

Regenxbio, Inc.

RGX-202 interim data promising, pivotal expected in

Maintain Rating: BUY | PO: 35.00 USD | Price: 21.36 USD

Data overall positive, functional data will solidify promise

RGNX stock surging (+40%; NBI: -1.11%) after presenting positive interim data for RGX-202 (Patient aged 12 at dosing had expression level at 75.7% of control). Combined with longer term follow-ups, functional data including NSAA, test of strength, caregiver feedback expected 2024e as guided by management, we see the next 12-18 months as a potentially transformative period for the company with substantially more data to add to the statistical profile especially with RGNX expecting to make pivotal determination in mid-2024, and to share initial functional assessment data in 2H24e (pivotal to start in later 2024), which will be especially important to further drive shares as we have pointed out before ([see our thoughts on why NSAA is important](#)). Maintain Buy and \$35 PO.

Expression level at 75.7% for 12 yrs old, no NSAA data

We summarize key data points presented including **1)** patient aged 12 years old had expression level at 75.7%, **2)** tolerable safety profile with no SAE reported so far. In our view, the data shown is promising especially in the 12 yr old patient; while we see a notable reduction in the older child, our KOL checks say that children older than 7 are generally harder to treat with options limited, and given the progressive nature of DMD, muscle is harder to show functional improvement as the child ages.

202 vs Elevydis: younger cohort can be even better

As a reminder, Sarepta's Elevydis (covered by Tazeen Ahmed), from its FDA label of results of subjects receiving 1.33×10^{14} vg/kg demonstrated expression levels of 43%-54% micro-dystrophin of control (age 4-8). In comparison, RGX-202 demonstrated expression levels of 39%-76% (age 4-12). While no data from Sarepta has been presented on its older cohorts (enrollment started), we see current '202 expression levels at least on-par with competitor, and dose level 2 could look even better in younger cohorts which is expected from the next update. In our view, the data so far is hitting our bar and future data should focus on expression data with longer follow-up, larger n.

Exhibit 1: Summary of RGX-202 Data

So far, we see promising expression data from both younger and older cohorts at both dose levels

	Patient	Age at Dosing (yrs)	Weight at Dosing (kg)	Western Blot (% Normal Control)	CK Levels (% reduction from baseline)
Dose Level 1	1	4.4	17.8	38.8	-43
Dose Level 1	2	10.5	28.3	11.1	-44
Dose Level 1	3	6.6	26.8	83.4	-93
Dose Level 2	4	12.1	24.3	75.7	-77

Source: BofA Global Research, Company Reports

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Equity

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Stock Data

Price	21.36 USD
Price Objective	35.00 USD
Date Established	5-Jan-2024
Investment Opinion	C-1-9
52-Week Range	11.83 USD - 24.51 USD
Mkt Val (mn) / Shares Out (mn)	949 USD / 44.4
Free Float	90.9%
Average Daily Value (mn)	15.87 USD
BofA Ticker / Exchange	RGNX / NAS
Bloomberg / Reuters	RGNX US / RGNX.OQ
ROE (2024E)	-92.8%
Net Dbt to Eqty (Dec-2023A)	-11.1%
ESGMeter™	Low

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Abbreviations:

AMD: Age-related macular degeneration
DMD: Duchenne Muscular Dystrophy
DR: Diabetic Retinopathy
MPS: mucopolysaccharidosis
NSAA: North Star Ambulatory Assessment
AAV: adeno-associated virus
AAO: America Academy of Ophthalmology
WMS: World Muscle Society
SAE: Severe adverse events
CT: C-terminal

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.

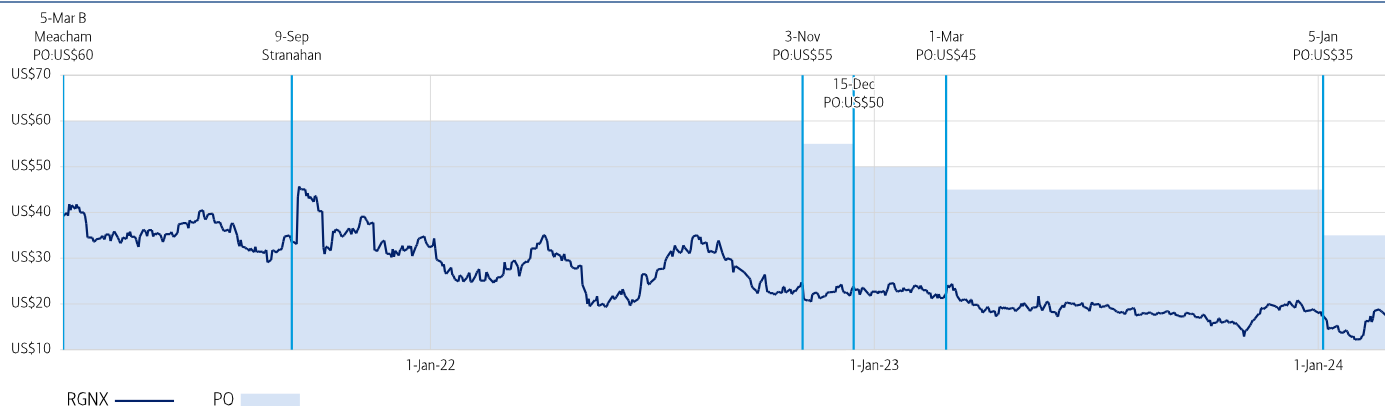
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Regenxbio (RGNX) Price Chart



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

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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%

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Buy	1895	53.62%	Buy	1083	57.15%
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Sell	807	22.84%	Sell	383	47.46%

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Neutral	≥ 0%	≤ 30%
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