Dyne Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Business Highlights

March 2, 2023

- Data Anticipated in the Second Half of 2023 from ACHIEVE Clinical Trial of DYNE-101 in DM1 and DELIVER Clinical Trial of DYNE-251 in DMD -

WALTHAM, Mass., March 02, 2023 (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 fourth quarter and full year 2022 and business highlights.

“2022 was a momentous year for Dyne and our commitment to the rare muscle disease community as we advanced not one, but two programs from our FORCE™ platform into clinical trials. This exciting transition into a clinical-stage company required important work across the organization to engage with individuals and families living with DM1 and DMD, clinicians treating these diseases, regulators and other stakeholders,” said Joshua Brumm, president and chief executive officer of Dyne. “We remain focused on driving to meaningful clinical data readouts for our ACHIEVE and DELIVER trials anticipated in the second half of 2023, including evaluating key biomarkers of dystrophin in DMD and splicing in DM1. With cash runway expected through 2024 and strong fundamentals across the business, we believe we are well positioned to achieve our near-term milestones and to advance our mission of delivering life-transforming therapies for people with serious muscle diseases.”

Business Highlights

- Enrollment continues in ACHIEVE, a Phase 1/2 global clinical trial evaluating DYNE-101 in adult patients with myotonic dystrophy type 1 (DM1). ACHIEVE, which is designed to be a registrational trial, consists of a 24-week multiple ascending dose (MAD) randomized, placebo-controlled period, a 24-week open-label extension and a 96-week long-term extension. The primary endpoints are safety and tolerability, with secondary endpoints of pharmacokinetics and pharmacodynamics, including change from baseline in splicing, as well as measures of muscle strength and function.
- Enrollment continues in DELIVER, a Phase 1/2 global clinical trial evaluating DYNE-251 in males with Duchenne muscular dystrophy (DMD) who have mutations amenable to exon 51 skipping therapy. DELIVER, which is designed to be a registrational trial, consists of a 24-week MAD randomized, placebo-controlled period, a 24-week open-label extension and a 96-week long-term extension. The primary endpoints are safety, tolerability and change from baseline in dystrophin levels as measured by Western blot. Secondary endpoints include measures of muscle function, exon skipping and pharmacokinetics.
- In recognition of Rare Disease Day, held annually on the last day of February, Dyne employees hosted members of the rare muscle disease community, and their perspectives are featured in a video available at https://www.dyne-tx.com/rare-disease-day-2023/.

Upcoming Events & Key 2023 Milestones

- Dyne anticipates reporting initial data in the second half of 2023 from:
  - the MAD placebo-controlled portion of the ACHIEVE trial of DYNE-101 in DM1 on safety, tolerability and splicing
  - the MAD placebo-controlled portion of the DELIVER trial of DYNE-251 in DMD on safety, tolerability and dystrophin
- Additional preclinical data supporting Dyne’s DMD program as well as overviews of the DELIVER and ACHIEVE trial designs will be featured in poster presentations during the Muscular Dystrophy Association (MDA) Clinical & Scientific Conference being held March 19-22, 2023.

Fourth Quarter and Full Year 2022 Financial Results

Cash position: Cash, cash equivalents and marketable securities were $256.0 million as of December 31, 2022, which is anticipated to fund operations through 2024.

Research and development (R&D) expenses: R&D expenses were $33.2 million and $42.3 million for the quarters ended December 31, 2022 and 2021, respectively. R&D expenses were $142.8 million and $121.3 million for the years ended December 31, 2022 and 2021, respectively.

General and administrative (G&A) expenses: G&A expenses were $7.0 million and $9.7 million for the quarters ended December 31, 2022 and 2021, respectively. G&A expenses were $28.2 million and $28.7 million for the years ended December 31, 2022 and 2021, respectively.

Net loss: Net loss for the quarter ended December 31, 2022 was $38.8 million, or $0.74 per basic and diluted share. This compares with a net loss of $51.8 million, or $1.00 per basic and diluted share, for the quarter ended December 31, 2021. Net loss for the year ended December 31, 2022 was $168.1 million, or $3.23 per basic and diluted share. This compares with a net loss of $149.3 million, or $2.93 per basic and diluted share, for the year ended December 31, 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. Dyne has a broad pipeline for serious muscle diseases, including clinical programs for myotonic dystrophy type 1 (DM1) and Duchenne muscular dystrophy (DMD), and a preclinical program for 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 reporting data from the DYNE-251 and DYNE-101 clinical trials, the trial design of the DYNE-251 and DYNE-101 clinical trials, and the sufficiency of Dyne's existing cash resources for the period anticipated, 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; uncertainties as to the availability and timing of results from 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; 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,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 33,191	$ 42,304	$ 142,760	$ 121,308
General and administrative	6,955	9,658	28,202	28,717
Total operating expenses	**40,146**	**51,962**	**170,962**	**150,025**
Loss from operations	(40,146)	(51,962)	(170,962)	(150,025)
Other (expense) income, net	1,319	175	2,863	734
Net loss	**$ (38,827)**	**$ (51,787)**	**$ (168,099)**	**$ (149,291)**
Net loss per share, basic and diluted	$ (0.74)	$ (1.00)	$ (3.23)	$ (2.93)
Weighted average common shares outstanding, basic and diluted	52,817,413	51,543,053	51,976,343	50,895,044

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

	December 31,	
	2022	**2021**
Assets		
Cash, cash equivalents and marketable securities	$ 256,012	$ 376,571
Other assets	50,313	49,092
Total Assets	**$ 306,325**	**$ 425,663**
Liabilities and Stockholders' Equity		
Liabilities	53,961	57,466
Stockholders' equity	252,364	368,197
Total liabilities and stockholders' equity	**$ 306,325**	**$ 425,663**

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