

**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 4, 2021

Dyne Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39509
(Commission
File Number)

36-4883909
(IRS Employer
Identification No.)

830 Winter Street
Waltham, Massachusetts
(Address of Principal Executive Offices)

02451
(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 4, 2021, Dyne Therapeutics, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the quarter and year ended December 31, 2020. 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 filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release issued by Dyne Therapeutics, Inc. on March 4, 2021</u>

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 4, 2021

By: /s/ Joshua Brumm

Name: Joshua Brumm

Title: President and Chief Executive Officer



Dyne Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Recent Highlights

- *Preclinical Data Further Validate FORCE™ Platform; Driving Toward IND Submissions for DM1, DMD and FSHD Programs Between Q4'21 and Q4'22 -*

- *Recent Appointments to Experienced Leadership Team Strengthen Company's Clinical Development Capabilities -*

- *Successful Financings Expected to Provide Cash Runway into the Second Half of 2024 -*

WALTHAM, Mass., March 4, 2021 – 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 2020 and recent business highlights.

“2020 was a transformational year for Dyne. We delivered validating data for our FORCE™ platform and programs, further strengthened our exceptional team with the addition of highly experienced leaders and completed our IPO. Together with earlier financings in 2020 and the follow-on public offering completed in January 2021, we have raised more than \$550 million, which we expect to support us into the second half of 2024. We begin 2021 focused on driving our DM1, DMD and FSHD programs to the clinic as we pursue our goal of delivering potentially life-transforming therapies to people living with serious muscle diseases,” said Joshua Brumm, president and chief executive officer of Dyne.

Recent Highlights

- In January 2021, Dyne announced new preclinical data from its myotonic dystrophy type 1 (DM1) program demonstrating robust RNA knockdown of toxic human nuclear *DMPK*, the genetic basis of the disease. To assess the ability of its lead DM1 candidate to reduce toxic human nuclear *DMPK* RNA, Dyne developed an innovative hTfR1/DMSXL mouse model that expresses the human TfR1 (hTfR1) and carries a human *DMPK* gene that represents a severe DM1 phenotype with more than 1,000 CTG repeats. In this model, two doses (2 x 10 mg/kg) of Dyne's candidate resulted in significant toxic human nuclear *DMPK* knockdown at 14 days: 60 percent in the heart; 56 percent in the diaphragm; 54 percent in the tibialis anterior and 39 percent in the gastrocnemius. In the study, Dyne's candidate was well tolerated. Dyne expects to share data from the hTfR1/DMSXL model at a scientific meeting during 2021.
 - The Company further strengthened its leadership team with the appointment of Wildon Farwell, M.D., MPH, as chief medical officer, announced separately today, and Ashish Dugar, Ph.D., MBA, as senior vice president, global head of medical affairs, in February 2021.
 - In January 2021, Dyne completed its follow-on public offering of 6,000,000 shares of its common stock at a public offering price of \$28.00 per share. Gross proceeds of the offering before deducting the underwriting discount and commissions and offering expenses were approximately \$168 million. Dyne expects its cash, cash equivalents and marketable securities as of December
-



31, 2020, together with the net proceeds from the January 2021 public offering, will be sufficient to fund its operating expenses and capital expenditure requirements into the second half of 2024.

Upcoming Scientific & Investor Conference Presentations

- Dyne is scheduled to participate in the 2021 MDA Virtual Clinical & Scientific Conference. Romesh Subramanian, Ph.D., chief scientific officer, will present as part of the panel “Therapeutic Considerations for Dominant Neuromuscular Diseases,” and Oxana Beskrovnaya, Ph.D., senior vice president, head of research, will participate in the “Non-viral Delivery in Neuromuscular Disease” session. Both presentations will take place on March 15, 2021 and will be available to registered attendees at: <https://mdavirtualconference.org/>.
- Dr. Beskrovnaya also intends to present on Dyne’s FORCE platform during the virtual 7th Cold Spring Harbor Laboratory meeting on Nucleic Acid Therapies on March 24, 2021, which is accessible to registered participants at: <https://meetings.cshl.edu/meetings.aspx?meet=NAT&year=21>.
- Mr. Brumm and Dr. Subramanian are scheduled to participate in a virtual fireside chat during Stifel’s 3rd Annual CNS Day on April 1, 2021 at 10:30 am ET. A live webcast will be available in the Investors & Media section of Dyne’s website at <https://investors.dyne-tx.com/investors-and-media> and a replay will be accessible for 90 days following the presentation.

Fourth Quarter and Full Year 2020 Financial Results

Cash position: Cash, cash equivalents and marketable securities were \$345.3 million as of December 31, 2020. Additionally, in January 2021, Dyne completed a public offering of common stock, with gross proceeds totaling approximately \$168 million.

Research and development (R&D) expenses: R&D expenses were \$22.1 million and \$4.3 million for the quarters ended December 31, 2020 and 2019, respectively. R&D expenses were \$45.2 million and \$11.0 million for the years ended December 31, 2020 and 2019, respectively.

General and administrative (G&A) expenses: G&A expenses were \$6.5 million and \$1.2 million for the quarters ended December 31, 2020 and 2019, respectively. G&A expenses were \$13.4 million and \$2.8 million for the years ended December 31, 2020 and 2019, respectively.

Net loss: Net loss for the quarter ended December 31, 2020 was \$28.6 million, or \$0.64 per basic and diluted share. This compares with a net loss of \$5.4 million, or \$2.10 per basic and diluted share, for the quarter ended December 31, 2019. Net loss for the year ended December 31, 2020 was \$59.4 million, or \$4.13 per basic and diluted share. This compares with a net loss of \$14.9 million, or \$6.08 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's broad portfolio of therapeutic candidates for serious muscle diseases includes programs 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, plans, objectives of management, the expected timeline for submitting investigational new drug applications and achieving proof-of-concept data readouts and the sufficiency of its cash resources, 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 and clinical trials; the timing of and Dyne's ability to submit investigational new drug applications; whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials; uncertainties related to Dyne's ability to obtain sufficient cash resources to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements for the anticipated periods; 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 Annual Report on Form 10-K for the year ended December 31, 2020 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.

Contact:

Dyne Therapeutics
Amy Reilly
areilly@dyne-tx.com
857-341-1203

Dyne Therapeutics, Inc.
Condensed Consolidated Statement of Operations
(in thousands, except share and per share data)

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 22,098	\$ 4,259	\$ 45,200	\$ 11,800
General and administrative	6,502	1,211	13,447	2,100
Total operating expenses	28,600	5,470	58,647	13,900
Loss from operations	(28,600)	(5,470)	(58,647)	(13,900)
Other (expense) income	(49)	67	(790)	(1,000)
Net loss	\$ (28,649)	\$ (5,403)	\$ (59,437)	\$ (14,900)
Net loss per share—basic and diluted	\$ (0.64)	\$ (2.10)	\$ (4.13)	\$ (6.00)
Weighted-average common shares outstanding used in net loss per share—basic and diluted	45,058,494	2,567,007	14,395,955	2,442,000

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

	<u>December 31,</u>	<u>December 31,</u>
	2020	2019
Assets		
Cash, cash equivalents and marketable securities	\$ 345,314	\$ 14,632
Other assets	8,020	1,804
Total assets	\$ 353,334	\$ 16,436
Liabilities and Stockholders' Equity		
Liabilities	10,967	2,400
Stockholders' equity	342,367	14,036
Total liabilities and stockholders' equity	\$ 353,334	\$ 16,436