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

August 9, 2023

- *Presented positive interim data from intravitreal 4D-150 Phase 1/2 PRISM clinical trial for patients with wet age-related macular degeneration (wet AMD)*
- *Completed target enrollment of 50 patients in the randomized Phase 2 Dose Expansion stage of the PRISM clinical trial in July, nearly two quarters ahead of initially projected enrollment completion*
- *Presented positive interim data from aerosolized 4D-710 Phase 1/2 AEROW clinical trial for patients with cystic fibrosis lung disease*
- *Anticipate multiple clinical data and regulatory interaction updates on lead clinical-stage product candidates 4D-150 in wet AMD and 4D-710 in cystic fibrosis lung disease over the next 12 months*
- *Entered license agreement with Astellas Pharma in July and received $20 million upfront with potential future milestones of up to $942.5 million, including potential near-term development milestones of $15 million for the initial target*
- *Strong balance sheet, closing the quarter with $310 million in cash, cash equivalents, and marketable securities, which includes net proceeds from upsized public offering of $138 million in common stock in May, expected to be sufficient to fund operations into the first half of 2026*

EMERYVILLE, Calif., Aug. 09, 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 second quarter 2023 financial results and provided operational highlights.

“We are excited by the significant progress we have made across our large market product candidate portfolio in the second quarter,” said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. “In ophthalmology, we presented positive interim clinical data from the Dose Exploration stage of our Phase 1/2 PRISM clinical trial of 4D-150, which demonstrated excellent tolerability, clinical activity and initial long term durability in high anti-VEGF need patients that we believe support an emerging best-in-class profile. In pulmonology, we presented positive interim clinical data from cohort 1 from the 4D-710 Phase 1/2 AEROW clinical trial for the treatment of cystic fibrosis lung disease, demonstrating widespread and high-level CFTR transgene expression and initial clinical activity in a population who otherwise have no disease-modifying treatment options. Lastly, we continue to execute on business development, including the collaboration with Astellas in July, demonstrating the value of our clinically de-risked customized and evolved vectors for delivery of genetic medicine payloads. Our focus remains on relentlessly executing on our corporate objectives and look forward to sharing multiple key clinical and regulatory milestones over the next 12 months. Our strong cash position and capital-efficient operations continue to provide the foundation for long-term value creation.”

Recent Highlights in Large Market Ophthalmology Portfolio

- Rapidly advanced 4D-150 in wet AMD
  - Presented positive interim data from Dose Exploration stage with three dose cohorts (3E10, 1E10, and 6E9 vg/eye; n=5 each) at ARVO and ASRS 2023 Annual Meetings (data as of July 3, 2023):
    - Well tolerated with no Grade ≥1 inflammatory cells, no vasculitis and no hypotony
    - Dose response demonstrated in favor of high dose 3E10 vg/eye, including 100% reduction in supplemental anti-VEGF injections in 4 evaluable patients and reduction in mean central subfield thickness (CST) reduction at 36 weeks of follow-up
    - Durable response beyond 1 year in 3E10 vg/eye dose cohort, with 3 of 4 evaluable patients injection-free at up to 80 weeks of follow-up
  - Completed target enrollment of 50 patients in the randomized Phase 2 Dose Expansion stage of the PRISM clinical trial in July, nearly two quarters ahead of initial projections
- In April, acquired the rights and know-how for short-form complement factor H (sCFH) from Aevitas and announced sCFH as payload for 4D-175 product candidate for geographic atrophy (GA)

Recent Highlights in Pulmonary Portfolio

- Presented positive interim clinical and lung biopsy biomarker data for 4D-710 in cystic fibrosis lung disease from all three dose level patients in the Phase 1/2 AEROW clinical trial at the ECFS 2023 Annual Meeting (data as of April 12, 2023):
  - Meaningful improvement in cystic fibrosis-related quality of life measured by Cystic Fibrosis Questionnaire-Revised respiratory symptom score (CFQ-R-R) and improved or stabilized percent predicted FEV_1
  - Bronchoscopy sample results demonstrated widespread and consistent CFTR transgene protein expression in 92-99% of lung airway cells with CFTR protein expression levels significantly above those in normal control lung tissues
  - No post-dosing 4D-710–related adverse events, dose-limiting toxicities (DLTs) or severe adverse events (SAEs)

Expected Upcoming Milestones

- 4D-150 for Wet AMD and DME:
  - Phase 2 Dose Expansion (N=50) initial interim data expected in H1 2024
  - Update regarding Phase 3 pivotal trial plans expected in Q1 2024 after anticipated initial discussion with FDA in Q4 2023
  - First patient enrolled in Phase 2 SPECTRA clinical trial for DME expected in Q3 2023

- Initial interim 4D-150 for DME Phase 2 data expected in 2024

- 4D-175 for GA:
  - Program update expected in Q4 2023
  - IND filing expected in H1 2024
- 4D-710 for Cystic Fibrosis Lung Disease:
  - Phase 1/2 Dose Exploration interim data (cohorts 1 & 2) at North American Cystic Fibrosis Conference (NACFC) expected in November 2023
  - Dose selection for and initiation of Phase 2 Dose Expansion stage expected in H2 2023
  - Update on development plan for modulator combination expected in Q4 2023
  - Update regarding FDA discussion on pivotal endpoints expected Q1 2024 after anticipated initial discussion with FDA in Q4 2023
- 4D-310 for Fabry Disease Cardiomyopathy:
  - Program update expected in H2 2023
  - Interim clinical data with minimum follow-up of 12 months on all 6 patients treated to date (1E13 vg/kg dose level) expected in H1 2024

Financial and Corporate Highlights

- In May, closed an upsized underwritten public offering of our common stock including full exercise of underwriters' option to purchase additional shares with gross proceeds of $138 million
- In July, announced a license agreement with Astellas under which Astellas gains rights to utilize 4DMT's proprietary intravitreal retinotropic R100 vector for genetic targets implicated in rare monogenic ophthalmic diseases. 4DMT received $20 million upfront, and may receive potential future option fees and milestones of up to $942.5 million including potential near-term development milestones of $15 million for the initial target and mid-single digit to double-digit, sub-teen royalties on net sales of all licensed products

Q2 2023 Financial Results

Cash and Cash Equivalents and Marketable Securities: Cash and cash equivalents and marketable securities were $310 million as of June 30, 2023, as compared to $218 million as of December 31, 2022. The net change in cash was primarily a result of cash used in operations that was offset by approximately $129 million of net proceeds from our public offering of common stock completed in May. We also received a $20 million cash upfront payment from our license agreement with Astellas in July. We currently expect cash and cash equivalents, inclusive of net proceeds from the upfront payment from Astellas, to be sufficient to fund operations into the first half of 2026.

R&D Expenses: Research and development expenses were $23.6 million for the quarter ended June 30, 2023 as compared to $20.4 million for the second 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 $8.8 million for the quarter ended June 30, 2023 as compared to $8.2 million for the second quarter of 2022.
Net Loss: Net loss was $29.6 million for the quarter ended June 30, 2023, as compared to $28.1 million for the second quarter 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. 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 June 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 June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Collaboration and license revenue	$ 239	$ 162	$ 538	$ 1,382
Operating expenses:				
Research and development	23,584	20,422	43,002	39,819
General and administrative	8,791	8,166	16,777	16,381
Total operating expenses	32,375	28,588	62,779	56,200
Loss from operations	(32,136)	(28,426)	(62,241)	(54,818)
Other income (expense), net:	2,520	340	3,943	394
Net loss	$ (29,616)	$ (28,086)	$ (58,298)	$ (54,424)
Net loss per share, basic and diluted	$ (0.77)	$ (0.87)	$ (1.63)	$ (1.69)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	38,429,934	32,324,392	35,709,614	32,263,015

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

	June 30,	December 31
	2023	**2022**
Cash and cash equivalents and marketable securities	$ 310,343	$ 218,462
Working capital	304,027	204,780
Total assets	352,035	261,846
Total liabilities	27,359	30,509
Accumulated deficit	(372,788)	(314,490)
Total stockholders' equity	324,676	231,337

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