

Agios Pharmaceuticals

Pyrukynd program poised for new populations: Thoughts post the 4Q23 call

Reiterate Rating: BUY | PO: 49.00 USD | Price: 25.87 USD

Pivotal progress continues into 2024

Agios announced an encouraging 4Q23 update today with a focus on the ongoing Pyrukynd launch in PKD and key pivotal programs to expand the label into additional indications. While 4Q Pyrukynd revenue was slightly lower q/q (-4%) with \$7.1M (v \$7.9M cons.), we note the reduction was based on lower customer inventory levels and we think the growing unique patient enrollment forms (178 total from 160 3Q) and 109 patients on treatment (from 100 3Q) show an encouraging increase in usage. [After positive pivotal data from the ENERGIZE trial earlier this year \(see report\)](#), we look for a significant reduction in transfusion burden from the ENERGIZE-T trial (mid-year) to highlight the therapeutic benefit of Pyrukynd in thal and support a regulatory filing by YE24. We model a 2025 launch of Pyrukynd in thal and risk-adjusted peak sales of \$776M (75% PoS). With multiple pivotal trials ongoing including SCD, which had encouraging phase 2 [data at ASH \(see report\)](#), we think Agios is positioning itself well for broad commercialization of Pyrukynd. Given the ongoing launch of Pyrukynd in PKD and progress towards label expansion, we maintain Buy and \$49 PO.

Thalassemia launch in view with filing expected by YE

Along with a comprehensive commercial update of Pyrukynd in PKD, Agios focused on launch plans for thal including expanding its launch capabilities and scope from ultra rare disease to a rare disease market. If approved, mitapivat could be the first therapy approved for all types of thal and address the unmet need across the disease population.

Agios remains on track with label expansion efforts

Building upon the late stage clinical focus [discussed at a recent conference \(see report\)](#), we think Agios remains on track to deliver pivotal readouts this year with ENERGIZE-T (mid-24) and ACTIVATE-kids (YE24) and complete enrollment in SCD (YE24) and pediatric TD-PKD (YE24). The company discussed earlier stage programs including dosing the phase 2b AG-946 trial which could build upon positive [data in MDS \(see report\)](#). Agios also plans to dose the phase 1 study of AG-181 for the treatment of PKU in early 2024. We look for derisking data to add the earlier stage programs to our model.

Model updates

We update our model for 4Q23 reporting and now model 2024 and 2025 EPS of -\$6.47 (from -\$6.09) and -\$5.96 (from -\$5.48), respectively. Agios has \$806.4M cash and cash equivalents and a cash runway into at least 2026.

See our catalyst calendar below (Exhibit 1):

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	(4.23)	(6.33)	(6.47)	(5.96)	(4.24)
EPS Change (YoY)	NM	-49.6%	-2.2%	7.9%	28.9%
Consensus EPS (Bloomberg)			(5.20)	(5.47)	(3.76)
DPS	0.01	0	0	0	0
Valuation (Dec)					
Free Cash Flow Yield*	-21.7%	-20.4%	-21.5%	-21.5%	-17.5%

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

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Timestamp: 15 February 2024 10:37AM EST

15 February 2024

Equity

Key Changes

(US\$)	Previous	Current
2024E Rev (m)	45.5	44.2
2025E Rev (m)	131.2	127.4
2024E EPS	-6.09	-6.47
2025E EPS	-5.48	-5.96
2026E EPS	-3.83	-4.24
2024E EBITDA (m)	-376.5	-397.9
2025E EBITDA (m)	-335.8	-361.0
2026E EBITDA (m)	-253.4	-277.0

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Stock Data

Price	25.87 USD
Price Objective	49.00 USD
Date Established	3-Jan-2024
Investment Opinion	C-1-9
52-Week Range	19.80 USD - 29.23 USD
Mkt Val (mn) / Shares Out (mn)	1,446 USD / 55.9
Free Float	98.4%
Average Daily Value (mn)	22.58 USD
BofA Ticker / Exchange	AGIO / NAS
Bloomberg / Reuters	AGIO US / AGIO.OQ
ROE (2024E)	-64.0%
Net Dbt to Eqty (Dec-2023A)	-55.5%
ESGMeter TM	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".

PKD: pyruvate kinase deficiency

Thal: thalassemia

TD-PKD: transfusion dependent PKD

SCD: sickle cell disease

ASH: American Society of Hematology conference

iQprofileSM Agios Pharmaceuticals

iQmethodSM – Bus Performance*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Return on Capital Employed	-26.5%	-31.3%	-46.0%	-74.5%	-76.5%
Return on Equity	-19.4%	-37.0%	-64.0%	-112.8%	-110.5%
Operating Margin	-2,732.1%	-1,459.5%	-917.1%	-288.2%	-105.2%
Free Cash Flow	(314)	(295)	(311)	(311)	(253)

iQmethodSM – Quality of Earnings*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash Realization Ratio	NM	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	-12.7%	-55.5%	-88.7%	-63.8%	-61.5%
Interest Cover	NA	NA	NA	NA	NA

Income Statement Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Sales	14	27	44	127	268
% Change	NA	88.4%	64.7%	188.3%	110.6%
Gross Profit	13	24	39	112	236
% Change	NA	91.0%	62.3%	188.3%	110.6%
EBITDA	(380)	(383)	(398)	(361)	(277)
% Change	-3.1%	-0.6%	-3.9%	9.3%	23.3%
Net Interest & Other Income	157	39	34	15	6
Net Income (Adjusted)	(232)	(352)	(416)	(395)	(276)
% Change	NM	-52.0%	-18.2%	5.1%	30.0%

Free Cash Flow Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Net Income from Cont Operations (GAAP)	(232)	(352)	(371)	(352)	(276)
Depreciation & Amortization	9	9	7	6	5
Change in Working Capital	(16)	(1)	(1)	(21)	(41)
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	(70)	54	57	60	63
Capital Expenditure	(5)	(5)	(4)	(3)	(3)
Free Cash Flow	-314	-295	-311	-311	-253
% Change	23.9%	6.1%	-5.5%	0.2%	18.6%
Share / Issue Repurchase	3	3	3	3	303
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	0	0	0	0	0

Balance Sheet Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash & Equivalents	139	447	439	131	181
Trade Receivables	2	5	8	24	50
Other Current Assets	691	91	92	102	123
Property, Plant & Equipment	23	19	16	14	11
Other Non-Current Assets	383	383	83	84	84
Total Assets	1,239	945	638	354	451
Short-Term Debt	0	0	0	0	0
Other Current Liabilities	63	64	68	74	80
Long-Term Debt	0	0	0	0	0
Other Non-Current Liabilities	75	75	75	75	75
Total Liabilities	138	140	143	149	156
Total Equity	1,101	806	495	205	295
Total Equity & Liabilities	1,239	945	638	354	451

* 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

872,918

Quarterly Earnings Estimates

	2023	2024
Q1	-1.47A	-1.61E
Q2	-1.51A	-1.55E
Q3	-1.64A	-1.53E
Q4	-1.72A	-1.78E

Exhibit 1: Agios Catalyst Calendar

We look for positive data from ENERGIZE-T to support filing for approval in thalassemia by YE24.

Company	Asset	Indication	Event	Timing	Importance
Agios	Mitapivat	SCD	Phase 3 data	2025	High
Agios	Mitapivat	SCD	Complete phase 3 enrollment	YE24	Moderate
Agios	AG-946	LR-MDS	Initiate phase 2b	mid-2024	Low
Agios	Mitapivat	TDT	Phase 3 ENERGIZE-T data	mid-2024	High
Agios	Mitapivat	Pediatric PKD	Data from ACTIVATEkids-T	YE24	High
Agios	Mitapivat	Pediatric PKD	Complete enrollment ACTIVATE-kids	YE24	Moderate
Agios	Mitapivat	Pediatric PKD	Data from ACTIVATEkids	2025	High
Agios	AG-181	PKU	Initiate dosing	Early 2024	Low
Agios	Mitapivat	Thalassemia	File for regulatory approval	YE24	High

Source: BofA Global Research, company reports

BofA GLOBAL RESEARCH

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 \$9/share for PKD, \$17/share for thalassemia, \$3/share for SCD, \$7/share for Pyrukynd ex-US royalties, and \$13/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
	HUTCHMED	HCM	HCM US	Alec W. Stranahan
	Immatics	IMTX	IMTX US	Alec W. Stranahan
	Insmem 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
	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
	Traverse 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

US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
NEUTRAL				
	AbbVie	ABBV	ABBV US	Geoff Meacham
	Alecto, 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
	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
	Kymira 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
	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
	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
RSTR				
	Gilead Sciences Inc.	GILD	GILD US	Geoff Meacham

iQmethodSM Measures Definitions

Business Performance

Return On Capital Employed

Return On Equity

Operating Margin

Earnings Growth

Free Cash Flow

Quality of Earnings

Cash Realization Ratio

Asset Replacement Ratio

Tax Rate

Net Debt-To-Equity Ratio

Interest Cover

Valuation Toolkit

Price / Earnings Ratio

Price / Book Value

Dividend Yield

Free Cash Flow Yield

Enterprise Value / Sales

EV / EBITDA

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

Numerator

Cash Flow From Operations

Capex

Tax Charge

Net Debt = Total Debt – Cash & Equivalents

EBIT

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

Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill

Amortization

Shareholders' Equity

Sales

N/A

N/A

Denominator

Net Income

Depreciation

Pre-Tax Income

Total Equity

Interest Expense

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



Valuation Toolkit

Numerator

Denominator

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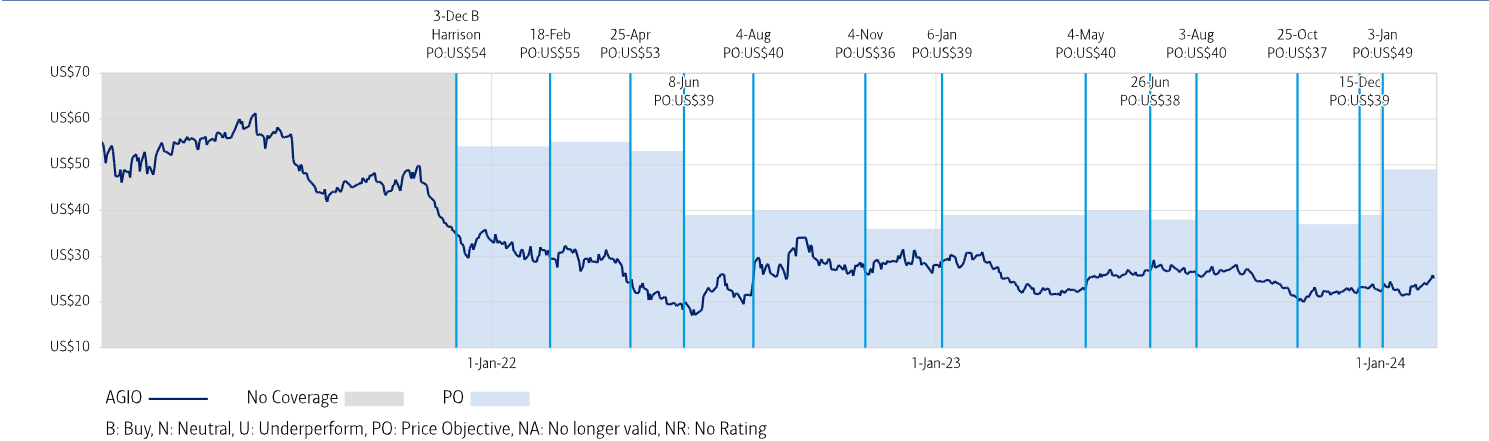
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Agios (AGIO) Price Chart



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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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