

US Biopharmaceuticals

Roche 4Q23 earnings: read-throughs to our coverage universe

Industry Overview

Vabysmo growth vs Eylea decline / Eylea HD competition

Roche (covered by Sachin Jain/Graham Parry) slightly missed on 2023 revenue (CHF 58.7B, -1% cons) and EPS (CHF 14.31). We'd add that Roche will host a Neurology Update event (March 11) and Pharma Day (September 30). From Roche's pipeline, we're most interested in data from the Carmot acquisition (CT-388, CT-868) and data from its anti-TL1A asset for IBD (RVT-3101). That said, we remain focused on Vabysmo, which was ahead of overall 2023 expectations by 1% to CHF 2.4B (+324% y/y). 4Q results (CHF 696M, +6% q/q and +32% y/y), were driven by uptake in naïve patients to 42% (2Q/3Q: 30% / 37% in the US) with switches likely declining (2Q/3Q: 70% / 63%). US market share reached 22% (2Q/3Q: 15%/19%) in wAMD and 15% (2Q/3Q: 9%/12%) in DME. While 4Q US Eylea sales (-7% q/q and -10% y/y, excluding Eylea HD) will not be a surprise given Regeneron reported preliminary results (\$1.34B US Eylea; \$123M US Eylea HD), we think Roche's optimistic 2024 outlook for Vabysmo, driven by label expansion into RVO and strategic pricing/contracting (at par with current SOC vs ~20% premium pricing of Eylea HD), does not bode well for US Eylea (2024: \$5.2B, +\$690M cons) and Eylea HD (2024: \$609M, -\$1B cons). Furthermore, reimbursement in the EU (now covered in EU5) may begin to impact ex-US sales. We maintain Underperform (\$710 PO) on REGN and view competition in the retinal space as underappreciated.

Hemlibra to face competition with marstacimab?

Hemlibra (Hemophilia A) maintains ~40% share (flat from 3Q) of patients in the US/EU-5, with ~24,000 patients (+2,000 patients from 3Q) treated globally (2023: CHF 4.1B, +8% y/y). Pfizer's marstacimab is differentiated from Hemlibra in that it's effective in both A/B patients and has a convenient once-weekly, flat subcutaneous dosing (PDUFA: 2H24, likely 4Q24), with Roche acknowledging growing competition in Hemophilia, though still confident in the franchise overall. Maintain Neutral on PFE, \$35 PO.

Growing skepticism with TIGIT Skyscraper-01

Roche delayed timing of SKYSCRAPER-01 (PD-L1 + TIGIT) final OS data in 1L NSCLC to 2H24 (from 1Q24) at the January HC conference, which we think is due to a muted delta on efficacy and likely has negative readthrough broadly for TIGIT molecules, including Gilead's/Arcus's (the latter covered by Jason Zemansky) TIGIT combo. Tecentriq (PD-L1 inhibitor) slightly missed consensus (CHF 3.8B, -1% cons), and failed to meet its primary endpoint in adjuvant SCCHN (head and neck cancer). Maintain Buy on GILD, \$95 PO.

CD20xCD3 expectations in 2024: 1L DLBCL, new entrant

Polivy (CD79b ADC) continues to grow (2023: CHF 837M, +108% y/y) due to 1L DLBCL uptake with potential upside from DLBCL genetic subtypes in 2024. We continue to look for phase 1b data from Lunsumio and Columvi (CD20xCD3) combos in 1L DLBCL and pivotal 2L+ updates in 2024 (Columvi, STARGLO; Lunsumio, SUNMO). Overall, we see 2023 sales from Roche's assets (2023: Columvi: CHF 28M; Lunsumio: CHF 58M) as having a positive read-through to AbbVie/Genmab's Epcinly (2023: \$50M; 4Q: \$36M, +\$8M cons). That said, we think Regeneron's odronextamab may be disadvantaged entering the treatment landscape as an IV formulation and third-to-market; we take a wait-and-see approach on commercial execution. We now expect an update on the phase 3 VERONA study of AbbVie / Roche's Venclexta for MDS in 2024, which could suggest a more limited delta on survival events if delayed. Maintain Neutral on ABBV, \$165 PO.

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Refer to important disclosures on page 5 to 9. Analyst Certification on page 3. Price Objective Basis/Risk on page 2.

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Abbreviations

AMD: age-related macular degeneration
CD: cluster of differentiation
CHF: Swiss Franc
DLBCL: diffuse large B-cell lymphoma
MDS: Myelodysplastic Syndrome
DME: diabetic macular edema
RVO: retinal vein occlusion
FDA: Food and Drug Administration
1L: first line
LOE: loss of exclusivity
NSCLC: non-small cell lung cancer
PD-L1: programmed cell death ligand-1
OS: overall survival
FDA: Food and Drug Administration
PD-L1: programmed death-ligand 1
subQ: subcutaneous
ADC: antibody drug conjugate
TIGIT: T cell immunoreceptor with Ig and ITIM domains
F/X: foreign exchange
IV: intravenous
PDUFA: Prescription Drug User Fee Act
SOC: standard of care
IBD: inflammatory bowel disease
TL1A: tumor necrosis factor-like cytokine 1A

Stocks mentioned

Prices and ratings for stocks mentioned in this report

BofA Ticker	Bloomberg ticker	Company name	Price	Rating
ABBV	ABBV US	AbbVie	US\$ 43.10	B-2-7
GILD	GILD US	Gilead Sciences Inc.	US\$ 264.75	B-1-7
PFE	PFE US	Pfizer	US\$ 203.05	B-2-7
REGN	REGN US	Regeneron Pharmaceut	US\$ 57.67	B-3-9

Price objective basis & risk**AbbVie (ABBV)**

Our \$165 price objective (PO) is based on a 50/50 blended valuation of our DCF and 2025 non-GAAP EPS estimate P/E multiple of 12x (giving a value of \$145). Our 12x P/E multiple lags peers (18.0x) due to concentration risk of the company's assets and LOE concerns to limit significant growth in the future. We assume a 7% WACC and a -1% terminal growth in our estimates to arrive at our \$185 DCF valuation.

Downside risks are underachievement of key growth drivers, clinical pipeline failure(s), and reduced cash flow generation to pay down debt or dividend.

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.

Pfizer (PFE)

Our \$35/share for Pfizer is based on a 50/50 blended average of our discounted cash flow (DCF) analysis and P/E multiple based on the large cap global therapeutics group. For our DCF, we use a weighted-average cost of capital (WACC) of 7% and 1% terminal growth for an intrinsic value of \$47/share. Our P/E analysis assumes a 10x multiple of our 2025 EPS estimate, which yields a \$24 intrinsic value.

Downside risks: 1) sales downside, 2) inability for pipeline to overcome patent loss of exclusivities (LOEs) after 2025, 3) M&A transactions that are perceived to be value destructive.

Regeneron Pharmaceuticals Inc. (REGN)

Our \$710 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 (\$161/share), Sanofi collaboration revenue including Dupixent and other product revenues (\$334/share), Libtayo (\$59/share), early pipeline assets (\$65/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.

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.

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
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	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

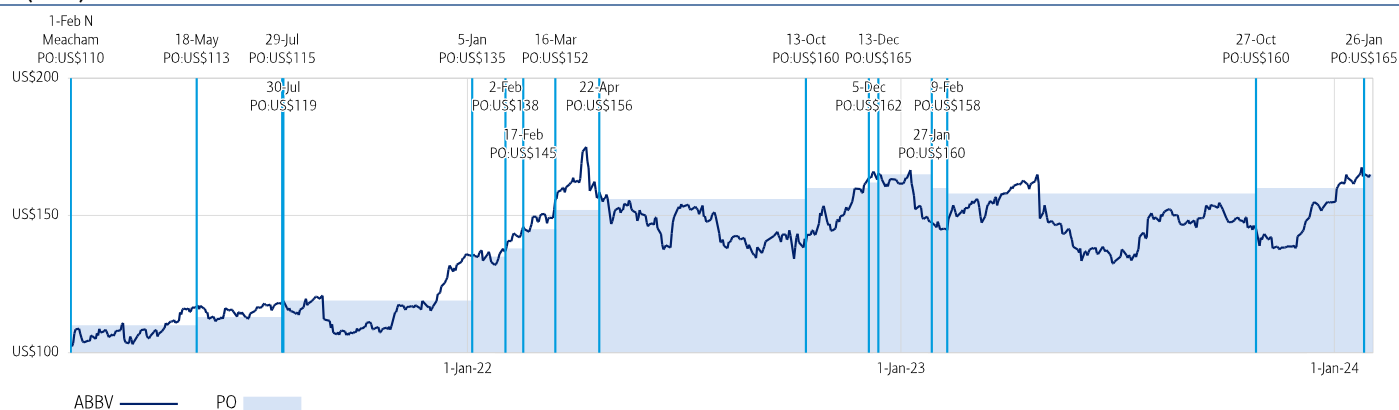
US - Biopharmaceuticals Coverage Cluster

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

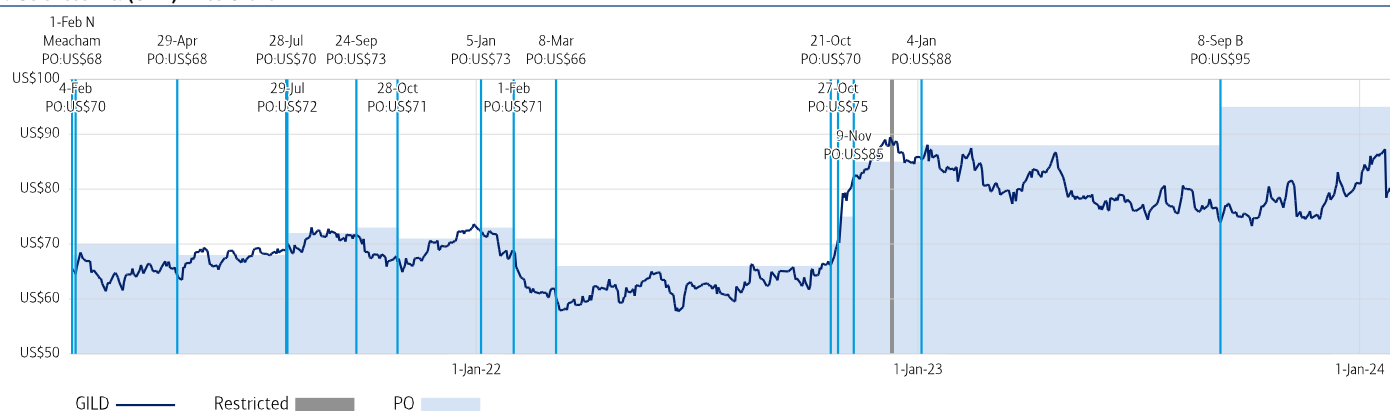
AbbVie (ABBV) Price Chart



B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

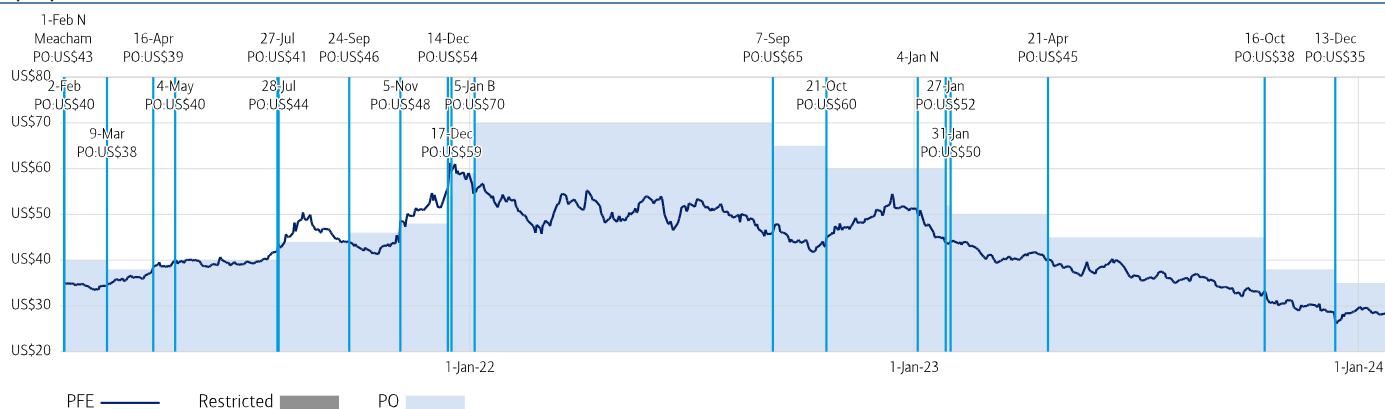
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Gilead Sciences Inc. (GILD) Price Chart



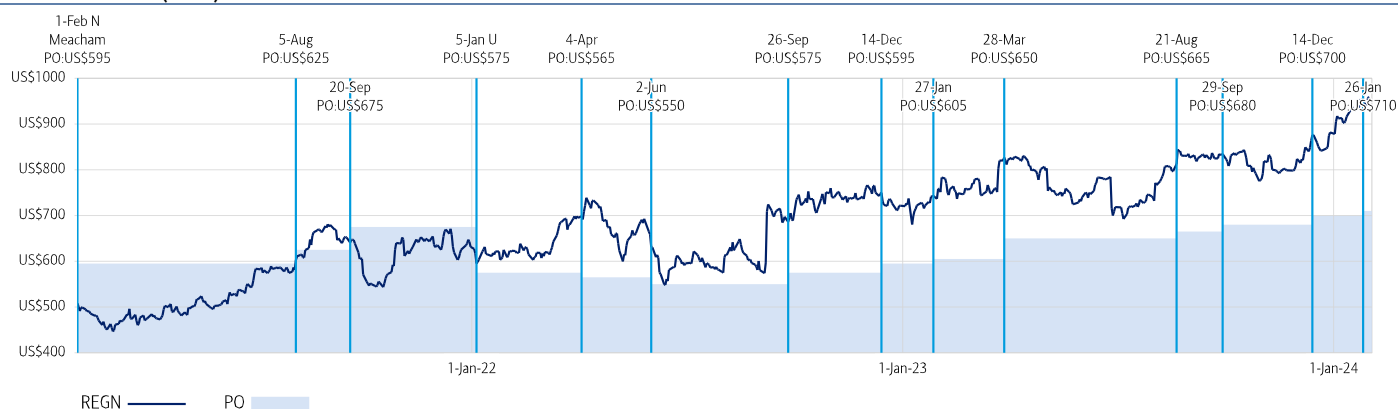
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Pfizer (PFE) Price Chart

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Regeneron Pharmaceut (REGN) Price Chart

B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

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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%

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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}
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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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