## 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 10, 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<br>Identification No.) |

5858 HORTON STREET
#455
EMERYVILLE, California
(Address of Principal Executive Offices)

Emerging growth company ⊠

94608 (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)) П 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: **Trading** Title of each class Symbol(s) Name of each exchange on which registered Common Stock, \$0.0001 par value per share Nasdag Global Select Market **FDMT** 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).

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.  $\Box$ 

#### Item 2.02 Results of Operations and Financial Condition.

On May 10, 2023, 4D Molecular Therapeutics, Inc. ("4DMT") announced its financial results for the three months ended March 31, 2023. A copy of 4DMT's press release, titled "4D Molecular Therapeutics Reports First 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<br>Number | Description                                                                                                                                  |
|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| 99.1              | Press Release, dated May 10, 2023 titled "4D Molecular Therapeutics Reports First 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.                          |                                                                            |

Date: May 10, 2023

By: /s/ August J. Moretti

August J. Moretti
Chief Financial Officer

### 4D Molecular Therapeutics Reports First Quarter 2023 Financial Results and Operational Highlights

- Presented positive interim data from intravitreal 4D-150 Phase 1/2 PRISM clinical trial for wet age-related macular degeneration (wet AMD) at the 2023 ARVO Annual Meeting
- On track for completion of enrollment of the Phase 2 Dose Expansion Stage of the PRISM clinical trial in Q3 2023
- Acquired all worldwide rights to short-form human complement factor H (sCFH) from Aevitas Therapeutics, Inc. and announced sCFH as payload for 4D-175 lead product candidate for geographic atrophy (GA)
- Multiple additional clinical data updates on clinical-stage product candidates expected later in 2023, including on 4D-710 for cystic fibrosis lung disease in Q2 2023
- Closed upsized public offering of common stock including full exercise of underwriters' option to purchase additional shares with total net proceeds of approximately \$129 million
- Cash, cash equivalents and marketable securities inclusive of net proceeds from the public offering expected to be sufficient to fund operations into the first half of 2026

EMERYVILLE, Calif., May 10, 2023 (GLOBE NEWSWIRE) -- 4D Molecular Therapeutics (Nasdaq: FDMT, 4DMT, or the Company) a clinical-stage biotherapeutics company harnessing the power of directed evolution for genetic medicines targeting large market diseases, today reported first quarter 2023 financial results and provided operational highlights.

"We are pleased with the progress of our large market ophthalmology portfolio this year. In April at ARVO, we released positive interim clinical data on all three dose cohorts in the Dose Exploration stage of our Phase 1/2 PRISM clinical trial of 4D-150 for the treatment of wet AMD. We observed excellent tolerability and clinical activity in these high anti-VEGF need patients that we believe support a differentiated profile. We are excited to see faster than expected enrollment of the Phase 2 Dose Expansion stage of the PRISM trial and believe this highlights the belief by investigators that 4D-150 has potential to be a transformative treatment for patients with wet AMD. We also announced the acquisition of the rights and know-how for sCFH from Aevitas for use in our preclinical product candidate 4D-175 for treatment of GA," said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. "We believe we have the opportunity to build a franchise in large market ophthalmology with 4D-150 for the treatment of wet AMD and diabetic macular edema (DME) and 4D-175 in for GA, each using our retinotropic vector R100. Our capital-efficient operations and strong cash position are expected to support operations into the first half of 2026."

#### Recent Highlights in Large Market Ophthalmology Portfolio

- Significant progress advancing the 4D-150 program for the intravitreal treatment of patients with wet AMD and with DME
  - o Presented positive interim data from the three dose cohorts studied (3E10, 1E10, and 6E9 vg/eye; n=5 each) in the Dose Exploration stage of the Phase 1/2 PRISM clinical trial for wet AMD in April at the ARVO 2023 Conference
    - All three doses were well-tolerated and demonstrated clinical activity
    - Dose response observed in favor of 3E10 vg/eye vs lower doses of 1E10 and 6E9 vg/eye

- In the 3E10 vg/eye cohort, 4 of 4 (100%) of Phase 2 BCVA-eligible patients remained injection-free at 36 weeks with a mean reduction in central subfield thickness (CST) of 72μm
- o Enrollment in Phase 2 Dose Expansion (n=50) stage of the PRISM is more than 50% completed
- Acquired the rights and know-how for sCFH from Aevitas Therapeutics, Inc. and announced sCFH as payload for 4D-175 product candidate for GA

#### **Expected Upcoming Milestones**

- 4D-150 for Wet AMD and DME:
  - o Enrollment of the Phase 2 randomized Dose Expansion stage of the PRISM clinical trial expected to complete in Q3 2023
  - Initial interim 4D-150 for wet AMD Phase 2 data expected in H1 2024
  - o Enrollment of the Phase 2 SPECTRA clinical trial for DME expected to begin in Q3 2023
  - o Initial interim 4D-150 for DME Phase 2 data expected in H1 2024
- 4D-175 for GA:
  - o Program update expected in Q4 2023
- 4D-710 for Cystic Fibrosis Lung Disease:
  - Interim data from the Dose Exploration stage of the Phase 1/2 AEROW clinical trial expected to be presented at a scientific conference in Q2 2023
  - Update on development plan for modulator combination expected in 2H 2023
- 4D-310 for Fabry Disease Cardiomyopathy:
  - Program update expected in 2H 2023

#### First Quarter 2023 Financial Results

Cash and Cash Equivalents and Marketable Securities: Cash and cash equivalents and marketable securities were \$202 million as of March 31, 2023, as compared to \$218 million as of December 31, 2022. The decrease in cash was primarily a result of cash used in operations, which was partially offset by \$9.6M of net proceeds from the sale of shares pursuant to our Open Market Sales Agreement. In addition, in May 2023 we completed a public offering of common stock that resulted in us receiving net proceeds of approximately \$129 million. We currently expect cash and cash equivalents, inclusive of net proceeds from the May 2023 offering, to be sufficient to fund operations into the first half of half of 2026.

*R&D Expenses:* Research and development expenses were \$22.4 million for the quarter ended March 31, 2023 as compared to \$19.4 million for the first quarter of 2022. This increase was primarily driven by the progression of our existing clinical trials, primarily 4D-150, along with increased payroll and stock-based compensation expense.

G&A Expenses: General and administrative expenses were \$8.0 million for the quarter ended March 31, 2023 as compared to \$8.2 million for the first quarter of 2022.

Net Loss: Net loss was \$28.7 million for the guarter ended March 31, 2023, as compared to \$26.3 million for the first guarter of 2022.

#### **About 4DMT**

4DMT is a clinical-stage biotherapeutics company harnessing the power of directed evolution for genetic medicines targeting large market diseases. 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 (Fabry disease cardiomyopathy). 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-310, 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.

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 the therapeutic potential, and clinical benefits, as well as the plans and related timing for the clinical development of 4D-150, 4D-710, 4D-310, 4D-125, 4D-110, and 4D-175; and the expectation that the company's current cash position will be sufficient to fund operations into the first half of 2026. The words "may," "might," "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 guarter ended March 31, 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 March 31, |            |      |            |
|---------------------------------------------------------------------------------------------|------------------------------|------------|------|------------|
|                                                                                             | 2023                         |            | 2022 |            |
| Revenue:                                                                                    |                              |            |      |            |
| Collaboration and license revenue                                                           | \$                           | 298        | \$   | 1,219      |
| Operating expenses:                                                                         |                              |            |      |            |
| Research and development                                                                    |                              | 22,412     |      | 19,381     |
| General and administrative                                                                  |                              | 7,992      |      | 8,230      |
| Total operating expenses                                                                    |                              | 30,404     |      | 27,611     |
| Loss from operations                                                                        |                              | (30,106)   |      | (26,392)   |
| Other income, net                                                                           |                              | 1,424      |      | 54         |
| Net loss                                                                                    | \$                           | (28,682)   | \$   | (26,338)   |
| Net loss per share, basic and diluted                                                       | \$                           | (0.88)     | \$   | (0.82)     |
| Weighted-average shares outstanding used in computing net loss per share, basic and diluted |                              | 32,723,530 |      | 32,232,378 |

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

|                                                  | March 31,<br>2023 |    | December 31,<br>2022 |  |
|--------------------------------------------------|-------------------|----|----------------------|--|
| Cash, cash equivalents and marketable securities | \$<br>201,859     | \$ | 218,462              |  |
| Working capital                                  | 195,762           |    | 204,780              |  |
| Total assets                                     | 244,021           |    | 261,846              |  |
| Total liabilities                                | 25,415            |    | 30,509               |  |
| Accumulated deficit                              | (343,172)         |    | (314,490)            |  |
| Total stockholders' equity                       | 218,606           |    | 231,337              |  |

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