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): March 10, 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 March 10, 2022, Dyne Therapeutics, Inc. (the "Company") issued a press release announcing the Company's financial results for the year ended December 31, 2021. 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 March 10, 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: March 10, 2022

By: /s/ Joshua Brumm

Name: Joshua Brumm

Title: President and Chief Executive Officer

Dyne Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Recent Highlights

- Response to FDA for DYNE-251 IND in DMD on Track for Submission in the Second Quarter of 2022 -

- Initiation of Patient Dosing in Multiple Ascending Dose Clinical Trials for DYNE-251 in DMD and DYNE-101 in DM1 Planned in Mid-2022 -

WALTHAM, Mass., March 10, 2022 – Dyne Therapeutics, Inc. (Nasdaq: DYN), a muscle disease company focused on advancing innovative life-transforming therapeutics for people living with genetically driven diseases, today reported financial results for the fourth quarter and full year 2021 and recent business highlights.

“In 2021 we made significant achievements throughout the business. We generated platform-validating preclinical data across our programs, including demonstrating sustained knockdown of toxic nuclear *DMPK* RNA and correction of splicing in DM1 and robust exon skipping and dystrophin expression in DMD. We also submitted our first IND for DYNE-251 in DMD in the fourth quarter, further strengthened our leadership team with multiple key hires, and completed a $168 million financing at the start of the year, extending our cash runway into the second half of 2024,” said Joshua Brumm, president and chief executive officer of Dyne. “We begin 2022 laser focused on advancing our programs into the clinic. We are on track to submit our response to the FDA for our DYNE-251 IND in DMD in the second quarter. In addition, as part of our global clinical development strategy, we now anticipate submitting regulatory filings in multiple countries for DYNE-101 in DM1 in the second quarter, with the goal of initiating patient dosing in clinical trials for both DYNE-251 and DYNE-101 in mid-2022. We believe we have the team, platform and pipeline in place to execute on our mission of delivering life-transforming therapies for people living with serious muscle diseases.”

Recent Highlights

- In December 2021, Dyne submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) to initiate a clinical trial of DYNE-251 in patients with Duchenne muscular dystrophy (DMD) amenable to skipping exon 51. As previously announced, Dyne received a clinical hold letter from the FDA on January 14, 2022 requesting additional clinical and non-clinical information for DYNE-251. The Company expects to submit its response to the FDA in the second quarter of 2022 with data from existing and ongoing studies, and if satisfactory to the FDA, plans to begin dosing patients in a Phase 1/2 global multiple ascending dose (MAD) clinical trial of DYNE-251 in mid-2022.
- In recognition of Rare Disease Day, held annually on the last day of February, Dyne hosted individuals and families living with DMD, myotonic dystrophy type 1 (DM1) and facioscapulohumeral muscular dystrophy (FSHD). Their perspectives are featured in a video available here: https://www.dyne-tx.com/rdd2022/

- On March 3, 2022, the Company announced the appointment of Carlo Incerti, M.D., to its Board of Directors. Dr. Incerti brings to Dyne more than three decades of experience in the biopharmaceutical industry, including in global rare disease drug development.

Upcoming Events and Milestones

- Preclinical data from Dyne's DM1 and DMD programs that were presented during the World Muscle Society Virtual Congress and Muscle Study Group Annual Scientific Meeting in fall 2021 will be featured in encore presentations during the 2022 Muscular Dystrophy Association (MDA) Clinical & Scientific Conference being held March 13-16, 2022, and will be available to registered attendees at: https://mdaconference.org/.
- Dyne management is scheduled to participate in a virtual fireside chat during Stifel's 4th Annual CNS Day on March 28, 2022 at 1:00 p.m. A live webcast 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 following the presentation.
- The Company expects to submit its response to the FDA for the DYNE-251 IND in DMD in the second quarter of 2022 with the goal of dosing patients in a Phase 1/2 global MAD clinical trial in mid-2022.
- Dyne now plans to submit regulatory filings in multiple countries for DYNE-101 in DM1 in the second quarter of 2022, and in accordance with its previous guidance, expects to initiate patient dosing in a global MAD clinical trial in mid-2022.
- Dyne expects to submit an IND for DYNE-301 in FSHD in the second half of 2022.

Fourth Quarter and Full Year 2021 Financial Results

Cash position: Cash, cash equivalents and marketable securities were $376.6 million as of December 31, 2021, which is anticipated to fund operations into the second half of 2024.

Research and development (R&D) expenses: R&D expenses were $42.3 million and $22.1 million for the quarters ended December 31, 2021 and 2020, respectively. R&D expenses were $121.3 million and $45.2 million for the years ended December 31, 2021 and 2020, respectively.

General and administrative (G&A) expenses: G&A expenses were $9.7 million and $6.5 million for the quarters ended December 31, 2021 and 2020, respectively. G&A expenses were $28.7 million and $13.4 million for the years ended December 31, 2021 and 2020, respectively.

Net loss: Net loss for the quarter ended December 31, 2021 was $51.8 million, or $1.00 per basic and diluted share. This compares with a net loss of $28.6 million, or $0.64 per basic and diluted share, for the quarter ended December 31, 2020. Net loss for the year ended December 31, 2021 was $149.3 million, or $2.93 per basic and diluted share. This compares with a net loss of $59.4 million, or $4.13 per basic and diluted share, for the year ended December 31, 2020.

About Dyne Therapeutics

Dyne Therapeutics is building a leading muscle disease company dedicated to 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 therapeutic 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 expected timeline for submitting its response to the FDA's clinical hold letter, submitting regulatory filings and dosing patients in trials and the anticipated design of the trials, 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 conduct of research activities and the initiation and completion of preclinical studies and clinical trials; uncertainties as to the availability and timing of results from preclinical studies; uncertainties as to the timing of and Dyne's ability to submit and obtain regulatory clearance for investigational new drug applications and other regulatory filings and initiate clinical trials, including with respect to its response to the DYNE-251 clinical hold letter and its ability to obtain regulatory clearance of the DYNE-251 IND; whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials; whether investigators and regulatory agencies will agree with the design of Dyne's planned 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-K 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
(in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 42,304	$ 22,098	$ 121,308	$ 45,200
General and administrative	9,658	6,502	28,717	13,447
Total operating expenses	**51,962**	**28,600**	**150,025**	**58,647**
Loss from operations	(51,962)	(28,600)	(150,025)	(58,647)
Other (expense) income, net	175	(49)	734	(790)
Net loss	**$ (51,787)**	**$ (28,649)**	**$ (149,291)**	**$ (59,437)**
Net loss per share, basic and diluted	$ (1.00)	$ (0.64)	$ (2.93)	$ (4.13)
Weighted average common shares outstanding, basic and diluted	51,543,053	45,058,494	50,895,044	14,395,955

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

	December 31,	
	2021	**2020**
Assets		
Cash, cash equivalents and marketable securities	$ 376,571	$ 345,314
Other assets	49,092	8,020
Total Assets	**$ 425,663**	**$ 353,334**
Liabilities and Stockholders' Equity		
Liabilities	57,466	10,967
Stockholders' equity	368,197	342,367
Total liabilities and stockholders' equity	**$ 425,663**	**$ 353,334**

Contact:

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