4DMT Reports Full Year 2023 Financial Results and Operational Highlights

February 29, 2024

- *Presented positive interim data from randomized Dose Expansion cohort of the Phase 2 PRISM study evaluating 4D-150 in wet AMD patients with severe disease activity and high treatment burden, enabling advancement into Phase 3 pivotal development, with initiation expected in Q1 2025*
- *Positive interim clinical data for 4D-710 in cystic fibrosis and 4D-310 in Fabry disease continue to demonstrate the potential of these product candidates and the efficient delivery, transgene expression and clinical activity of 4DMT's three clinical-stage vectors*
- *Strategic agreements with Astellas Pharma in rare monogenic retinal diseases and Arbor Biotechnologies in CNS gene editing continue to validate the versatility of 4DMT's Therapeutic Vector Evolution platform*
- *Completed upsized public follow-on offering with total gross proceeds of $300 million supplements our cash position of $299 million (as of December 31, 2023) and extends our operational runway into the first half of 2027*

EMERYVILLE, Calif., Feb. 29, 2024 (GLOBE NEWSWIRE) -- 4D Molecular Therapeutics (Nasdaq: FDMT, 4DMT or the Company), a leading clinical-stage genetic medicines company focused on unlocking the full potential of genetic medicines to treat large market diseases, today reported full year 2023 financial results and provided operational highlights.

"2023 was a transformative year for 4DMT with incredible progress across our product pipeline and platform in multiple therapeutic areas, especially for our lead program 4D-150 in wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME)," said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. "Robust enrollment ahead of schedule across multiple cohorts in the PRISM clinical trial of patients with wet AMD and the SPECTRA clinical trial of patients with DME have set the stage for multiple important data readouts in 2024, starting with our recent positive interim data at Angiogenesis, Exudation, and Degeneration 2024 Conference in the hardest-to-treat wet AMD patients. As of the most recent data update, 110 patients have been dosed with 4D-150 with no clinically significant inflammation, which continues to build on the emerging profile of 4D-150 as a potentially best-in-class long-acting genetic medicine with the opportunity for broad market adoption. We look forward to further updates in the broad wet AMD population and DME patients in the second half of 2024, setting the stage for our first Phase 3 clinical trial in wet AMD currently expected to initiate in the first quarter of 2025. We also look forward to providing updates on other key programs beyond 4D-150 in 2024, including 4D-175 for geographic atrophy, 4D-710 for cystic fibrosis and 4D-310 for Fabry disease cardiomyopathy. Our recent financing and resulting cash position allows us to execute on our vision of becoming a fully integrated, next-generation genetic medicines company."

Recent Highlights in Large Market Ophthalmology Portfolio

- **4D-150 for Wet Age-Related Macular Degeneration:**
  - Rapidly advanced intravitreal 4D-150 for wet AMD in the Phase 1/2 PRISM clinical trial
    - Randomized Dose Expansion cohort (N=51) in patients with severe disease activity and high treatment burden presented at Angiogenesis, Exudation, and Degeneration 2024 Conference (data cutoff January 19, 2024):
      - Favorable safety profile demonstrated, with no significant or recurrent intraocular inflammation, and no 4D-150–related serious adverse events (SAEs) or study eye SAEs. All patients were off steroids
      - At 24 weeks, 4D-150 resulted in robust reductions in overall treatment burden, % of patients with 0-1 injections, % of patients injection-free, plus improved retinal anatomical control vs. the aflibercept control
    - Durable responses demonstrated beyond 1 year in Phase 1 3E10 vg/eye dose cohort, with 3 patients injection-free through 80–104 weeks (up to 2 years) of follow-up
    - Enrollment completed ahead of schedule in Phase 2 PRISM Population Extension cohort (N=32) evaluating 4D-150 in patients with broad disease activity and treatment burden versus the Dose Expansion cohort
  - Received RMAT and PRIME designations, enabling increased collaboration between the FDA and EMA on regulatory planning
  - Announced preliminary pivotal Phase 3 clinical trial design and plans
- **4D-150 for Diabetic Macular Edema:**
  - Enrollment and dosing completed ahead of schedule in Dose Confirmation cohort (N=22) of the Phase 2 SPECTRA clinical trial in DME

Recent Highlights in Pulmonary Portfolio

- **4D-710 for Cystic Fibrosis Lung Disease:**
  - Presented positive interim data from the Phase 1/2 AEROW clinical trial at the North American Cystic Fibrosis Conference
  - Dose ranging continues (5E14 – 2E15 vg) with lung biopsy CFTR expression significantly above normal controls, demonstrating the feasibility of efficient delivery and CFTR transgene expression at lower doses; first participant dosed in lower dose Cohort 3 (5E14 vg)
  - Received Rare Pediatric Disease Designation in January 2024 and Orphan Drug Designation from FDA in February 2024

Recent Highlights in Cardiology Portfolio

- **4D-310 for Fabry Disease Cardiomyopathy:**
  - Interim clinical and biopsy data from Phase 1/2 INGLAXA clinical trials presented in the late-breaking session at WORLD*Symposium* ™ 2024:
    - 4D-310 demonstrated clinically meaningful improvements on multiple cardiac endpoints through 12-24 months in five evaluable patients
    - Cardiac biopsies from one patient at week 6 and 24 showed robust and durable delivery, transgene expression and clearance of Gb3 substrate in cardiomyocytes
    - Safety and tolerability profile maintained; previously reported cases of atypical hemolytic uremic syndrome (aHUS) (n=3) have fully resolved
  - Reached agreement with FDA on a proposed plan to address clinical hold. Single non-human primate safety study evaluating intravenous 4D-310 with the rituximab/sirolimus immunosuppressive regimen underway

Strategic Agreements & Partnerships

- In July 2023, entered license agreement with Astellas Pharma for their use of R100 vector for genetic targets implicated in rare monogenic ophthalmic diseases 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
- In December 2023, entered strategic partnership with Arbor Biotechnologies to engineer, co-develop and co-commercialize AAV-delivered CRISPR/Cas-based therapeutics for up to six product candidates in the CNS therapeutic area

Expected Upcoming Milestones

- **4D-150 for Wet AMD:**
  - Phase 2 PRISM Population Extension cohort (N=32) in patients with broad disease activity and treatment burden:
    - Initial interim 24-week landmark analysis expected in Q3 2024
  - Phase 3 Planning:
    - Additional FDA and EMA regulatory interactions under RMAT and PRIME planned in Q2 2024; update expected in Q3 2024
    - Phase 3 clinical trial initiation expected in Q1 2025
- **4D-150 for DME:**
  - Phase 2 SPECTRA clinical trial Dose Confirmation cohort (N=22):
    - Initial interim 24-week landmark data expected in H2 2024
- **4D-175 for Geographic Atrophy:**
  - IND filing expected in Q2 2024
  - Phase 1 initiation expected in H2 2024
- **4D-710 for CF Lung Disease:**
  - Update on FDA feedback on development plan for monotherapy and approved CF modulator combination regimens expected in Q1 2024
  - Interim update from Phase 1/2 AEROW clinical trial expected in mid-2024
- **4D-725 for A1AT Deficiency Lung Disease:**
  - Program update and initiation of IND-enabling studies expected in 2024
- **4D-310 for Fabry Disease Cardiomyopathy:**
  - FDA submission of preclinical NHP safety data in combination with rituximab/sirolimus immunosuppression regimen expected in Q2 2024
- **4D-110 for Choroideremia and 4D-125 for X-Linked Retinitis Pigmentosa:**
  - Program updates expected in 2024

Full Year 2023 Financial Results

Cash and Cash Equivalents and Marketable Securities: Cash and cash equivalents and marketable securities were $299 million as of December 31, 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. In addition, in February 2024 we completed a public offering of common stock and prefunded warrants that resulted in us receiving net proceeds of approximately $281 million. We currently expect cash and cash equivalents to be sufficient to fund operations into the first half of 2027.

R&D Expenses: Research and development expenses were $97.1 million for 2023, as compared to $80.3 million for 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 $36.5 million for 2023, as compared to $32.9 million for 2022.

Net Loss: Net loss was $100.8 million for 2023, as compared to net loss of $107.5 million for 2022.

About 4DMT

4DMT is a leading clinical-stage genetic medicines company focused on unlocking the full potential of genetic medicines to treat large market diseases

in ophthalmology and pulmonology. 4DMT's proprietary invention platform, Therapeutic Vector Evolution, 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 wholly owned and partnered product candidates. Our product design, development, and manufacturing engine helps us efficiently create and advance our diverse product pipeline with the goal of revolutionizing medicine with potential curative therapies for millions of patients. Currently, 4DMT is advancing five clinical-stage and two preclinical product candidates, each tailored to address rare and large market diseases in ophthalmology, pulmonology, and cardiology. In addition, 4DMT is also advancing programs in CNS through a gene editing partnership. 4D Molecular Therapeutics™, 4DMT™, Therapeutic Vector Evolution™, and the 4DMT logo are trademarks of 4DM.

All of our product candidates are in clinical or preclinical development and have not yet been approved for marketing by the FDA or any other regulatory authority. No representation is made as to the safety or effectiveness of our product candidates for the therapeutic uses for which they are being studied.

Learn more at www.4DMT.com and follow us on LinkedIn.

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 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*)

	Year Ended December 31,	
	2023	**2022**
Collaboration and license revenue	$ 20,723	$ 3,129
Operating expenses:		
Research and development	97,096	80,253
General and administrative	36,494	32,908
Total operating expenses	133,590	113,161
Loss from operations	(112,867)	(110,032)
Other income (expense), net:	12,030	2,538
Net loss	$ (100,837)	$ (107,494)
Net loss per share, basic and diluted	$ (2.58)	$ (3.32)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	39,130,067	32,351,221

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

	As of December 31,	
	2023	**2022**
Cash and cash equivalents and marketable securities	$ 299,186	$ 218,462
Working capital	277,637	204,780
Total assets	339,891	261,846
Total liabilities	32,062	30,509
Accumulated deficit	(415,327)	(314,490)
Total stockholders' equity	307,829	231,337

Contacts:

Media:

Katherine Smith
Inizio Evoke Comms
Katherine.Smith@inizioevoke.com

Investors:

Julian Pei

Head of Investor Relations and Corporate Communications
Investor.Relations@4DMT.com