Dyne Therapeutics Reports First Quarter 2022 Financial Results and Business Highlights

May 2, 2022

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

WALTHAM, Mass., May 02, 2022 (GLOBE NEWSWIRE) -- 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 of 2022 and business highlights.

"We are fully focused on advancing multiple programs to the clinic. We are executing on our plans to submit in the second quarter our response to the FDA relating to our IND for DYNE-251 in DMD as well as regulatory filings in multiple countries for DYNE-101 in DM1 with the goal to initiate patient dosing for both of these candidates in mid-2022. We also continue to engage with thought leaders, advocacy groups and patients to support rapid initiation of dosing for our planned multiple ascending dose clinical trials," said Joshua Brumm, president and chief executive officer of Dyne. "We are proud of the extensive preclinical data we have generated for our programs to date and the work the team has done to advance DYNE-251 and DYNE-101 towards the clinic – a major step in our mission to deliver life-transforming therapies for people with serious muscle diseases."

Upcoming Events and Milestones

- Dyne is executing on its plans for the second quarter of 2022 to:
  - submit its response to the U.S. Food and Drug Administration's clinical hold letter for the Investigational New Drug (IND) application to initiate a clinical trial of DYNE-251 in patients with Duchenne muscular dystrophy (DMD) amenable to skipping exon 51; and
  - submit regulatory filings in multiple countries for DYNE-101 in myotonic dystrophy type 1 (DM1).
- The Company expects to initiate patient dosing in global multiple ascending dose (MAD) clinical trials for DYNE-251 in DMD and DYNE-101 in DM1 in mid-2022, subject to clearance from applicable regulatory authorities.
- Additional preclinical data from Dyne's DM1 program will be highlighted during the 25 th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT), being held May 16-19, 2022, in Washington, D.C. and virtually. The oral presentation entitled, "Repeat Dosing with DYNE-101 is Well Tolerated and Leads to a Sustained Reduction of *DMPK* RNA Expression in Key Muscles for DM1 Pathology in hTfR1/DMSXL Mice and NHPs," is scheduled for May 16, 2022 at 10:45 a.m. ET.
- Dyne expects to submit an IND for DYNE-301 in facioscapulohumeral muscular dystrophy (FSHD) in the second half of 2022.

First Quarter 2022 Financial Results

Cash position: Cash, cash equivalents and marketable securities were $323.2 million as of March 31, 2022, which is anticipated to fund operations into the second half of 2024.

Research and development (R&D) expenses: R&D expenses were $28.2 million for the quarter ended March 31, 2022, compared to $18.6 million for the quarter ended March 31, 2021.

General and administrative (G&A) expenses: G&A expenses were $7.5 million for the quarter ended March 31, 2022, compared to $6.5 million for the quarter ended March 31, 2021.

Net loss: Net loss for the quarter ended March 31, 2022 was $35.6 million, or $0.69 per basic and diluted share. This compares with a net loss of $25.0 million, or $0.50 per basic and diluted share, for the quarter ended March 31, 2021.

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 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, the anticipated design of the trials 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; 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-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 March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 28,236	$ 18,625
General and administrative	7,547	6,509
Total operating expenses	**35,783**	**25,134**
Loss from operations	(35,783)	(25,134)
Other (expense) income, net	200	166
Net loss	**$ (35,583)**	**$ (24,968)**
Net loss per share—basic and diluted	$ (0.69)	$ (0.50)
Weighted-average common shares outstanding used in net loss per share—basic and diluted	51,601,444	49,472,497

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

	March 31,	December 31,
	2022	**2021**
Assets		
Cash, cash equivalents and marketable securities	$ 323,150	$ 376,571
Other assets	64,612	49,092
Total assets	**$ 387,762**	**$ 425,663**
Liabilities and Stockholders’ Equity		
Liabilities	51,303	57,466
Stockholders’ equity	336,459	368,197
Total liabilities and stockholders’ equity	**$ 387,762**	**$ 425,663**

Contact:

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