

US Biopharmaceuticals

Extended FDA review still allows for April launch timeline

Industry Overview

Liquidia remains prepared to launch

Liquidia announced the FDA is not issuing an action letter in time for the initial January 24 PDUFA date for Yutrepia in PH-ILD, highlighting the delay is not due to the NDA package and that the FDA did not request any additional clinical data. We met with management who discussed the collaboration with and support from the FDA throughout the regulatory process including the amendment filing and remains confident in a launch of Yutrepia in April 2024. With regulatory exclusivity for Tyvaso in PH-ILD set to expire March 31, 2024, we note anticipated launch timelines of Yutrepia in PAH and PH-ILD could remain intact, but we look for the final FDA review decision to update our model. [As one of our 2024 top picks \(see report\)](#), we think Liquidia remains in a solid position to launch Yutrepia in both PAH and PH-ILD when possible and we look for finalized FDA review details to determine the path for a Yutrepia approval in PH-ILD. Maintain Buy, PO \$15.

Management discussion highlighted supportive FDA

The company highlighted that the FDA was supportive of an amendment filing to the original NDA for Yutrepia to add PH-ILD and noted the PR phrasing “amended or supplemented” was intended to mirror the language in the statute regarding 30-month stays, which management still believes is not likely due to the ‘327 patent being issued in November 2023, after the NDA amendment submission by Yutrepia (July 2023). [With the legal resolution of the ‘793 patent \(see report\)](#), we look for the announcement of the injunction to be lifted to allow for the launch of Yutrepia in PAH and continue to anticipate a launch in 2024.

Yutrepia PDUFA push reads through positive for United

While we look for finalized details from the FDA, we note the review extension adds some questions surrounding the potential launch of Yutrepia in PH-ILD which is overall positive for United, but we highlight the extension is not related to the NDA package and the previously established tentative approval of Yutrepia in PAH met regulatory standards for quality, safety, and efficacy. We note United has previously established exclusivity in PH-ILD until March 31, therefore the review extension announced today does not in our view change the anticipated launch date of Yutrepia in PH-ILD. Maintain Underperform, PO \$178.

25 January 2024

Equity
United States
Biopharmaceuticals

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PH-ILD: pulmonary hypertension and
interstitial lung disease

PAH: pulmonary arterial hypertension

Stocks mentioned

Prices and ratings for stocks mentioned in this report

BofA Ticker	Bloomberg ticker	Company name	Price	Rating
LQDA	LQDA US	Liquidia Corporation	US\$ 12.06	C-1-9
UTHR	UTHR US	United Therapeutics	US\$ 218.81	B-3-9

Source: BofA Global Research

Price objective basis & risk

Liquidia Corporation (LQDA)

Our \$15/share price objective is based on an net present value (NPV) analysis of Yutrepia (\$12/share), collaboration revenues (\$2/share), and net cash (\$1/share). We use a weighted average cost of capital (WACC) of 13%, in line with similar companies in our coverage universe and a -50% terminal growth rate.

Downside risks: 1) additional competition in the market, 2) delayed full approval of Yutrepia.

Upside risk: 1) higher-than-expected uptake of Yutrepia once approved

United Therapeutics Corporation (UTHR)

Our 12-month price objective for United of \$178/share is based on our net present value (NPV) analysis. We forecast sales for each of the approved products, Remodulin, Tyvaso, Orenitram, Adcirca, and Unituxin. We assume a WACC of 13%, in line with peer commercial companies of similar size and risk and varying terminal values for each asset based on its characteristics and patent life. Given these assumptions, we estimate a value of \$18/share for Remodulin, \$57/share for Tyvaso, \$12/share for Orenitram, \$6/share Unituxin, \$1/share for the pipeline, and \$83/share for net cash.

Upside risks: 1) better-than-expected PAH sales despite generic and branded competition, 2) successful launch of next-generation Remodulin and Tyvaso delivery devices near-term that meaningfully improves growth, 3) robust uptake of Orenitram following the updated FREEDOM-EV label, 4) stabilizing or improving gross to net adjustments, and 5) success of a number of pipeline programs, resulting in accelerated approval, development, and commercialization.

Downside risks: 1) faster-than-expected erosion of sales across the commercial portfolio due to generics or branded competition, with similarly increasing gross-to-net adjustments, 2) efforts to launch a next-generation drug delivery device may experience further setbacks, delaying their launches, and 3) other development programs, including those evaluating the portfolio in other categories of PH, may experience limited success.

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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
	Insmmed 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
	Traverse 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	BMJ	BMJ 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
	Kymira Therapeutics	KYMR	KYMR US	Geoff Meacham
	Moderna	MRNA	MRNA US	Geoff Meacham
	Pfizer	PFE	PFE US	Geoff Meacham
	Recursion Pharmaceuticals, Inc.	RXRJ	RXRJ 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



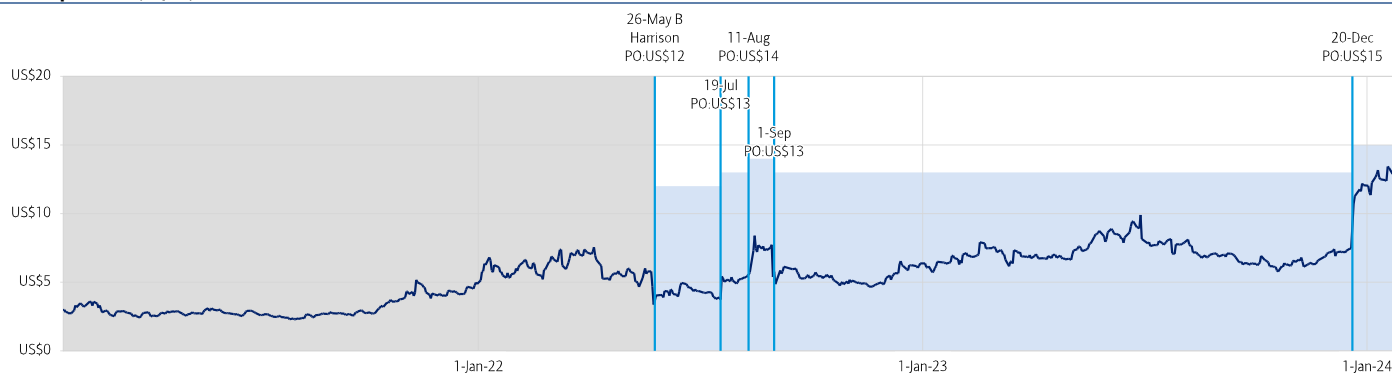
US - Biopharmaceuticals Coverage Cluster

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

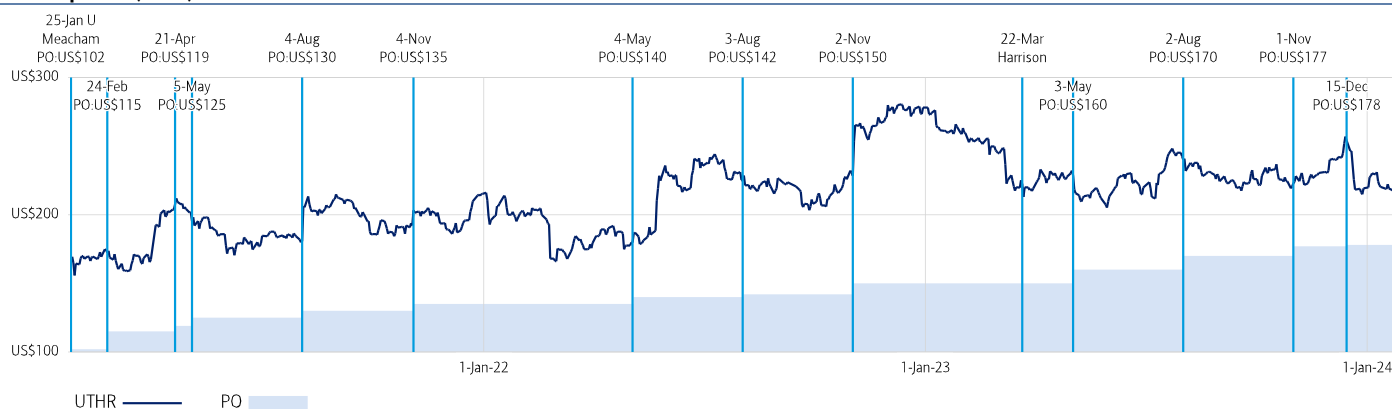
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Liquidia Corporation (LQDA) Price Chart



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United Therapeutics (UTHR) Price Chart



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%

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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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