

Apellis Pharmaceuticals

CHMP adopts negative opinion on Syfovre as expected; Maintain Buy

Maintain Rating: BUY | PO: 77.00 USD | Price: 66.25 USD

US remains key commercial opportunity for Syfovre

Apellis (APLS) announced the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion for pegcetacoplan (Syfovre) for geographic atrophy (GA). The news do not come as a surprise as the company had already announced they expected a negative opinion following the oral examination meeting in December (see our [Dec 14 note](#)). APLS has plans to appeal the decision and seek re-examination focusing on highlighting the data supporting functional benefit, which was the key point of debate for European regulators. Recall, management has commented that safety observations of vasculitis were not part of the reason for the original negative trending vote. A decision on the re-examination is expected at the April 22-25th meeting with a final decision expected in early July. We reiterate our view that the US remains the key commercial opportunity and we continue to be encouraged by the cadence of the launch so far beating Street expectations despite the emergence of unexpected safety events. We currently model \$3.6bn in worldwide risk-adjusted peak sales including \$3.2bn in US peak sales. We await further color on the path forward in the EU and expectations for 2024 including evolving competitive dynamics in GA. We maintain our Buy rating with \$77 PO.

Estimates (Dec) (US\$)	2021A	2022A	2023E	2024E	2025E
EPS	(8.86)	(6.12)	(4.98)	(1.93)	0.12
GAAP EPS	(8.86)	(6.15)	(4.99)	(1.94)	0.11
EPS Change (YoY)	-93.0%	30.9%	18.6%	61.2%	NM
Consensus EPS (Bloomberg)			(4.50)	(1.49)	1.41
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	NM	NM	NM	NM	552.1x
GAAP P/E	NM	NM	NM	NM	602.3x
EV / EBITDA*	9.1x	8.0x	7.8x	5.7x	4.8x
Free Cash Flow Yield*	-7.2%	-6.6%	-5.7%	-0.2%	4.2%

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

26 January 2024

Equity

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Stock Data

Price	66.25 USD
Price Objective	77.00 USD
Date Established	8-Jan-2024
Investment Opinion	C-1-9
52-Week Range	19.83 USD - 94.75 USD
Mrkt Val (mn) / Shares Out (mn)	7,851 USD / 118.5
Free Float	84.9%
Average Daily Value (mn)	170.56 USD
BofA Ticker / Exchange	APLS / NAS
Bloomberg / Reuters	APLS US / APLS.OQ
ROE (2023E)	-305.8%
Net Dbt to Eqty (Dec-2022A)	-254.8%
ESGMeter TM	High

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iQprofileSM Apellis Pharmaceuticals

iQmethodSM – Bus Performance*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Return on Capital Employed	-60.6%	-77.7%	-89.7%	-26.2%	3.6%
Return on Equity	-371.2%	-353.7%	-305.8%	-51.8%	1.7%
Operating Margin	-805.7%	-788.4%	-154.1%	-28.7%	4.4%
Free Cash Flow	(564)	(515)	(444)	(17)	333

iQmethodSM – Quality of Earnings*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash Realization Ratio	NM	NM	NM	NM	22.8x
Asset Replacement Ratio	0x	0x	0x	0x	0x
Tax Rate	NM	NM	NM	NM	14.0%
Net Debt-to-Equity Ratio	-223.3%	-254.8%	-146.7%	-103.1%	-98.1%
Interest Cover	-40.5x	-25.1x	-22.7x	-7.8x	1.6x

Income Statement Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Sales	67	75	366	714	1,003
% Change	-73.4%	13.3%	385.6%	94.9%	40.6%
Gross Profit	67	75	366	714	1,003
% Change	-73.4%	13.3%	385.6%	94.9%	40.6%
EBITDA	843	957	988	1,347	1,597
% Change	99.1%	13.6%	3.1%	36.4%	18.5%
Net Interest & Other Income	(210)	(57)	(26)	(27)	(28)
Net Income (Adjusted)	(748)	(649)	(591)	(233)	15
% Change	-117.0%	13.2%	9.1%	60.6%	NM

Free Cash Flow Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Net Income from Cont Operations (GAAP)	(746)	(652)	(591)	(234)	14
Depreciation & Amortization	1,379	1,552	1,552	1,552	1,552
Change in Working Capital	(67)	51	10	11	12
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	(1,129)	(1,465)	(1,413)	(1,345)	(1,242)
Capital Expenditure	(1)	(2)	(2)	(2)	(2)
Free Cash Flow	-564	-515	-444	-17	333
% Change	-240.1%	8.7%	13.7%	96.1%	NM
Share / Issue Repurchase	396	400	333	400	0
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	0	0	0	0	0

Balance Sheet Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash & Equivalents	640	552	442	824	1,157
Trade Receivables	10	8	8	9	10
Other Current Assets	174	159	171	184	199
Property, Plant & Equipment	6	6	8	10	12
Other Non-Current Assets	52	35	35	35	35
Total Assets	882	759	663	1,062	1,413
Short-Term Debt	8	30	30	30	30
Other Current Liabilities	124	138	151	166	182
Long-Term Debt	189	93	93	93	93
Other Non-Current Liabilities	362	330	172	93	54
Total Liabilities	683	590	446	381	358
Total Equity	199	169	218	681	1,055
Total Equity & Liabilities	882	759	663	1,062	1,413

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

Company Sector

Biotechnology

Company Description

Apellis Pharmaceuticals (APLS) is a biotechnology company developing therapeutics that target a part of our immune system called complement pathway. The company's lead asset pegcetacoplan is approved for paroxysmal nocturnal hemoglobinuria (PNH) and geographic atrophy (GA) in the US. APLS is also evaluating peg' in kidney, neurology and other hematology indications (in partnership with Sobi), and APL-9 in inhibiting complement activation in gene therapy.

Investment Rationale

We rate APLS shares a Buy. We believe that the mechanism of action of its lead asset is differentiated by targeting the master switch in the complement pathway. Clinical data and approval in lead indications, such as PNH and GA, in our view, is supportive of its potential in addressing indications of high unmet need. We think the risk/benefit profile of Syfovre has largely been resolved following initial reports of ORV, which is reflected by the strong trajectory of the launch so far.

Stock Data

Average Daily Volume 2,520,515

Quarterly Earnings Estimates

	2022	2023
Q1	-1.42A	-1.56A
Q2	-1.47A	-1.02A
Q3	-1.75A	-1.17A
Q4	-1.48A	-1.02E



Price objective basis & risk

Apellis Pharmaceuticals (APLS)

Our price objective (PO) of \$77 is based on a probability-adjusted net present value (NPV) analysis that includes \$15/share for peg' in PNH and \$73/share for peg' in GA and -\$11/share for pipeline/corporate expenses and cash. The remainder of our valuation comes from pipeline and net cash.

Our discounted cash flow (DCF)-based model assumes sales out to 2036 with no terminal growth, with weighted average cost of capital (WACC) of 9% for PNH and GA, and 12% for pipeline.

Upside risks to our PO are 1) better-than-expected penetration in PNH and/or GA, 2) clarity around reports of rare events of occlusive retinal vasculitis following Syfovre injection, 3) less-than-expected neovascularization event in GA in real-world use, 34) faster-than-expected uptake of peg' in GA, and 5) positive data from other complement-related indications, such as C3G, and CAD.

Downside risks to our PO are 1) higher-than-expected neovascularization or occlusive retinal vasculitis events in GA in real-world setting, 2) better-than-expected results from competitors, 3) delay or failure to obtain regulatory approval, and 4) failure to expand into other complement-related indications.

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
	PepGen Inc	PEPG	PEPG US	Tazeen Ahmad
	Prothena Corporation	PRTA	PRTA 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
	SAGE Therapeutics	SAGE	SAGE US	Tazeen Ahmad
UNDERPERFORM				
	Achilles Therapeutics	ACHL	ACHL US	Tazeen Ahmad
	Fate Therapeutics	FATE	FATE US	Tazeen Ahmad

US - Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	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

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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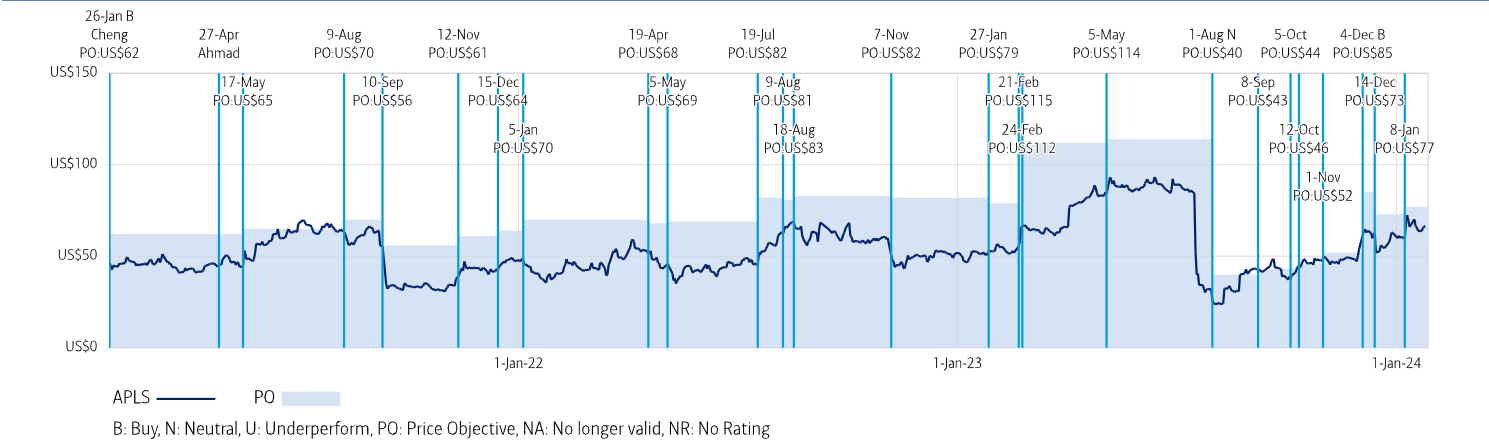
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Apellis (APLS) Price Chart



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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%

^{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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