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): October 10, 2021

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, California 94608
(Address of principal executive offices, including 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**	**The 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 October 10, 2021, 4D Molecular Therapeutics, Inc. ("4DMT") announced interim safety and clinical activity data from the Phase 1/2 clinical trial of intravitreal 4D-125 in patients with advanced X-linked retinitis pigmentosa (XLRP). The interim data were presented on October 10, 2021 in a late-breaking presentation at the American Society of Retina Specialists (ASRS) 39th Annual Meeting.

4D-125 Interim Clinical Data Summary

The data described are from the first-in-human, on-going Phase 1/2 dose escalation and dose expansion clinical trial assessing intravitreal 4D-125, 4DMT's targeted and evolved R100-based product candidate for XLRP. As of the data cutoff date (September 1, 2021), eight patients with clinically advanced XLRP due to RPGR gene mutation had been enrolled. A standard 3+3 dose escalation design was used, followed by a dose expansion cohort. Patients were enrolled in one of three dose cohorts: dose-escalation cohort 1 (3E11 vg/eye; n=3), dose-escalation cohort 2 (1E12 vg/eye n=3) and the dose expansion cohort (1E12vg/eye; n=2 to date). Patients enrolled in the dose escalation cohorts of the first-in-human clinical trial had clinically-advanced XLRP, with patients having limited or no measurable remaining photoreceptor area or retinal sensitivity. As of the data cutoff date, two dose escalation patients (n=1 at 3E11 vg/eye; n=1 at 1E12 vg/eye) were evaluable for clinical activity defined as having both measurable ellipsoid-zone area (EZ Area) by spectral domain optical coherence tomography (SD-OCT) and retinal sensitivity by microperimetry in both the treated and untreated control eye with at least six months follow-up; dose expansion cohort patients (n=2) had not yet reached six months follow-up but are expected to be evaluable with sufficient follow up. On-going enrollment in the dose expansion cohort is expected to enroll patients with less advanced disease than those enrolled in dose escalation, and who we expect to be evaluable for clinical activity based on central reading center confirmation at screening.

Interim Safety Data Summary

- 4D-125 was well-tolerated in all eight XLRP patients, including in five patients at the top dose level of 1E12 vg/eye.
- No dose-limiting toxicities or serious adverse events were observed.
- No chronic inflammation was observed.
- Transient, grade 1+ anterior chamber and/or vitreous cells were observed in two of the eight patients at a single protocol-defined assessment timepoint (SUN[1] & NEI[2] grading scales)
    - One patient had grade 1+ vitreous and anterior chamber cells
    - One additional patient had grade 1+ vitreous chamber cells

Interim Clinical Activity Summary

- In the two dose escalation patients who were evaluable for clinical activity in both the treated and untreated control eyes, interim data from both patients demonstrated anatomical retina preservation as measured by EZ Area progression, a measurement of intact photoreceptors, in the treated eye as compared to the untreated control eye in the same patient. In addition, interim data from both patients demonstrated functional improvements as measured by increases in the mean retinal sensitivity in the treated eye, and a greater number of loci gaining ³ 7 dB sensitivity in the treated eye, as compared to the untreated control eye in the same patient.
    - Patient 3 (3E11 vg/eye cohort – 9 months follow-up): Decreases from baseline EZ Area were -12.4% in the treated eye compared to -16.2% in the untreated control eye (~23% lower relative progression rate). An increase in mean retinal sensitivity was demonstrated, with an increase of +1.65 dB in the treated eye from baseline compared to +0.25 dB in the untreated control eye. The number of loci gaining greater than ³ 7 dB sensitivity were six in the treated eye compared to one in the untreated control eye.
    - Patient 5 (1E12 vg/eye cohort – 6 months follow-up): Decreases from baseline EZ Area were -20.2% in the treated eye compared to -28.7% in the untreated control eye (~30% lower relative progression rate). An increase in mean retinal sensitivity was demonstrated, with an increase of +0.90 dB in the

treated eye from baseline compared to +0.10* dB in the untreated control eye. The number of loci gaining greater than ³ 7 dB sensitivity were three in the treated eye compared to zero in the untreated control eye.

* *note: microperimetry data for this patient's untreated eye were evaluable at 4 months but not available at month 6 due to an inability to fixate with the untreated control eye at that visit.*

1. *Standardization of Uveitis Nomenclature Grading Scheme - SUN Working Group 2005 (Jabs et al., 2005)*
2. *National Eye Institute Grading System for Vitreous Cells - (Mahendradas, Khanna, Kawali, & Shetty, 2014)*

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 4DMT's clinical development plans for 4D-125. 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, but not limited to: the impact of COVID-19 on countries or regions in which 4DMT has operations or does business, as well as on the timing and anticipated results of 4DMT's clinical trials, strategy and future operations; the delay of any current or planned clinical trials for the development of 4DMT's drug candidates, the risk that the results of its clinical trials, including any initial data therefrom, may not be predictive of future clinical trial results, including those from current and future clinical trials; 4DMT's ability to successfully demonstrate the safety and efficacy of its drug candidates; the timing and outcome of 4DMT's planned interactions with regulatory authorities; and obtaining, maintaining and protecting its intellectual property. 4DMT discusses many of these risks in greater detail under the heading "Risk Factors" contained in its quarterly report on Form 10-Q for the quarter ended June 30, 2021, which is on file with the Securities and Exchange Commission. 4DMT 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: October 13, 2021

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