Dyne Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results and Recent Business Highlights

March 2, 2026

- Planned submission for U.S. Accelerated Approval of z-rostudirsen on track for Q2 2026; potential launch in Q1 2027 -

- Positive topline results reported from Phase 1/2 DELIVER trial of z-rostudirsen in exon 51 skip amenable Duchenne muscular dystrophy (DMD); additional long-term data to be presented at MDA -

- Completion of enrollment in registrational expansion cohort of Phase 1/2 ACHIEVE trial of z-basivarsen in myotonic dystrophy type 1 (DM1) expected in Q2 2026; Phase 3 trial design to be presented at MDA -

- Advancing four development candidates for the potential treatment of DMD amenable to skipping of exons 53, 45, 44, and 55 -

- Year-end cash of $1.1 billion; reaffirming expected cash runway into Q1 2028 -

WALTHAM, Mass., March 02, 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 fourth quarter and full year 2025 and recent business highlights.

“Dyne is entering a critical period of transformation as we advance programs from our clinically validated FORCE platform toward commercialization, with our first potential launch in DMD in less than 12 months, if Priority Review is granted and approval is received. The positive topline results we reported in December for z-rostudirsen further demonstrate the potential of the FORCE platform to safely and effectively deliver drug payloads broadly and deeply into targeted tissues, all with the goal of providing functional improvement to patients in urgent need of new therapies,” said John Cox, president and chief executive officer of Dyne.

“In 2026, we are focused on disciplined execution across our two lead programs with the goal of delivering potential best-in-class therapies to patients as quickly as possible. We are actively preparing a submission for U.S. Accelerated Approval of z-rostudirsen, positioning us for a potential launch planned for the first quarter of next year. We have added seven new sites since September to the ACHIEVE trial of z-basivarsen in DM1, and we continue to accelerate patient screening and enrollment, which we believe will enable completion of enrollment in the second quarter. At the same time, we expect to initiate two field-defining Phase 3 trials in DMD and DM1, as we continue to advance and expand our differentiated pipeline based on the FORCE platform,” concluded Mr. Cox.

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

Positive topline results from Registrational Expansion Cohort (REC) of DELIVER trial

- In December 2025, Dyne reported that the REC (n=32) met its primary endpoint, demonstrating a statistically significant change from baseline in muscle content-adjusted dystrophin expression to 5.46% of normal at six months ($p<0.0001$), a 7-fold change from baseline.
- Improvement relative to placebo was observed across all six prespecified topline functional endpoints. Two of these measures, Time to Rise (TTR) Velocity and 10-Meter Walk/Run (10MWR) Velocity, both improved relative to placebo at six months with a nominal $p<0.05$, even though the trial was not powered to demonstrate statistical significance in any of the functional measures. [1]
- Lung function, the loss of which is a leading cause of mortality in DMD, as measured by Forced Vital Capacity Percent Predicted (FVC%p), was preserved at 6 months compared to a decline in placebo.
- In addition, positive long-term results from the DELIVER trial showed sustained functional improvement across the same six endpoints out to 24 months, for participants treated with z-rostudirsen in the 10 mg/kg Q4W cohort of the multiple ascending dose (MAD) portion of the trial who were dose escalated to 20 mg/kg Q4W in the open-label extension period.
- Z-rostudirsen continued to demonstrate a favorable safety profile, [2] and most related treatment emergent adverse events (TEAEs) were mild or moderate.
- These results, along with additional long-term data showing the potential preservation of cardiopulmonary function, will be presented at the 2026 Muscular Dystrophy Association (MDA) Clinical & Scientific Conference being held March 8-11, 2026, in Orlando, FL, and virtually.

Key milestones for z-rostudirsen

- Dyne plans to submit a Biologics License Application (BLA) for U.S. Accelerated Approval in Q2 2026.

- Dyne remains on track to initiate a global confirmatory Phase 3 clinical trial of z-rostudirsen in Q2 2026. Dyne has aligned with the U.S. Food and Drug Administration (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.

Zeleciment basivarsen (z-basivarsen, also known as DYNE-101) in DM1

Key milestones for z-basivarsen

- Dyne expects to complete enrollment of 60 participants in the ACHIEVE REC 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 patients in the 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.
- Dyne remains on track to initiate a global confirmatory Phase 3 clinical trial of z-basivarsen in March 2026. Dyne has aligned with the FDA on the Phase 3 trial design and protocol.
    - The design of this Phase 3 trial will be presented at the 2026 MDA Clinical & Scientific Conference being held March 8-11, 2026, in Orlando, FL, and virtually.
- Dyne also continues to pursue approval pathways outside of the U.S. for z-basivarsen in DM1.

Other Exons in DMD

- 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, into IND-enabling studies.
- These programs are designed to enable the production of near full-length dystrophin in patients with DMD amenable to skipping of exons 53, 45, 44, or 55 by utilizing the same FORCE^{TM} platform (Fab, linker, and payload chemistry) as z-rostudirsen.

Fourth Quarter and Full Year 2025 Financial Results

Cash position: Cash, cash equivalents and marketable securities were $1.1 billion as of December 31, 2025. The Company continues to expect that its cash, cash equivalents and marketable securities as of December 31, 2025, will be sufficient to fund its operations into the first quarter of 2028.

Research and development (R&D) expenses: R&D expenses were $95.4 million and $81.8 million for the quarters ended December 31, 2025 and 2024, respectively. R&D expenses were $398.3 million and $281.4 million for the years ended December 31, 2025 and 2024, respectively.

General and administrative (G&A) expenses: G&A expenses were $20.7 million and $15.3 million for the quarters ended December 31, 2025 and 2024, respectively. G&A expenses were $69.9 million and $62.5 million for the years ended December 31, 2025 and 2024, respectively.

Net loss: Net loss for the quarter ended December 31, 2025 was $112.0 million, or $0.76 per basic and diluted share. This compares with a net loss of $89.5 million, or $0.88 per basic and diluted share, for the quarter ended December 31, 2024. Net loss for the year ended December 31, 2025 was $446.2 million, or $3.47 per basic and diluted share. This compares with a net loss of $317.4 million, or $3.37 per basic and diluted share, for the year ended December 31, 2024.

1. Post-hoc analysis; prespecified statistical analysis plan did not include formal hypothesis testing for any functional endpoint.
2. Z-rostudirsen safety data as of August 19, 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 a preclinical programs for facioscapulohumeral muscular dystrophy (FSHD) and Pompe disease. 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 and plans, objectives of

management; the potential of the FORCE platform, the potential of zeleciment basivarsen (z-basivarsen, also known as DYNE-101), zeleciment rostudirsen (z-rostudirsen, also known as DYNE-251), DYNE-253, DYNE-245, DYNE-244 and DYNE-255; the anticipated timelines for initiating additional clinical trials, reporting additional data from the ACHIEVE and DELIVER 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 95,431	$ 81,804	$ 398,333	$ 281,406
General and administrative	20,698	15,303	69,851	62,480
Total operating expenses	**116,129**	**97,107**	**468,184**	**343,886**
Loss from operations	(116,129)	(97,107)	(468,184)	(343,886)
Other (expense) income, net	4,174	7,567	21,970	26,468
Net loss	**$ (111,955)**	**$ (89,540)**	**$ (446,214)**	**$ (317,418)**
Net loss per share, basic and diluted	$ (0.76)	$ (0.88)	$ (3.47)	$ (3.37)
Weighted average common shares outstanding, basic and diluted	147,618,963	101,982,168	128,442,723	94,143,565

	December 31, 2025	December 31, 2024
Assets		
Cash, cash equivalents and marketable securities	$ 1,110,562	$ 642,268
Other assets	76,396	48,966
Total assets	**$ 1,186,958**	**$ 691,234**
Liabilities and Stockholders' Equity		
Liabilities	214,829	61,396
Stockholders' equity	972,129	629,838
Total liabilities and stockholders' equity	**$ 1,186,958**	**$ 691,234**

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