BofA GLOBAL RESEARCH



Krystal Biotech

4Q23 Earnings Takeaways: Strong print bolsters 2024 outlook

Reiterate Rating: BUY | PO: 168.00 USD | Price: 152.06 USD

Big beat on earnings add substantial confidence to launch

KRYS shares trading up on big beat in 4Q23 (+35%, NBI: flat), a much-needed and well-timed rebound after the narrow sales miss in 3Q23 (\$8.6M actual vs \$9.3M cons) and growing concerns regarding launch trajectory; we see 4Q23 earnings as effectively addressing investor concerns. As a reminder (see our earnings preview note), our estimates pre-earnings projected \$29M 2023 Vyjuvek sales (2023 cons: \$34.6M), and Vyjuvek's performance In 2023 reported today (\$50.7M) beat our expectations and also consensus quite significantly. With many bright spots in the print (35% of the 1.2k identified patient base in patient start forms, 228 reimbursement approvals for Vyjuvek while patient compliance with once weekly treatment while on drug at 96%, permanent J-code received in January 2024), we see clear road to a stronger-than-expected launch heading forward and update our model accordingly. Reiterate Buy and raise PO to \$168 (from \$140 prior) on higher near-term Vyjuvek sales and peak of \$1.2B (\$934M prior).

EU approval can add to topline, we increase our 2024 est.

With a MAA now under review by EMA with a decision anticipated in 2H24e, we see possible ex-US expansion adding to sales momentum over the coming quarters (we currently assess conservative estimate of 68% LoS for EU approval). While Vyjuvek peak sales remains the biggest swing factor for valuation, we see EU approval as having a meaningful effect on sales likely realized in 2025+. We adjust our 2024 estimates of Vyjuvek US sales (increase from \$188M to \$224M, 2024 cons: \$194.9M) to align with a faster-than-expected ramp-up, as well as marginally steeper trajectory to peak sales in 2036e assuming 40% peak share (versus 30% prior). Positive directional commentary from the company on patient receptivity and adherence, in our view, also helps inform longer-term timing/magnitude of sales and we expect robust sales trends to continue.

Notable clinical catalysts

2024 watch-list: Initial phase 1 data for KB407 in CF, cohort 3 from the phase 1 study KB301 for lateral canthal lines (<u>see latest aesthetics update</u>) in 1H24e. The addition of KB707 in our view leverages the company's previous clinical experience and expands the broader potential of HSV-1 platform. Key catalysts to watch include: **1**) first-in-human intramural KB707 data in 2024, **2**) first patient dosed with inhaled KB707 in 1H24e.

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	(5.49)	0.44	1.43	2.61	5.98
EPS Change (YoY)	-74.8%	NM	225.0%	82.5%	129.1%
Consensus EPS (Bloomberg)			0.07	4.48	5.69
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	NM	345.6x	106.3x	58.3x	25.4x
EV / EBITDA*	NM	NM	141.0x	57.9x	18.7x
Free Cash Flow Yield*	-3.6%	-2.3%	1.4%	2.1%	4.8%
* For full definitions of <i>IQ</i> method SM measures, see page 5.					

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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. 12663970

Timestamp: 26 February 2024 12:05PM EST

26 February 2024

Equity

Key Changes		
(US\$)	Previous	Current
Price Obj.	140.00	168.00
2024E Rev (m)	184.9	223.6
2025E Rev (m)	372.8	313.5
2026E Rev (m)	608.5	482.4
2024E EPS	-1.21	1.43
2025E EPS	2.67	2.61
2026E EPS	7.59	5.98

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Stock Data

Price	152.06 USD
Price Objective	168.00 USD
Date Established	26-Feb-2024
Investment Opinion	C-1-9
52-Week Range	70.51 USD - 152.60 USD
Mrkt Val (mn) / Shares Out	4,289 USD / 28.2
(mn)	
Free Float	87.4%
Average Daily Value (mn)	48.15 USD
BofA Ticker / Exchange	KRYS / NAS
Bloomberg / Reuters	KRYS US / KRYS.OQ
ROE (2024E)	4.9%
Net Dbt to Eqty (Dec-2023A)	-45.0%
ESGMeter™	Low

ESGMeter is not indicative of a company's future stock price performance and is not an investment recommendation or rating. ESGMeter is independent of BofA Global Research's equity investment rating, volatility risk rating, income rating, and price objective for that company. For full details, refer to "BofA ESGMeter Methodology".

Abbreviations:

DEB: dystrophic epidermolysis

bullosa

HSV: herpes simplex virus **IL-2/12:** interleukin 2/12

G/N: gross-to-net **CF:** cystic fibrosis

AATD: alpha-1 antitrypsin deficiency

iQprofile[™] Krystal Biotech

IQmethod *** – Bus Performance*					
(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Return on Capital Employed	-23.1%	-15.0%	2.5%	5.1%	12.3%
Return on Equity	-25.1%	1.9%	4.9%	7.2%	13.3%
Operating Margin	NA	-216.4%	10.5%	20.0%	42.7%
Free Cash Flow	(154)	(101)	59	91	204

*i***Q**method SM − **Quality of Earnings***

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash Realization Ratio	NM	-7.2x	2.0x	1.5x	1.2x
Asset Replacement Ratio	13.1x	3.2x	4.3x	4.3x	4.3x
Tax Rate	NM	4.6%	NM	NM	14.1%
Net Debt-to-Equity Ratio	-29.3%	-45.0%	-35.9%	-44.8%	-43.2%
Interest Cover	NA	NA	NA	NA	NA

Income Statement Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Sales	0	51	224	313	482
% Change	NA	NA	341.0%	40.2%	53.9%
Gross Profit	0	48	201	282	458
% Change	NA	NA	322.7%	40.2%	62.4%
EBITDA	(141)	(106)	28	69	212
% Change	-115.5%	24.9%	NM	143.5%	209.7%
Net Interest & Other Income	5	123	17	15	14
Net Income (Adjusted)	(140)	12	40	78	189
% Change	-100.7%	NM	229.2%	92.7%	142.0%

Free Cash Flow Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Net Income from Cont Operations (GAAP)	(140)	12	40	78	189
Depreciation & Amortization	4	4	5	6	6
Change in Working Capital	3	(38)	(6)	(7)	(4)
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	33	(67)	40	40	40
Capital Expenditure	(53)	(12)	(20)	(25)	(28)
Free Cash Flow	-154	-101	59	91	204
% Change	-32.1%	34.5%	NM	54.1%	123.1%
Share / Issue Repurchase	35	203	20	300	20
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	0	0	0	0	0

Balance Sheet Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash & Equivalents	162	358	326	594	682
Trade Receivables	NA	NA	NA	NA	NA
Other Current Assets	222	230	355	496	640
Property, Plant & Equipment	162	161	177	196	217
Other Non-Current Assets	13	69	71	73	75
Total Assets	558	818	929	1,359	1,614
Short-Term Debt	2	1	2	2	3
Other Current Liabilities	27	32	39	49	54
Long-Term Debt	7	7	8	10	11
Other Non-Current Liabilities	NA	NA	NA	NA	NA
Total Liabilities	36	40	50	62	68
Total Equity	522	779	879	1,297	1,546
Total Equity & Liabilities	558	818	929	1,359	1,614

^{*} For full definitions of $\emph{\textbf{IQ}}\textit{method}^{\text{SM}}$ measures, see page 5.

Company Sector

Biotechnology

Company Description

Krystal Biotech is a late clinical-stage biotech company developing differentiated HSV-based gene therapies for inherited dermatological and respiratory diseases. Using their proprietary Skin TARgeted Delivery (STAR-D) platform and modified HSV-1 viral vectors, Krystal has developed a unique pipeline of gene therapies with both higher cargo capacity and redosing ability expanding applicability to larger, chronic indications.

Investment Rationale

Krystal offers a compelling approach to gene therapy given 1) differentiated transient HSV-1 platform, 2) high valuation ceiling on expanded chronic applications (CF, AATD, aesthetics), 3) phase 3 derisking data from Vyjuvek for DEB, 4) deep manufacturing capabilities supporting commercial launch, and 5) partnership opportunities for later-stage studies or new pipeline candidates.

Stock Data

Average Daily Volume 316,682

Quarterly Earnings Estimates

	2023	2024
Q1	NAA	NAE
Q2	NAA	NAE
Q3	NAA	NAE
Q4	NAA	NAE



Model Changes

Exhibit 1: KRYS Model Changes

We adjust revenue estimates to account for faster-than-expected ramp-up, OpEx to align with guidance

	2024E		2025E		2026E	
\$ in thousands	Prior	Current	Prior	Current	Prior	Current
B-VEC	182	224	344	313	487	459
KB301	0	0	3	0	20	5
KB407	0	0	6	0	33	8
KB408	0	0	0	0	5	5
Total other pipeline/platform	0	0	0	0	0	0
Total Revenues	185	224	373	313	608	482
Costs of goods sold	18	22	37	31	30	24
Research and development	62	56	74	67	85	77
General and administrative	155	122	194	152	223	175
Operating income (loss)	(51)	24	67	63	269	206
Interest and other income, net	16	17	14	15	13	14
Interest expense	0	0	0	0	0	0
Unrealized gain (loss) on available-for-sale securities	0	0	0	0	0	0
Income tax benefit (expense)	0	0	0	0	(40)	(31)
Consolidated net income (loss)	(35)	40	81	78	242	189
Net income (loss) per share	(1.21)	1.43	2.67	2.61	7.59	5.98
Shares outstanding, diluted ('000)	28,971	28,274	30,410	29,937	31,832	31,581

Source: BofA Global Research estimates

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Price objective basis & risk

Krystal Biotech (KRYS)

Our \$168/share price objective is based on a probability-adjusted net present value (NPV) for rare dermatology (\$128/share), respiratory, including cystic fibrosis (CF) and AATD (\$9/share), aesthetics through the Jeune subsidiary (\$5/share), the discovery pipeline (\$4/share), and cash (\$21/share). We apply probabilities of success from 9% (aesthetics) to 100% (Vyjuvek), a weighted-average cost of capital (WACC) of 10-13%, and -3% (rare derm) to 2% (early pipeline) terminal growth rate.

Downside risks: 1) Vyjuvek launch uptake slower than anticipated, 2) HSV-1 technology fails to yield compelling data in expanded chronic indications, 3) competitors produce more convincing data for competing therapies, 4) regulatory and/or reimbursement landscape changes unfavorably for gene therapies, and 5) funding is insufficient to move forward pipeline aspirations or further commercial/manufacturing build out.

Analyst Certification

I, Alec W. Stranahan, 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	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
	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

US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	Vertex Pharmaceuticals Inc.	VRTX	VRTX US	Geoff Meacham
	Werewolf Therapeutics	HOWL	HOWL US	Jason Zemansky
	Xencor	XNCR	XNCR US	Alec W. Stranahan
NEUTRAL				
NEOTRAL	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 Editas Medicine	CYTK EDIT	CYTK US	Jason Zemansky
			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
UNDERPERFORM				
	AlloVir, Inc.	ALVR	ALVR US	Jason Zemansky
	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
	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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*IQ*method[™] Measures Definitions

Business Performance	Numerator
Return On Capital Employed	NOPAT = (EBIT + Interest Income) × (1 — Tax Rate) + Goodwill Amortization
Return On Equity	Net Income
Operating Margin	Operating Profit
Earnings Growth	Expected 5 Year CAGR From Latest Actual

Quality of Earnings	Numerator
Free Cash Flow	Cash Flow From Operations — Total Capex
Earnings Growth	Expected 5 Year CAGR From Latest Actual

Capex
Tax Charge
Net Debt = Total Debt — Cash & Equivalents
EBIT

Valuation Toolkit	Numerator
Price / Earnings Ratio	Current Share Price
Price / Book Value	Current Share Price
Dividend Yield	Annualised Declared Cash Dividend
Free Cash Flow Yield	Cash Flow From Operations – Total Capex
Enterprise Value / Sales	FV = Current Share Price × Current Shares + Minority Fquity + Net Deb

Cash Flow From Operations

Enterprise Value / Sales	EV = Current Share Price × Current Shares + Minority Equity + Net Debt +
	Other LT Liabilities
EV / EBITDA	Enterprise Value

Denominator

Total Assets — Current Liabilities + ST Debt + Accumulated Goodwill
Amortization
Shareholders' Equity
Sales

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



Cash Realization Ratio

Valuation Toolkit Numerator Denominator

Manethod Suis the set of BofA Global Research standard measures that serve to maintain global consistency under three broad headings: Business Performance, Quality of Earnings, and validations. The key features of iQmethod are: A consistently structured, detailed, and transparent methodology. Guidelines to maximize the effectiveness of the comparative valuation process, and to identify some common pitfalls.

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Krystal (KRYS) 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%

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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%
Inderperform	N/A	≥ 20%

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