

Xenon Pharmaceuticals

4Q wrap: details on MDD pivotal program + narrowing of FOS topline

Reiterate Rating: BUY | PO: 56.00 USD | Price: 47.20 USD

4Q update: Ph3 FOS remains on track for 1H/mid-'25

Xenon's 4Q update was focused on pipeline updates, including 1) narrowing XEN1101 (epilepsy) Ph3 X-TOLE2 enrollment completion timeline now late-'24/early-25 (vs 2H24 prior); and 2) added details on '1101 Ph3 MDD plans (more below). Overall, the updates were not material and we make no changes to any of our XEN1101 development timelines or assumptions regarding competitive positioning. The key company catalyst remains X-TOLE2 data which remains on track for mid-'25 readout and we are highly confident '1101 replicating strong profile demonstrated in the first completed pivotal. Exiting 4Q, we reiterate our Buy rating and \$56/sh PO given '1101's peak sales potential in epilepsy and MDD.

Details revealed for MDD pivotal program

In April, Xenon will meet with FDA for an end-of-phase-2 meeting to discuss XEN1101 MDD trial design. The development path for MDD is well established, thus we expect the meeting to be straightforward. On the call, management did specify 1) it will use HAMD17 as the primary endpoint and given less variability versus MADRS, which makes sense based on supportive Ph2, 2) dose - XENE plans to prioritize 20mg as single drug dose arm versus prior consideration of 25mg, as former offers more commercially attractive tolerability profile. XENE plans to initiate first Ph3 in 2H24 and will run three Ph3s to mitigate risk against placebo response. Our 50% POS for XEN1101 in MDD is supported by X-NOVA's proof-of-concept data and we model ~\$1.2bn peak sales in 2029e.

Early pipeline: Nav1.7s advancing into IND

There was some discussion on the call regarding XENE's early-stage pipeline, with a focus on Nav1.7 for treatment of pain. Nav1.7 is similar to Vertex's Nav1.8 which reported favorable clinical data in pain. XENE believes Nav1.7 may have some advantages over 1.8 given more genetic validation for Nav1.7 as a target in pain. XENE expects it could be in a position to advance either a Nav1.1 (for seizure disorders) or Nav1.7 candidate into the clinic by next year, though refrained from offering details on an anticipated lead candidate.

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	(2.06)	(2.73)	(3.14)	(2.72)	(2.96)
EPS Change (YoY)	-16.4%	-32.5%	-15.0%	13.4%	-8.8%
Consensus EPS (Bloomberg)			(3.21)	(3.65)	(2.98)
DPS	0	0	0	0	0
Valuation (Dec)					
Free Cash Flow Yield*	-3.7%	-5.2%	-5.1%	-5.1%	-4.9%

* For full definitions of *IQmethod*SM measures, see page 4.

29 February 2024

Equity

Key Changes

(US\$)	Previous	Current
2025E Rev (m)	57.2	70.2
2026E Rev (m)	135.0	161.2
2024E EPS	-2.82	-3.14
2025E EPS	-2.61	-2.72
2026E EPS	-2.75	-2.96

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Stock Data

Price	47.20 USD
Price Objective	56.00 USD
Date Established	2-Jan-2024
Investment Opinion	C-1-9
52-Week Range	27.99 USD - 50.98 USD
Mkt Val (mn) / Shares Out (mn)	3,560 USD / 75.4
Free Float	99.7%
Average Daily Value (mn)	18.49 USD
BofA Ticker / Exchange	XENE / NAS
Bloomberg / Reuters	XENE US / XENE.OQ
ROE (2024E)	-29.6%
Net Dbt to Eqty (Dec-2023A)	-48.7%
ESGMeter TM	Low

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".

Acronyms:

FDA: food & drug administration
FOS: focal onset seizures
HAMD-17: Hamilton depression rating scale
IND: investigational new drug
MDD: major depressive disorder

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Timestamp: 29 February 2024 08:20PM EST

iQprofileSM Xenon Pharmaceuticals

iQmethodSM – Bus Performance*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Return on Capital Employed	-20.8%	-29.2%	-26.3%	-26.7%	-39.6%
Return on Equity	-22.7%	-28.0%	-29.6%	-30.1%	-44.9%
Operating Margin	-1,368.9%	NA	-4,210.2%	-259.9%	-123.3%
Free Cash Flow	(130)	(184)	(183)	(181)	(173)

iQmethodSM – Quality of Earnings*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash Realization Ratio	NM	NM	NM	NM	NM
Asset Replacement Ratio	4.2x	3.4x	0x	0.2x	5.3x
Tax Rate	NM	0.2%	NM	NM	NM
Net Debt-to-Equity Ratio	-30.6%	-48.7%	-46.5%	-33.6%	-2.4%
Interest Cover	NA	NA	NA	NA	NA

Income Statement Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Sales	9	0	5	70	161
% Change	-48.8%	-100.0%	NA	1,304.4%	129.6%
Gross Profit	9	0	5	65	149
% Change	-48.8%	NM	NA	NM	128.8%
EBITDA	(129)	(213)	(210)	(182)	(198)
% Change	-64.8%	-65.9%	1.7%	13.3%	-9.0%
Net Interest & Other Income	4	31	0	0	0
Net Income (Adjusted)	(125)	(182)	(211)	(183)	(199)
% Change	-62.1%	-46.0%	-15.4%	13.3%	-8.9%

Free Cash Flow Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Net Income from Cont Operations (GAAP)	(125)	(182)	(211)	(183)	(199)
Depreciation & Amortization	0	1	1	1	0
Change in Working Capital	(7)	(2)	25	0	26
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	4	2	2	2	1
Capital Expenditure	(2)	(2)	0	0	(2)
Free Cash Flow	-130	-184	-183	-181	-173
% Change	-81.0%	-40.9%	0.4%	1.2%	4.2%
Share / Issue Repurchase	0	264	0	0	0
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	168	367	314	183	9
Trade Receivables	3	4	2	4	8
Other Current Assets	384	384	377	381	383
Property, Plant & Equipment	NA	NA	NA	NA	NA
Other Non-Current Assets	13	14	14	13	15
Total Assets	568	769	706	580	416
Short-Term Debt	0	1	1	1	1
Other Current Liabilities	11	9	25	30	62
Long-Term Debt	0	0	0	0	0
Other Non-Current Liabilities	8	8	8	8	8
Total Liabilities	19	18	34	39	71
Total Equity	550	751	672	542	344
Total Equity & Liabilities	568	769	706	580	416

* For full definitions of iQmethodSM measures, see page 4.

Company Sector

Biotechnology

Company Description

Xenon Pharmaceuticals (XENE) is a late clinical-stage biotech that is focused on the development of small molecules that target human channelopathies, which may have utility in numerous CNS disorders. Lead drug XEN1101 is entering registration-enabling trials for FOS, and undergoing trials in PGTCs and MDD. Xenon's other pipeline drug, XEN496, is in clinical-stage for the treatment of a rare pediatric epilepsy.

Investment Rationale

We rate XENE Buy and like the company based on 1) 1101's competitive product profile (strong early anti-seizure data + simplicity of dosing) positioning the drug as potential blockbuster ASM, 2) upside optionality with potential '1101 label expansion (PGTCs and/or MDD dual benefit), and 3) '1101 differentiated product profile including ease of dosing and lack of titration will help position its adoption in competitive epilepsy market.

Stock Data

Average Daily Volume 391,784

Quarterly Earnings Estimates

	2023	2024
Q1	-0.62A	NAE
Q2	-0.72A	NAE
Q3	-0.79A	NAE
Q4	-0.65A	NAE

Price objective basis & risk

Xenon Pharmaceuticals (XENE)

Our \$56 price objective (PO) is based on a risk-adjusted sum-of-the-parts analysis. 1) XEN1101 launches in 2025 and risk-adjusted FOS sales reach est. \$1.5bn by 2039, 2) 80% POS for lead FOS indication, 80% POS for PGTCs, and 65% POS for MDD, 4) No terminal value beyond 2040 LOE, 5) 10% discount rate.

Downside risks to our PO: 1) emerging retinal AE in ongoing FOS studies, 2) failure or disappointing results on confirmatory Ph3 FOS study, 3) failure or disappointing results on PGTCs and/or MDD studies.

Upside risks to our PO: 1) better-than-expected results from Ph3 PGTCs study, 2) better-than-expected results from MDD POC studies, 3) clinical success in FOS leading to better adoption and/or steeper market ramp.

Analyst Certification

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US - Specialty Pharma & Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
	Arcellx, Inc.	ACLX	ACLX US	Jason M. Gerberry
	Arrowhead Pharmaceuticals	ARWR	ARWR US	Jason M. Gerberry
	bluebird bio	BLUE	BLUE US	Jason M. Gerberry
	Exelixis	EXEL	EXEL US	Jason M. Gerberry
	Fractyl Health	GUTS	GUTS US	Jason M. Gerberry
	Immunovant, Inc.	IMVT	IMVT US	Jason M. Gerberry
	Intra-Cellular Therapies	ITCI	ITCI US	Jason M. Gerberry
	Ionis	IONS	IONS US	Jason M. Gerberry
	Jazz Pharmaceuticals	JAZZ	JAZZ US	Jason M. Gerberry
	Lyra Therapeutics	LYRA	LYRA US	Jason M. Gerberry
	Oculus Holding AG	OCS	OCS US	Jason M. Gerberry
	Relay Therapeutics	RLAY	RLAY US	Jason M. Gerberry
	Teva Pharmaceuticals	TEVA	TEVA US	Jason M. Gerberry
	Vaxcyte Inc	PCVX	PCVX US	Jason M. Gerberry
	Xenon Pharmaceuticals	XENE	XENE US	Jason M. Gerberry
NEUTRAL				
	Alkermes	ALKS	ALKS US	Jason M. Gerberry
	Amphastar Pharmaceuticals	AMPH	AMPH US	Jason M. Gerberry
	Axsome Therapeutics	AXSM	AXSM US	Jason M. Gerberry
	Galapagos	GLPG	GLPG US	Jason M. Gerberry
	ProKidney Corp	PROK	PROK US	Jason M. Gerberry
	Roivant	ROIV	ROIV US	Chi M. Fong
UNDERPERFORM				
	Bausch Health Cos Inc	BHC	BHC US	Jason M. Gerberry
	FibroGen Inc.	FGEN	FGEN US	Jason M. Gerberry
	Harmony Biosciences	HRMY	HRMY US	Jason M. Gerberry
	Organon	OGN	OGN US	Jason M. Gerberry
	Viartis Inc.	VTRS	VTRS US	Jason M. Gerberry



US - Specialty Pharma & Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
RSTR	Tarsus Pharmaceuticals	TARS	TARS US	Jason M. Gerberry

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

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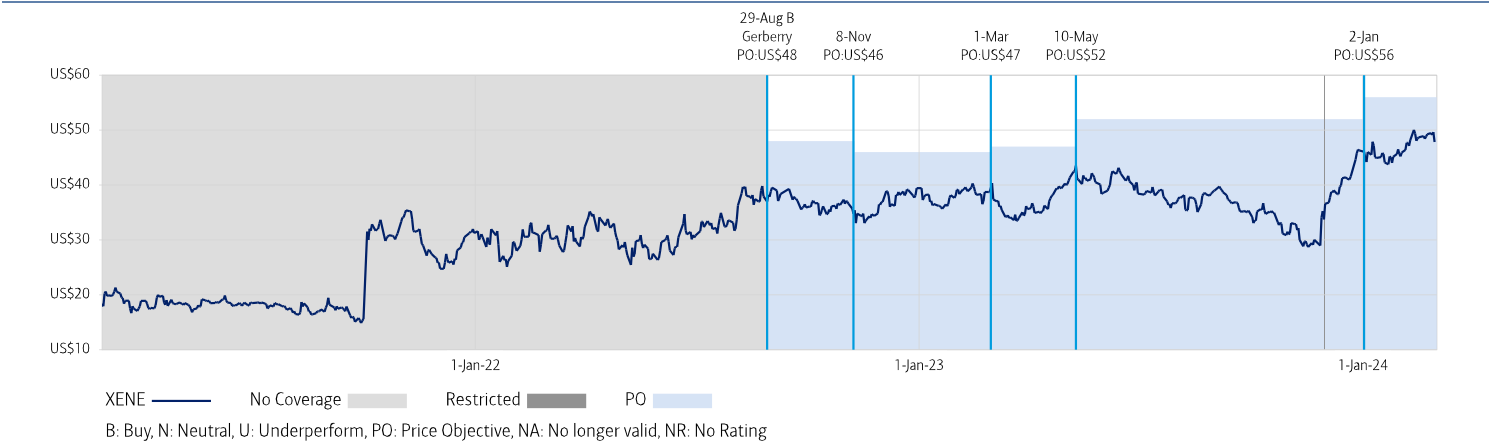
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Xenon Pharma (XENE) Price Chart



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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%

^{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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