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): May 09, 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 May 9, 2024, 4D Molecular Therapeutics, Inc. ("4DMT") announced its financial results for the three months ended March 31, 2024. A copy of 4DMT's press release, titled "4DMT Reports First 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 May 9, 2024, titled "4DMT Reports First 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: May 9, 2024

By: /s/ Uneek Mehra

Uneek Mehra
Chief Financial and Business Officer

Exhibit 99.1

4DMT Reports First Quarter 2024 Financial Results and Operational Highlights

- *Announced positive interim data from PRISM Phase 2 Dose Expansion cohort evaluating 4D-150 in wet AMD patients with severe disease activity and high treatment burden enabling advancement into Phase 3 expected by Q1 2025*
- *Interim 24-week landmark analysis from PRISM Phase 2 Population Extension cohort evaluating 4D-150 in broader wet AMD population expected to be presented at the American Society of Retina Specialists (ASRS) Annual Scientific Meeting on July 17-20, 2024*
- *Interim clinical data from Phase 1/2 AEROW clinical trial expected to be presented at the European Cystic Fibrosis Society (ECFS) Conference on June 5-8, 2024*
- *Announced positive interim data for 4D-310 in Fabry disease cardiomyopathy, demonstrating durable responses on cardiac endpoints and promising cardiac biopsy results*
- *Completed upsized public follow-on offering with total gross proceeds of $337 million; $589 million in cash and equivalents as of March 31, 2024 expected to fund operations into H1 2027*

EMERYVILLE, Calif., May. 9, 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 first quarter 2024 financial results and provided operational highlights.

“The first quarter of 2024 kicks off another transformative year for 4DMT with exceptional progress across our product pipeline and platform in multiple therapeutic areas, particularly our lead program 4D-150 in large market VEGF-driven retinal diseases,” said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. “With robust clinical activity from 4D-150 demonstrated in our initial interim 24-week results from the Phase 2 PRISM Dose Expansion cohort in the severe disease activity wet AMD patient population, we set the stage for additional important data readouts in 2024, including 24-week results from the Phase 2 PRISM Population Extension cohort in the broader wet AMD patient population expected to be announced at ASRS in July and 24-week results from the Phase 2 SPECTRA Dose Confirmation cohort in DME expected to be announced in the fourth quarter. We believe the emerging profile of 4D-150 shows its potential to be the best-in-class, long-acting genetic medicine for broad market use in VEGF-driven retinal diseases, and we look forward to completing alignment with the FDA and EMA to rapidly advance 4D-150 into its first pivotal trial for global development. Building on the success of intravitreal R100, we are also encouraged by the preclinical results from 4D-175 that we shared today at the 2024 Association for Research in Vision and Ophthalmology (ARVO) Annual Scientific Meeting and are looking forward to bringing the program into the clinic for treatment of geographic atrophy in the second half of the year, demonstrating the power of our modular vectors and product engine. In addition, we continue to advance towards important milestones for 4D-710 for cystic fibrosis, 4D-725 for A1AT deficiency and 4D-310 for Fabry disease cardiomyopathy. Our successful financing puts us in a strong position to execute on all our corporate objectives, with expected cash runway into the first half of 2027.”

Recent Highlights in Large Market Ophthalmology Portfolio

- **4D-150 for Wet Age-Related Macular Degeneration (wet AMD):**
  - Rapidly advanced intravitreal 4D-150 for wet AMD in the Phase 2 PRISM clinical trial
    - Randomized Dose Expansion cohort (N=51) in patients with severe disease activity and high treatment burden presented at Angiogenesis, Exudation, and Degeneration 2024 Conference in February (data cutoff January 19, 2024):

- Favorable safety profile demonstrated, with no significant or recurrent intraocular inflammation, and no 4D-150–related serious adverse events (SAEs) or study eye SAEs; All patients were off steroids
- At 24 weeks, high dose of 4D-150 (3E10 vg/eye) resulted in robust reductions in overall treatment burden of 89%, percent of patients with 0-1 injections of 84%, percent of patients injection-free of 63%, plus improved retinal anatomical control vs. the aflibercept control arm

▪ Durable responses demonstrated beyond one year in Phase 1 3E10 vg/eye dose cohort, with three patients injection-free through 80–104 weeks (up to 2 years) of follow-up

o Announced preliminary pivotal Phase 3 clinical trial design with additional regulatory interactions with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) under RMAT (Regenerative Medicine Advanced Therapy) and PRIME (Priority Medicines) designations underway

o Successfully completed the qualified person (QP) inspection of our GMP manufacturing facilities and operations resulting in issuance of a QP Declaration enabling distribution of investigational medicinal products (IMP) in the EU territories

- **4D-175 for Geographic Atrophy:**

o Preclinical data for 4D-175 for geographic atrophy presented in an oral presentation at the 2024 ARVO Annual Scientific Meeting in May:

▪ Short-form complement factor H (sCFH) transgene-derived protein showed functional activity consistent with wild type full-length CFH in*in vitro*experiments

▪ Dose-dependent transgene expression and inhibition of alternative complement pathway by 4D-175 demonstrated in human retinal pigment epithelium (RPE) cells

▪ Intravitreal administration of 4D-175 to non-human primates (NHP) was safe and well tolerated and resulted in robust transgene expression in the retina and RPE/choroid, resulting in sCFH levels above target therapeutic concentrations in the aqueous humor

▪ Presentation can be found on our website under Scientific Presentations

Recent Highlights in Pulmonology Portfolio

- **4D-710 for Cystic Fibrosis (CF) Lung Disease:**

o Nine patients dosed to-date in Phase 1/2 AEROW clinical trial across four dose levels (range of 2.5E14 to 2E15 vg)

o Conducted initial pivotal study interactions with the FDA and EMA; Company has clear registration path for 4D-710 for treatment of cystic fibrosis (CF) lung disease in people with CF who are ineligible for or cannot tolerate approved CF modulator therapies

o Completed in-house process development of a suspension Good Manufacturing Practice (GMP) ready manufacturing process for 4D-710 at 500 liter scale for the pivotal study

Recent Highlights in Cardiology Portfolio

- **4D-310 for Fabry Disease Cardiomyopathy:**

o Interim clinical and biopsy data from Phase 1/2 INGLAXA clinical trials presented in the late-breaking session at WORLD*Symposium*™ 2024 in February:

▪ 4D-310 demonstrated clinically meaningful improvements on multiple cardiac endpoints through 12-24 months in five evaluable patients

        - Cardiac biopsies from one patient at week 6 and 24 showed robust and durable delivery, transgene expression and clearance of Gb3 substrate in cardiomyocytes
        - Safety and tolerability profile maintained; previously reported cases of atypical hemolytic uremic syndrome (aHUS) (n=3) have fully resolved

Expected Upcoming Milestones

- **4D-150 for Wet AMD:**
    - Phase 2 PRISM Population Extension cohort (N=32) in the broader wet AMD patient population:
        - Initial interim 24-week landmark analysis expected to be presented at the ASRS Annual Scientific Meeting on July 17-20, 2024
    - Phase 3 planning:
        - Update on Phase 3 clinical trial design expected in Q3 2024
        - First Phase 3 clinical trial initiation expected in Q1 2025
- **4D-150 for DME:**
    - Phase 2 SPECTRA clinical trial Dose Confirmation cohort (N=22):
        - Initial interim 24-week landmark analysis expected in Q4 2024
- **4D-175 for Geographic Atrophy:**
    - IND filing expected in Q2 2024
    - Phase 1 initiation expected in H2 2024
- **4D-710 for CF Lung Disease:**
    - Phase 1/2 AEROW clinical trial interim clinical data expected at the ECFS Conference on June 5-8, 2024, including safety, lung biomarker and clinical activity data on all nine patients dosed across four dose level cohorts
        - Phase 2 Expansion cohort dose selection expected to be shared in conjunction with interim data at ECFS
    - Phase 3 pivotal trial initiation expected in H2 2025
- **4D-725 for Alpha-1-Antitrypsin (A1AT) Deficiency Lung Disease:**
    - Program update expected in 2024
- **4D-310 for Fabry Disease Cardiomyopathy:**
    - FDA submission of preclinical NHP safety data in combination with rituximab/sirolimus immunosuppression regimen expected in Q2 2024
- **4D-110 for Choroideremia and 4D-125 for X-Linked Retinitis Pigmentosa:**
    - Program updates expected in 2024

Q1 2024 Financial Results

Cash and Cash Equivalents and Marketable Securities: Cash and cash equivalents and marketable securities were $589 million as of March 31, 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 $27.9 million for the first quarter of 2024, as compared to $22.4 million for the first quarter of 2023. This increase was driven by the progression of our existing clinical trials, primarily 4D-150 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 $10.3 million for the first quarter of 2024, as compared to $8.0 million for the first quarter of 2023.

*Net Loss:*Net loss was $32.4 million for the first quarter of 2024, as compared to net loss of $28.7 million for the first 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 five clinical-stage and two preclinical product candidates, 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®, 4D®, 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 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.comand 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 March 31,	
	2024	**2023**
Revenue:		
Collaboration and license revenue	$ 28	$ 298
Operating expenses:		
Research and development	27,870	22,412
General and administrative	10,294	7,992
Total operating expenses	38,164	30,404
Loss from operations	(38,136)	(30,106)
Other income, net	5,735	1,424
Net loss	$ (32,401)	$ (28,682)
Net loss per share, basic and diluted	$ (0.66)	$ (0.88)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	49,271,984	32,723,530

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

	March 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 588,853	$ 299,186
Working capital	519,186	277,637
Total assets	629,884	339,891
Total liabilities	29,323	32,062
Accumulated deficit	(447,728)	(415,327)
Total stockholders' equity	600,561	307,829

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