

US Biopharmaceuticals

SMid Biotech 4Q23 Wraps: HOWL and ALVR

Estimate Change

We highlight updates—as well as our takes—from the following companies after their 4Q23 earnings. Our ratings remain the same, with our estimate changes discussed below:

HOWL: Positive '24 setup overshadows solid earnings

Although Werewolf's 4Q earnings were admittedly mixed, we were encouraged by a GAAP EPS loss of (\$0.33) that came in ahead of consensus (\$0.42) even as revenues missed (\$1.5M vs. \$4.6M, respectively)—demonstrating the team's disciplined spending. That said, we suspect focus remains on the company's clinical progress, where updates were understandably more limited. Sentiment on the name has continued to improve (YTD HOWL +59% vs. NBI flat) following last Nov's impressive presentation at SITC, which provided solid early support for the company's masking platform that has long kept us positive on the story (see our final takes on the WTX-124 data). That said, we still see opportunities for further upside near term, with Werewolf confirming plans to present additional interim dose escalation monotherapy and initial combo data from IL-2 INDUKINE '124 in 1H24 along with the first monotherapy updates from IL-12 INDUKINE '330 phase 1 in 2Q24. Given IL-2's established efficacy, we'd argue that further signs of '124's efficacy, absent any of the toxicities that have weighed use of the native molecule, would be very well received by investors—with positive early safety data from '330 similarly capable of driving a potential re-rating after previous attempts to leverage the potent T-cell/ macrophage activator were ultimately derailed by potent, systemic side effects. Following the print, we updated our model and now forecast 2024e EPS of (\$1.69) vs. (\$1.71) prior. Reiterate Buy and \$10 PO.

ALVR: Lack of clarity still weighs; Reiterate U/P, \$1 PO

In our view, AlloVir's 4Q print prompted more questions than answers. On the financial front, GAAP EPS missed consensus (-\$0.10), largely driven by a \$18.6M impairment cost associated with the wind-down of the three pivotal posoleucel trials last December. Likely of greater concern for investors, though, was the lack of any insight on why the studies were trending negative, as well as, more importantly, next steps for both the program and platform. Admittedly there've been few updates following the DSMB's December recommendation (see our takes on the decision), with the 2023 10K adding only that the company is continuing its review, leaving the timeline undefined. To be fair, we recognize the likely issues determining what went wrong, which beyond the approach/ molecule itself may well include frailty of allo-HCT recipients, the inherent complexities of transplants, and/or heterogeneity of practices among/ between centers. Regardless, with management conceding it's also looking at alternatives that include a possible merger, sale, or divestiture of assets, we think the uncertainty is likely to continue to weigh on the story over the near-term. Thus, despite laudable efforts to conserve capital in the meantime (the 95% workforce reduction initiated in January is expected to be largely complete by mid-April), we remain cautious on the near-term opportunity. After updating our model to incorporate the latest financials, we now forecast 2024e EPS of (\$0.49) vs. (\$0.45) prior. Reiterate Underperform and a \$1 PO.

15 March 2024

Equity United States Biopharmaceuticals

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Abbreviations:

SITC: Society for Immunotherapy of Cancer **DSMB**: Data and Safety Monitoring Board

IL-2: interleukin-2

IL-12: interleukin-12

allo-HCT: allogeneic hematopoietic cell transplant

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Refer to important disclosures on page 5 to 8. Analyst Certification on page 3. Price
Objective Basis/Risk on page 3.

Timestamp: 15 March 2024 09:06PM EDT

Model Update

We've updated our Werewolf and AlloVir models to reflect the 4Q print (Exhibit 1 and Exhibit 2, respectively).

Exhibit 1: HOWL 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
WTX-124	\$	- \$	- \$	- \$	-
Total Revenue	\$ 12	\$	\$ 11	\$ 12	

	202	4E	202	5E
\$ in millions (ex. per share items)	Prior	Current	Prior	Current
Revenue	\$ 10	\$ 9	\$ 11	\$ 12
COGS	-	-	=	=
Gross Profit	10	9	11	12
R&D	66	61	76	79
SG&A	23	21	26	25
Operating Income	(79)	(73)	(91)	(92)
Other income, net	3	3	3	4
Taxes	=	=	=	=
GAAP Net Income	(77)	(69)	(88)	(88)
GAAP EPS	(1.71)	(1.69)	(1.66)	(1.97)
Shares Outstanding - Diluted	45	41	53	45

Source: BofA Global Research estimates

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Exhibit 2: ALVR Model Changes for 2024E and 2025EWe've provided our model changes for 2024e and 2025e below

	2024	E		2025	E	
\$ in millions (ex. per share items)	Prior		Current	Prior		Current
Net Product Sales	\$ -	\$	-	\$ -	\$	-
Other Revenue	-		-	-		-
Total Revenue	\$ _	\$	-	\$ -	\$	-

	202	24E	202	5E
\$ in millions (ex. per share items)	Prior	Current	Prior	Current
Revenue	\$ -	\$ -	\$ -	\$ -
COGS	-	-	-	-
Gross Profit	(0.1)	(0.1)	0.0	(0.0)
R&D	35	47	33	40
SG&A	24	19	23	15
Operating Income	(58)	(66)	(56)	(55)
Income before income taxes	(51)	(56)	(48)	(44)
Taxes	-	-	-	-
GAAP Net Income	(51)	(56)	(48)	(44)
GAAP EPS	(0.45)	(0.49)	(0.42)	(0.39)
Shares Outstanding - Diluted	115	114	115	115

Source: BofA Global Research estimates

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Price objective basis & risk

AlloVir, Inc. (ALVR, \$0.7789, C-3-9)

Our 12-month price objective (PO) is based on our NPV analysis of revenue forecasts and estimated margin assumptions. We model posoleucel for treatment of BKV in kidney transplant patients (LOS 15%) starting globally in 2026. In addition, we assume a collective value for the pipeline. Given a WACC of 14%, in line with peers of similar size and risk, and a terminal growth rate between -10% and -12.5%, based on the development timeline, we estimate a value of \$1/ share PO, supporting our U/P rating.

Upside risks to our PO:

1) clear insights into posoleucel setbacks with an addressable near-term path forward, 2) robust activity of posoleucel in kidney transplant/ SOT, 3) success/ advancement of the early-stage pipeline, including ALVR106 and '1072, 4) favorable pricing/ commercial support from payers/ transplant centers, and 5) rapid uptake/ adoption

Downside risks to our PO:

1) lack of insight into posoleucel's phase 3s in allo-HSCT, 2) negative readthroughs to the SOT platform, 3) unsuccessful expansion into additional indications/ success of early-stage pipeline, 4) unfavorable pricing/ commercial support, 5) modest uptake/ adoption by transplant centers, and 6) competition from other anti-viral or cell therapy developers

Werewolf Therapeutics (HOWL, \$6.14, C-1-9)

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

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US - Biopharmaceuticals Coverage Cluster

nvestment 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
	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	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
	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
		TVTX	TVTX US	
	Travere Therapeutics Inc	TSBX	TSBX US	Greg Harrison, CFA
	Turnstone Biologics Vertex Pharmaceuticals Inc.	VRTX	VRTX US	Geoff Meacham Geoff Meacham
	Werewolf Therapeutics	HOWL	HOWL US	Jason Zemansky
	Xencor	XNCR	XNCR US	Alec W. Stranahan
UTRAL				
	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	BEAM US	
	Beam Therapeutics	BIIB	BIIB US	Greg Harrison, CFA Geoff Meacham
	Biogen Inc.			Geoff Meacham
	Bristol-Myers Squibb	BMY	BMY US	
	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	Alec W. Stranahan
	Y-mAbs Therapeutics, Inc	YMAB	YMAB US	Alec W. Stranahan
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NDERPERFORM				
	AlloVir, Inc.	ALVR	ALVR US	Jason Zemansky
	CureVac	CVAC	CVAC US	Geoff Meacham



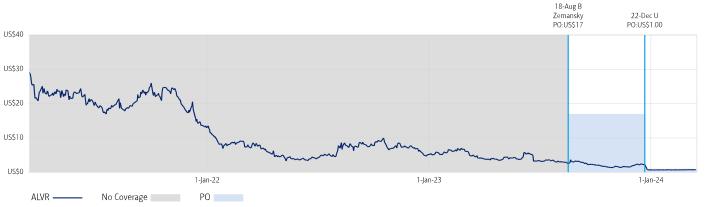
US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	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

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AlloVir (ALVR) 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.

Werewolf Therap. (HOWL) 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%
Underperform	N/A	≥ 20%

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