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): February 08, 2025

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 8.01 Other Events

On February 8, 2025, 4D Molecular Therapeutics, Inc. (the "Company") reported positive initial interim 52-week data from the Phase 2b Population Extension cohort of the PRISM clinical trial evaluating 4D-150 in a broad wet age-related macular degeneration ("wet AMD") patient population. Additional data were provided on the durability of aflibercept expression for up to two years.

Topline 52-Week Efficacy Results for 4D-150 3E10 vg/eye (Planned Phase 3 Dose) from Phase 2b Population Extension Cohort of PRISM (Data Cut-Off January 15, 2025):

- Phase 2b (n=30): Broad Wet AMD Disease Activity
  - *Supplemental aflibercept injections:*
    - 83% reduction, representing 0.97 mean supplemental injections per patient over 52-weeks vs. 6.0 injections projected with on-label aflibercept 2 mg Q8W
    - 70% 0-1 injection
    - 57% injection-free
  - Improved and maintained best corrected visual acuity ("BCVA") of +2.2 letters
  - Durable central subfield thickness ("CST") improvement with fewer fluctuations, as measured by optical coherence tomography ("OCT"), of -11 µm; -13 µm in supplemental injection-free patients
- Phase 2b (n=15): Recently Diagnosed Subgroup
  - *Supplemental aflibercept injections:*
    - 94% reduction, representing 0.33 mean supplemental injections per patient over 52-weeks vs. 6.0 injections projected with on-label aflibercept 2 mg Q8W
    - 87% 0-1 injection
    - 80% injection-free
  - Improved and maintained BCVA of +3.1 letters
  - Durable CST improvement with fewer fluctuations, as measured by OCT, of -10 µm; -20 µm in supplemental injection-free patients

4D-150 Safety Update from PRISM (Data Cut-Off January 15, 2025):

- 4D-150 continues to be well tolerated during up to three years of follow up in all patients treated with 3E10 vg/eye
  - 2.8% (2 of 71) had 4D-150–related 1+ intraocular inflammation ("IOI") (SUN/NEI scales); transient 1+ vitreous cells noted at a single timepoint, as previously reported
  - 99% (70 of 71) completed steroid prophylaxis taper on schedule
  - 99% (70 of 71) remained completely off steroids
- No 4D-150–related hypotony, endophthalmitis, vasculitis, occlusive/non-occlusive retinal vasculitis, or choroidal effusions observed to date

PRISM Durability Update from All 3E10 vg/eye Cohorts:

- Aqueous humor concentrations were studied serially every three months
- Durable and stable aflibercept expression demonstrated, with up to two years of follow-up, with aqueous humor concentrations consistently within projected therapeutic range

4D-150 Program Milestones:

- 4FRONT-1 and 4FRONT-2 expected to initiate in Q1 and Q3 2025, respectively
- Two-year Phase 1/2a and 18-month Phase 2b PRISM data expected in Q4 2025
- Primary endpoint 52-week topline data from both 4FRONT-1 and 4FRONT-2 expected in H2 2027

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements regarding the Company's clinical development plans for its product candidates, including 4D-150, timing for the announcement of results from ongoing clinical trials, anticipated resource allocations and cash runway, the therapeutic potential, and clinical benefits and market potential of 4DMT's product candidates, as well as the regulatory interactions regarding 4D-150. In some cases you can identify these statements by forward-looking words such as "may," "will," "continue," "anticipate," "intend," "could," "project," "expect" or the negative or plural of these words or similar expressions. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including risks and uncertainties that are described in greater detail in the section entitled "Risk Factors" in the Company's most recent Quarterly Report on Form 10-Q as well as any subsequent filings with the Securities and Exchange Commission. The Company expressly disclaims any intent or obligation to update these forward-looking statements, except as required by law.

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 hereunto duly authorized.

4D MOLECULAR THERAPERUTICS, INC.

Date: February 10, 2025

By: /s/ Uneek Mehra

Uneek Mehra
Chief Financial and Business Officer