BofA SECURITIES

US Biopharmaceuticals

4Q EPS wrap: FGEN, GLPG, RLAY

Price Objective Change

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Equity
United States
Biopharmaceuticals

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RLAY: timeline intact ahead of key data updates in 2H

RLAY's (Relay) 4Q print was a relative non-event with the company reaffirming timelines for '24E clinical data updates. Our primary focus remains on the 2H Ph1 data updates on RLY2608 (PIK3CA inhibitor) for the treatment of metastatic breast cancer (mBC) which will include two datasets: 1) doublet combination with fulvestrant in 2L+ mBC – the data should offer an initial read on the durability of RLY2608 relative to approved regimens (capivasertib, alpelisib), 2) triplet combo with ribociclib/fulvestrant – a focus on safety which should help inform dose selection for triplet in subsequent advancement into 1L trial. RLAY also reaffirmed its timeline for RLY4008 (FGFR2 inhibitor), with data in tumor agnostic setting and a regulatory path update both expected in 2H. Model wise, we tweak EPS estimates based on the 4Q print. We reiterate Buy on upside potential from clinical catalysts; PO to $25 (vs $27 prior) on updated net cash balance.

GLPG: minor setbacks in CAR-T programs

GLPG's (Galapagos) 4Q update contained incremental pipeline updates and minor setbacks for the company's CAR-T portfolio. Within its oncology portfolio, GLPG now expects US IND submission for GLPG5101 for r/r NHL by mid-year followed by an IND for 5201 in r/r CLL later this year (vs 1H24 prior). GLPG looks to set up the first US site and complete prerequisite tasks including tech transfer and 1H validation runs. While we are intrigued by the value proposition of 7-day vein-to-vein timeline and fresh CAR-T cell delivery, we await clarity on GLPG's ability to fine tune in-spec manufacturing success rates and scale the manufacturing process beyond initial few trial sites. In autoimmune, GLPG has decided to discontinue developing its CD19 CAR-T for SLE (lupus), citing late mover status in the crowded competitive landscape and risk/benefit considerations, though the company plans to continue evaluating CAR-Ts in other immunology / neurology indications (e.g. multiple sclerosis, myasthenia gravis). Given the pipeline setbacks, we lower our PO to $41 (vs $44 prior) as we lower pipeline revenue forecast as we reiterate Neutral on balanced risk/reward.

FGEN: roxa + pipeline updates non-thesis changing

FGEN's (Fibrogen) 4Q offered a few commercial and pipeline updates, but nothing thesis changing. On the commercial front, FGEN announced it has regained geographical rights to Roxadustat (from AZN; most notably US rights) except for China rights. Per our conversations with management, the company is most optimistic about partnering US rights given perceived capital efficient development in the MDS anemia indication + patent extensions/orphan exclusivity opportunity. On the pipeline, FGEN announced a slight delay for the pamrev LAPIS trial readout (local pancreatic cancer), due to a slowdown in event rates; the company now expects data in 2Q vs. prior 1Q readout. The focus of the investor call was on the upcoming Ph3 pamrev readout (2Q) in metastatic pancreatic cancer and a Ph1 readout for FG-3246's (CD46 ADC) monotherapy dose expansion data (1Q) in mCRPC patients. We remain Underperform given a) uncertain duration of roxa in China, b) pamrev clinical programs carry low odds of clinical success; and c) the CD46 ADC is also high-risk for the pre-chemo mCRPC setting. ***Note cont'd on page 2.***

Acronyms:
PIK3CA, FGFR2, CD19, CD46: drug targets
CAR-T: cell therapy
IND: investigational new drug
I&I: inflammation & immunology
r/r: relapsed / refractory
CLL: chronic lymphocytic leukemia
NHL: non-hodgkin's lymphoma
Roxa: Roxadustat (drug)
AZN: AstraZeneca (covered by BofA Analyst Sachin Jain)
MDS: myelodysplastic syndrome
LAPIS: clinical trial
mCRPC: metastatic castration resistant prostate cancer
ADC: antibody drug candidate
Chemo: chemotherapy

We update our model for 4Q financials, remove roxa's ex-US AZN royalties and align 2024+ operating expenses with company guidance. We maintain Underperform and $0.50 PO on a difficult stock setup.

Exhibit 1: Summary of model changes
We summarize estimate changes made with this report

Ticker	PO ($)		Revenue ($m)						EPS ($)					
			Old			Current			Old			Current		
	Old	New	2023E	2024E	2025E	2023E	2024E	2025E	2023E	2024E	2025E	2023E	2024E	2025E
FGEN	0.5	0.5	173	158	147	148	158	147	(2.36)	(1.08)	(0.81)	(2.92)	(1.03)	(0.81)
GLPG	44	41	593	264	267	784	264	267	0.85	(3.66)	(2.92)	3.21	(0.85)	(0.87)
RLAY	27	25	26	0	67	26	0	67	(3.01)	(3.44)	(2.65)	(2.79)	(3.33)	(2.58)

Source: BofA Global Research estimates

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Exhibit 2: Stocks mentioned in this report
Ratings and stock prices of stock tickers mentioned in this report

Ticker	Company name	Rating	Stock price
FGEN	FibroGen Inc	C-3-9	1.85
GLPG	Galapagos NV	B-2-9	36.50
RLAY	Relay Therapeutics Inc	C-1-9	10.16

Source: BofA Global Research, Bloomberg

BofA GLOBAL RESEARCH

Price objective basis & risk

FibroGen Inc. (FGEN)

Our $0.50 PO is based on risk-adj DCF. We assume: (1) risk-adjustment (% POS) to roxa programs include approx. blended 98% for CKD (ex-US) and 45% for CIA (chemotherapy). (2) 11% discount rate, consistent with our other SMID Biotech coverage, and no terminal value as we forecast through the end of roxa patent life (2033). We risk-adjust roxa cashflows starting in 2026 based on ongoing patent litigation and potential generic entry in 2026-2028 timeframe.

Upside risks to our PO: (1) Roxa CKD wins appeals and LOE to 30+ (2) roxa labeling for cardiovascular risk/cancer is better than our expectations, (3) competitor data readouts show weaker efficacy/safety profile relative to roxa.

Downside risks to our PO: (1) Roxa ex-US launch underperforms vs. our projections due to low demand and/or lower net pricing, (2) competitor data is superior to roxa on efficacy/safety.

Galapagos (GLPG)

Our $41 price objective (PO) is based on a risk-adjusted DCF analysis. We assume the following: (1) Jyseleca forecast for approved indications in the form of royalties, (2) modest pipeline contribution, (3) 9.5% discount rate and 0% terminal growth rate.

Downside risk to our PO: (1) failure of clinical trials, (2) worse-than-expected filgotinib safety profile and/or label.

Upside risks to our PO: (1) acquisition at a premium, (2) higher-than-expected filgotinib sales

Relay Therapeutics (RLAY)

Our PO of $25 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

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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

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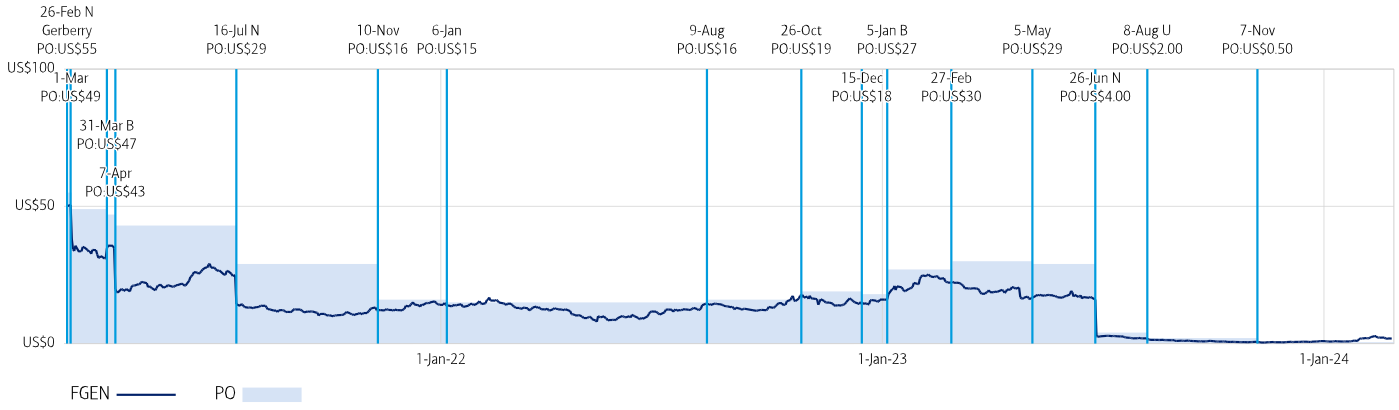
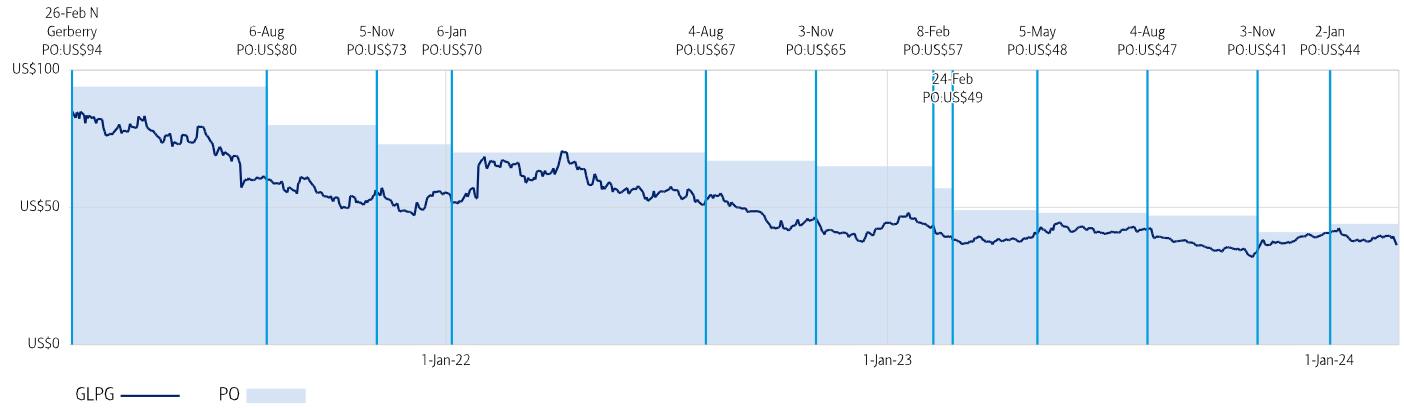
FibroGen (FGEN) Price Chart



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.

Galapagos (GLPG) Price Chart



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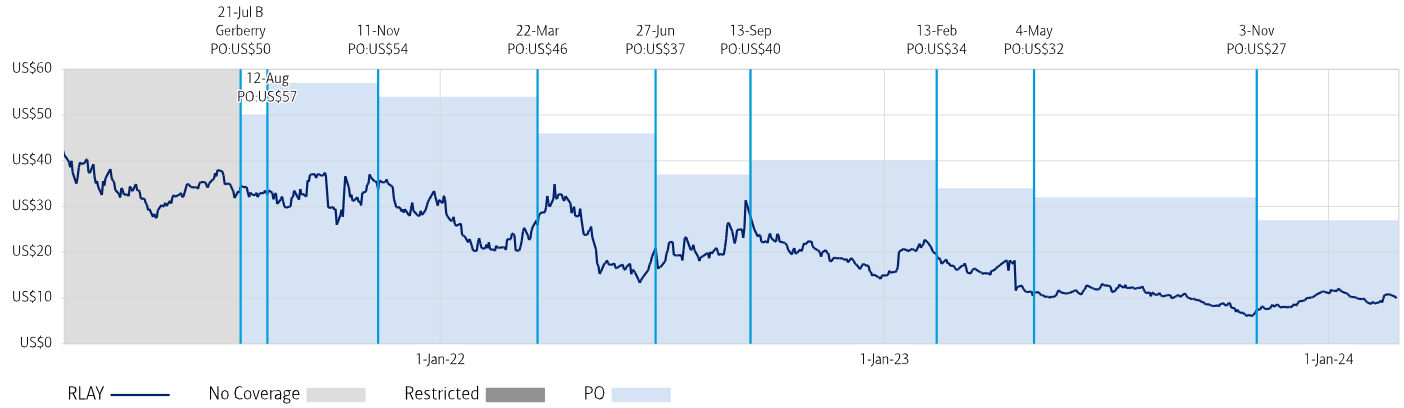
Relay (RLAY) Price Chart



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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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Underperform	N/A	≥ 20%

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