

## US Biopharmaceuticals

Day 1 Key Highlights from SF conference:  
SWTX, RXRX, DAWN, NVAX

## Industry Overview

We summarize key takeaways of important presentations from the SF conference for our coverage companies including SWTX, RXRX, DAWN and NVAX ([see our 2024 outlook report](#)).

**SWTX: goal is clear as ever, two drugs approved by YE**

SWTX stock is trading up (+9.4%; NBI: 2.38%) on the day of the presentation at the SF conference. We think the company's goal cannot be more clear for 2024 and hence will be the areas of investor focus which are **1) Ogsiveo sales**, **2) mirdametinib approval**. From the sentiment of the management, we see Ogsiveo sales/uptake to be mostly straight-forward with little hurdles (our [KOL checks in December](#) have shown that Ogsiveo is already being prescribed), especially with Ogsiveo being the first approved targeted therapy able to decrease tumor growth. Moreover, we see management reiterating mirdametinib's prowess over selumetinib (Astrazeneca) in the Q&A session, mentioning patients' difficulty to stay on selumetinib. We suspect that this comment is in part due to the fact that selumetinib must be taken on an empty stomach (a feat which has proven difficult especially for NF1 patients such as children of school age), which is a hurdle which mirdametinib has effectively obviated. We therefore continue to view the SpringWork story positively and maintain Buy and our \$50 PO.

**RXRX: progress impressive, AI validation to be watched**

RXRX stock is trading with strength (+5.7%, NBI: +2.38%) after the company announced continued and deeper collaborative relationship with NVIDIA as well as the LOWE drug discovery software at the conference (Large Language Model-Orchestrated Workflow Engine). LOWE was developed at Valence labs (acquired by Recursion in May 2023), which focused on using foundation models to simulate biological/chemical systems, in hope that machines will be able to comprehend and infer based on experimental results and perform hypothesis testing just like a normal human-like researcher. That said, while we mostly applaud the effort and continue to believe that AI is indeed the future of drug discovery, we believe concrete evidence in the form of clinical data is still needed to validate the AI platform. Until then, we see movements in stock as being affected by factors non-fundamental to the company, and maintain Neutral, \$14 PO.

**DAWN: April 30<sup>th</sup> PDUFA will be next binary for shares**

Launch continues to be key priority for DAWN as management reiterated at the SF conference. We see management remaining confident as they already place their vision on commercialization, mentioning that the sales team is already in place to commercialize tovorafenib once approved (PDUFA April 30<sup>th</sup> 2024). That said, we reiterate our concerns given regulatory endpoint misalignment (RANO-LGG vs HGG), open-label study design without a comparator arm (drug benefits not accurately quantifiable), lowered ORR when using RANO-LGG (MR not likely to be included on the label according to antecedent cases in D/T), and hampered growth in children which raises questions on true risk/benefit for tovorafenib. Maintain Underperform, \$10 PO.

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Equity  
United States  
Biopharmaceuticals

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**Abbreviations:**

**YE:** Year end  
**NBI:** Nasdaq biotech  
**KOL:** Key opinion leader  
**NF1:** Neurofibromatosis type 1  
**RANO-LGG/HGG:** neuro-oncology-high/low grade glioma  
**PDUFA:** Prescription drug user fee act  
**D/T:** Dabrafenib/trametinib  
**FDA:** Food and drugs administration  
**CDC:** Center of disease control  
**C-19:** Covid 19  
**MR:** Minor response  
**ORR:** Overall response rate

**DAWN:** Day One  
**NVAX:** Novavax  
**RXRX:** Recursion  
**SWTX:** SpringWorks

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**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: 09 January 2024 05:30AM EST

**NVAX: covid market shrinking, cost-cutting ahead**

NVAX stock has traded a few legs down in the past year (-58%; NBI: +2.38%) given shrinking C-19 market and diminishing demand. While we do see Novavax's recently securing FDA authorizations and CDC recommendations in hand as a positive, meaning that commercial rollout for Novavax's vaccine is well underway, we think significant hurdles still exist ahead in terms of capturing a market meaningful enough to drive shares. That said, we do see the company's commentary on "becoming more than a one-product company" (combo vaccine to enter phase 3 in 2H24, and expected approval in 2026, malaria in the works) reassuring for shareholders. With the company still guiding to lower 2023 OpEx (~\$1.15B-\$1.25B; prior: \$1.3B-\$1.4B) 2024 OpEx (~\$750M) in light of cost-reduction/restructuring, we do see room, although slim, for the company to rebound in the longer-term. However, we continue to see NVAX to command a fringe share of the shrinking C-19 market (as evident from the YoY step-down in sales for Moderna's mRNA vaccines: 2022: ~\$18.4B; 2023: ~\$6B; 2024 guidance: ~\$4B). Maintain Underperform and \$4 PO.

**Exhibit 1: Companies mentioned**

Companies mentioned in this report

BofA Ticker	Bloomberg ticker	Company name	Price	Rating
DAWN	DAWN US	Day One	US\$ 14.94	C-3-9
NVAX	NVAX US	Novavax	US\$ 5.15	C-3-9
RXR	RXR US	Recursion	US\$ 12.61	C-2-9
SWTX	SWTX US	SpringWorks	US\$ 41.53	C-1-9

Source: BofA Global Research

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**Price objective basis & risk****Day One Biopharmaceuticals (DAWN)**

Our \$10/share price objective is based on a probability adjusted NPV for tovorafenib in r/r pLGG (\$2/sh), tovorafenib for 1L pLGG (\$1/sh), tovorafenib for RAF-driven solid tumors (\$1/sh), pimasertib/tovorafenib combo for RAF-driven solid tumors (\$1/sh), and cash (\$5/sh). We apply a WACC of 10-12% and 1% (tovorafenib) to 3% (pima/tovo combo) terminal growth rate.

Downside risks to our PO are: 1) FDA red flags FIREFLY-1 trial design and delays tovorafenib approval, 2) lack of urgency for FDA to approve tovorafenib given high survival rate for current pLGG patients, 3) new RANO-LGG endpoint can result in lower ORR than previously reported, 4) D+T combo presents as further competition with randomized trial design setting a bar hard for tovorafenib to reach, 5) lack of platform innovation with all assets acquired could mean potential for future lacking, 6) small end market size can affect topline contribution even with approval, 7) rapidly expiring patents for pimasertib can give room for biosimilars to erode market share

Upside risks to our PO are: 1) FDA approves tovorafenib with no delays given unmet need and compelling data package, 2) BRAF-driven solid tumors substudy trial continues to readout positively, 3) FIREFLY-2 phase 3 pivotal for 1L pLGG reads out positively and earlier than expected, 4) clear pipeline strategy and potential for future synergy in combos starting with pimasertib/tovorafenib, which opens up larger market in solid tumors.

**Novavax (NVAX)**

Our \$4/sh price objective is based on probability-adjusted net present value (NPV) of lead assets Nuvaxovid (\$-3/share), NanoFlu (\$2/share), ResVax (\$0/share), other pipeline (\$-1/share), and cash (\$6/share). We use a weighted-average cost of capital (WACC) of 10-13% and terminal values ranging from -12% (COVID-19) to 2% (other pipeline). We apply probabilities of success including 100% for Nuvaxovid in EU/ROW, 64% for NanoFlu, 7% for ResVax, and 4% for other pipeline.

Upside risks: 1) Nuvaxovid use could be stronger than expected, 2) assets in flu, RSV, and malaria may find a path to regulatory approval, 3) additional pipeline candidates may be nominated for novel disease areas, 4) competing therapies may show worse-than-expected efficacy/safety.

Downside risks: 1) omicron efficacy and heterologous boost benefit could wane, 2) Nuvaxovid revenue durability may miss consensus' high expectations, 3) sustained operating expense may erode profits, 4) regulatory path unclear for RSV/flu, 5) competition across pipeline disease areas could continue to intensify, 6) lack of early pipeline could leave a profitability gap 2023-2027.

**Recursion Pharmaceuticals, Inc. (RXRX)**

Our \$14 PO is based on a probability-adjusted NPV of Recursion's lead pipeline assets, including REC-4881 (\$5/sh), REC-2282 (\$3/sh), REC-994 (\$2/sh), REC-3964 (\$3/sh), and



REC-3599 (\$0/sh). We also assign value to platform and collaborations (\$10/sh), as well as expenses for platform buildout (-\$11/sh). We apply a 14% WACC (we project revenues out through 2038), in-line with other biotech companies of similar size and stage of clinical development. Current cash and equivalents contributes \$2/share to our valuation.

Upside risks would come from pipeline updates or further external validation of the platform.

Downside risks to our PO are: 1) clinical trial failures, 2) better than expected data from competitors, 3) dilution from cash raises.

### **SpringWorks (SWTX)**

Our \$50/share price objective is based on a probability-adjusted net present value (NPV) for nirogacestat mono (\$23/share), nirogacestat combo (\$2/share), mirdametinib (\$12/share), BGB-3245 (\$1/share), TEAD inhibitor program (\$1/share), EGFR inhibitor program (\$1/share), and cash (\$8/share). We apply probabilities of success from 3% (EGFR, TEAD) to 76% (nirogacestat), a weighted-average cost of capital (WACC) of 10-13%, and -4% (nirogacestat) to -1% (early pipeline) terminal growth rate.

Downside risks are: 1) nirogacestat regulatory review experiences setbacks or final label is more limited than expected, 2) nirogacestat launch delayed or uptake slower than anticipated, 3) nirogacestat fails to yield compelling data in combination with BCMA therapies, 4) competitors produce more convincing data for competing therapies, 5) regulatory and/or reimbursement landscape changes unfavorably, and 6) funding is insufficient to move forward pipeline aspirations or further commercial/manufacturing build out.

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## US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
<b>BUY</b>				
	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
<b>NEUTRAL</b>				
	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
<b>UNDERPERFORM</b>				
	AlloVir, Inc.	ALVR	ALVR US	Jason Zemansky



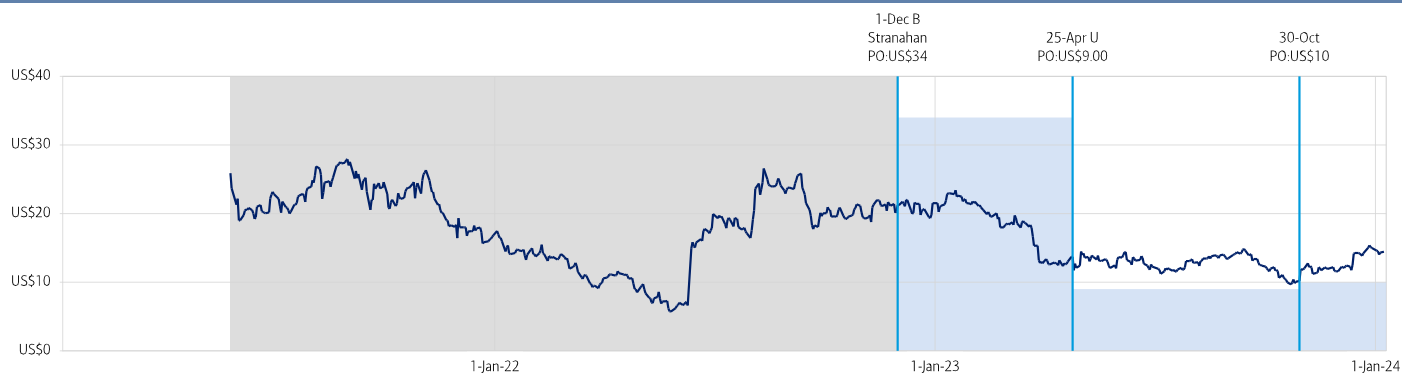
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Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	CureVac	CVAC	CVAC US	Geoff Meacham
	Day One Biopharmaceuticals	DAWN	DAWN US	Alec W. Stranahan
	LianBio	LIAN	LIAN US	Geoff Meacham
	Novavax	NVAX	NVAX US	Alec W. Stranahan
	Regeneron Pharmaceuticals 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

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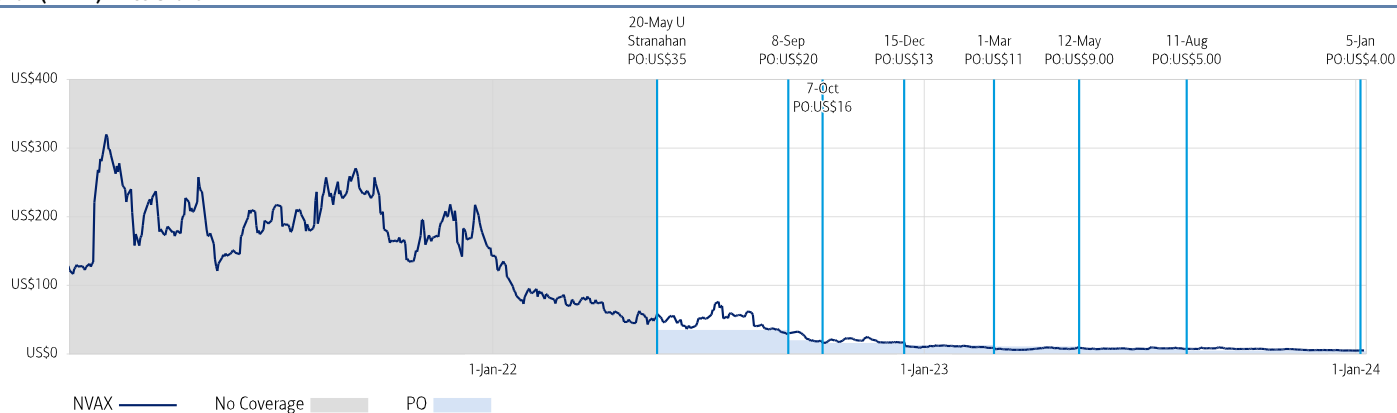
## Day One (DAWN) Price Chart



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.

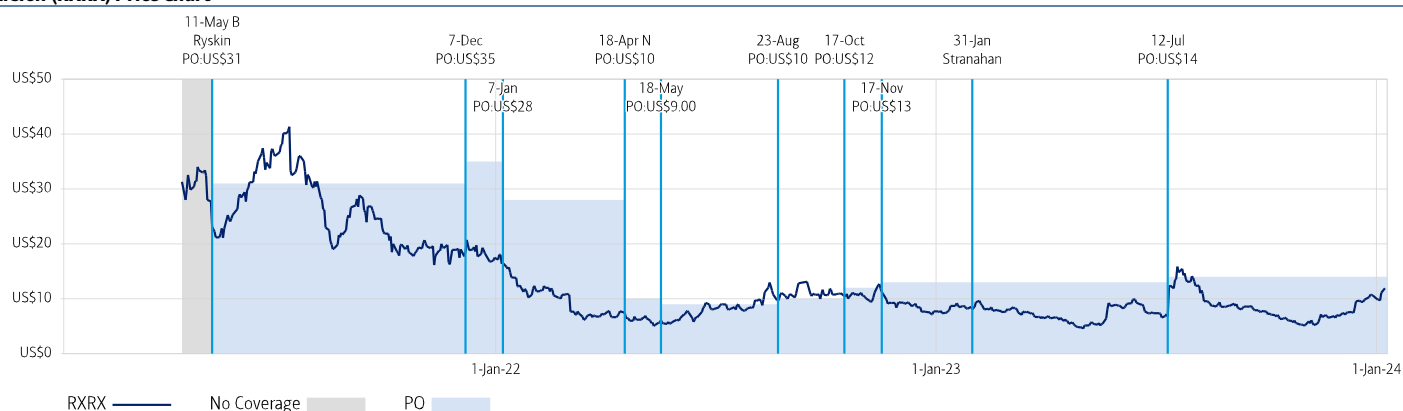
## Novavax (NVAX) Price Chart



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

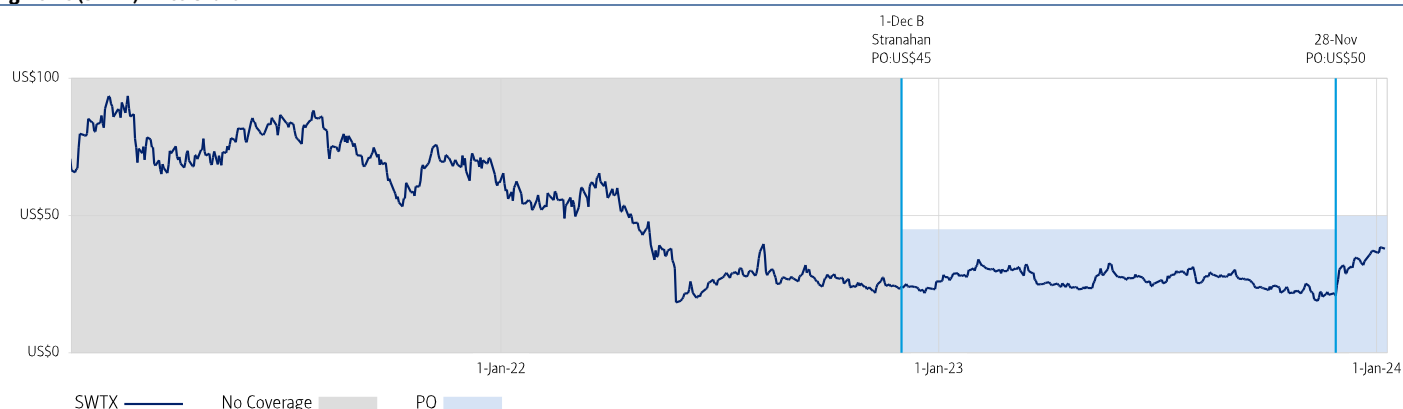
The Investment Opinion System is contained at the end of the report under the heading "Fundamental Equity Opinion Key". Dark grey shading indicates the security is restricted with the opinion suspended. Medium grey shading indicates the security is under review with the opinion withdrawn. Light grey 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.

### Recursion (RXRX) Price Chart



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### SpringWorks (SWTX) Price Chart



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Coverage Universe	Count	Percent	Inv. Banking Relationships <sup>R1</sup>	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 <sup>R1</sup>	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%

<sup>R1</sup> 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 <sup>R2</sup>
Buy	≥ 10%	≤ 70%
Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

<sup>R2</sup> 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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