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): August 12, 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 August 12, 2021, 4D Molecular Therapeutics, Inc. ("4DMT") announced its unaudited financial results for the quarter ended June 30, 2021. A copy of 4DMT's press release, titled "4D Molecular Therapeutics Reports Financial Results for the Second 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 August 12, 2021 titled "4D Molecular Therapeutics Reports Financial Results for the Second 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: August 12, 2021

By: /s/ August J. Moretti

August J. Moretti
Chief Financial Officer

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

Emeryville, CA – August 12, 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 second quarter of 2021, and provided operational highlights.

“Harnessing the power of directed evolution to develop targeted gene therapies is central to 4DMT, and this past quarter we continued to make substantial progress towards our goal,” said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. “Importantly, we initiated the expansion of our cGMP manufacturing facilities to support commercial-scale production of our clinical product candidates. Notably, we believe we are the first AAV gene therapy company to successfully complete cGMP manufacturing of primate-evolved targeted vectors, and we achieved this milestone with three different clinical product candidates. This achievement underscores the promise of our Therapeutic Vector Evolution platform, which empowers us to invent targeted and evolved vectors that package efficiently during our proprietary manufacturing process. In addition, we enhanced our leadership team with the additions of Carolyne Zimmermann as Chief Business Officer and Nadine Greiner, Ph.D., as Chief Human Resources Officer. We remain on track to announce clinical data from each of our three ongoing clinical programs and to initiate clinical development with product candidates in wet AMD and cystic fibrosis by the end of this year.”

Recent Operational Highlights

- Initiated the expansion of current Good Manufacturing Practices (cGMP) compliant manufacturing facilities and analytical laboratories at 4DMT headquarters in Emeryville, CA to support manufacturing and analytical testing of current and future product candidates. The expanded facility will enable commercial-scale manufacturing of our clinical product candidates and expansion of our analytical development capabilities, including laboratories dedicated for developing potency assays.
- Appointed Carolyne Zimmermann as Chief Business Officer. Ms. Zimmermann brings over 27 years of leadership experience in life sciences corporate and business development, including from her prior roles at Johnson & Johnson Innovation and Novartis Pharmaceuticals.
- Appointed Nadine Greiner, Ph.D. as Chief Human Resources Officer. Ms. Greiner has served as head of human resources for 25 years at organizations including California Pacific Medical Center, the Palo Alto Medical Foundation at Sutter Health, The Institute on Aging, and Bank of America. She holds a dual Ph.D. in Organization Development and Clinical Psychology.
- Updated our rare disease ophthalmologic portfolio: reported positive initial safety data from the Phase 1 clinical trial of 4D-110 in choroideremia and the Phase 1/2 clinical trial of 4D-125 in X-linked retinitis pigmentosa (XLRP) and regained global rights to 4D-110. We expect to report initial clinical activity data from the Phase 1 clinical trial of 4D-110 in choroideremia and the Phase 1/2 clinical trial of 4D-125 in XLRP in the fourth quarter of 2021. We also plan to submit to the FDA safety and efficacy data from the 4D-110 Phase 1 clinical trial along with a new 4D-110 clinical study protocol in the fourth quarter of 2021.

Expected Upcoming Milestones

- Initial clinical data from the Phase 1/2 clinical trial of 4D-310 in Fabry disease expected in the fourth quarter of 2021

- Initial clinical activity data from the Phase 1/2 clinical trial of 4D-125 in XLRP expected in the fourth quarter of 2021
- Initial clinical activity data from the Phase 1 clinical trial of 4D-110 in choroideremia expected in the fourth quarter of 2021
- Initiation of a clinical trial with 4D-150 in wet AMD expected in the fourth quarter of 2021
- Initiation of a clinical trial with 4D-710 in cystic fibrosis lung disease expected in the fourth quarter of 2021

Financial Results for the Second Quarter Ended June 30, 2021

Cash and Cash Equivalents: Cash and cash equivalents were $243.7 million as of June 30, 2021. We expect cash and cash equivalents to be sufficient to fund operations into the second half of 2023.

Revenue: Total revenue was $14.6 million for the quarter ended June 30, 2021, as compared to $3.6 million for the quarter ended June 30, 2020. The increase was primarily driven by increased revenue recognized under the Roche collaboration agreement as a result of adjustments to the transaction price and total budgeted costs due to the termination of the agreement which will become effective in the third quarter of 2021.

R&D Expenses: Research and development expenses were $15.2 million for the quarter ended June 30, 2021, as compared to $15.7 million for the quarter ended June 30, 2020. This decrease was primarily driven by decreased external manufacturing expense, which was partially offset by increased preclinical and clinical trial expense and payroll and stock-based compensation expense.

G&A Expenses: General and administrative expenses were $7.0 million for the quarter ended June 30, 2021, as compared to $3.1 million for the quarter ended June 30, 2020. This increase was primarily due to increased payroll and stock-based compensation expense, business insurance expense and professional service expenses.

Net Loss: Net loss was $7.6 million for the quarter ended June 30, 2021, as compared to $15.2 million for the quarter ended June 30, 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 initial clinical activity data being available for 4D-125's Phase 1/2 clinical trial, initial clinical activity data being available for 4D-110's Phase 1 clinical trial and initial clinical data for 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; whether the expansion of our manufacturing facilities will support commercial-scale production and expand our analytical development capabilities; 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Collaboration and license revenue	$ 14,580	$ 3,508	$ 16,580	$ 6,919
Collaboration and license revenue, related parties	—	125	—	249
Total revenue	14,580	3,633	16,580	7,168
Operating expenses:				
Research and development	15,223	15,720	27,992	28,878
General and administrative	6,953	3,062	12,496	6,716
Total operating expenses	22,176	18,782	40,488	35,594
Loss from operations	(7,596)	(15,149)	(23,908)	(28,426)
Other income (expense):	7	(4)	(87)	113
Net loss and comprehensive loss	$ (7,589)	$ (15,153)	$ (23,995)	$ (28,313)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.28)	$ (2.92)	$ (0.90)	$ (5.46)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	26,739,149	5,183,955	26,715,014	5,183,900

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

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 243,743	$ 276,726
Working capital	238,882	265,912
Total assets	254,934	288,331
Accumulated deficit	(159,674)	(135,679)
Total stockholders' equity	240,646	256,387

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