Dyne Therapeutics Reports First Quarter 2026 Financial Results and Recent Business Highlights

May 11, 2026

- Positive pre-BLA meeting completed with FDA for z-rostudirsen in exon 51 DMD; on track for BLA submission in Q2 2026 and potential launch in Q1 2027 -

- Positive cardiopulmonary results and long-term dystrophin data from Phase 1/2 DELIVER trial of z-rostudirsen in exon 51 DMD presented at MDA conference -

- Completion of enrollment in registrational expansion cohort of Phase 1/2 ACHIEVE trial of z-basivarsen in DM1 on track for Q2 2026; global confirmatory Phase 3 HARMONIA trial initiated -

- New preclinical data to be presented at ASGCT underscore differentiated capability of clinically validated FORCE™ platform to cross the blood-brain barrier -

WALTHAM, Mass., May 11, 2026 (GLOBE NEWSWIRE) -- Dyne Therapeutics, Inc. (Nasdaq: DYN), a clinical-stage company focused on delivering functional improvement for people living with genetically driven neuromuscular diseases, today reported financial results for the first quarter of 2026 and recent business highlights.

“Following positive topline data late last year, we continue to ramp up activities to support a potential launch of z-rostudirsen in DMD in the first quarter of 2027,” said John Cox, president and chief executive officer of Dyne. “We are grateful to the FDA for a collaborative pre-BLA meeting, where we aligned on the contents of our planned BLA submission for U.S. Accelerated Approval of z-rostudirsen, which is on track for this quarter.”

“In DM1, we have reached our target of 60 participants in the registrational expansion cohort of the ACHIEVE trial of z-basivarsen. Based on a recent acceleration in the number of participants in screening, we currently expect to exceed this target when we complete enrollment later this quarter. As we look toward the important expected readout in the first quarter of 2027, we continue to be driven by our goal to deliver functional improvement for individuals living with DM1. We remain committed to disciplined execution as we advance our two lead programs and broader pipeline and aim to maximize returns for our shareholders,” concluded Mr. Cox.

Zeleciment rostudirsen (z-rostudirsen, also known as DYNE-251) in DMD (Duchenne muscular dystrophy)

Positive cardiopulmonary results and long-term dystrophin data from the DELIVER trial

- In March 2026, at the 2026 Muscular Dystrophy Association (MDA) Clinical & Scientific Conference, Dyne presented positive results of new analyses of cardiac and pulmonary function among all DELIVER participants who were randomized to z-rostudirsen treatment at baseline (any dose[1]) and for whom cardiac magnetic resonance imaging and/or pulmonary function data were available.
- At the 2026 MDA Conference, Dyne also presented long-term data on dystrophin production from four participants in the DELIVER trial who had been dosed with 20 mg/kg Q4W for at least 12 months (67-104 weeks) at the time of an optional biopsy. Unadjusted dystrophin production in these participants reached an average of 9.48% of normal (n=4) as compared to 0.52% at baseline (n=3), and muscle content-adjusted dystrophin production reached an average of 18.33% of normal (n=4) as compared to 1.47% at baseline (n=3).
- In previously reported safety and tolerability data from 86 total participants enrolled in the DELIVER trial and followed for up to 36 months, z-rostudirsen demonstrated a favorable safety profile,[2] and most related treatment emergent adverse events (TEAEs) were mild or moderate. The most commonly reported related TEAEs were pyrexia (fever) and headache. No related serious TEAEs were observed in the registrational expansion cohort (REC).

Key milestones for z-rostudirsen

- Dyne has completed a positive pre-BLA meeting with the U.S. Food and Drug Administration (FDA) and remains on track to submit a Biologics License Application (BLA) for U.S. Accelerated Approval in Q2 2026.
- Dyne plans to initiate a global confirmatory Phase 3 clinical trial of z-rostudirsen in Q2 2026. Dyne has aligned with the FDA on the Phase 3 trial design and protocol.
- Dyne continues to expect a potential U.S. launch of z-rostudirsen in Q1 2027, assuming the FDA grants Priority Review and approval is received on the anticipated timeline.
- Dyne also continues to pursue approval pathways outside of the U.S. for z-rostudirsen in patients with DMD who are amenable to exon 51 skipping.
- In addition to z-rostudirsen, Dyne is advancing four development candidates (DYNE-253, DYNE-245, DYNE-244 and DYNE-255) for the potential treatment of DMD amenable to skipping of exons 53, 45, 44, and 55, respectively.

Zeleciment basivarsen (z-basivarsen, also known as DYNE-101) in DM1 (myotonic dystrophy type 1)

Phase 3 HARMONIA trial underway

- Dyne initiated the global confirmatory Phase 3 HARMONIA trial of z-basivarsen in March 2026. Dyne has aligned with the FDA on the Phase 3 trial design and protocol, which was presented at the 2026 MDA Clinical & Scientific Conference.

Key milestones for z-basivarsen

- Dyne has reached its enrollment target of 60 participants in the ACHIEVE REC. Dyne plans to allow any participants currently in screening to enroll if they meet all eligibility criteria. As a result, Dyne expects to complete enrollment of more than 60 participants in Q2 2026.
- Data from this cohort are planned for Q1 2027 to support a potential BLA submission for U.S. Accelerated Approval in early Q3 2027.
    - Dyne intends to use data from the REC and from the already enrolled participants in the multiple ascending dose (MAD) and ongoing long-term extension portions of the ACHIEVE trial to support a potential submission for Accelerated Approval in the U.S.
- Dyne expects a potential U.S. launch of z-basivarsen in Q1 2028, assuming FDA grants Priority Review and approval is received on the anticipated timeline.
- Dyne also continues to pursue approval pathways outside of the U.S. for z-basivarsen in DM1.

New preclinical data showing robust central nervous system (CNS) activity in nonhuman primates with FORCE platform

- This week, Dyne is presenting new preclinical data highlighting the differentiated capability of the clinically validated FORCE platform to cross the blood-brain barrier. The oral presentation will take place on Wednesday, May 13, at 10:30 a.m. ET at the American Society of Gene + Cell Therapy (ASGCT) 2026 Annual Meeting being held in Boston, MA, and virtually.

First Quarter Financial Results

Cash position: Cash, cash equivalents and marketable securities were $972.2 million as of March 31, 2026. The Company continues to expect that its cash, cash equivalents and marketable securities as of March 31, 2026, will be sufficient to fund its operations into the first quarter of 2028.

Research and development (R&D) expenses: R&D expenses were $100.9 million for the three months ended March 31, 2026 compared to $106.4 million for the three months ended March 31, 2025. The decrease in R&D expense was primarily due to the timing of manufacturing batches of z-rostudirsen and z-basivarsen.

General and administrative (G&A) expenses: G&A expenses were $24.4 million for the three months ended March 31, 2026 compared to $15.9 million for the three months ended March 31, 2025. The increase in G&A expenses was primarily due to increased costs in preparation for the potential launch of z-rostudirsen.

Net loss: Net loss for the three months ended March 31, 2026 was $120.9 million, or $0.73 per basic and diluted share. This compares with a net loss of $115.4 million, or $1.05 per basic and diluted share, for the three months ended March 31, 2025.

About Dyne Therapeutics

Dyne Therapeutics is focused on delivering functional improvement for people living with genetically driven neuromuscular diseases. We are developing therapeutics that target muscle and the central nervous system (CNS) to address the root cause of disease. The company is advancing clinical programs for Duchenne muscular dystrophy (DMD) and myotonic dystrophy type 1 (DM1) as well as preclinical programs for facioscapulohumeral muscular dystrophy (FSHD), Pompe disease and multiple DMD mutations. At Dyne, we are on a mission to deliver functional improvement for individuals, families and communities. Learn more at 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, projections and plans; objectives of management; the potential of the FORCE platform; the potential of zeleciment basivarsen (z-basivarsen, also known as DYNE-101) and zeleciment rostudirsen (z-rostudirsen, also known as DYNE-251); the anticipated timelines for initiating additional clinical trials, reporting data from clinical trials, enrolling registrational cohorts, submitting applications for marketing approval and launching commercially; the availability of expedited approval pathways for z-basivarsen and z-rostudirsen; expectations regarding the potential timing of regulatory approval, commercial launch and the 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," "will" 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 clinical trials; uncertainties as to the availability and timing of results from clinical trials; uncertainties as to 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, debt service obligations 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.

1. The majority of participants at the 24 month timepoint initiated treatment at the 0.7–2.8 mg/kg Q4W dose levels. Because most participants accrued substantial time on doses lower than the registrational dose of 20 mg/kg z-rostudirsen Q4W, the observed long-term efficacy potentially does not reflect the effect of continuously maintaining 20 mg/kg Q4W.
2. Z-rostudirsen (DYNE-251) safety data as of August 19, 2025.

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

	Three Months Ended March 31,	
	2026	**2025**
Operating expenses:		
Research and development	$ 100,889	$ 106,447
General and administrative	24,387	15,925
Total operating expenses	**125,276**	**122,372**
Loss from operations	(125,276)	(122,372)
Other income, net	4,422	7,011
Net loss	**$ (120,854)**	**$ (115,361)**
Net loss per share, basic and diluted	$ (0.73)	$ (1.05)
Weighted average common shares outstanding, basic and diluted	165,036,604	109,911,628

Dyne Therapeutics, Inc.
Condensed Consolidated Balance Sheet Data
(in thousands)

	March 31, 2026	December 31, 2025
Assets		
Cash, cash equivalents and marketable securities	$ 972,156	$ 1,110,562
Other assets	107,794	76,396
Total assets	**$ 1,079,950**	**$ 1,186,958**
Liabilities and Stockholders' Equity		
Liabilities	214,895	214,829
Stockholders' equity	865,055	972,129
Total liabilities and stockholders' equity	**$ 1,079,950**	**$ 1,186,958**

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