4DMT Reports First Quarter 2025 Financial Results, Operational Highlights and Expected Upcoming Milestones

May 8, 2025

- *Enrolled first patients in first 4D-150 Phase 3 clinical trial (4FRONT-1) in wet AMD, with over 50 clinical trial sites open to date*
- *Initiation of second 4D-150 Phase 3 clinical trial (4FRONT-2) expected in Q3 2025, with topline data from both 4FRONT-1 and 4FRONT-2 expected in H2 2027*
- *RMAT designation received from FDA for 4D-150 in DME, adding to previous regulatory designations of RMAT and PRIME (EMA) for 4D-150 in wet AMD*
- *$458 million in cash, cash equivalents, and marketable securities as of March 31, 2025, expected to fund planned operations into 2028*

EMERYVILLE, Calif., May 08, 2025 (GLOBE NEWSWIRE) -- 4D Molecular Therapeutics (Nasdaq: FDMT, 4DMT or the Company), a leading late-stage biotechnology company advancing durable and disease-targeted therapeutics with potential to transform treatment paradigms and provide unprecedented benefits to patients, today reported Q1 2025 financial results, provided operational highlights and outlined expected upcoming milestones.

“The first quarter of 2025 marked a pivotal moment for 4DMT as we focused our pipeline on our highest value programs, 4D-150 and 4D-710, reported compelling 4D-150 Phase 2 results in wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME), and initiated our first 4D-150 Phase 3 clinical trial 4FRONT-1 in wet AMD,” said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. “With strong Phase 1/2 data, optimized Phase 3 trial design, and a world-class leadership team, we are well positioned to execute on our mission to dramatically improve lives and outcomes for patients living with retinal vascular diseases with 4D-150, a backbone therapy designed to provide long-lasting relief from frequent and burdensome injections. Our strong balance sheet provides us an expected operational runway into 2028, enabling us to deliver topline results from both wet AMD Phase 3 clinical trials in H2 2027 without raising additional capital. We look forward to sharing data and programmatic updates in H2 2025 for both our 4D-150 program in wet AMD and DME and our 4D-710 program in cystic fibrosis lung disease.”

Recent Corporate Highlights

- **Focused Pipeline and Extended Cash Runway**
  - Identified core programs: 4D-150 for wet AMD and DME and 4D-710 for cystic fibrosis (CF) lung disease
  - Paused significant additional capital allocation and investment, pending additional financing or partnerships, for 4D-175 for geographic atrophy, 4D-725 for alpha-1 antitrypsin deficiency lung disease, and 4D-310 for Fabry disease cardiomyopathy
  - Terminated development of 4D-110 for choroideremia and 4D-125 for X-linked retinitis pigmentosa
  - Paused investment into new preclinical product candidates
  - As a result, cash runway was extended into 2028 and includes full execution and topline 52-week data from 4FRONT-1 and 4FRONT-2 Phase 3 clinical trials in wet AMD, as well as ongoing Phase 1 & 2 clinical development of 4D-150 in DME and 4D-710 in CF

Recent Highlights and Expected Milestones in Large Market Ophthalmology Portfolio

- **4D-150 for wet AMD:**
  - 4FRONT Global Phase 3 Program:
    - Enrolled first patients in North American clinical trial, 4FRONT-1
    - Global clinical trial, 4FRONT-2, expected to initiate in Q3 2025
    - Primary endpoint 52-week topline data from both 4FRONT-1 and 4FRONT-2 expected in H2 2027
  - PRISM Phase 1/2 Clinical Trial:
    - Presented positive 52-week results from 3E10 vg/eye (Phase 3 dose) arm of Phase 2b Population Extension cohort (best available data as of January 15, 2025):
      - In the broad population (n=30), 3E10 vg/eye demonstrated 83% reduction in injection burden vs. projected on-label aflibercept 2 mg Q8W; 70% of patients required 0-1 supplemental injection and 57% were injection-free
      - In the recently diagnosed subgroup (n=15), which most resembles the Phase 3 4FRONT-1 and 4FRONT-2 patient populations, 3E10 vg/eye demonstrated 94% reduction in injection burden vs. projected on-label aflibercept 2 mg Q8W; 87% of patients required 0-1 supplemental injection and 80% were injection-free
      - Improved and maintained best corrected visual acuity (BCVA) and central subfield thickness (CST) with fewer fluctuations
      - 4D-150 continues to be well tolerated during up to three years of follow-up in all patients (n=71) treated with 3E10 vg/eye dose, with the highest 4D-150-related intraocular inflammation (SUN/NEI scales) observed as mild (1+) vitreous cells at a single timepoint in 2.8% (2 of 71) of patients

- Presented biomarker data from patients treated with 3E10 vg/eye in Phase 1/2a and 2b cohorts supporting ongoing multi-year durability with stable aqueous humor aflibercept concentrations consistently within projected therapeutic range with up to two years of follow-up (best available data as of November 20, 2024)
- 2-year data from Phase 1/2a and 18-month data from Phase 2b cohorts expected in Q4 2025

- **4D-150 for DME:**
  - SPECTRA Part 1 Clinical Trial:
    - Presented positive interim 32-week data (data cutoff: December 13, 2024)
      - Across all patients dosed to date, 4D-150 continues to be well-tolerated, with no intraocular inflammation observed at any timepoint or dose level
      - Post-3 loading doses of aflibercept, 3E10 vg/eye demonstrated strong signals of clinical activity, with sustained gain of BCVA of +8.4 letters and reduction of CST of -194 µm from baseline
      - 3E10 vg/eye achieved an 86% reduction in injection burden vs. projected on-label aflibercept 2 mg Q8W and dose response, with 61% reduction vs. the lower-dose cohort at 1E10 vg/eye, with 0.6 mean supplemental injections per patient, with stringent supplemental injection criteria
    - 52-week interim data update expected at a scientific conference in Q3 2025
  - Phase 3 Planning:
    - Announced alignment with U.S. Food and Drug Administration (FDA) on registrational path
      - FDA aligned with proposed single Phase 3 clinical trial being acceptable for the basis of a BLA submission for 4D-150 in DME, based on review of data from SPECTRA and PRISM (wet AMD) clinical trials to date and planned global Phase 3 clinical development program for wet AMD
      - Per FDA feedback, the Company may proceed to Phase 3 (SPECTRA Part 2 no longer needed), and the FDA is aligned with key design elements of a Phase 3 clinical trial with approximately 300-400 patients total with a primary endpoint of BCVA noninferiority vs. on-label aflibercept 2 mg (5 loading doses and Q8W) and revised supplemental injection criteria
    - Received Regenerative Medicine Advanced Therapy (RMAT) designation from FDA, validating 4D-150's potential to address the significant unmet medical needs in treating DME
    - Next steps pending final FDA and EMA alignment on Phase 3 clinical trial design and funding pathway

Recent Highlights and Expected Milestones in Pulmonology Program

- **4D-710 for CF Lung Disease:**
  - Ongoing enrollment extension of three additional participants in Cohort 4 (target enrollment of n=6) of Phase 1 stage of AEROW clinical trial (target total enrollment of n=16 participants)
  - Interim data from AEROW clinical trial and program update expected at a scientific conference in H2 2025

Q1 2025 Financial Results

Cash position: Cash, cash equivalents, and marketable securities were $458 million as of March 31, 2025, as compared to $505 million as of December 31, 2024. The net decrease in cash was primarily a result of cash used in operations. We currently expect cash, cash equivalents, and marketable securities to be sufficient to fund planned operations into 2028.

R&D Expenses: Research and development expenses were $40.7 million for the first quarter of 2025, as compared to $27.9 million for the first quarter of 2024. This increase was primarily driven by the initiation of our first Phase 3 clinical trial of 4D-150 in wet AMD, including increased personnel and professional services to support Phase 3 development.

G&A Expenses: General and administrative expenses were $12.9 million for the first quarter of 2025, as compared to $10.3 million for the first quarter of 2024. This increase was primarily driven by professional services.

Net Loss: Net loss was $48.0 million for the first quarter of 2025, as compared to net loss of $32.4 million for the first quarter of 2024.

About 4DMT

4DMT is a leading late-stage biotechnology company advancing durable and disease-targeted therapeutics with potential to transform treatment paradigms and provide unprecedented benefits to patients. Our lead product candidate 4D-150 is designed to be a backbone therapy forming the foundation of treatment of blinding retinal vascular diseases by providing multi-year sustained delivery of anti-VEGF (aflibercept and anti-VEGF-C) with a single, safe, intravitreal injection, which substantially reduces the treatment burden associated with current bolus injections. Our lead indication for 4D-150 is wet age-related macular degeneration, which is currently in Phase 3 development, and second indication is diabetic macular edema. Our second product candidate is 4D-710, which is the first known genetic medicine to demonstrate successful delivery and expression of the CFTR transgene in the lungs of people with cystic fibrosis after aerosol delivery. 4D Molecular Therapeutics™, 4DMT™, Therapeutic Vector Evolution™, an the 4DMT logo are trademarks of 4DMT.

All of our product candidates are in clinical or preclinical development and have not yet been approved for marketing by the U.S. Food and Drug Administration 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, as well as the plans, announcements and related timing for the clinical development of our product candidates and interactions with FDA 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.

4D Molecular Therapeutics, Inc.

Statements of Operations
(Unaudited)
(*in thousands, except share and per share amounts*)

	Three months ended March 31,	
	2025	**2024**
Revenue:		
Collaboration and license revenue	$ 14	$ 28
Operating expenses:		
Research and development	40,699	27,870
General and administrative	12,936	10,294
Total operating expenses	53,635	38,164
Loss from operations	(53,621)	(38,136)
Other income, net	5,649	5,735
Net loss	$ (47,972)	$ (32,401)
Net loss per share, basic and diluted	$ (0.86)	$ (0.66)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	55,744,047	49,271,984

4D Molecular Therapeutics, Inc.

Balance Sheet Data
(Unaudited)
(*in thousands*)

	March 31, 2025	**December 31, 2024**
Cash, cash equivalents and marketable securities	$ 458,441	$ 505,460
Total assets	515,729	560,384
Total liabilities	46,006	49,778
Accumulated deficit	(624,167)	(576,195)
Total stockholders’ equity	469,723	510,606

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Source: 4D Molecular Therapeutics, Inc.