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): November 3, 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 **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 November 3, 2022, Dyne Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the quarter ended September 30, 2022. 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 November 3, 2022
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: November 3, 2022

By: /s/ Joshua Brumm

Name: Joshua Brumm

Title: President and Chief Executive Officer

Dyne Therapeutics Reports Third Quarter 2022 Financial Results and Business Highlights

- DYNE-101 ACHIEVE and DYNE-251 DELIVER Clinical Trials Underway with Data Anticipated in the Second Half of 2023 -

WALTHAM, Mass., November 3, 2022 – 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 third quarter of 2022 and business highlights.

“In the third quarter of 2022 we marked incredibly important milestones for Dyne with the initiation of patient clinical trials for our two lead product candidates, DYNE-101 and DYNE-251. Individuals living with DM1 and DMD are in urgent need of new and better therapeutic options. We are inspired by these communities and the clinicians treating them and are grateful for their input and support,” said Joshua Brumm, president and chief executive officer of Dyne. “We are focused on executing on our global trials, ACHIEVE and DELIVER, which are designed to be registrational, and driving towards meaningful clinical data readouts from both anticipated in the second half of 2023.”

Business Highlights

- The ACHIEVE trial evaluating DYNE-101 for the treatment of myotonic dystrophy type 1 (DM1) is underway. It is a Phase 1/2 global clinical trial 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 ACHIEVE 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, and the secondary endpoints include pharmacokinetics and pharmacodynamics, including change from baseline in splicing, as well as measures of muscle strength and function. Data from the MAD placebo-controlled portion of the ACHIEVE trial on safety, tolerability and splicing are anticipated in the second half of 2023.

- The DELIVER trial, a Phase 1/2 global clinical trial evaluating DYNE-251 for the treatment of Duchenne muscular dystrophy (DMD) mutations amenable to exon 51 skipping, is ongoing. The 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 DELIVER 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. Data from the MAD placebo-controlled portion of the DELIVER trial on safety, tolerability and dystrophin are anticipated in the second half of 2023.

- In October 2022, Dyne announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for DYNE-251. The FDA grants Fast Track designation to facilitate the

development and expedite the review of drugs to treat serious conditions and fill an unmet medical need, with the ultimate goal of getting important new drugs to patients earlier.

- Dyne presented preclinical data from its DMD programs at the World Muscle Society Congress in October 2022, including foundational *in vivo* data underpinning the clinical development program for DYNE-251 targeting exon 51 and the first *in vitro* data for a FORCE™ conjugate targeting exon 53.

- Dyne hosted a “Spotlight on the Clinic" virtual investor event in September 2022 highlighting its clinical programs in DM1 and DMD. Speakers included neuromuscular disease experts, Valeria Sansone, M.D., Ph.D., Clinical and Scientific Director at Clinical Center NeMO; and Professor of Neurology, University of Milan, Richard Finkel, M.D., Director of the Center for Experimental Neurotherapeutics at St. Jude Children’s Research Hospital, as well as members of Dyne’s leadership team.

- Preclinical data supporting Dyne’s efforts in DMD were published online in a “Breakthrough Article” in Nucleic Acids Research, in August 2022. The data demonstrated that the FORCE platform achieved robust and durable dystrophin expression in multiple muscle tissues and significant improvement in muscle function in the *mdx* mouse model of DMD.

Upcoming Investor Conferences

Management is scheduled to present at the following investor conferences in November:

- Credit Suisse 31st Annual Healthcare Conference, presentation on November 9, 2022 at 11:00 a.m. PT (2:00 p.m. ET) in Rancho Palos Verdes, CA
- Jefferies London Healthcare Conference, fireside chat on November 16, 2022 at 12:20 p.m. GMT (7:20 a.m. ET) in London
- Stifel 2022 Healthcare Conference, fireside chat on November 16, 2022 at 11:30 a.m. ET in New York
- Piper Sandler 34th Annual Healthcare Conference, fireside chat on November 29, 2022 at 11:00 a.m. ET in New York

A live webcast of each presentation will be available in the Investors & Media section of Dyne’s website at https://investors.dyne-tx.com/news-and-events/events-and-presentations and a replay will be accessible for 90 days.

Third Quarter 2022 Financial Results

Cash position: Cash, cash equivalents and marketable securities were $248.1 million as of September 30, 2022, which is anticipated to fund operations through 2024.

Research and development (R&D) expenses: R&D expenses were $34.7 million for the quarter ended September 30, 2022, compared to $36.5 million for the quarter ended September 30, 2021.

General and administrative (G&A) expenses: G&A expenses were $7.6 million for the quarter ended September 30, 2022, compared to $6.3 million for the quarter ended September 30, 2021.

Net loss: Net loss for the quarter ended September 30, 2022 was $41.4 million, or $0.80 per basic and diluted share. This compares with a net loss of $42.6 million, or $0.83 per basic and diluted share, for the quarter ended September 30, 2021.

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 seen with other approaches. Dyne has a broad portfolio of programs for serious muscle diseases, including candidates for myotonic dystrophy type 1 (DM1), Duchenne muscular dystrophy (DMD) and 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; uncertainties associated with the impact of the COVID-19 pandemic on Dyne's business and operations; 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 September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 34,670	$ 36,510	$ 109,570	$ 79,007
General and administrative	7,609	6,256	21,247	19,058
Total operating expenses	**42,279**	**42,766**	**130,817**	**98,065**
Loss from operations	(42,279)	(42,766)	(130,817)	(98,065)
Other (expense) income, net	894	184	1,545	560
Net loss	**$ (41,385)**	**$ (42,582)**	**$ (129,272)**	**$ (97,505)**
Net loss per share—basic and diluted	$ (0.80)	$ (0.83)	$ (2.50)	$ (1.92)
Weighted-average common shares outstanding used in net loss per share—basic and diluted	51,795,446	51,320,940	51,692,899	50,676,668

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

	September 30, 2022	December 31, 2021
Assets		
Cash, cash equivalents and marketable securities	$ 248,142	$ 376,571
Other assets	51,537	49,092
Total assets	**$ 299,679**	**$ 425,663**
Liabilities and Stockholders' Equity		
Liabilities	49,935	57,466
Stockholders' equity	249,744	368,197
Total liabilities and stockholders' equity	**$ 299,679**	**$ 425,663**

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