

Alnylam Pharmaceuticals

Takeaways from our group meeting with
ALNY management

Maintain Rating: BUY | PO: 246.00 USD | Price: 162.81 USD

APOLLO-B suggests outsized benefit with monotherapy

We hosted the ALNY mgmt team (CEO, CMO and CCO) and our conversation focused on changes to the statistical plan for HELIOS-B (see our [Feb 16 note](#)). Mgmt reiterated the changes were primarily driven by long-term data from the APOLLO-B study where they saw the greatest benefit in the monotherapy subgroup. On the timing of the decision, they noted they wanted to ensure they had all the possible information available from APOLLO-B as well as enough time to discuss the changes with regulators. They reiterated they remain confident in the potential to show outcomes benefit in the overall population but think the magnitude of effect will be highest in monotherapy, which will allow them to be better positioned from a commercial perspective. Mgmt reiterated topline data is expected in late June/early July and they expect to include some subgroup analyses including background tafamidis. We remain confident on a positive outcome from HELIOS-B and think the changes could help highlight the differentiated profile of Amvuttra in ATTR-CM, which our KOL agrees on (see inside for more). We maintain our Buy with \$246 PO.

Disease halting would be key point of differentiation

The company noted that data from APOLLO-B showed stabilization of patients based on 6MWT (age-consistent decline) and stable KCCQ as well as biomarkers, which they think is a key point of differentiation over other therapies were patients continue to decline despite seeing survival benefit. They noted APOLLO-B showed trending survival benefit despite the short duration of the trial and not being powered for this, which gives them confidence in the potential for HELIOS-B to show outcomes benefit. They noted evidence of earlier outcomes benefit is possible and would also be a differentiator.

Reimbursement dynamics would favor Amvuttra

On the commercial opportunity, mgmt highlighted they expect monotherapy will dominate the ATTR-CM market at least until tafamidis' LOE as reimbursement for combination will be challenging. The company noted that beyond potential to show a differentiated profile halting disease progression, they anticipate payor dynamics to favor Amvuttra. They highlighted taf' is a part D drug resulting in high out-of-pocket cost to pts, and IRA changes will further impact coverage by increasing burden on payors. Amvuttra is a part B drug, which will give them a competitive advantage. They also highlighted that in the ex-US ATTR-PN market, where taf' and Amvuttra are available, Amvuttra has 90% market share underscoring physicians' view of a more favorable profile for Amvuttra, which could translate to the ATTR-CM market.

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)			(2.70)	(0.99)	3.31
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	NM	NM	NM	NM	158.1x
EV / EBITDA*	NM	NM	NM	247.4x	51.5x
Free Cash Flow Yield*	-3.0%	0.2%	-1.1%	1.5%	3.7%

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

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Stock Data

Price	162.81 USD
Price Objective	246.00 USD
Date Established	13-Dec-2023
Investment Opinion	B-1-9
52-Week Range	143.52 USD - 218.88 USD
Mkt Val (mn) / Shares Out (mn)	20,505 USD / 125.9
Free Float	99.7%
Average Daily Value (mn)	165.85 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](#)".

Abbreviations

6MWT: 6-minute walk test
ALNY: Alnylam
ATTR-CM/PN: Transthyretin amyloidosis -
cardiomyopathy/polyneuropathy
IRA: Inflation Reduction Act
KCCQ: Kansas City cardiomyopathy questionnaire
KOL: Key opinion leaders
LOE: Loss of exclusivity
Mgmt: Management
pts: patients

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 1,018,689

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

Takeaways from our KOL on new HELIOS-B statistical plan

We discussed the recently announced changes with an expert cardiologist at a large academic center. Our KOL commented that he sees the changes positively and increase his confidence in a positive outcome. He thinks the trial being overenrolled and having fewer-than-expected patients on background tafamidis increase the chances to see benefit in the monotherapy population. In his view, the choice of secondary endpoints is appropriate as these reflect clinically relevant measures and additional analysis on important biomarkers like NT-proBNP (N-terminal pro b-type natriuretic peptide) will still be available even if it is not included as part of the formal statistical analysis. He noted that he thinks the trial has a 70-80% likelihood of succeeding. He highlighted that he will focus on the primary endpoint in the monotherapy arm, and thinks that there is potential to show superior benefit to competitors, but we will need to wait for the data. He noted that even if the outcomes benefit is comparable to other competitors, he still thinks vutrisiran would provide additional advantage in terms of ease of dosing. While he would like to see some trending benefit in the tafamidis subgroups as evidence for potential in combination, he does not think this would be a requirement for clinical uptake. In his view, if HELIOS-B is positive, Amvuttra would become his drug of choice for new patients or patients who are progressing on tafamidis.



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

I, Tazeen Ahmad, 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 - 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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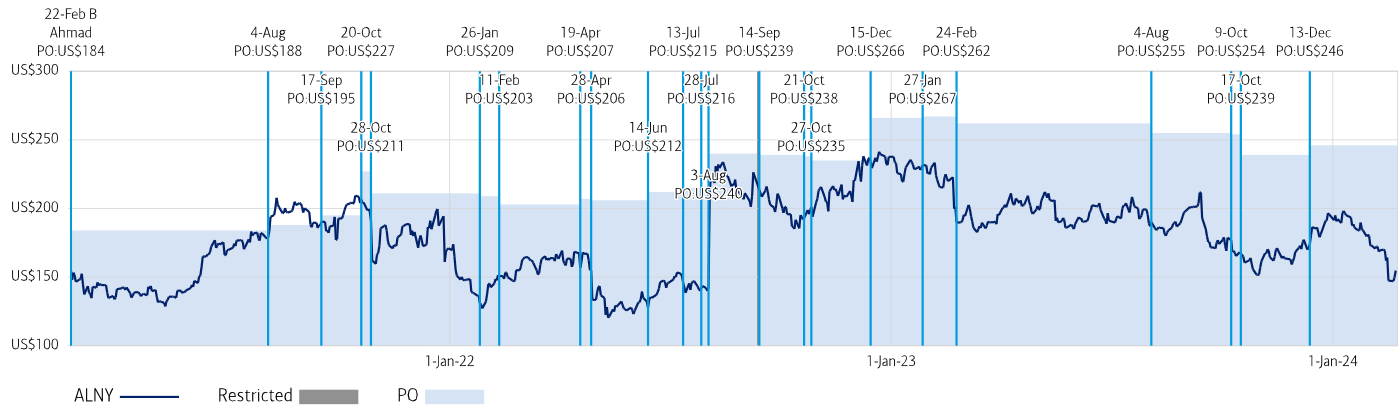
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Alnylam (ALNY) Price Chart



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%

^{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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