BofA SECURITIES

Ionis

Competitor update to CM trial plan offers mixed read-through to IONS

Maintain Rating: BUY | PO: 62.00 USD | Price: 47.46 USD

Update supports Ionis trial plan; class efficacy TBD vs SOC

Today, competitor ALNY (covered by Tazeen Ahmad) announced a 3-month pushout and a change in statistical plan for its Phase 3 trial (HELIOS B) in TTR-cardiomyopathy (CM), driven by longer follow-up data from adjacent APOLLO B study in CM. In our view, the competitor's update offers mixed read-through to IONS and its own Ph3 CM trial. On the positive side, the update further reinforces IONS' decision to upsize its trial in 2022 to improve the study's statistical powering. Also, IONS has the flexibility to tweak its readout/statistical plan based on HELIOS B results. As such, we do not see negative impact on the likelihood of success for IONS' trial at this juncture. However, the update also adds to uncertainty around efficacy/effect size of the TTR silencer class relative to standard of care (SOC) tafamidis (TTR stabilizer); our prior KOL checks suggest differentiated efficacy from TTR silencer could be an important factor in capturing meaningful market share from tafamidis. Despite today's mixed readthrough, we continue to like IONS setup ahead of catalyst-rich next 12 months. Maintain Buy.

IONS Ph3 trial is >2x the size of competitors' trials

Recall in '22, IONS upsized its Ph3 CM trial (Cardio-TTRansform) from 750 to 1400+ patients and extended maximum study duration from 30mo to 32mo driven by early diagnosis of CM (patients less sick at baseline) due to tafamidis approval and improved diagnostic tool. IONS has the option to readout study results as early as 1H25 or follow last patient through 32mo ('26 readout in that case). At a study size of 1438, IONS Ph3 trial is over 2x the size of ATTRibute-CM & HELIOS B (n= around 630-660; Exhibit 1).

Larger trial may offer buffer rooms for clinical risks

ALNY updated the primary endpoint analysis to test both allcomer and subgroup of patients who were tafamidis-naïve at baseline, citing data from APOLLO B and payers' feedback pointing to potential reimbursement challenges for TTR silencer/tafamidis combo ahead of tafamidis LOE. ALNY also noted the 3mo pushout of HELIOS B readout would skew more patients to the full 36mo follow-up period and thus enhance study powering. At current juncture, it is unclear whether IONS will have an option to boost its Ph3 study duration beyond 32mo. However, we believe >2x trial sizing should offer better powering across subgroup analyses and more buffer rooms to offset 4mo shorter maximum duration vs HELIOS B (note: survival benefit started to manifest after 24mo in another contemporary CM trial [ATTRibute-CM]).

We look to clarity on IONS' approach with key biomarker

Per our prior KOL checks, KOLs view reductions in NT-proBNP (biomarker) as important (commercially) to understanding of superiority of silencers vs. stabilizers (which could only stabilize or delay increase of NT-proBNP in prior trials), given contemporary CM trials are not designed to test head-to-head efficacy between TTR silencers and tafamidis. A removal of NT-proBNP from key secondary endpoints of HELIOS B suggest possibly protracted timeline to get clarity on silencers' impact on NT-proBNP. IONS is capturing data on NT-proBNP but it is not clear to us whether the measure is a formal secondary analysis. We look to IONS' approach for the biomarker at next earnings call.

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15 February 2024

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Stock Data

Price	47.46 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
Mrkt Val (mn) / Shares Out (mn)	6,809 USD / 143.5
Free Float	96.5%
Average Daily Value (mn)	52.42 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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TTR: transthyretin
IONS: Ionis
ALNY: Alnylam
KOL: expert
Mo: month
TBD: to be determined
LOE: loss of exclusivity

Exhibit 1: Comparisons of ATTR-CM Ph3 trial design
IONS' CARDIO TTRansform is the largest Ph3 CM trial conducted to date

	ATTR-ACT (tafamidis)	ATTRibute-CM (acoramidis)	APOLLO-B (patisiran)	HELIOS-B (vutrisiran)	Cardio-TTRansform (eplontersen)
Baseline					
Enrollment	441	632	360	655	1438
Randomization	3:2	1:1	1:1	1:1	1:1
Trial period	Dec 2013 - Feb 2018	Mar 2019 - May 2023	Sept 2019 - June 2022	Nov 2019 - May 2024	Mar 2020 - TBD
Duration of double-blind period	30 months	30 months	12 months	30 to 36 months (60% through 36mo, remainder 33mo+)	Up to 32 months (full 32 months for all patients if study progressed to full completion in 2026)
Tafamidis use at baseline	0% / N/A	25%	25% (vs protocol cap ≤30%)	40%	Target ~50% but no cap set Ionis: "well balanced" between tafamidis and naïve patients
Tafamidis drop-in protocol	0% / N/A	Drop-in allowed after 12mo	Drop-in allowed anytime	Drop-in allowed after 12mo	Drop-in allowed anytime
Tafamidis drop-in rate	0% / N/A	15% drug, 23% placebo	2-3% drop-in	"Below internal assumptions"	"Very, very low"
# pts on tafamidis at baseline (estimate)	0	158	90	262	719
# pts not on tafamidis at baseline (estimate)	441	474	270	393	719
P-value on key efficacy measures at month 30+					
Composite primary endpoint	p<0.001 (Finkelstein–Schoenfeld; sponsor and FDA review) - All-cause mortality, CV hospitalization	p<0.0001 (Finkelstein–Schoenfeld; sponsor) - All-cause mortality, CV hospitalization, change from baseline in NT-proBNP, change from baseline in 6MWT	Not applicable	TBD (Andersen-Gill; sponsor) - all-cause mortality, CV hospitalization, and urgent heart failure visits; duo testing in allcomer and tafamidis-naïve (at baseline); stat sig if p<0.05 for both or p<0.025 for either	TBD (Andersen-Gill; sponsor) - CV mortality, CV hospitalization, urgent heart failure visits
All-cause mortality	p<0.001 (Finkelstein–Schoenfeld; sponsor) p=0.007 (Kaplan Meier; FDA review) p=0.026 (Cox proportional hazard; label)	p=0.057 (Cochran-Mantel-Haenszel; sponsor) p=0.15 (Cox proportional hazard; sponsor)	Not applicable	TBD	TBD
CV mortality	Not presented, but benefit in all-cause mortality was driven by CV-mortality (FDA review)	p=0.037 (Cochran-Mantel-Haenszel; sponsor) p=0.089 (Cox proportional hazard; sponsor)	Not applicable	TBD	TBD
CV hospitalization	p<0.0001 (Poisson regression; label)	p<0.0001 (Negative binomial regression; sponsor)	Not applicable	TBD	TBD
CV mortality + CV hospitalization	p<0.001 (Finkelstein–Schoenfeld; FDA review)	Not presented	Not applicable	TBD	TBD
All-cause mortality + CV hospitalization	p=0.0006 (Finkelstein–Schoenfeld; FDA review)	Not presented	Not applicable	TBD	TBD
All-cause mortality + all-cause hospitalization	p=0.009 (Finkelstein–Schoenfeld; FDA review)	Not presented	Not applicable	TBD	TBD

Source: FDA.gov, company reports

BofA GLOBAL RESEARCH

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

Analyst Certification

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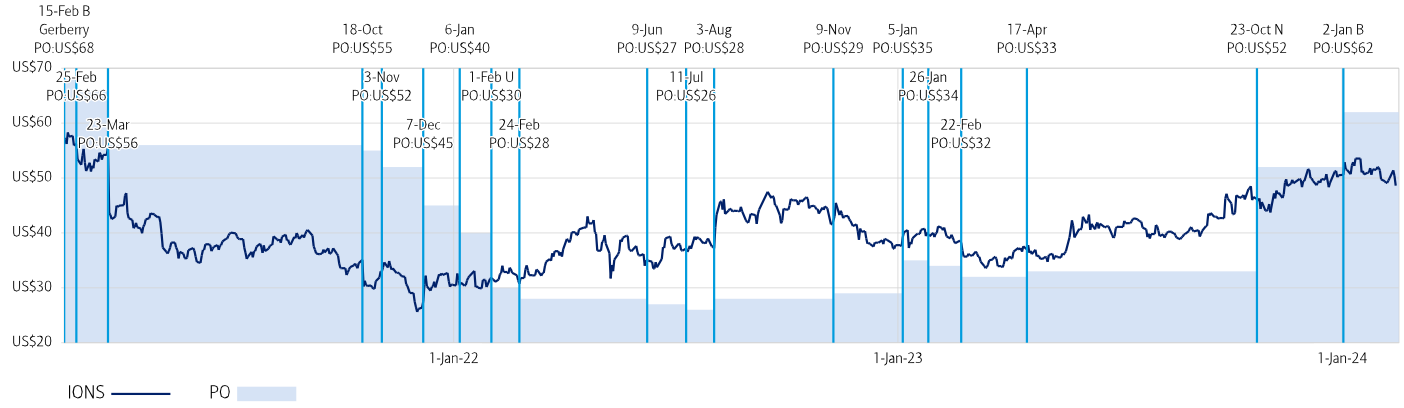
Ionis (IONS) Price Chart



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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%

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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