4DMT Reports Full Year 2024 Financial Results, Operational Highlights and Expected Upcoming Milestones

February 28, 2025

- *Presented positive interim data through 52 weeks and beyond for 4D-150 in wet AMD from PRISM Phase 1/2 clinical trial highlighting robust and durable clinical activity across diverse patient populations and continued favorable tolerability*
- *Announced positive interim 32-week data for 4D-150 in DME from Part 1 of SPECTRA clinical trial and alignment with FDA for a single Phase 3 trial being acceptable for the basis of BLA submission for 4D-150 in DME when combined with data generated from 4FRONT Phase 3 trials in wet AMD*
- *4FRONT Phase 3 program in wet AMD on track with initiation of 4FRONT-1 expected in March 2025 and 4FRONT-2 in Q3 2025, with topline data from both studies expected in 2H 2027*
- *Strategically focused pipeline to optimize resource allocation and extend cash runway to advance product candidates with strongest clinical proof of concept: 4D-150 for wet AMD and DME and 4D-710 for cystic fibrosis*
- *$505 million in cash, cash equivalents and marketable securities as of December 31, 2024, expected to fund planned operations into 2028*

EMERYVILLE, Calif., Feb. 28, 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 full year 2024 financial results, provided operational highlights and outlined expected upcoming milestones.

“2024 was a landmark year for 4DMT, driven by groundbreaking clinical advancements toward Phase 3 trials that position us for even greater success in 2025 and beyond,” said David Kirn, M.D., Co-founder and Chief Executive Officer of 4DMT. “The data from the PRISM and SPECTRA clinical trials have highlighted 4D-150's potential to become the first backbone therapy for retinal vascular diseases by providing patients and physicians with long-lasting and continuous disease control, plus freedom from frequent bolus injections. 4D-150’s target product profile is designed to allow for seamless adoption into retina clinic practices and for pricing flexibility augmented by our low cost of goods. With the imminent start of our Phase 3 studies for 4D-150 in wet AMD, our team, investigators and clinical sites are energized to rapidly recruit patients to deliver topline results in the second half of 2027. We believe rapid enrollment in 4D-150 Phase 3 studies that mirror enrollment rates seen in our Phase 1/2 studies would validate the potential for future widespread adoption of 4D-150 in retina clinics, strengthening our path toward transforming the retinal vascular disease treatment paradigm.”

Recent Corporate Highlights

- **Focused Pipeline and Extended Cash Runway:**
  - Core programs: 4D-150 for wet AMD and DME and 4D-710 for cystic fibrosis (CF)
  - Paused significant additional capital allocation and investment, pending additional financing or partnerships for the following therapeutics:
    - 4D-175 for geographic atrophy
    - 4D-725 for alpha-1 antitrypsin deficiency lung disease
    - 4D-310 for Fabry disease cardiomyopathy
  - Terminated the development of the early-stage rare disease clinical programs evaluating 4D-110 for choroideremia and 4D-125 for X-linked retinitis pigmentosa
  - Paused investment into new preclinical product candidates
  - As a result, cash runway 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, and ongoing Phase 1 & 2 clinical development of 4D-150 in DME and 4D-710 in CF

Recent Highlights in Large Market Ophthalmology Portfolio

- **4D-150 for Wet AMD:**
  - Presented positive 52-week results from 3E10 vg/eye (Phase 3 dose) arm of Phase 2b Population Extension cohort of PRISM clinical trial (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% 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% required 0-1 supplemental injection and 80% were injection-free
    - Improved and maintained best corrected visual acuity (BCVA) and durable central subfield thickness (CST) improvement 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 1+ vitreous cells at a single

timepoint in 2.8% (2 of 71) of patients

- Presented interim data from PRISM supporting multi-year durability:
  - In September 2024, presented interim data for patients treated with 3E10 vg/eye (n=24) with variable follow-up ranging from 56 weeks to 2.5 years from Phase 1/2a cohorts in severe disease activity population, demonstrating (data cutoff: September 3, 2024):
    - Consistent and durable overall reduction in annualized injection burden, with 83% overall reduction through 52 weeks vs. prior year
    - Three patients reached 2 to 2.5 years of follow-up, and all were injection-free
    - BCVA maintained and durable CST improvement with fewer fluctuations versus aflibercept control arm
  - Durable and stable aqueous humor concentrations consistently within projected therapeutic range demonstrated with up to two years of follow-up (best available data as of November 20, 2024)
- Provided Phase 3 4FRONT program overview and update:
  - 4FRONT-1 and 4FRONT-2 clinical trial designs:
    - Primary endpoint: BCVA noninferiority of 4D-150 3E10 vg/eye to aflibercept 2 mg Q8W
    - Enrichment criteria: randomization requires on study demonstration of aflibercept responsiveness
    - Disclosed supplemental aflibercept injection criteria optimized to protect primary BCVA endpoint and highlight key secondary endpoint of reduction of supplemental treatment burden vs. aflibercept comparator
  - 4FRONT-1 to enroll treatment-naïve population, and 4FRONT-2 to enroll both treatment-naïve and previously treated population diagnosed within the last six months; target enrollment of 400 patients per trial

- **4D-150 for DME:**
  - Presented positive interim 32-week data from the 4D-150 SPECTRA clinical trial (data cutoff: December 13, 2024)
    - Across all DME patients dosed to date, 4D-150 continues to be well tolerated with no intraocular inflammation observed at any timepoint or dose level
    - 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. 1E10 vg/eye, with 0.6 mean supplemental injections per patient, with stringent supplemental injection criteria
  - 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

Recent Highlights in Pulmonology Program

- **4D-710 for CF Lung Disease:**
  - Enrollment for Cohorts 3 & 4 (5E14 & 2.5 vg dose levels, n=3 each) in Phase 1 AEROW clinical trial completed in November 2024, follow-up ongoing
  - Enrollment extension of three additional participants in Cohort 4 ongoing

Expected Upcoming Milestones in Large Market Ophthalmology Portfolio

- **4D-150 for Wet AMD:**
  - 4FRONT-1 and 4FRONT-2 Phase 3 clinical trials expected to initiate in March and Q3 2025, respectively
  - 2-year data from Phase 1/2a and 18-month data from Phase 2b cohorts of PRISM clinical trial expected in Q4 2025
  - Primary endpoint 52-week topline data from both 4FRONT-1 and 4FRONT-2 expected in H2 2027
- **4D-150 for DME:**
  - 52-week interim data update from Part 1 of SPECTRA expected at a scientific conference in Q3 2025

Expected Upcoming Milestones in Pulmonology Program

- **4D-710 for CF Lung Disease:**
  - Interim data and program update from AEROW clinical trial expected at a scientific conference in H2 2025

Full Year 2024 Financial Results

Cash position: Cash, cash equivalents and marketable securities were $505 million as of December 31, 2024, as compared to $299 million as of December 31, 2023. The net increase in cash was primarily a result of cash inflows from a public offering of common stock and prefunded warrants we

completed in February 2024, as well as a partial exercise of underwriters' option to purchase additional shares that resulted in us receiving net proceeds of approximately $316 million partially offset by 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 $141.3 million for 2024, as compared to $97.1 million for 2023. This increase was driven by the progression of our existing clinical trials, primarily Phase 2 4D-150 trials 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 $46.6 million for 2024, as compared to $36.5 million for 2023.

Net Loss: Net loss was $160.9 million for 2024, as compared to net loss of $100.8 million for 2023.

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 Annual Report on Form 10-K 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
(*in thousands, except share and per share amounts*)

	Year Ended December 31,	
	2024	**2023**
Revenue:		
Collaboration and license revenue	$ 37	$ 20,723
Operating expenses:		
Research and development	141,299	97,096
General and administrative	46,579	36,494
Total operating expenses	187,878	133,590
Loss from operations	(187,841)	(112,867)
Other income, net	26,973	12,030
Net loss	$ (160,868)	$ (100,837)
Net loss per share, basic and diluted	$ (2.98)	$ (2.58)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	53,943,741	39,130,067

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

	As of December 31,

	2024	2023
Cash, cash equivalents and marketable securities	$ 505,460	$ 299,186
Total assets	560,384	339,891
Total liabilities	49,778	32,062
Accumulated deficit	(576,195)	(415,327)
Total stockholders' equity	510,606	307,829

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