UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): July 28, 2025

Dyne Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-39509**	**36-4883909**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
1560 Trapelo Road **Waltham, Massachusetts** **(Address of Principal Executive Offices)**		**02451** **(Zip Code)**

Registrant's telephone number, including area code: (781) 786-8230

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, $0.0001 par value per share	**DYN**	**Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On July 28, 2025, Dyne Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter ended June 30, 2025. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filling.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Dyne Therapeutics, Inc. on July 28, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DYNE THERAPEUTICS, INC.

Date: July 28, 2025

By: /s/ John G. Cox

Name: John G. Cox

Title: President and Chief Executive Officer

Exhibit 99.1

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

- Expected cash runway extended into Q3 2027, beyond multiple potential inflection points including Dyne's first planned commercial launch in early 2027 -

- Registrational Expansion Cohort of DELIVER Trial of DYNE-251 in DMD fully enrolled to support potential submission for U.S. Accelerated Approval in early 2026 -

- Registrational Expansion Cohort of ACHIEVE Trial of DYNE-101 in DM1 ongoing to support potential submission for U.S. Accelerated Approval in late 2026 -

WALTHAM, Mass., July 28, 2025 – 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 2025 and recent business highlights.

"This quarter we made significant progress on our clinical and regulatory plans for our DM1 and DMD investigational therapies, as we advance both programs toward potential U.S. Accelerated Approval submissions in 2026 and possible commercial launches in 2027," said John Cox, president and chief executive officer of Dyne. "We also strengthened our balance sheet, extending our cash runway into the third quarter of 2027 and believe we are well funded to achieve multiple value-creating milestones including two data readouts in DM1 and DMD, two potential U.S. Accelerated Approval submissions in those indications, and the potential launch of DYNE-251 in DMD in the U.S."

DYNE-101 in Myotonic Dystrophy Type 1 (DM1)

- In June 2025, Dyne announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to DYNE-101 for the treatment of DM1.
    - Additionally, Dyne submitted a revised protocol to the FDA for the Registrational Expansion Cohort of the ACHIEVE trial with video hand opening time (vHOT) as the primary endpoint, to serve as an intermediate clinical endpoint for U.S. Accelerated Approval.
    - Dyne also reported new positive long-term data from adult DM1 patients enrolled in the randomized, placebo-controlled multiple ascending dose (MAD) portion of the DYNE-101 ACHIEVE trial, including data from the 6.8 mg/kg Q8W cohort (n=6) at up to 12 months.
- Dyne plans to complete enrollment of 60 patients in the Registrational Expansion Cohort of the ACHIEVE trial in Q4 2025.
- Data from this cohort are planned for mid-2026 to support a potential U.S. Accelerated Approval Biologics License Application (BLA) submission in late 2026.
- Dyne plans to initiate a confirmatory Phase 3 clinical trial in Q1 2026.
- Dyne also continues to pursue approval pathways outside of the U.S. for DYNE-101 in DM1.

DYNE-251 in Duchenne Muscular Dystrophy (DMD)

- Dyne has completed enrollment of 32 patients in the Registrational Expansion Cohort of the DELIVER trial. Data from this cohort are planned for late 2025.
- Dyne anticipates a potential BLA submission for U.S. Accelerated Approval in early 2026.
- Dyne also continues to pursue approval pathways outside of the U.S. for DYNE-251 in patients with DMD who are amenable to exon 51 skipping.

DYNE-302 in Facioscapulohumeral Muscular Dystrophy (FSHD)

- In June 2025, Dyne presented new preclinical data demonstrating the potential of DYNE-302 to achieve functional improvement in FSHD at the 32nd Annual FSHD Society's International Research Congress.

Financing Updates

- In June 2025, Dyne entered into a $275 million non-dilutive senior secured term loan facility with Hercules Capital, Inc. The loan facility consists of five tranches, including an initial term loan of $100 million funded at closing, and three additional term loan tranches totaling up to $115 million, which can be drawn at Dyne's option subject to achievement of specified clinical, regulatory and commercial milestones. A final term loan tranche of up to $60 million is available, subject to Hercules' approval.
- In July 2025, Dyne completed an underwritten public offering of 27,878,788 shares of its common stock at a public offering price of $8.25 per share. The gross proceeds from the offering before deducting underwriting discounts and commissions and offering expenses payable by Dyne were approximately $230 million.

Cash Runway

Dyne expects that its existing cash, cash equivalents and marketable securities, including the net proceeds from the July 2025 public offering and initial term loan tranche from Hercules Capital, will be sufficient to fund its operating expenses, debt service obligations, and capital expenditure requirements into the third quarter of 2027.

Based on the company's current plans and anticipated timelines, Dyne estimates that these funds would be sufficient to enable the company to:

- Obtain data from the registrational expansion cohorts of the ACHIEVE and DELIVER clinical trials;
- Submit BLAs to the FDA for DYNE-251 in DMD and DYNE-101 in DM1 using the Accelerated Approval pathway; and
- Commercially launch DYNE-251 in the U.S. if approved by the FDA.

Second Quarter Financial Results

Cash position: Cash, cash equivalents and marketable securities were $683.9 million as of June 30, 2025. In July 2025, the Company completed an underwritten public offering of 27,878,788 shares of its common stock for estimated net proceeds of approximately $215.2 million. The Company expects that its cash, cash equivalents and marketable securities as of June 30, 2025, together with the net proceeds from the July 2025 underwritten public offering, will be sufficient to fund its operations into the third quarter of 2027.

Research and development (R&D) expenses: R&D expenses were $99.2 million for the three months ended June 30, 2025 compared to $62.3 million for the three months ended June 30, 2024.

General and administrative (G&A) expenses: G&A expenses were $16.6 million for the three months ended June 30, 2025 compared to $9.7 million for the three months ended June 30, 2024.

Net loss: Net loss for the three months ended June 30, 2025 was $110.9 million, or $0.97 per basic and diluted share. This compares with a net loss of $65.1 million, or $0.70 per basic and diluted share, for the three months ended June 30, 2024.

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 myotonic dystrophy type 1 (DM1) and Duchenne muscular dystrophy (DMD), and 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 DYNE-101 and 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 DYNE-101 and DYNE-251; expectations regarding the timing and 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," 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 preclinical studies and clinical trials; uncertainties as to the availability and timing of results from preclinical studies and 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,	
	2025	**2024**
Operating expenses:		
Research and development	$ 99,236	$ 62,263
General and administrative	16,555	9,699
Total operating expenses	**115,791**	**71,962**
Loss from operations	(115,791)	(71,962)
Other (expense) income, net	4,934	6,860
Net loss	**$ (110,857)**	**$ (65,102)**
Net loss per share, basic and diluted	$ (0.97)	$ (0.70)
Weighted average common shares outstanding, basic and diluted	113,873,126	92,507,815

	June 30, 2025	**December 31, 2024**
Assets		
Cash, cash equivalents and marketable securities	$ 683,925	$ 642,268
Other assets	45,067	48,966
Total assets	**$ 728,992**	**$ 691,234**
Liabilities and Stockholders' Equity		
Liabilities	157,547	61,396
Stockholders' equity	571,445	629,838
Total liabilities and stockholders' equity	**$ 728,992**	**$ 691,234**

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