

Ionis

Another Ph3 win for IONS in wholly-owned rare disease: donidalorsen in HAE

Maintain Rating: BUY | PO: 62.00 USD | Price: 50.98 USD

Ph3 success for doni on both Q4W and Q8W dosing

Today, Ionis (IONS) announced positive Ph3 topline results of donidalorsen in hereditary angioedema (HAE), which met the primary endpoint in reduction in the rate of HAE attacks on both Q4W ($p < 0.001$) and Q8W dosing regimens ($p = 0.004$). The press release also noted favorable safety/tolerability and no serious adverse events from doni-treated patients. We believe today's positive update further de-risks donidalorsen and positions IONS to have two wholly-owned drugs in rare disease portfolio approved by 2025E (doni HAE [US wholly-owned], along with olezarsen in FCS in late 2024E). IONS plans to present detailed Ph3 data at an upcoming medical conference by mid-year, where potential venue candidates include AAI (May 3-7) and EAACI (May 31-June 3). Also expected in mid-year are results from Ph3 open label extension and Switch cohort, the latter evaluating patients transitioning from an approved prophylactic HAE treatment to doni and the data could facilitate switches in the commercial setting. We model \$600m nominal revenue of donidalorsen to IONS at peak (75% POS; majority from US sales), a discount to current run rate of Takhzyro (annualizing at \$1.2bn+ sales [$> 70\%$ US]) pending clarity on doni's competitive profile. We maintain our Buy rating on favorable risk/reward ahead of catalyst rich 2024.

Outstanding question: competitive positioning

The key outstanding question is on doni's competitive profile vs standard of care (Takeda's Takhzyro) and late-stage pipeline competitor (CSL's garadacimab). At IONS' detailed data presentation, we will look for magnitude treatment benefit of donidalorsen in reduction in attack rate, proportion of patients remain attack-free, and optionality of extending dose schedule to Q8W (vs Takhzyro indicated for Q2W/Q4W and gara studied for Q4W). Gara is under regulatory review, with FDA approval decision est. in 2H24. Based on our physician checks, Q4W will likely be the primary dosing interval (confirmed with IONS) but we believe the optionality of offering Q8W could matter for some physicians/patients. Based on our conversations with IONS, we expect the company to market doni's ease of auto-injector SQ dosing with the broadest range of dosing intervals. On the flip side, the HAE prophylaxis market is getting increasingly competitive and fragmented, thus we do not see significant upside to our \$600m peak nominal forecast.

22 January 2024

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Stock Data

Price	50.98 USD
Price Objective	62.00 USD
Date Established	2-Jan-2024
Investment Opinion	B-1-9
52-Week Range	32.69 USD - 54.44 USD
Mkt Val (mn) / Shares Out (mn)	7,314 USD / 143.5
Free Float	96.6%
Average Daily Value (mn)	62.28 USD
BofA Ticker / Exchange	IONS / NAS
Bloomberg / Reuters	IONS US / IONS.OQ
ROE (2023E)	-101.2%
Net Dbt to Eqty (Dec-2022A)	67.3%
ESGMeter™	High

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Q2/4/8W: every 2-/ 4- / 8-weeks
POS: likelihood of success
FCS: Familial chylomicronemia syndrome
CSL: Commonwealth Serum Laboratories
FDA: US Food and Drug Administration
AAI: American Association of Immunologists
EAACI: European Academy of Allergy and Clinical Immunology

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Timestamp: 22 January 2024 11:25AM EST

Price objective basis & risk

Ionis (IONS)

Our \$62 price objective (PO) is based on a risk-adjusted DCF analysis, in which we assume: (1) risk-adjustment to pipeline programs based on abundance and strength of supportive clinical data, with <30% POS generally assigned to early-stage programs vs. >50% POS for mid-to-late stage assets, (2) the biggest value drivers in our DCF valuation are Wainua, Olezarsen, and Spinraza, (3) we assign marginal value to more speculative, early-stage program, (4) we assume 9.5% discount rate and 0% terminal growth rate.

Downside risks to our PO: 1) key product sales underperform relative to our forecast, 2) failure of key clinical trials, 3) competitor clinical data outperform vs. our expectation.

Upside risks to our PO: 1) delay to regulatory approval of competitors' drug products, 2) failure of competitors' clinical trials, 3) better than expected clinical data readouts

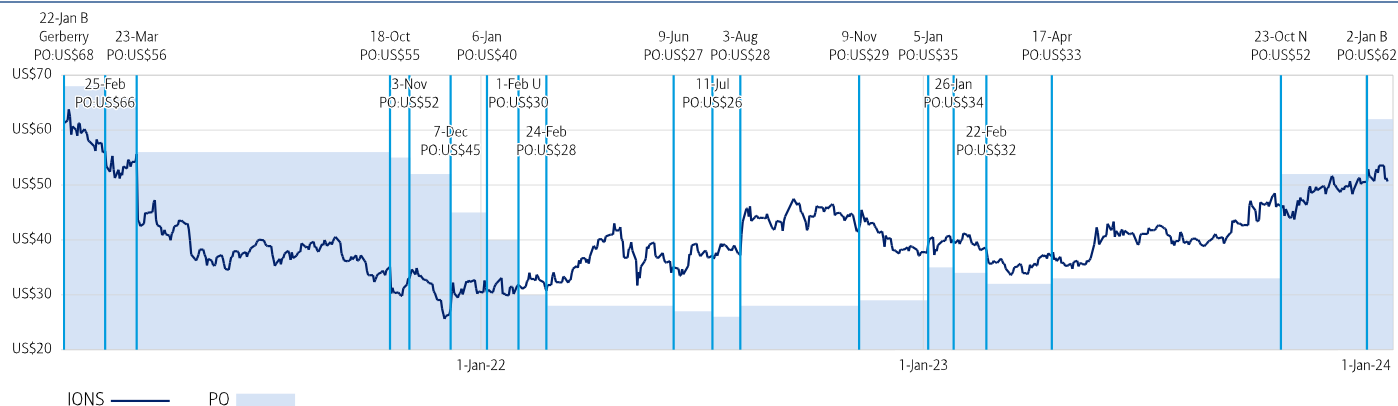
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Disclosures

Important Disclosures

Ionis (IONS) Price Chart



IONS — PO

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%

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