

Apellis Pharmaceuticals

FY23 Syfovre revenues beat expectations and highlight strong demand; reiterate Buy

Reiterate Rating: BUY | PO: 77.00 USD | Price: 59.61 USD

Management estimates 95% market share for Syfovre

Apellis (APLS) reported preliminary 4Q23 Syfovre revenue of \$114mn (+52% q/q, ours: \$94mn, consensus: \$87mn), beating estimates, and 4Q23 Empaveli revenue of \$24mn (+1% q/q, ours: \$28mn, consensus: \$29mn). The company highlighted that 62K vials, including commercial and sample vials, were distributed in 4Q, with a total of 160K distributed in 2023 since the launch. Management highlighted that it estimates that 95% of GA patients on treatment are using Syfovre. On the EU regulatory review, the company reiterated that it expects a negative CHMP opinion, which it plans to appeal, with a final EC decision expected in 3Q. Management noted that the focus of the appeal will be on highlighting encouraging microporimetry data and its correlation to functional benefit. We are encouraged by a strong 4Q and clear evidence of continued demand as physicians have grown more confident with the risk/benefit profile of Syfovre. We continue to look for color on the outcome of the EU regulatory process, which if positive could provide upside to our estimates, and additional updates from the pipeline in 2024. We reiterate our Buy rating with a new \$77 PO.

Ph 3 VALIANT data in C3G and IC-MPGN in mid-2024

Management also noted progress with Empaveli in PNH, highlighting 10% of demand coming from treatment-naïve patients in 2023 and the recent approval of the Empaveli injector. The company noted that it sees an attractive commercial opportunity in C3G and IC-MPGN, for which it estimates ~5K patients in the US with no approved therapies. Management highlighted positive ph 2 data from the NOBLE study showing reduction in C3 deposition after 12 weeks, which is not achieved by off-label use of C5 inhibitors. The ph 3 VALIANT study evaluating SC pegcetacoplan in C3G and IC-MPGN is expected to read out in mid-2024. Management also highlighted focus on advancing the early-stage pipeline, with APL-3007 (siRNA) starting dose escalation and updates from the gene editing collaboration with Beam Therapeutics expected in 2024.

Model changes

In our DCF-based model, we roll the quarter and adjust our Syfovre estimates based on the preannouncement and increase our near-term estimates. We now model FY24 Syfovre sales of \$550mn. We also assume a more conservative stance on Empaveli in PNH based on recent trends and increase our pipeline value to \$700mn (from \$450mn) to account for the potential commercial opportunity in C3G and IC-MPGN and progress in the early-stage pipeline. These changes result in our new \$77 PO (previously \$73).

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)			(4.58)	(1.63)	1.07
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	NM	NM	NM	NM	496.8x
GAAP P/E	NM	NM	NM	NM	541.9x
EV / EBITDA*	8.2x	7.2x	7.0x	5.1x	4.3x
Free Cash Flow Yield*	-8.0%	-7.3%	-6.3%	-0.2%	4.7%

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

08 January 2024

Equity

Key Changes

(US\$)	Previous	Current
Price Obj.	73.00	77.00
2023E Rev (m)	349.4	366.3
2024E Rev (m)	657.9	713.9
2025E Rev (m)	1,001.7	1,003.5
2023E EPS	-5.09	-4.98
2024E EPS	-2.32	-1.93
2025E EPS	0.10	0.12

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Stock Data

Price	59.61 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)	7,064 USD / 118.5
Free Float	84.9%
Average Daily Value (mn)	153.05 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™	High

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See inside for abbreviations

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Timestamp: 08 January 2024 03:05PM EST

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 2567,601

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

Abbreviations

C3/5: Complement 3/5

C3G: C3 glomerulopathy

CHMP: Committee for medicinal products for human use

DCF: discounted cash flow

GA: Geographic atrophy

IC-MPGN-: Immune complex mediated membranoproliferative glomerulonephritis

K: thousand

ph: phase

PNH: Paroxysmal nocturnal hemoglobinuria

PO: price objective

SC: subcutaneous

siRNA: silencing RNA

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 encompasses \$15/share for peg' in PNH and \$73/share for peg' in GA and -\$15/share for pipeline/corporate expenses and \$3/share for 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

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

Denominator

Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill Amortization

Shareholders' Equity

Sales

N/A

N/A

Quality of Earnings

Cash Realization Ratio

Asset Replacement Ratio

Tax Rate

Net Debt-To-Equity Ratio

Interest Cover

Numerator

Cash Flow From Operations

Capex

Tax Charge

Net Debt = Total Debt – Cash & Equivalents

EBIT

Denominator

Net Income

Depreciation

Pre-Tax Income

Total Equity

Interest Expense

Valuation Toolkit

Price / Earnings Ratio

Price / Book Value

Dividend Yield

Free Cash Flow Yield

Enterprise Value / Sales

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

Diluted Earnings Per Share (Basis As Specified)

Shareholders' Equity / Current Basic Shares

Current Share Price

Market Cap = Current Share Price × Current Basic Shares

Sales

EV / EBITDA

Basic EBIT + Depreciation + Amortization

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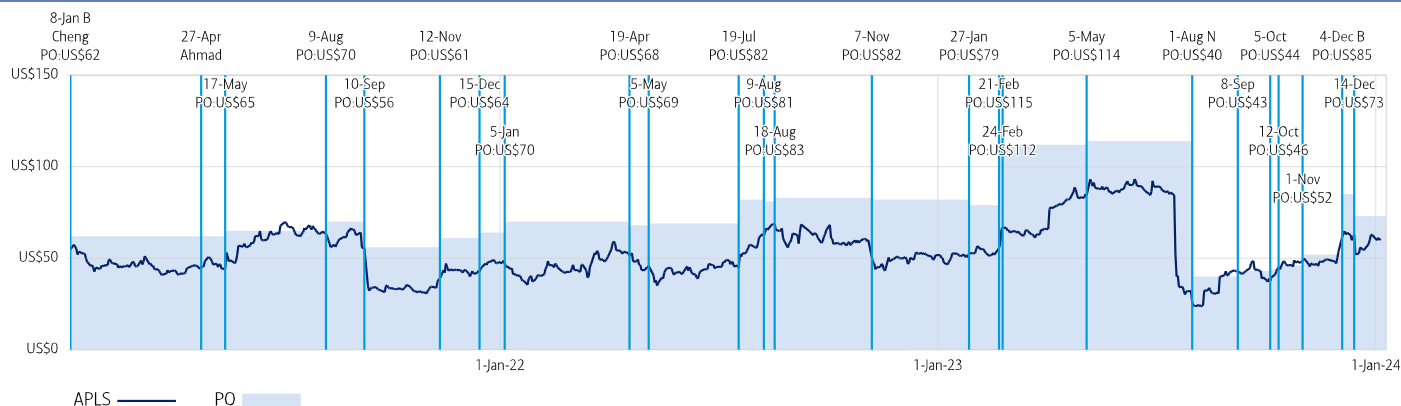
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Apellis (APLS) Price Chart



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 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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