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): May 13, 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 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

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 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 2.02 Results of Operations and Financial Condition.

On May 13, 2021, 4D Molecular Therapeutics, Inc. ("4DMT") announced its unaudited financial results for the quarter ended March 31, 2021. A copy of 4DMT's press release, titled "4D Molecular Therapeutics Reports Financial Results for the First Quarter of 2021 and Provides Operational Highlights," is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated May 13, 2021 titled "4D Molecular Therapeutics Reports Financial Results for the First Quarter of 2021 and Provides Operational Highlights"
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: May 13, 2021

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

Exhibit 99.1

4D Molecular Therapeutics Reports Financial Results for the First Quarter of 2021 and Provides Operational Highlights

Emeryville, CA – May 13, 2021 – 4D Molecular Therapeutics (Nasdaq: FDMT), a clinical-stage gene therapy company harnessing the power of directed evolution for targeted gene therapies, announced financial results for the first quarter of 2021, and provided operational highlights.

“We continue to relentlessly execute and innovate as demonstrated by achievements in our first full quarter as a public company,” said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. “The company remains on track to announce initial clinical data from both our 4D-310 Fabry disease product candidate and our 4D-125 XLRP product candidate in the second half of this year. In addition, we remain on track to initiate clinical trials in the second half of this year for 4D-150, our wet AMD and DME product candidate, and for 4D-710, our cystic fibrosis lung disease product candidate. We also recently expanded our technology platform to include applications of machine learning, and yesterday, at the annual ASGCT conference, we presented preclinical non-human primate data from 4D-150.”

Recent Operational Highlights

- Presented preclinical data from non-human primate (NHP) studies at the American Society for Gene and Cell Therapy (ASGCT) 24th Annual Meeting. For the first-time, 4DMT described the design of 4D-150, a dual transgene, intravitreal gene therapy designed to inhibit four distinct VEGF family members for the treatment of wet age-related macular degeneration (AMD) and diabetic macular edema (DME). Preclinical NHP studies demonstrated significant efficacy in the laser-induced choroidal neovascularization (CNV) model, including complete CNV suppression at the lowest dose of 1E11 vg/eye. In addition, a preclinical acute biodistribution study demonstrated high anti-VEGF levels within the NHP eye, with no evidence of uveitis or retinal abnormality.
- Entered into a collaboration focused on applying machine learning technology to the AAV vector capsid datasets generated from 4DMT’s Therapeutic Vector Evolution platform. This research will be conducted with U.C. Berkeley investigators Jennifer Listgarten, Ph.D and David Schaffer, Ph.D., global leaders in machine learning, computational biology, AAV directed evolution and gene therapy.

Expected Upcoming Milestones

- Initial clinical data from the Phase 1/2 clinical trial of 4D-310 in Fabry disease expected in the second half of 2021
- Initial clinical data from the Phase 1/2 clinical trial of 4D-125 in X-Linked Retinitis Pigmentosa (XLRP) expected in the second half of 2021
- Initiation of a clinical trial with 4D-150 in wet AMD and diabetic macular edema expected in the second half of 2021
- Initiation of a clinical trial with 4D-710 in cystic fibrosis lung disease expected in the second half of 2021

Financial Results for the First Quarter Ended March 31, 2021

Cash and Cash Equivalents: Cash and cash equivalents were $259.9 million as of March 31, 2021. We expect cash and cash equivalents to be sufficient to fund operations into mid-2023.

Revenue: Total revenue was $2.0 million for the quarter ended March 31, 2021, as compared to $3.5 million for the quarter ended March 31, 2020. The decrease was primarily driven by decreased revenue recognized under the Roche collaboration agreement.

R&D Expenses: Research and development expenses were $12.8 million for the quarter ended March 31, 2021, as compared to $13.2 million for the quarter ended March 31, 2020. This decrease was primarily driven by decreased external manufacturing expense, which was partially offset by higher payroll and stock-based compensation expense.

G&A Expenses: General and administrative expenses were $5.5 million for the quarter ended March 31, 2021, as compared to $3.7 million for the quarter ended March 31, 2020. This increase was primarily due to higher payroll and stock-based compensation expense and higher business insurance expense.

Net Loss: Net loss was $16.4 million for the quarter ended March 31, 2021, as compared to $13.2 million for the quarter ended March 31, 2020.

About 4DMT

4DMT is a clinical-stage company harnessing the power of directed evolution for targeted gene therapies. 4DMT seeks to unlock the full potential of gene therapy using its platform, Therapeutic Vector Evolution, which combines the power of directed evolution with approximately one billion synthetic capsid sequences to invent evolved vectors for use in targeted gene therapy products. The company is initially focused in three therapeutic areas: ophthalmology, cardiology, and pulmonology. The 4DMT targeted and evolved vectors are invented with the goal of being delivered through clinically routine, well-tolerated and minimally invasive routes of administration, transducing diseased cells in target tissues efficiently, having reduced immunogenicity and, where relevant, having resistance to pre-existing antibodies. 4DMT is currently conducting three clinical trials: 4D-125 is in a Phase 1/2 clinical trial for XLRP patients, 4D-110 is in a Phase 1 clinical trial for choroideremia patients and 4D-310 is in a Phase 1/2 clinical trial for Fabry disease patients.

Cautionary Note Regarding Forward-Looking Statements

This press release 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 plans and timelines for the clinical development of 4D-310, 4D-125, 4D-110, 4D-150 and 4D-710, including the therapeutic potential and clinical benefits thereof; the estimated timing of clinical data being available for 4D-125's Phase 1/2 clinical trial and 4D-310's Phase 1/2 clinical trial; the estimated timing of initiating the clinical trials for 4D-150 and 4D-710; expectations on how long our cash and cash equivalents can fund operations; expectations regarding current and future interactions with the U.S. Food and Drug Administration (FDA); and 4D Molecular Therapeutics' strategy, business plans and focus. 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 press release 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 press release, including, without limitation, risks associated with: the impact of COVID-19 on countries or regions in which we have operations or do business, as well as on the timing and anticipated results of our clinical trials, strategy and future operations; the delay of any current or planned clinical trials for the development of 4D Molecular Therapeutics' drug candidates, the risk that the results of our clinical trials may not be predictive of future results in connection with future clinical trials; 4D Molecular Therapeutics' ability to successfully demonstrate the safety and efficacy of its drug candidates; the timing and outcome of our planned interactions with regulatory authorities; and obtaining, maintaining and protecting our intellectual property. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in 4D Molecular Therapeutics' most recent Quarterly Report on Form 10-Q to be filed on or about the date hereof, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent 4D Molecular Therapeutics' views only as of today and should not be relied upon as representing its views as of any subsequent date. 4D Molecular Therapeutics 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.

4D-310, 4D-125 and 4D-110 are our product candidates in clinical trials and have not yet been approved for marketing by the US FDA or any other regulatory authority. No representation is made as to the safety or effectiveness of 4D-310, 4D-125, or 4D-110 for the therapeutic use for which they are being studied.

4D Molecular Therapeutics, Inc.
Condensed Statements of Operations and Comprehensive Loss
(Unaudited)
(*in thousands, except share and per share amounts*)

	Three Months Ended March 31,	
	2021	**2020**
Revenue:		
Collaboration and license revenue	$ 2,000	$ 3,411
Collaboration and license revenue, related parties	—	124
Total revenue	2,000	3,535
Operating expenses:		
Research and development	12,769	13,158
General and administrative	5,543	3,654
Total operating expenses	18,312	16,812
Loss from operations	(16,312)	(13,277)
Other income (expense):	(94)	117
Net loss and comprehensive loss	$ (16,406)	$ (13,160)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.61)	$ (2.54)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	26,690,167	5,183,845

4D Molecular Therapeutics, Inc.
Condensed Balance Sheet Data
(Unaudited)
(*in thousands*)

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 259,865	$ 276,726
Working capital	250,585	265,912
Total assets	270,114	288,331
Accumulated deficit	(152,085)	(135,679)
Total stockholders' equity	242,431	256,387

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