

Agios Pharmaceuticals

ENERGIZE excites with positive pivotal data to start off 2024

Reiterate Rating: BUY | PO: 49.00 USD | Price: 22.83 USD

Strong responses support movement to label expansion

Agios announced positive phase 3 data from the pivotal ENERGIZE study evaluating mitapivat in non-transfusion dependent thalassemia (NTDT) with a statistically significant (2-sided $p < 0.0001$) hemoglobin (Hb) responder rate of 42.3% vs. 1.6% placebo patients. While we look for full analysis of the data in an upcoming medical meeting, we think the results today add support to the company's plans to file for a label expansion of Pyrukynd to include thalassemia and we model a launch in 2025 and risk-adj. peak sales of \$776M (75% PoS). With over 50% of thal patients as NTDT, we think the company is poised to address a larger population with significant unmet need based on the update today. Agios also noted established diagnoses globally for thalassemia and highlighted active preparations for commercial launch in the US and other geographies. We update the PoS for the thalassemia program in our model to 75% (from 45%), resulting in a new PO of \$49 (from \$39). Given the ongoing launch of mitapivat in PKD and the encouraging progress towards label expansion into larger indications, we reiterate our Buy with a new PO of \$49 (from \$39).

Data details

The phase 3, double-blind, randomized, placebo-controlled, multicenter ENERGIZE study (N=194) evaluated 100mg twice-daily mitapivat in patients with NTDT with a primary endpoint of hemoglobin response defined as ≥ 1.0 g/dL increase in average Hb concentration from Week 12 through Week 24 compared to baseline. Secondary endpoints were also statistically significant with encouraging changes from baseline on the FACIT-Fatigue subscale score and change from baseline in average hemoglobin concentration. Safety was similar across mitapivat and placebo arms, and we note 4 subjects in the mitapivat arm (3.1% vs. 0% in placebo) experienced AEs leading to discontinuation.

ENERGIZE-T is also key to filing by YE24

Planning to build upon the positive data announced today, the company is preparing to announce data from the fully enrolled, phase 3 ENERGIZE-T study in mid-24 which is evaluating mitapivat in patients with transfusion dependent thalassemia. If data continues to be supportive, Agios plans to file for the approval of mitapivat in thalassemia by YE24.

See our catalyst calendar below (Exhibit 1):

| Estimates (Dec) (US\$) | 2021A | 2022A | 2023E | 2024E | 2025E |
|---------------------------|--------|--------|--------|--------|--------|
| EPS | 26.55 | (4.23) | (6.11) | (6.29) | (5.52) |
| EPS Change (YoY) | NM | NM | -44.4% | -2.9% | 12.2% |
| Consensus EPS (Bloomberg) | | | (6.23) | (5.02) | (6.02) |
| DPS | 0.01 | 0.01 | 0 | 0 | 0 |
| Valuation (Dec) | | | | | |
| P/E | 0.9x | NM | NM | NM | NM |
| Free Cash Flow Yield* | -32.4% | -24.6% | -22.4% | -23.7% | -22.6% |

* For full definitions of *IQmethod*SM measures, see page 5.

03 January 2024

Equity

Key Changes

| (US\$) | Previous | Current |
|------------------|----------|---------|
| Price Obj. | 39.00 | 49.00 |
| 2025E Rev (m) | 112.8 | 131.2 |
| 2025E EPS | -5.80 | -5.52 |
| 2025E EBITDA (m) | -354.3 | -338.1 |

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Stock Data

| | |
|---------------------------------|-----------------------|
| Price | 22.83 USD |
| Price Objective | 49.00 USD |
| Date Established | 3-Jan-2024 |
| Investment Opinion | C-1-9 |
| 52-Week Range | 19.80 USD - 31.56 USD |
| Mrkt Val (mn) / Shares Out (mn) | 1,276 USD / 55.9 |
| Free Float | 98.6% |
| Average Daily Value (mn) | 11.29 USD |
| BofA Ticker / Exchange | AGIO / NAS |
| Bloomberg / Reuters | AGIO US / AGIO.OQ |
| ROE (2023E) | -40.0% |
| Net Dbt to Eqty (Dec-2022A) | -12.7% |
| ESGMeter™ | High |

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"](#).

AEs: adverse events

PoS: probability of success

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Timestamp: 03 January 2024 09:54AM EST

iQprofileSM Agios Pharmaceuticals

iQmethodSM – Bus Performance*

| (US\$ Millions) | 2021A | 2022A | 2023E | 2024E | 2025E |
|----------------------------|--------|-----------|-----------|---------|---------|
| Return on Capital Employed | -31.8% | -26.5% | -30.0% | -43.9% | -64.7% |
| Return on Equity | 189.7% | -19.4% | -40.0% | -60.9% | -96.2% |
| Operating Margin | NA | -2,732.1% | -1,377.6% | -847.8% | -262.3% |
| Free Cash Flow | (413) | (314) | (285) | (303) | (288) |

iQmethodSM – Quality of Earnings*

| (US\$ Millions) | 2021A | 2022A | 2023E | 2024E | 2025E |
|--------------------------|--------|--------|--------|--------|--------|
| Cash Realization Ratio | -0.3x | NM | NM | NM | NM |
| Asset Replacement Ratio | 0.6x | 0.6x | 0.6x | 0.6x | 0.6x |
| Tax Rate | NM | NM | NM | NM | NM |
| Net Debt-to-Equity Ratio | -15.7% | -12.7% | -55.9% | -88.6% | -68.8% |
| Interest Cover | NA | NA | NA | NA | NA |

Income Statement Data (Dec)

| (US\$ Millions) | 2021A | 2022A | 2023E | 2024E | 2025E |
|------------------------------|--------------|--------------|---------------|--------------|--------------|
| Sales | 0 | 14 | 27 | 46 | 131 |
| % Change | -100.0% | NA | 92.8% | 65.8% | 188.2% |
| Gross Profit | 0 | 13 | 24 | 40 | 115 |
| % Change | NM | NA | 93.2% | 65.4% | 188.2% |
| EBITDA | (369) | (380) | (370) | (379) | (338) |
| % Change | -20.6% | -3.1% | 2.8% | -2.5% | 10.7% |
| Net Interest & Other Income | 22 | 157 | 37 | 24 | 15 |
| Net Income (Adjusted) | 1,605 | (232) | (383) | (406) | (368) |
| % Change | NM | NM | -65.4% | -5.9% | 9.4% |

Free Cash Flow Data (Dec)

| (US\$ Millions) | 2021A | 2022A | 2023E | 2024E | 2025E |
|--|---------------|--------------|-------------|--------------|-------------|
| Net Income from Cont Operations (GAAP) | (357) | (232) | (341) | (361) | (329) |
| Depreciation & Amortization | 9 | 9 | 9 | 7 | 6 |
| Change in Working Capital | (37) | (16) | (2) | (1) | (22) |
| Deferred Taxation Charge | NA | NA | NA | NA | NA |
| Other Adjustments, Net | (23) | (70) | 54 | 57 | 60 |
| Capital Expenditure | (6) | (5) | (5) | (4) | (3) |
| Free Cash Flow | -413 | -314 | -285 | -303 | -288 |
| % Change | -35.1% | 23.9% | 9.2% | -6.1% | 4.9% |
| Share / Issue Repurchase | 37 | 3 | 3 | 3 | 3 |
| Cost of Dividends Paid | (1) | 0 | 0 | 0 | 0 |
| Change in Debt | 0 | 0 | 0 | 0 | 0 |

Balance Sheet Data (Dec)

| (US\$ Millions) | 2021A | 2022A | 2023E | 2024E | 2025E |
|---------------------------------------|--------------|--------------|------------|------------|------------|
| Cash & Equivalents | 203 | 139 | 457 | 457 | 172 |
| Trade Receivables | 0 | 2 | 5 | 9 | 25 |
| Other Current Assets | 861 | 691 | 91 | 92 | 102 |
| Property, Plant & Equipment | 29 | 23 | 19 | 16 | 14 |
| Other Non-Current Assets | 345 | 383 | 383 | 83 | 84 |
| Total Assets | 1,438 | 1,239 | 955 | 657 | 396 |
| Short-Term Debt | 0 | 0 | 0 | 0 | 0 |
| Other Current Liabilities | 60 | 63 | 63 | 66 | 71 |
| Long-Term Debt | 0 | 0 | 0 | 0 | 0 |
| Other Non-Current Liabilities | 86 | 75 | 75 | 75 | 75 |
| Total Liabilities | 146 | 138 | 138 | 141 | 147 |
| Total Equity | 1,292 | 1,101 | 817 | 515 | 249 |
| Total Equity & Liabilities | 1,438 | 1,239 | 955 | 657 | 396 |

* For full definitions of iQmethodSM measures, see page 5.

Company Sector

Pharmaceuticals

Company Description

Agios is a commercial stage biotechnology company developing small molecules that alter cellular metabolism for genetically defined diseases. Its lead product, mitapivat, is approved in adult PK deficiency, and in development for pediatric PK deficiency, thalassemia, and sickle cell disease.

Investment Rationale

Agios targets genetically defined diseases with small molecule medicines to regulate cellular metabolism. We think the company will benefit from the launch of mitapivat in PKD and progressing towards approval in other indications. The upcoming launch, clinical pipeline, and preclinical assets give us confidence in the probability of success in these programs.

Stock Data

Average Daily Volume

494,731

Quarterly Earnings Estimates

| | 2022 | 2023 |
|----|--------|--------|
| Q1 | -1.74A | -1.47A |
| Q2 | -1.68A | -1.51A |
| Q3 | -1.49A | -1.64A |
| Q4 | 0.66A | -1.51E |

Exhibit 1: Agios Catalyst Calendar

We look for positive data from ENERGIZE-T to build upon the update today and support filing by YE24.

| Company | Asset | Indication | Event | Timing | Importance |
|---------|-----------|---------------|--|----------|------------|
| Agios | Mitapivat | SCD | Phase 3 data | 2025 | High |
| Agios | AG-946 | LR-MDS | Initiate phase 2b | mid-2024 | Low |
| Agios | Mitapivat | TDT | Phase 3 ENERGIZE-T data | 2H24 | High |
| Agios | Mitapivat | Pediatric PKD | Data from ACTIVATEkids/ ACTIVATEkids-T | 2025 | High |
| Agios | Mitapivat | Thalassemia | File for regulatory approval | YE24 | High |

Source: BofA Global Research, company reports

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Price objective basis & risk

Agios Pharmaceuticals (AGIO)

Our \$49/share price objective is based on a probability-adjusted (40-100%) net present value (NPV) analysis of 1 commercial program and 2 programs under development. We use a weighted-average cost of capital (WACC) of 13%, similar to other commercial companies in our coverage universe and a -25% terminal growth rate. Given these assumptions, we estimate a value of \$6/share for PKD, \$18/share for thalassemia, \$4/share for SCD, \$7/share for Pyrukynd ex-US royalties, and \$14/share for net cash.

Downside risks: 1) soft market uptake, 2) dangerous safety signals, 3) superior competitor data.

Analyst Certification

I, Greg Harrison, CFA, 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 |
| | 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 |
| | Insmid 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 |
| | 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 |
| | Traverse Therapeutics Inc | TVTX | TVTX US | Greg Harrison, CFA |
| | Turnstone Biologics | TSBX | TSBX US | Geoff Meacham |
| | Vertex Pharmaceuticals Inc. | VRTX | VRTX US | Geoff Meacham |

US - Biopharmaceuticals Coverage Cluster

| Investment rating | Company | BofA Ticker | Bloomberg symbol | Analyst |
|---------------------|---------------------------------|-------------|------------------|--------------------|
| | 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 | BMJ | BMJ 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 |
| | Kymera Therapeutics | KYMR | KYMR US | Geoff Meacham |
| | Moderna | MRNA | MRNA US | Geoff Meacham |
| | Pfizer | PFE | PFE US | Geoff Meacham |
| | Recursion Pharmaceuticals, Inc. | RXR | RXR 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 |
| UNDERPERFORM | | | | |
| | AlloVir, Inc. | ALVR | ALVR US | Jason Zemansky |
| | CureVac | CVAC | CVAC US | Geoff Meacham |
| | Day One Biopharmaceuticals | DAWN | DAWN US | Alec W. Stranahan |
| | LianBio | LIAN | LIAN US | Geoff Meacham |
| | 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 |

IQmethodSM Measures Definitions**Business Performance**

Return On Capital Employed

Return On Equity

Operating Margin

Earnings Growth

Free Cash Flow

Numerator

NOPAT = (EBIT + Interest Income) × (1 – Tax Rate) + Goodwill Amortization

Net Income

Operating Profit

Expected 5 Year CAGR From Latest Actual

Cash Flow From Operations – Total Capex

Denominator

Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill

Amortization

Shareholders' Equity

Sales

N/A

N/A

Quality of Earnings

Cash Realization Ratio

Asset Replacement Ratio

Tax Rate

Net Debt-To-Equity Ratio

Interest Cover

Numerator

Cash Flow From Operations

Capex

Tax Charge

Net Debt = Total Debt – Cash & Equivalents

EBIT

Denominator

Net Income

Depreciation

Pre-Tax Income

Total Equity

Interest Expense

Valuation Toolkit

Price / Earnings Ratio

Price / Book Value

Dividend Yield

Free Cash Flow Yield

Enterprise Value / Sales

Numerator

Current Share Price

Current Share Price

Annualised Declared Cash Dividend

Cash Flow From Operations – Total Capex

EV = Current Share Price × Current Shares + Minority Equity + Net Debt +

Other LT Liabilities

Enterprise Value

Denominator

Diluted Earnings Per Share (Basis As Specified)

Shareholders' Equity / Current Basic Shares

Current Share Price

Market Cap = Current Share Price × Current Basic Shares

Sales

Basic EBIT + Depreciation + Amortization

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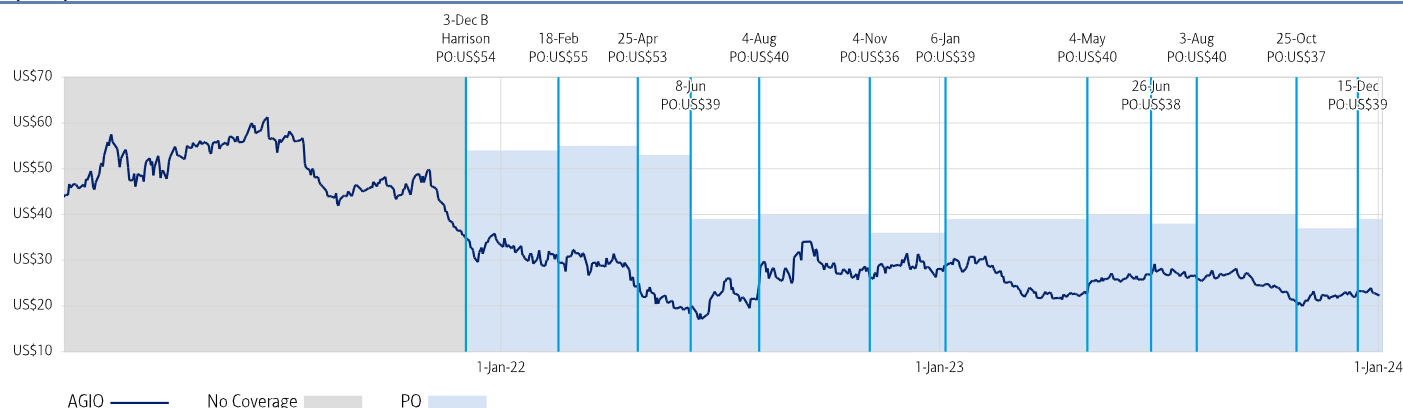
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Disclosures

Important Disclosures

Agios (AGIO) Price Chart



AGIO — No Coverage PO
 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.

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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% |

^{R2} Ratings dispersions may vary from time to time where BofA Global Research believes it better reflects the investment prospects of stocks in a Coverage Cluster.

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