
**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 20, 2026

Dyne Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39509
(Commission
File Number)

36-4883909
(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 8.01 Other Events.

On July 20, 2026, Dyne Therapeutics, Inc. (the “Company”) announced that the U.S. Food and Drug Administration (“FDA”) has accepted for review its biologics license application (“BLA”) for zeleciment rostudirsen (z-rostudirsen, also known as DYNE-251) for the treatment of individuals with Duchenne muscular dystrophy (“DMD”) amenable to exon 51 skipping. The FDA has granted the BLA Priority Review and assigned a Prescription Drug User Fee Act target action date of January 21, 2027. The Company continues to expect a potential U.S. launch of z-rostudirsen in the first quarter of 2027, assuming approval is received on the anticipated timeline.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Current Report on Form 8-K, including statements regarding the Company’s strategy, future operations, prospects and plans, objectives of management, the potential of the FORCE™ platform, the clinical and therapeutic potential of z-rostudirsen, the potential of z-rostudirsen to advance the treatment paradigm in Duchenne muscular dystrophy, expectations regarding the timing and outcome of interactions with regulatory authorities and the timing of regulatory authority action, and expectations regarding the timing of commercialization of z-rostudirsen, 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. The Company 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 FDA’s and other regulatory authorities’ interpretation of the data from the Company’s clinical trials and the regulatory approval process; whether the Company’s cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; as well as the risks and uncertainties identified in the Company’s filings with the Securities and Exchange Commission (“SEC”), including the Company’s most recent Form 10-Q and in subsequent filings the Company may make with the SEC. In addition, the forward-looking statements included in this Current Report on Form 8-K represent the Company’s views as of the date of this Current Report. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company 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 the Company’s views as of any date subsequent to the date hereof.

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 20, 2026

By: /s/ John G. Cox
Name: John G. Cox
Title: President and Chief Executive Officer
