

Ionis

Upgrade to Buy and \$62 PO on favorable setup ahead of catalyst rich 2024

Rating Change: BUY | PO: 62.00 USD | Price: 50.59 USD

Multiple de-risking catalysts in '24 for high revenue drugs

We upgrade IONS to Buy (from Neutral) and raise our PO to \$62 from \$52, as we see '24-25 as catalyst-rich, further validating IONS' expansive R&D pipeline. We are bullish on four pipeline programs with validating clinical data; each program also represents a meaningful commercial opportunity with \$300m-\$600m peak royalties (high margin) or \$600m-\$1bn peak sales estimates (Exhibit 1). The recent Wainua approval in polyneuropathy (PN; partnered with AZN (AstraZeneca)) with a clean label indicates IONS' improved antisense (ASO) platform can mitigate legacy safety issues, which bodes well for the safety (and competitive) profile of IONS' other mid-/late-stage ASOs.

Cardiomyopathy drug remains a key investor focus

Wainua for cardiomyopathy (CM) is a key value driver (25% of our SOTP (sum of the parts)). In 2024, we look to competitor ALNY's (Alnylam, covered by BofA Global Research analyst Tazeen Ahmad) HELIOS B (Ph3) readout in 1H24 as important validation for TTR (transthyretin) silencers in the potentially large CM category (same mechanism as Wainua). A positive HELIOS B trial would de-risk Wainua CM ahead of IONS' own Ph3 readout in 1H25E. IONS' more conservative Ph3 powering assumptions (2x larger than HELIOS B) reduces the risk of missing on statistical significance on the key primary endpoint. Even as second-mover, we view AZN as a strong commercial partner for Wainua. Last, we believe IONS broader portfolio can largely support current valuation even without Wainua CM (Exhibit 2: our SOTP ex-CM is \$48 vs stock at ~\$50).

Catalyst-rich 2024, multiple mid-/late-stage trial readouts

Key catalysts: (1) donidalorsen Ph3 topline in HAE (hereditary angioedema) in 1H24: we will look for a repeat of Ph2 profile, which would support a best-in-class profile vs Takeda's Takhzyro; (2) ION582 Ph1/2 update in Angelman (rare neuro disease) in mid-24: we believe the Street has assigned negligible value to ION582. Competitor's (RARE (Ultragenyx)) 1H24 update may further de-risk the ASO approach ahead of IONS mid-year readout; (3) olezarsen for triglyceride (TG; fat) reduction: potential approval in FCS (rare fat disorder) in 2H24E and Ph3 topline in bigger market SHTG (severe hypertriglyceridemia) in 1H25E.

Model changes: higher (risk-adjusted) revenue forecast

Our \$62 PO is driven by (1) higher Wainua forecast on removal of risk adjustment and modestly higher nominal sales on PN approval with a clean label. Given we see positive readthrough to IONS' ASO platform, we raise our forecast of IONS' broad pipeline. Net effects to SOTP: +\$1/shr to Wainua, +\$2/shr on doni (faster ramp to \$600m peak), +\$5/shr to broader platform pipeline. We also layer in a forecast for ION582 in Angelman based on IONS' preliminary Ph1/2 update in Nov, adding another +\$2/shr.

Estimates (Dec) (US\$)	2021A	2022A	2023E	2024E	2025E
EPS	(0.21)	(1.90)	(3.20)	(3.23)	(2.85)
EPS Change (YoY)	94.0%	-804.8%	-68.4%	-0.9%	11.8%
Consensus EPS (Bloomberg)			(3.28)	(3.46)	(2.71)
DPS	0	0	0	0	0
Valuation (Dec)					
EV / EBITDA*	702.4x	NM	NM	NM	NM
Free Cash Flow Yield*	0.3%	-1.1%	-4.1%	-4.5%	-4.0%

* For full definitions of *IQmethod*SM measures, see page 5.

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02 January 2024

Equity

Key Changes

(US\$)	Previous	Current
Inv. Opinion	B-2-9	B-1-9
Inv. Rating	NEUTRAL	BUY
Price Obj.	52.00	62.00
2023E Rev (m)	654.9	642.9
2024E Rev (m)	609.7	618.2
2025E Rev (m)	654.5	713.8
2023E EPS	-3.12	-3.20
2024E EPS	-3.27	-3.23
2025E EPS	-3.17	-2.85

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Stock Data

Price	50.59 USD
Price Objective	62.00 USD
Date Established	2-Jan-2024
Investment Opinion	B-1-9
52-Week Range	32.69 USD - 52.27 USD
Mkt Val (mn) / Shares Out (mn)	7,258 USD / 143.5
Free Float	96.6%
Average Daily Value (mn)	54.85 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 TM	High

ESGMeter is not indicative of a company's future stock price performance and is not an investment recommendation or rating. ESGMeter is independent of BofA Global Research's equity investment rating, volatility risk rating, income rating, and price objective for that company. For full details, refer to ["BofA ESGMeter Methodology"](#).

iQprofileSM Ionis

iQmethodSM – Bus Performance*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Return on Capital Employed	-0.5%	-10.3%	-19.8%	-22.9%	-21.0%
Return on Equity	-3.6%	-38.7%	-101.2%	-127.6%	-142.1%
Operating Margin	-3.7%	-70.1%	-66.7%	-79.1%	-61.8%
Free Cash Flow	19	(78)	(297)	(325)	(286)

iQmethodSM – Quality of Earnings*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash Realization Ratio	NM	NM	NM	NM	NM
Asset Replacement Ratio	0.3x	0.3x	0.3x	0.3x	0.3x
Tax Rate	3.3%	NM	NM	15.0%	17.0%
Net Debt-to-Equity Ratio	41.7%	67.3%	266.3%	122.8%	NM
Interest Cover	-3.4x	-41.1x	-26.8x	NA	NA

Income Statement Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Sales	810	587	643	618	714
% Change	11.1%	-27.5%	9.6%	-3.8%	15.5%
Gross Profit	799	573	634	606	699
% Change	11.5%	-28.3%	10.7%	-4.4%	15.4%
EBITDA	12	(343)	(361)	(421)	(373)
% Change	NM	NM	-5.2%	-16.6%	11.4%
Net Interest & Other Income	0	153	1	(60)	(60)
Net Income (Adjusted)	(29)	(270)	(458)	(467)	(416)
% Change	94.0%	-821.3%	-69.5%	-2.0%	11.0%

Free Cash Flow Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Net Income from Cont Operations (GAAP)	(29)	(270)	(458)	(467)	(416)
Depreciation & Amortization	42	68	69	69	68
Change in Working Capital	(114)	32	11	(1)	(3)
Deferred Taxation Charge	0	0	0	0	0
Other Adjustments, Net	132	110	100	91	83
Capital Expenditure	(12)	(18)	(19)	(17)	(19)
Free Cash Flow	19	-78	-297	-325	-286
% Change	NM	NM	-281.2%	-9.6%	12.0%
Share / Issue Repurchase	12	12	12	550	12
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	251	(50)	(100)	0	0

Balance Sheet Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash & Equivalents	869	716	294	482	171
Trade Receivables	62	23	26	25	29
Other Current Assets	1,414	1,416	1,379	1,370	1,358
Property, Plant & Equipment	178	184	191	196	203
Other Non-Current Assets	89	89	89	89	89
Total Assets	2,612	2,428	1,978	2,162	1,849
Short-Term Debt	4	0	0	0	0
Other Current Liabilities	237	253	250	259	268
Long-Term Debt	1,188	1,138	1,038	1,038	1,038
Other Non-Current Liabilities	412	412	412	412	412
Total Liabilities	1,840	1,802	1,699	1,709	1,718
Total Equity	772	626	279	453	132
Total Equity & Liabilities	2,612	2,428	1,978	2,162	1,849

* For full definitions of iQmethodSM measures, see page 5.

Company Sector

Biotechnology

Company Description

Ionis Pharmaceuticals is a biotechnology company focused on discovery and development of RNA-targeted therapeutics. The company's drug platform is called antisense technology which aims to modify/reduce the production of disease-causing proteins by binding/destroying RNA so that the amount of disease-causing protein is dramatically decreased. IONS has three commercial drugs approved in major markets, four drugs in Ph3 of development and over 30 medicines in early to mid-stage development.

Investment Rationale

We rate IONS Buy on favorable stock setup ahead of catalyst-rich path in 2024-1H25. There will be multiple mid-/late-stage clinical readouts that can increase likelihood of success for four assets with \$300m-1bn nominal peak revenue estimates (Wainua, donidalorsen, olezarsen, ION582). Approval of Wainua in polyneuropathy with a clean label indicates ION's improved antisense (ASO) platform can mitigate legacy safety issues, effectively validating the safety profile of IONS' broader pipeline.

Stock Data

Average Daily Volume 1,084,292

Quarterly Earnings Estimates

	2022	2023
Q1	NA	NAA
Q2	NA	NAA
Q3	NA	NAA
Q4	NA	NA

Acronyms:

ALNY: Alnylam (covered by Tazeen Ahmad)

AZN: AstraZeneca

RARE: Ultragenyx (covered by Tazeen Ahmad)

Exhibit 1: Abbreviated catalyst tracker of IONS in next 12-18 months

Multiple catalysts that can increase the likelihood of success of four IONS assets with \$300m-1bn peak revenue estimates

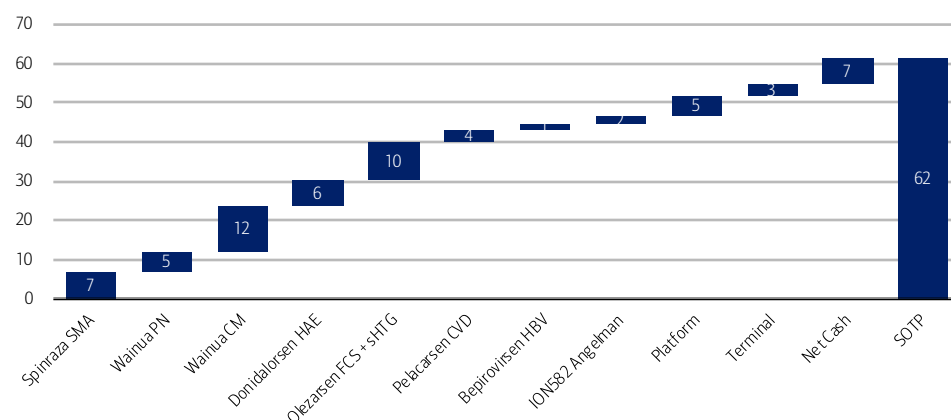
Drug	Events	Nominal sales/revenue est	Type of revenue to IONS	POS
Wainua PN	Commercial launch (2024)	\$200m	Royalty	100%
Wainua CM	ALNY's Ph3 HELIOS B readout (1H24), IONS' Ph3 Cardio-TTRansform readout (1H25E)	\$600m	Royalty	75%
Donidalorsen	Ph3 topline (1H24), switch study (mid-24)	\$600m	Sales (ex-US royalty)	75%
ION582	RARE's Ph1/2 expansion update (1H24), IONS' Ph1/2 escalation update (mid-24)	\$300m	Royalty	30%
Olezarsen FCS	Regulatory filing (early 2024), potential approval decision (2H24E)	\$100m*	Sales (ex-US royalty)**	95%
Olezarsen sHTG	Ph3 topline (1H25E)	\$1bn	Sales (ex-US royalty)**	75%

Source: BofA Global Research estimates. Note: *assume orphan pricing without sHTG, **assume IONS will out-license olezarsen for ex-US royalty similar to donidalorsen.

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Exhibit 2: IONS SOTP

We estimate IONS is worth \$62 on a risk-adjusted SOTP DCF, or \$48 without contribution from Wainua CM



Source: BofA Global Research estimates

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Exhibit 3: IONS catalyst tracker

We highlight potential catalyst events for IONS next 12-18 months

Category: Pipeline		
Drug	Event	Timing
Vutrisian (TTR competitor)	Ph3 topline results of HELIOS B in CM	1H24E
Donidalorsen (PKK)	Ph3 data in HAE (placebo controlled)	1H24E
Donidalorsen (PKK)	Ph3 data in HAE (OASIS Plus - Switch)	Mid 2024E
ION582 / BIIB121 (UBE3A)	Ph1/2 data in Angelman syndrome (MAD + a cut of LTE)	Mid 2024E
ION541 / BIIB105 (ATXN2)	Ph1/2 data in ATXN2-repeats and broad ALS	Mid 2024E
IONIS-FB-LRx	Ph2 topline in geographic atrophy	2H24E
Olezarsen (APOC3)	Ph3 data in sHTG	1H25E
Wainua (TTR)	Ph3 results of CARDIO-TTRansform in CM	1H25E (earliest)
AKCEA-APO(a)-LRx / TQJ230	Ph3 outcomes trial readout (HORIZON study) in Lp(a) CV disease	2025E
Category: Regulatory, Corporate		
Drug	Event	Timing
IONS	FY24 guidance	4Q call (Feb 2024)
Wainua (TTR)	Commercial launch of eplontersen in PN	2024
Olezarsen (APOC3)	Olezarsen US approval decision	2H24E

Source: Company reports, clinicaltrials.gov, BofA Global Research estimates. Note: CM: cardiomyopathy, HAE: hereditary angioedema, MAD: multi-ascending dose, LTE: long-term extension, ALS: amyotrophic lateral sclerosis, sHTG: severe hypertriglyceridemia, CV: cardiovascular, PN: polyneuropathy, TTR, PKK, UBE3A, ATXN2, APOC3, TTR: drug targets.

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

I, Jason M. Gerberry, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or view expressed in this research report.

US - Specialty Pharma & Biotechnology Coverage Cluster

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	Arrowhead Pharmaceuticals	ARWR	ARWR US	Jason M. Gerberry
	bluebird bio	BLUE	BLUE US	Jason M. Gerberry
	Exelixis	EXEL	EXEL US	Jason M. Gerberry
	Immunovant, Inc.	IMVT	IMVT US	Jason M. Gerberry
	Intra-Cellular Therapies	ITCI	ITCI US	Jason M. Gerberry
	Ionis	IONS	IONS US	Jason M. Gerberry
	Jazz Pharmaceuticals	JAZZ	JAZZ US	Jason M. Gerberry
	Lyra Therapeutics	LYRA	LYRA US	Jason M. Gerberry
	Oculus Holding AG	OCS	OCS US	Jason M. Gerberry
	ProKidney Corp	PROK	PROK US	Jason M. Gerberry
	Relay Therapeutics	RLAY	RLAY US	Jason M. Gerberry
	Tarsus Pharmaceuticals	TARS	TARS US	Jason M. Gerberry
	Teva Pharmaceuticals	TEVA	TEVA US	Jason M. Gerberry
	Vaxcyte Inc	PCVX	PCVX US	Jason M. Gerberry
	Xenon Pharmaceuticals	XENE	XENE US	Jason M. Gerberry
NEUTRAL				
	Alkermes	ALKS	ALKS US	Jason M. Gerberry
	Amphastar Pharmaceuticals	AMPH	AMPH US	Jason M. Gerberry
	Axsome Therapeutics	AXSM	AXSM US	Jason M. Gerberry
	Galapagos	GLPG	GLPG US	Jason M. Gerberry
	Harmony Biosciences	HRMY	HRMY US	Jason M. Gerberry
	Roivant	ROIV	ROIV US	Chi M. Fong
UNDERPERFORM				
	Bausch Health Cos Inc	BHC	BHC US	Jason M. Gerberry
	FibroGen Inc.	FGEN	FGEN US	Jason M. Gerberry
	Organon	OGN	OGN US	Jason M. Gerberry
	Viartis Inc.	VTRS	VTRS US	Jason M. Gerberry

iQmethodSM Measures Definitions

Business Performance

Return On Capital Employed

Return On Equity
Operating Margin
Earnings Growth
Free Cash Flow

Quality of Earnings

Cash Realization Ratio
Asset Replacement Ratio
Tax Rate
Net Debt-To-Equity Ratio
Interest Cover

Valuation Toolkit

Price / Earnings Ratio
Price / Book Value
Dividend Yield
Free Cash Flow Yield
Enterprise Value / Sales

EV / EBITDA

Numerator

NOPAT = (EBIT + Interest Income) × (1 – Tax Rate) + Goodwill Amortization

Net Income
Operating Profit
Expected 5 Year CAGR From Latest Actual
Cash Flow From Operations – Total Capex

Numerator

Cash Flow From Operations
Capex
Tax Charge
Net Debt = Total Debt – Cash & Equivalents
EBIT

Numerator

Current Share Price
Current Share Price
Annualised Declared Cash Dividend
Cash Flow From Operations – Total Capex
EV = Current Share Price × Current Shares + Minority Equity + Net Debt + Other LT Liabilities
Enterprise Value

Denominator

Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill Amortization
Shareholders' Equity
Sales
N/A
N/A

Denominator

Net Income
Depreciation
Pre-Tax Income
Total Equity
Interest Expense

Denominator

Diluted Earnings Per Share (Basis As Specified)
Shareholders' Equity / Current Basic Shares
Current Share Price
Market Cap = Current Share Price × Current Basic Shares
Sales

Basic EBIT + Depreciation + Amortization

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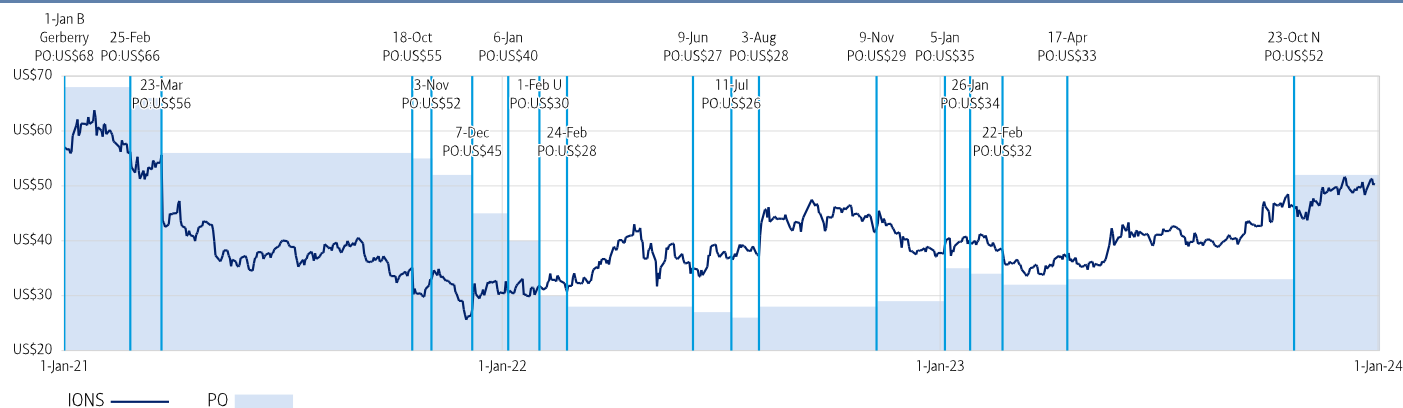
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Disclosures

Important Disclosures

Ionis (IONS) Price Chart



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

The Investment Opinion System is contained at the end of the report under the heading "Fundamental Equity Opinion Key". Dark grey shading indicates the security is restricted with the opinion suspended. Medium grey shading indicates the security is under review with the opinion withdrawn. Light grey shading indicates the security is not covered. Chart is current as of a date no more than one trading day prior to the date of the report.

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%

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