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 12, 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 May 12, 2022, 4D Molecular Therapeutics, Inc. ("4DMT") announced its financial results for the quarter ended March 31, 2022. A copy of 4DMT's press release, titled "4D Molecular Therapeutics Reports First Quarter 2022 Financial Results and Provides Corporate Updates," 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 12, 2022 titled "4D Molecular Therapeutics Reports First Quarter 2022 Financial Results and Provides Corporate Updates"
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 12, 2022

By: /s/ August J. Moretti

August J. Moretti
Chief Financial Officer

Exhibit 99.1

4D Molecular Therapeutics Reports First Quarter 2022 Financial Results and Provides Corporate Updates

Emeryville, CA – May 12, 2022 – 4D Molecular Therapeutics, Inc. (Nasdaq: FDMT), a clinical-stage biotherapeutics company harnessing the power of directed evolution for targeted genetic medicines, announced first quarter 2022 financial results and provided corporate updates.

“We made significant progress in the first quarter of this year in moving several key programs of our diverse pipeline of clinical-stage genetic medicines,” said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. “In January, we announced treatment of the first patient with 4D-150 for wet AMD, and in February we presented compelling initial clinical data on 4D-310 for Fabry disease at the WORLD Symposium. In addition, we reported treatment of the first patient in our Phase 1/2 trial of 4D-710 for cystic fibrosis. Finally, we completed construction of our commercial-scale GMP manufacturing facility, which is expected to provide clinical trial material for our five product candidates across three therapeutic areas, and which underscores our phase-appropriate internal manufacturing strategy and commitment to capital stewardship. Our team is continuing to enroll multiple clinical trials for our product candidates, all of which use internally developed targeted and evolved vectors to unlock the full potential of genetic medicines for countless patients.”

Recent Corporate Highlights

- Dosed the first patient in its Phase 1/2 clinical trial of 4D-710 in patients with cystic fibrosis. The Phase 1/2 clinical trial is a multicenter, open-label, dose-escalation and dose-expansion trial.
- Presented updated clinical data from the ongoing Phase 1/2 clinical trial of 4D-310 in patients with Fabry disease at the 18th Annual WORLDSymposium. The data presented demonstrated mean AGA enzyme activity was within, or significantly above, the normal range in all of the first three patients including patients with pre-existing high titer antibodies to AGA. Initial clinical data on cardiac imaging and cardiac-related quality-of-life endpoints suggested encouraging effects. In addition, 4D-310 had a manageable safety profile, without dose-limiting toxicity.
- Presented choroideremia natural history study data at the Association for Research in Vision and Ophthalmology (ARVO) annual meeting. The choroideremia natural history data show a strong correlation between the anatomical preserved autofluorescence (FAF) endpoint and a functional retinal sensitivity endpoint. These data have important implications for quantification and monitoring of anatomical disease progression, including strengthening the importance of FAF area as a key endpoint in on-going and future clinical trials.
- Completed the build out of a commercial-scale GMP manufacturing facility at our Emeryville headquarters which is expected to provide clinical trial material for each of our five product candidates across three therapeutic areas. Clinical trial material produced from this facility is expected to support each product candidate’s pivotal studies, and the facilities will provide a broad range of analytical capabilities, including potency assay development and validation. The production capacity provided by our facilities and added capabilities are designed to shorten product development timelines, reduce cost, and improve quality.

Expected Upcoming Milestones

- Provide initial clinical data from the 4D-150 Phase 1/2 clinical trial for wet AMD in mid-2023
- Provide clinical data update from the 4D-310 Phase 1/2 clinical trial of 4D-310 in Fabry disease in the first half of 2023
- Continue enrollment and follow-up in the 4D-710 Phase 1/2 clinical trial for cystic fibrosis
- Continue enrollment and follow-up in the Phase 1/2 clinical trials for both 4D-125 for X-linked retinitis pigmentosa and 4D-110 for choroideremia and provide program updates in the first half of 2023

First Quarter 2022 Financial Results

Cash and Cash Equivalents and Marketable Securities: Cash and cash equivalents and marketable securities were $284.5 million as of March 31, 2022, as compared to $315.4 million as of December 31, 2021. The cash, cash equivalents and marketable securities reflect the receipt of net proceeds of approximately $111 million from our October 2021 public offering, which was offset by cash used in operations. We expect cash and cash equivalents and marketable securities to be sufficient to fund operations into the second half of 2024.

Revenue: Total revenue was $1.2 million for the quarter ended March 31, 2022, as compared to $2 million for the quarter ended March 31, 2021.

R&D Expenses: Research and development expenses were $19.4 million for the quarter ended March 31, 2022, as compared to $12.8 million for the first quarter of 2021. This increase was primarily driven by the progression of our existing clinical trials for 4D-310, 4D-125, 4D-150 and 4D-710 along with increased payroll and stock-based compensation expense.

G&A Expenses: General and administrative expenses were $8.2 million for the quarter ended March 31, 2022, as compared to $5.5 million for the first quarter of 2021. This increase was primarily due to increased payroll, stock-based compensation, insurance, and professional service expenses.

Net Loss: Net loss was $26.3 million for the quarter ended March 31, 2022, as compared to $16.4 million for the first quarter of 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-310 for Fabry disease, 4D-150 for wet AMD, 4D-125 for XLRP, 4D-110 for choroideremia and 4D-710 for cystic fibrosis.

4D-310, 4D-150, 4D-125, 4D-110 and 4D-710 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-310, 4D-150, 4D-125, 4D-110 or 4D-710 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; whether the expansion of 4D Molecular Therapeutics' manufacturing facilities will support commercial-scale production and expand our analytical development capabilities; the potential results or success of the first patient dosing in 4D Molecular Therapeutics' 4D-710 Phase 1/2 clinical trial; the implications of clinical data for 4D-310's Phase 1/2 clinical trial; the ability to continue to enroll 4D Molecular Therapeutics' ongoing clinical trials; the implications for quantification and monitoring of anatomical disease progression in future clinical trials based on choroideremia data; 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 March 31,	
	2022	**2021**
Revenue:		
Collaboration and license revenue	$ 1,219	$ 2,000
Total revenue	1,219	2,000
Operating expenses:		
Research and development	19,381	12,769
General and administrative	8,230	5,543
Total operating expenses	27,611	18,312
Loss from operations	(26,392)	(16,312)
Other income (expense), net:	54	(94)
Net loss	$ (26,338)	$ (16,406)
Net loss per share, basic and diluted	$ (0.82)	$ (0.61)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	32,232,378	26,690,167

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

	March 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 284,515	$ 315,429
Working capital	230,956	239,942
Total assets	324,926	353,487
Total liabilities	28,870	34,380
Accumulated deficit	(233,334)	(206,996)
Total stockholders' equity	296,056	319,107

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