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

July 29, 2026

- Biologics License Application (BLA) for z-rostudirsen in exon 51 DMD accepted for review by FDA; Priority Review granted; PDUFA target action date set for January 21, 2027 -

- Completed enrollment of 71 participants in registrational expansion cohort of Phase 1/2 ACHIEVE trial of z-basivarsen in DM1; topline data planned for Q1 2027 -

- Investigational New Drug (IND) Application cleared by FDA for DYNE-302 in FSHD -

- Expected cash runway into Q2 2028 -

WALTHAM, Mass., July 29, 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 second quarter of 2026 and recent business highlights.

“We continue to make significant progress as we execute on our goal of delivering functional improvement for people living with genetically driven neuromuscular diseases,” said John Cox, president and chief executive officer of Dyne. “The FDA’s acceptance of our BLA for z-rostudirsen marks an important milestone for individuals living with DMD amenable to exon 51 skipping and a defining step in Dyne’s evolution toward becoming a commercial-stage company in the near future.”

“Across our portfolio, we have achieved key clinical and regulatory milestones, including completion of enrollment in the registrational expansion cohort of ACHIEVE, initiation of the global confirmatory Phase 3 HARMONIA and FORZETTO trials, and FDA clearance of our IND for FSHD, underscoring the breadth of opportunity enabled by our FORCE™ platform. With a potential U.S. approval of z-rostudirsen in January 2027, we are investing in the capabilities needed to support patients, execute successfully as a commercial organization and maximize long-term shareholder value.”

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

Phase 3 FORZETTO trial underway

- Dyne initiated the global confirmatory Phase 3 FORZETTO trial of z-rostudirsen in May 2026. Dyne has aligned with the U.S. Food and Drug Administration (FDA) on the Phase 3 trial design and protocol, which was presented at the 19th International Congress on Neuromuscular Diseases (ICNMD 2026).

Key milestones for z-rostudirsen

- Dyne’s BLA was accepted for review by the FDA in July 2026, with Priority Review granted (Prescription Drug User Fee Act (PDUFA) target action date set for 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.
- 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)

Clinical trial execution progress

- Dyne completed enrollment of 71 participants in the registrational expansion cohort (REC) of ACHIEVE in June 2026.
- Dyne began dosing participants in the global confirmatory Phase 3 HARMONIA trial of z-basivarsen in July 2026.

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 multiple ascending dose (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.
- Dyne also continues to pursue approval pathways outside of the U.S. for z-basivarsen in DM1.

DYNE-302 in FSHD (facioscapulohumeral muscular dystrophy)

IND clearance and Phase 1 trial overview

- Dyne received clearance from the FDA in July 2026 for its IND application to initiate a Phase 1 clinical trial for DYNE-302 in FSHD. DYNE-302 leverages the same FORCE™ platform as Dyne's first two clinical programs, z-rostudirsen in exon 51 DMD and z-basivarsen in DM1.
- Dyne plans to evaluate DYNE-302 in a Phase 1 randomized, placebo-controlled, double-blind, MAD clinical trial in ambulatory adult individuals with FSHD. The primary endpoint will be safety and tolerability. The trial will also assess pharmacokinetics and pharmacodynamics, including change from baseline in muscle DUX4 transcriptome and plasma KHDC1L levels, which Dyne has independently identified as a DUX4-regulated biomarker in FSHD.
- Dyne intends to pursue a traditional approval pathway in the U.S. for DYNE-302.

Financing Updates

- Dyne entered into an amendment to its non-dilutive senior secured term loan facility with Hercules Capital, Inc. in June 2026, expanding its debt facility to up to $400 million.
- Dyne completed an underwritten public offering of 21,045,000 shares of its common stock at a public offering price of $20.50 per share in July 2026. The gross proceeds from the offering before deducting underwriting discounts and commissions and offering expenses payable by Dyne were approximately $431 million.

Second Quarter Financial Results

Cash position: Cash, cash equivalents and marketable securities were $898.5 million as of June 30, 2026. In July 2026, the Company completed an underwritten public offering of 21,045,000 shares of its common stock for estimated net proceeds of approximately $405.0 million. The Company expects that its cash, cash equivalents and marketable securities as of June 30, 2026, together with the net proceeds from the July 2026 underwritten public offering, will be sufficient to fund its operations into the second quarter of 2028.

Research and development (R&D) expenses: R&D expenses were $152.2 million for the three months ended June 30, 2026 compared to $99.2 million for the three months ended June 30, 2025. The increase in R&D expense was primarily due to increased manufacturing activity and higher clinical costs related to z-rostudirsen and z-basivarsen during the three months ended June 30, 2026.

General and administrative (G&A) expenses: G&A expenses were $29.5 million for the three months ended June 30, 2026 compared to $16.6 million for the three months ended June 30, 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 June 30, 2026 was $178.6 million, or $1.08 per basic and diluted share. This compares with a net loss of $110.9 million, or $0.97 per basic and diluted share, for the three months ended June 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-253, DYNE-245, DYNE-244, 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 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 June 30,	
	2026	**2025**
Operating expenses:		
Research and development	$ 152,169	$ 99,236
General and administrative	29,492	16,555
Total operating expenses	**181,661**	**115,791**
Loss from operations	(181,661)	(115,791)
Other income, net	3,105	4,934
Net loss	**$ (178,556)**	**$ (110,857)**
Net loss per share, basic and diluted	$ (1.08)	$ (0.97)
Weighted average common shares outstanding, basic and diluted	165,451,388	113,873,126

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

	June 30, 2026	**December 31, 2025**
Assets		
Cash, cash equivalents and marketable securities	$ 898,475	$ 1,110,562
Other assets	95,538	76,396
Total assets	**$ 994,013**	**$ 1,186,958**
Liabilities and Stockholders’ Equity		
Liabilities	291,862	214,829
Stockholders' equity	702,151	972,129
Total liabilities and stockholders' equity	**$ 994,013**	**$ 1,186,958**

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