

**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): September 28, 2026

4D Molecular Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39782
(Commission
File Number)

47-3506994
(IRS Employer
Identification No.)

5858 Horton Street #455
Emeryville, California
(Address of Principal Executive Offices)

94608
(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 September 28, 2026, 4D Molecular Therapeutics, Inc. (the “Company”) reported that the first patients have been enrolled across multiple sites in the 4SIGHT Phase 3 clinical trial evaluating 4D-150 for the treatment of diabetic macular edema (“DME”). The Company also reported 2-year data from the SPECTRA clinical trial.

4SIGHT: Phase 3 Trial Design and Regulatory Pathway

4SIGHT is a global Phase 3 multicenter, randomized, double-masked, aflibercept 2 mg (“Q8W”) comparator-controlled trial of intravitreal 4D-150 in treatment-naïve patients with DME (N=514). All patients will receive five aflibercept loading doses. The primary endpoint is non-inferiority in the mean change from baseline in best corrected visual acuity (“BCVA”) at Week 52. The key secondary endpoints are treatment burden reduction, comparing the number of aflibercept injections received in the 4D-150 arm versus the aflibercept comparator arm through Week 52, and the proportion of participants with a ≥ 2 -step improvement from baseline in Early Treatment Diabetic Retinopathy Study Diabetic Retinopathy Severity Scale (“ETDRS-DRSS”) at Week 52. Patients in both arms will be eligible for supplemental aflibercept injections.

Similarly to the 4FRONT Phase 3 wet AMD trials, randomization requires on-trial demonstration of aflibercept responsiveness following the first three of five loading doses during the run-in period (central subfield thickness (“CST”) $\geq 10\%$ reduction and ≤ 400 μm or CST < 315 μm).

4D-150 for DME has U.S. Food and Drug Administration (“FDA”) Regenerative Medicine Advanced Therapy designation, and the Company has alignment with the FDA and the European Medicines Agency on potential Biologics License Application and marketing authorization application filings with the single 4SIGHT Phase 3 DME trial, based on data generated to date for 4D-150 in both the SPECTRA and PRISM clinical trials combined with data from the two Phase 3 clinical trials in the 4FRONT wet AMD program.

2-Year Results from SPECTRA Clinical Trial (Data Cutoff of March 12, 2026):

- Safety Results (N=22):
 - 4D-150 was well tolerated, with no intraocular inflammation at any timepoint
 - No ocular serious adverse events
 - No hypotony, endophthalmitis, vasculitis, choroidal effusions or retinal artery occlusions
 - No progression to proliferative diabetic retinopathy or vitreous hemorrhage
- Clinical Activity Results for Phase 3 Dose (3E10 vg/eye, n=9):
 - Mean gain in BCVA of +10.8 letters
 - Mean reduction in CST of -176 μm , as measured by optical coherence tomography
- Supplemental Injections:
 - Utilized stringent supplemental criteria to maximize patient safety while assessing initial clinical activity
 - Post-aflibercept loading doses (3), patients required substantially fewer injections compared to on-label aflibercept 2mg Q8W:
 - 61% overall treatment burden reduction (5.2 mean supplemental injections per patient vs. 13.0 injections projected with on-label aflibercept 2 mg Q8W)
 - 75% estimated overall treatment burden reduction utilizing 4SIGHT Phase 3 supplemental injection criteria, which are more in line with contemporary Phase 3 trials (3.2 estimated mean supplemental injections per patient vs. 13.0 injections projected with on-label aflibercept 2 mg Q8W; retrospective estimate, actual results in 4SIGHT may differ)
 - 2 of 9 (22%) remained injection-free

Forward-Looking Statements

This Current Report on Form 8-K 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, treatment-burden reduction, durability and clinical benefits of, as well as the plans, announcements and related timing for the clinical development, regulatory interactions, and potential commercialization of our product candidates, including 4D-150. In some cases, you can identify these statements by forward-looking words such as “may,” “will,” “anticipate,” “intend,” “estimate,” “project,” “potential” 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 filed on August 13, 2026, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent the Company’s views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company 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.

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 THERAPEUTICS, INC.

Date: September 28, 2026

By: /s/ Kristian Humer
Kristian Humer
Chief Financial Officer