

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 10, 2021

4D Molecular Therapeutics Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39782
(Commission File Number)

47-3506994
(IRS Employer
Identification No.)

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

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))
- 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 10, 2021, 4D Molecular Therapeutics, Inc. ("4DMT") announced its unaudited financial results for the quarter ended September 30, 2021. A copy of 4DMT's press release, titled "4D Molecular Therapeutics Reports Financial Results for the Third Quarter of 2021 and Provides Operational Highlights," is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto.



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

Emeryville, CA – November 10, 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 third quarter of 2021, and provided operational highlights.

“4DMT continues to advance our diverse pipeline of product candidates that utilize our targeted and evolved vectors invented through Therapeutic Vector Evolution. Over this past quarter we released promising initial clinical data on three programs, including on 4D-310 for Fabry disease,” said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. “We also opened INDs for both our wet AMD product candidate 4D-150 and for our cystic fibrosis product candidate 4D-710. Finally, we significantly strengthened our balance sheet through a follow-on offering of common stock raising net proceeds to 4DMT of approximately \$111 million. Looking ahead to 2022, the company expects to have five product candidates in clinical development in three different therapeutic areas, including for both rare and large market diseases. By harnessing the power of directed evolution to develop targeted gene therapies, 4DMT is continuing our mission to unlock the full potential of gene therapy for countless patients.”

Recent Operational Highlights

- Provided clinical data updates on 3 programs, including first-ever clinical activity data from two 4DMT targeted and evolved vectors: C102 for systemic low dose cardiovascular delivery and R100 for routine intravitreal delivery.
 - Phase 1/2 data from the C102-product candidate 4D-310 for Fabry disease, which demonstrated AGA enzyme activity that was within, or significantly above, the normal range in all three patients (up to 25-fold above mean normal AGA activity) including patients with high titer antibodies to AGA. In addition, 4D-310 had a manageable safety profile, without dose-limiting toxicity.
 - Phase 1/2 data from the R100-based gene therapies 4D-125 for XLRP and 4D-110 for choroideremia, which demonstrated both intravitreal product candidates were well tolerated at planned doses and were associated with signs of clinical activity, including reduced photoreceptor loss by ellipsoid zone area and reduced retinal pigment epithelium loss by fundus autofluorescence (4D-110). 4DMT expects to continue enrollment at the 1E12 vg/eye dose level for 4D-125 and at the 3E11 vg/eye dose level for 4D-110.
- In October 2021, 4DMT announced the pricing of a public offering of common stock with expected total gross proceeds of approximately \$119 million, before deducting underwriting discounts, commissions and other offering expenses.
- Received clearance from the U.S. Food and Drug Administration (FDA) for the 4DMT Investigational New Drug (IND) Applications for the Phase 1/2 clinical trials of 4D-150 for wet age-related macular degeneration (wet AMD) and of 4D-710 for cystic fibrosis.

- Received clearance from the Taiwan Food and Drug Administration for the 4DMT Investigational New Drug (IND) Application for the Pacific Rim Phase 1/2 clinical trial of 4D-310 for Fabry disease. 4DMT also announced that this clinical trial is designed to include cardiac biopsies post-treatment to assess 4D-310 delivery to the heart.

Expected Upcoming Milestones

- Interim clinical data from the Phase 1/2 clinical trial of 4D-310 in Fabry disease expected in 2022
- First patient dosing in the 4D-150 Phase 1/2 clinical trial for wet AMD expected in the first quarter of 2022
- First patient dosing in the 4D-710 Phase 1/2 clinical trial for cystic fibrosis expected in the first half of 2022
- Continued enrollment in both the 4D-125 for x-linked retinitis pigmentosa and 4D-110 for choroideremia Phase 1/2 clinical trials

Financial Results for the Third Quarter Ended September 30, 2021

Cash and Cash Equivalents and Marketable Securities: Cash and cash equivalents and marketable securities were \$227 million as of September 30, 2021. In addition, the October 2021 public offering of common stock resulted in net proceeds of approximately \$111 million. 4DMT has granted the underwriters a 30-day option to purchase up to an additional 712,500 shares of common stock at the public offering price, less underwriting discounts and commissions. We currently expect cash and cash equivalents, inclusive of net proceeds from the offering, to be sufficient to fund operations into the second half of 2024.

Revenue: Total revenue was \$1.4 million for the quarter ended September 30, 2021, as compared to \$7.4 million for the quarter ended September 30, 2020. This decrease was primarily driven by decreased revenue recognized under the Roche collaboration agreement, which was terminated in September 2021.

R&D Expenses: Research and development expenses were \$15.8 million for the quarter ended September 30, 2021, as compared to \$11.6 million for the quarter ended September 30, 2020. This increase was primarily driven by increased payroll and stock-based compensation expense.

G&A Expenses: General and administrative expenses were \$8.2 million for the quarter ended September 30, 2021, as compared to \$3.7 million for the quarter ended September 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 \$22.2 million for the quarter ended September 30, 2021, as compared to \$7.8 million for the quarter ended September 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

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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 advancing five product candidates in clinical development: 4D-310 for Fabry disease, 4D-150 for wet AMD, 4D-125 for XLRP, 4D-710 for cystic fibrosis and 4D-110 for choroideremia. 4D Molecular Therapeutics™, 4DMT™, Therapeutic Vector Evolution™, and the 4DMT logo are trademarks of 4DMT.

4D-310, 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-310, 4D-125 or 4D-110 for the therapeutic use for which they are being studied.

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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 clinical data being available for 4D-310's Phase 1/2 clinical trial; the estimated timing of initiating the clinical trials for 4D-150 and 4D-710; expectations for continued enrollment in the clinical trials for 4D-110 and 4D-125; expectations on how long our cash and cash equivalents can fund operations; 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Collaboration and license revenue	\$ 1,366	\$ 7,421	\$ 17,946	\$ 14,340
Collaboration and license revenue, related parties	—	—	—	249
Total revenue	1,366	7,421	17,946	14,589
Operating expenses:				
Research and development	15,840	11,555	43,832	40,433
General and administrative	8,187	3,682	20,683	10,398
Total operating expenses	24,027	15,237	64,515	50,831
Loss from operations	(22,661)	(7,816)	(46,569)	(36,242)
Other income (expense):	422	(17)	335	96
Net loss	\$ (22,239)	\$ (7,833)	\$ (46,234)	\$ (36,146)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.82)	\$ (1.51)	\$ (1.72)	\$ (6.97)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	27,022,380	5,197,982	26,818,595	5,188,628

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

	September 30, 2021	December 31, 2020
Cash and cash equivalents	\$ 90,989	\$ 276,726
Marketable securities	136,180	—
Working capital	154,360	265,912
Total assets	240,618	288,331
Accumulated deficit	(181,913)	(135,679)
Total stockholders' equity	224,134	256,387

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