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): July 17, 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 Number)**

5858 Horton Street #455
Emeryville, CA 94608
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (510) 505-2680

Not Applicable
(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	The Nasdaq Stock Market LLC

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 July 17, 2024, 4D Molecular Therapeutics, Inc. (the "Company") announced initial interim 24-week landmark data from the Population Extension cohort of its Phase 2 clinical trial ("PRISM"), which evaluated intravitreal 4D-150 in a broad wet age-related macular degeneration ("wet AMD") patient population and provided other updates with respect to 4D-150. The interim data were presented on July 17, 2024 at the American Society of Retina Specialists Annual Scientific Meeting held in Stockholm, Sweden.

Phase 2 PRISM Interim Results for Intravitreal 4D-150 in a Broad Wet AMD and Other 4D-150 Updates

The Population Extension cohort of the Company's Phase 2 clinical trial for wet AMD ("PRISM") is a clinical trial evaluating 4D-150 in patients with broad disease activity and no minimum or maximum central subfield thickness ("CST"), and with patients who had received between one and six anti-VEGF injections in the prior 12 months. The Population Extension enrolled 45 patients at two dose level arms: 30 patients at 3E10 vg/eye (the planned Phase 3 dose) and 15 at 1E10 vg/eye (low dose control). The dose arms enrolled in the cohort were generally well-balanced with mean CST at 329 mm and mean number of actual injections in the prior 12 months was 4.4.

In the Population Expansion cohort, as of the most recent data cutoff date (June 24, 2024), interim results from the trial include the following:

- 4D-150 was safe and well-tolerated at both dose levels as of the most recent data cutoff:
  - Planned Phase 3 Dose (3E10 vg/eye): (i) no anterior chamber inflammation (30 of 30 patients), (ii) no significant vitreous inflammation (30 of 30 patients; trace vitreal cells noted in one patient) and (iii) all 30 patients completed local steroid prophylaxis on schedule and did not resume steroid treatment.
  - Low Dose (1E10 vg/eye): (i) no significant anterior chamber inflammation (15 of 15 patients; trace anterior chamber cells noted in one patient) and (ii) no vitreous inflammation in 14 of 15 patients and one patient with mild to moderate inflammation (1 of 45 total, ~2% overall); vitreous cells also observed in untreated fellow eye.
  - No 4D-150-related serious adverse events ("SAEs") or study eye SAEs were observed.
  - No hypotony, retinal vasculitis, choroidal effusions, retinal artery occlusions were observed.
- 24-week landmark analysis as of the most recent data cutoff date for key efficacy endpoints included the following results:
  - Planned Phase 3 Dose (3E10 vg/eye) demonstrated robust anti-VEGF treatment reduction:
    - 89% reduction in mean annualized injection rate.
    - 93% received 0 or 1 injection.
    - 77% injection-free; dose response evident as compared to 60% on low dose arm.
  - Low Dose (1E10 vg/eye) also demonstrated robust anti-VEGF treatment reduction:
    - 91% reduction in mean annualized injection rate.
    - 100% received 0 or 1 injection.
    - 60% injection-free.

- Visual acuity and retina anatomic outcomes included the following results:
    - Improved mean best corrected visual acuity ("BCVA") in Planned Phase 3 Dose (3E10 vg/eye) arm patients: +4.2 Early Treatment Diabetic Retinopathy Study ("ETDRS") letter improvement from baseline overall, and +4.7 letter improvement observed for injection-free patients.
    - BCVA dose response favored the Planned Phase 3 Dose (3E10 vg/eye) with a +5.7 letter improvement in BCVA versus patients in the low dose arm.
    - CST: sustained and greater anatomic control without fluctuations for the 3E10 vg/eye dose arm; improvement (decrease) in CST from baseline greater in supplemental injection-free patients than in overall population (-32 vs -9 mm).

As of the most recent data cutoff date (June 24, 2024), long-term follow-up results from the Phase 1 clinical trial for 4D-150 include the following:

- All three Phase 1 patients treated with 3E10 vg/eye previously reported as injection-free beyond 52 weeks remained injection-free through approximately 2 to 2.5 years of follow-up.
- Mean BCVA remained unchanged from baseline through approximately 2 years (+1 letter from baseline).
- Mean CST remained stable, without fluctuations, and decreased from baseline through approximately 2 years (-110 microns from baseline).
- Safety results maintained in all 15 patients treated to the cutoff date (up to 2.5 years of follow-up) with no new inflammation and no change in steroid status observed.

As of the most recent data cutoff date (June 24, 2024), overall safety results across wet AMD and diabetic macular edema ("DME") patients treated with 4D-150 include the following:

- 4D-150 continued to have a favorable safety profile and was well tolerated across all patients dosed to-date (n=139) in both PRISM (wet AMD, n=117) and SPECTRA (DME, n=22) clinical trials.
- 51 patients treated in the PRISM and SPECTRA studies at 3E10 vg/eye dose and topical corticosteroid prophylactic regimen had no significant inflammation, hypotony, retinal vasculitis, choroidal effusions, retinal artery occlusions with up to 2.5 years of follow-up; no recurrent inflammation post-steroid taper was observed.
- 22 DME patients treated in the SPECTRA study had no inflammation, hypotony, retinal vasculitis, choroidal effusions, retinal artery occlusions with up to 36-weeks of follow-up; patients completed topical corticosteroid prophylactic regimen on schedule and did not resume steroid treatment.

The Company continues to work with the U.S. Food and Drug Administration and European Medicines Agency, under the RMAT and PRIME designations, to finalize its planned Phase 3 clinical trial design, which the Company expects to announce in September 2024. The Company anticipates the Phase 3 clinical trial will be initiated in the first quarter of 2025.

The Company also expects to release 52-week landmark analysis for both its Dose Expansion cohort (patients with severe disease activity and high treatment burden) and its Population Extension cohort (patients with broad disease activity) in February 2025.

For DME, the Company expects to release an initial 24-week landmark analysis from its SPECRTRA trial's Dose Confirmation cohort in the fourth quarter of 2024.

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 statements regarding the

Company's clinical development plans for 4D-150 and timing for the announcement of results from ongoing clinical trials. 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, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

4D MOLECULAR THERAPEUTICS, INC.

Date: July 17, 2024

By: /s/ Uneek Mehra
Uneek Mehra
Chief Financial and Business Officer