BofA SECURITIES

Regenxbio, Inc.

Rare disease pipeline strong in 2024, momentum expected to continue

Maintain Rating: BUY | PO: 35.00 USD | Price: 14.57 USD

Pair of positive readouts injects momentum to 2024

RGNX shares traded up (+11%; NBI: -1.52%) on a pair of positive readouts, namely (1) RGX-121 CAMPSITE topline pivotal readout is enough to support BLA filing 2H24e; and (2) RGX-202 additional interim data in DUCHENNE is enough to support pivotal trial initiation 2H24e. Stock price reaction after a recent investor conference was mildly disappointing to many (see our report on the conference), which could be a result of (1) optically negative news on the SRPT (Sarepta, covered by BofA Global Research analyst Tazeen Ahmad) litigation (see our thoughts on the litigation); (2) suprachoroidal data recently presented (see our thoughts on the data here) still not conclusively better than subretinal with many questioning commercial uptake potential; (3) corporate restructuring still very much prevalent, which is never a positive sign; (4) key '314 subretinal phase 3 readout still 9-12 months; hence investors unlikely to hold the stock through volatility. That said, we expect the second half of this year to reverse negative sentiment accrued over the from past few months. Maintain Buy and $35 PO.

RGX-121 pivotal results impress, FDA alignment key

In the pivotal phase, MPS II patients treated with RGX-121 achieved decreased CSF levels of D2S6 below maximum attenuated disease levels at 16 weeks (86% median reduction in D2S6). As a reminder, the last readout from the asset came in SSEIM 2022, which demonstrated a robust safety profile but no clear-cut efficacy metrics (D2S6 CSF levels). Investor concerns on efficacy were addressed with the pivotal readout combined with continually robust safety profile (n=25), which we consider to be impressive especially heading into 2H24 BLA filings. Moreover, company has also pointed out that trial investigators have chosen to discontinue SOC intravenous ERT or to keep patients ERT-naïve (80% of patients were ERT-free at the pivotal dose level, last time point), which we consider to be another qualitative positive. That said, key going forward is alignment with FDA on issues such as endpoint, package submission, which following an RMAT meeting reported to have happened at the end of 2023, should be mostly addressed. Duration of response could also be an area for FDA scrutiny. But based on an expected priority review, potential approval of the planned BLA could result in receipt of a rare pediatric disease review voucher in 2025e.

RGX-202 interim update adds incremental confidence

New 3mo assessment in a third patient at dose level 1 demonstrates the largest increase in micro-dystrophin expression (patient aged 6.6 years old had expression level at 83.4% of control), putting the average at three months for all three patients at 44.4%. The company remains on-track to initiate pivotal trial in 2H24e for RGX-202, which we consider to be at least in line with Elevydis (although we do note n is small). RGNX expects to make a pivotal determination in mid-2024 and to share initial functional assessment data (NSAA data) in 2H24e, which will be especially important to further drive shares (see our thoughts on why NSAA is important). That said, data today is certainly a step in the right direction.

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Equity

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Stock Data

Price	14.57 USD
Price Objective	35.00 USD
Date Established	5-Jan-2024
Investment Opinion	C-1-9
52-Week Range	11.83 USD - 25.32 USD
Mrkt Val (mn) / Shares Out (mn)	641 USD / 44.0
Free Float	91.2%
Average Daily Value (mn)	8.90 USD
BofA Ticker / Exchange	RGNX / NAS
Bloomberg / Reuters	RGNX US / RGNX.OQ
ROE (2023E)	-22.0%
Net Dbt to Eqty (Dec-2022A)	-18.8%
ESGMeter™	Low

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Abbreviations:
AAO: America Academy of Ophthalmology
AAV: adeno-associated virus
AMD: Age-related macular degeneration
BLA: biologic license application
CSF: Cerebrospinal fluid

D2S6: biomarker
DMD: Duchenne Muscular Dystrophy
DR: Diabetic Retinopathy
ERT: enzyme replacement therapy
MPS: mucopolysaccharidosis
NSAA: North Star Ambulatory Assessment
RMAT: regenerative medicine advanced therapy
SAE: Severe adverse events
SOC: standard of care

WMS: World Muscle Society

Price objective basis & risk

Regenxbio, Inc. (RGNX)
Our $35/share price objective is based on a probability-adjusted net present value (NPV) analysis of its four internal clinical programs, as well as royalties from partnered programs. We use a weighted-average cost of capital (WACC) of 10-12% and no terminal value (we project revenues through 2038), similar to other early-stage companies in our coverage universe. We ascribe $7 for RGX-314 in wAMD, $6 for RGX-202 in DMD, $0/$0 for MPS I/II, $13 for partnered programs, and approximately $9 for cash.

Downside risks: 1) failure of ongoing clinical trials, 2) emergence of untoward safety signals, 3) failure of partnered programs which reduces economics owed to Regenxbio, 4) difficulties in commercializing gene therapies, 5) manufacturing issues as capabilities are brought in house, 6) litigation risk that could jeopardize the NAV platform IP estate or cause undue legal/court fees.

Analyst Certification

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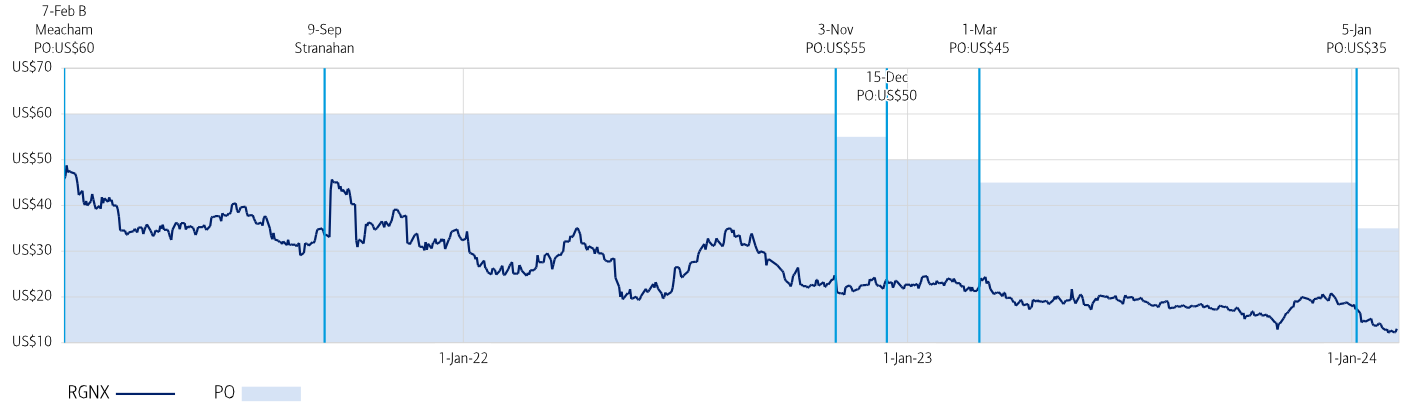
Regenxbio (RGNX) Price Chart



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%

[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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