

US Biopharmaceuticals

The Priority Review: Week of January 1st, 2024

Industry Overview

Generally optimistic on Biopharma in 2024

We released our 2024 outlook ([See our 2024 outlook note](#)) this week, and while there are concerns on generalist interest (ex-Lilly, Merck, and Vertex) we're positive on Biopharma in 2024. We think growth expectations (single digit top and bottom line) fit the sector's mid-teens multiple. We're optimistic on innovation, with cures for sickle cell, non-opioid pain drugs, and the growing evidence on the efficacy of GLP-1s in indications beyond obesity. Biopharma is putting cashing to work for M&A, highlighting the value of innovative drugs. That said, we still have major patent cliffs effecting half of the space and the upcoming election increases headline risk & limits defense for the sector rally.

Bristol to Neutral, Lilly & Merck remain top picks

We moved to Neutral from Buy on Bristol ([see our note on the downgrade](#)), as while we're not fundamentally negative, our upside thesis of new product launches comforting investors on the 3 patent cliffs hasn't played out. Following recent inline to modest misses on key launches, we don't think 2024 is commercial tipping point. Our favorite names, Lilly and Merck, are stocks with differentiated growth. We're eager to hear Lilly's 2024 guidance (BofA +\$3B on rev, +\$1 on EPS vs consensus), and think the conservatism/aggression of their tone at JPM will be key to look out for. Alzheimer's approval in 1Q could be a new narrative for generalist investors. Merck's major event this year will be the approval/launch of sotracept in pulmonary hypertension. We made Gilead a favorite in biotech this year, following our upgrade ([see our note on the upgrade](#)) last fall. We're 2x what we consider low consensus growth estimates (low single digit for revs, high single digit for EPS), as HIV demand is back and we're approaching a \$4B run rate in hemeonc, which we view as an underappreciated asset.

Investors see 2023 trends continuing into 2024

Following investor meetings in NYC this week, we've noticed the following themes emerge 1) there's justification for investing in 2023's standout names Lilly (strong script trends for Zepbound) and Vertex (acute pain / vanzacaftor data). 2) Investors are curious about sentiment and potential re-ratings on stocks that have less LOE risk but limited growth (Amgen, Gilead, Biogen, Regeneron), and we see investor debates picking up on the names this year. 3) among the names with LOE issues (AbbVie, Pfizer, Bristol, to an extent JNJ) investors prefer AbbVie early in the year, as their erosion curve could flatten in 6-9 months. [See our company by company overview for 2024.](#)

Regeneron and Vertex names to watch at JPM

We released our JPM preview today ([see our preview note](#)). Regeneron typically gives 4Q Eylea sales at JPM - last year they felt the brunt of the initial Vabysmo launch though trends have stabilized. If Eylea demand is weaker, they may play up initial HD demand and the potential for an Eylea settlement. We like that Biomarin will have a new CEO to complement activist engagement. Vertex may have phase 3 data in acute pain for VX-548 or vanzacaftor data in CF, and we think the stock could move on good news despite high investor probabilities of success. Moderna's setup isn't great in our view following a late rally in 2023, along with weaker Spikevax numbers and higher opex.

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Instructions for the Analysts:

Please provide the full text of your script below for review by the Supervisory Analyst. The approved script will be delivered to the video team for upload to the teleprompter.

As a reminder, all security-specific references should include a corresponding ticker reference in Document Options.



2024 outlook

- [2024 US Biopharma Outlook report](#)
- [2024 Company Profiles report](#)
- [Bristol \(BMY\) Downgrade note](#)
- [Kymera \(KMYR\) Downgrade note](#)
- [LianBio \(LIAN\) Downgrade note](#)

3Q23 earnings reports

- J&J: [Initial thoughts on the JNJ 3Q23 results](#) and [thoughts post the JNJ 3Q23 call](#)
- Merck: [Initial thoughts on MRK 3Q23 results](#) and [thoughts post the 3Q23 MRK call](#)
- Bristol: [Initial Thoughts on BMY 3Q23 results](#) and [thoughts post the BMY 3Q23 call](#)
- AbbVie: [Initial thoughts on ABBV 3Q23 results](#) and [thoughts post the ABBV 3Q23 call](#)
- Pfizer: [Initial thoughts on PFE 3Q23 results](#) and [thoughts post the PFE 3Q23 call](#)
- Amgen: [Initial thoughts on AMGN 3Q23 results](#) and [thoughts post the AMGN 3Q23 call](#)
- Kiniksa: [thoughts post the KNSA 3Q23 call](#)
- BioMarin: [Initial thoughts on BMRN 3Q23 results](#) and [thoughts post the BMRN 3Q23 call](#)
- Moderna: [Initial thoughts on MRNA 3Q23 results](#) and [thoughts post the MRNA 3Q23 call](#)
- Regeneron: [Initial thoughts on REGN 3Q23 results](#) and [thoughts post the REGN 3Q23 call](#)
- Lilly: [Initial thoughts on LLY 3Q23 results](#) and [thoughts post the LLY 3Q23 call](#)
- Vertex: [Initial thoughts on VRTX 3Q23 results](#) and [thoughts post the VRTX 3Q23 call](#)
- Gilead: [Initial thoughts on GILD 3Q23 results](#) and [thoughts post the GILD 3Q23 call](#)
- Biogen: [Initial thoughts on BIIB 3Q23 results](#) and [thoughts post the BIIB 3Q23 call](#)
- Royalty: [thoughts post the RPRX 3Q23 call](#)

3Q23 earnings read-through notes

- Sanofi: [Sanofi read-through to our coverage](#)
- Roche: [Roche read-through to our coverage](#)
- Johnson & Johnson (J&J): [JNJ read-through to our coverage](#)
- GlaxoSmithKline: [GSK read-through to our coverage](#)

Key takes from our CEO/CFO call series

- Kiniksa (March 30) – [KNSA call takeaways](#) and [KNSA quotes and transcript](#)
- Amylyx (April 6) – [AMLX call takeaways](#) and [AMLX quotes and transcript](#)
- CRISPR (April 14) – [CRSP call takeaways](#) and [CRSP quotes and transcript](#)
- Pfizer (May 4) – [PFE call takeaways](#) and [PFE quotes and transcript](#)
- Bristol (May 5) – [BMY call takeaways](#) and [BMY quotes and transcript](#)
- Lilly (May 9) – [LLY call takeaways](#) and [LLY quotes and transcript](#)
- Biogen (May 12) – [BIIB call takeaways](#) and [BIIB quotes and transcript](#)
- AbbVie (May 18) – [ABBV call takeaways](#) and [ABBV quotes and transcript](#)
- J&J (May 19) – [JNJ call takeaways](#) and [JNJ quotes and transcript](#)
- Royalty Pharma (June 1) – [RPRX call takeaways](#) and [RPRX quotes and transcript](#)
- BioMarin (June 2) – [BMRN call takeaways](#) and [BMRN quotes and transcript](#)
- Gilead (June 8) – [GILD call takeaways](#) and [GILD quotes and transcript](#)
- Moderna (June 16) – [MRNA call takeaways](#) and [MRNA quotes and transcript](#)
- Vertex (June 21) – [VRTX call takeaways](#) and [VRTX quotes and transcript](#)

Key takes from our Vegas Healthcare Conference

- [Vegas Healthcare Conference Day 1 takeaways](#)
- [Vegas Healthcare Conference Day 2 take aways](#)
- [Vegas Healthcare Conference wrap up](#)

Upcoming catalysts, investor days and regulatory dates

- J.P Morgan Healthcare Conference, January 8 – 11, 2024
- Pfizer Oncology R&D Day, February 29, 2024



Abbreviations:

GLP-1: glucagon like peptide

KOL: key opinion leader

DPN: diabetic peripheral neuropathy

IO: immuno-oncology

T2D: type 2 diabetes

CAR-T: chimeric antigen receptor T-cell

BCMA: B-cell maturation antigen

MDS: myelodysplastic syndromes

ASH: American Society of Hematology

ADC: antibody drug conjugate

INT: investigational individualized neoantigen therapy

Exhibit 1: Stocks mentioned

Prices and ratings for stocks mentioned in this report

BofA Ticker	Bloomberg ticker	Company name	Price	Rating
BMRN	BMRN US	BioMarin	US\$ 96.95	B-1-9
BMJ	BMJ US	Bristol-Myers Squibb	US\$ 50.81	B-1-7
LLY	LLY US	Eli Lilly	US\$ 571.96	B-1-7
GILD	GILD US	Gilead Sciences Inc.	US\$ 80.56	B-1-7
MRK	MRK US	Merck & Co.	US\$ 105.83	A-1-7
MRNA	MRNA US	Moderna	US\$ 85.99	C-2-9
REGN	REGN US	Regeneron Pharmaceut	US\$ 864.15	B-3-9
VRTX	VRTX US	Vertex Pharmaceutica	US\$ 408.55	B-1-9

Source: BofA Global Research

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Price objective basis & risk**BioMarin (BMRN)**

Our valuation approach for BMRN shares employs a discounted cash flow analysis of approved and pipeline products reflected in our \$170 price objective. We value BioMarin shares using a sum-of-the-parts net present value (NPV) analysis of approved assets, which assumes a weighted average cost of capital (WACC) of 4.5% and terminal growth rate of -5.5%. Under our assumptions, our NPV analysis suggests a legacy product value of \$55/share, Roctavian and Voxzogo of \$95/share, early stage pipeline of \$11/share and cash value of \$9/share.

Risks to our price objective are 1) faster-than-expected revenue runoff from Kuvan, 2) competition from other orphan drug developers, 3) slower-than-expected growth of new drug launches, and 4) clinical trial failures.

Bristol-Myers Squibb (BMJ)

Our \$60 price objective (PO) is based on a 50/50 blended average of our risk-adjusted discounted cash flow (DCF) and P/E multiple applied to 2024E EPS. Our DCF assumes 7% WACC and -4% terminal growth rate, and we assume an approximate 8x 2024 P/E multiple given an impending patent cliff and risks associated with later-stage pipeline.

Risks to our PO are 1) uninspiring readouts from late-stage trials in key I/O indications,

2) more rapid deceleration of Revlimid erosion than expected, 3) negative outcomes from the company's later-stage pipeline assets in development, 4) pressures from headline risks facing the sector (including drug pricing reform), and 5) negative patent rulings.

Eli Lilly and Company (LLY)

Our \$700 price objective is based on a probability-adjusted net present value (NPV) analysis of franchise verticals including Endocrinology (\$393/share), Oncology (\$127/share), Cardiovascular (\$4/share), Neuroscience (\$12/share), Immunology (\$28/share), other pharmaceutical products and early pipeline assets (\$150/share), as well as approximately -\$15/share in net cash. We use a WACC ranging from 5% for approved products to 9% for pipeline products, depending on the stage of development. We apply terminal values ranging from -12% (cardiology) to 1% (endocrinology) based on projected sales decline following loss of exclusivity within each business vertical.

Risks to our price objective are 1) better-than-expected launches of competing products, 2) emerging clinical data for pipeline assets that does not confirm prior observations, 3) failure to effectively commercialize approved products, 4) potential drug pricing system restructuring in the US.

Gilead Sciences Inc. (GILD)

Our \$95 price objective is based on a sum-of-the parts net present value (NPV) analysis. We forecast sales of key franchises or products to 2030 using a weighted average cost of capital (WACC) of 8%, and include a terminal value where appropriate. Under these assumptions, we value the HIV franchise at \$80/share, HCV and HDV at \$7/share, the Kite platform at \$8/share, remdesivir at \$2/share, Trodelvy at \$9/share, with the pipeline at \$5/share and net cash at -\$15/share.

Upside risks: 1) stronger-than-expected sales of Biktarvy in HIV and faster uptake of Descovy in PrEP, 2) greater durability of HCV revenues, 3) rapid uptake of Kite, 4) and success of the oncology pipeline may lead investors to assign further value to these programs.

Downside risks: 1) moderating sales of Biktarvy, Genvoya, Odefsey, and Descovy due to competition, which may include long-acting injectable formulations, 2) greater than expected erosion of HCV revenues, 3) limited upside from Gilead's CAR-Ts, 4) the oncology pipeline may have limited clinical success or be meaningfully delayed.

Merck & Co. (MRK)

Our \$130 price objective (PO) is based on the intrinsic value of Merck standalone. We use a 50/50 blended average of our P/E multiple applied to 2024E EPS (we think the current 17x vs. 18x peer average makes sense to reflect continued strength of Merck's core growth franchises but broader Keytruda concentration risk concerns) and risk-adjusted DCF (7% WACC and -2% terminal growth rate).

Risks to our PO are 1) impressive competitor readouts results in key immuno-oncology (I/O) indications, 2) more rapid declines across the diabetes franchise than expected, 3) negative outcomes from the company's later-stage assets in ongoing development, and 4) pressures from headline risks facing the sector (including drug pricing reform).

Moderna (MRNA)

Our PO of \$120 is based on a probability-adjusted NPV of six different parts including prophylactic vaccines (\$91/share), systemic secreted cell surface therapeutics (\$1/share), cancer vaccines (\$4/share), intratumoral immune-oncology (\$2/share), cardiovascular diseases (\$0/share) and systemic intracellular therapeutics (\$1 share), and net cash (\$22/share). We estimate sales of 46 pipeline programs that are slated to move forward with probability of success ranging from 6% to 95%. We use a WACC of 10% and

terminal growth rate of -30%.

Upside risks to our PO are: 1) faster than expected pipeline development, 2) cleaner than expected safety findings, 3) accelerated product approvals, 4) stronger than expected launches, 5) lower competition, 6) moderating cash burn, and 7) potential upside from coronavirus vaccine program.

Downside risks to our PO are: 1) lower than expected revenues from the COVID-19 program, 2) unexpected safety findings, 3) slower than expected pipeline development/approvals, 4) more intense competition, and 5) accelerating cash burn.

Regeneron Pharmaceuticals Inc. (REGN)

Our \$700 price objective is based on a probability-adjusted net present value (NPV) analysis of Eylea, including outside of US (OUS) revenues from the Bayer collaboration (\$164/share), Sanofi collaboration revenue including Dupixent and other product revenues (\$329/share), Libtayo (\$56/share), early pipeline assets (\$60/share), and the rest from net cash. We use a weighted-average cost of capital (WACC) ranging from 7% for approved products to 10% for pipeline products and terminal growth ranging from -3 to 3%. Upside risks to our price objective are 1) better-than-expected Eylea growth trajectory, 2) a larger contribution of Dupixent to Regeneron's topline from commercial uptake in new indications, and 3) better-than-expected economics realized by Regeneron from joint ventures. Downside risks to our price objective are 1) slower-than-expected growth from product sales, particularly Eylea and Dupixent, 2) failure to obtain approval for additional indications for Dupixent, and 3) pipeline setbacks.

Vertex Pharmaceuticals Inc. (VRTX)

Our 12-month price objective for Vertex of \$450/share is based on our net present value (NPV) analysis. We forecast sales for each of the approved products, Kalydeco, Orkambi, Symdeko, and Trikafta through 2030. We assume a weighted-average cost of capital (WACC) of 9%, in line with peer companies of similar size and risk and varying terminal growth rates for each asset based on its characteristics and patent life (-50% to 2%). Given these assumptions, we estimate a value of \$4/share for Kalydeco, \$2/share for Orkambi, \$0/share for Symdeko, \$335/share for Trikafta, \$31/share for CTX001, \$17/share for VX-548, \$46/share in net cash, and \$15/share for the pipeline.

Risks to our price objective are 1) payer pushback on pricing, 2) difficulty in securing reimbursement agreements, particularly in the EU, 3) clinical trial failures, and 4) new competitors in cystic fibrosis.

Analyst Certification

I, Geoff Meacham, 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.

Special Disclosures

BofA Securities is currently acting as financial advisor to Bristol-Myers Squibb Co. in connection with its proposed acquisition of RayzeBio, Inc., which was announced on December 26, 2023.

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
	Insmid 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.	RXR	RXR 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

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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