

4D Molecular Therapeutics, Inc.

4D-310 update in Fabry disease suggests long-term clinical benefit; Maintain Buy

Maintain Rating: BUY | PO: 82.00 USD | Price: 28.63 USD

NHP data to support R/S regimen to be submitted in 2Q

4D Molecular Therapeutics (FDMT) presented an update on the INGLAXA phase 1/2 trial evaluating 4D-310 in Fabry disease at WORLDSymposium. The update included data from 6 patients treated with the prophylactic corticosteroid immunosuppressive regimen. Recall, the company is currently exploring a protocol amendment to use a rituximab/sirolimus (R/S) immunosuppressive regimen after 3 cases of aHUS (atypical hemolytic uremic syndrome) were observed resulting in a clinical hold. Improvements across several cardiac endpoints were seen in 5 evaluable patients including global longitudinal strain (contractility assessment), peak VO₂ (cardiopulmonary exercise testing) and cardiac quality of life. Cardiac biopsy data from one patient also suggested robust and durable transgene expression in cardiac tissue. Importantly, no new safety signals were reported and all aHUS events have fully resolved. The company plans to submit data from a non-human primate (NHP) study to support the protocol amendment to use the R/S regimen and restart enrollment. In our view, '310's cardiac targeting could address Fabry-related cardiomyopathy, which remains an unmet need with current enzyme replacement therapy, and is differentiated from other gene therapy approaches. However, we note '310 is a minor contributor to our valuation (\$2/sh) and we see wet age-related macular degeneration as the key commercial opportunity. We are encouraged by continued signs of clinical benefit and await further color on next steps for the program. We maintain our Buy with \$82 PO.

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%
Consensus EPS (Bloomberg)			(2.61)	(2.95)	(3.14)
DPS	0	0	0	0	0
Valuation (Dec)					
Free Cash Flow Yield*	-5.2%	-6.5%	-5.4%	-9.7%	-15.0%

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

12 February 2024

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Stock Data

Price	28.63 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
Mrkt Val (mn) / Shares Out (mn)	1,515 USD / 52.9
Free Float	94.0%
Average Daily Value (mn)	41.76 USD
BofA Ticker / Exchange	FDMT / NAS
Bloomberg / Reuters	FDMT US / FDMT.OQ
ROE (2023E)	-41.6%
Net Dbt to Eqty (Dec-2022A)	-21.5%
ESGMeter™	Low

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iQprofileSM 4D Molecular Therapeutics, Inc.

iQmethodSM – 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)

iQmethodSM – 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
Net Income (Adjusted)	(71)	(107)	(104)	(170)	(252)
% Change	-25.8%	-50.7%	3.7%	-63.8%	-48.5%

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)
Free Cash Flow	-78	-98	-82	-146	-227
% Change	-50.7%	-25.5%	16.4%	-78.2%	-54.8%
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
Total Assets	353	262	297	404	361
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
Total Liabilities	34	31	30	30	30
Total Equity	319	231	267	374	331
Total Equity & Liabilities	353	262	297	404	361

* For full definitions of iQmethodSM 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 1,492,333

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



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

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
	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
	Ocular Therapeutix	OCUL	OCUL 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
NEUTRAL				
	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
UNDERPERFORM				
	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

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

$\text{NOPAT} = (\text{EBIT} + \text{Interest Income}) \times (1 - \text{Tax Rate}) + \text{Goodwill Amortization}$

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

$\text{EV} = \text{Current Share Price} \times \text{Current Shares} + \text{Minority Equity} + \text{Net Debt} +$

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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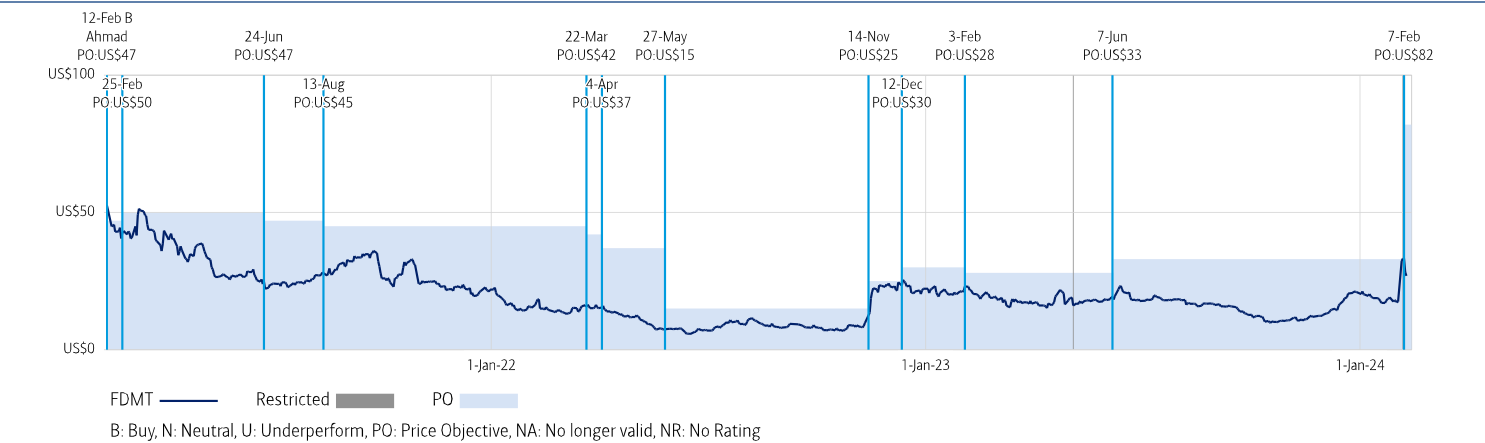
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4D Molecular (FDMT) Price Chart



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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%

^{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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