

## Pharvaris

# FDA lifts clinical hold on deucricitibant prophylaxis program; Reiterate U/P

Reiterate Rating: UNDERPERFORM | PO: 13.00 USD | Price: 27.29 USD

## Several risk factors remain despite clinical hold resolution

PHVS announced the FDA has lifted the clinical hold on the IND evaluating deucricitibant as an oral prophylaxis HAE treatment. Recall, the program has been on clinical hold since August 2022 with the company recently submitting a 26-wk rodent toxicology study to the FDA around YE23. Despite the US clinical hold, PHVS continued to progress the program ex-US and reported out positive ph 2 CHAPTER-1 data in December (see our [initial takes](#)). On next steps, mgmt guides to requesting an end-of-phase 2 meeting with the FDA to ensure alignment on key elements of the planned ph 3 CHAPTER-3 study. While we are encouraged by the lifting of the US clinical hold (and knew it was a matter of when, not if), we maintain our view that the ph 3 trial results will still need validation given HAE therapies historically see a much higher treatment effect in ph 2 studies than in ph 3 given the smaller trial size and lower patient variability. We also note the company plans to initiate the ph 3 study using their extended-release formulation, which we think adds additional risk for a different clinical profile to emerge (ph 2 evaluated the IR formulation). We highlight the HAE space continues to be one of the more crowded rare disease markets with clinical competitor Ionis Pharmaceuticals (ticker: IONS; covered by Jason Gerberry) today announcing their ph 3 prophylaxis program met its primary endpoint of reduction in rate of HAE attacks (full readout expected at an upcoming medical congress). We note we continue to assume that most pts will go for the most efficacious drug regardless of how it is dosed. We reiterate our Underperform with new \$13 PO (prev. \$11; see model changes) and will speak with doctors to get updated views on where they see this therapy fitting in versus other HAE therapies, such as BCRX's currently approved oral Orladeyo.

## Changes to our DCF-based model

We increase our LoS for the prophylaxis program to 40% (prev. 30%) given the resolution of the US clinical hold. We look for updated company guidance on program timelines after the end-of-phase 2 meeting and continue to assume a 2027/2028 EU launch. We now model peak risk-adjusted sales for prophylactic deucricitibant of \$225mn (nominal: \$563mn) in 2034. We also slightly tweak operating expenses in line with trend. These changes result in a \$2 increase to our PO.

Estimates (Dec) (EUR)	2021A	2022A	2023E	2024E	2025E
EPS	(1.40)	(2.26)	(2.13)	(2.18)	(2.30)
EPS Change (YoY)	73.9%	-61.4%	5.8%	-2.3%	-5.5%
Consensus EPS (Bloomberg)			(2.25)	(2.07)	(2.45)
DPS	0	0	0	0	0
Valuation (Dec)					
Free Cash Flow Yield*	-4.3%	-5.8%	-6.0%	-7.0%	-8.4%

\* For full definitions of *IQmethod*<sup>SM</sup> measures, see page 5.

22 January 2024

### Equity

#### Key Changes

(EUR)	Previous	Current
Price Obj.	US\$11.00	US\$13.00
2025E EPS	-2.27	-2.30

**Tazeen Ahmad**  
Research Analyst  
BofAS  
+1 646 855 4236  
[tazeen.ahmad@bofa.com](mailto:tazeen.ahmad@bofa.com)

**Daniel Giraldo**  
Research Analyst  
BofAS  
[daniel.giraldoperez@bofa.com](mailto:daniel.giraldoperez@bofa.com)

**Jeremiah Lorentz**  
Research Analyst  
BofAS  
[jeremiah.lorentz@bofa.com](mailto:jeremiah.lorentz@bofa.com)

### Stock Data

Price	27.29 USD
Price Objective	13.00 USD
Date Established	22-Jan-2024
Investment Opinion	C-3-9
52-Week Range	6.02 USD - 29.80 USD
Mkt Val (mn) / Shares Out (mn)	1,226 USD / 44.9
Free Float	75.8%
Average Daily Value (mn)	5.61 USD
BofA Ticker / Exchange	PHVS / NAS
Bloomberg / Reuters	PHVS US / PHVS.OQ
ROE (2023E)	-45.0%
Net Dbt to Eqty (Dec-2022A)	-108.3%
ESGMeter™	Low

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See page 3 for abbreviations

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Timestamp: 22 January 2024 11:48AM EST

# iQprofile<sup>SM</sup> Pharvaris

## iQmethod<sup>SM</sup> – Bus Performance\*

(EUR Millions)	2021A	2022A	2023E	2024E	2025E
Return on Capital Employed	-32.4%	-43.9%	-45.9%	-38.1%	-36.4%
Return on Equity	-28.4%	-43.1%	-45.0%	-37.9%	-36.8%
Operating Margin	NA	NA	NA	NA	NA
Free Cash Flow	(45)	(67)	(66)	(79)	(95)

## iQmethod<sup>SM</sup> – Quality of Earnings\*

(EUR Millions)	2021A	2022A	2023E	2024E	2025E
Cash Realization Ratio	NM	NM	NM	NM	NM
Asset Replacement Ratio	1.7x	0.8x	1.0x	1.1x	1.4x
Tax Rate	NM	0.9%	0.8%	0.7%	0.6%
Net Debt-to-Equity Ratio	-102.1%	-108.3%	-106.1%	-105.3%	-105.1%
Interest Cover	NA	NA	NA	NA	NA

## Income Statement Data (Dec)

(EUR Millions)	2021A	2022A	2023E	2024E	2025E
Sales	0	0	0	0	0
% Change	NA	NA	NA	NA	NA
Gross Profit	0	0	0	0	0
% Change	NA	NA	NA	NA	NA
EBITDA	(54)	(87)	(97)	(113)	(132)
% Change	-116.3%	-60.1%	-12.4%	-15.8%	-17.4%
Net Interest & Other Income	11	11	11	11	11
<b>Net Income (Adjusted)</b>	<b>(43)</b>	<b>(76)</b>	<b>(86)</b>	<b>(101)</b>	<b>(120)</b>
<b>% Change</b>	<b>-64.3%</b>	<b>-78.8%</b>	<b>-12.1%</b>	<b>-17.8%</b>	<b>-19.3%</b>

## Free Cash Flow Data (Dec)

(EUR Millions)	2021A	2022A	2023E	2024E	2025E
Net Income from Cont Operations (GAAP)	(43)	(75)	(86)	(101)	(120)
Depreciation & Amortization	0	0	0	0	0
Change in Working Capital	1	8	2	2	2
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	(3)	0	17	20	23
Capital Expenditure	0	0	0	0	0
<b>Free Cash Flow</b>	<b>-45</b>	<b>-67</b>	<b>-66</b>	<b>-79</b>	<b>-95</b>
<b>% Change</b>	<b>-107.6%</b>	<b>-50.4%</b>	<b>1.4%</b>	<b>-18.7%</b>	<b>-20.6%</b>
Share / Issue Repurchase	144	9	150	150	150
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	0	0	0	0	0

## Balance Sheet Data (Dec)

(EUR Millions)	2021A	2022A	2023E	2024E	2025E
Cash & Equivalents	209	162	245	317	372
Trade Receivables	1	0	0	0	0
Other Current Assets	2	5	5	5	5
Property, Plant & Equipment	0	0	0	0	0
Other Non-Current Assets	0	0	0	0	0
<b>Total Assets</b>	<b>212</b>	<b>168</b>	<b>251</b>	<b>323</b>	<b>378</b>
Short-Term Debt	0	0	0	0	0
Other Current Liabilities	7	18	19	21	23
Long-Term Debt	0	0	0	0	0
Other Non-Current Liabilities	0	1	1	1	1
<b>Total Liabilities</b>	<b>7</b>	<b>18</b>	<b>20</b>	<b>22</b>	<b>24</b>
<b>Total Equity</b>	<b>205</b>	<b>149</b>	<b>231</b>	<b>300</b>	<b>353</b>
<b>Total Equity &amp; Liabilities</b>	<b>212</b>	<b>168</b>	<b>251</b>	<b>323</b>	<b>378</b>

\* For full definitions of iQmethod<sup>SM</sup> measures, see page 5.

## Company Sector

Biotechnology

## Company Description

Pharvaris (PHVS) is a clinical-stage biotechnology company developing oral bradykinin B2 receptor antagonists. Its lead programs are in early development as acute on-demand treatment and prophylaxis option in hereditary angioedema (HAE). The company is also evaluating potential expansion to other opportunities, such as allergy and immunology, cardiovascular, neurology, and others.

## Investment Rationale

We rate PHVS an Underperform. We believe its bradykinin B2 receptor antagonist approach is a well-validated mechanism in HAE, based on prior precedence set by approved Firazyr in the acute setting. We look for additional validation for its pipeline assets in HAE near term and its differentiation from others in the competitive landscape.

## Stock Data

Average Daily Volume 205,416

## Quarterly Earnings Estimates

	2022	2023
Q1	-0.48A	-0.67A
Q2	-0.38A	-0.63A
Q3	-0.25A	-0.67A
Q4	-0.61A	-0.71E

## Abbreviations

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FDA: Food and Drug Administration

HAE: hereditary angioedema

IND: investigational new drug

LoS: likelihood-of-success

Mgmt: management

Ph: phase

Pts: patients

Wk: week

## Price objective basis & risk

### Pharvaris (PHVS)

Our \$13 PO is based on our DCF-based valuation with \$10/sh assigned to HAE programs in both prophylaxis and acute on-demand settings. The remainder of our valuation comes from pipeline and corporate expenses, and cash. Our assumptions are based on 12% WACC for the acute on-demand program and prophylaxis program, 6% COGS, 15-20% GTN, and 10%-20% peak penetrations in target indications.

Upside risks to our price objective are: 1) positive data and additional validation in HAE, 2) superior efficacy or safety profile compared to standard of care or other competitors in the pipeline, 3) pipeline expansion to other indications outside of HAE.

Downside risks are: 1) failure to show efficacy in HAE, 2) unexpected side effect, 3) inferior efficacy or safety profile compared to standard of care or other competitors, and 4) competitors entry in HAE.

## Analyst Certification

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<b>BUY</b>				
	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
<b>NEUTRAL</b>				
	Acadia Pharmaceuticals	ACAD	ACAD US	Tazeen Ahmad
	Incyte Corporation	INCY	INCY US	Tazeen Ahmad
	SAGE Therapeutics	SAGE	SAGE US	Tazeen Ahmad
<b>UNDERPERFORM</b>				
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	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

## iQmethod<sup>SM</sup> 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 &amp; 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

Basic EBIT + Depreciation + Amortization

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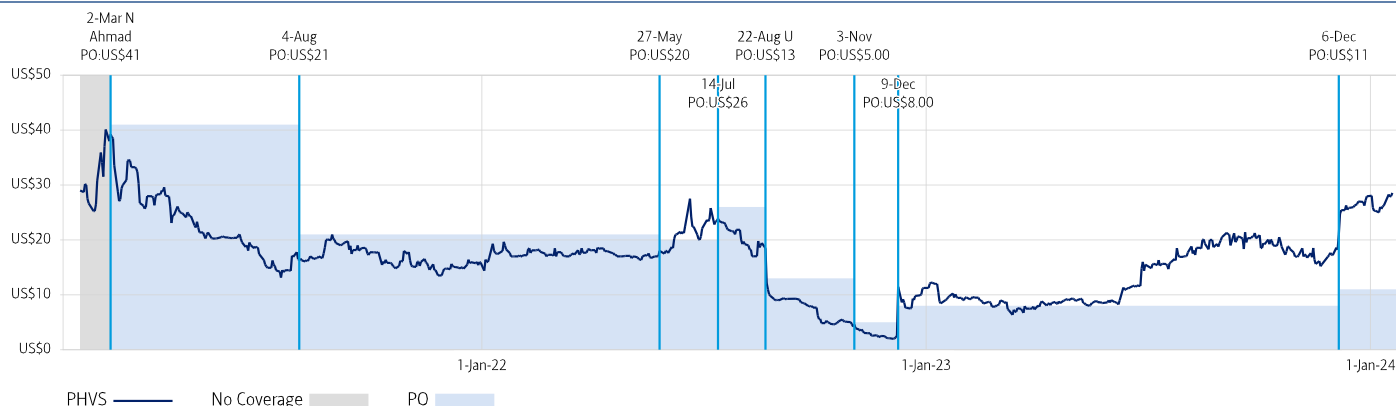
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### Pharvaris (PHVS) Price Chart



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.

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Coverage Universe	Count	Percent	Inv. Banking Relationships <sup>R1</sup>	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%

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Coverage Universe	Count	Percent	Inv. Banking Relationships <sup>R1</sup>	Count	Percent
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Hold	832	23.54%	Hold	454	54.57%
Sell	807	22.84%	Sell	383	47.46%

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