

## 4D Molecular Therapeutics, Inc.

# Ph 2 PRISM data helps us see wet AMD market better; Reit. Buy with new \$82 PO

Reiterate Rating: BUY | PO: 82.00 USD | Price: 28.24 USD

## New data suggests oppy for fewer injections

FDMT, a biotechnology company developing gene therapies with a focus on ophthalmology indications, reported positive ph 2 data from the PRISM study for 4D-150 in wAMD (progressive eye disease resulting in vision loss). The results suggest significant clinical benefit, clean safety profile, which has been a key point of debate around wAMD gene therapies, and positive readthrough to next in development DME program. We raise our LoS to 50% (from 15%) and now estimate \$2.8bn in risk-adjusted peak sales (prev. \$842mn) for 4D-150 in wAMD, contributing \$62/sh to our PO. We reiterate our Buy rating with \$82 PO (prev. \$33; see inside for model changes).

## Ph 2 data support clinically meaningful efficacy/safety

At 6 months, 63% of patients at the highest dose (3E10 vg/eye) were injection free and had 89% reduction in annualized anti-VEGF injection rate – which could help gain share in a crowded market of chronically delivered injections. We note the trial enrolled a severe patient population with ~10 mean annualized anti-VEGF injections and 442µm CST at baseline. Our KOLs had mentioned they would see an 80% reduction in annualized injection rate and 50% injection freedom at 6 months as clinically meaningful. We think these data suggest a competitive risk-benefit profile combined with intravitreal delivery, which our KOLs have noted would be preferred over other methods and facilitate uptake. We await ph 2 data from the population expansion cohort (N=32) evaluating 4D-150 in less severe wAMD pts in 2H and the interim ph 2 data in DME in 2H, which could significantly increase the commercial opportunity for 4D-150.

## Ph 1 update suggests long-term durability and safety

PRISM enrolled 50 wAMD pts into 2 dose cohorts of 4D-150, 3E10vg/eye (N=20) and 1E10vg/eye (N=20), and one aflibercept 2mg Q8W arm (N=10). BCVA remained stable in all cohort suggesting noninferiority of 4D-150 to aflibercept. Additionally, the high dose cohort showed CST stability through month 6 compared to high variability in the aflibercept arm. Importantly, only one instance of 1+ anterior mixed cells was reported at a single timepoint at the lowest dose, which resolved by the next visit. An update on the ph 1 trial showed 3 pts at the highest dose remained injection free for up to 2 years while maintaining a clean safety profile. We think these initial results are supportive of durability of efficacy and long-term safety, but we will continue to monitor for longer term follow-up in a larger number of patients.

## Ph 3 study in wAMD expected to initiate in 1Q25

FDMT commented the 3E10vg/eye dose was selected for ph 3 and they plan to conduct a non-inferiority trial vs aflibercept 2mg Q8W. They expect to enroll a broad wAMD population with ~225 pts per arm and will provide an update in 3Q following engagement with regulators and initiate the ph 3 program in 1Q25.

Estimates (Dec) (US\$)	2021A	2022A	2023E	2024E	2025E
EPS	(2.57)	(3.32)	(2.65)	(3.18)	(4.44)
EPS Change (YoY)	70.9%	-29.2%	20.2%	-20.0%	-39.6%
DPS	0	0	0	0	0
Valuation (Dec)					
Free Cash Flow Yield*	-5.2%	-6.6%	-5.5%	-9.8%	-15.2%

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

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Timestamp: 07 February 2024 04:38PM EST

07 February 2024

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### Stock Data

Price	28.24 USD
Price Objective	82.00 USD
Date Established	7-Feb-2024
Investment Opinion	C-1-9
52-Week Range	9.44 USD - 35.61 USD
Mkt Val (mn) / Shares Out (mn)	1,495 USD / 52.9
Free Float	94.0%
Average Daily Value (mn)	32.64 USD
BofA Ticker / Exchange	FDMT / NAS
Bloomberg / Reuters	FDMT US / FDMT.QQ
ROE (2023E)	-41.6%
Net Dbt to Eqty (Dec-2022A)	-21.5%
ESGMeter <sup>TM</sup>	Low

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](#)".

### See inside for abbreviations

# iQprofile<sup>SM</sup> 4D Molecular Therapeutics, Inc.

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

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Return on Capital Employed	-20.9%	-33.0%	-35.0%	-45.2%	-61.4%
Return on Equity	-24.8%	-39.1%	-41.6%	-52.9%	-71.4%
Operating Margin	-395.5%	-3,516.5%	-548.1%	NA	NA
Free Cash Flow	(78)	(98)	(82)	(146)	(227)

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

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash Realization Ratio	NM	NM	NM	NM	NM
Asset Replacement Ratio	6.0x	4.8x	0.8x	0.8x	0.8x
Tax Rate	NM	NM	NM	NM	NM
Net Debt-to-Equity Ratio	-47.6%	-21.5%	-61.1%	-75.7%	-76.2%
Interest Cover	NA	NA	NA	NA	NA

## Income Statement Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Sales	18	3	21	0	0
% Change	32.5%	-82.7%	562.9%	-100.0%	NA
Gross Profit	18	3	21	0	0
% Change	32.5%	-82.7%	562.9%	NM	NA
EBITDA	(70)	(108)	(111)	(178)	(261)
% Change	-26.4%	-54.2%	-3.4%	-59.8%	-46.6%
Net Interest & Other Income	0	3	10	11	11
<b>Net Income (Adjusted)</b>	<b>(71)</b>	<b>(107)</b>	<b>(104)</b>	<b>(170)</b>	<b>(252)</b>
<b>% Change</b>	<b>-25.8%</b>	<b>-50.7%</b>	<b>3.7%</b>	<b>-63.8%</b>	<b>-48.5%</b>

## Free Cash Flow Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Net Income from Cont Operations (GAAP)	(71)	(107)	(104)	(170)	(252)
Depreciation & Amortization	2	2	2	2	2
Change in Working Capital	(15)	(1)	0	0	0
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	15	19	21	23	25
Capital Expenditure	(9)	(12)	(2)	(2)	(2)
<b>Free Cash Flow</b>	<b>-78</b>	<b>-98</b>	<b>-82</b>	<b>-146</b>	<b>-227</b>
<b>% Change</b>	<b>-50.7%</b>	<b>-25.5%</b>	<b>16.4%</b>	<b>-78.2%</b>	<b>-54.8%</b>
Share / Issue Repurchase	114	0	129	276	200
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	153	52	165	286	254
Trade Receivables	0	0	0	0	0
Other Current Assets	103	168	92	81	71
Property, Plant & Equipment	14	22	22	21	21
Other Non-Current Assets	83	19	18	16	15
<b>Total Assets</b>	<b>353</b>	<b>262</b>	<b>297</b>	<b>404</b>	<b>361</b>
Short-Term Debt	1	3	2	2	2
Other Current Liabilities	15	13	13	13	13
Long-Term Debt	0	0	0	0	0
Other Non-Current Liabilities	18	15	15	15	15
<b>Total Liabilities</b>	<b>34</b>	<b>31</b>	<b>30</b>	<b>30</b>	<b>30</b>
<b>Total Equity</b>	<b>319</b>	<b>231</b>	<b>267</b>	<b>374</b>	<b>331</b>
<b>Total Equity &amp; Liabilities</b>	<b>353</b>	<b>262</b>	<b>297</b>	<b>404</b>	<b>361</b>

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

## Company Sector

Biotechnology

## Company Description

4D Molecular Therapeutics (FDMT) is a clinical-stage biotechnology company developing next-generation gene therapies using proprietary evolved vectors for indications in ophthalmology, cardiology, and pulmonology. The platform has demonstrated encouraging proof of concept in non-human primates, and could deliver best-in-class gene therapies in multiple indications. Clinical assets 4D-125, 4D-310, and 4D-110 are nearing initial data that will potentially validate the platform in humans.

## Investment Rationale

We rate FDMT shares Buy. We believe its evolved vector platform is highly differentiated and has multiple advantages over existing gene therapies. Preclinical data demonstrated the ability of their proprietary vectors to deliver genes to target tissues in an efficient and safe manner. We see the potential for their therapies to shift the treatment paradigm in target indications. Early-stage assets offer potential upside to its valuation.

## Stock Data

Average Daily Volume 1,155,761

## Quarterly Earnings Estimates

	2022	2023
Q1	-0.82A	-0.88A
Q2	-0.87A	-0.77A
Q3	-0.79A	-0.24A
Q4	-0.85A	-0.82E

## Model changes

In our DCF-based model, we roll the quarter and increase our likelihood of success (LoS) for 4D-150 in wAMD to 50% (prev. 15%). We also increase our US peak penetration estimates to 10% (prev. 5%) as we think the data is supportive of broader uptake. We lower the WACC for the program to 12% (prev. 14%) and assume gross-to-net of 20% based on management commentary. We also increase the LoS for 4D-150 in diabetic macular edema (DME) to 25% (prev. 10%) as we think there is direct positive readthrough from positive data in wAMD to this program. We push our launch estimates in wAMD to 2028 (prev. 2027) and DME to 2029 (prev. 2028) based on current estimated timelines for the phase 3 program. We also update cash and share count based on the recent \$300mn public offering. These changes result in our new \$82 PO (prev. \$33).

## Abbreviations

CST: Central subfield thickness

DME: diabetic macular edema

FDMT: 4D Molecular Therapeutics

KOL: Key opinion leader

Oppy: opportunity

ph: phase

pts: patients

Q8W: Every 8 weeks

VEGF: vascular endothelial growth factor

vg: viral genomes

WACC: weighted average cost of capital

wAMD: wet age-related macular degeneration



## Price objective basis & risk

### 4D Molecular Therapeutics, Inc. (FDMT)

Our price objective (PO) of \$82 is based on a probability-adjusted NPV analysis. Our valuation includes 4D-310 in Fabry (\$2/share), 4D-150 in wet age-related macular degeneration (\$63/share) and in diabetic macular edema (\$10/share), and 4D-710 in cystic fibrosis (\$5/share). The remainder of our valuation comes from pipeline and cash. Our discounted cash flow (DCF)-based model goes out to 2040, with 12-14% WACC for all stand-alone indications, 14% WACC for pipeline expenses, and no terminal value.

Upside risks to our PO are 1) positive clinical results in ongoing studies, 2) accelerated timeline to approval, 3) superior market penetration to our current assumptions, and 4) advances of the early-stage pipeline into the clinic.

Downside risks to our PO are 1) failure to demonstrate safety and efficacy in clinical trials, 2) lower than expected market uptake, 3) delays in manufacturing scale-up, and 4) approval of competing products.

## Analyst Certification

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Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
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	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
	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
	Prothena Corporation	PRTA	PRTA US	Tazeen Ahmad
	SAGE Therapeutics	SAGE	SAGE US	Tazeen Ahmad
<b>UNDERPERFORM</b>				
	Achilles Therapeutics	ACHL	ACHL US	Tazeen Ahmad
	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

US - Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst

iQmethod<sup>SM</sup> 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

$$\text{NOPAT} = (\text{EBIT} + \text{Interest Income}) \times (1 - \text{Tax Rate}) + \text{Goodwill Amortization}$$
  
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  
$$\text{EV} = \text{Current Share Price} \times \text{Current Shares} + \text{Minority Equity} + \text{Net Debt} + \text{Other LT Liabilities}$$
  
Enterprise Value

Denominator

$$\text{Total Assets} - \text{Current Liabilities} + \text{ST Debt} + \text{Accumulated Goodwill Amortization}$$
  
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  
$$\text{Market Cap} = \text{Current Share Price} \times \text{Current Basic Shares}$$
  
Sales  
  
Basic EBIT + Depreciation + Amortization

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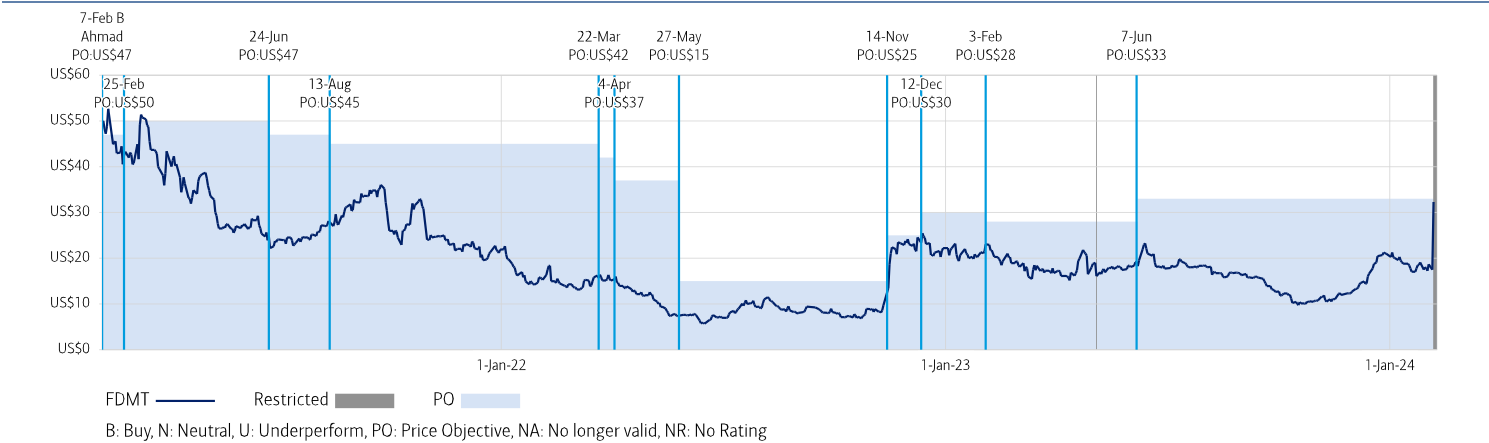
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### 4D Molecular (FDMT) Price Chart



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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%

### Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships <sup>R1</sup>	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 <sup>R2</sup>
Buy	≥ 10%	≤ 70%
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