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 11, 2022

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, California	**94608**
(Address of Principal Executive Offices)	**(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 2.02 Results of Operations and Financial Condition.

On August 11, 2022, 4D Molecular Therapeutics, Inc. ("4DMT") announced its financial results for the quarter ended June 30, 2022. A copy of 4DMT's press release, titled "4D Molecular Therapeutics Reports Second Quarter 2022 Financial Results and Provides 4D-310 Program Update" 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 11, 2022 titled "4D Molecular Therapeutics Reports Second Quarter 2022 Financial Results and Provides 4D-310 Program Update"
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 11, 2022

By: /s/ August J. Moretti

August J. Moretti
Chief Financial Officer

Exhibit 99.1

4D Molecular Therapeutics Reports Second Quarter 2022 Financial Results and Provides 4D-310 Program Update

- *Five clinical-stage product candidates on track for multiple clinical data updates in 2023*
- *Cash, cash equivalents and marketable securities sufficient to fund operations into the first half of 2025*
- *4D-310 Phase 1/2 clinical trial eligible patient population expanded to include females with Fabry disease*

Emeryville, CA – August 11, 2022 – 4D Molecular Therapeutics, Inc. (Nasdaq: FDMT), a clinical-stage biotherapeutics company harnessing the power of directed evolution for targeted genetic medicines, announced second quarter 2022 financial results and provided corporate updates.

"Maintaining our momentum from the first quarter, we have continued to execute on our clinical and corporate milestones, making progress across all of our on-going clinical trials," said David Kirn, M.D., Co-founder, President and Chief Executive Officer of 4DMT. "In addition, the protocol amendment for the 4D-310 Phase 1/2 clinical trial in Fabry disease will expand access for female patients, enable the assessment of an alternative steroid-sparing immune-suppression regimen, and provide investigators the flexibility to enroll patients concurrently across all cohorts. We have maintained our focus on efficient cash utilization and building value across the pipeline. Our team is committed to relentless execution as we make progress toward key clinical data readouts throughout 2023."

Update on 4D-310 Phase 1/2 Clinical Trial for Fabry Disease

- In June 2022, 4DMT filed a protocol amendment with the U.S. Food and Drug Administration (FDA) for the ongoing Phase 1/2 clinical trial of 4D-310 for Fabry disease. The protocol amendment is intended to expand the eligible patient population, including the addition of female Fabry patients, and to examine an alternative, steroid-sparing immune-suppression regimen in a newly added cohort.
- The protocol amendment now also enables investigators to enroll patients concurrently across cohorts. As a result, the 4D-310 Phase 1/2 clinical trial is enrolling patients concurrently across 3 cohorts at the 1E13 vg/kg dose level.
- Per the original protocol, the initial two cohorts are in negative and low neutralizing anti-capsid antibody (NAbs) patient populations and utilize a tapered prednisone immune-suppression regimen administered prior to and concomitantly with 4D-310. Per the protocol amendment, an additional cohort was added to examine a steroid-sparing immunosuppression regimen of tapered rituximab and sirolimus administered prior to and concomitantly with 4D-310. The company continues to expect to provide a clinical data update in the 1st half of 2023.

Second Quarter 2022 Financial Results

Cash, Cash Equivalents and Marketable Securities: Cash, cash equivalents and marketable securities were $261.6 million as of June 30, 2022. We expect cash, cash equivalents and marketable securities to be sufficient to fund operations into the first half of 2025.

Revenue: Total revenue for the quarter ended June 30, 2022, was $0.2 million, as compared to $14.6 million for the quarter ended June 30, 2021.

R&D Expenses: Research and development expenses were $20.4 million for the quarter ended June 30, 2022, as compared to $15.2 million for the quarter ended June 30, 2021. This increase was primarily driven by the progression of our five existing clinical product candidates, including clinical trial expenses for 4D-150 (for wet AMD), 4D-310 (for Fabry disease) and 4D-710 (for cystic fibrosis lung disease).

G&A Expenses: General and administrative expenses were $8.2 million for the quarter ended June 30, 2022, as compared to $7.0 million for the quarter ended June 30, 2021. This increase was primarily due to increased payroll, stock-based compensation, insurance and professional service expenses.

Net Loss: Net loss was $28.1 million for the quarter ended June 30, 2022, as compared to $7.6 million for the quarter ended June 30, 2021.

About 4DMT

4DMT is a clinical-stage biotherapeutics company harnessing the power of directed evolution for targeted genetic medicines. 4DMT seeks to unlock the full potential of genetic medicines using its platform, Therapeutic Vector Evolution, which combines the power of directed evolution with approximately one billion synthetic capsid sequences to invent targeted and evolved vectors for use in our products. The company is initially focused on five clinical-stage products in three therapeutic areas for both rare and large market diseases: ophthalmology, cardiology (including Fabry disease) and pulmonology. The 4DMT targeted and evolved vectors are invented with the goal of being delivered at relatively low doses 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. The five 4DMT product candidates in clinical development are: 4D-150 for wet AMD, 4D-310 for Fabry disease, 4D-710 for cystic fibrosis, 4D-125 for XLRP, and 4D-110 for choroideremia.

4D-150, 4D-310, 4D-710, 4D-125, and 4D-110 are 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-150, 4D-310, 4D-710, 4D-125, and 4D-110 for the therapeutic use for which they are being studied. 4D Molecular Therapeutics™, 4DMT™, Therapeutic Vector Evolution™, and the 4DMT logo are trademarks of 4DMT.

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 implications of clinical data for 4D-310's Phase 1/2 clinical trial; the potential outcomes as a result the amended protocol for the 4D-310 Phase 1/2 clinical trial, including outcomes resulting from the expanded eligible patient populations, concurrent patient enrollment across cohorts, and the assessment for an alternative steroid-sparing immune suppression regimen in a newly added cohort of 4D-310; the ability to continue to enroll 4D Molecular Therapeutics' ongoing clinical trials; expectations on how long our cash and cash equivalents

can fund operations; 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 Molecular Therapeutics, Inc.
Statements of Operations (Unaudited)
(*in thousands, except share and per share amounts*)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
Collaboration and license revenue	$ 162	$ 14,580	$ 1,382	$ 16,580
Total revenue	162	14,580	1,382	16,580
Operating expenses:				
Research and development	20,422	15,223	39,819	27,992
General and administrative	8,166	6,953	16,381	12,496
Total operating expenses	28,588	22,176	56,200	40,488
Loss from operations	(28,426)	(7,596)	(54,818)	(23,908)
Other income (expense), net:	340	7	394	(87)
Net loss	$ (28,086)	$ (7,589)	$ (54,424)	$ (23,995)
Net loss per share, basic and diluted	$ (0.87)	$ (0.28)	$ (1.69)	$ (0.90)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	32,324,392	26,739,149	32,263,015	26,715,014

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

	June 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 261,620	$ 315,429
Working capital	232,192	239,942
Total assets	302,936	353,487
Total liabilities	30,419	34,380
Accumulated deficit	(261,420)	(206,996)
Total stockholders' equity	272,517	319,107

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