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): November 09, 2023

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 November 9, 2023, 4D Molecular Therapeutics, Inc. ("4DMT") announced its financial results for the three months ended September 30, 2023. A copy of 4DMT's press release, titled "4DMT Reports Third Quarter 2023 Financial Results and 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 November 9, 2023 titled "4DMT Reports Third Quarter 2023 Financial Results and 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: November 9, 2023

By: /s/ Uneek Mehra

Uneek Mehra
Chief Financial and Business Officer
Principal Financial and Accounting Officer

Exhibit 99.1

4DMT Reports Third Quarter 2023 Financial Results and Operational Highlights

- *Rapidly advanced 4D-150 development for wet age-related macular degeneration (wet AMD): completed enrollment of PRISM Phase 2 Dose Expansion nearly two quarters earlier than expected and enrolled first patient in Population Extension cohort*
- *Interim data update from 4D-150 PRISM Phase 2 Dose Expansion (n=50; high anti-VEGF need patients) in wet AMD expected in early 2024; update on FDA feedback on Phase 3 pivotal trial plans expected in Q1 2024*
- *Received European Medicines Agency's Priority Medicines (PRIME) designation for 4D-150 for treatment of wet AMD*
- *Announced positive interim data from 4D-710 Phase 1/2 AEROW clinical trial for cystic fibrosis; update on FDA interaction expected in Q1 2024*
- *Gained alignment with FDA on plan to lift clinical hold on 4D-310 for Fabry disease cardiomyopathy; interim Phase 1/2 data update expected in Q1 2024*
- *$320 million in cash and equivalents, operational runway currently expected into the first half of 2026*

EMERYVILLE, Calif., Nov. 9, 2023 (GLOBE NEWSWIRE) -- 4D Molecular Therapeutics (Nasdaq: FDMT, 4DMT, or the Company) a genetic medicines company with three novel, highly targeted next generation AAV vectors currently in human clinical studies, today reported third quarter 2023 financial results and provided operational highlights.

“The third quarter of 2023 was another period of tremendous progress across our large market product candidate portfolio,” said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. “In our ophthalmology portfolio, the European Medicines Agency has awarded PRIME designation to intravitreal 4D-150 which validates the promising clinical data to date in wet AMD patients. We also enrolled the first patient in the Population Extension cohort to the PRISM clinical trial to include the broader wet AMD patient population with lower anti-VEGF need. In our pulmonology portfolio, we presented positive interim clinical and lung biopsy biomarker data for 4D-710 in the Phase 1/2 AEROW clinical trial for the treatment of cystic fibrosis lung disease, and we selected a dose to move forward into Phase 2. We remain highly focused in executing our corporate objectives and look forward to sharing multiple key clinical and regulatory milestones over the next few months."

Recent Highlights in Large Market Ophthalmology Portfolio

- Rapidly advanced intravitreal 4D-150 for wet AMD
  - Completed target enrollment of 50 patients in the randomized Phase 2 Dose Expansion stage of the PRISM clinical trial, nearly two quarters ahead of initial projections
    - Enrolled patients with high anti-VEGF need (annualized mean anti-VEGF injection frequency in preceding 12 months was approximately 10)
    - No reported treatment-emergent Grade ≥1 inflammatory cells or required deviations from protocol-specified topical corticosteroid taper with maximum follow-up through 20 weeks (best available data as of July 3, 2023)
  - Presented positive interim data from Dose Exploration stage with three dose cohorts (3E10, 1E10, and 6E9 vg/eye; n=5 each) at ASRS 2023 Annual Meeting

- Dosed first patient in Population Extension cohort (n=up to 45) of the Phase 2 PRISM clinical trial including broader wet AMD patient population with lower anti-VEGF need (1-6 anti-VEGF injections in preceding 12 months)
- Granted PRIME designation by the European Medicines Agency

- Enrolled first patient in the Dose Confirmation stage (n=18-24) of the Phase 2 SPECTRA clinical trial evaluating intravitreal 4D-150 in patients with DME

Recent Highlights in Pulmonary Portfolio

- Presented positive interim data from aerosolized 4D-710 Phase 1/2 AEROW clinical trial:
  - Generally well-tolerated across Cohorts 1 and 2 (1E15 and 2E15 vg; n=7) with up to 17 months follow-up
  - Promising, reproducible, CFTR expression significantly above normal across all participants and all lung tissue samples collected (n=34), substantially exceeding target profile
  - Durable clinical activity through 12 months in Cohort 1
    - No pulmonary exacerbations reported beyond 3 months and through up to 17 months of follow-up in all 3 participants
  - Cohort 1 dose level (1E15 vg) selected to continue into Phase 2
  - Dose ranging continues (5E14 – 2E15 vg) with lung biopsy CFTR expression profile demonstrating feasibility of effective treatment at lower doses; first patient dosed in lower dose Cohort 3 (5E14 vg)
- In August 2023, the Company executed an amendment to the Cystic Fibrosis Foundation Agreement increasing the funding commitment under that agreement by $2.8 million to a total of $6.3 million, which covers anticipated spend for further development of our aerosolized lung epithelium gene delivery vectors. This amendment brings the total historical commitment to over $20 million

Recent Highlights in Cardiology Portfolio

- Reached an agreement with the FDA on a proposed plan to address the clinical hold on 4D-310 and continue clinical development
  - Initiated single non-human primate (NHP) study evaluating the safety and biodistribution of intravenous (IV) 4D-310 with the rituximab/sirolimus (R/S) immunosuppressive regimen compared to the prior prednisone regimen
  - Amended INGLAXA protocol to minimize risk of atypical hemolytic uremic syndrome associated with IV AAV dosing, including addition of R/S immunosuppressive regimen

Expected Upcoming Milestones

- 4D-150 for Wet AMD:
  - Phase 2 Dose Expansion (n=50) interim data update early 2024
  - Update on FDA feedback on Phase 3 pivotal trial plans in Q1 2024
  - Interim data update from Population Extension cohort in wet AMD in 2024
- 4D-150 for DME:
  - Initial interim data from Dose Confirmation stage (n=18-24) of Phase 2 SPECTRA clinical trial in 2024

- 4D-175 for GA:
  - IND filing in H1 2024
- 4D-710 for Cystic Fibrosis (CF) Lung Disease:
  - Update on FDA feedback on development plan for monotherapy and approved CF modulator combination regimens in Q1 2024
  - Interim Phase 1 data update in mid-2024
- 4D-725 for A1AT Deficiency Lung Disease:
  - Program update in 2024
- 4D-310 for Fabry Disease Cardiomyopathy:
  - Interim data update, with follow-up of at least 12-18 months for all 6 patients dosed and additional biopsy data in Q1 2024
  - FDA submission of preclinical NHP data in Q2 2024

Q3 2023 Financial Results

Cash and Cash Equivalents and Marketable Securities: Cash and cash equivalents and marketable securities were approximately $320 million as of September 30, 2023, as compared to $218 million as of December 31, 2022. The net increase in cash was primarily a result of cash inflows from $129 million of net proceeds from our public offering of common stock completed in May, $19 million of net proceeds under our Open Market Sales Agreement, and the $20 million upfront payment in connection with the Astellas License Agreement and was partially offset by cash used in operations. We currently expect cash and cash equivalents to be sufficient to fund operations into the first half of 2026.

R&D Expenses: Research and development expenses were $25.1 million for the quarter ended September 30, 2023 as compared to $18.9 million for the third quarter of 2022. This increase was driven by the progression of our existing clinical trials, primarily 4D-150 in wet AMD and DME, along with increased payroll and stock-based compensation expense due to higher headcount.

G&A Expenses: General and administrative expenses were $9.1 million for the quarter ended September 30, 2023 as compared to $8.1 million for the third quarter of 2022.

Net Loss: Net loss was $10.3 million for the quarter ended September 30, 2023, as compared to net loss of $25.7 million for the third quarter of 2022. The decrease in net loss was primarily a result of the $20 million upfront payment in connection with the Astellas License Agreement.

About 4DMT

4DMT is a genetic medicines company with three novel, highly targeted next generation AAV vectors currently in human clinical studies targeting multiple large market diseases in ophthalmology and pulmonology, plus other therapeutic areas. 4DMT seeks to unlock the full potential of genetic medicines using its proprietary invention platform, Therapeutic Vector Evolution, which combines the power of the Nobel Prize-winning technology, directed evolution, with approximately one billion synthetic AAV capsid-derived sequences to invent customized and evolved vectors for use in our product candidates. All of our vectors are proprietary to 4DMT and were invented at 4DMT, including the vectors utilized in our clinical-stage and preclinical pipeline product candidates: R100, A101, and C102. The Company is initially focused on five clinical-stage product candidates in three therapeutic areas for both rare and large market diseases: ophthalmology, pulmonology, and cardiology. The 4DMT customized and evolved vectors were 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. 4DMT is currently advancing five product candidates in clinical development: 4D-150 for wet AMD and DME, 4D-710 for cystic fibrosis lung disease, 4D-310 for Fabry disease cardiomyopathy, 4D-125 for XLRP, and 4D-110 for choroideremia. The 4D preclinical product candidates in development are: 4D-175 for geographic atrophy and 4D-725 for AATLD.

4D-150, 4D-710, 4D-310, 4D-125, and 4D-110 are our product candidates in clinical development 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-710, 4D-310, 4D-125, or 4D-110 for the therapeutic uses for which they are being studied.

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 the therapeutic potential, and clinical benefits of 4DMT's product candidates, as well as the plans, announcements and related timing for the clinical development of our clinical and preclinical product candidates, and statements regarding our financial performance, results of operations and anticipated cash runway. 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 risks and uncertainties that 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. Our results for the quarter ended September 30, 2023 are also not necessarily indicative of our operating results for any future periods.

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

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Revenue:				
Collaboration and license revenue	$ 20,204	$ 500	$ 20,742	$ 1,882
Operating expenses:				
Research and development	25,066	18,940	71,068	58,753
General and administrative	9,112	8,055	25,889	24,441
Total operating expenses	34,178	26,995	96,957	83,194
Loss from operations	(13,974)	(26,495)	(76,215)	(81,312)
Other income, net	3,718	804	7,661	1,197
Net loss	$ (10,256)	$ (25,691)	$ (68,554)	$ (80,115)
Net loss per share, basic and diluted	$ (0.24)	$ (0.79)	$ (1.81)	$ (2.48)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	42,256,629	32,385,791	37,884,363	32,305,074

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

	September 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 319,664	$ 218,462
Working capital	310,080	204,780
Total assets	361,613	261,846
Total liabilities	31,679	30,509
Accumulated deficit	(383,044)	(314,490)
Total stockholders' equity	329,934	231,337

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