chain fatty acid oxidation disorder

LDAC: low-dose cytarabine

LT: long-term

LVEF: left ventricular ejection fraction

MAC: mycobacterium avium complex

MoA: mechanism of action

MPAL: mixed phenotype acute leukemia

MTD: maximally tolerated dose

NCFB: non-cystic fibrosis bronchiectasis

NDA: new drug application

NIC: next-in-class

NPM1m/ KMT2Ar: mutational subtypes in leukemia

NSCLC: non-small cell lung cancer

NSP: neutrophil serine proteases

NTM-PD: non-tuberculosis mycobacteria pulmonary disease

NYHA: New York Heart Association functional classification

OBAD: optimum biologically active dose

oHCM: obstructive hypertrophic obstructive cardiomyopathy

OM: omecamtiv mecarbil

ORR: objective/ overall response rate

OS: overall survival

OUS: outside of the US

PAH: pulmonary arterial hypertension

PBC: primary biliary cirrhosis

PCSK9s: proprotein convertase subtilisin/kexin type 9s

PD-(L)1: programmed death-(ligand) 1

PDAC: pancreatic ductal adenocarcinoma

PDUFA: Prescription Drug User Fee Act

PE: pulmonary exacerbations

PH-ILD: pulmonary hypertension – interstitial lung disease

PIK3CA: phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha

PFS: progression free survival

PK/PD: pharmacokinetic/ pharmacodynamic

PMM: Primary Mitochondrial Myopathy

PoC: proof-of-concept

PPARδ: peroxisome proliferator-activated receptor delta

PRO: patient reported outcome

pVO2: peak oxygen uptake

PVR: pulmonary vascular resistance

QD: once daily dosing

QID: four times daily dosing

QTc: corrected QT interval

QoL-B: quality of life bronchiectasis score

R/R: relapsed/ refractory

RCC: renal cell carcinoma

RDE: recommended dose for expansion

RIPA: Revenue Interest Purchase Agreement

ROTR: Real-Time Oncology Review

SITC: Society for Immunotherapy of Cancer

SoC: standard of care

TIGIT: T cell immunoreceptor with Ig and ITIM domains

TPIP: treprostinil palmitil inhalation powder

vHC: virus-associated hemorrhagic cystitis

Price objective basis & risk

AlloVir, Inc. (ALVR)

Our 12-month price objective (PO) is based on our NPV analysis of revenue forecasts and estimated margin assumptions. We model posoleucel for treatment of BKV in kidney transplant patients (LOS 15%) starting globally in 2026. In addition, we assume a collective value for the pipeline. Given a WACC of 14%, in line with peers of similar size and risk, and a terminal growth rate between -10% and -12.5%, based on the development timeline, we estimate a value of $1/ share PO, supporting our U/P rating.

Upside risks to our PO:
1) clear insights into posoleucel setbacks with an addressable near-term path forward, 2) robust activity of posoleucel in kidney transplant/ SOT, 3) success/ advancement of the early-stage pipeline, including ALVR106 and '1072, 4) favorable pricing/ commercial support from payers/ transplant centers, and 5) rapid uptake/ adoption

Downside risks to our PO:

1) lack of insight into posoleucel's phase 3s in allo-HSCT, 2) negative readthroughs to the SOT platform, 3) unsuccessful expansion into additional indications/ success of early-stage pipeline, 4) unfavorable pricing/ commercial support, 5) modest uptake/ adoption by transplant centers, and 6) competition from other anti-viral or cell therapy developers

Arcus Biosciences (RCUS)

Our 12-month price objective (PO) is based on our NPV analysis of revenue forecasts and estimated margin assumptions. We forecast sales of dom (anti-TIGIT), etruma (anti-A2a/A2b receptor), and zim (anti-PD-1), with profits and royalties distributed in accordance with partnership agreements. This includes sales of dom adjusted by an LOS range of 30-45% (vs. 20-30% prior) by indication, etruma (LOS: 15-20%) and zim (LOS: 15-45%). Given a WACC of 12% and a terminal growth rate ranging from 0% to -50%, we estimate a value of $2/ share for the partnerships ($5/sh for dom, $2/sh for zim, $1/sh for etruma, $9/sh for licenses/ milestones). Together with $13/sh for net cash and $1/sh for the pipeline, our PO is $23/ share.

Upside risks to our PO: 1) validation of clinical targets, 2) clear signals of clinical efficacy with good tolerability, 3) similar robust signals from the early pipeline, 4) expansion of collaboration deals for these assets, 5) accelerated regulatory timelines, and 6) strong commercial support from payers and providers

Downside risks to our PO: 1) clinical trial failures, 2) emergence of meaningful safety risks likely to pose regulatory and/or commercial headwinds, 3) limited signs of synergistic efficacy of combo regimens,4) regulatory delays, 5) competition from other players, 6) financial risks due to available cash to fund activities, 7) commercial pushback from payers and providers, and 8) current partners opting to discontinue their collaborations.

Cytokinetics, Incorporated (CYTK)

Our PO of $85 is based on our NPV analysis of revenue forecasts and estimated margin assumptions. We forecast probability adjusted sales of the late-stage pipeline with profits/ royalties distributed for Astellas and Ji Xing partnerships. This includes OUS milestones/ royalties for OM for HFrEF with a LoS of 30% and aficamten for oHCM, nHCM, and HFpEF with a weighted average LoS of 93%. Given a WACC of 7%, in line with peers of similar size and risk, and a terminal growth rate from -5% to -40% based on the molecule, we estimate $2/sh for OM and $74/sh for aficamten. Together with $6/sh for net cash and $3/sh for the early pipeline we derive a PO of $85/sh PO.

Upside risks to our PO: 1) complete SEQUOIA data suggesting best in class potential for aficamten, 2) accelerated regulatory timelines, 3) strong commercial support from providers and payers, including inclusion in guidelines, and 4) continued partnerships across the portfolio.

Downside risks to our PO: 1) low to zero OUS milestones/ royalties for OM, 2) complete SEQUIOA data that suggests aficamten is less competitive, 3) emergence of meaningful safety risks across the pipeline, posing regulatory and/or commercial headwinds, 4) regulatory delays, 5) competition from other players, 6) financial risks due to available cash to fund activities, and 7) commercial pushback from payers and providers.

Esperion (ESPR)

Our 12-month price objective (PO) is based on our NPV analysis of revenue forecasts and estimated margin assumptions. We forecast sales of bempedoic acid with a terminal growth rate of -50%, supplemented by milestones and ROW royalties with a terminal growth rate of -50%. Given a WACC of 8% in-line with similar commercial-stage biotechs, we estimate a PO of $4.00/ share.

Upside risks to our PO:
1) favorable resolution of the milestone dispute with DSE, 2) near-term label expansion to reflect CLEAR Outcomes, 3) strong support from (esp) community-based providers to broadly administer BA to patients, 4) expanded payer coverage, 5) robust adoption and growth OUS, supporting royalty growth and milestones, and 6) pipeline success, including an oral PSCK9 inhibitor and a next gen ACLY inhibitor.

Downside risks to our PO:
1) unfavorable resolution of milestone agreement with DSE, 2) label expansion delays, 3) slow uptake among prescribers, especially those in community settings, 4) payer pushback, including poor formulary positioning and use restrictions, 5) underwhelming uptake OUS, limiting royalties/ collaboration milestones, 6) competition from other lipid modifying therapies, and 7) difficulties securing funding to support commercial and development activities.

Insmed Incorporated (INSM)
Our 12-month PO is based on our NPV analysis of revenue forecasts assumptions. We model sales of Arikayce for refractory NTM-PD and frontline expansion (modified by a LOS of 80%). We assume a collective value for the pipeline: Brensocatib in NCFB (LOS: 65%), with potential expansion into CF (LOS: 20%), CRSsNP, and HS (LOS: 15%) and TPIP for PAH and PH-ILD (LOS: 50%). Given a WACC of 15%, in line with peers of similar size and risk, and a terminal growth rate of -10%, -40%, we estimate a value of $12/sh for Arikayce, $18/sh for Brensocatib, $8/sh for TPIP, $0.62/sh for the early pipeline, and $-2/sh for net cash, resulting in $37/sh.

Upside risks: 1) Arikayce full approval, 2) validation of Brensocatib in phase 3, with strong clinical efficacy and no safety concerns, 3) robust efficacy/ safety profile for TPIP in PAH and PH-ILD, 4) growth of translational medicine pipeline, including on-track IND-approvals, and 5) indications of strong commercial support from payers/ community-based providers.

Downside risks: 1) failure to achieve full approval/ commercial expansion of Arikayce in the EU and Japan, 2) failure to meet safety/ efficacy profile in Brensocatib (phase 3), especially due to meaningful infection risk, 3) marginal tolerability improvements, diminished efficacy, and/ or lack of differentiation of TPIP, 4) competition from disease modifying PAH agents, 5) failure of translational medicine pillar, 6) regulatory delays, and 7) commercial pushback from payers/providers.

Kura Oncology (KURA)
Our 12-month price objective (PO) is based on our NPV analysis of revenue forecasts and estimated margin assumptions. We model ziftomenib with the first approval in NPM1m R/R AML in 2025 (LOS 65%), followed by 1L NPM1m in 2028 (LOS 40%), and 1L KMT2Am in 2029 (LOS 30%). We also model tipifarnib in HNSCC with a LOS of 40%. We assume a collective value for the pipeline. Given a WACC of 10%, in line with peers of similar size and risk, and a terminal growth rate between -25% and -50%, based on the timeline, we estimate a value of $31/ share PO, supporting our Buy rating.

Upside Risks to our PO
1) initial approval of ziftomenib in R/R NPM1m AML, 2) by robust efficacy in frontline, 3) favorable efficacy/ safety profile in 1L KMT2Ar AML, 4) durable response in maintenance AML 4) competitive safety and administrative profile, 5) tolerable safety profile of tipifarnib combinations, with no evidence of overlapping TEAEs, and 6) strong commercial support from payers/ community-based providers to broadly administer portfolio candidates.

Downside Risks to our PO
1) failure to achieve approval for ziftomenib in R/R NPM1m AML, 2) poor risk/ benefit of

KMT2Ar AML beyond R/R, especially due to emergence of meaningful DS, 3) lack of clinically meaningful efficacy in frontline and/ or maintenance settings, 4) limited differentiation between ziftomenib and revumenib, 5) DLTs associated with tipifarnib combos, 6) regulatory delays, and 7) commercial pushback from payers and providers.

Reneo Pharmaceuticals (RPHM)

Our 12-month price objective (PO) is based on our SOTP NPV analysis, which reflects our revenue and margin assumptions. We forecast cash/equivalents of $100M reduced by an estimated $75M operating expenses in 2024, even after accounting for the 70% reduction in FTEs. Together with a modest value of the pre-clinical pipeline (assuming a 2029 launch with an LoS of 5%), a WACC of 20% (in line with peers of similar size/ risk), and a terminal growth rate of -10%, we estimate PO of $1.45, supporting our U/P rating.

Upside risks: 1) signs of efficacy of mavodelpar in PMM (e.g., an unrecognized subgroup), 2) identification of an alternative indication for the early-stage pipeline, and 3) ability to raise additional cash

Downside risks: 1) greater than expected cash spend, 2) inability to identify an alternative indication, and 3) failure of the early-stage pipeline/ assets (e.g., limited efficacy, high tox)

Syndax Pharmaceuticals (SNDX)

Our 12-month price objective (PO) is based on our NPV analysis of revenue forecasts and estimated margin assumptions. We model revumenib with the first approval in KMT2Ar R/R ALL/ AML in 2024 (LOS 85%), followed by NPM1m in 2025 (LOS 65%), and expansion into the frontline: KMT2Ar (2028: LOS 45%) and NPM1m (2029: LOS 40%). We also model axatilimab in R/R cGVHD in 2024 with a LOS of 85%. We assume a collective value for the pipeline. Given a WACC of 10%, in line with peers of similar size and risk, and a terminal growth rate between -10% and -50%, based on the molecule type, we estimate a value of $29/ share PO, supporting our Buy rating.

Upside Risks to our PO:
1) near-term approval of revumenib in KMT2Ar AML and ALL, 2) approval of axatilimab in cGVHD, 3) robust efficacy/ synergy of revumenib in combination with SoC induction therapy in 1L, 4) solid efficacy/ safety as a maintenance therapy with a clean combination profile, and 5) indications of strong commercial support from payers/community-based providers to broadly administer portfolio candidates.

Downside Risks to our PO:
1) failure to achieve full approval of revumenib in KMT2Ar acute leukemias, 2) failure to achieve approval of axatilimab in R/R cGVHD, 3) regulatory delays, 4) safety issues complicating the combination profile, especially QTc prolongation, 5) lack of clinically relevant activity in the maintenance setting, 6) competitive headwinds, and 7) commercial pushback from payers and providers.

Werewolf Therapeutics (HOWL)

Our 12-month price objective (PO) is based on our NPV analysis of revenue forecasts and estimated margin assumptions. We model sales of WTX-124 (IL-2 INDUKINE) in metastatic melanoma and RCC modified by a risk-adjusted likelihood of success of 25%. We also assume a collective value for the pipeline, which includes sales of '124 in other tumor types and potential revenues for WTX-330 (IL-12) and WTX-630 (IFN-a). Given a WACC of 12%, in line with peers of similar size and risk, and a terminal growth rate of -5%, we estimate a value of $3/sh for WTX-124, $4/sh for net cash, and $3/sh for the pipeline, resulting in $10/sh PO.

Upside risks: 1) validation of clinical synergies between CPIs and cytokines, 2) clear early signals of efficacy of WTX-124 in melanoma and RCC with good tolerability, 3) similar

robust signals from the pipeline (i.e., '330 and '613), 4) collaboration deals with established oncology players, 5) accelerated regulatory timelines, and 6) strong commercial support from payers and prescribers

Downside risks: 1) clinical trial failures of the pipeline, especially due to issues with the platform, 2) meaningful safety risks, posing regulatory and/or commercial headwinds, 3) limited signs of synergistic efficacy when paired with established oncology treatments, 4) regulatory delays, 5) competition from other modified cytokines, 6) financial risks due to available cash to fund activities, and 7) commercial pushback from payers and providers

Analyst Certification

I, Jason Zemansky, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or view expressed in this research report.

US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
	89bio, Inc	ETNB	ETNB US	Geoff Meacham
	Acumen Pharma	ABOS	ABOS US	Geoff Meacham
	Agios Pharmaceuticals	AGIO	AGIO US	Greg Harrison, CFA
	Amylyx Pharmaceuticals	AMLX	AMLX US	Geoff Meacham
	BioMarin	BMRN	BMRN US	Geoff Meacham
	BioXcel Therapeutics	BTAI	BTAI US	Greg Harrison, CFA
	BridgeBio Pharma	BBIO	BBIO US	Greg Harrison, CFA
	Bristol-Myers Squibb	BMY	BMY US	Geoff Meacham
	Caribou	CRBU	CRBU US	Geoff Meacham
	CRISPR Therapeutics	CRSP	CRSP US	Geoff Meacham
	Eli Lilly and Company	LLY	LLY US	Geoff Meacham
	Erasca	ERAS	ERAS US	Alec W. Stranahan
	Esperion	ESPR	ESPR US	Jason Zemansky
	Exscientia	EXAI	EXAI US	Alec W. Stranahan
	Gilead Sciences Inc.	GILD	GILD US	Geoff Meacham
	HUTCHMED	HCM	HCM US	Alec W. Stranahan
	Immatics	IMTX	IMTX US	Alec W. Stranahan
	Insmed Incorporated	INSM	INSM US	Jason Zemansky
	Intellia Therapeutics	NTLA	NTLA US	Greg Harrison, CFA
	Janux Therapeutics	JANX	JANX US	Geoff Meacham
	Keros	KROS	KROS US	Greg Harrison, CFA
	Kiniksa Pharmaceuticals, Ltd.	KNSA	KNSA US	Geoff Meacham
	Krystal Biotech	KRYS	KRYS US	Alec W. Stranahan
	Kura Oncology	KURA	KURA US	Jason Zemansky
	Kymera Therapeutics	KYMR	KYMR US	Geoff Meacham
	LianBio	LIAN	LIAN US	Geoff Meacham
	Liquidia Corporation	LQDA	LQDA US	Greg Harrison, CFA
	Lyell Immunopharma	LYEL	LYEL US	Geoff Meacham
	MeiraGTx	MGTX	MGTX US	Alec W. Stranahan
	Merck & Co.	MRK	MRK US	Geoff Meacham
	Mineralys Therapeutics	MLYS	MLYS US	Greg Harrison, CFA
	Neumora Therapeutics	NMRA	NMRA US	Geoff Meacham
	Rani Therapeutics	RANI	RANI US	Geoff Meacham
	Regenxbio, Inc.	RGNX	RGNX US	Alec W. Stranahan
	Rocket Pharmaceuticals, Inc.	RCKT	RCKT US	Greg Harrison, CFA
	Royalty Pharma	RPRX	RPRX US	Geoff Meacham
	Sana Biotechnology	SANA	SANA US	Geoff Meacham
	SpringWorks	SWTX	SWTX US	Alec W. Stranahan
	Syndax Pharmaceuticals	SNDX	SNDX US	Jason Zemansky
	Travere Therapeutics Inc	TVTX	TVTX US	Greg Harrison, CFA
	Turnstone Biologics	TSBX	TSBX US	Geoff Meacham
	Vertex Pharmaceuticals Inc.	VRTX	VRTX US	Geoff Meacham
	Werewolf Therapeutics	HOWL	HOWL US	Jason Zemansky
	Xencor	XNCR	XNCR US	Alec W. Stranahan
NEUTRAL				
	AbbVie	ABBV	ABBV US	Geoff Meacham
	Alector, Inc	ALEC	ALEC US	Greg Harrison, CFA
	Amgen Inc.	AMGN	AMGN US	Geoff Meacham
	Arcus Biosciences	RCUS	RCUS US	Jason Zemansky
	Beam Therapeutics	BEAM	BEAM US	Greg Harrison, CFA
	Biogen Inc.	BIIB	BIIB US	Geoff Meacham
	Cytokinetics, Incorporated	CYTK	CYTK US	Jason Zemansky
	Editas Medicine	EDIT	EDIT US	Greg Harrison, CFA
	IGM Biosciences	IGMS	IGMS US	Greg Harrison, CFA
	Johnson & Johnson	JNJ	JNJ US	Geoff Meacham
	Moderna	MRNA	MRNA US	Geoff Meacham
	Pfizer	PFE	PFE US	Geoff Meacham
	Recursion Pharmaceuticals, Inc.	RXRX	RXRX US	Alec W. Stranahan
	Revolution Medicines	RVMD	RVMD US	Alec W. Stranahan
	Tyra Biosciences	TYRA	TYRA US	Greg Harrison, CFA
	Vir	VIR	VIR US	Geoff Meacham
	Y-mAbs Therapeutics, Inc	YMAB	YMAB US	Alec W. Stranahan

US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
UNDERPERFORM				
	AlloVir, Inc.	ALVR	ALVR US	Jason Zemansky
	CureVac	CVAC	CVAC US	Geoff Meacham
	Day One Biopharmaceuticals	DAWN	DAWN US	Alec W. Stranahan
	Novavax	NVAX	NVAX US	Alec W. Stranahan
	Regeneron Pharmaceuticals Inc.	REGN	REGN US	Geoff Meacham
	Reneo Pharmaceuticals	RPHM	RPHM US	Jason Zemansky
	TG Therapeutics	TGTX	TGTX US	Alec W. Stranahan
	United Therapeutics Corporation	UTHR	UTHR US	Greg Harrison, CFA

Disclosures

Important Disclosures

Equity Investment Rating Distribution: Health Care Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships [R1]	Count	Percent
Buy	234	60.94%	Buy	115	49.15%
Hold	80	20.83%	Hold	36	45.00%
Sell	70	18.23%	Sell	29	41.43%

Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships [R1]	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
Hold	832	23.54%	Hold	454	54.57%
Sell	807	22.84%	Sell	383	47.46%

[R1] Issuers that were investment banking clients of BofA Securities or one of its affiliates within the past 12 months. For purposes of this Investment Rating Distribution, the coverage universe includes only stocks. A stock rated Neutral is included as a Hold, and a stock rated Underperform is included as a Sell.

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Investment rating	Total return expectation (within 12-month period of date of initial rating)	Ratings dispersion guidelines for coverage cluster[R2]
Buy	≥ 10%	≤ 70%
Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

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