# 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): September 6, 2022**

# 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**<br>**Waltham, Massachusetts** | **02451** |
|---|---|
| **(Address of Principal Executive Offices)** | **(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.**

*DYNE-251 Update*

On September 6, 2022, Dyne Therapeutics, Inc. (the "Company") announced that the first patient has been dosed in its Phase 1/2 clinical trial, DELIVER, evaluating DYNE-251 for the treatment of Duchenne muscular dystrophy ("DMD") mutations amenable to exon 51 skipping.

The DELIVER trial is a Phase 1/2 global clinical trial evaluating DYNE-251, consisting of a 24-week multiple ascending dose ("MAD") randomized placebo-controlled period, a 24-week open-label extension and a 96-week long-term extension. The trial, which is designed to be registrational, is expected to enroll approximately 46 ambulant and non-ambulant males with DMD who are ages 4 to 16 and have mutations amenable to exon 51 skipping therapy. The primary endpoints are safety, tolerability and change from baseline in dystrophin levels as measured by Western blot. Secondary endpoints include measures of muscle function, exon skipping and pharmacokinetics. The Company anticipates reporting data from the MAD placebo-controlled portion of the DELIVER trial on safety, tolerability and dystrophin in the second half of 2023.

In the MAD placebo-controlled portion of the DELIVER trial, patients will be randomized to receive DYNE-251 or placebo every four weeks intravenously based on a global protocol designed to incorporate feedback from multiple regulatory authorities, including on starting dose. Patient cohorts will be dosed from 0.7 mg/kg to 40 mg/kg (approximate PMO dose) in the United States. Outside the United States, starting doses and number of cohorts will vary by region. Following the placebo-controlled period, patients may transition to DYNE-251 treatment in the open-label portion of the trial and in the long-term extension.

*DYNE-101 Update*

On September 6, 2022, the Company announced the initiation of its Phase 1/2 clinical trial, ACHIEVE, evaluating DYNE-101 for the treatment of myotonic dystrophy type 1 ("DM1"). The first patient in the trial is expected to be dosed in September 2022.

The ACHIEVE trial is a Phase 1/2 global clinical trial evaluating DYNE-101, consisting of a 24-week MAD randomized placebo-controlled period, a 24-week open-label extension and a 96-week long-term extension. The trial, which is designed to be registrational, is expected to enroll approximately 64 adult patients with DM1 who are 18 to 49 years of age. The primary endpoints are safety and tolerability. Secondary endpoints include pharmacokinetics and pharmacodynamics, including change from baseline in splicing, as well as measures of muscle strength and function. The Company anticipates reporting data from the MAD placebo-controlled portion of the ACHIEVE trial on safety, tolerability and splicing in the second half of 2023.

The ACHIEVE trial is designed to efficiently optimize dose level and frequency. In the MAD portion of the trial, patients will be randomized to receive DYNE-101 or placebo intravenously every four weeks or every eight weeks for 24 weeks, depending on cohort. Patient cohorts will be dosed from 1.8 mg/kg to 10.2 mg/kg (approximate ASO dose) across four cohorts. Following the placebo-controlled period, patients may transition to DYNE-101 treatment in the open-label portion of the trial and in the long-term extension.

*FSHD Program Update*

On September 12, 2022, the Company announced that it is prioritizing its focus and resources on its clinical programs, DYNE-101 in DM1 and DYNE-251 in DMD. The Company remains committed to advancing its facioscapulohumeral muscular dystrophy ("FSHD") program but is deferring the Investigational New Drug ("IND") application submission for DYNE-301 originally targeted for the second half of 2022. The Company plans to provide an update on the FSHD program in 2023.

*Cash Runway Update*

As a result of deferring the IND submission for DYNE-301, the Company expects that its existing cash, cash equivalents and marketable securities will enable it to fund its operating expenses and capital expenditure

requirements through 2024. The Company has based this estimate on assumptions that may prove to be wrong, and it could exhaust its available capital resources sooner than it expects.

**Forward-Looking Statements**

This Form 8-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this 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 anticipated timelines for dosing patients in the DYNE-101 clinical trial and for reporting data from the DYNE-251 and DYNE-101 clinical trials, the trial design of the Company's DYNE-251 and DYNE-101 clinical trials, the expected timeline for submitting an investigational new drug application for the Company's FSHD program and the sufficiency of the Company's existing 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. 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; the timing of and the Company's ability to initiate and enroll patients in clinical trials; whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials; whether the Company's cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; uncertainties associated with the impact of the COVID-19 pandemic on the Company's business and operations; 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 Form 8-K represent the Company's views as of the date of this Form 8-K. 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 of this Form 8-K.

**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: September 12, 2022

By: /s/ Joshua Brumm

Name: Joshua Brumm

Title: President and Chief Executive Officer