BofA SECURITIES

US Biopharmaceuticals

Our Day 1 Conference Takeaways: INSM, HOWL, SNDX

Industry Overview

Summarized below are our takes from today's presentations and management meetings...

INSM: Updates light, with focus on clinical execution NT

There were few surprises from Insmed's presentation this afternoon, with focus largely on clinical milestones beyond the recent business updates (see our thoughts). Still, we thought management did a solid job setting a positive tone for the 1L opportunity for Arikayce in NTM-PD where the team highlighted encouraging feedback from regulatory bodies on the ARISE topline (see our takes). Beyond Arikayce, we found commentary on the late-stage clinical pipeline also promising. While not new, the presentation framed expectations heading into ASPEN (2Q24e), where we continue to be optimistic, given 1) a hit on the primary ($p< 0.01$) for either dose a win—minimizing concerns surrounding a dose-dependent response, and 2) potential to file for approval on a less robust ($p< 0.05$) effect, supplemented by robust WILLOW data. Further, with topline phase 2 for TPIP in PH-ILD also 2Q24e, we'd argue continued signs of solid safety/ tolerability permitting higher dose exposure—i.e. a solid proportion of patients reaching the 640µg dose—(see our takes on the update) would further de-risk the pro-drug mechanism. Ultimately, ahead of a catalyst rich 2024, where we see many opportunities capable of driving a re-rating, coupled with a solid cash position to support clinical development, we like the risk/ reward for shares at current levels. Maintain Buy and a $37 PO.

HOWL: Acute focus in building off initial, encouraging data

We were encouraged by management, who acknowledged the strength of early IL-2 '124 data, though stressed acute focus remains on execution (our SITC takes). Indeed, with a lack of DLTs thus far, management was optimistic only a few (if that) additional cohorts would be necessary, with the goal of presenting a cogent plan/ rationale to regulators. Longer-term, there was recognition of questions notably on 1) duration of therapy and 2) possible combo partners—though Werewolf felt additional updates would provide at least some clarity, beginning with the next interim monotherapy/ initial combo data (reaffirmed: 1H24). Further, the team was hopeful additional positive safety/ efficacy signals would further bolster sentiment weighed by competitor setbacks—including from thus-far undruggable IL-12 ('330 initial phase 1 data 2Qe; see our YA24 takes). Above all, Werewolf stressed it intends to be disciplined on spend, noting updated cash guidance (≥1Q25 vs. 4Q24 prior). With management's experience becoming a key aspect of the story, we are positive on the underappreciated, novel platform. Maintain Buy; $10 PO.

SNDX: Commercial picture emerges, bracing solid NT story

As expected, today's presentation was sparse in the form of new information, with focus on recent positive data updates at ASH as the LT profile continues to materialize (see our takes on the investor event). Unsurprisingly, there were questions on the combo strategy, with management highlighting 1) 1L "unfit" ven/aza/rev, and 2) "fit" 7+3 as the foundational pillars. Syndax also noted potential optionality in other genotypes, *NUP98*, and tumor types. Ultimately, while acknowledging the growing competitive landscape—with Kura/ JNJ (covered by Geoff Meacham)—management highlighted their likely FIC benefit as a key advantage, something we would agree with, at least initially. Thus, with solid opportunity for NT growth on the back of two potential commercial approvals, we see favorable risk/ reward for shares at current levels. Maintain Buy and a $29 PO.

Timestamp: 09 January 2024 12:45AM EST

09 January 2024

Equity
United States
Biopharmaceuticals

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Abbreviations:
INSM: Insmed
SNDX: Syndax
HOWL: Werewolf Therapeutics
ACC: American College of Cardiology
NYHA: New York Heart Association
NDA: New Drug Application
MAA: Marketing Authorization Application
FDA: Food and Drug Administration
EMA: European Medical Agencies
MoA: mechanism of action
LoS: likelihood of success
TPIP: treprostinil palmitil inhalation powder
PH-ILD: pulmonary hypertension with interstitial lung disease
PE: pulmonary exacerbations
NT: near-term
NTM-PD: non-tuberculosis mycobacteria pulmonary disease
1L: frontline
NCFB: non cystic fibrosis bronchiectasis
DLT: dose limiting toxicities
IL-2/IL-12: interleukin 2 and 12
LT: longer-term
ASH: American Society of Hematology
R/R: relapsed/ refractory
NUP98: genotype
FIC: first in class

Exhibit 1: Stocks mentioned
Prices and ratings for stocks mentioned in this report

BofA Ticker	Bloomberg ticker	Company name	Price	Rating
INSM	INSM US	Insmed	US$ 29.93	C-1-9
SNDX	SNDX US	Syndax	US$ 22.79	C-1-9
HOWL	HOWL US	Werewolf Therap.	US$ 5.1	C-1-9

Source: BofA Global Research

BofA GLOBAL RESEARCH

Price objective basis & risk

Insmed Incorporated (INSM)

Our 12-month PO is based on our NPV analysis of revenue forecasts assumptions. We model sales of Arikayce for refractory NTM-PD and frontline expansion (modified by a LOS of 80%). We assume a collective value for the pipeline: Brensocatib in NCFB (LOS: 65%), with potential expansion into CF (LOS: 20%), CRSsNP, and HS (LOS: 15%) and TPIP for PAH and PH-ILD (LOS: 50%). Given a WACC of 15%, in line with peers of similar size and risk, and a terminal growth rate of -10%, -40%, we estimate a value of $12/sh for Arikayce, $18/sh for Brensocatib, $8/sh for TPIP, $0.62/sh for the early pipeline, and $-2/sh for net cash, resulting in $37/sh.

Upside risks: 1) Arikayce full approval, 2) validation of Brensocatib in phase 3, with strong clinical efficacy and no safety concerns, 3) robust efficacy/ safety profile for TPIP in PAH and PH-ILD, 4) growth of translational medicine pipeline, including on-track IND-approvals, and 5) indications of strong commercial support from payers/ community-based providers.

Downside risks: 1) failure to achieve full approval/ commercial expansion of Arikayce in the EU and Japan, 2) failure to meet safety/ efficacy profile in Brensocatib (phase 3), especially due to meaningful infection risk, 3) marginal tolerability improvements, diminished efficacy, and/ or lack of differentiation of TPIP, 4) competition from disease modifying PAH agents, 5) failure of translational medicine pillar, 6) regulatory delays, and 7) commercial pushback from payers/providers.

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.

Werewolf Therapeutics (HOWL)
Our 12-month price objective (PO) is based on our NPV analysis of revenue forecasts and estimated margin assumptions. We model sales of WTX-124 (IL-2 INDUKINE) in metastatic melanoma and RCC modified by a risk-adjusted likelihood of success of 25%. We also assume a collective value for the pipeline, which includes sales of '124 in other tumor types and potential revenues for WTX-330 (IL-12) and WTX-630 (IFN-a). Given a WACC of 12%, in line with peers of similar size and risk, and a terminal growth rate of -5%, we estimate a value of $3/sh for WTX-124, $4/sh for net cash, and $3/sh for the pipeline, resulting in $10/sh PO.

Upside risks: 1) validation of clinical synergies between CPIs and cytokines, 2) clear early signals of efficacy of WTX-124 in melanoma and RCC with good tolerability, 3) similar robust signals from the pipeline (i.e., '330 and '613), 4) collaboration deals with established oncology players, 5) accelerated regulatory timelines, and 6) strong commercial support from payers and prescribers

Downside risks: 1) clinical trial failures of the pipeline, especially due to issues with the platform, 2) meaningful safety risks, posing regulatory and/or commercial headwinds, 3) limited signs of synergistic efficacy when paired with established oncology treatments, 4) regulatory delays, 5) competition from other modified cytokines, 6) financial risks due to available cash to fund activities, 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
	Janux Therapeutics	JANX	JANX US	Geoff Meacham
	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
	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
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	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	VIR US	Geoff Meacham
	Y-mAbs Therapeutics, Inc	YMAB	YMAB US	Alec W. Stranahan
UNDERPERFORM				
	AlloVir, Inc.	ALVR	ALVR US	Jason Zemansky

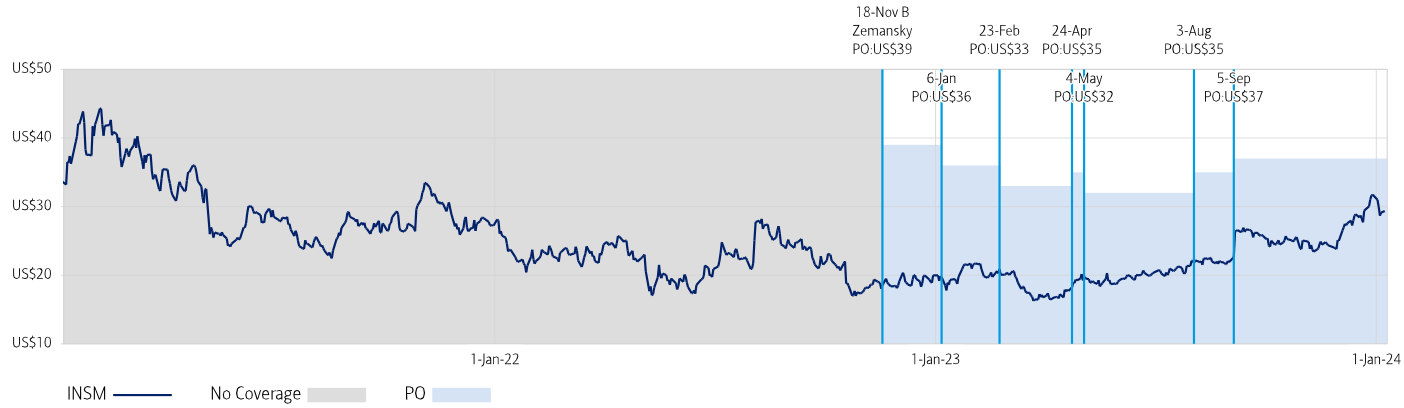
US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	CureVac	CVAC	CVAC US	Geoff Meacham
	Day One Biopharmaceuticals	DAWN	DAWN US	Alec W. Stranahan
	LianBio	LIAN	LIAN US	Geoff Meacham
	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

Disclosures

Important Disclosures

Insmed (INSM) Price Chart



B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

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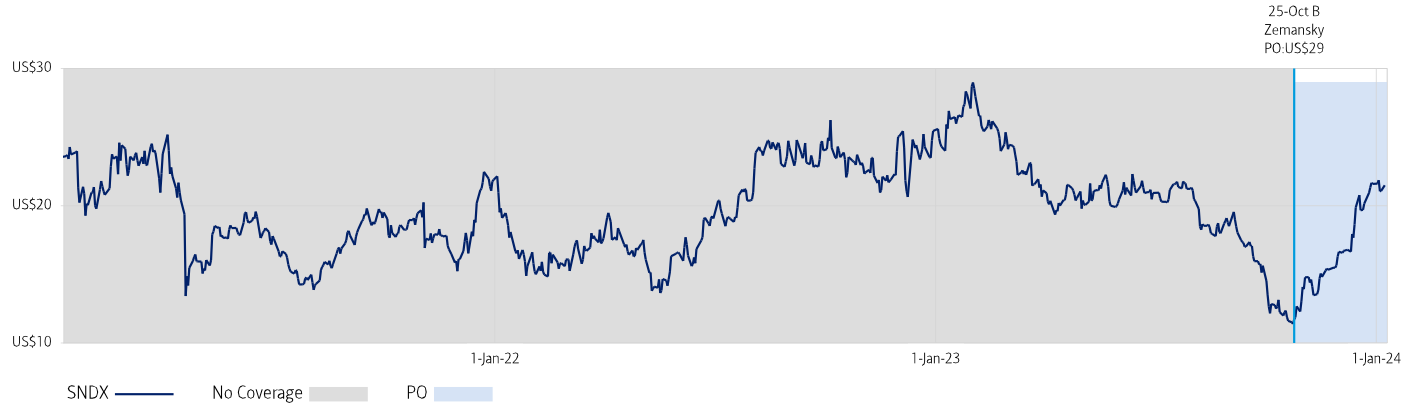
Syndax (SNDX) Price Chart



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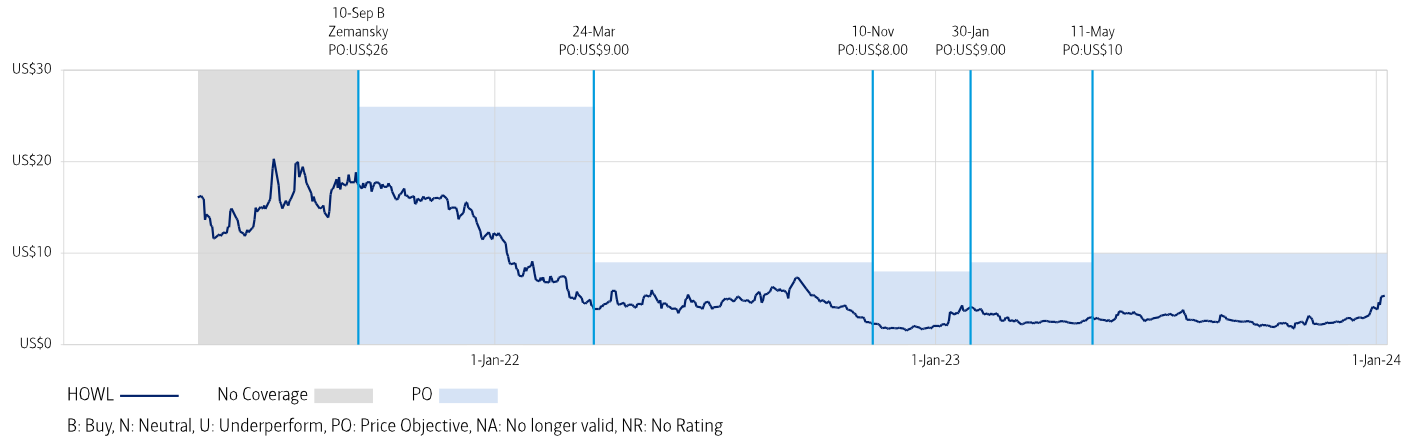
Werewolf Therap. (HOWL) Price Chart



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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%

[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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