

Syndax Pharmaceuticals

Commercial set-up starting as focus pivots to execution; our 4Q takes

Reiterate Rating: BUY | PO: 29.00 USD | Price: 24.41 USD

Quiet 4Q headlined by commercial, strategy updates

Syndax's 4Q update was solid, in our view, which, while not surprisingly light on major updates, provided investors with the first insights into the company's commercial plans along with key development updates. Indeed, while GAAP EPS (-\$0.06) came in below on higher OpEx, much of the discussion focused on the initial prep-work following last Dec's FDA submissions of revumenib and axatilimab. An Aug 28 PDUFA (with Priority Review) has been set for the latter, with the team expecting a 3Q date for the former. After exercising its co-commercialization option with partner Incyte (covered by Tazeen Ahmad), Syndax is building out its sales team to support both launches simultaneously, with leadership already in place. Under its agreement, the company is responsible for 30% of the axatilimab salesforce and given Incyte's experience/ infrastructure we see reasons to be optimistic for uptake—with additional benefits from targeting the same prescriber base for revumenib. In terms of development updates, while the company confirmed the initiation of a revumenib/ 7+3 combo phase 1 in treatment naïve mNPM1 or KMT2Ar AML, with plans to initiate a pivotal in 1L rev + ven/aza "unfit" AML by YE, news it was exploring axatilimab in IPF came as a positive update. We thought the pre-clinical data and scientific rationale were compelling, although given the overall lack of success in the space, we suspect most on the Street are unlikely to assign much value to the program absent good phase 2 results. Nonetheless, given what we expect to be a relatively low bar for entry, IPF could easily provide another leg of growth with the asset, in our view, already providing solid downside support (2030e adj. BofA \$92M vs \$109M cons). With overall increasing confidence into the near-term upside, we continue to see further upside to shares following 2023's positive momentum. Reiterate Buy and \$29 PO

As competitive positioning clarifies, still room for both

In our view, investor debate remains focused on the competitive position of revumenib vs. rival Kura's ziftomenib. Syndax confirmed plans to report R/R mNPM1 pivotal data 4Q, supporting potential approval 2025—likely relatively in-line with Kura's timeline. While we think we're a ways away from having the critical efficacy/ safety insights necessary to clarify competitive dynamics, we continue to see the overall market as more likely to be shared vs. winner take all, supporting our overall positive outlook on revumenib's upside (2030e BofA unadj. \$922M vs. \$909M cons).

Model Updates

Following the 4Q report, we have updated our model and now forecast 2024e EPS of (\$3.44) vs. (\$3.13) prior. See page 3 for further details.

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	(2.46)	(2.98)	(3.44)	(1.06)	0.33
EPS Change (YoY)	NM	-21.1%	-15.4%	69.2%	NM
Consensus EPS (Bloomberg)			(3.10)	(2.27)	(0.82)
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	NM	NM	NM	NM	74.0x
EV / EBITDA*	NM	NM	NM	NM	359.7x
Free Cash Flow Yield*	-6.4%	-7.7%	-11.7%	-3.5%	3.5%
* For full definitions of <i>IQ</i> method SM measures, see page 6.					

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Refer to important disclosures on page 7 to 9. Analyst Certification on page 4. Price
Objective Basis/Risk on page 4.

28 February 2024

Equity

Key Changes		
(US\$)	Previous	Current
2024E Rev (m)	73.8	62.0
2025E Rev (m)	202.1	135.5
2026E Rev (m)	337.6	270.2
2024E EPS	-3.13	-3.44
2025E EPS	-2.00	-1.06
2026E EPS	-0.61	0.33

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Stock Data

Price	24.41 USD
Price Objective	29.00 USD
Date Established	25-Oct-2023
Investment Opinion	C-1-9
52-Week Range	11.22 USD - 25.75 USD
Mrkt Val (mn) / Shares Out	2,074 USD / 85.0
(mn)	
Free Float	96.0%
Average Daily Value (mn)	27.40 USD
BofA Ticker / Exchange	SNDX / NAS
Bloomberg / Reuters	SNDX US / SNDX.OQ
ROE (2024E)	-50.5%
Net Dbt to Eqty (Dec-2023A)	-53.3%

Abbreviations:

NT: near term

R&D: research and development
PDUFA: Prescription Drug User Act
KMT2Ar/ NPM1m: mutant subclasses
CR/ CRh: complete response/ with partial

hematologic recovery **QTc:** corrected QT interval

AML/ALL: acute myeloid leukemia/ acute lymphoblastic leukemia

<cont on page 3>

iQprofile[™] Syndax Pharmaceuticals

iQmethod SM − Bus Performance*					
(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Return on Capital Employed	-30.0%	-36.8%	-45.4%	-18.8%	5.9%
Return on Equity	-34.1%	-41.0%	-50.5%	-20.9%	6.6%
Operating Margin	NA	NA	-473.0%	-93.5%	1.8%
Free Cash Flow	(134)	(161)	(242)	(73)	72
<i>iQ</i> method [™] – Quality of Earnings*					
(US\$ Millions)	2022A	2023A	2024E	2025E	2026
Cash Realization Ratio	NM	NM	NM	NM	2.2×
Asset Replacement Ratio	0x	0x	4.9x	3.9x	3.4x
Tax Rate	NM	NM	NM	NM	NM
Net Debt-to-Equity Ratio	-15.9%	-53.3%	-59.6%	-61.5%	-73.2%
Interest Cover	NA	NA	NA	NA	NA
Income Statement Data (Dec)					
(US\$ Millions)	2022A	2023A	2024E	2025E	2026
Sales	0	0	62	135	270
% Change	-100.0%	NA	NA	118.5%	99.5%
Gross Profit	0	0	36	88	207
% Change	NM	NA	NA	143.7%	133.8%
EBITDA	(152)	(230)	(293)	(127)	5
% Change	NM	-51.6%	-27.5%	56.8%	NM
Net Interest & Other Income	(140)	(200)	23	25 (102)	27 32
Net Income (Adjusted) % Change	(149) NM	(209) -40.2%	(271) -29.2%	(102) 62.4%	NM
Free Cash Flow Data (Dec) (US\$ Millions)	2022A	2023A	2024E	2025E	2026
Net Income from Cont Operations (GAAP)	(149)	(209)	(271)	(102)	32
Depreciation & Amortization	0	0	0	0	0
Change in Working Capital	2	32	(6)	(9)	(2)
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	14	17	34	37	41
Capital Expenditure	0	0	0	0	C
Free Cash Flow	-134	-161	-242	-73	72
% Change	NM	-20.1%	-50.8%	69.7%	NM
Share / Issue Repurchase	NA	NA	NA	NA	NA
Cost of Dividends Paid	0	0	0	0	C
Change in Debt	(21)	0	0	0	C
Balance Sheet Data (Dec)					
(US\$ Millions)	2022A	2023A	2024E	2025E	2026
Cash & Equivalents	74	295	308	279	386
Trade Receivables	NA 11.5	NA	NA 244	NA 102	NA 160
Other Current Assets	415	285	244	193	160
Property, Plant & Equipment Other Non-Current Assets	1	1 31	2 31	2 31	21
Total Assets	6 497	613	585	504	31 578
TOTAL MOSELS	0	0	0	0	0
Short-Tarm Daht		U			51
Short-Term Debt Other Current Liabilities		58	6/	50	
Other Current Liabilities	29	58 0	67 0	50 0	
Other Current Liabilities Long-Term Debt	29 0	0	0	0	C
Other Current Liabilities Long-Term Debt Other Non-Current Liabilities	29 0 1	0	0	0 1	0 1
Other Current Liabilities Long-Term Debt	29 0	0	0	0	0 1 51 527

Company Sector

Biotechnology

Company Description

Syndax Pharmaceuticals is a clinical stage biopharmaceutical company focused on oncology and immunology. Their primary value driver, revumenib, is a menin inhibitor currently in development for R/R KMT2Ar and NPM1m AML/ ALL with potential to expand into the frontline and maintenance settings in combination with SoC. Their late-stage platform also consists of axatilimab partnered with Incyte, a CSF-1R inhibitor mAb against cGVHD, with possible optionality in pulmonary disorders.

Investment Rationale

In our view, Syndax is well-funded to support the potential NT launch of two clinical assets. While we acknowledge several risks for their lead asset revumenib, we continue to see strong likelihood of approval in KMT2Ar AML/ALL, followed by NPM1m AML, and potential for label expansion--with solid uptake in the 1L and maintenance KMT2Ar subclass. Ultimately, bolstered by likely support from the Incyte-partnered CSF-1R inhibitor, we continue to see solid risk/ reward supportive of our Buy rating.

Stock Data

Average Daily Volume

1,122,692

Quarterly Earnings Estimates

	2023	2024
Q1	-0.59A	-1.08E
Q2	-0.64A	-1.11E
Q3	-0.73A	-0.96E
04	-1.00A	-0.42F

Model Updates

We've updated our Syndax model to reflect the 4Q earnings update and management commentary (Exhibit 1).

Exhibit 1: Syndax Model Changes for 2024E and 2025E

We've provided our model changes for 2024e and 2025e below

	2024E		2025E	
\$ in millions (ex. per share items)	Prior	Current	Prior	Current
product revenue	\$ - \$	-	\$ - \$	
Total Revenue	\$ 74	\$ 62	\$ 202	\$ 135

	202	4E	202	5E
\$ in millions (ex. per share items)	Prior	Current	Prior	Current
Revenue	\$ 74	\$ 62	\$ 202	\$ 135
COGS	7	3	22	17
Gross Profit	(30)	36	83	88
R&D	171	244	180	123
SG&A	79	85	85	92
Operating Income	(280)	(293)	(182)	(127)
Other income, net Taxes	4	23	5 -	25 -
GAAP Net Income	(276)	(271)	(177)	(102)
GAAP EPS	(3.13)	(3.44)	(2.00)	(1.06)
Shares Outstanding - Diluted	88	79	89	96

Source: BofA Global Research estimates

BofA GLOBAL RESEARCH

Abbreviations:

NT: near term

R&D: research and development **PDUFA:** Prescription Drug User Act **KMT2Ar/ NPM1m:** mutant subclasses

CR/ CRh: complete response/ with partial hematologic recovery

QTc: corrected QT interval

AML/ALL: acute myeloid leukemia/ acute lymphoblastic leukemia

FIC: first in class R/R: relapsed/ refractory

CSF-1R: colony stimulating factor 1 receptor

ASH: American Society of Hematology

 $\textbf{SoC:} \ \text{standard of care}$

FDA: Food and Drug Administration

YE : year end



Price objective basis & risk

Syndax Pharmaceuticals (SNDX)

Our 12-month price objective (PO) is based on our NPV analysis of revenue forecasts and estimated margin assumptions. We model revumenib with the first approval in KMT2Ar R/R ALL/ AML in 2024 (LOS 85%), followed by NPM1m in 2025 (LOS 65%), and expansion into the frontline: KMT2Ar (2028: LOS 45%) and NPM1m (2029: LOS 40%). We also model axatilimab in R/R cGVHD in 2024 with a LOS of 85%. We assume a collective value for the pipeline. Given a WACC of 10%, in line with peers of similar size and risk, and a terminal growth rate between -10% and -50%, based on the molecule type, we estimate a value of \$29/ share PO, supporting our Buy rating.

Upside Risks to our PO:

1) near-term approval of revumenib in KMT2Ar AML and ALL, 2) approval of axatilimab in cGVHD, 3) robust efficacy/ synergy of revumenib in combination with SoC induction therapy in 1L, 4) solid efficacy/ safety as a maintenance therapy with a clean combination profile, and 5) indications of strong commercial support from payers/community-based providers to broadly administer portfolio candidates.

Downside Risks to our PO:

1) failure to achieve full approval of revumenib in KMT2Ar acute leukemias, 2) failure to achieve approval of axatilimab in R/R cGVHD, 3) regulatory delays, 4) safety issues complicating the combination profile, especially QTc prolongation, 5) lack of clinically relevant activity in the maintenance setting, 6) competitive headwinds, and 7) commercial pushback from payers and providers.

Analyst Certification

I, Jason Zemansky, 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
	Insmed Incorporated	INSM	INSM US	Jason Zemansky
	Intellia Therapeutics	NTLA	NTLA US	Greg Harrison, CFA
	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

US - Biopharmaceuticals Coverage Cluster

nvestment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	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
	Travere 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
EUTRAL				
	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	BMY	BMY 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.	RXRX	RXRX US	Alec W. Stranahan
	Tyra Biosciences	TYRA	TYRA US	Greg Harrison, CFA
	Vir	VIR	VIRUS	Alec W. Stranahan
	Y-mAbs Therapeutics, Inc	YMAB	YMAB US	Alec W. Stranahan
	i minos merapeutics, me	HVIAD	LIMINU 03	AICC VV. Sciananan
NDERPERFORM				
	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
CTD				J
STR				
	Janux Therapeutics	JANX	JANX US	Alec W. Stranahan



*IQ*method[™] Measures Definitions

•		
Business Performance	Numerator	Denominator
Return On Capital Employed	NOPAT = (EBIT + Interest Income) × (1 - Tax Rate) + Goodwill Amortization	Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill
		Amortization
Return On Equity	Net Income	Shareholders' Equity
Operating Margin	Operating Profit	Sales
Earnings Growth	Expected 5 Year CAGR From Latest Actual	N/A
Free Cash Flow	Cash Flow From Operations – Total Capex	N/A
Quality of Earnings	Numerator	Denominator
Cash Realization Ratio	Cash Flow From Operations	Net Income
Asset Replacement Ratio	Capex	Depreciation
Tax Rate	Tax Charge	Pre-Tax Income
Net Debt-To-Equity Ratio	Net Debt = Total Debt - Cash & Equivalents	Total Equity
Interest Cover	EBIT	Interest Expense
Valuation Toolkit	Numerator	Denominator
Price / Earnings Ratio	Current Share Price	Diluted Earnings Per Share (Basis As Specified)
Price / Book Value	Current Share Price	Shareholders' Equity / Current Basic Shares
Dividend Yield	Annualised Declared Cash Dividend	Current Share Price
Free Cash Flow Yield	Cash Flow From Operations – Total Capex	Market Cap = Current Share Price × Current Basic Shares
Enterprise Value / Sales	EV = Current Share Price × Current Shares + Minority Equity + Net Debt +	Sales
F	Other LT Liabilities	

EV / EBITDA Enterprise Value Basic EBIT + Depreciation + Amortization

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Disclosures

Important Disclosures

Syndax (SNDX) 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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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%
Inderperform	N/A	≥ 20%

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