

**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 6, 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 May 6, 2021, Dyne Therapeutics, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the quarter ended March 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 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 May 6, 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: May 6, 2021

By: /s/ Joshua Brumm

Name: Joshua Brumm

Title: President and Chief Executive Officer



Dyne Therapeutics Reports First Quarter 2021 Financial Results and Business Highlights

- On Track to Submit INDs for DM1, DMD and FSHD Programs Between the Fourth Quarter of 2021 and the Fourth Quarter of 2022 -

- Well-Resourced with Cash Runway Expected into the Second Half of 2024 -

WALTHAM, Mass., May 6, 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 first quarter 2021 and business highlights.

“We continued to make significant progress to start 2021, including generating new preclinical data in our DM1 program that will be featured during the upcoming ASGCT Annual Meeting, further strengthening our leadership team with key appointments and enhancing our financial foundation with cash runway expected into the second half of 2024,” said Joshua Brumm, president and chief executive officer of Dyne. “We are focused on executing across all aspects of the business as we drive our three programs to the clinic, advance our efforts to deliver life-transforming therapies to patients and pursue our goal of building the world’s leading muscle disease company.”

Upcoming Events & Presentations

- New preclinical data from Dyne’s myotonic dystrophy type 1 (DM1) program will be featured in presentations during the American Society of Gene & Cell Therapy (ASGCT) 24th Annual Meeting, to be held virtually May 11-14, 2021. The presentations will include new data, expanding upon initial findings reported in January 2021 utilizing an innovative hTfR1/DMSXL mouse model developed by Dyne, as well as results from *in vitro* studies.
 - o Romesh Subramanian, Ph.D., chief scientific officer, will present on *Splice Correction and Reduction of Toxic DMPK RNA In Vitro and In Vivo Utilizing Novel Antibody Targeted Antisense Oligonucleotides* during the “Hot Topics and Remaining Challenges in RNAi and Oligonucleotide Therapy for 2021” scientific symposium, on Friday, May 14, 2021, at 10:26 a.m. ET.
 - o Stefano Zanotti, Ph.D., director, mechanistic biology, is scheduled to deliver an oral presentation on Friday, May 14, 2021, at 1:15 p.m. ET, entitled *The FORCETM Platform Achieves Robust Knock Down of Toxic Human Nuclear DMPK RNA and Foci Reduction in DM1 Cells and in Newly Developed hTfR1/DMSXL Mouse Model*.
- Following the ASGCT presentations, Dyne plans to host a live webcast event on May 14, 2021 at 4:00 p.m. ET to review the company’s DM1 program and preclinical data, and to provide an overview of the disease and treatment challenges. Joining management on the call will be Charles Thornton, M.D., the Saunders Distinguished Professor of Neuromuscular Research at the University of Rochester, and a leading expert in DM1. The live event and replay will be available in the Investors & Media section of Dyne’s website at <https://investors.dyne-tx.com/investors-and-media>.



- Management is scheduled to participate in a fireside chat during Jefferies Virtual Healthcare Conference being held June 1-4, 2021.
- An abstract featuring data from Dyne's FSHD preclinical program has been accepted for an oral presentation during the virtual 28th Annual FSHD Society International Research Congress being held June 24-25, 2021.

First Quarter 2021 Financial Results

Cash position: Cash, cash equivalents and marketable securities were \$483.1 million as of March 31, 2021.

Research and development (R&D) expenses: R&D expenses were \$18.6 million for the first quarter of 2021 compared to \$6.1 million for the first quarter of 2020.

General and administrative (G&A) expenses: G&A expenses were \$6.5 million during the first quarter of 2021 compared to \$1.8 million for the first quarter of 2020.

Net loss: Net loss was \$25.0 million or \$0.50 per common share for the first quarter of 2021 compared to \$7.9 million, or \$0.90 per common share for the first quarter of 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 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.

Contact:

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

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 18,625	\$ 6,089
General and administrative	6,509	1,764
Total operating expenses	25,134	7,853
Loss from operations	(25,134)	(7,853)
Other (expense) income, net	166	(33)
Net loss	\$ (24,968)	\$ (7,886)
Net loss per share—basic and diluted	\$ (0.50)	\$ (0.90)
Weighted-average common shares outstanding used in net loss per share—basic and diluted	49,472,497	8,756,513

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

	March 31,	December 31,
	2021	2020
Assets		
Cash, cash equivalents and marketable securities	\$ 483,085	\$ 345,314
Other assets	8,625	8,020
Total assets	\$ 491,710	\$ 353,334
Liabilities and Stockholders' Equity		
Liabilities	13,450	10,967
Stockholders' equity	478,260	342,367
Total liabilities and stockholders' equity	\$ 491,710	\$ 353,334