UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 08, 2024

4D Molecular Therapeutics Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39782**	**47-3506994**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
5858 HORTON STREET #455 EMERYVILLE, California		**94608**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 510 505-2680

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	FDMT	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On August 8, 2024, 4D Molecular Therapeutics, Inc. ("4DMT") announced its financial results for the three months ended June 30, 2024. A copy of 4DMT's press release, titled "4DMT Reports Second Quarter 2024 Financial Results and Operational Highlights" is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated August 8, 2024, titled "4DMT Reports Second Quarter 2024 Financial Results and Operational Highlights"
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

4D MOLECULAR THERAPEUTICS, INC.

Date: August 8, 2024

By: /s/ Uneek Mehra

Uneek Mehra
Chief Financial and Business Officer

Exhibit 99.1

4DMT Reports Second Quarter 2024 Financial Results and Operational Highlights

- *Announced positive interim results from the Population Extension cohort of the Phase 2 PRISM clinical trial for 4D-150 in a broad wet age-related macular degeneration (wet AMD) population, which includes patients representative of the planned Phase 3 study population, affirming favorable safety profile and robust clinical activity*
- *Strengthened senior leadership team and announced formation of a world class Ophthalmology Advisory Board to drive late-stage development of 4D-150 in wet AMD and diabetic eye diseases*
- *PRISM Phase 1/2 interim data, which includes longest available follow-up in patients with severe disease activity (Dose Exploration and Expansion) and broad disease activity (Population Extension), are expected to be presented at the 24th EURETINA Congress on September 19, 2024*
- *In conjunction with the EURETINA presentation, the Company will host a virtual 4D-150 Development Day to discuss the PRISM interim data and final Phase 3 design in wet AMD with details to be announced ahead of the event*
- *U.S. Food and Drug Administration (FDA) removed clinical hold on the Phase 1/2 INGLAXA study for 4D-310 in Fabry disease cardiomyopathy; enrollment expected to resume in H2 2024*
- *$578 million in cash and equivalents as of June 30, 2024, expected to fund operations into H1 2027*

EMERYVILLE, Calif., August 8, 2024 (GLOBE NEWSWIRE) -- 4D Molecular Therapeutics (Nasdaq: FDMT, 4DMT or the Company), a leading clinical-stage genetic medicines company focused on unlocking the full potential of genetic medicines to treat large market diseases, today reported second quarter 2024 financial results, provided operational highlights and outlined expected upcoming milestones.

“4DMT continues to drive strong progress and execution toward our goal of becoming a leading late-stage genetic medicines company. We are excited to bolster our senior leadership team with clinical and commercial experts and honored to welcome world-renowned retinal disease experts to our Ophthalmology Advisory Board, which will support our strategy to be a leader in large market ophthalmology indications,” said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. “At our inaugural 4D-150 Development Day in September 2024, we plan to report on the durability of 4D-150 by presenting the longest available follow-up data from the Phase 2 PRISM study in wet AMD patients who have been followed through up to 2.5 years and discuss the final wet AMD Phase 3 clinical trial design.”

Recent Corporate Highlights

- **Bolstered Senior Leadership Team:**
  - Dhaval Desai, PharmD, joined as Chief Development Officer; will oversee late-stage product development, Medical Affairs, Scientific Communications, Regulatory and Quality operations. Dr. Desai was most recently SVP & Chief Development Officer at Iveric Bio (an Astellas company) where he led development and approval of IZERVAY™
  - Christopher Simms named Chief Commercial Officer, effective September 25, 2024; will oversee Pre-commercial and Commercial organizations and pre-launch preparations and development. Mr. Simms was most recently SVP & Chief Commercial Officer at Iveric Bio (an Astellas company) where he led commercial strategy and execution for the launch of IZERVAY

- Carlos Quezada-Ruiz, M.D., FASRS, joined as SVP, Therapeutic Area Head, Ophthalmology; will lead the Ophthalmology franchise and oversee early- and late-stage clinical development. Dr. Quezada-Ruiz was most recently Group Medical Director, Ophthalmology at Genentech where he led clinical development and approval of VABYSMO and SUSVIMO

- **Formation of Ophthalmology Advisory Board** comprised of world-renowned retina specialists and thought leaders to support development strategy and registration across large market ophthalmology indications including wet AMD, DME, diabetic retinopathy and geographic atrophy: Dr. Arshad Khanani (Chair), Dr. David Boyer, Dr. Frank Holz, Dr. Anat Loewenstein, Dr. Dante Pieramici

Recent Highlights in Large Market Ophthalmology Portfolio

- **4D-150 for wet AMD & DME (Data cutoff: June 24, 2024):**
  - 4D-150 continues to be safe and well tolerated in 139 patients treated to date across wet AMD (PRISM clinical trial) and DME (SPECTRA clinical trial)
    - No significant inflammation reported in 51 patients treated to date with planned Phase 3 dose (3E10 vg/eye) and topical corticosteroid regimen
    - Overall rate of mild (Grade 1) inflammation ~2%; previously reported episode of mild to moderate inflammation in low dose patient (1E10 vg/eye) determined by Principal Investigator to be not related to 4D-150
  - Presented initial interim 24-week landmark data from the Population Extension cohort of the PRISM Phase 2 Clinical Trial at the American Society of Retina Specialists (ASRS) Annual Scientific Meeting in July:
    - Two loading doses of aflibercept at Week -1 and Week 4 are consistent with loading regimens seen in earlier lines of treatment of wet AMD to maintain patient safety during ramp up of aflibercept transgene expression over 8-12 weeks
    - Robust reduction in anti-VEGF injection treatment burden demonstrated in 30 patients treated with planned Phase 3 dose (3E10 vg/eye) with 89% reduction in annualized injection rate; 93% of patients received 0 or 1 injection and 77% were injection-free
    - Improvement in mean best corrected visual acuity (BCVA) from baseline at 3E10 vg/eye dose (+4.2 letters)
    - 3E10 vg/eye dose demonstrated sustained and greater anatomic control without fluctuations
- **4D-175 for Geographic Atrophy:**
  - Received FDA clearance of Investigational New Drug (IND) application for 4D-175

Recent Highlights in Other Pipeline Programs

- **4D-710 for Cystic Fibrosis (CF) Lung Disease:**
  - Positive interim data from Phase 1/2 AEROW clinical trial of aerosolized 4D-710 for modulator-ineligible/-intolerant cystic fibrosis presented at 47th European Cystic Fibrosis Conference in June:
    - Aerosolized 4D-710 was well tolerated at doses up to 1E15 vg (n=6)
    - Clinically meaningful improvements in ppFEV$_1$ at 12 months observed in 2 of 3 trial participants with mild to moderate baseline lung function impairment (ppFEV$_1$50-80%) and >6 months follow up

        - Dose-dependent and widespread 4D-710-mediated CFTR transgene RNA and protein expression observed in all lung biopsies from all trial participants evaluated to date
        - Pre-existing AAV immunity cross-reactive with A101 did not affect transgene expression, biological activity or safety
        - 1E15 vg dose cleared for evaluation in Phase 2 Dose Expansion cohort
- **4D-310 for Fabry Disease Cardiomyopathy:**
    - FDA removed clinical hold on the Phase 1/2 INGLAXA study for 4D-310 in Fabry disease cardiomyopathy

Expected Upcoming Milestones in Large Market Ophthalmology

- **4D-150 for Wet AMD:**
    - Interim longest available follow up data up to 2.5 years from its Phase 1/2 PRISM clinical trial evaluating intravitreal 4D-150 in wet AMD are expected to be presented at the 24thEURETINA Congress on September 19, 2024:
        - **Severe disease activity:** Phase 1 Dose Exploration cohort, Phase 2 Dose Expansion cohort
        - **Broad disease activity (which includes patients representative of the planned Phase 3 study population):** Phase 2 Population Extension cohort
    - 52-week landmark analyses for both 1) severe disease activity (Dose Expansion) & 2) broad wet AMD disease activity (Population Extension) cohorts of PRISM expected in February 2025 (last patient, last visit January 2025)
    - First Phase 3 clinical trial initiation expected in Q1 2025
- **4D-150 for DME:**
    - Interim data from SPECTRA Phase 2 Part 1 Dose Confirmation cohort (n=22) expected in Q4 2024
- **Virtual 4D-150 Development Day Planned in September 2024:**
    - Company will host a Corporate Webcast during which senior leadership and key opinion leaders will review clinical data from the PRISM clinical trial and final wet AMD Phase 3 clinical trial design
    - Participating key opinion leaders and details regarding the webcast will be provided in advance of the event
- **4D-175 for Geographic Atrophy:**
    - Phase 1 enrollment expected to begin in H2 2024

Expected Upcoming Milestones in Other Pipeline Programs

- **4D-710 for CF Lung Disease:**
    - Interim data update from AEROW clinical trial is expected in mid-2025
    - Phase 3 initiation is expected in H2 2025
- **4D-725 for Alpha-1-Antitrypsin Deficiency Lung Disease:**
    - Program update expected in Q4 2024
- **4D-310 for Fabry Disease Cardiomyopathy:**

- Resume enrollment in H2 2024 with program update expected in 2025

- **4D-110 for Choroideremia and 4D-125 for X-Linked Retinitis Pigmentosa:**
  - Program updates expected in Q4 2024

Q2 2024 Financial Results

Cash and Cash Equivalents and Marketable Securities: Cash and cash equivalents and marketable securities were $578 million as of June 30, 2024, as compared to $299 million as of December 31, 2023. The net increase in cash was primarily a result of cash inflows from approximately $316 million of net proceeds from our public offering of common stock completed in February including partial exercise of underwriters' option to purchase additional shares. We currently expect cash and cash equivalents to be sufficient to fund operations into the first half of 2027.

R&D Expenses: Research and development expenses were $31.9 million for the second quarter of 2024, as compared to $23.6 million for the second quarter of 2023. This increase was driven by the progression of our existing clinical trials, primarily Phase 2 4D-150 trials in wet AMD and DME, along with increased payroll and stock-based compensation expense due to higher headcount.

G&A Expenses: General and administrative expenses were $10.6 million for the second quarter of 2024, as compared to $8.8 million for the second quarter of 2023.

Net Loss: Net loss was $35.0 million for the second quarter of 2024, as compared to net loss of $29.6 million for the second quarter of 2023.

About 4DMT

4DMT is a leading clinical-stage genetic medicines company focused on unlocking the full potential of genetic medicines to treat large market diseases in ophthalmology and pulmonology. 4DMT's proprietary invention platform, Therapeutic Vector Evolution, combines the power of the Nobel Prize-winning technology, directed evolution, with approximately one billion synthetic AAV capsid-derived sequences to invent customized and evolved vectors for use in our wholly owned and partnered product candidates. Our product design, development, and manufacturing engine helps us efficiently create and advance our diverse product pipeline with the goal of revolutionizing medicine with potential curative therapies for millions of patients. Currently, 4DMT is advancing six clinical-stage and one preclinical product candidate, each tailored to address rare and large market diseases in ophthalmology, pulmonology and cardiology. In addition, 4DMT is also advancing programs in CNS through a gene editing partnership. 4D Molecular Therapeutics™, 4DMT™, Therapeutic Vector Evolution™, and the 4DMT logo are trademarks of 4DMT.

All of our product candidates are in clinical or preclinical development and have not yet been approved for marketing by the U.S. Food and Drug Administration (FDA) or any other regulatory authority. No representation is made as to the safety or effectiveness of our product candidates for the therapeutic uses for which they are being studied.

Learn more at www.4DMT.com and follow us on LinkedIn.

Forward Looking Statements:

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding the therapeutic potential and clinical benefits of, as well as the plans, announcements and related timing for the clinical development of, 4DMT's product candidates, and statements regarding our financial performance, results of operations and anticipated cash runway. The words "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including risks and uncertainties that are described in greater detail in the section entitled "Risk Factors" in 4D Molecular Therapeutics' most recent Quarterly Report on Form 10-Q to be filed on or about the date hereof, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent 4D Molecular Therapeutics' views only as of today and should not be relied upon as representing its views as of any subsequent date. 4D Molecular Therapeutics explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

4D Molecular Therapeutics, Inc.
Statements of Operations
(Unaudited)
(*in thousands, except share and per share amounts*)

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Revenue:				
Collaboration and license revenue	$ 5	$ 239	$ 33	$ 538
Operating expenses:				
Research and development	31,860	23,584	59,727	46,002
General and administrative	10,601	8,791	20,898	16,777
Total operating expenses	42,461	32,375	80,625	62,779
Loss from operations	(42,456)	(32,136)	(80,592)	(62,241)
Other income, net	7,503	2,520	13,238	3,943
Net loss	$ (34,953)	$ (29,616)	$ (67,354)	$ (58,298)
Net loss per share, basic and diluted	$ (0.63)	$ (0.77)	$ (1.29)	$ (1.63)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	55,282,754	38,335,219	52,277,369	35,661,995

4D Molecular Therapeutics, Inc.
Balance Sheet Data
(Unaudited)
(*in thousands*)

	June 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 577,661	$ 299,186
Working capital	533,230	277,637
Total assets	620,117	339,891
Total liabilities	31,777	32,062
Accumulated deficit	(482,681)	(415,327)
Total stockholders' equity	588,340	307,829

Contacts:

Media:

Katherine Smith
Inizio Evoke Comms
Katherine.Smith@inizioevoke.com

Investors:

Julian Pei
Head of Investor Relations and Corporate Communications
Investor.Relations@4DMT.com