

Amylyx Pharmaceuticals

4Q modest growth better than expected; PHOENIX data coming up

Reiterate Rating: BUY | PO: 40.00 USD | Price: 15.31 USD

US net patient add stable; PHOENIX remains key LT driver

AMLX shares are strong today (+21%; XBI +3%) given Relyvrio's 4Q sales of \$108M (versus consensus \$102M) were better-than-expected and alleviated some investor concerns on potential declining sales due to discontinuations greater than new scripts. Indeed, while US net patient add has slowed down over the past few quarters (4Q/3Q/2Q/1Q: flat/ +100/ +800/ +1,700), we remain encouraged by the \$400M/year run rate one-year post-launch and ex-US growth despite limited access ex-US. Importantly, we'd argue that it's a matter of "when and not if" Relyvrio achieves >\$1.5B in peak sales if the PHOENIX trial succeeds, which remains the key value driver and determinant of Relyvrio's outlook. Looking ahead, we anticipate continued sales growth given the elimination of 5% co-pay in the catastrophic phase with the Part D redesign as well as continued commercial execution/education. Overall, we continue to like the risk-reward setup going into PHOENIX topline in 1H24 (before or during 2Q) and remain optimistic on the trial outcome. As such, we reiterate our Buy rating but lower our PO to \$40 (from \$42) to reflect a more modest revenue growth in 2024/25 and higher OpEx as the company continues to invest in pipeline programs.

TUDCA-ALS: Timing unsure & less relevant at this point

Over the past few months, investors have been waiting eagerly on the publication of TUDCA-ALS results to use it as a readthrough to PHOENIX outcome. That said, we believe investor sentiments have largely baked into the downside scenario on the TUDCA-ALS data given the delay in publication as most investors were expecting topline data in late December or early January. To that end, we see limited downside risk on TUDCA-ALS readout given 1) timing of results will be too close to PHOENIX data, 2) the trial only evaluates one of Relyvrio's components, and 3) data will likely be too murky to interpret given potentially high dropout rates since the trial was run during COVID. That being said, we believe even a slight positive trend would give investors higher confidence on PHOENIX readout.

Model changes

We adjusted our model following 4Q results and now forecast 2024 revenue of \$480M and EPS of \$0.40.

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	(3.39)	0.70	0.40	2.48	4.50
EPS Change (YoY)	74.6%	NM	-42.9%	520.0%	81.5%
Consensus EPS (Bloomberg)			1.75	2.23	3.36
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	NM	21.9x	38.3x	6.2x	3.4x
EV / EBITDA*	NM	23.9x	21.7x	4.1x	2.3x
Free Cash Flow Yield*	-17.6%	5.5%	-17.1%	23.3%	33.9%

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

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Timestamp: 22 February 2024 01:57PM EST

22 February 2024

Equity

Key Changes

(US\$)	Previous	Current
Price Obj.	42.00	40.00
2024E Rev (m)	653.5	480.0
2025E Rev (m)	905.0	713.3
2026E Rev (m)	1,104.2	909.1
2024E EPS	3.01	0.40
2025E EPS	5.03	2.48
2026E EPS	6.30	4.50
2024E EBITDA (m)	251.4	45.6
2025E EBITDA (m)	449.3	240.8
2026E EBITDA (m)	597.4	425.6

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Stock Data

Price	15.31 USD
Price Objective	40.00 USD
Date Established	22-Feb-2024
Investment Opinion	C-1-9
52-Week Range	11.82 USD - 38.32 USD
Mkt Val (mn) / Shares Out (mn)	1,034 USD / 67.5
Free Float	83.5%
Average Daily Value (mn)	14.15 USD
BofA Ticker / Exchange	AMLX / NAS
Bloomberg / Reuters	AMLX US / AMLX.OQ
ROE (2024E)	5.4%
Net Dbt to Eqty (Dec-2023A)	-19.3%
ESGMeter™	NLA

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iQprofileSM Amylyx Pharmaceuticals

iQmethodSM – Bus Performance*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Return on Capital Employed	-81.9%	7.1%	5.3%	35.7%	44.5%
Return on Equity	-92.5%	10.1%	5.4%	36.0%	44.7%
Operating Margin	-905.7%	10.2%	7.6%	31.8%	45.7%
Free Cash Flow	(182)	57	(177)	240	351

iQmethodSM – Quality of Earnings*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash Realization Ratio	NM	1.3x	-5.8x	1.4x	1.1x
Asset Replacement Ratio	5.2x	3.4x	1.5x	0.7x	0.3x
Tax Rate	NM	9.3%	22.0%	22.0%	22.0%
Net Debt-to-Equity Ratio	-18.4%	-19.3%	-11.3%	-33.8%	-61.3%
Interest Cover	NA	NA	NA	NA	NA

Income Statement Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Sales	22	381	480	713	909
% Change	7,700.0%	1,612.9%	26.1%	48.6%	27.4%
Gross Profit	19	355	446	671	864
% Change	NM	NM	25.6%	50.2%	28.8%
EBITDA	(201)	41	46	241	426
% Change	-143.1%	NM	9.9%	428.2%	76.8%
Net Interest & Other Income	4	15	0	0	0
Net Income (Adjusted)	(198)	49	28	177	324
% Change	-125.6%	NM	-42.6%	526.1%	83.1%

Free Cash Flow Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Net Income from Cont Operations (GAAP)	(198)	49	28	177	324
Depreciation & Amortization	0	3	9	14	10
Change in Working Capital	23	16	15	6	1
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	(5)	(2)	(216)	54	19
Capital Expenditure	(3)	(9)	(14)	(10)	(3)
Free Cash Flow	-182	57	-177	240	351
% Change	-142.7%	NM	NM	NM	45.9%
Share / Issue Repurchase	2	2	2	2	2
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	63	122	47	190	543
Trade Receivables	15	133	120	107	91
Other Current Assets	304	432	323	347	341
Property, Plant & Equipment	3	9	13	10	3
Other Non-Current Assets	7	7	7	7	7
Total Assets	391	703	511	661	985
Short-Term Debt	0	0	0	0	0
Other Current Liabilities	47	67	87	94	95
Long-Term Debt	0	0	0	0	0
Other Non-Current Liabilities	4	4	4	4	4
Total Liabilities	51	71	91	98	99
Total Equity	341	632	420	563	886
Total Equity & Liabilities	391	703	511	661	985

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

Company Sector

Pharmaceuticals

Company Description

Amylyx (AMLX) is a commercial-stage biopharmaceutical company developing therapies for ALS (a.k.a. Lou Gehrig's disease) and other neurodegenerative diseases. Founded in 2013 and based in Cambridge, Massachusetts, the company's main asset is AMX0035 or Relyvrio (sodium phenylbutyrate + taurursodiol).

Investment Rationale

We rate AMLX Buy based on expected strong market uptake of AMX0035 in ALS despite modest benefit given the unmet need and low reimbursement hurdle.

Stock Data

Average Daily Volume 924,009

Quarterly Earnings Estimates

	2023	2024
Q1	NAA	NA
Q2	NAA	NA
Q3	NAA	NA
Q4	NAA	NA



Price objective basis & risk

Amylyx Pharmaceuticals (AMLX)

Our \$40 PO is based on probability-adjusted NPV analysis of AMX0035 in ALS (\$34/sh) and net cash (\$6/sh). We model AMX0035 revenues through 2035 in key markets including US, Canada, and Europe, and apply a 15% WACC and -35% terminal growth rate.

Upside Risks to our PO

1) Positive confirmatory phase 3 PHOENIX trial readout in 2024 that drives strong market uptake, especially in OUS markets, 2) better than expected reimbursement and market uptake.

Downside Risks to our PO

1) failure to receive approval in EU, 2) commercial pushback from payers and providers, 3) failure of confirmatory phase 3 PHOENIX trial, resulting in pushback from payers and providers and drug could be withdrawn from the market.

Analyst Certification

I, Geoff Meacham, 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
	Insmo 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
	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

US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	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
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
	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.	RXR	RXR 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

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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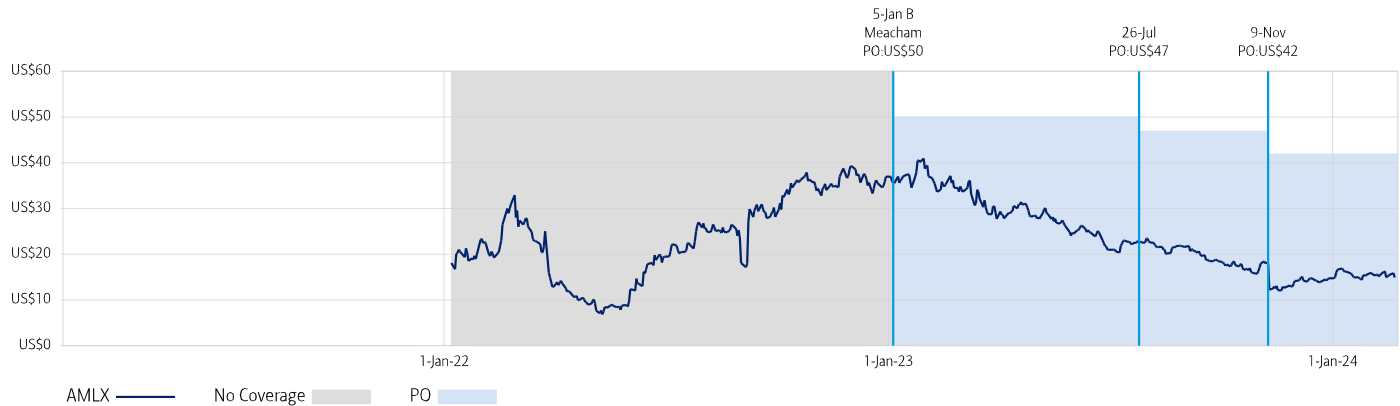
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Amylyx (AMLX) Price Chart



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.

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Buy	≥ 10%	≤ 70%
Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

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