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

November 5, 2025

- Topline data from Registrational Expansion Cohort of DELIVER trial of zeleciment rostudirsen (z-rostudirsen, also known as DYNE-251) in DMD on track for December 2025 to support potential submission for U.S. Accelerated Approval in Q2 2026 -

- FDA recently granted Breakthrough Therapy Designation to z-rostudirsen for the treatment of patients with DMD amenable to exon 51 skipping -

- U.S. sites activated in ACHIEVE trial of zeleciment basivarsen (z-basivarsen, also known as DYNE-101) in DM1; completion of enrollment now expected in early Q2 2026 -

- Additional one-year clinical data from ACHIEVE trial demonstrating sustained functional improvement across multiple clinical measures recently presented at WMS -

- Reaffirming expected cash runway into Q3 2027, beyond Dyne's first planned commercial launch of z-rostudirsen in DMD and potential z-basivarsen BLA submission in DM1 -

WALTHAM, Mass., Nov. 05, 2025 (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 third quarter of 2025 and recent business highlights.

"Our lead programs in DMD and DM1 have now each been granted Breakthrough Therapy Designation by the FDA and are advancing toward anticipated U.S. Accelerated Approval submissions, as we aim to further validate the potential of our FORCE platform to safely and effectively deliver multiple drug payloads broadly and deeply into muscle and the CNS. We believe z-rostudirsen has the potential to transform the lives of individuals living with DMD amenable to exon 51 skipping, and we are excited to share topline data in December," said John Cox, president and chief executive officer of Dyne.

"We continue to advance z-basivarsen toward a U.S. Accelerated Approval submission in DM1 and now anticipate full enrollment in the ongoing Registrational Expansion Cohort of our ACHIEVE trial in early Q2 2026. This is a change from previous guidance of Q4 2025, but, starting in September, we initiated a significant expansion of clinical trial sites for ACHIEVE, including the recent activation of the first sites in the U.S. We expect that the additional sites will enable full enrollment of the planned 60 participants on this timeline. Importantly, we believe that the progress we have made across both programs positions us to launch two potentially best-in-class medicines within roughly one year of each other, beginning with z-rostudirsen potentially in Q1 2027," concluded Mr. Cox.

Zeleciment basivarsen (z-basivarsen, also known as DYNE-101) in Myotonic Dystrophy Type 1 (DM1)

First U.S. sites activated and enrolling in Registrational Expansion Cohort (REC) of ACHIEVE trial

- Dyne initiated the U.S. site activation process in June 2025 after submitting a revised protocol for the REC to the U.S. Food and Drug Administration (FDA) with video hand opening time (vHOT) as the primary endpoint; U.S. site activation began in September and U.S. patient enrollment and dosing was initiated in October.

ACHIEVE REC enrollment of 60 participants expected to be completed in early Q2 2026

- Dyne anticipates a potential BLA (Biologics License Application) 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 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.
- Dyne remains on track to initiate a confirmatory Phase 3 clinical trial in Q1 2026.
- Dyne also continues to pursue approval pathways outside of the U.S. for z-basivarsen in DM1.

Additional one-year clinical data demonstrating functional improvement across multiple measures

- In October 2025, Dyne presented additional one-year clinical data from the ACHIEVE trial of z-basivarsen at the 30th Annual International Congress of the World Muscle Society (WMS). These data demonstrated clinically meaningful functional improvement across multiple measures at the selected registrational dose of 6.8 mg/kg Q8W, including assessments of function and strength, as well as patient- and clinician-reported outcomes.

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

"Z-rostudirsen has the potential to provide functional improvement for patients with DMD amenable to exon 51 skipping, with a favorable safety profile and the convenience of monthly dosing," said Doug Kerr, M.D., Ph.D., chief medical officer of Dyne. "Prior data from DELIVER demonstrated that DMD patients treated with z-rostudirsen can achieve dystrophin levels well above those possible with currently approved therapies for exon 51, as well as unprecedented improvements across multiple functional outcomes. We look forward to reporting topline data next month from the Registrational Expansion Cohort of DELIVER – the first potentially registrational data emerging from Dyne's FORCE platform. I expect this to be a validating milestone for our pipeline and platform, but I am even more excited for these data to form the basis of a potential submission for U.S. Accelerated Approval in the second quarter of next year."

DELIVER REC topline results expected in December 2025

- Dyne completed enrollment of 32 patients in the REC of the DELIVER trial in March 2025 and expects to announce data for the 6-month primary analysis in December 2025.
    - The primary endpoint of the REC is the change from baseline in dystrophin protein by Western blot at 6 months. Dyne expects these data, along with comprehensive data from the MAD portion of the DELIVER trial, including safety, to support a potential submission for U.S. Accelerated Approval.
    - Dyne also plans to report data on secondary endpoints, including functional assessments, although the REC is not powered to demonstrate statistical significance on these endpoints.
- In August 2025, the FDA granted Breakthrough Therapy Designation to z-rostudirsen for the treatment of patients with DMD, amenable to exon 51 skipping.

Z-rostudirsen remains on track for potential launch in Q1 2027

- Dyne continues to anticipate a potential BLA submission for U.S. Accelerated Approval in Q2 2026.
- Dyne continues to expect a potential U.S. launch of z-rostudirsen in Q1 2027, assuming FDA grants Priority Review.
- 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.

Third Quarter Financial Results

"We believe we have sufficient funds to generate data from two registrational trials, submit two BLAs for U.S. Accelerated Approval, and launch our first commercial product," said Erick Lucera, chief financial officer of Dyne. "We are on track with the buildout of a capital-efficient rare disease commercial organization, along with our CMC infrastructure. Our management team is in place to operate effectively and create long-term value for shareholders."

Cash position: Cash, cash equivalents and marketable securities were $791.9 million as of September 30, 2025. The Company continues to expect that its cash, cash equivalents and marketable securities as of September 30, 2025, will be sufficient to fund its operations into the third quarter of 2027.

Research and development (R&D) expenses: R&D expenses were $97.2 million for the three months ended September 30, 2025 compared to $92.8 million for the three months ended September 30, 2024.

General and administrative (G&A) expenses: G&A expenses were $16.7 million for the three months ended September 30, 2025 compared to $12.9 million for the three months ended September 30, 2024.

Net loss: Net loss for the three months ended September 30, 2025 was $108.0 million, or $0.76 per basic and diluted share. This compares with a net loss of $97.1 million, or $0.96 per basic and diluted share, for the three months ended September 30, 2024.

About Dyne Therapeutics
Dyne Therapeutics is focused on 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 are designed to overcome limitations in delivery to muscle tissue 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 zeleciment basivarsen (z-basivarsen, also known as DYNE-101) and zeleciment rostudirsen (z-rostudirsen, also known as 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 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 September 30,	
	2025	**2024**
Operating expenses:		
Research and development	$ 97,219	$ 92,800
General and administrative	16,673	12,859
Total operating expenses	**113,892**	**105,659**
Loss from operations	(113,892)	(105,659)
Other (expense) income, net	5,851	8,534
Net loss	**$ (108,041)**	**$ (97,125)**
Net loss per share, basic and diluted	$ (0.76)	$ (0.96)
Weighted average common shares outstanding, basic and diluted	141,810,881	100,882,042

	September 30, 2025	December 31, 2024
Assets		
Cash, cash equivalents and marketable securities	$ 791,887	$ 642,268
Other assets	75,172	48,966
Total assets	**$ 867,059**	**$ 691,234**
Liabilities and Stockholders’ Equity		
Liabilities	175,276	61,396
Stockholders' equity	691,783	629,838
Total liabilities and stockholders' equity	**$ 867,059**	**$ 691,234**

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