

Apellis Pharmaceuticals

Update suggests safety events still rare but further color needed; Move to Neutral

Rating Change: NEUTRAL | PO: 40.00 USD | Price: 25.75 USD

ORV rates remain low; clarity needed on long-term use

At a medical meeting (ASRS), APLS provided an update on a still rare number of cases of occlusive retinal vasculitis (ORV), which causes temporary or permanent vision loss, following Syfovre injection in patients with geographic atrophy (GA). The company reported 7 confirmed cases (4 occlusive, 3 non-occlusive) plus one not confirmed case. Note ASRS committee reported slightly higher (8 plus 3 not confirmed). So far, 68K vials have been distributed and the company estimates ~60K injections. The updated data indicates trends are in line with what our several KOL checks in the last two weeks would consider acceptable. We adopt more conservative estimates as we wait to see how physicians change Syfovre use. Our doctor checks indicate doctors will need a couple quarters to monitor ORV rates. As such we move to Neutral with \$40 PO. We emphasize, however, that the situation remains in flux and any positive changes to sales trends in coming weeks could lead to upside to our estimates.

No manufacturing issues found but cause still unclear

Management reported that no manufacturing issues have been identified, including potential contaminants like endotoxins. APLS reiterated the events were not related to a single manufacturing lot. Review of the clinical trial data re-confirmed that no cases of ORV were seen and there was no indication of immunogenicity to the drug. Our KOLs highlighted they look for color on these reported cases and whether there are any underlying characteristics in these patients that could have predisposed them to these rare events. Additionally, 30-month data from the GALE showed GA lesion reduction was 39% and 32% with monthly and EOM dosing, respectively, between months 24-30 compared to a projected sham arm further support long-term benefit from Syfovre. We plan to survey physicians to get a better understanding of near-term use.

Assuming a more conservative stance on Syfovre uptake

In our model, we update for 2Q results, cash and share count. Despite the strong initial launch, we expect more moderate use given the recent safety events. We lower our near-term estimates (3Q and 4Q23 sales deceleration to \$40mn/\$30mn, respectively, and 2024 sales to \$159mn (prev. \$393mn) and risk-adj. peak sales estimates to \$2.5bn (prev. \$6bn). We model a \$400mn cash raise in 2024 but note that if sales trends deteriorate more than we expect, additional funding may be needed.

Estimates (Dec) (US\$)	2021A	2022A	2023E	2024E	2025E
EPS	(8.86)	(6.12)	(5.52)	(5.62)	(4.50)
GAAP EPS	(8.86)	(6.15)	(5.53)	(5.63)	(4.51)
EPS Change (YoY)	-93.0%	30.9%	9.8%	-1.8%	19.9%
Consensus EPS (Bloomberg)			(5.35)	(3.15)	0.61
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	NM	NM	NM	NM	NM
GAAP P/E	NM	NM	NM	NM	NM
Dividend Yield	0%	0%	0%	0%	0%
EV / EBITDA*	3.5x	3.1x	3.2x	3.3x	2.9x
Free Cash Flow Yield*	-18.6%	-17.0%	-16.7%	-15.2%	-7.7%

* For full definitions of *IQmethod*SM measures, see page 4.

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Timestamp: 01 August 2023 06:00AM EDT

01 August 2023

Equity

Key Changes

(US\$)	Previous	Current
Inv. Opinion	C-1-9	C-2-9
Inv. Rating	BUY	NEUTRAL
Price Obj.	114.00	40.00
2023E Rev (m)	280.4	269.6
2024E Rev (m)	620.7	386.6
2025E Rev (m)	1,031.9	558.7
2023E EPS	-6.01	-5.52
2024E EPS	-4.45	-5.62
2025E EPS	-0.90	-4.50

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Stock Data

Price	25.75 USD
Price Objective	40.00 USD
Date Established	1-Aug-2023
Investment Opinion	C-2-9
52-Week Range	27.88 USD - 94.75 USD
Mkt Val (mn) / Shares Out (mn)	3,032 USD / 117.7
Average Daily Value (mn)	123.41 USD
BofA Ticker / Exchange	APLS / NAS
Bloomberg / Reuters	APLS US / APLS.OQ
ROE (2023E)	-403.1%
Net Dbt to Eqty (Dec-2022A)	-254.8%
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

APLS: Apellis

ASRS: American society of retinal specialists

EOM: every other month

KOL: Key opinion leader

iQprofileSM Apellis Pharmaceuticals

iQmethodSM – Bus Performance*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Return on Capital Employed	-60.6%	-77.7%	-105.4%	-139.1%	-98.7%
Return on Equity	-371.2%	-353.7%	-403.1%	-410.6%	-197.4%
Operating Margin	-805.7%	-788.4%	-232.5%	-167.8%	-93.2%
Free Cash Flow	(564)	(515)	(507)	(462)	(232)

iQmethodSM – Quality of Earnings*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash Realization Ratio	NM	NM	NM	NM	NM
Asset Replacement Ratio	0x	0x	0x	0x	0x
Tax Rate	NM	NM	NM	NM	NM
Net Debt-to-Equity Ratio	-223.3%	-254.8%	-165.5%	-112.2%	-94.8%
Interest Cover	-40.5x	-25.1x	-25.2x	-24.8x	-19.0x

Income Statement Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Sales	67	75	270	387	559
% Change	-73.4%	13.3%	257.5%	43.4%	44.5%
Gross Profit	67	75	270	387	559
% Change	-73.4%	13.3%	257.5%	43.4%	44.5%
EBITDA	843	957	925	903	1,031
% Change	99.1%	13.6%	-3.4%	-2.4%	14.2%
Net Interest & Other Income	(210)	(57)	(26)	(27)	(28)
Net Income (Adjusted)	(748)	(649)	(653)	(677)	(551)
% Change	-117.0%	13.2%	-0.5%	-3.7%	18.6%

Free Cash Flow Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Net Income from Cont Operations (GAAP)	(746)	(652)	(654)	(678)	(551)
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	-507	-462	-232
% Change	-240.1%	8.7%	1.7%	8.9%	49.7%

Balance Sheet Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash & Equivalents	640	552	379	318	486
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	601	556	742
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	155	174	383
Total Equity & Liabilities	882	759	601	556	742

* For full definitions of iQmethodSM measures, see page 4.

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 Neutral. 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 undermet need. However, we look for more color on long-term of uptake in GA given recent reports of rare safety events that could limit uptake in this large indication.

Stock Data

Average Daily Volume 4,792,651

Quarterly Earnings Estimates

	2022	2023
Q1	-1.42A	-1.56A
Q2	-1.47A	-1.02A
Q3	-1.75A	-1.37E
Q4	-1.48A	-1.52E

Price objective basis & risk

Apellis Pharmaceuticals (APLS)

Our price objective (PO) of \$40 is based on a probability-adjusted net present value (NPV) analysis that includes \$15/share for peg' in PNH and \$34/share for peg' in GA (previously \$105/share) and -\$11/share for pipeline/corporate expenses and cash (previously -\$7/share). 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

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
	Achilles Therapeutics	ACHL	ACHL US	Tazeen Ahmad
	Alnylam Pharmaceuticals	ALNY	ALNY US	Tazeen Ahmad
	Amicus Therapeutics	FOLD	FOLD 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
	Cerevel Therapeutics Holdings, Inc	CERE	CERE US	Tazeen Ahmad
	Denali Therapeutics	DNLI	DNLI US	Tazeen Ahmad
	Galera Therapeutics	GRTX	GRTX US	Tazeen Ahmad
	Inozyme Pharma, Inc.	INZY	INZY US	Tazeen Ahmad
	Neurocrine Biosciences	NBIX	NBIX US	Tazeen Ahmad



US - Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	PepGen Inc	PEPG	PEPG US	Tazeen Ahmad
	Prothena Corporation	PRTA	PRTA US	Tazeen Ahmad
	SAGE Therapeutics	SAGE	SAGE 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
	Annexon Biosciences	ANNX	ANNX US	Tazeen Ahmad
	Apellis Pharmaceuticals	APLS	APLS US	Tazeen Ahmad
	Cyteir Therapeutics	CYT	CYT US	Tazeen Ahmad
	Incyte Corporation	INCY	INCY US	Tazeen Ahmad
	Pyxis Oncology Inc	PYXS	PYXS US	Tazeen Ahmad
	Rhythm Pharmaceuticals	RYTM	RYTM US	Tazeen Ahmad
UNDERPERFORM				
	ADC Therapeutics SA	ADCT	ADCT US	Tazeen Ahmad
	Fate Therapeutics	FATE	FATE US	Tazeen Ahmad
	Fulcrum Therapeutics	FULC	FULC US	Tazeen Ahmad
	Pharvaris	PHVS	PHVS US	Tazeen Ahmad
	Prelude Therapeutics	PRLD	PRLD US	Tazeen Ahmad
	PTC Therapeutics	PTCT	PTCT US	Tazeen Ahmad
RSTR				
	VectivBio AG	VECT	VECT 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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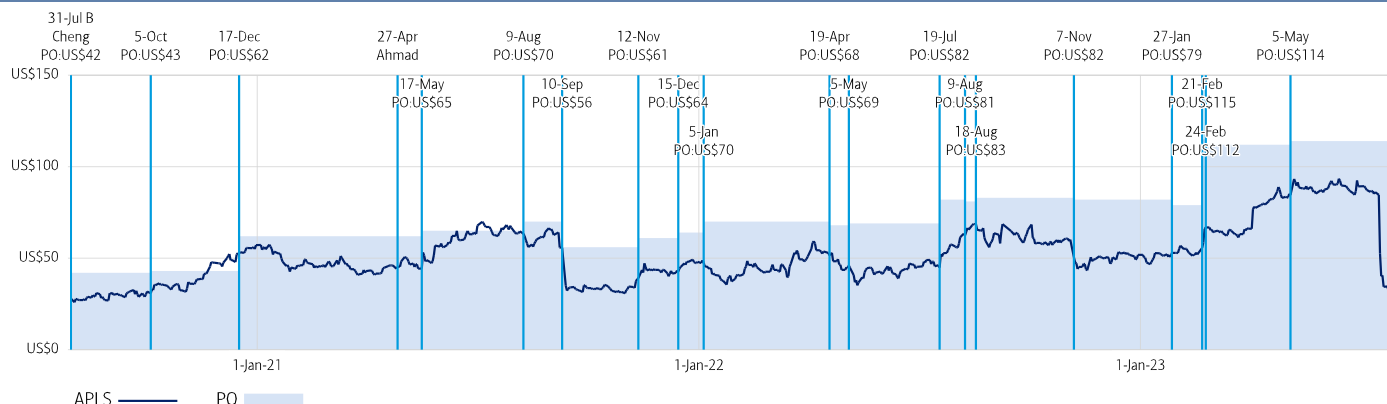
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Important Disclosures

Apellis (APLS) 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 30 Jun 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	Count	Percent
Buy	236	57.84%	Buy	105	44.49%
Hold	87	21.32%	Hold	38	43.68%
Sell	85	20.83%	Sell	22	25.88%

Equity Investment Rating Distribution: Global Group (as of 30 Jun 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	Count	Percent
Buy	1877	53.28%	Buy	1040	55.41%
Hold	815	23.13%	Hold	464	56.93%
Sell	831	23.59%	Sell	385	46.33%

^{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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