BofA SECURITIES

US Biopharmaceuticals

Monday conference takeaways: BBIO, UTHR, BEAM, RCKT

Industry Overview

BridgeBio highlights strong pipeline with acoramidis focus

BridgeBio presented a corporate update at a healthcare conference, highlighting new analyses of the benefit of acoramidis on survival and in patients switching from Tafamidis. Building upon encouraging clinical data (see report), we think the BridgeBio is in a strong position to launch acoramidis in ATTR-CM and we model $62M in 2024 sales and $4.4B in risk-adj. peak sales (95% PoS). The company also announced data from the CAH gene therapy highlighting transgene activity and early signs of cortisol production. With a phase 2 readout expected in 3Q24, we look for the company to make a go/no-go decision on the continued development of the CAH program. Beyond the acoramidis launch and phase 2 CAH readout, BridgeBio also plans to fully enroll multiple phase 3 trials in 2024 (achondroplasia, ADH1, LGMD2i) and we look for future readouts to support approvals. The company is now guiding towards an ADH1 readout in early 2025 due to slow site start up, but highlighted strong progression since, and we outline all catalysts for our company in the exhibit below (Exhibit 1). As one of our top picks for 2024 (see our Year Ahead 2024 report), we think BridgeBio is prepared for a notable year with a broad clinical pipeline and key late stage programs including acoramidis and low-dose infigratinib. Maintain Buy, PO $50.

Beam prepares for initial data with first '101 dosing done

Beam announced a positive corporate update with the initial dosing and successful engraftment of the first patient treated with BEAM-101 as part of the phase 1/2 BEACON trial. With plans to make significant enrollment progress in the BEACON trial, including sequential treatment for the first 3 patients in the sentinel cohort followed by parallel dosing for the subsequent expansion cohort (initiating 1H24), the company plans to announce initial BEACON data from multiple patients in 2H24. Beam also is set to make development progress in the ESCAPE platform with phase 1 enabling studies initiating in 2024, trial initiation for the BEAM-302 program in 1H24, and an IND on track for filing in 1H24 for the BEAM-301 program. While we think additional applications specifically the AATD program could be a valuable opportunity for Beam, we look for further progress towards derisking data to add to our model. The company also highlighted early stage research programs for liver-targeting products are in development with collaborations with Pfizer and Apellis. With the recent restructuring extending the cash runway (see report), Beam ended 2023 with approximately $1.2B in cash and cash equivalents and has a cash runway into 2027. While we see encouraging potential from Beam base editing we note few near term derisking catalysts while the company progresses into the clinic and we maintain Neutral, PO $35.

See our updated catalyst calendar (Exhibit 1) and takeaways from United Therapeutics and Rocket Pharma below:

08 January 2024

Equity
United States
Biopharmaceuticals

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ATTR-CM: transthyretin amyloidosis cardiomyopathy

CAH: congenital adrenal hyperplasia

ADH1: autosomal dominant hypocalcemia type 1

LGMD2i: limb girdle muscular dystrophy type 2i

SCD: sickle cell disease

AATD: alpha-1 antitrypsin deficiency

Refer to important disclosures on page 6 to 10. Analyst Certification on page 4. Price Objective Basis/Risk on page 3.
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Timestamp: 08 January 2024 07:37PM EST

United outlines 2024 strategy driven by Tyvaso growth

United Therapeutics gave a broad corporate overview in a company presentation today, highlighting the organ manufacturing programs and potential differentiation of Tyvaso compared to Liquidia's Yutrepia. After the recent oral arguments (see report) resulted in Liquidia's favor, we see a clear path towards an approval for the direct competitor to Tyvaso in pulmonary arterial hypertension (PAH) and potentially pulmonary hypertension and interstitial lung disease (PH-ILD), but note United plans to continue to pursue legal action. The company highlighted the potential advantages of Tyvaso DPI including the low flow delivery supporting drug delivery deep into the lungs. While we think competition over time could erode United's hold on the PAH and PH-ILD market, we think continued market growth from Tyvaso including Tyvaso DPI (dry powder inhaler) in PH-ILD could drive 2024 revenues and we model $1.3B for 2024 Tyvaso sales. United also highlighted expectations for new prescriptions to be driven by PH-ILD noting around 40% of referral forms are indicated for PH-ILD patients. Looking at the clinical programs the company plans to complete enrollment for TETON 1 by YE24 and complete the trial for the ralinepag program in 2025. United took time to review the broad organ manufacturing program highlighting four platforms providing different clinical opportunities and with management noting a potential movement into the clinic in 2025, we look for addition derisking data to add to our model. Maintain Underperform, PO $178.

Rocket ready for launch and pivotal development in 2024

With an approval for LAD-1 approaching (PDUFA March 31), Rocket announced an encouraging corporate update as the company prepares to transition into a commercial stage gene therapy company. With management noting plans for interim updates (see report) from the ongoing pivotal trial in Danon, our focus continues to center around the Danon program, and we model $1.1B risk-adj. peak sales for the program (PoS 60%). The company reviewed the phase 2 trial design for Danon disease including the coprimary endpoint of LAMP2 protein and left ventricular mass change from baseline at 12 months with a concurrent natural history study. With improvements seen at 6 months in the phase 1 pediatric subjects with updated immunomodulation regimens from both components we look for signs of improvement from anticipated 2024 updates. Looking at the Fanconi anemia program the company remains on track to file simultaneous BLA/MAA applications in 1H24. The company also highlighted plans to move into a phase 2 trial for PKD and reviewed the early stage cardiac focused targets. Rocket has a cash runway into 2026. As one of our top picks for 2024, we think Rocket is prepared for a strong 2024 with commercial launches and pivotal data updates anticipated and we maintain Buy, PO $37.

Exhibit 1: Catalyst Calendar
We look for initial clinical data from the BEACON trial in 2H24.

Company	Asset	Indication	Event	Timing	Importance
Beam	BEAM-101	SCD	BEACON trial readout	2H24	High
Beam	BEAM-101	SCD	Expansion cohort initiation	1H24	Moderate
Beam	BEAM-201	T-ALL/T-LL	Initial data	2024	High
Beam	BEAM-301	GSD1a	Regulatory filing	1H24	Low
Beam	BEAM-302	AATD	Trial initation	1H24	Moderate
BridgeBio	Acoramidis	ATTR-CM	Global marketing authorization applications	2024	Moderate
BridgeBio	Encaleret	ADH1	Complete enrollment	2024	Moderate
BridgeBio	Gene therapy	CAH	Phase 2 data readout	2024	High
BridgeBio	BBP-418	LGMD2i	FORTIFY topline data	late 24/ early 2025	High
BridgeBio	BBO-8520	Oncology	IND filing	2024	Low
Rocket	RP-L201	LAD-1	PDUFA	31-Mar-24	High
Rocket	RP-L301	PKD	Pivotal phase 2 trial initiation	4Q23	Low
Rocket	RP-A501	Danon disease	Danon female study initiation	4Q23	Low

Exhibit 1: Catalyst Calendar
We look for initial clinical data from the BEACON trial in 2H24.

Company	Asset	Indication	Event	Timing	Importance
Rocket	RP-A501	Danon disease	Pivotal trial interim update	2024	High
Rocket	RP-L201	LAD-1	LAD-1 moderate study initiation	4Q23	Low
Rocket	RP-L102	Fanconi anemia	BLA-MAA filing	1H24	High
Rocket	RP-L102	Fanconi anemia	Complementation Groups C&G IND submission	2024	Low
Rocket	BAG3-association DCM	BAG3-DCM	IND filing	2024	Low
United	Ralinepag	PAH	ADVANCE OUTCOMES study data	2025	High
United	Tyvaso	IPF	TETON 1 and 2 enrollment completion	YE24	Moderate
United	Tyvaso	IPF	TETON data	2025	High

Source: BofA Global Research, company reports

BofA GLOBAL RESEARCH

Stocks mentioned

Prices and ratings for stocks mentioned in this report

BofA Ticker	Bloomberg ticker	Company name	Price	Rating
BEAM	BEAM US	Beam Therapeutics	US$ 27.86	C-2-9
BBIO	BBIO US	BridgeBio Pharma	US$ 38.74	C-1-9
RCKT	RCKT US	Rocket Pharma	US$ 29.59	C-1-9
UTHR	UTHR US	United Therapeutics	US$ 231.04	B-3-9

Source: BofA Global Research

Price objective basis & risk

Beam Therapeutics (BEAM)

Our $35/share price objective is based on a probability adjusted (30%) NPV analysis of its primary program under development. We use a WACC of 15%, similar to other early-stage companies in our coverage universe and a -2% terminal growth rate.

Downside risks: 1) failure of early clinical trials, 2) dangerous safety signals, 3) superior competitor data, 4) soft market uptake.

BridgeBio Pharma (BBIO)

Our net present value (NPV) sum-of-the-parts valuation gives a price objective of $50/share for BridgeBio, which includes $34/share for acoramidis, $3/share for ribitol in LGMD2i, $11/share for infigratinib in achondroplasia, $5/share for encaleret, $5/share for CAH gene therapy, and -$8/share in net cash. We assume a weighted-average cost of capital (WACC) of 15% and terminal growth rates ranging from -50% to 0%.

Downside risks to our price objective are 1) clinical trial failures, 2) inability to raise capital to fund development programs, and 3) superior data from competitors.

Upside risks to our price objective are 1) stronger-than-expected uptake in infigratinib, 2) unexpected de-risking data for early programs, and 3) clinical trial failures from competing companies.

Rocket Pharmaceuticals, Inc. (RCKT)

Our $37/share price objective is based on a probability-adjusted (35%-90%) net present value (NPV) analysis of its four programs under development. We use a weighted-average cost of capital (WACC) of 15%, similar to other early-stage companies in our coverage universe, and terminal growth rate of -2%. Given these assumptions, we estimate a value of $9/share for RP-L102 (Fanconi anemia), $21/share for RP-A501 (Danon disease), $2/share for RP-L201 (LAD-1), $1/share for RP-L301 (PKD), and $4/share in net cash.

Risks: 1) failure of early clinical trials, 2) emergence of unacceptable safety signals, 3) shorter efficacy duration than expected, and 4) commercialization failures.

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.

Analyst Certification

I, Greg Harrison, CFA, 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

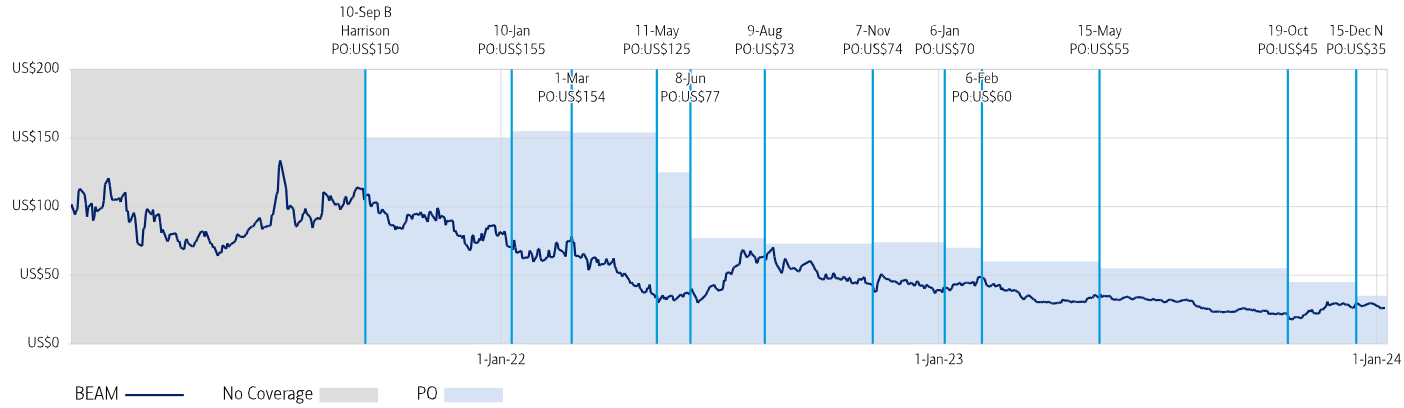
US - Biopharmaceuticals Coverage Cluster

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

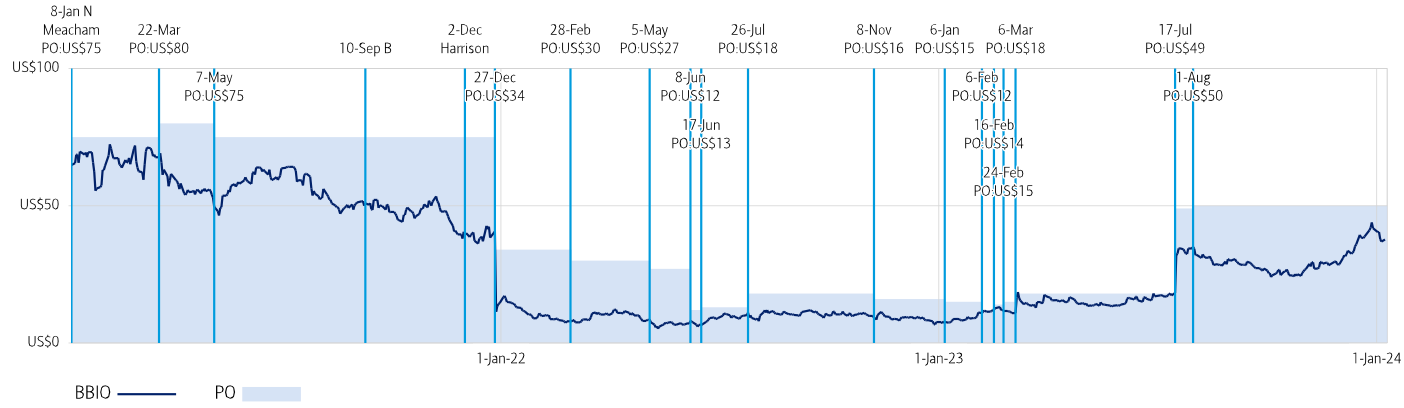
Beam Therapeutics (BEAM) Price Chart



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.

BridgeBio Pharma (BBIO) Price Chart



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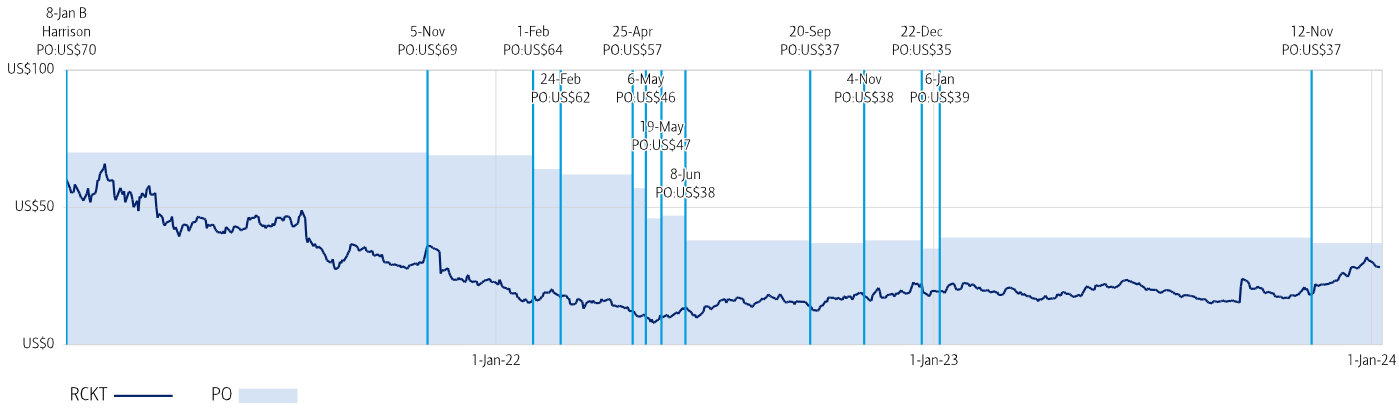
Rocket Pharma (RCKT) Price Chart



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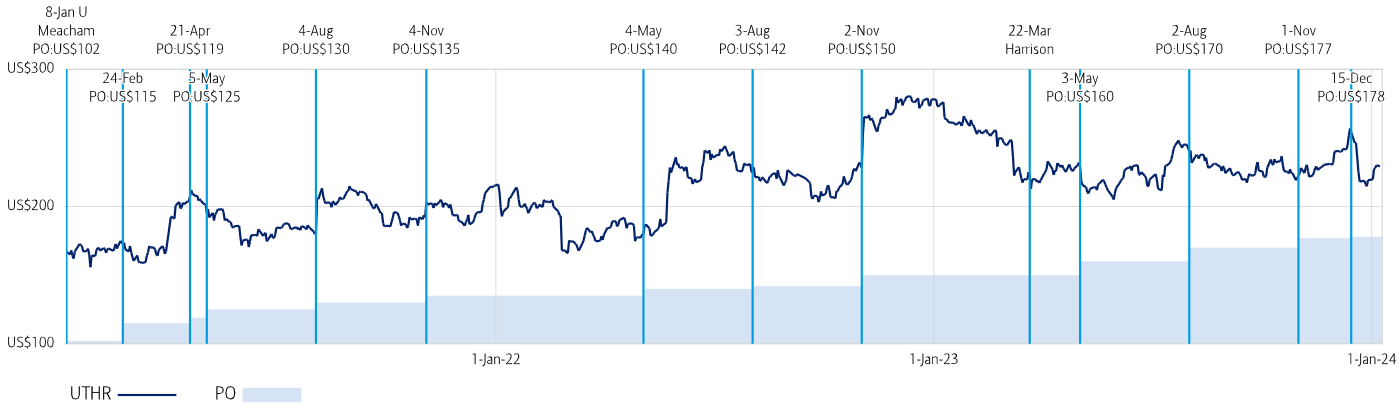
United Therapeutics (UTHR) Price Chart



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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%

[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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