Dyne Therapeutics Reports Second Quarter 2022 Financial Results and Business Highlights

August 4, 2022

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

WALTHAM, Mass., Aug. 04, 2022 (GLOBE NEWSWIRE) -- 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 second quarter of 2022 and business highlights.

"We are executing on our global development strategy, including achieving our first regulatory clearances for our DYNE-251 and DYNE-101 clinical trials. We also continue to engage globally with regulators, as well as clinicians and members of the Duchenne and myotonic dystrophy communities as we prepare to begin dosing patients in both trials shortly," said Joshua Brumm, president and chief executive officer of Dyne. "The second half of the year looks to be very exciting, as we work to bring DYNE-251 and DYNE-101 into the clinic and advance our efforts to help address unmet needs for people living with serious muscle diseases."

Business Highlights

- In July 2022, Dyne announced that the New Zealand Medicines and Medical Devices Safety Authority cleared Dyne's clinical trial application to initiate its Phase 1/2 multiple ascending dose (MAD) clinical trial of DYNE-101 in patients with myotonic dystrophy type 1 (DM1). The Company expects to initiate dosing patients in the trial in mid-2022 and also anticipates receiving regulatory clearance in additional countries for DYNE-101.

- In July 2022, Dyne announced that the U.S. Food and Drug Administration (FDA) lifted the clinical hold and cleared its Investigational New Drug (IND) application to initiate its Phase 1/2 MAD clinical trial of DYNE-251 in patients with Duchenne muscular dystrophy (DMD) amenable to skipping exon 51. The Company expects to begin dosing patients in the trial in mid-2022.

- In May 2022, new *in vivo* data from DYNE-101 were presented at the American Society of Gene & Cell Therapy (ASGCT) 25th Annual Meeting that demonstrated robust knockdown of *DMPK* RNA in multiple muscles with low monthly dosing in an innovative hTfR1/DMSXL mouse model developed by Dyne and in non-human primates.

Second Quarter 2022 Financial Results

Cash position: Cash, cash equivalents and marketable securities were $291.8 million as of June 30, 2022, which is anticipated to fund operations into the second half of 2024.

Research and development (R&D) expenses: R&D expenses were $46.7 million for the quarter ended June 30, 2022, compared to $23.9 million for the quarter ended June 30, 2021.

General and administrative (G&A) expenses: G&A expenses were $6.1 for the quarter ended June 30, 2022, compared to $6.3 million for the quarter ended June 30, 2021.

Net loss: Net loss for the quarter ended June 30, 2022 was $52.3 million, or $1.01 per basic and diluted share. This compares with a net loss of $30.0 million, or $0.58 per basic and diluted share, for the quarter ended June 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 dosing patients in the DYNE-251 trial and the DYNE-101 trial, the expectation of regulatory clearances in additional countries and Dyne's cash runway, 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; 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 for the period anticipated or at all; 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 June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 46,664	$ 23,872	$ 74,899	$ 42,496
General and administrative	6,091	6,293	13,638	12,802
Total operating expenses	**52,755**	**30,165**	**88,537**	**55,298**
Loss from operations	(52,755)	(30,165)	(88,537)	(55,298)
Other (expense) income, net	451	210	650	375
Net loss	**$ (52,304)**	**$ (29,955)**	**$ (87,887)**	**$ (54,923)**
Net loss per share—basic and diluted	$ (1.01)	$ (0.58)	$ (1.70)	$ (1.09)
Weighted-average common shares outstanding used in net loss per share—basic and diluted	51,679,536	51,216,254	51,640,706	50,349,193

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

	June 30,	December 31,
	2022	**2021**
Assets		
Cash, cash equivalents and marketable securities	$ 291,838	$ 376,571
Other assets	48,188	49,092
Total assets	**$ 340,026**	**$ 425,663**
Liabilities and Stockholders' Equity		
Liabilities	52,967	57,466
Stockholders' equity	287,059	368,197
Total liabilities and stockholders' equity	**$ 340,026**	**$ 425,663**

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