

Syndax Pharmaceuticals

Clear progress as evolution into commercial player con't; Thoughts post 3Q

Reiterate Rating: BUY | PO: 29.00 USD | Price: 14.78 USD

Stage set for two year-end regulatory submissions

Not surprisingly, Syndax's 3Q results were relatively quiet in the wake of last month's pivotal revumenib AUGMENT readout. That said, with the story shifting from a clinical to a commercial one, we thought the early messaging/ tone were encouraging—further supportive of our positive thesis (see [our SNDX initiation](#)). GAAP EPS beat (+\$0.05) with OpEx ticking up ahead of 2024's two likely approvals/ launches, but attention easily remains on revumenib's clinical profile and, to a lesser extent, it's competitive positioning vs Kura's ziftomenib. Though we think few disagree both menin inhibitors should share the market, less clear currently is the extent—with acute focus on signals likely to be key determinants. We still think the 23% CR/CRh topline (see [our AUGMENT takes](#)) positions Syndax well to leverage its first-mover advantage given the lack of options for KMT2Ar. Updated phase 1 data in NPM1m AML may also bolster uptake, with reported CR/CRh of 36% vs. Kura's 35%—though we suspect there may be some debate over how three additional patients were incorporated into Syndax's dataset. Admittedly, there are questions over revumenib's safety/ tolerability, particularly rates of DS and QTc prolongation, where it may be some time before it's known how, if indeed at all, revumenib is disadvantaged when it comes to combo regimens. That said, with Syndax still likely, in our opinion, to capture early momentum with at least a ~1yr lead to market, we continue to see unappreciated NT upside potential (2026e unadj: \$250M vs. \$216M cons). And, with downside support from axatilimab, on track for a '24 submission for R/R GVHD, we see compelling risk/ reward for shares at current levels. Maintain Buy; \$29 PO.

Updated AUGMENT data reveal solid, durable responses

Syndax also announced updated data from the phase 1 KMT2Ar portion of AUGMENT this morning, which in our view look favorable: ORR 58% (vs. 59% prior), CR/CRh of 24% (vs. 33%). Admittedly, the decline in the latter may give some pause, but we'd argue attenuation isn't uncommon given 1) larger patient numbers (N: +34), and 2) longer follow-up (cutoff >12 mos), which should help assuage any concerns heading into the presentation of the full phase 2 results at ASH (San Diego, Dec 10, **#2907**). Also at ASH, Syndax plans to present data from their all-oral regimen in AML (SAVE; phase 1/2, Dec 9, **#58**) and updates from maintenance therapy in AUGMENT (Dec 11, **#4950**).

Model Updates

Following the 3Q report, we have updated our model and now forecast 2023e EPS of (\$3.16) vs. (\$3.25) prior. See page 3 for further details.

Estimates (Dec) (US\$)	2021A	2022A	2023E	2024E	2025E
EPS	0.46	(2.46)	(3.16)	(3.13)	(2.00)
EPS Change (YoY)	NM	NM	-28.5%	0.9%	36.1%
Consensus EPS (Bloomberg)			(2.98)	(3.01)	(2.27)
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	32.1x	NM	NM	NM	NM
GAAP P/E	32.1x	NM	NM	NM	NM
EV / EBITDA*	35.5x	NM	NM	NM	NM
Free Cash Flow Yield*	2.8%	-13.0%	-20.1%	-23.5%	-14.5%

* For full definitions of *IQmethod*SM measures, see page 6.

03 November 2023

Equity

Key Changes

(US\$)	Previous	Current
2023E EPS	-3.25	-3.16
2024E EPS	-3.14	-3.13
2025E EPS	-2.05	-2.00

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Stock Data

Price	14.78 USD
Price Objective	29.00 USD
Date Established	25-Oct-2023
Investment Opinion	C-1-9
52-Week Range	11.22 USD - 29.86 USD
Mkt Val (mn) / Shares Out (mn)	1,029 USD / 69.6
Average Daily Value (mn)	37.32 USD
BofA Ticker / Exchange	SNDX / NAS
Bloomberg / Reuters	SNDX US / SNDX.OQ
ROE (2023E)	-51.5%
Net Dbt to Eqty (Dec-2022A)	-15.9%

Abbreviations:

NPM1m: nucleophosmin 1 gene mutation
KMT2Ar: KMT2A gene rearrangement
QTc: corrected QT interval
R/R: relapsed/ refractory
AML: acute myeloid leukemia
ALL: acute lymphoblastic leukemia
ASH: American Society of Hematology
SoC: standard of care
1L: frontline

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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.

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Timestamp: 03 November 2023 01:51AM EDT

iQprofileSM Syndax Pharmaceuticals

iQmethodSM – Bus Performance*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Return on Capital Employed	6.6%	-30.0%	-46.3%	-64.7%	-57.2%
Return on Equity	7.5%	-34.1%	-51.5%	-72.0%	-63.7%
Operating Margin	18.8%	NA	NA	-379.3%	-89.9%
Free Cash Flow	29	(134)	(207)	(241)	(149)

iQmethodSM – Quality of Earnings*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash Realization Ratio	1.2x	NM	NM	NM	NM
Asset Replacement Ratio	3.0x	0x	4.5x	4.9x	3.9x
Tax Rate	NM	NM	NM	NM	NM
Net Debt-to-Equity Ratio	-49.5%	-15.9%	-23.8%	-33.9%	-11.2%
Interest Cover	20.3x	NA	NA	NA	NA

Income Statement Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Sales	140	0	0	74	202
% Change	9,109.6%	-100.0%	NA	NA	173.9%
Gross Profit	140	0	0	(30)	83
% Change	NM	NM	NA	NA	NM
EBITDA	26	(152)	(230)	(280)	(182)
% Change	NM	NM	-51.5%	-21.8%	35.1%
Net Interest & Other Income	(1)	2	4	4	5
Net Income (Adjusted)	25	(149)	(226)	(276)	(177)
% Change	NM	NM	-51.4%	-21.9%	35.8%

Free Cash Flow Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Net Income from Cont Operations (GAAP)	25	(149)	(226)	(276)	(177)
Depreciation & Amortization	0	0	0	0	0
Change in Working Capital	(10)	2	0	14	5
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	14	14	19	21	23
Capital Expenditure	0	0	0	0	0
Free Cash Flow	29	-134	-207	-241	-149
% Change	NM	NM	-54.8%	-16.6%	38.1%

Balance Sheet Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash & Equivalents	222	74	98	121	22
Trade Receivables	NA	NA	NA	NA	NA
Other Current Assets	226	415	349	293	243
Property, Plant & Equipment	1	1	2	2	3
Other Non-Current Assets	0	6	6	6	6
Total Assets	450	497	455	422	274
Short-Term Debt	0	0	0	0	0
Other Current Liabilities	21	29	44	66	72
Long-Term Debt	20	0	0	0	0
Other Non-Current Liabilities	1	1	1	1	1
Total Liabilities	41	30	45	67	73
Total Equity	408	467	410	355	201
Total Equity & Liabilities	450	497	455	422	274

* For full definitions of iQmethodSM measures, see page 6.

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 2524974

Quarterly Earnings Estimates

	2022	2023
Q1	-0.63A	-0.59A
Q2	-0.62A	-0.64A
Q3	-0.58A	-0.73A
Q4	-0.62A	-1.15E

Model Updates

We've updated our Syndax model to reflect the 3Q earnings update and management commentary (Exhibit 1).

Exhibit 1: Syndax Model Changes for 2023E and 2024E

We've provided our model changes for 2023e and 2024e below

\$ in millions (ex. per share items)	2023E		2024E	
	Prior	Current	Prior	Current
product revenue	\$ -	\$ -	\$ -	\$ -
Total Revenue	\$ -	\$ -	\$ 74	\$ 74

\$ in millions (ex. per share items)	2023E		2024E	
	Prior	Current	Prior	Current
Revenue	\$ -	\$ -	\$ 74	\$ 74
COGS	-	-	7	7
Gross Profit	-	-	(30)	(30)
R&D	160	160	171	171
SG&A	79	70	89	79
Operating Income	(239)	(230)	(290)	(280)
Other income, net	4	4	4	4
Taxes	-	-	-	-
GAAP Net Income	(235)	(226)	(286)	(276)
GAAP EPS	(3.25)	(3.16)	(3.14)	(3.13)
Shares Outstanding - Diluted	72	72	91	88

Source: BofA Global Research

BofA GLOBAL RESEARCH

Abbreviations:

NPM1m: nucleophosmin 1 gene mutation

KMT2Ar: KMT2A gene rearrangement

QTc: corrected QT interval

R/R: relapsed/ refractory

AML: acute myeloid leukemia

ALL: acute lymphoblastic leukemia

ASH: American Society of Hematology

SoC: standard of care

1L: frontline

R/R: relapsed/ refractory

CSF-1R: colony stimulating factor 1 receptor

cGVHD: chronic graft vs host disease

QTc: corrected QT interval

DS: differentiation syndrome

NDA: New Drug Application

BLA: Biologics License Application

ORR: overall response rates

CR/CRh: complete response vs complete response with partial hematologic recovery



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
	AlloVir, Inc.	ALVR	ALVR US	Jason Zemansky
	Amylyx Pharmaceuticals	AMLX	AMLX US	Geoff Meacham
	Beam Therapeutics	BEAM	BEAM 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
	Bristol-Myers Squibb	BMJ	BMJ US	Geoff Meacham
	Caribou	CRBU	CRBU US	Geoff Meacham
	CRISPR Therapeutics	CRSP	CRSP US	Geoff Meacham
	Eli Lilly and Company	LLY	LLY US	Geoff Meacham
	Erasca	ERAS	ERAS US	Alec W. Stranahan
	Esperion	ESPR	ESPR US	Jason Zemansky
	Exscientia	EXAI	EXAI US	Alec W. Stranahan
	Gilead Sciences Inc.	GILD	GILD US	Geoff Meacham
	HUTCHMED	HCM	HCM US	Alec W. Stranahan
	IGM Biosciences	IGMS	IGMS US	Greg Harrison, CFA
	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	Geoff Meacham
	Keros	KROS	KROS US	Greg Harrison, CFA

US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	Kiniksa Pharmaceuticals, Ltd.	KNSA	KNSA US	Geoff Meacham
	Krystal Biotech	KRYS	KRYS US	Alec W. Stranahan
	Kura Oncology	KURA	KURA US	Jason Zemansky
	Kymira Therapeutics	KYMR	KYMR US	Geoff Meacham
	LianBio	LIAN	LIAN US	Geoff Meacham
	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
	Reneo Pharmaceuticals	RPHM	RPHM US	Jason Zemansky
	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
	Tyra Biosciences	TYRA	TYRA US	Greg Harrison, CFA
	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
	Biogen Inc.	BIIB	BIIB US	Geoff Meacham
	Cytokinetics, Incorporated	CYTK	CYTK US	Jason Zemansky
	Editas Medicine	EDIT	EDIT US	Greg Harrison, CFA
	Johnson & Johnson	JNJ	JNJ US	Geoff Meacham
	Moderna	MRNA	MRNA US	Geoff Meacham
	Pfizer	PFE	PFE US	Geoff Meacham
	Recursion Pharmaceuticals, Inc.	RXR	RXR US	Alec W. Stranahan
	Revolution Medicines	RVMD	RVMD US	Alec W. Stranahan
	Vir	VIR	VIR US	Geoff Meacham
	Y-mAbs Therapeutics, Inc	YMAB	YMAB US	Alec W. Stranahan
UNDERPERFORM				
	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
	TG Therapeutics	TGTX	TGTX US	Alec W. Stranahan
	United Therapeutics Corporation	UTHR	UTHR US	Greg Harrison, CFA
RVW				
	Homology	FIXX	FIXX US	Jason Zemansky

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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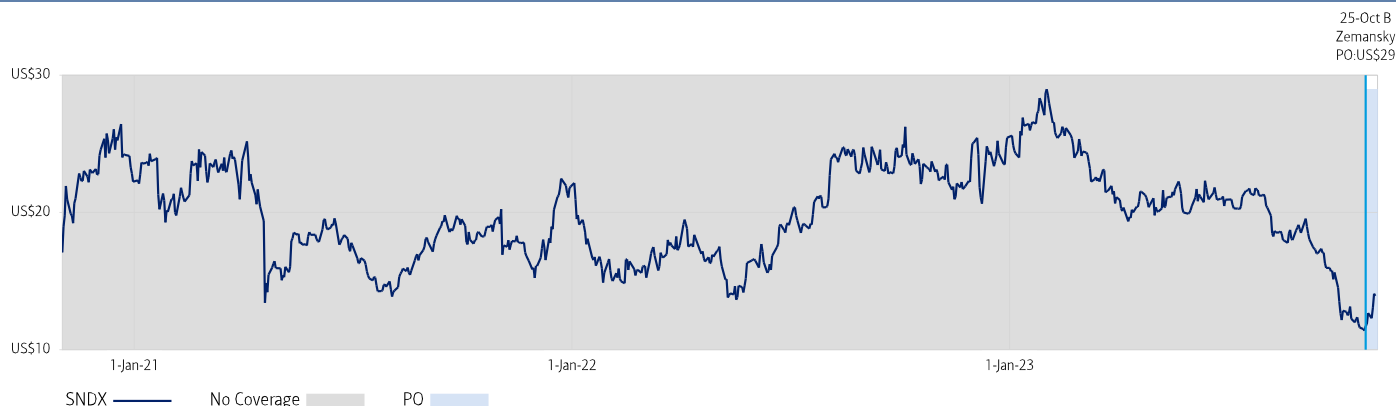
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Disclosures

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 30 Sep 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	Count	Percent
Buy	233	60.21%	Buy	113	48.50%
Hold	83	21.45%	Hold	33	39.76%
Sell	71	18.35%	Sell	25	35.21%

Equity Investment Rating Distribution: Global Group (as of 30 Sep 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	Count	Percent
Buy	1869	53.48%	Buy	1046	55.97%
Hold	828	23.69%	Hold	461	55.68%
Sell	798	22.83%	Sell	370	46.37%

^{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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