

## Amylyx Pharmaceuticals

## Complete PHOENIX failure in ALS a surprise; Moving to Neutral

Rating Change: NEUTRAL | PO: 4.00 USD | Price: 3.52 USD

## PHOENIX trial disappoints; no subgroup benefits either

Following Amylyx's announcement this morning that its ALS drug, Relyvrio, failed to demonstrate incremental benefit compared to placebo from the confirmatory PHOENIX trial, we downgrade AMLX to Neutral from Buy and lower our PO to \$4 from \$40. Specifically, the trial did not meet the primary endpoint of ALSFRS-R at Week 48 ( $p=0.667$ ), nor was there statistical significance in secondary endpoint. As a result, Amylyx is pausing promotion of Relyvrio and will engage with regulators on next steps, including potentially taking Relyvrio off the market. Overall, the news was disappointing and we move our rating to Neutral given uncertainty about the long-term outlook for Amylyx's, balanced by fair valuation (shares are trading below \$5/shr cash).

## Topline data worse than expected

Investors were surprised by the earlier-than-expected announcement today given prior timing of 2Q before topline release. Importantly, the topline data fall into the worst-case scenario with  $p=0.667$ , suggesting there's no trend observed from the data, including pre-specified subgroup analyses. That said, given the unmet needs in ALS, we think Relyvrio will likely stay on the market until we get better clarity on overall survival data (with low expectations), expected in 2025/26, as well as FDA's decision on keeping the drug on the market.

## PSP and Wolfram provide optionality

Investors have zero expectations for Amylyx's earlier stage programs, including progressive supranuclear palsy (PSP) and Wolfram syndrome (WS) in light of PHOENIX results. That said, given AMLX's current valuation and market condition, we could see an upside scenario if the company were to announce positive data. We expect to see phase 2 Wolfram HELIOS preliminary data in 2Q24 and interim data from the Phase 3 PSP study ahead of topline results in 2025/26.

## Model changes

We adjusted our model following today's announcement. We lowered our peak revenue forecast to ~\$300M (vs. prior \$1.5B), assuming Relyvrio remains on the market.

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	(3.39)	0.70	(1.85)	(2.54)	(0.91)
EPS Change (YoY)	74.6%	NM	NM	-37.3%	64.2%
Consensus EPS (Bloomberg)			1.09	1.79	2.48
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	NM	5.0x	NM	NM	NM
EV / EBITDA*	NM	4.9x	NM	NM	NM
Free Cash Flow Yield*	-76.4%	23.7%	-140.8%	-16.2%	13.6%

\* For full definitions of *IQmethod*<sup>SM</sup> measures, see page 5.

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Timestamp: 08 March 2024 12:50PM EST

08 March 2024

## Equity

## Key Changes

(US\$)	Previous	Current
Inv. Opinion	C-1-9	C-2-9
Inv. Rating	BUY	NEUTRAL
Price Obj.	40.00	4.00
2024E Rev (m)	480.0	300.0
2025E Rev (m)	713.3	209.9
2026E Rev (m)	909.1	239.0
2024E EPS	0.40	-1.85
2025E EPS	2.48	-2.54
2026E EPS	4.50	-0.91
2024E EBITDA (m)	45.6	-121.8
2025E EBITDA (m)	240.8	-167.6
2026E EBITDA (m)	425.6	-55.5

## Geoff Meacham

Research Analyst  
BoFA  
+1 646 855 1004  
geoff.meacham@bofa.com

## Charlie Yang

Research Analyst  
BoFA  
+1 646 855 5732  
charlie.yang@bofa.com

## Alexandria Hammond

Research Analyst  
BoFA  
alexandria.hammond@bofa.com

## Stock Data

Price	3.52 USD
Price Objective	4.00 USD
Date Established	8-Mar-2024
Investment Opinion	C-2-9
52-Week Range	11.82 USD - 38.32 USD
Mkt Val (mn) / Shares Out (mn)	239 USD / 67.8
Free Float	83.1%
Average Daily Value (mn)	4.68 USD
BoFA Ticker / Exchange	AMLX / NAS
Bloomberg / Reuters	AMLX US / AMLX.OQ
ROE (2024E)	-32.7%
Net Dbt to Eqty (Dec-2023A)	-19.3%
ESGMeter <sup>TM</sup>	NLA

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:

ALSFRS-R: Revised Amyotrophic Lateral Sclerosis

Functional Rating Scale

# iQprofile<sup>SM</sup> Amylyx Pharmaceuticals

## iQmethod<sup>SM</sup> – Bus Performance\*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Return on Capital Employed	-81.9%	7.1%	-29.1%	-137.3%	-76.1%
Return on Equity	-92.5%	10.1%	-32.7%	-158.2%	-89.4%
Operating Margin	-905.7%	10.2%	-43.7%	-86.4%	-27.4%
Free Cash Flow	(182)	57	(336)	(39)	32

## iQmethod<sup>SM</sup> – Quality of Earnings\*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash Realization Ratio	NM	1.3x	NM	NM	NM
Asset Replacement Ratio	5.2x	3.4x	1.5x	0.7x	0.3x
Tax Rate	NM	9.3%	NM	NM	NM
Net Debt-to-Equity Ratio	-18.4%	-19.3%	-22.3%	-2.5%	-41.2%
Interest Cover	NA	NA	NA	NA	NA

## Income Statement Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Sales	22	381	300	210	239
% Change	7,700.0%	1,612.9%	-21.2%	-30.0%	13.8%
Gross Profit	19	355	279	197	227
% Change	NM	NM	-21.5%	-29.3%	15.0%
EBITDA	(201)	41	(122)	(168)	(55)
% Change	-143.1%	NM	NM	-37.6%	66.9%
Net Interest & Other Income	4	15	0	0	0
<b>Net Income (Adjusted)</b>	<b>(198)</b>	<b>49</b>	<b>(131)</b>	<b>(181)</b>	<b>(65)</b>
% Change	-125.6%	NM	NM	-38.3%	63.9%

## Free Cash Flow Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Net Income from Cont Operations (GAAP)	(198)	49	(131)	(181)	(65)
Depreciation & Amortization	0	3	9	14	10
Change in Working Capital	23	16	15	(5)	(14)
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	(5)	(2)	(216)	144	106
Capital Expenditure	(3)	(9)	(14)	(10)	(3)
<b>Free Cash Flow</b>	<b>-182</b>	<b>57</b>	<b>-336</b>	<b>-39</b>	<b>32</b>
% Change	-142.7%	NM	NM	88.5%	NM
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	38	1	36
Trade Receivables	15	133	75	31	24
Other Current Assets	304	432	128	94	84
Property, Plant & Equipment	3	9	13	10	3
Other Non-Current Assets	7	7	7	7	7
<b>Total Assets</b>	<b>391</b>	<b>703</b>	<b>261</b>	<b>143</b>	<b>153</b>
Short-Term Debt	0	0	0	0	0
Other Current Liabilities	47	67	87	80	62
Long-Term Debt	0	0	0	0	0
Other Non-Current Liabilities	4	4	4	4	4
<b>Total Liabilities</b>	<b>51</b>	<b>71</b>	<b>91</b>	<b>84</b>	<b>66</b>
<b>Total Equity</b>	<b>341</b>	<b>632</b>	<b>170</b>	<b>59</b>	<b>87</b>
<b>Total Equity &amp; Liabilities</b>	<b>391</b>	<b>703</b>	<b>261</b>	<b>143</b>	<b>153</b>

\* For full definitions of iQmethod<sup>SM</sup> 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 Neutral based on uncertainty about the AMX0035 outlook, balanced by valuation (with shares trading below cash).

## Stock Data

Average Daily Volume 1,329,205

## 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 \$4 PO is based on remaining cash by 'YE24 (\$4/sh).

#### Upside Risks to our PO

1) Relyvrio remains on the market, 2) better-than-expected market uptake, 3) positive data from earlier stage programs

#### Downside Risks to our PO

1) commercial pushback from payers and providers and 2) 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
<b>BUY</b>				
	89bio, Inc	ETNB	ETNB US	Geoff Meacham
	Acumen Pharma	ABOS	ABOS US	Geoff Meacham
	Agios Pharmaceuticals	AGIO	AGIO US	Greg Harrison, CFA
	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
	Insmid 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



**US - Biopharmaceuticals Coverage Cluster**

<b>Investment rating</b>	<b>Company</b>	<b>BofA Ticker</b>	<b>Bloomberg symbol</b>	<b>Analyst</b>
	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
<b>NEUTRAL</b>				
	AbbVie	ABBV	ABBV US	Geoff Meacham
	Alector, Inc	ALEC	ALEC US	Greg Harrison, CFA
	Amgen Inc.	AMGN	AMGN US	Geoff Meacham
	Amylyx Pharmaceuticals	AMLX	AMLX 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.	RXRJ	RXRJ 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
<b>UNDERPERFORM</b>				
	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<sup>SM</sup> 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 &amp; 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

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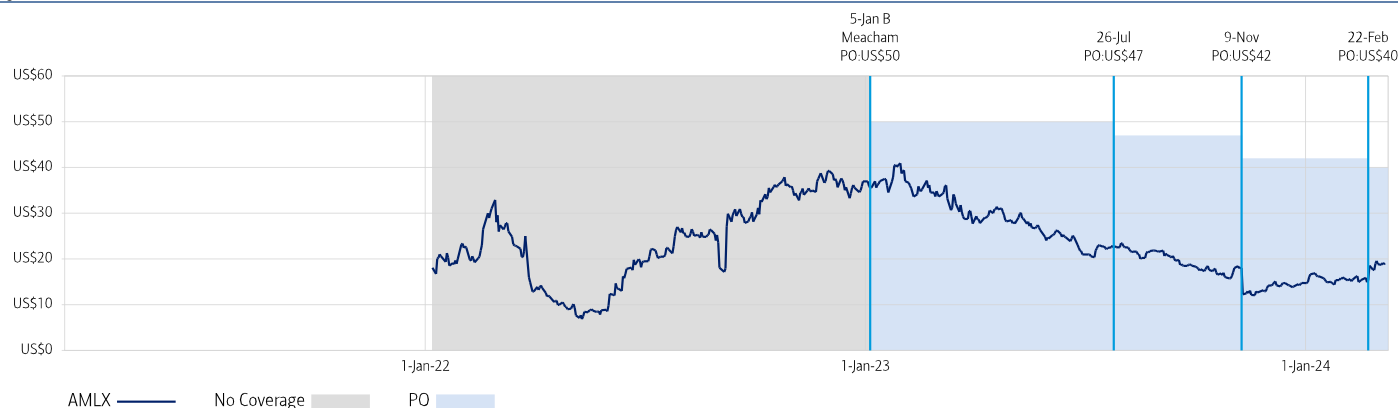
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#### Amylyx (AMLX) Price Chart



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 <sup>R1</sup>	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 <sup>R1</sup>	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%

<sup>R1</sup> 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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