Dyne Therapeutics Reports First Quarter 2025 Financial Results and Recent Business Highlights

May 8, 2025

- FDA (CDER) Type C meeting held in May 2025 for DYNE-101 in DM1 and Dyne plans to provide a regulatory update following receipt of meeting minutes -

- Registrational Expansion Cohort of ACHIEVE Trial of DYNE-101 in DM1 initiated to support potential submission for U.S. Accelerated Approval in H1 2026 -

- Registrational Expansion Cohort of DELIVER Trial of DYNE-251 in DMD fully enrolled to support potential submission for U.S. Accelerated Approval in early 2026 -

WALTHAM, Mass., May 08, 2025 (GLOBE NEWSWIRE) -- Dyne Therapeutics, Inc. (Nasdaq: DYN), a clinical-stage company focused on advancing life-transforming therapeutics for people living with genetically driven neuromuscular diseases, today reported financial results for the first quarter of 2025 and recent business highlights.

“Our two lead programs continue to demonstrate compelling and favorable data, including evidence of functional improvement across multiple measures in DM1 and DMD. We are urgently advancing both programs toward potential U.S. Accelerated Approval submissions in 2026 and possible commercial launches in 2027,” said John Cox, president and chief executive officer of Dyne. “I am also thrilled to welcome Erick, Vik and Ron to the Dyne leadership team, which now includes a new role for Oxana as chief innovation officer. Together, our team has the proven experience and capabilities to efficiently drive the business, deliver therapies that bring functional improvement and create significant shareholder value.”

DYNE-101 in DM1

- Dyne participated in a Type C meeting with the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA) in May 2025 and discussed the path to regulatory approval, including U.S. Accelerated Approval, for DYNE-101 in DM1.
- Dyne has initiated a global placebo-controlled Registrational Expansion Cohort in the ACHIEVE trial that will include up to 48 participants with full enrollment planned for mid-2025.
    - Data from this cohort is planned for H1 2026 to support a potential U.S. Accelerated Approval Biologics License Application (BLA) submission in H1 2026.
- Dyne also continues to advance preparations for a Phase 3 trial with the goal of initiating the trial in 2025.
- Management plans to provide a regulatory update for DYNE-101 following receipt of final FDA meeting minutes and the company’s incorporation of regulatory feedback.
- Dyne is also pursuing expedited approval pathways globally for DYNE-101.

DYNE-251 in DMD

- In April 2025, the European Commission granted Orphan Drug Designation to DYNE-251 for the treatment of patients with DMD who are amenable to exon 51 skipping.
- Dyne has fully enrolled the Registrational Expansion Cohort of 32 patients as part of the DELIVER trial. Data from this cohort are planned for late 2025.
- Dyne anticipates a potential BLA submission for U.S. Accelerated Approval in early 2026.
- Dyne continues to pursue expedited approval pathways globally for DYNE-251 in patients with DMD who are amenable to exon 51 skipping.

New Leadership Appointments

Dyne recently strengthened its leadership team in preparation for potential regulatory filings, approvals and commercial launches of DYNE-101 and DYNE-251:

- Erick Lucera, chief financial officer (CFO), brings more than thirty years of capital markets, operational and investment experience in the life science industry to his leadership role at Dyne.
- Vikram (Vik) Ranade, PhD, chief business officer (CBO) is driving business development, corporate strategy and strategic partnerships to support the company’s late-stage clinical and commercialization plans.
- Ranjan (Ron) Batra, PhD, chief scientific officer (CSO) is leading the company’s research strategy, pipeline development

and activities supporting clinical development.

- Oxana Beskrovnaya, PhD, the company's previous CSO, has taken on a new role as our chief innovation officer (CIO) and is developing and advancing Dyne's comprehensive strategy to maximize the value of its FORCE™ platform across multiple tissues, therapeutic areas and indications.

First Quarter Financial Results

Cash position: Cash, cash equivalents and marketable securities were $677.5 million as of March 31, 2025. The company expects that its cash, cash equivalents and marketable securities as of March 31, 2025 will be sufficient to fund its operations at least into the second half of 2026.

Research and development (R&D) expenses: R&D expenses were $106.4 million for the quarter ended March 31, 2025 compared to $44.5 million for the quarter ended March 31, 2024.

General and administrative (G&A) expenses: G&A expenses were $15.9 million for the quarter ended March 31, 2025 compared to $24.6 million for the quarter ended March 31, 2024.

Net loss: Net loss for the quarter ended March 31, 2025 was $115.4 million, or $1.05 per basic and diluted share. This compares with a net loss of $65.6 million, or $0.81 per basic and diluted share, for the quarter ended March 31, 2024.

About Dyne Therapeutics

Dyne Therapeutics is discovering and advancing innovative life-transforming therapeutics for people living with genetically driven neuromuscular diseases. Leveraging the modularity of its FORCE™ platform, Dyne is developing targeted therapeutics that deliver to muscle and the central nervous system (CNS). Dyne has a broad pipeline for neuromuscular diseases, including clinical programs for myotonic dystrophy type 1 (DM1) and Duchenne muscular dystrophy (DMD) and preclinical programs for facioscapulohumeral muscular dystrophy (FSHD) and Pompe disease. For more information, please visit https://www.dyne-tx.com/, and follow us on X, LinkedIn and Facebook.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release, including statements regarding Dyne's strategy, future operations, prospects and plans, objectives of management, the potential of the FORCE platform, the potential of DYNE-101 and DYNE-251, the anticipated timelines for reporting additional data from the ACHIEVE and DELIVER clinical trials, initiating and enrolling registrational cohorts, initiating additional clinical trials, submitting applications for marketing approval and commercial launches, the availability of expedited approval pathways for DYNE-101 and DYNE-251, expectations regarding the timing and outcome of interactions with regulatory authorities, and the sufficiency of Dyne's cash resources for the period anticipated, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," or "would," or the negative of these terms, or other comparable terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Dyne may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including: uncertainties inherent in the identification and development of product candidates, including the initiation and completion of preclinical studies and clinical trials; uncertainties as to the availability and timing of results from preclinical studies and clinical trials; the timing of and Dyne's ability to enroll patients in clinical trials; whether results from preclinical studies and data from clinical trials will be predictive of the final results of the clinical trials or other trials; whether data from clinical trials will support submission for regulatory approvals; uncertainties as to the FDA's and other regulatory authorities' interpretation of the data from Dyne's clinical trials and acceptance of Dyne's clinical programs and as to the regulatory approval process for Dyne's product candidates; whether Dyne's cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; as well as the risks and uncertainties identified in Dyne's filings with the Securities and Exchange Commission (SEC), including the company's most recent Form 10-Q and in subsequent filings Dyne may make with the SEC. In addition, the forward-looking statements included in this press release represent Dyne's views as of the date of this press release. Dyne anticipates that subsequent events and developments will cause its views to change. However, while Dyne may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Dyne's views as of any date subsequent to the date of this press release.

Dyne Therapeutics, Inc.
Condensed Consolidated Statement of Operations
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 106,447	$ 44,539
General and administrative	15,925	24,618
Total operating expenses	**122,372**	**69,157**
Loss from operations	(122,372)	(69,157)
Other (expense) income, net	7,011	3,508
Net loss	**$ (115,361)**	**$ (65,649)**
Net loss per share, basic and diluted	$ (1.05)	$ (0.81)
Weighted average common shares outstanding, basic and diluted	109,911,628	81,043,741

	March 31, 2025	December 31, 2024
Assets		
Cash, cash equivalents and marketable securities	$ 677,492	$ 642,268
Other assets	43,582	48,966
Total assets	**$ 721,074**	**$ 691,234**
Liabilities and Stockholders' Equity		
Liabilities	52,101	61,396
Stockholders' equity	668,973	629,838
Total liabilities and stockholders' equity	**$ 721,074**	**$ 691,234**

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