BofA SECURITIES

US Biopharmaceuticals

What caught our attention in SF (Day 2): IMVT, ITCI, BLUE, OGN, RLAY

Industry Overview

We flag company updates from a competitor healthcare conference with a focus on updates that represent 'new messaging', shifts in investment narratives and/or warrant further interrogation. The note continues page 2.

IMVT: mgmt bullish CIDP on dose-response

Immunovant offered a pretty uneventful update mainly reiterating clinical development timelines / value proposition of its FcRn franchise. With that said, 2024 should be eventful with two important clinical readouts (CIPD + MG) which should shed some light on whether deeper IgG reductions translate to better anti-FcRn clinical response. We expect to exit 2024 with a better sense of where IMVT plans to focus is larger R&D investments for follow-on '1402 (versus smaller Ph2 pilot studies). During Q&A, mgmt did indicate that it strongly believes '1401 (bato) will show a dose-response in an upcoming (1H24) CIDP trial, which we believe could be a trigger initiation a '1402 pivotal trial in that population. Further, the company still sounds bullish on recent Ph2 Graves' data and we believe that indication is a prime candidate for near-term Ph3 investment (see our report). During Q&A, management suggested competitor FcRn players with IV delivery or cumbersome subQ delivery formats could be disadvantaged in chronic treatment indications. We note that outside of the FcRn space, Biohaven plans to disclose Ph1 HV data for its IgG degrader in 1H24 which warrants monitoring. We maintain Buy on IMVT's FcRn opportunity in autoimmune diseases with attractive risk/reward into '24+ product profile shaping de-risking catalysts.

ITCI: Caplyta '24 growth levers + color on Ph3 MDD

Intra-cellular's fireside chat was primarily focused on 2024 Caplyta growth levers. Caplyta is (currently) used mainly for treatment of bipolar depression (~80% of sales). While formal Caplyta revenue guidance will come on the 4Q call, the company expects strong growth seen in 2023 to continue in 2024 aided by improved depth and breadth of the prescriber base. Management flagged a few marketing initiatives that only partially benefited 2023 but should have a full impact in 2024 like two large Part D plans re-negotiated in December (unrestricted drug access vs. prior 2-step edits). Management did indicate those two re-negotiated Part D plans would slightly increase GTN deductions but wouldn't have a major change versus the low 30% level communicated on the 3Q call. Ahead of the key 1Q24 Ph3 readout (study 501) for Caplyta in adjunctive MDD, management discussed several data scenarios and trial risks. We continue to view aMDD as the biggest label expansion opportunity for Caplyta while the company still plans to meet with FDA regarding the regulatory path for the mixed features indication (1Q24). We maintain Buy on Caplyta's label expansion into additional mood disorders.

BLUE: near-term financing + '24 sickle cell launch

Bluebird Bio's fireside chat was largely focused Lyfgenia (Sickle Cell) gene therapy launch readiness, including some added color around payer reimbursement and early revenue recognition. **Continued on page 2**.

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Acronyms:
CIDP: chronic demyelinating polyneuropathy
FcRn: immune receptor (target)
FDA: food & drug administration
GTN: gross-to-net deductions
HV: healthy volunteer
IgG: immunoglobulin antibody
IV: intravenous
(a)MDD: (adjunctive) major depressive disorder
MG: myasthenia gravis
Q&A: question & answer
R&D: research & development
SubQ: subcutaneous
Mgmt: management

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Timestamp: 09 January 2024 08:28PM EST

At the end of '23, Bluebird had guided to 85-105 new patient starts across all three of its gene therapy products and Lyfgenia is expected to account for the majority. Bluebird continues to frame new starts as the key value creating event with the majority expected to be cell infused (revenue recognizing event) resulting in ~$300m revenue dispersed over 2024-25. In terms of Lyfgenia reimbursement, 200m lives are currently covered (~60% of population) and Bluebird is in advanced discussions with 15 Medicaid Agencies which could bump up coverage to ~80%. Bluebird management declined to elaborate on specific details around its outcome-based agreements with payers for competitive reasons. On timing of cell collection to infusion, Bluebird indicated the duration could be highly variable based on the number of cell collection rounds needed (several weeks to months), product manufacturing, and patient appointment scheduling. On Bluebird's cash runway, management indicated current cash offers runway to 1Q25 and a near-term non-dilutive financing agreement (debt, royalty, BD deal) could be the final funding event needed to ensure bridging to profitability. Any reversal of the FDA's priority review voucher denial would be upside to management's cash projections. Our 2030e Lyfgenia sales of $579m (above cons at $473m). Our Buy rating is driven by underappreciated Lyfgenia's revenue opportunity in SCD.

Acronyms: BD: business development; FDA: food & drug administration; SCD: sickle cell disease.

OGN: 2024 outlook, China & Nexplanon LOE

At today's fireside chat, OGN discussed some of the elements that went into its initial 2024 outlook (provided yesterday) which called for low-SD revenue growth with adjusted EBITDA (at the mid-point) that was inline with Bloomberg consensus. Per Organon, stable 2024 expenses were an important factor in the '24 guide and the company's China segment should see some slight tailwinds in 2024. Organon plans to offer more details on longer-term EBITDA outlook on its 4Q EPS call. Management believes uncertainty around a dividend cut was a key 2023 stock overhang, thus it was important for the company to communicate maintaining its dividend as the top capital allocation priority. On M&A, the CEO indicated that transformative M&A is unlikely in 2024 whereas bolt-ons are more likely (3.5x leverage good steady state target for OGN). On the recent LLY deal for EU commercialization rights to Emgality (migraine), management sounded bullish on doing more of these types of deals leveraging its scale to pull those products into its commercial infrastructure. Regarding Nexplanon, CEO indicated possible 2029 US LOE vs prior stated 2027, citing 5-yr durability study though we note a) Teva recently disclosed a generic Nexplanon program, and b) the FDA bioequivalence guidance includes an exception for accelerated in-vitro release study for demonstrating generic sameness, assuming the testing method can be developed and validated.

Acronyms: PR: press release; SD: single-digit; BBG: Bloomberg; EPS: earnings; Mgmt: management; LLY: Eli Lilly; EU: Europe; LOE: loss of exclusivity; VBP: volume-based procurement

RLAY: framing multiple 2024 clinical data updates

In a fireside chat, Relay (RLAY) discussed key 2024 R&D milestones that included: 1) RLY-4008 (FGFR2i) – the company plans to provide pivotal data in CCC (bile duct cancer), updated expansion data in broader solid tumors, and registrational strategy for the drug by 2H24; 2) RLY-2608 (PIK3CAi) – the company expects to provide a Ph1 update for the '2608/fulvestrant doublet in 2L+ mBC in 2H24 and initial safety data of '2608/ribo/fulvestrant triplet in 2L+ mBC also in 2H24. '2608 is being developed in larger (commercial) indications and was the focus of the discussion. The 2H doublet data will feature dose expansion data for RP2D 600mg BID (n=20) and a lower dose of 400mg BID per FDA's request (Project Optimus). In response to a question on dose ceiling, RLAY continues to collect data on higher doses (800mg BID, 1000mg BID) though the company believes 600mg is the appropriate RP2D based on PK/PD modeling. RLAY initiated a second doublet expansion cohort with the 600mg BID dose in 4Q23 to

enroll more patients with hotspot mutations (eg H1047X) vs initial cohort which was biased toward non-hot spot mutations. On '2608 triplet in 1L mBC, RLAY highlighted a cleaner PIK3CAi could capture additional patients and enable faster Ph3 enrollment citing relatively restrictive enrollment criteria on metabolic baseline from Roche's Ph3 study (INAVO120). Lastly, RLAY formally announced de-prioritization of follow-on PIK3CAi RLY-5836, which did not come as a surprise as management had stated '2608 set a high bar for '5836 to beat. Our '24 focus for '2608 remains on the durability data of '2608 doublet in 2L+ mBC (CBR, PFS metrics) and combinability of '2608 in the triplet regimen (safety and tolerability). Maintain Buy on upside potential from clinical catalysts.

Acronyms: FGFR2, PIK3CA: drug targets, i: inhibitor, L: line of therapy, mBC: metastatic breast cancer, RP2D: recommended Phase 2 dose, BID: oral twice daily, FDA: US Food and Drug Administration, PK/PD: pharmacology, H1047X: mutation, CBR: clinical benefit rate, PFS: progression free survival

Exhibit 1: Stocks mentioned in this report
Ratings and stock prices of stock tickers mentioned in this report

Ticker	Company name	Rating	Stock price
BLUE	Bluebird Bio Inc	C-1-9	1.37
IMVT	Immunovant Inc	C-1-9	43.79
ITCI	Intra-Cellular Therapies Inc	C-1-9	70.75
OGN	Organon & Co	B-3-7	16.20
RLAY	Relay Therapeutics Inc	C-1-9	11.87

Source: BofA Global research, Bloomberg

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Price objective basis & risk

bluebird bio (BLUE)

Our $5 PO is based on risk-adjusted discounted cash flow (DCF) analysis. Our DCF assumptions include (1) risk adjustment to programs dependent on their stage and strength of available data, including 100% combined probability of success (POS) for LentiGlobin-TDT, -SCD, and Lenti-D-CALD, (2) no value for earlier-stage programs that lack clinical data, (3) a 10% discount rate and -10% terminal growth value (end of loss of exclusivity period in 2034).

Downside risks to our PO: (1) cancer safety risk for LentiGlobin, (2) LentiGlobin launch underperforming relative to our forecast, either due to limited demand or inability to adequately supply the market, (3) failure to show durable drug response in future data updates involving key assets, (4) competitor data showing efficacy/safety superior to that of company's lead programs, and (5) high cash burn and projected capital expenditure, which may require equity raises.

Upside risks to our PO: (1) clinical data shows superiority relative to competitor programs, and (2) LentiGlobin launch exceeds our expectations.

Immunovant, Inc. (IMVT)

Our $51 price objective (PO) is based on a risk-adjusted sum-of-the-parts analysis. 1) batoclimab launches in 2025 and total FcRn nominal sales reach $4.5bn by 2035e, 2) 75% POS for Myasthenia Gravis and Thyroid Eye Disease indications, 2) 65% POS for CIDP, 3) 50% POS for Graves' Disease, 4) no terminal value beyond batoclimab's 2040 LOE and 1402's 2043 LOE, 5) 11% discount rate.

Downside risks to our PO: 1) inability for batoclimab/1401 to adequately mitigate LDL

safety signal in clinical trials, 2) less competitive 1402 product profile, and 3) failure to demonstrate efficacy in future clinical trials.

Upside risks to our PO:1) better than expected outcomes in MG, CIDP, and TED clinical trials, 2) clinical success in trials leading to a steeper market ramp and/or penetration.

Intra-Cellular Therapies (ITCI)
Our $82 price objective (PO) is based on a risk-adjusted sum-of-the-parts analysis. 1) Caplyta risk-adjusted sales climb to $2bn by 2027E, before loss-of-exclusivity (LOE) in 2034, 2) no terminal value, 3) operating margin reaching low-60s percentage, 4) 9% discount rate.

Downside risks to our PO: 1) lower-than-expected commercial uptake of Caplyta in schizophrenia, continued COVID disruption keeping a lid on script growth, 2) BPD commercial execution risk, 3) potential setbacks on ITCI's execution on pipeline clinical development plan, e.g. adjunctive MDD, mixed features.

Upside risks to our PO: 1) better-than-expected commercial uptake of Caplyta in schizophrenia, 2) bipolar depression launch significantly above our estimates, 3) further pipeline validation beyond our assumptions, for e.g. Caplyta in adjunctive MDD, mixed features

Organon (OGN)
Our $12 PO for OGN is based on 5.75x EV/EBITDA multiple on our '24E EBITDA. We believe the multiple is justified vs peers trading at 6-10x given the potential growth outlook for Nexplanon and biosimilars.

Upside risks to our PO are: (1) higher-than-anticipated Nexplanon peak sales as it expands within the long-acting reversible contraceptive (LARC) category, (2) higher-than-expected operating leverage leading to higher EBITDA margin.

Downside risks to our PO are: (1) reduced uptake of Nexplanon in the LARC category or slow rebound by the LARC category due to C19 other factors and (2) steeper erosion of established brands than expected.

Relay Therapeutics (RLAY)
Our PO of $27 is based on a risk-adjusted, SOTP DCF. We assume: 1) a discount rate of 12% for a Ph2 clinical-stage company, 2) likelihood of success (POS) of 5-65% for the FGFR2 program across multiple tumor types, 3) POS of 30% for the PIK3CA program in HER2- breast cancer, 4) 10% POS for platform pipeline, 5) loss of exclusivities of lead programs in the 2040-41E timeframe.

Downside risks: 1) clinical trial failure, 2) FGFR2i or PIK3CAi fails to show differentiated clinical profile vs existing therapies, 3) dilutive equity raise

Upside risks: 1) clinical advancement of FGFR2i or PIK3CAi program, 2) FGFR2i or PIK3CAi finds utility in additional tumor indications, 3) acquisition at a premium

Analyst Certification

I, Jason M. Gerberry, 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.

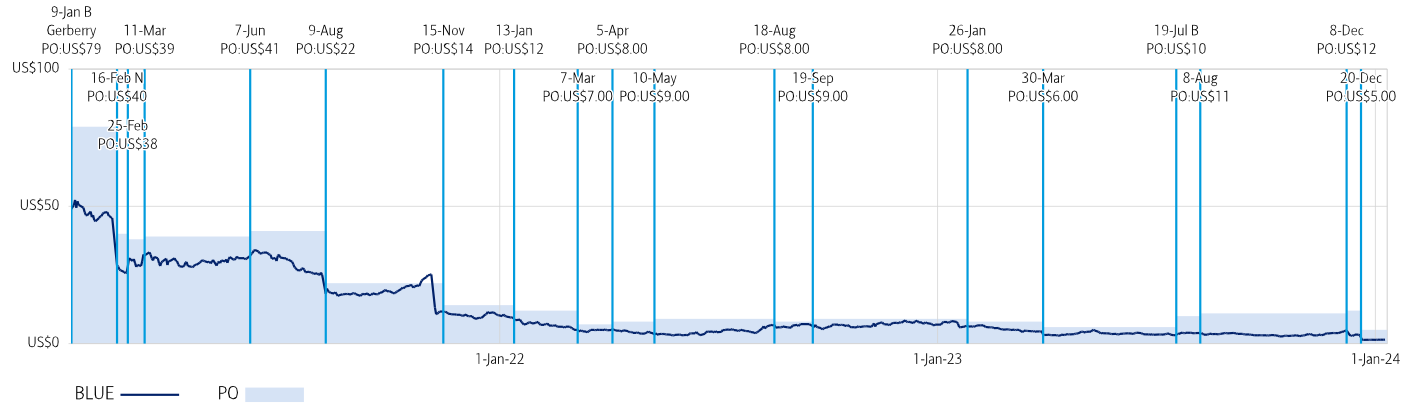
US - Specialty Pharma & Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
	Arcellx, Inc.	ACLX	ACLX US	Jason M. Gerberry
	Arrowhead Pharmaceuticals	ARWR	ARWR US	Jason M. Gerberry
	bluebird bio	BLUE	BLUE US	Jason M. Gerberry
	Exelixis	EXEL	EXEL US	Jason M. Gerberry
	Immunovant, Inc.	IMVT	IMVT US	Jason M. Gerberry
	Intra-Cellular Therapies	ITCI	ITCI US	Jason M. Gerberry
	Ionis	IONS	IONS US	Jason M. Gerberry
	Jazz Pharmaceuticals	JAZZ	JAZZ US	Jason M. Gerberry
	Lyra Therapeutics	LYRA	LYRA US	Jason M. Gerberry
	Oculis Holding AG	OCS	OCS US	Jason M. Gerberry
	Relay Therapeutics	RLAY	RLAY US	Jason M. Gerberry
	Tarsus Pharmaceuticals	TARS	TARS US	Jason M. Gerberry
	Teva Pharmaceuticals	TEVA	TEVA US	Jason M. Gerberry
	Vaxcyte Inc	PCVX	PCVX US	Jason M. Gerberry
	Xenon Pharmaceuticals	XENE	XENE US	Jason M. Gerberry
NEUTRAL				
	Alkermes	ALKS	ALKS US	Jason M. Gerberry
	Amphastar Pharmaceuticals	AMPH	AMPH US	Jason M. Gerberry
	Axsome Therapeutics	AXSM	AXSM US	Jason M. Gerberry
	Galapagos	GLPG	GLPG US	Jason M. Gerberry
	ProKidney Corp	PROK	PROK US	Jason M. Gerberry
	Roivant	ROIV	ROIV US	Chi M. Fong
UNDERPERFORM				
	Bausch Health Cos Inc	BHC	BHC US	Jason M. Gerberry
	FibroGen Inc.	FGEN	FGEN US	Jason M. Gerberry
	Harmony Biosciences	HRMY	HRMY US	Jason M. Gerberry
	Organon	OGN	OGN US	Jason M. Gerberry
	Viatris Inc.	VTRS	VTRS US	Jason M. Gerberry

Disclosures

Important Disclosures

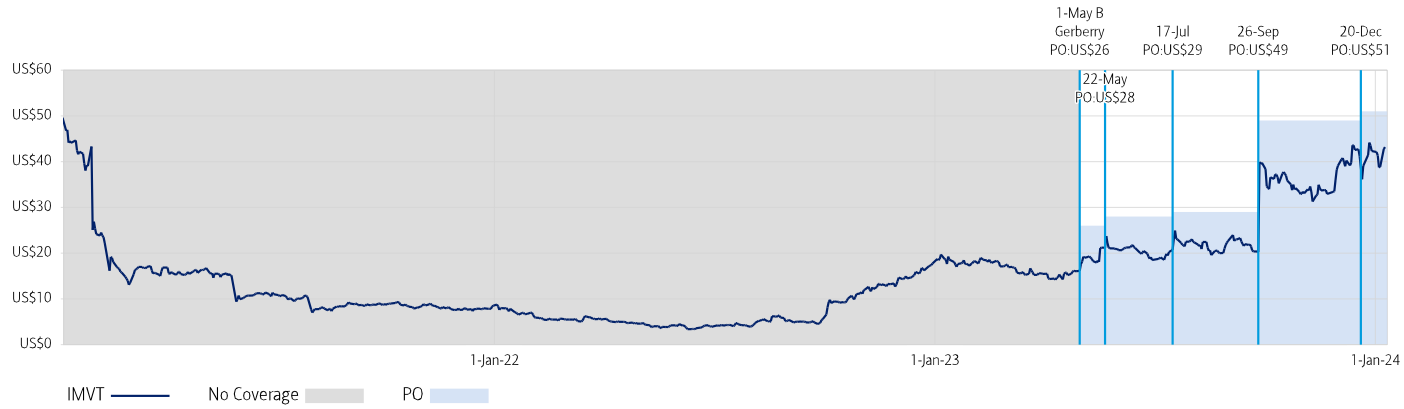
bluebird bio (BLUE) Price Chart



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.

Immunovant, (IMVT) Price Chart



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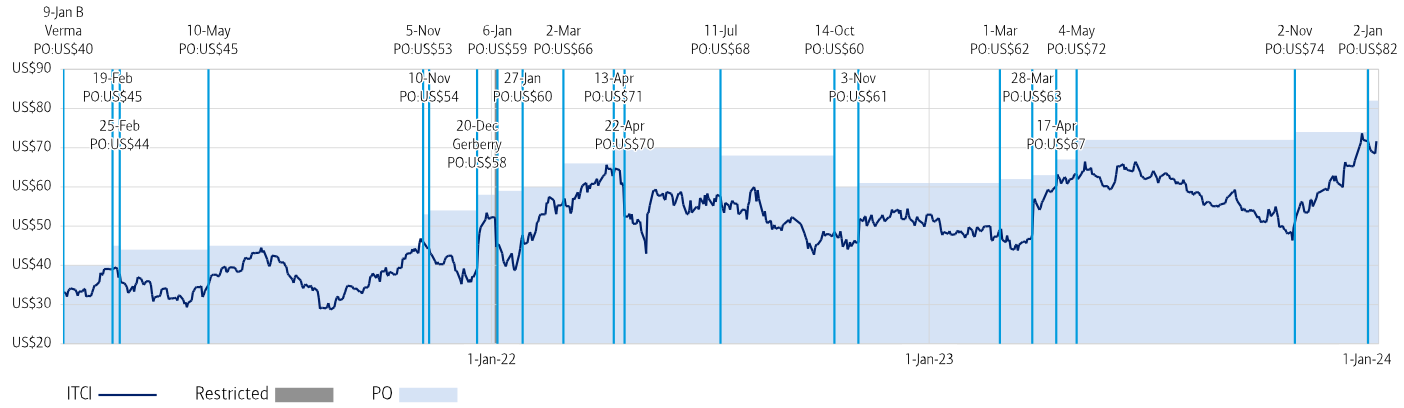
Intra-Cellular (ITCI) Price Chart



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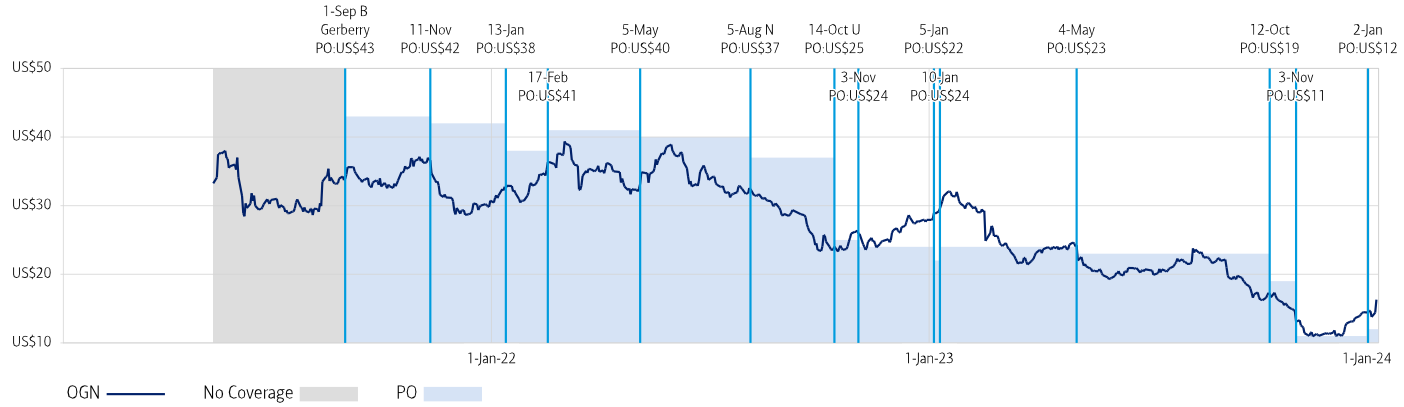
Organon (OGN) Price Chart



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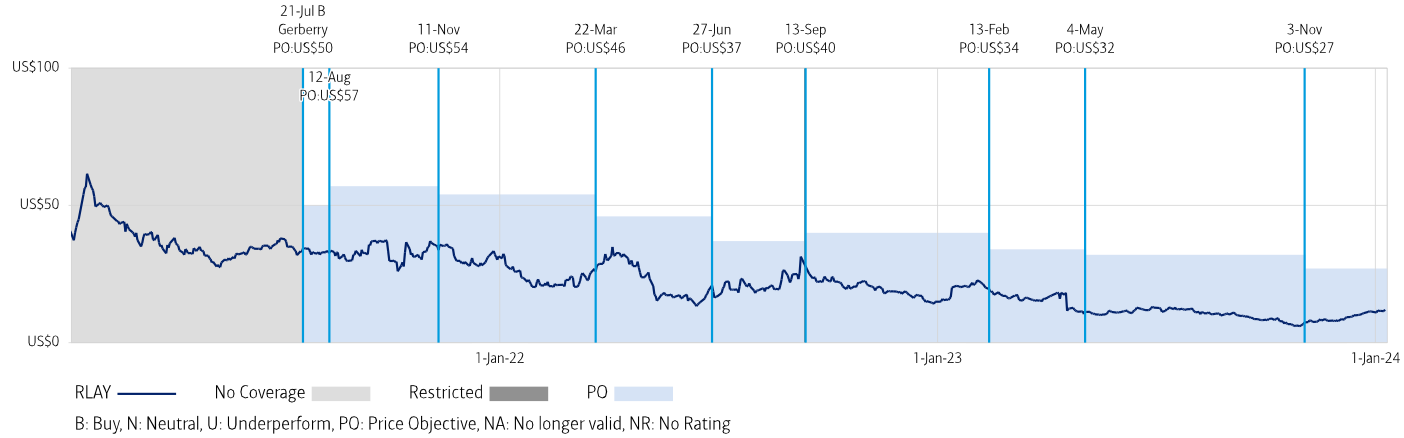
Relay (RLAY) Price Chart



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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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