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

November 5, 2026

- Biologics License Application (BLA) for z-rostudirsen in exon 51 Duchenne muscular dystrophy (DMD) under priority review by FDA; PDUFA target action date of January 21, 2027 -

- Additional one-year clinical data from Phase 1/2 ACHIEVE trial of z-basivarsen for myotonic dystrophy type 1 (DM1) presented at WMS and AANEM continued to support improvement at 6 months in video hand opening time (vHOT) as an early indicator of clinical benefit -

- Topline data from ACHIEVE registrational expansion cohort (REC) planned for Q1 2027 -

- Preclinical data presented at NMSG support the ongoing development of four investigational therapies for DMD amenable to skipping of exons 44, 45, 53, or 55 -

WALTHAM, Mass., Nov. 05, 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 third quarter of 2026 and recent business highlights.

"As we work toward potential commercialization, we are investing across multiple programs with the goal of unlocking the full value of our FORCE™ platform," said John Cox, president and chief executive officer of Dyne. "This includes preparations for the potential U.S. launch of z-rostudirsen for exon 51 DMD, if approved, and topline data from the registrational expansion cohort of the ACHIEVE trial for z-basivarsen in DM1, both expected in the first quarter of 2027. At the same time, we are advancing HARMONIA, the only Phase 3 clinical trial in DM1 currently enrolling participants and progressing four preclinical DMD programs that have the potential to expand our reach to over one third of individuals living with Duchenne."

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

Key milestones for z-rostudirsen

- Dyne's BLA is under priority review by the FDA with a Prescription Drug User Fee Act (PDUFA) target action date of January 21, 2027.
- Dyne continues to expect a potential U.S. launch of z-rostudirsen in Q1 2027, assuming approval is received on the anticipated timeline.
- The ongoing confirmatory Phase 3 FORZETTO trial of z-rostudirsen is intended to support conversion of Accelerated Approval, if granted, to traditional approval in the U.S. and to support ex-U.S. marketing applications.
- In addition to z-rostudirsen, Dyne is advancing four development candidates (DYNE-244, DYNE-245, DYNE-253 and DYNE-255) for the potential treatment of DMD amenable to skipping of exons 44, 45, 53, and 55, respectively. Preclinical data supporting the ongoing development of these investigational therapies was recently presented at the 27th Annual Neuromuscular Study Group (NMSG) Scientific Meeting.

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

Additional one-year clinical data from Phase 1/2 ACHIEVE trial

- Dyne presented additional one-year efficacy data from the multiple ascending dose (MAD) portion of the ongoing Phase 1/2 ACHIEVE clinical trial of z-basivarsen at the 31st Annual International Congress of the World Muscle Society (WMS) and the 2026 Annual Meeting of the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM).
- Data from a pooled dose group of participants initially enrolled in the MAD portion of ACHIEVE showed functional improvement versus baseline, versus placebo and versus a matched natural history cohort across multiple measures at 12 months.

Key milestones for z-basivarsen

- Topline data from the ACHIEVE REC are planned for Q1 2027 to support a potential BLA submission for U.S. Accelerated Approval in Q3 2027.
  - Dyne intends to use data from the REC and from the already enrolled participants in the MAD and ongoing long-term extension portions of the ACHIEVE trial to support this potential BLA submission.
- Dyne expects a potential U.S. launch of z-basivarsen in H1 2028, assuming the FDA grants Priority Review and approval is received on the anticipated timeline.

- The ongoing confirmatory Phase 3 HARMONIA trial of z-basivarsen is intended to support conversion of Accelerated Approval, if granted, to traditional approval in the U.S. and to support ex-U.S. marketing applications.

Third Quarter Financial Results

Cash position: Cash, cash equivalents and marketable securities were $1.134 billion as of September 30, 2026. The Company expects that its cash, cash equivalents and marketable securities as of September 30, 2026, will be sufficient to fund its operations into the second quarter of 2028.

Research and development (R&D) expenses: R&D expenses were $161.7 million for the three months ended September 30, 2026 compared to $97.2 million for the three months ended September 30, 2025. The increase in R&D expense was primarily due to increased manufacturing activity for z-rostudirsen and higher clinical trial costs related to conducting the ongoing FORZETTO and HARMONIA Phase 3 trials for z-rostudirsen and z-basivarsen, respectively.

General and administrative (G&A) expenses: G&A expenses were $35.3 million for the three months ended September 30, 2026 compared to $16.7 million for the three months ended September 30, 2025. The increase in G&A expenses was primarily due to preparation for the potential launch of z-rostudirsen, including an increase in headcount.

Net loss: Net loss for the three months ended September 30, 2026 was $193.6 million, or $1.06 per basic and diluted share. This compares with a net loss of $108.0 million, or $0.76 per basic and diluted share, for the three months ended September 30, 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), zeleciment rostudirsen (z-rostudirsen, also known as DYNE-251), DYNE-244, DYNE-245, DYNE-253, DYNE-255 and DYNE-302; the anticipated timelines for initiating additional clinical trials, reporting data from clinical trials, submitting applications for marketing approval and launching commercially; the availability of an expedited approval pathway for z-basivarsen; expectations regarding the potential timing and likelihood of regulatory approval and commercial launch; 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; 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,	
	2026	**2025**
Operating expenses:		
Research and development	$ 161,744	$ 97,219
General and administrative	35,330	16,673
Total operating expenses	**197,074**	**113,892**
Loss from operations	(197,074)	(113,892)
Other income, net	3,522	5,851
Net loss	**$ (193,552)**	**$ (108,041)**
Net loss per share, basic and diluted	$ (1.06)	$ (0.76)
Weighted average common shares outstanding, basic and diluted	181,765,918	141,810,881

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

	September 30, 2026	December 31, 2025
Assets		
Cash, cash equivalents and marketable securities	$ 1,134,386	$ 1,110,562
Other assets	100,416	76,396
Total assets	**$ 1,234,802**	**$ 1,186,958**
Liabilities and Stockholders' Equity		
Liabilities	303,869	214,829
Stockholders' equity	930,933	972,129
Total liabilities and stockholders' equity	**$ 1,234,802**	**$ 1,186,958**

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