BofA SECURITIES

Regenxbio, Inc.

Retina 2024 Meeting: RGX-314 shows promise to support pivotal study

Maintain Rating: BUY | PO: 35.00 USD | Price: 15.27 USD

New AAVIATE interim checks boxes, full data next up

RGNX stock traded flat/marginally up on positive data from RGX-314 (wAMD) (+0.97%; NBI: -0.9%), including results from the phase 2 AAVIATE study. As a reminder, we note that since the July 2023 update (see our thoughts on the update), primary focus has been on whether suprachoroidal administration can achieve subretinal-like levels of efficacy in wAMD (BCVA improvement, decrease in rescue injections, etc.) while upholding consistent safety profiles in terms of IOIs. That said, we see the update today as adding incremental confidence given (1) -80% in annualized injection rate at dose level 3 (50% injection free); and (2) zero cases of IOI in subset of dose level 3 with short-course prophylactic topical steroids. That said, we continue to see that the data support a potential pivotal study in suprachoroidal (potentially to be announced later in 2H24), but we expect this decision will be up to RGNX and ABBV (AbbVie) based on the totality of the clinical data. Maintain Buy and $35 PO.

Robust safety profile adds possibility of dosing higher

While we see efficacy profile for RGX-314 at dose level three on-par with dose levels 1/2, namely (**1**) BCVA change (DL1: -2.8 letters, DL2: -1.0 letters, DL3: -2.2 letters); and (**2**) CRT change (DL1: -2.5µm, DL2: -12.0 µm, DL3: +6.5µm), we note that both BCVA and CRT did not improve in proportion to increased dosage. That said, we do note that the current six-month follow-up time is likely not enough to differentiate between curves from different dose levels, with further follow-ups being able to exhibit clearer separation between these curves. Moreover, with safety profile still being robust as before, we therefore also see possibility of dosing higher to achieve higher BCVA/CRT improvements as a viable next step for the asset. While the company has not been clear on whether the option is a possibility, our conversation with management demonstrated confidence in the current data, emphasizing that injection burden reduction, while dependent on stability of BCVA and CRT (which RGX-314 have achieved), remains the most needle-moving factor in progressing the asset further.

We project lucrative wAMD market, pivotal is the focus

Potential market setup for RGX-314 (wAMD) in the US is shaping up to be very lucrative; 25-30% of patients observed in the clinic qualify as needing frequent treatments even when they are receiving EYLEA, etc.; hence the opportunity to have a one-time treatment will initially appeal to that subset of the population and likely grow further over time. While we do note that ~25% of patients potentially being put on RGX-314 (wAMD) treatment seems on the higher end initially (our model projects 0.3% penetration initially with peak penetration at 6.5% in 2032), we do see a possibility of that number being reached especially given the unmet need and current difficulties extending the dosing window for that subset of the population. Capture of even 10-15% of the wAMD market therefore represents significant upside potential to our estimates.

16 January 2024

Equity

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Stock Data

Price	15.27 USD
Price Objective	35.00 USD
Date Established	5-Jan-2024
Investment Opinion	C-1-9
52-Week Range	12.76 USD - 25.32 USD
Mrkt Val (mn) / Shares Out (mn)	672 USD / 44.0
Free Float	91.2%
Average Daily Value (mn)	8.95 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:
KOL: Key opinion leader
wAMD: wet Age-related macular degeneration
FDA: Food and Drug Administration
NBI: Nasdaq biotech index
DL: Dose level
BCVA: best corrected visual acuity
CRT: central retinal thickness
IOI: intraocular inflammation

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Refer to important disclosures on page 3 to 5. Analyst Certification on page 2. Price Objective Basis/Risk on page 2. **12646809**

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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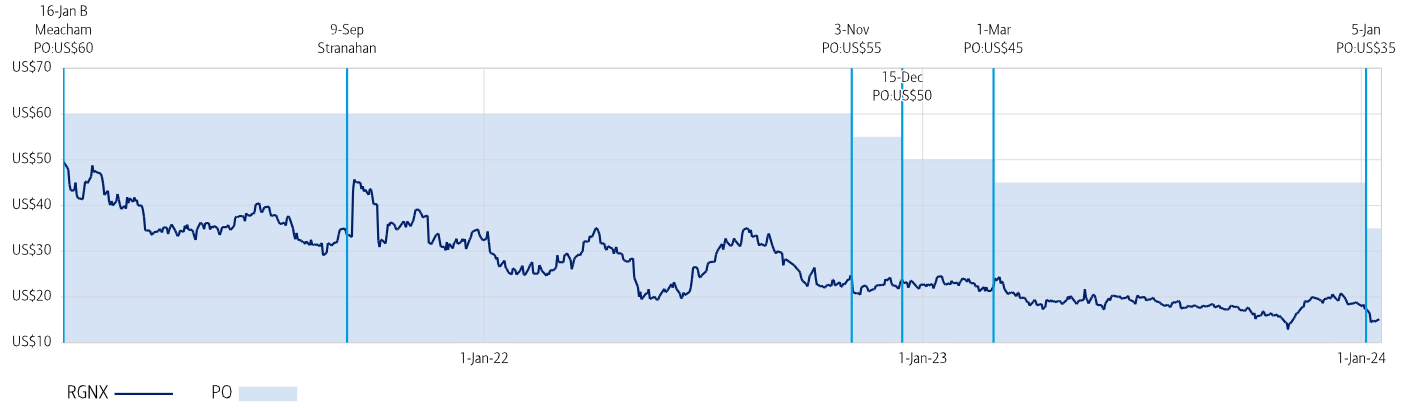
Regenxbio (RGNX) Price Chart



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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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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