

Alnylam Pharmaceuticals

New statistical analysis for HELIOS-B pushes readout to mid-24

Reiterate Rating: BUY | PO: 246.00 USD | Price: 147.43 USD

Changes seem appropriate but raise questions

Alnylam (ALNY) announced changes to the statistical analysis plan for HELIOS-B (more below) and noted they now expect the readout in late June/early July with a late-24 filing. Subgroup analyses including pts on/off background tafamidis are expected at the topline. We caught up with mgmt and they noted that the decision was informed based on long-term follow up from APOLLO-B and updates in the ATTR space. They noted they expect the monotherapy market will be a key area of focus as they expect combination therapy will be challenging due to payor dynamics, which they already see in mixed phenotype pts. While we think the changes are appropriate and could address some of the key concerns raised by investors, we think the timing of the decision raises questions around the readout. We are hosting the ALNY mgmt team (CEO, CMO and CCO) next week in New York and expect to get more clarity on the update. We also plan to discuss the new plan with our KOLs before adjusting our estimates. We remain encouraged by the large commercial opportunity for vutrisiran in ATTR-CM, which we see as the key value driver. We reiterate our Buy with \$246 PO.

Monotherapy subgroup now part of primary analysis

The primary analysis for HELIOS-B will now be conducted when the last patient reaches month 33 (prev. month 30) with the double-blind period remaining at 36 months. Additionally, the primary endpoint will now be analyzed in the overall population and the monotherapy population (no baseline tafamidis; 60% of pts). The secondary endpoints analyzed was also refined to focus on key clinically relevant endpoints (6MWT, KCCQ, all-cause mortality, NYHA Class). The study will be considered positive if the primary endpoint is met in both analyses with a $p \leq 0.05$ or in one analysis with a $p \leq 0.025$.

Multi-doing of ALN-APP cleared by FDA

The company reported FDA has cleared multi-dosing in the ph 1 trial of ALN-APP at doses up to 180mg. An interim update from part B is expected in late-24. The company also reiterated topline ph 2 data for KARDIA-2 is expected in early-24.

4Q revenues in-line with expectations

4Q revenues for Onpattro of \$79mn, Amvuttra of \$175mn, Givlaari of \$59mn and Oxlumo of \$33mn in-line with expectations. The company provided FY24 product revenue guidance of \$1.4-1.5bn. Mgmt highlighted continued growth of ATTR franchise and highlighted over >85% of ATTR-PN pts in the US are now on Amvuttra. In our DCF-based model, we update for 4Q results, cash and share count. We also slightly push our launch estimates for vutri' in ATTR-CM based on new timelines, and adjust out revenue and op ex estimates according to company guidance.

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	(9.30)	(3.52)	(5.90)	(1.90)	1.03
EPS Change (YoY)	-29.2%	62.2%	-67.6%	67.8%	NM
Consensus EPS (Bloomberg)			(3.17)	0.15	4.51
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	NM	NM	NM	NM	143.1x
EV / EBITDA*	NM	NM	NM	226.5x	47.2x
Free Cash Flow Yield*	-3.3%	0.2%	-1.3%	1.7%	4.1%

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

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Timestamp: 16 February 2024 05:58AM EST

16 February 2024

Equity

Key Changes

(US\$)	Previous	Current
2024E Rev (m)	1,831.3	1,835.4
2025E Rev (m)	2,815.0	2,573.2
2026E Rev (m)	NA	3,311.4
2024E EPS	-6.08	-5.90
2025E EPS	-0.63	-1.90
2026E EPS	NA	1.03

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Stock Data

Price	147.43 USD
Price Objective	246.00 USD
Date Established	13-Dec-2023
Investment Opinion	B-1-9
52-Week Range	143.52 USD - 225.22 USD
Mkt Val (mn) / Shares Out (mn)	18,568 USD / 125.9
Free Float	99.7%
Average Daily Value (mn)	125.44 USD
BofA Ticker / Exchange	ALNY / NAS
Bloomberg / Reuters	ALNY US / ALNY.OQ
ROE (2024E)	NA
Net Dbt to Eqty (Dec-2023A)	NA
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".

See inside for abbreviations

iQprofileSM Alnylam Pharmaceuticals

iQmethodSM – Bus Performance*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Return on Capital Employed	-24.3%	-8.9%	-14.7%	-0.7%	7.7%
Return on Equity	-526.1%	NM	NM	NM	25.1%
Operating Margin	-75.7%	-15.4%	-25.3%	-1.0%	9.5%
Free Cash Flow	(613)	42	(236)	315	755

iQmethodSM – Quality of Earnings*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash Realization Ratio	NM	NM	NM	NM	6.0x
Asset Replacement Ratio	0.8x	0.6x	0.6x	0.6x	0.6x
Tax Rate	NM	NM	NM	NM	NM
Net Debt-to-Equity Ratio	NM	NM	NM	-153.6%	-109.3%
Interest Cover	-5.0x	-11.0x	-6.9x	-0.4x	4.7x

Income Statement Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Sales	1,037	1,828	1,835	2,573	3,311
% Change	22.9%	76.2%	0.4%	40.2%	28.7%
Gross Profit	869	1,518	1,542	2,178	2,769
% Change	23.4%	74.8%	1.6%	41.3%	27.1%
EBITDA	(700)	(185)	(358)	93	444
% Change	-13.0%	73.5%	-93.3%	NM	380.1%
Net Interest & Other Income	(342)	(151)	(193)	(193)	(193)
Net Income (Adjusted)	(1,131)	(440)	(756)	(251)	140
% Change	-32.6%	61.1%	-71.9%	66.8%	NM

Free Cash Flow Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Net Income from Cont Operations (GAAP)	(1,131)	(440)	(756)	(251)	140
Depreciation & Amortization	86	97	107	117	129
Change in Working Capital	(36)	11	10	4	(3)
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	540	437	473	520	572
Capital Expenditure	(72)	(62)	(68)	(75)	(83)
Free Cash Flow	-613	42	-236	315	755
% Change	14.6%	NM	NM	NM	139.4%
Share / Issue Repurchase	259	147	162	178	196
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	166	25	0	0	0

Balance Sheet Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash & Equivalents	866	813	739	1,233	2,185
Trade Receivables	238	328	393	472	566
Other Current Assets	1,588	1,842	1,864	1,887	1,914
Property, Plant & Equipment	523	526	488	446	399
Other Non-Current Assets	331	321	321	321	321
Total Assets	3,546	3,830	3,805	4,359	5,385
Short-Term Debt	42	42	46	50	55
Other Current Liabilities	726	926	1,019	1,121	1,233
Long-Term Debt	1,017	1,021	1,021	1,021	1,021
Other Non-Current Liabilities	1,920	2,062	2,062	2,062	2,062
Total Liabilities	3,705	4,051	4,147	4,254	4,371
Total Equity	(158)	(221)	(342)	105	1,014
Total Equity & Liabilities	3,546	3,830	3,805	4,359	5,385

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

Company Sector

Biotechnology

Company Description

Alnylam Pharmaceuticals (ALNY) is a biotechnology company developing gene silencing therapeutics in rare disorders, such as ATTR, AHP, and PH1. The company's lead assets are Onpattro and Amvuttra, approved for hereditary ATTR polyneuropathy, Givlaari, approved for AHP, and Oxlumo, approved for PH1. ALNY is also in late-stage development for follow-on asset Vutrisiran in ATTR, and other pipeline assets. The company also has several partnerships in place.

Investment Rationale

We rate ALNY with a Buy rating, as we see significant upside potential from its growth in ATTR. Onpattro sales metrics continue to signal favorable uptake consistent with our doctor survey. We also see meaningful advantages from follow-on Vutrisiran in ATTR. The company also has Givlaari approved in AHP, Oxlumo approved in PH1, and a versatile RNAi technology platform that can potentially be applied to a variety of diseases.

Stock Data

Average Daily Volume 850,873

Quarterly Earnings Estimates

	2023	2024
Q1	-1.40A	-1.56E
Q2	-1.50A	-1.49E
Q3	2.19A	-1.48E
Q4	-1.10A	-1.38E

Abbreviations

6MWT: 6-minute walk test

ATTR-CM/PN: transthyretin amyloidosis cardiomyopathy/polyneuropathy

CCO: Chief Commercial Officer

CEO: Chief Executive Officer

CMO: Chief Medical Officer

KCCQ: Kansas city cardiomyopathy questionnaire

KOLs: Key Opinion Leaders

mgmt: management

NYHA: New York heart association

ph: phase

pts: patients



Price objective basis & risk

Alnylam Pharmaceuticals (ALNY)

Our PO of \$246 for ALNY consists of \$4/share for Onpattro, \$112/share for Vutrisiran, \$23/share for Givlaari and Lumasiran, \$6/share for Leqvio, \$7/share for Fitusiran, \$20/share for ALN-AGT, \$63/sh for other pipeline and partnered assets and \$11/sh for net cash. We apply a WACC of 9% for commercial-stage assets, 10% for Vutrisiran in ATTR-CM, 10% for other late stage pipeline, and 11% for ALN-AGT.

Upside risks to our PO are 1) better-than-expected uptake of its marketed stage assets, 2) approval of Onpattro and Vutrisiran in ATTR cardiomyopathy, 3) early-stage pipeline advancing into late-stage development, and 4) positive results from partnered programs.

Downside risks to our PO are 1) slower-than-expected uptake of commercial assets, 2) unexpected safety in its siRNA-based assets, and 3) higher-than-expected expenses.

Analyst Certification

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US - Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
	4D Molecular Therapeutics, Inc.	FDMT	FDMT US	Tazeen Ahmad
	Alnylam Pharmaceuticals	ALNY	ALNY US	Tazeen Ahmad
	Amicus Therapeutics	FOLD	FOLD US	Tazeen Ahmad
	Annexon Biosciences	ANNX	ANNX US	Tazeen Ahmad
	Apellis Pharmaceuticals	APLS	APLS US	Tazeen Ahmad
	Argenx SE	ARGX	ARGX US	Tazeen Ahmad
	Arvinas	ARVN	ARVN US	Tazeen Ahmad
	Ascendis Pharma	ASND	ASND US	Tazeen Ahmad
	Biocryst Pharmaceuticals Inc	BCRX	BCRX US	Tazeen Ahmad
	BioNTech	BNTX	BNTX US	Tazeen Ahmad
	Denali Therapeutics	DNLI	DNLI US	Tazeen Ahmad
	Inozyme Pharma, Inc.	INZY	INZY US	Tazeen Ahmad
	Merus	MRUS	MRUS US	Tazeen Ahmad
	Neurocrine Biosciences	NBIX	NBIX US	Tazeen Ahmad
	Ocular Therapeutix	OCUL	OCUL US	Tazeen Ahmad
	PepGen Inc	PEPG	PEPG US	Tazeen Ahmad
	Rhythm Pharmaceuticals	RYTM	RYTM US	Tazeen Ahmad
	Sarepta Therapeutics	SRPT	SRPT US	Tazeen Ahmad
	Ultragenyx Pharmaceuticals	RARE	RARE US	Tazeen Ahmad
NEUTRAL				
	Acadia Pharmaceuticals	ACAD	ACAD US	Tazeen Ahmad
	Incyte Corporation	INCY	INCY US	Tazeen Ahmad
	Prothena Corporation	PRTA	PRTA US	Tazeen Ahmad
	SAGE Therapeutics	SAGE	SAGE US	Tazeen Ahmad
UNDERPERFORM				
	Achilles Therapeutics	ACHL	ACHL US	Tazeen Ahmad
	Fate Therapeutics	FATE	FATE US	Tazeen Ahmad
	Fulcrum Therapeutics	FULC	FULC US	Tazeen Ahmad
	Pharvaris	PHVS	PHVS US	Tazeen Ahmad
	PTC Therapeutics	PTCT	PTCT US	Tazeen Ahmad

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

$\text{NOPAT} = (\text{EBIT} + \text{Interest Income}) \times (1 - \text{Tax Rate}) + \text{Goodwill Amortization}$

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

$\text{EV} = \text{Current Share Price} \times \text{Current Shares} + \text{Minority Equity} + \text{Net Debt} +$

Other LT Liabilities

Enterprise Value

Denominator

$\text{Total Assets} - \text{Current Liabilities} + \text{ST Debt} + \text{Accumulated Goodwill}$

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

$\text{Market Cap} = \text{Current Share Price} \times \text{Current Basic Shares}$

Sales

Basic EBIT + Depreciation + Amortization

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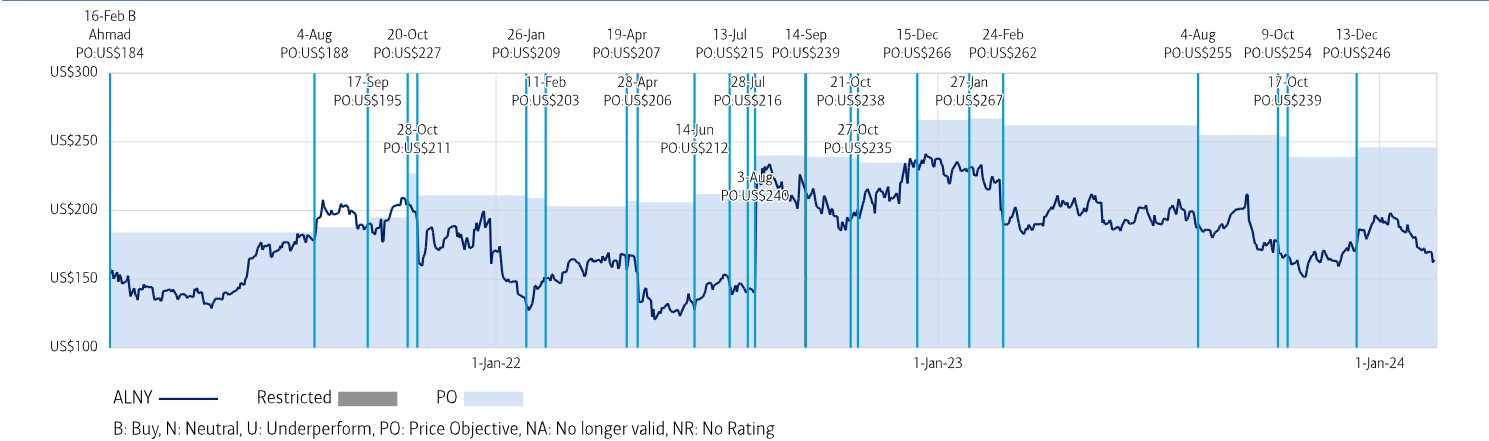
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Alnylam (ALNY) Price Chart



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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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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%

^{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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