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): May 2, 2024

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**	**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 2.02 Results of Operations and Financial Condition.

On May 2, 2024, Dyne Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter ended March 31, 2024. 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 May 2, 2024
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: May 2, 2024

By: /s/ John G. Cox

Name: John G. Cox

Title: President and Chief Executive Officer

Exhibit 99.1

Dyne Therapeutics Reports First Quarter 2024 Financial Results and Recent Business Highlights

- Additional Clinical Data from ACHIEVE Trial of DYNE-101 in DM1 and DELIVER Trial of DYNE-251 in DMD Anticipated in the Second Half of 2024 -

WALTHAM, Mass., May 2, 2024 – Dyne Therapeutics, Inc. (Nasdaq: DYN), a clinical-stage muscle disease company focused on advancing innovative life-transforming therapeutics for people living with genetically driven diseases, today reported financial results for the first quarter of 2024 and recent business highlights.

“I am excited about the opportunity that Dyne, its FORCE™ platform and pipeline present
for individuals living with serious muscle diseases,” said John Cox, president and chief executive officer of Dyne. “The initial datasets announced in January from our DM1 and DMD programs were promising, and we look forward to reporting additional data from multiple, higher dose cohorts from the ACHIEVE and DELIVER trials during the second half of 2024. With a strong team and cash position, we are focused on executing across the business, including progressing towards initiating registrational cohorts in both trials by year-end.”

Business Highlights

- **Organizational**
  - In March 2024, John Cox was appointed president, CEO and a member of the Board of Directors, bringing to Dyne extensive executive experience in the biotechnology industry across various operating roles, including rare disease commercialization.

- **Phase 1/2 ACHIEVE clinical trial of DYNE-101 in adults with myotonic dystrophy type 1 (DM1)**
  - The ACHIEVE trial is ongoing and recently completed enrollment in the 6.8 mg/kg Q8W cohort.
  - Positive initial clinical data from ACHIEVE reported in January 2024 were featured in oral presentations at the Muscular Dystrophy Association (MDA) Clinical & Scientific Conference in March 2024 and the 14th International Myotonic Dystrophy Consortium Meeting in April 2024.

- **Phase 1/2 DELIVER clinical trial of DYNE-251 in males with Duchenne muscular dystrophy (DMD) amenable to exon 51 skipping**
  - The DELIVER trial is ongoing and recently completed enrollment in the 40 mg/kg Q8W cohort.
  - Positive initial clinical data from DELIVER reported in January 2024 were featured in oral presentations at the MDA Clinical & Scientific Conference in March 2024 and the American Academy of Neurology 2024 Annual Meeting in April 2024.

Key 2024 Milestones

- Dyne anticipates reporting data from multiple, higher dose cohorts from both the ACHIEVE and DELIVER trials in the second half of 2024 with the goal of initiating registrational cohorts by the end of 2024.

First Quarter 2024 Financial Results

Cash position: Cash, cash equivalents and marketable securities were $453.5 million as of March 31, 2024. In addition, subsequent to March 31, 2023, the company received $24.3 million from the sale of stock through its “at the market” offering program. The Company’s cash, cash equivalents and marketable securities are anticipated to fund operations through 2025.

Research and development (R&D) expenses: R&D expenses were $44.5 million for the quarter ended March 31, 2024, compared to $37.5 million for the quarter ended March 31, 2023.

General and administrative (G&A) expenses: G&A expenses were $24.6 million for the quarter ended March 31, 2024, compared to $7.9 million for the quarter ended March 31, 2023.

Net loss: Net loss for the quarter ended March 31, 2024 was $65.6 million, or $0.81 per basic and diluted share. This compares with a net loss of $44.2 million, or $0.78 per basic and diluted share, for the quarter ended March 31, 2023.

About Dyne Therapeutics

Dyne Therapeutics is a clinical-stage muscle disease company focused on advancing innovative life-transforming therapeutics for people living with genetically driven diseases. With its proprietary FORCE™ platform, Dyne is developing modern oligonucleotide therapeutics that are designed to overcome limitations in delivery to muscle tissue. Dyne has a broad pipeline for serious muscle diseases, including clinical programs for myotonic dystrophy type 1 (DM1) and Duchenne muscular dystrophy (DMD) and a preclinical program for facioscapulohumeral muscular dystrophy (FSHD). For more information, please visit 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 trial design of the DYNE-101 and DYNE-251 clinical trials, the anticipated timelines for reporting data from the DYNE-101 and DYNE-251 clinical trials and initiating registrational cohorts, plans to optimize dose and dose regimen for DYNE-101 and DYNE-251 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; the timing of and Dyne's ability to initiate and enroll patients in clinical trials; whether results from preclinical studies and initial data from early clinical trials will be predictive of the final results of the clinical trials or future trials; 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 the regulatory approval process; whether Dyne's cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses 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 (Unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 44,539	$ 37,536
General and administrative	24,618	7,928
Total operating expenses	**69,157**	**45,464**
Loss from operations	(69,157)	(45,464)
Other income (expense), net	3,508	1,277
Net loss	**$ (65,649)**	**$ (44,187)**
Net loss per share—basic and diluted	$ (0.81)	$ (0.78)
Weighted-average common shares outstanding used in net loss per share—basic and diluted	81,043,741	56,325,864

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

	March 31, 2024	December 31, 2023
Assets		
Cash, cash equivalents and marketable securities	$ 453,547	$ 123,100
Other assets	68,732	41,982
Total assets	**$ 522,279**	**$ 165,082**
Liabilities and Stockholders' Equity		
Liabilities	44,224	73,790
Stockholders' equity	478,055	91,292
Total liabilities and stockholders' equity	**$ 522,279**	**$ 165,082**

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