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 2, 2023

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, CA 94608
(Address of principal executive offices)(Zip Code)

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

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 2, 2023, 4D Molecular Therapeutics, Inc. ("4DMT" or the "Company") reported program updates for 4D-150 for diabetic macular edema and 4D-310 for Fabry disease cardiomyopathy.

4D-150 for Diabetic Macular Edema

4DMT, a clinical-stage biotherapeutics company harnessing the power of directed evolution for targeted genetic medicines, announced FDA clearance of the Investigational New Drug Application ("IND") for 4D-150, an R100 vector-based intravitreal genetic medicine, for the treatment of patients with Diabetic Macular Edema ("DME"). 4D-150 was already in clinical development for patients with wet age-related macular degeneration ("wet AMD") under a separate IND.

The Phase 2 SPECTRA clinical trial is designed to assess 4D-150 in patients with DME. The study design consists of a Dose Confirmation stage followed by a masked Dose Expansion stage, in which patients will be randomized to receive a single intravitreal injection at one of two dose levels of 4D-150 or aflibercept in a 1:1:1 ratio (n=54 patients). The doses to be evaluated in DME are anticipated to be between 6E9 to 3E10 vg/eye. The IND clearance enables the initiation of SPECTRA clinical study sites, and 4DMT expects to begin enrollment in the third quarter of 2023.

Initial Cohort 1 data (n=5) from the Phase 1 portion of the Phase 1/2 PRISM clinical trial with 4D-150 for wet AMD demonstrated a reduction in annualized anti-VEGF injection rate by over 95%, further validating the potential of the Company's intravitreal R100 vector for other large market eye diseases such as geographic atrophy.

On January 9, 2023, 4DMT disclosed that it had initiated the randomized Phase 2 portion of the Phase 1/2 PRISM clinical trial for 4D-150 in patients with wet AMD. This portion of the trial is now enrolling patients. In addition, the Company intends to present interim data for dose Cohorts 1, 2 & 3 (n=15) at the 2023 ARVO Annual Meeting scheduled to be held April 23, 2023 to April 27, 2023. Patients from all three dose Cohorts are anticipated to have at least six months follow-up after 4D-150 treatment at the time of the interim data cut-off.

4D-310 for Fabry Disease Cardiomyopathy

On January 9, 2023, the Company announced that no additional patients will be enrolled in the current 4D-310 Fabry disease clinical trials, and that the program will be evaluated in the second half of 2023 after 12-month clinical data are obtained on all six of the currently enrolled patients, including on-going safety and cardiac endpoints for a potential pivotal trial as recommended by the FDA: peak VO2 (CPET), Quality-of-life (KCCQ) and left ventricular function by global longitudinal strain (echocardiography). The Company also reported 3 instances of atypical hemolytic uremic syndrome (aHUS). Additionally, the Company reported improvements in all cardiac endpoints listed above in patients (n=3) who reached 12 months follow up, and the single available cardiac biopsy was positive for widespread genome delivery and transgene expression from 4D-310.

Consistent with the Company's plans for the program as noted above and as communicated to the FDA, the FDA subsequently notified the Company of a Clinical Hold pursuant to CFR §312.42 (b)(iv). In its notification, the FDA acknowledged the Company's paused enrollment worldwide, directed the Company to continue long term follow up of treated patients under the current IND, and noted that it would provide feedback regarding the 4D-310 trials within 30 days. The IND for 4D-310 remains open and active. The Company intends to present detailed safety, cardiac biopsy and cardiac efficacy data at the WORLD*Symposium* on February 25, 2023.

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 plans for the clinical development and timing of announcements relating to the Company's product candidates 4D-150 and 4D-310. 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 Current Report on Form 8-K 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 Current Report on Form 8-K, 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. 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 thereunto duly authorized.

4D MOLECULAR THERAPEUTICS, INC.

Date: February 2, 2023

By: /s/ August J. Moretti
August J. Moretti
Chief Financial Officer