

Apellis Pharmaceuticals

ORV update suggests rates remain low and Syfovre demand continues in 3Q

Maintain Rating: NEUTRAL | PO: 40.00 USD | Price: 30.76 USD

Update indicates ORV rate remains low at ~0.01%

Apellis (APLS) provided an update on the events of occlusive retinal vasculitis (ORV) following Syfovre injection and the ongoing investigation. The company highlighted that 8 cases of retinal vasculitis (5 occlusive and 3 non-occlusive) have been confirmed to date. Additionally, APLS noted that >78K vials have been distributed since launch including commercial and sample vials. Importantly, the company noted that >26K vials have been distributed in 3Q. While it is unclear the exact number of injections given since the launch, the rates of ORV remain at ~0.01%, which is in-line with our survey indicated would be a tolerable rate. We view the update positively as it indicates these cases are still rare and demand for Syfovre continues following these observations. We will continue to monitor for updates on ORV rates and demand near-term that could provide upside to our estimates. We also await color on demand dynamics following the J-code in October. We currently model \$40mn for 3Q sales and \$154mn for FY23. We maintain our Neutral with \$40 PO.

Only one more confirmed ORV case since last update

On the reported cases of ORV, management noted one more case was confirmed since the last update and confirmed that all events have occurred after the first Syfovre injection. The company noted that 2 patients experienced severe vision impairment and are unlikely to recover. One patient remained stable at baseline vision and 2 patients recovered nearly back to baseline. The outcome of the remaining 3 patients is still unclear. Additionally, 2 more reported cases have not been confirmed yet. One in which the patient recovered, and another case reported in August.

Potential issue with needle found but cause still unclear

As part of the ongoing investigation, APLS discovered internal structural variations in 19-gauge filter needles distributed with some kits. The company had been distributing kits with 18- or 19-gauge filter needles but is now exclusively distributing kits with 18-gauge filter needles and recommending discontinuing use of 19-gauge filter needles. Importantly, there is no clear causal correlation between a specific type of needle and ORV cases, but we think it is prudent for the company to minimize any variability in the procedure as a safety precaution. We will continue to look for more color on the company's investigation into the cause of these rare events.

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)			(5.04)	(3.82)	(0.77)
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*	4.2x	3.7x	3.8x	3.9x	3.4x
Free Cash Flow Yield*	-15.6%	-14.2%	-14.0%	-12.7%	-6.4%
* For full definitions of <i>IQ</i> method [™] measures, see page 4.					

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Refer to important disclosures on page 5 to 7. Analyst Certification on page 3. Price
Objective Basis/Risk on page 3.

Timestamp: 22 August 2023 07:10PM EDT

22 August 2023

Equity

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Stock Data

 Price
 30.76 USD

 Price Objective
 40.00 USD

 Date Established
 1-Aug-2023

 Investment Opinion
 C-2-9

 52-Week Range
 19.83 USD
 - 94.75 USD

 Mrkt Val (mn) / Shares Out
 3,622 USD / 117.7

 (mn)
 - 94.75 USD

Average Daily Value (mn) 229.07 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™ High

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iQprofile[™] Apellis Pharmaceuticals

(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)
iQmethod [™] – Quality of Earnings*					
(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash Realization Ratio	NM	NM	NM	NM	NM
Asset Replacement Ratio	0x	0x	Ox	0x	Ox
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	2025
Sales	67	75	270	387	559
% Change	-73.4%	13.3%	257.5%	43.4%	44.5%
Gross Profit	67	75	277.570	387	559
% Change	-73.4%	13.3%	257.5%	43.4%	44.5%
9		957	925	903	
EBITDA	843				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
	8	30	30	30	30
Chart Tarm Daht	ŏ				
Short-Term Debt	124		151	166	182
Other Current Liabilities	124	138			00
Other Current Liabilities Long-Term Debt	189	93	93	93	
Other Current Liabilities Long-Term Debt Other Non-Current Liabilities	189 362	93 330	93 172	93 93	54
Other Current Liabilities Long-Term Debt Other Non-Current Liabilities Total Liabilities	189 362 683	93 330 590	93 172 446	93 93 381	93 54 358
Other Current Liabilities Long-Term Debt Other Non-Current Liabilities	189 362	93 330	93 172	93 93	54

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 7,446,974

Quarterly Earnings Estimates

	2022	2023
Q1	-1.42A	-1.56A
Q2	-1.47A	-1.02A
Q3	-1.75A	-1.37E
04	-1.48A	-1.52E

* For full definitions of \emph{IQ} method $^{\text{SM}}$ measures, see page 4.

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 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

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
	Denali Therapeutics	DNLI	DNLIUS	Tazeen Ahmad
	Inozyme Pharma, Inc.	INZY	INZY 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
	Turnstone Biologics	TSBX	TSBX US	Geoff Meacham
	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
	Cerevel Therapeutics Holdings, Inc	CERE	CERE US	Tazeen Ahmad



US - Biotechnology Coverage Cluster

Investment rating	Company	Bof A Ticker	Bloomberg symbol	Analyst
	Cyteir Therapeutics	CYT	CYT US	Tazeen Ahmad
	Incyte Corporation	INCY	INCY US	Tazeen Ahmad
	Pyxis Oncology Inc	PYXS	PYXS US	Tazeen Ahmad
	SAGE Therapeutics	SAGE	SAGE 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

Qmethod [™] Measures Definitions

Business Performance	Numerator	Denominator
Return On Capital Employed	NOPAT = (EBIT + Interest Income) \times (1 - Tax Rate) + Goodwill Amortization	Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill
		Amortization
Return On Equity	Net Income	Shareholders' Equity
Operating Margin	Operating Profit	Sales
Earnings Growth	Expected 5 Year CAGR From Latest Actual	N/A
Free Cash Flow	Cash Flow From Operations — Total Capex	N/A
Quality of Earnings	Numerator	Denominator
Cash Realization Ratio	Cash Flow From Operations	Net Income
Asset Replacement Ratio	Capex	Depreciation
Tax Rate	Tax Charge	Pre-Tax Income
Net Debt-To-Equity Ratio	Net Debt = Total Debt - Cash & Equivalents	Total Equity
Interest Cover	EBIT	Interest Expense
Valuation Toolkit	Numerator	Denominator
Price / Earnings Ratio	Current Share Price	Diluted Earnings Per Share (Basis As Specified)
Price / Book Value	Current Share Price	Shareholders' Equity / Current Basic Shares
Dividend Yield	Annualised Declared Cash Dividend	Current Share Price
Free Cash Flow Yield	Cash Flow From Operations – Total Capex	Market Cap = Current Share Price × Current Basic Shares
Enterprise Value / Sales	EV = Current Share Price × Current Shares + Minority Equity + Net Debt +	Sales
•	Other LT Liabilities	
EV/EBITDA	Enterprise Value	Basic EBIT + Depreciation + Amortization
	•	•

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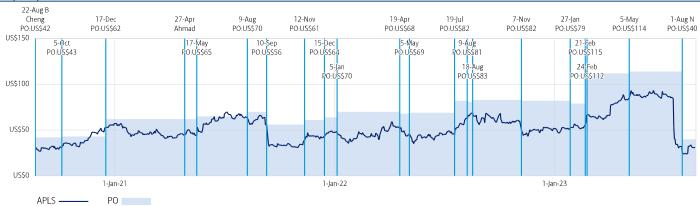
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Apellis (APLS) Price Chart



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%

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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%
Mautual	> O0/₂	< 200/-

 $^{^{}R2} Ratings\ dispersions\ may\ vary\ from\ time\ to\ time\ where\ BofA\ Global\ Research\ believes\ it\ better\ reflects\ the\ investment\ prospects\ of\ stocks\ in\ a\ Coverage\ Cluster.$

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Underperform

≥ 20%

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