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): August 3, 2023

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 August 3, 2023, Dyne Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter ended June 30, 2023. 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 August 3, 2023
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: August 3, 2023

By: /s/ Joshua Brumm

Name: Joshua Brumm

Title: President and Chief Executive Officer

Dyne Therapeutics Reports Second Quarter 2023 Financial Results and Business Highlights

- On Track to Report Initial Data from ACHIEVE Clinical Trial of DYNE-101 in DM1 and DELIVER Clinical Trial of DYNE-251 in DMD During the Second Half of 2023 -

WALTHAM, Mass., August 3, 2023 – 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 second quarter of 2023 and business highlights.

“This is an exciting time for the entire Dyne team as we continue to enroll and dose patients in our ACHIEVE and DELIVER trials and are on track to report our first clinical data from both during the second half of this year, including evaluating important biomarkers of splicing in DM1 and dystrophin in DMD,” said Joshua Brumm, president and chief executive officer of Dyne. “In addition to progressing our clinical programs, we were also pleased to present preclinical data at ASGCT in May demonstrating the FORCE™ platform achieved TfR1-mediated delivery to the CNS, building on previous work showing delivery to skeletal, smooth and cardiac muscle in multiple well-validated preclinical models. CNS symptoms contribute significantly to the burden of neuromuscular disease, and we look forward to further exploring this application of the FORCE platform. Our commitment to advancing the treatment and care of individuals living with rare muscle diseases continues to drive our efforts with a sense of urgency.”

Business Highlights

- Enrollment continues in ACHIEVE, a Phase 1/2 global clinical trial evaluating DYNE-101 in adult patients with myotonic dystrophy type 1 (DM1). ACHIEVE, which is designed to be a registrational trial, consists 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 primary endpoints are safety and tolerability, with secondary endpoints of pharmacokinetics and pharmacodynamics, including change from baseline in splicing, as well as measures of muscle strength and function.

- Enrollment continues in DELIVER, a Phase 1/2 global clinical trial evaluating DYNE-251 in males with Duchenne muscular dystrophy (DMD) who have mutations amenable to exon 51 skipping. DELIVER, which is designed to be a registrational trial, consists of a 24-week MAD, randomized, placebo-controlled period, a 24-week open-label extension and a 96-week long-term extension. 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.

- New preclinical data were featured in an oral presentation at the American Society of Gene & Cell Therapy (ASGCT) 26th Annual Meeting in May 2023 demonstrating the FORCE platform achieved delivery to the central nervous system (CNS) in non-human primates and robust pharmacological effects in the brain in a model of DM1.

- The European Medicines Agency (EMA) granted orphan drug designation for DYNE-101 in DM1 in May 2023.

Key 2023 Milestones

- Dyne anticipates reporting initial data in the second half of 2023 from:
  - the MAD placebo-controlled portion of the ACHIEVE trial of DYNE-101 in DM1 on safety, tolerability and splicing; and
  - the MAD placebo-controlled portion of the DELIVER trial of DYNE-251 in DMD on safety, tolerability and dystrophin.

Second Quarter 2023 Financial Results

Cash position: Cash, cash equivalents and marketable securities were $207.7 million as of June 30, 2023, which is anticipated to fund operations through 2024.

Research and development (R&D) expenses: R&D expenses were $59.1 million for the quarter ended June 30, 2023, compared to $46.7 million for the quarter ended June 30, 2022.

General and administrative (G&A) expenses: G&A expenses were $7.6 million for the quarter ended June 30, 2023, compared to $6.1 million for the quarter ended June 30, 2022.

Net loss: Net loss for the quarter ended June 30, 2023 was $64.9 million, or $1.08 per basic and diluted share. This compares with a net loss of $52.3 million, or $1.01 per basic and diluted share, for the quarter ended June 30, 2022.

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 Twitter, 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 anticipated timelines for reporting data from the DYNE-251 and DYNE-101 clinical trials, the trial design of the DYNE-251 and DYNE-101 clinical trials, and the sufficiency of Dyne'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. 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 will be predictive of the results of later preclinical studies and clinical trials; 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 June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 59,130	$ 46,664	$ 96,667	$ 74,899
General and administrative	7,606	6,091	15,533	13,638
Total operating expenses	**66,736**	**52,755**	**112,200**	**88,537**
Loss from operations	(66,736)	(52,755)	(112,200)	(88,537)
Other (expense) income, net	1,834	451	3,111	650
Net loss	**$ (64,902)**	**$ (52,304)**	**$ (109,089)**	**$ (87,887)**
Net loss per share—basic and diluted	$ (1.08)	$ (1.01)	$ (1.88)	$ (1.70)
Weighted-average common shares outstanding used in net loss per share—basic and diluted	59,835,087	51,679,536	58,090,142	51,640,706

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

	June 30, 2023	December 31, 2022
Assets		
Cash, cash equivalents and marketable securities	$ 207,733	$ 256,012
Other assets	43,688	50,313
Total assets	**$ 251,421**	**$ 306,325**
Liabilities and Stockholders' Equity		
Liabilities	44,544	53,961
Stockholders' equity	206,877	252,364
Total liabilities and stockholders' equity	**$ 251,421**	**$ 306,325**

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