BofA SECURITIES

# Cytokinetics, Incorporated

# Pressing reset on afi: KOLs see top-line as solid, but questions cloud commercial view

**Maintain Rating: NEUTRAL | PO: 85.00 USD | Price: 79.00 USD**

## Absent differentiation, price and REMS may decide winner

CYTK shares have been volatile after reports of an imminent take-out gave way to news the deal had fallen through (v. WSJ). We're not downplaying the acute need for de-risked assets by large-caps seeking to offset patent cliffs, but with management intimating it isn't seeking a buyer, we suspect investors are taking a renewed look at aficamten—with an eye towards its commercial potential—as the team mulls launching alone. Indeed, easily overlooked at the time, while SEQUOIA's solid top-line helped fuel the take-out narrative, its efficacy ($pVO_2$: +1.74 mL/ kg/min) and safety (LVEF<50%: 3.5%) were below levels our KOLs/ investors felt necessary to differentiate it from Bristol's (covered by Geoff Meacham) Camzyos, i.e., 1.8-2.0 and 1-2%, respectively.

To explore this topic and key focus points ahead of the data presentation (likely ESC-HF, May 11-14), we reviewed the top-line with our KOLs. Overall, while our experts were positive, they stopped short of calling the data a clear "home run". Indeed, while they wouldn't be surprised to see directional improvements vs. Camzyos' EXPLORER, they ultimately felt the two datasets would largely overlap. And while acknowledging afi's improved PK/ PD, lacking clear differentiation on efficacy, our KOLs felt commercial dynamics would largely come down to its REMS and pricing/ access. But given 1) skepticism afi's monitoring requirements will be less involved and 2) Bristol's improving competitive position, with growing evidence of long-term benefit (data at ACC, Apr 6-8 and ESC, Aug 30-Sept 2) and possibly a less restrictive REMS (see our FDA expert's takes), we continue to see uncertainties over Cytokinetics' ability to capture and grow share. Afi may well dominate, but until there's greater clarity, Maintain Neutral, $85 PO.

**Cytokinetics reports 4Q earnings today at 4pm ET; see its website for details**

## How much upside driven by afi itself… vs. trial design?

We'd argue much of the current debate centers on the extent to which SEQUOIA's design contributed to afi's performance. Indeed, while Cytokinetics was quick to stress effects were "consistent" regardless of background characteristics, our KOLs still foresee acute focus on the forest plots at the data presentation. We suspect much of the initial focus is on beta-blockers given the outsized benefit those not on treatment experienced in EXPLORER—with background use lower in SEQUOIA (61% vs. 76%; our SEQUOIA preview report). That said, as sharp-eyed investors likely noticed, patients in China (~16% of the study) outperformed in SEQUOIA ($pVO_2$: +2.38 mL/kg/min). With this cohort absent from EXPLORER (China was addressed in a separate trial), we wouldn't be surprised if further questions are raised, underscoring complexities in establishing either candidate as a clear winner.

| Estimates (Dec) (US$) | 2021A | 2022A | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|
| EPS | (2.80) | (4.33) | (4.79) | (4.22) | (3.41) |
| EPS Change (YoY) | -42.1% | -54.6% | -10.6% | 11.9% | 19.2% |
| Consensus EPS (Bloomberg) | | | (4.92) | (4.46) | (3.45) |
| DPS | 0 | 0 | 0 | 0 | 0 |
| **Valuation (Dec)** | | | | | |
| Free Cash Flow Yield* | -2.5% | -4.0% | -3.7% | -4.0% | -1.9% |

* For full definitions of *iQmethod*℠ measures, see page 16.



Timestamp: 27 February 2024 05:00AM EST

**27 February 2024**

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### Stock Data

| | |
|---|---|
| Price | 79.00 USD |
| Price Objective | 85.00 USD |
| Date Established | 27-Dec-2023 |
| Investment Opinion | C-2-9 |
| 52-Week Range | 25.98 USD - 110.25 USD |
| Mrkt Val (mn) / Shares Out (mn) | 7,746 USD / 98.1 |
| Free Float | 98.8% |
| Average Daily Value (mn) | 222.62 USD |
| BofA Ticker / Exchange | CYTK / NAS |
| Bloomberg / Reuters | CYTK US / CYTK.OQ |
| ROE (2023E) | NA |
| Net Dbt to Eqty (Dec-2022A) | NA |
| ESGMeter™ | Medium |

**ESGMeter is not indicative of a company's future stock price performance and is not an investment recommendation or rating. ESGMeter is independent of BofA Global Research's equity investment rating, volatility risk rating, income rating, and price objective for that company.** For full details, refer to "BofA ESGMeter Methodology".

**Abbreviations**:

**WSJ**: Wall Street Journal

**pVO2**: peak oxygen uptake

**LVEF**: left ventricular ejection fraction

**KOLs**: key opinion leaders

**ESC-HF**: Heart Failure - Heart Failure conference

**PK/PD**: pharmacokinetic/pharmacodynamic

**REMS**: Risk Evaluation and Mitigation Strategies

**ACC**: American College of Cardiology conference

**PK/PD**: pharmacokinetics/ pharmacodynamics

BMY: Bristol-Myers Squibb

See page 13 for additional abbreviations

# *iQprofile*℠ Cytokinetics, Incorporated

***iQ***method℠ **– Bus Performance***

| (US$ Millions) | 2021A | 2022A | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|
| Return on Capital Employed | -26.4% | -34.3% | -41.6% | -48.5% | -45.6% |
| Return on Equity | -120.5% | -572.1% | NM | NM | NM |
| Operating Margin | -264.5% | -342.8% | -490.8% | -584.1% | -177.1% |
| Free Cash Flow | (191) | (311) | (288) | (310) | (150) |

***iQ***method℠ **– Quality of Earnings***

| (US$ Millions) | 2021A | 2022A | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|
| Cash Realization Ratio | NM | NM | NM | NM | NM |
| Asset Replacement Ratio | 21.5x | 1.9x | 1.8x | 0.7x | 0.3x |
| Tax Rate | NM | NM | NM | NM | NM |
| Net Debt-to-Equity Ratio | -26.8% | NM | NM | NM | NM |
| Interest Cover | -11.3x | -16.7x | -13.0x | -10.7x | -8.3x |

**Income Statement Data (Dec)**

| (US$ Millions) | 2021A | 2022A | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|
| Sales | 70 | 95 | 78 | 64 | 164 |
| % Change | 26.2% | 34.3% | -17.6% | -18.3% | 156.6% |
| Gross Profit | 70 | 95 | 78 | 64 | 142 |
| % Change | 26.2% | 34.3% | -17.6% | -18.3% | 122.7% |
| EBITDA | (184) | (318) | (356) | (341) | (258) |
| % Change | -99.8% | -73.0% | -11.9% | 4.4% | 24.1% |
| Net Interest & Other Income | (29) | (65) | (74) | (34) | (42) |
| **Net Income (Adjusted)** | **(215)** | **(389)** | **(457)** | **(406)** | **(332)** |
| **% Change** | **-69.2%** | **-80.6%** | **-17.5%** | **11.1%** | **18.4%** |

**Free Cash Flow Data (Dec)**

| (US$ Millions) | 2021A | 2022A | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|
| Net Income from Cont Operations (GAAP) | (215) | (389) | (457) | (406) | (332) |
| Depreciation & Amortization | 2 | 6 | 26 | 32 | 31 |
| Change in Working Capital | 8 | (25) | 61 | (59) | (5) |
| Deferred Taxation Charge | NA | NA | NA | NA | NA |
| Other Adjustments, Net | 62 | 108 | 128 | 144 | 164 |
| Capital Expenditure | (49) | (11) | (46) | (21) | (8) |
| **Free Cash Flow** | **-191** | **-311** | **-288** | **-310** | **-150** |
| **% Change** | **NM** | **-62.4%** | **7.3%** | **-7.6%** | **51.7%** |
| Share / Issue Repurchase | 305 | 8 | 0 | 100 | 0 |
| Cost of Dividends Paid | 0 | 0 | 0 | 0 | 0 |
| Change in Debt | 0 | 508 | 125 | 100 | 0 |

**Balance Sheet Data (Dec)**

| (US$ Millions) | 2021A | 2022A | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|
| Cash & Equivalents | 113 | 66 | 57 | 67 | 11 |
| Trade Receivables | 52 | 0 | 18 | 17 | 16 |
| Other Current Assets | 371 | 729 | 589 | 472 | 380 |
| Property, Plant & Equipment | 73 | 80 | 100 | 90 | 67 |
| Other Non-Current Assets | 232 | 139 | 128 | 122 | 120 |
| **Total Assets** | **841** | **1,015** | **893** | **769** | **594** |
| Short-Term Debt | 0 | 0 | 0 | 0 | 0 |
| Other Current Liabilities | 72 | 85 | 168 | 110 | 108 |
| Long-Term Debt | 47 | 64 | 189 | 289 | 289 |
| Other Non-Current Liabilities | 478 | 974 | 1,048 | 1,130 | 1,226 |
| **Total Liabilities** | **597** | **1,123** | **1,405** | **1,529** | **1,623** |
| **Total Equity** | **244** | **(108)** | **(512)** | **(761)** | **(1,029)** |
| **Total Equity & Liabilities** | **841** | **1,015** | **893** | **769** | **594** |

* For full definitions of ***iQ***method℠ measures, see page 16.

## Company Sector

Biotechnology

## Company Description

Cytokinetics is a late-stage developmental biopharma with first- & next-in-class muscle activators & inhibitors that target the muscle to address cardiovascular and neuromuscular diseases. Currently the portfolio includes one late-, two early-stage, and a few preclinical platforms, including OM for HFrEF (potential OUS upside) and aficamten for oHCM (filing 2H24). Cytokinetics has entered into partnerships with established players to help commercialize these OUS.

## Investment Rationale

Despite solid topline results, we are cautious on the NT opportunity for aficamten given questions we--and our KOLs--have about the clinical/ commercial potential given pending the full data presentation, regulatory decisions, and commercial dynamics. We recognize optionality in the early stage pipeline, but see further de-risking necessary to attribute much value to these assets. For these reasons, we think the risk/reward profile is balanced, supportive of our Neutral rating.

## Stock Data

| | |
|---|---|
| Average Daily Volume | 2,817,973 |

## Quarterly Earnings Estimates

| | 2022 | 2023 |
|---|---|---|
| Q1 | -1.05A | -1.14A |
| Q2 | -0.23A | -1.34A |
| Q3 | -1.52A | -1.35A |
| Q4 | -1.45A | -1.47E |

# Updated aficamten deep-dive: what does SEQUOIA's top-line tell us?

## Background

### Aficamten remains a source of investor focus given questions over its upside

Cytokinetics' aficamten has been a major source of investor debate, specifically whether its profile is next-in-class or best-in-class—with clear implications on the company's valuation. Entering last year, bulls we spoke to argued afi's improved PK/PD was likely to translate into improved efficacy and safety, including a less onerous REMS, leaving it advantaged over rival Bristol's (Geoff Meacham) Camzyos. In contrast, we saw dynamics as more nuanced following discussions with multiple KOL cardiologists, community prescribers, marketing experts, and former regulators. Here, despite afi's better molecular profile, our contacts largely felt it and Camzyos—at least from a clinical standpoint—were more similar than not (see report: our BIC/FIC analysis), implying the commercial outlook was unlikely to be as straightforward as bulls expected.

At the end of December, Cytokinetics reported positive top-line results for its pivotal aficamten study in oHCM, SEQUOIA (see report: our top-line takes)—which, amongst circulating rumors the company was actively being explored as a take-out candidate, drove shares meaningful up (Dec 27: +83% vs. NBI +2%). CYTK share outperformance continued into early Jan, when WSJ, amongst other news organizations, reported the company was in late-stage discussions to be acquired by Novartis (covered by our EU pharma team Parry/ Jain). A few days later, however, it was reported Novartis had opted against a deal.

Following indications by Cytokinetics it isn't actively seeking a buyer, we suspect investors are taking a renewed look at aficamten with regards to its potential as the company mulls launching alone. Indeed, potential implications from Novartis' due diligence aside—and likely overlooked at the time—SEQUOIA's efficacy (pVO2: +1.74 mL/ kg/min) and safety (LVEF<50%: 3.5%) were below levels our KOLs/ investors felt necessary to differentiate it from Camzyos, i.e., 1.8-2.0 and 1-2%, respectively.

### KOLs: top-line is solid but lack of insights, leaves commercial outlook cloudy—with dynamics likely to favor price/ REMS absent clear differentiation

To get an updated view on afi's commercial outlook, we discussed SEQUOIA's top-line—along with management's disclosures—with our KOLs. Overall, while our experts were largely positive, they cautioned against reading too much into afi's improved efficacy (+0.34 mL/kg/min) and safety (-2.2% LVEF<50%) absent greater insights into the background characteristics. They also conceded it was unclear if either difference would translate into a meaningful, real-world clinical impact or benefit to patients.

Ultimately, given the top-line, our experts indicated they wouldn't be surprised if the two datasets end up largely overlapping, even if afi demonstrates similar directional improvements across the remaining secondaries. If this indeed is the case, unless afi's REMS is much less invasive/ involved, our KOLs felt commercial dynamics would largely come down to price—and warned affixing a premium to aficamten could advantage Camzyos.

According to our experts, the biggest key outstanding questions at this point are: 1) what will afi's REMS look like (and what is the likelihood the requirements for Camzyos are reduced); 2) what do SEQUOIA's forest plots reveal about its efficacy—especially with regards to background beta blocker use (and did anything else lead to heterogeneity in benefit); and 3) are there readthroughs from the data in oHCM to opportunities in the 1L or community settings?

## First impressions of SEQUOIA are positive but lacking details, overall insights/ implications harder to gauge

**Efficacy "not a surprise" but questions as to whether it's a clear "best-in-class"**

In terms of overall impressions, there was agreement among our KOLs the top-line was not a surprise. To be fair, some felt the selection of a single primary endpoint, $pVO_2$, had been a risk (see report: our SEQUOIA preview) given Bristol's Camzyos' (mavacamten) pivotal EXPLORER 1) had used a composite primary ($pVO_2$ and NHYA class), enabling multiple paths to success, and 2) despite the stat sig improvements in $pVO_2$ as secondary (p=0.0006), the 95% CI was rather large (1.4 mg/kg/min: 0.6 to 2.1).

That said, given validation of the class by Camzyos and aficamten's positive phase 2 updates, most thought the next-gen cardiac myosin inhibitor was likely to meaningfully improve peak oxygen uptake. And given clear correlations between outflow tract gradient and measures like NYHA class and KCCQ, our experts similarly expected the secondary efficacy endpoints to be positive as well. Indeed, many argued it would have been more an anomaly had these efficacy measures not been significant.

***SELECT KOL COMMENTARY***

*I'll start at the highest level that I would say I'm not certain anything has surprised me in terms of the results. There's no, "aha, wow, really was not expecting this!"*

*...that all of the secondary pre-specified endpoints were statistically significant, that is of no surprise because these are all interrelated. ... we know there's a direct relationship between improvement in outflow tract gradient and New York Heart Association class and KCCQ score and VO2 max based on EXPLORER, it would have been puzzling and bizarre if there wasn't a consistent, statistically significant improvement in the KCCQ score, the LVOT gradient, the New York Heart Association class, the 6MWD, etc... That's not taking anything away from it. It's just to say it's not surprising.*

That said, as to whether SEQUOIA's 1.74 mL/ kg/ min marked aficamten was clearly differentiated and "best-in-class" given Camzyos' +1.4 delta, our KOLs were far less certain. For one, heading into the readout, they—like investors we spoke with—felt aficamten would need to increase peak oxygen uptake ~1.8-2.0 mL/ kg/ min over placebo to be viewed as meaningfully improved on efficacy (see below for a discussion on safety). Arguably, some of this was driven by the usual cross-trial comparison caveats, with many expecting at least some level of improvement over Camzyos just by the improvements/ differences in trial design, participant selection, and administration/ logistics, even if only modest or subtle.

That said, on a deeper level there were questions over what exactly a +0.3 mL/ kg/ min improvement over Camzyos means, if anything. Indeed, it was unclear to our experts if this would translate into a real-world benefit for most oHCM patients, especially given a lack of clarity over the background and baseline characteristics (discussed below)—and without insights into the outcomes of more functional endpoints like NHYA class improvement and KCCQ score, readouts flagged as having greater clinical relevance.

***SELECT KOL COMMENTARY***

*...the converse of that is, do we believe that this is an outsized, differentiated product relative to a 1.74 vs. 1.4 and change mL/ kg/ minute difference? This is always the challenge of cross-trial comparisons of studies done at different times in different populations. And the honest answer is, I don't know.*

*...but I can't convince myself that 1.7 is demonstrably different than 1.4 without having a better sense of how close or different the baseline populations were.*

*Is this a blowing it out of the water difference? I'd make an argument that a 0.3, even at face value, is modest.*

*[I] think it's going to be hard to disconnect the conversation, absent a head-to-head comparative effectiveness study, to say how much of this was a drug specific effect and how much of this was a trial design effect...*

### Safety: challenging to evaluate LVEF<50% differences without baselines

There was similar uncertainty over how meaningful the 3.5% incidence of LVEF<50% was. As with $pVO_2$, there was certainly recognition the number was nominally improved over Camzyos' 5.7% in EXPLORER. But putting this into context was challenging. On one level, as with the primary outcome, the rate fell short of the threshold needed for differentiation ahead of the readout, i.e., 1-2% (see our SEQUOIA preview). At the same time, our KOLs again felt trial design could have played an outsized role. Recall, the entry criteria for SEQUOIA required a baseline LVEF of ≥60% in contrast to EXPLORER, ≥55%. With starting EF one of the biggest predictors of LVEF declines—patients at higher baseline levels are less likely to experience a <50% drop—SEQUOIA may have had a starting advantage.

And with the overall incidence relatively low—the difference of only a few patients has an outsized impact (recall: 5 in SEQUOIA vs. 7 in EXPLORER in the active arms had LVEF<50%)—our experts were unable to categorize this as a clear win for aficamten absent the baseline EF level in the active arm of SEQUOIA (not disclosed). Indeed, most felt if this comes in well above (~10%) EXPLORER's 74% (both arms), most prescribers would largely dismiss it as an advantage over Camzyos.

***SELECT KOL COMMENTARY***

*Theoretically, people starting with an on average higher ejection fraction means that you have more room to move. And we know that these drugs on average for both drugs drop ejection fraction. If you're starting at 90 and you drop by 30 points to 60, you're still above 50. You wouldn't get counted in this metric, but you still had a third of your heart function reduced by the nature of using this drug.*

*...you're beginning to select out a population, and you would imagine that there's a higher likelihood of people dropping below 50% if their EF coming into the trial was 65 versus 85. Just mathematically... SEQUOIA has put in a little bit more wiggle room to have fewer people... because they didn't have people with EFs of 58 or 59%.*

*if you came back to me and said, 85% is the average EF in the trial, now I walk away saying, I bet you this is all due to who was enrolled in the trial rather than a function of the drug as a unique, quote unquote, safer product...*

*And as you know, these are small numbers of patients. So even just small numbers making a difference can shift things appreciably*

## Commercial: Dynamics likely to come down to REMS and pricing/access

### KOLs: rest of data likely to be directionally better than Camzyos in EXPLORER—rather than substantially improved

Not surprising given this feedback, our KOLs stressed greater insights were needed to get a better sense of the commercial outlook. However, just based on the top-line numbers alone, our experts were skeptical the rest of the data would be head and shoulders better than Camzyos—especially after accounting for differences in trial design/ baseline characteristics. Indeed, most wouldn't be surprised if there's overall healthy overlap of the datapoints across the secondaries.

***SELECT KOL COMMENTARY***

*And I think what you would see is if you tried to overlay the point estimates and the confidence intervals—they present this for EXPLORER—for every endpoint, you'd see overlap. And there would be a healthy level of overlap*

*But I'm also not expecting when they present... and we see all of the data... I also don't think we're going to see big surprises*

*I'm not sure that even at the presentation... you would say, wow, this is hands down... I don't even need to see a REMS program. I don't even need to see the list price. I am going to prescribe this at the expense of no use of mavacamten whatsoever.*

### Feedback has long suggested commercial dynamics likely to be nuanced

Our KOLs have long stressed aficamten's commercial dynamics are likely to be nuanced, supporting our more reserved outlook and, at least near-term, Cytokinetics. Certainly, it was felt a best-in-class profile would be advantaged in terms of driving prescriber uptake/ payor reimbursement. But based on the phase 2 (REDWOOD-HCM) readouts, it wasn't clear afi was clearly differentiated on either safety (where there was consensus it wouldn't escape a REMS) or efficacy. At the same time, while there was recognition of aficamten's improved molecular properties, including a lack of drug-drug interactions and shorter half-life (allowing quicker onset and faster wash-outs), there were concerns 1) operationalizing these benefits would be challenging and/or 2) patients would be able to realize these benefits in the clinic (covered in depth in our BIC/FIC analysis).

At the same time—and potentially overlooked by the Street—our KOLs cautioned aficamten's entry would be unlikely to measurably expand the overall market. Indeed, beyond potentially increasing awareness, the same challenges responsible for Camzyos' slower-than-anticipated ramp (e.g., the logistical and administrative issues associated with operationalizing treatment/ REMS and costs related to the drug, echos, office visits, etc.), would also weigh on aficamten's uptake.

***SELECT KOL COMMENTARY***

*Give me a good cogent argument about why you wouldn't prescribe [aficamten]. And so, the two other pieces are, out of pocket cost payer access/ affordability issues. And then the last piece is the REMS...*

*you could make an argument that there's a large enough market for both drugs to exist. It's just a matter of penetrating into that market. I still think that there will be a slow—steady—but a slow uptake of cardiac myosin inhibitors in general*

*I think if you were to look at eligible individuals for mavacamten and those that are being prescribed mavacamten, there's... probably an appreciable delta. And that may be related to lack of awareness, challenges of operationalizing a drug like this, cost of the drug, cost of the echocardiogram, the REMS program, all of the above. I don't think aficamten sweeps in and says, we're addressing all of those things. So I think there will be headwinds in adoption of aficamten in the cardiac myosin inhibitor class*

*So let's just presume the drugs are identical in cost, meaning what patients are expected to pay and payor coverage is the same. I'm skeptical you're going to see people switching from mava to afi... Now, utilization of mava amongst eligible individuals, my impression is low, ... I think this is one of those situations where it's really competing on new starts.*

### With afi's improved PK/PD not viewed as a clear game changer, experts cautioned against premium pricing

A major pushback to our thesis has been that it fails to account for aficamten's improved molecular profile/ PK/ PD—with prescribers and regulators likely to see value in its shorter half-life and lack of DDIs. Our KOLs, however, felt that while an advantage, it's unlikely to be a game-changer, especially given the logistical challenges scheduling the necessary echocardiograms needed for up-titration and monitoring. Rather, they cautioned it might prompt Cytokinetics to affix a premium price to aficamten—which may give Camzyos the commercial edge.

***SELECT KOL COMMENTARY***

*I think what we're going to find is, there's a world of incremental things, shorter half-life, maybe—and we could debate what the driver of this is—lower rate of left ventricular EF<50%, lower drug interaction, more rapid, shorter half-life, which allows for more rapid titration. None of these stand alone as being like a game changer*

*One of the benefits is you have the advantage of being able to initiate and get people on drugs faster. Practically speaking, it's going to be a challenge for us to get echoes, which we already have a challenge with every four weeks now every two weeks...*

*...but stranger things have happened where companies... say, we believe we're a better mousetrap, and deserve a price premium for that. And now all of a sudden, we're more expensive. There are examples in cardiovascular medicine where that's been the case, and it's been the undoing of a drug.*

*[If] aficamten comes in... and even if it's a world of incrementalism, small things—drives decisions, [Bristol] begins to their lunch being eaten by Cytokinetics and they... figure out a way to work with the payers and get it at a lower cost. That, I think, is the hand that they'll have to play... That's not going to be lost on the payer community and that could flip, say, a 30/70 dynamic to a 70/30... I think payer related costs can be a huge lever to play*

## Open Questions: What are the key unknowns at this point likely to determine afi's market potential

Beyond their impressions of the data, we asked our experts to outline the remaining critical questions most likely to impact aficamten's commercial outlook. We describe below 3, providing context/ feedback for each: 1) what will the REMS look like; 2) what insights will be most relevant from SEQUOIA's full data presentation; and 3) what is the outlook for afi in the 1L and community settings?

### 1) What's aficamten's REMS going to look like?

According to our KOLs, the biggest remaining question—and the one likely to have the greatest overall impact on uptake—is what will afi's REMS look like? Specifically, will FDA require less monitoring vs. Camzyos. For its part, Cytokinetics has argued the safety data to date, along with aficamten's improved PK/PD, should support a less onerous program—pointing to FDA's feedback, including notably its approval of a less stringent/ more nuanced safety protocol in SEQUOIA as a potential signal the agency is likely to relax some of the restrictions it placed on Camzyos.

Here, though, our experts were skeptical monitoring requirements would be significantly relaxed, an outlook in-line with our regulatory KOLs, who saw the agency as likely to remain cautious given the potential of fatal outcomes—deferring to more at-risk patients even if these individuals are in the minority (see takes from our FDA KOL call). Indeed, most felt that even if only 3-4 patients out of every 100 treated experience an LVEF<50% (esp if they started a higher baseline LVEF), it would be too high a risk for the agency to meaningfully reduce overall monitoring—especially moving to a real-world setting, where there's less oversight and more advanced patients (cf. Camzyos' VALOR).

Admittedly, there are some subtleties with regards to afi's potential REMS, a dynamic somewhat reflected by the agency's approval of SEQUOIA's safety protocol (highlighted above)—where, unlike with EXPLORER, an LVEF<50% required a treatment down-titration, vs dose interruption (which only occurred when LVEF<40%). We discuss these topics in-depth below:

***SELECT KOL COMMENTARY***

*If you were to ask me what single piece is going to have the most dramatic impact on a differential approach to prescribing, it would be the REMS, if they came back and said FDA sees fit, I don't think this is going to happen, but if FDA did say this is a differentiated product that... requires a different REMS, that [is] less stringent, then you would say, "all of these other things are pointing in the right direction, but this is the cherry on top."*

*I can't fathom in my head how they a) can make an argument that the design of SEQUOIA somehow creates a scenario where a REMS isn't needed at all, or b) we follow them for every two weeks and only 3.5% of people have a drop in EF, absent being able to figure out exactly who that is and what five people... had these features. And if they didn't have these features, they never have a drop in their ejection fraction less than 50%, I'm very skeptical about that.*

*I think the FDA appropriately says, we see on-label use. We also will see clinicians make judgment calls... They will use off-label, and the level of follow up in a real-world setting is almost certain to be less than that which we see in a clinical trial. There's... protocol violations. "We started in class II and III patients. Now we're expanding to class IV." Those types of things are things that I think the FDA would say, that's what people would do with aficamten, just like they would do with mavacamten. Thus another reason to commit you to having a REMS*

### Does it matter if participants with LVEF <50% were asymptomatic? Unlikely...

During its sell-side event hosted in San Francisco, Cytokinetics reported none of the 5 participants in SEQUOIA with LVEF<50% were symptomatic—suggesting the drop was only transient, and that, if evaluated a few weeks later, LVEF reduction wouldn't have been there/ detected.

Our KOLs weren't as quick to see this as a potential source of differentiation. To be clear, they acknowledged not every oHCM patient with a low EF is symptomatic. They also conceded some of the declines observed may indeed have been transient, a byproduct of conducting echos every 2 weeks vs. 4—an admission that had the same protocol been used in EXPLORER, it was possible more incidences of LVEF<50% may have been identified.

That said, our experts were emphatic an LVEF<50% is abnormal, and given significant potential for a negative outcome, did not think any prescriber would feel comfortable taking a hands-off approach if a patient experienced such a drop—even if this individual were otherwise responding well to a cardiac myosin inhibitor. Similarly, they felt regulators would want these patients closely monitored, regardless of whether they were experiencing symptoms or not, given concerns they a) might eventually become symptomatic and b) could potentially continue to decline.

***SELECT KOL COMMENTARY***

*...this is the fear: you are giving a drug, dropping the EF... that leads to volume overload, symptoms of shortness of breath, lower extremity swelling, weight gain, etc. There is a clear time horizon as your heart function is going down, at which point you may be asymptomatic with a drop of an EF<50%. But the concern for all of us, and I assume the concern by the FDA is, if unchecked and continued, people could develop symptoms...*

*There is a clear time horizon as your heart function is going down, at which point you may be asymptomatic with an EF<50%.*

*I might make the argument, if you got an echocardiogram every two weeks with mavacamten, even though the drug takes longer to wear off, you might have seen things earlier on. Now it shouldn't change the rate of a drop below 50%, but it may be associated with less symptomatic individuals with an EF<50%*

*Listen, an EF<50% is abnormal. It could be mildly abnormal. It could be moderately abnormal. It could be severely abnormal. But it's abnormal.*

*Is it possible that a patient with an EF of 45, or let's get even very specific, 49%. He has no symptoms and continues to do well. And his HCM is well controlled. It's possible, but on the whole, first do no harm.*

### Is a unique REMS based on risk possible? Unlikely, given skepticism an accurate enough algorithm exists...

During the same event, Cytokinetics reported it was also exploring the potential of a novel REMS, one based on risk. Under the proposed plan, using data gleaned across its clinical studies, the company would derive an algorithm capable of categorizing patients by risk—with those more likely to experience/ suffer from an LVEF<50% subject to more monitoring while patients at lower risk would undergo echos less frequently.

Here again, our KOLs were skeptical. For one, they felt it would be challenging to derive an accurately predictive model, given 1) overall rates of LVEF<50% are relatively infrequent, making it challenging to use any sort of regression model; 2) there exists substantive heterogeneity from patient to patient owning to factors that likely include genetic mutation, underlying disease, heart muscle morphology, etc.; and 3) if such a predictive model could be developed, most felt FDA would more than likely just exclude those at risk from receiving treatment altogether.

***SELECT KOL COMMENTARY***

*...you'd have to do like probably a logistic regression model... and figure out what are all the covariates that could inform someone's EF dropping. Is it dose of aficamten? Is it baseline EF? Is it age? Is it sex? Is it comorbidities? And these are very infrequent events. It's really hard to figure out a predictive model.*

*...but maybe they have biomarker data or something else that would help.... but if that was the case, then I would make the argument if you're going to drop below 50%, and you could predict who these people are, then those are people that shouldn't be getting aficamten at all... why would you give it if you have to stop or down-titrate?*

### What are the background characteristics of the 5 in SEQUOIA with LVEF<50%? Are there participants with starting EFs >80% as there were in EXPLORER?

As described above, our KOLs will be acutely focused on the baseline LVEF rates in SEQUOIA—and whether its relatively more restrictive inclusion criteria (≥60%) than EXPLORER's (≥55%) translated into a meaningfully greater starting point (vs. 74%).

That said, most were hopeful Cytokinetics would disclose the background characteristics of the 6 participants in SEQUOIA (5 on aficamten; 1 on placebo) who experienced an LVEF<50%. Inasmuch as the biggest predictor is the patient's starting level (i.e., the rationale behind excluding patients with lower EFs to begin with), as EXPLORER revealed, there is still considerable heterogeneity among patient reactions. Indeed, as detailed in the supplement of the EXPLORER results publication (*Olivotto I, et al.,* Lancet 2020) among the 7 participants in the active arm with LVEF<50%: one had a baseline LVEF of 92% with two in the 80s (84% and 80%) and two in the 70s (74%, 70%).

We suspect a similar mix of patients with these drops (underscoring the overall unpredictability of responses)—including a few starting at relatively high baseline LVEFs—would add further support for not only more frequent monitoring but a broad one given clear challenges trying to identify those most at risk.

***SELECT KOL COMMENTARY***

*...people starting on average with a higher EF should be more protected... from falling into this camp. But when you actually look at the 9 patients in the supplemental appendix of The Lancet that looked at it, some people had ejection fractions as high as 90%. There were others who had ejection fractions at baseline of 55 or 60%.*

*...on the one hand, you could say, well, EF is the biggest predictor, but you would say even if it can happen that you start from a better place, from an EF standpoint, these things can still happen*

### How is Camzyos' REMS likely to evolve, if at all? Is a potential relaxation of the maintenance monitoring for both assets possible? Maybe...

In somewhat of a twist, our KOLs also indicated they wouldn't be surprised if the regulatory discussion on aficamten's REMS prompts a re-assessment of Camzyos'—specifically a relaxation of the long-term/ maintenance monitoring (i.e., 4 echos per year). To be fair, our experts stressed echocardiograms are a relatively non-invasive and benign diagnostic, with most HCM patients already undergoing 1-2/year. Still given costs and the ongoing logistical challenges of increasing the number ~4x the first year of initiating a cardiac myosin inhibitor and ~2-4x thereafter was a burden.

To be clear, none of the prescribers we spoke with felt regulators would end monitoring requirements altogether; that said, given feedback from the community regarding the overall number of echos—with the majority seemingly tolerating treatment well (i.e., only a small fraction of those on Camzyos or aficamten had an LVEF<50%)—the agency may opt to reduce the frequency of maintenance echos if a patient's EF remains constant (e.g., possibly 2-3/ year).

***SELECT KOL COMMENTARY***

*I think it's a reasonable thing to say, that's too onerous. It's expensive, and it's perhaps unnecessary. And hyper conservative, we'd like to say in follow up, longer term, that's the case. And then the question is, how many echoes do you need to prove at steady state on a stable dose, that you didn't have a drop in EF? That is a very reasonable thing, but I would say it should apply to both afi and mava.*

*I'm going to say if this is all related to the frequency of echoes in longer term follow up, it wouldn't surprise me if that would also apply to mavacamten. In other words, I don't think there's anything unique about aficamten that I can think of that wouldn't make it otherwise applicable*

*I'm making up a scenario, but you've had one follow up echo after the last dose titration [and] another one 12 weeks later, or whatever that time interval is. And if you have two data points that show a flat line, meaning your LVF is stable and not trending downward, then you can decrease the frequency of testing.*

*Maybe we don't need to follow these people closely... once a year, maybe lower than we want, but instead of every 12 weeks, it's every 2x year kind of a thing. I don't think it's ever going to be you don't need to be followed*

**2) What other insights are our KOLs looking for in the SEQUOIA presentation?**

Not unexpectedly, our KOLs were anxious to see the rest of SEQUOIA, including what the previously undisclosed background characteristics were as well as how the remaining outcomes (secondary endpoints, additional safety insights, extent and variability of treatment effect, etc.) compared to Camzyos/ EXPLORER.

Admittedly, most didn't anticipate many surprises, given again, expectations for more similarities than not in terms of the functional outputs. Still beyond baseline LVEF levels most were especially curious regarding:

***SELECT KOL COMMENTARY***

*I want to see all of the data, data related to secondary endpoints and see if there are some surprises. Not unlike the forest plot with mavacamten and EXPLORER. Is there any heterogeneity in the treatment effect? Some people who have an outsized treatment effect, some who have less.*

*There is some data that I'm definitely going to want to look at relative to what wasn't available in the baseline characteristics in the JACC Heart Failure paper that might make sense, more or less of some of the top line data that's been presented thus far.*

**Did background therapy, esp use of beta-blockers, influence outcomes? Experts doubtful impact negligible…**

Beyond LVEF, use of background therapy in SEQOUIA has been another key source of debate given its potential to exaggerate efficacy. Indeed, in EXPLORER, 76% of participants were on beta-blockers and 20% on calcium channel blockers, frequently prescribed for oHCM currently. In contrast, use of beta-blockers was far lower in SEQUOIA (61%), although there was greater use of CCBs (26.6%) and disopyramide (12.8%; disallowed in EXPLORER).

Likely in response to concerns lower use of beta-blockers could have helped drive the improved $pVO_2$ outcome, Cytokinetics initially said the treatment effect was "consistent" between those on and off therapy. During its sell-side event two weeks later, however, the team did concede there was a "modest" difference between the two populations.

Our KOLs weren't as convinced noting the significant difference in EXPLORER's forest plot for beta-blocker usage. To be fair, they conceded the error bars were quite large, likely a result of heterogeneity among the relatively small proportion of the cohort not on background therapy (23% mava/ 26% placebo). That said, given the clear evidence of an effect in EXPLORER—and the consistency of effect (the benefits of beta-blockers in oHCM have been demonstrated across several, albeit small studies)—our experts thought there would be similar difference in SEQUOIA. And, thus while likely not the sole contributor of SEQUOIA's improved $pVO_2$ vs EXPLORER, many believed it was a factor.

***SELECT KOL COMMENTARY***

*But if I recall correctly from EXPLORER, the point estimate for the effect in people who were on a background beta blocker and those who were not, both favored mavacamten. It's just that the effect size was more pronounced in those that were not on background therapy*

*... and part of this comes back to the issue of background therapy and other factors to understand, that effect, I will fast forward to say that we already know that they said that there was a consistent benefit between those on beta blockade vs. those that weren't, but consistent and what those numbers look like... they're both moving in the same direction, I get that, but does that drive any of that, those differences, etc.?*

*if EXPLORER had been done where there was a lower rate of background therapy, given the point estimates that we saw for no beta blocker being that much greater, would we have seen a 1.5 or 1.6 VO2 max difference?*

### 3) Is there any more clarity into afi's broader opportunities, beyond the population studied in SEQUOIA?

With many of details of SEQUOIA still unknown, our experts admitted it was challenging to accurately project how commercial dynamics between aficamten and Camzyos would likely play out. That being said, even as the top-line was also somewhat limited, they felt there were enough insights to add to the growing picture of aficamten's broader opportunity, beyond the more advanced oHCM patients studied in SEQUOIA:

#### KOLs still skeptical of upside in the 1L oHCM setting

A primary, early focus of Cytokinetics' development strategy is the 1L setting, with its MAPLE-HCM—a phase 3 comparing afi to beta-blocker metoprolol head-to-head—currently enrolling. To be fair, our KOLs agreed with the company's rationale, that while beta-blockers have been shown to improve some aspects of the disease, including symptoms and LVOT, there's less/ little benefit for exercise capacity and other measures (e.g., NT-proBNP). In addition, some have difficulties tolerating beta-blockers.

That said, both beta-blockers and calcium-channel blockers, both used in this setting, are generic, and as such, are available for considerably less than what aficamten's likely yearly gross price would be (Camzyos' current WAC represents an annual cost of ~$98k). Despite management's optimism a positive outcome in MAPLE will open access, with guideline updates prompting payers to relax restrictions, our experts have been largely skeptical—with SEQUOIA's top-line largely confirming this outlook.

Rather, to open access, it was felt aficamten's benefit would need to be striking, potentially requiring clear evidence of a survival benefit. But with afi's $pVO_2$ benefit not viewed as a clear homerun, few thought the MAPLE data would be dramatic enough. At the same time: 1) if metoprolol's improvements are stat sig/ meaningful by itself, it's likely to further empower payers to justify step-edits; and 2) given the complexities of oHCM, consensus was it would be extremely challenging to design a study capable of demonstrating a distinct survival benefit with a CMI.

***SELECT KOL COMMENTARY***

*[t]here is no way that we're going to see the payer community embrace this as first line therapy.*

*...if they don't tolerate a beta blocker, I'm going to go to a centrally acting calcium channel blocker. [I]f they don't tolerate that, then I'm going to go to the payer and say, "hey, they didn't tolerate these two other drugs, can we get them on..." But if they can tolerate a beta blocker, there is no way you're going to spend $80k list price drug when [beta blockers] are pennies on the dollar...*

*MAPLE-HCM is a is a sort of a head to head beta blocker versus, afi. Might that change the dynamic in the future? It could, but you're going to have to have a striking difference*

*And then, the question is, even if there's a benefit, a bigger bang for your buck, how much more expensive is it? Let's say it's $80,000 a year vs $10 a year or $20 a year. The community is going to say, fine, get on your beta blocker, which we already know has been proven to be effective... My gut reflex is, it's going to have to have a*

*staggering, overwhelming, dramatic effect to be in a situation where we see the payers embrace the notion that they would pay for a dramatic drug*

*This is a drug that... allows people to feel better and function further. To our best knowledge, it's not reducing hospitalization, it's not keeping people alive more. I just think the payers will say, we want people to feel better, but you always have the option of stepping through this, and if you don't feel well enough, call us up and we'll see whether or not we can get people authorized for that drug*

*I think it's going to be really challenging to show [a survival benefit]. What do most people die from with HCM? It's sudden death. Yes, you can die from pump failure and so-called burned out HCM, where the heart begins to fail. But you're disproportionately and overwhelmingly talking about sudden death.*

**Similarly, given logistics, expansion into community settings also looks unlikely**

By the same token, with SEQUOIA still suggesting regulators are likely to require a REMS for aficamten, our experts thought use within community settings would be limited. Specifically, administration, in and of itself, is not considered especially challenging. At least with Camzyos, the dosing and monitoring algorithm are clear, with echos a relatively non-invasive tool commonly used by prescribers. Rather, according to our KOLs, the logistical challenges come from keeping track of patients—and ensuring the echos are scheduled, completed, and read. According to our experts, this usually requires a dedicated office FTE, when most cardiology offices—even those at dedicated COEs—are relatively less resourced than, for example, oncology practices.

***SELECT KOL COMMENTARY***

*I think the argument is not that this is complex, it's not just sort of insert tab A into slot B, it's more complicated than that.... The challenge is, they need echos. And beyond the authorization piece, if you've got 5-7 patients like this, [how] do you [justify] the time doing this?*

*The biggest piece for us is, and we've consolidated all of our prescribing into our HCM clinic... I will facilitate it through our clinic primarily to have someone have their eyes on the patient. So if Mr. X that needs to start mavacamten or aficamten, somebody's got to go, did you have your echo scheduled? Did you show up and get it completed? Yes, they did. Okay, we're up adjusting the dose. Can we get the next echo scheduled? There's a lot of coordination and operational pieces that exist related to that. And that to me is a piece that is unlikely to change in this situation from my perspective overall*

**Abbreviations**:

**1L**: front-line

**BIC**: best in class

**CCBs**: calcium channel blockers

**CI**: confidence interval

**CMI**: cardiac myosin inhibitor

**COE**: centers of excellence

**DDI**: drug-drug interaction

**EF**: ejection fraction

**FDA**: Food and Drug Administration

**FTE**: full time employee

**(o/n) HCM**: obstructive/ non-obstructive hypertrophic cardiomyopathy

**HFpEF**: heart failure with preserved ejection fraction

**KCCQ**: Kansas City Cardiomyopathy Questionnaire

**kg**: kilogram

**KOL**: key opinion leader

**LVEF**: left ventricular ejection fraction

**mL**: milliliter

**min**: minute

**NHYA**: New York Heart Association (functional class)

**NIC**: next-in-class

**oHCM**: obstructive hypertrophic cardiomyopathy

**PK/PD**: pharmacokinetics/ pharmacodynamics

**pVO2**: peak oxygen uptake

**REMS**: Risk Evaluation and Mitigation Strategies

**WAC**: wholesale acquisition cost

## Price objective basis & risk

**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.

## 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 |
| | Caribou | CRBU | CRBU US | Geoff Meacham |
| | CRISPR Therapeutics | CRSP | CRSP US | Geoff Meacham |
| | Eli Lilly and Company | LLY | LLY US | Geoff Meacham |
| | 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 | Alec W. Stranahan |
| | 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 |
| | 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 |

**US - Biopharmaceuticals Coverage Cluster**

| Investment rating | Company | BofA Ticker | Bloomberg symbol | Analyst |
|---|---|---|---|---|
| | Regenxbio, Inc. | RGNX | RGNX US | Alec W. Stranahan |
| | Revolution Medicines | RVMD | RVMD 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 |
| | Bristol-Myers Squibb | BMY | BMY US | Geoff Meacham |
| | Cytokinetics, Incorporated | CYTK | CYTK US | Jason Zemansky |
| | Editas Medicine | EDIT | EDIT US | Greg Harrison, CFA |
| | Erasca | ERAS | ERAS US | Alec W. Stranahan |
| | Esperion | ESPR | ESPR US | Jason Zemansky |
| | Exscientia | EXAI | EXAI US | Alec W. Stranahan |
| | IGM Biosciences | IGMS | IGMS US | Greg Harrison, CFA |
| | Johnson & Johnson | JNJ | JNJ US | Geoff Meacham |
| | Kymera Therapeutics | KYMR | KYMR US | Geoff Meacham |
| | Moderna | MRNA | MRNA US | Geoff Meacham |
| | Pfizer | PFE | PFE US | Geoff Meacham |
| | Recursion Pharmaceuticals, Inc. | RXRX | RXRX US | Alec W. Stranahan |
| | Tyra Biosciences | TYRA | TYRA US | Greg Harrison, CFA |
| | Vir | VIR | VIR US | Alec W. Stranahan |
| | Y-mAbs Therapeutics, Inc | YMAB | YMAB US | Alec W. Stranahan |
| **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 |

# iQmethod℠ Measures Definitions

| Business Performance | Numerator | Denominator |
|---|---|---|
| Return On Capital Employed | NOPAT = (EBIT + Interest Income) × (1 − Tax Rate) + Goodwill Amortization | Total Assets − Current Liabilities + ST Debt + Accumulated Goodwill Amortization |
| Return On Equity | Net Income | Shareholders' Equity |
| Operating Margin | Operating Profit | Sales |
| Earnings Growth | Expected 5 Year CAGR From Latest Actual | N/A |
| Free Cash Flow | Cash Flow From Operations − Total Capex | N/A |

| Quality of Earnings | Numerator | Denominator |
|---|---|---|
| Cash Realization Ratio | Cash Flow From Operations | Net Income |
| Asset Replacement Ratio | Capex | Depreciation |
| Tax Rate | Tax Charge | Pre-Tax Income |
| Net Debt-To-Equity Ratio | Net Debt = Total Debt − Cash & Equivalents | Total Equity |
| Interest Cover | EBIT | Interest Expense |

| Valuation Toolkit | Numerator | Denominator |
|---|---|---|
| Price / Earnings Ratio | Current Share Price | Diluted Earnings Per Share (Basis As Specified) |
| Price / Book Value | Current Share Price | Shareholders' Equity / Current Basic Shares |
| Dividend Yield | Annualised Declared Cash Dividend | Current Share Price |
| Free Cash Flow Yield | Cash Flow From Operations − Total Capex | Market Cap = Current Share Price × Current Basic Shares |
| Enterprise Value / Sales | EV = Current Share Price × Current Shares + Minority Equity + Net Debt + Other LT Liabilities | Sales |
| EV / EBITDA | Enterprise Value | Basic EBIT + Depreciation + Amortization |

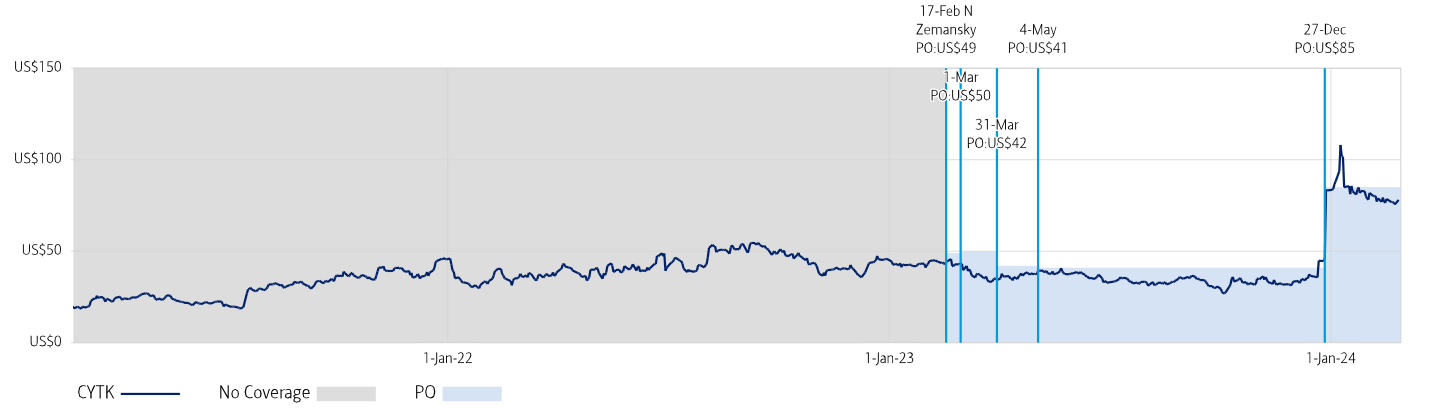
*iQmethod℠* is the set of BofA Global Research standard measures that serve to maintain global consistency under three broad headings: Business Performance, Quality of Earnings, and validations. The key features of iQmethod are: A consistently structured, detailed, and transparent methodology. Guidelines to maximize the effectiveness of the comparative valuation process, and to identify some common pitfalls.

*iQdatabase®* is our real-time global research database that is sourced directly from our equity analysts' earnings models and includes forecasted as well as historical data for income statements, balance sheets, and cash flow statements for companies covered by BofA Global Research.

# Disclosures

## Important Disclosures

**Cytokinetics (CYTK) Price Chart**




B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

The Investment Opinion System is contained at the end of the report under the heading "Fundamental Equity Opinion Key". Dark grey shading indicates the security is restricted with the opinion suspended. Medium grey shading indicates the security is under review with the opinion withdrawn. Light grey shading indicates the security is not covered. Chart is current as of a date no more than one trading day prior to the date of the report.

**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.

FUNDAMENTAL EQUITY OPINION KEY: Opinions include a Volatility Risk Rating, an Investment Rating and an Income Rating. VOLATILITY RISK RATINGS, indicators of potential price fluctuation, are: A - Low, B - Medium and C - High. INVESTMENT RATINGS reflect the analyst's assessment of both a stock's absolute total return potential as well as its attractiveness for investment relative to other stocks within its Coverage Cluster (defined below). Our investment ratings are: 1 - Buy stocks are expected to have a total return of at least 10% and are the most attractive stocks in the coverage cluster; 2 - Neutral stocks are expected to remain flat or increase in value and are less attractive than Buy rated stocks and 3 - Underperform stocks are the least attractive stocks in a coverage cluster. An investment rating of 6 (No Rating) indicates that a stock is no longer trading on the basis of fundamentals. Analysts assign investment ratings considering, among other things, the 0-12 month total return expectation for a stock and the firm's guidelines for ratings dispersions (shown in the table below). The current price objective for a stock should be referenced to better understand the total return expectation at any given time. The price objective reflects the analyst's view of the potential price appreciation (depreciation).

| 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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