Dyne Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Recent Business Highlights

February 27, 2025

- Received FDA Fast Track Designation for DYNE-101 in DM1 -

- Full enrollment of Registrational Expansion Cohort of ACHIEVE Trial of DYNE-101 in DM1 Planned for Mid-2025 to Support Submission for U.S. Accelerated Approval -

- Full Enrollment of Registrational Expansion Cohort of DELIVER Trial of DYNE-251 in DMD Planned for Q1 2025 to Support Submission for U.S. Accelerated Approval -

WALTHAM, Mass., Feb. 27, 2025 (GLOBE NEWSWIRE) -- Dyne Therapeutics, Inc. (Nasdaq: DYN), a clinical-stage neuromuscular disease company focused on advancing life-transforming therapeutics for people living with genetically driven diseases, today reported financial results for the fourth quarter and full year 2024 and recent business highlights.

"Our most recent clinical data for DYNE-101 from the ACHIEVE trial in DM1 patients showed substantial functional benefit, including the reversal of disease progression and improvement across a range of clinical measures, as well as a favorable safety profile. We believe that the compelling benefits seen with DYNE-101 result from addressing the underlying biology of this devastating neuromuscular disease through meaningful splicing correction," said John Cox, president and chief executive officer of Dyne. "With these results in hand, we are moving rapidly to initiate a Registrational Expansion Cohort to support a potential submission for U.S. Accelerated Approval. Furthermore, in DMD, we expect data from the ongoing DELIVER trial of DYNE-251 in late 2025 to support a potential submission for U.S. Accelerated Approval in early 2026, giving us the transformational opportunity to launch two important therapies in 2027."

DYNE-101 in DM1

- In January 2025, the U.S. Food and Drug Administration (FDA) granted Fast Track designation for DYNE-101 for the treatment of myotonic dystrophy type 1 (DM1).
- Dyne continues to pursue Accelerated Approval in the U.S. based on splicing as a surrogate endpoint and plans to initiate a global placebo-controlled Registrational Expansion Cohort in the ACHIEVE trial that will include up to 48 patients with full enrollment planned for mid-2025 and data from this cohort planned for H1 2026.
- Dyne intends to use data from the Registrational Expansion Cohort and from the already enrolled patients in the multiple ascending dose and ongoing long-term extension portions of the ACHIEVE trial to support a potential submission for Accelerated Approval in the U.S.
- Dyne is also pursuing expedited approval pathways globally for DYNE-101.
- Dyne anticipates a potential submission for U.S. Accelerated Approval in H1 2026.

DYNE-251 in DMD

- Dyne continues to pursue expedited approval pathways globally for DYNE-251 in patients with DMD who are amenable to exon 51 skipping.
- Dyne is currently enrolling the Registrational Expansion Cohort of approximately 32 patients as part of the DELIVER trial. Dyne anticipates completion of enrollment in Q1 2025 with data from this cohort planned for late 2025.
- Dyne anticipates a potential submission for U.S. Accelerated Approval in early 2026.

Fourth Quarter and Full Year 2024 Financial Results

Cash position: Cash, cash equivalents and marketable securities were $642.3 million as of December 31, 2024. During the first quarter of 2025, the Company received net proceeds of approximately $140.6 million from the sale of stock through its at-the-market offering program. The Company expects that its cash, cash equivalents and marketable securities as of December 31, 2024, together with the net proceeds from the Q1 2025 at-the-market offering, will be sufficient to fund its operations at least into the second half of 2026.

Research and development (R&D) expenses: R&D expenses were $81.8 million and $58.8 million for the quarters ended December 31, 2024 and 2023, respectively. R&D expenses were $281.4 million and $210.8 million for the years ended December 31, 2024 and 2023, respectively.

General and administrative (G&A) expenses: G&A expenses were $15.3 million and $8.8 million for the quarters ended December 31, 2024 and 2023, respectively. G&A expenses were $62.5 million and $31.4 million for the years ended December 31, 2024 and 2023, respectively.

Net loss: Net loss for the quarter ended December 31, 2024 was $89.5 million, or $0.88 per basic and diluted share. This compares with a net loss of $66.6 million, or $1.09 per basic and diluted share, for the quarter ended December 31, 2023. Net loss for the year ended December 31, 2024 was $317.4 million, or $3.37 per basic and diluted share. This compares with a net loss of $235.9 million, or $3.95 per basic and diluted share, for the year ended December 31, 2023.

About Dyne Therapeutics

Dyne Therapeutics is discovering and advancing innovative life-transforming therapeutics for people living with genetically driven neuromuscular diseases. Leveraging the modularity of its FORCE™ platform, Dyne is developing targeted therapeutics that deliver to muscle and the central nervous system (CNS). Dyne has a broad pipeline for neuromuscular diseases, including clinical programs for myotonic dystrophy type 1 (DM1) and Duchenne muscular dystrophy (DMD) and preclinical programs for facioscapulohumeral muscular dystrophy (FSHD) and Pompe disease. For more information, please visit https://www.dyne-tx.com/, and follow us on X, 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 potential of DYNE-101 and DYNE-251, the anticipated timelines for reporting additional data from the ACHIEVE and DELIVER clinical trials, enrolling registrational cohorts and initiating additional clinical trials, the availability of expedited approval pathways for DYNE-101 and DYNE-251, expectations regarding the timing of submitting applications for U.S. Accelerated Approval, and the sufficiency of Dyne's 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 enroll patients in clinical trials; whether results from preclinical studies and data from clinical trials will be predictive of the final results of the clinical trials or other trials; whether data from clinical trials will support submission for regulatory approvals; uncertainties as to the FDA's and other regulatory authorities' interpretation of the data from Dyne's clinical trials and acceptance of Dyne's clinical programs and as to the regulatory approval process for Dyne's product candidates; whether Dyne's cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; 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,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 81,804	$ 58,843	$ 281,406	$ 210,762
General and administrative	15,303	8,846	62,480	31,400
Total operating expenses	**97,107**	**67,689**	**343,886**	**242,162**
Loss from operations	(97,107)	(67,689)	(343,886)	(242,162)
Other (expense) income, net	7,567	1,050	26,468	6,225
Net loss	**$ (89,540)**	**$ (66,639)**	**$ (317,418)**	**$ (235,937)**
Net loss per share, basic and diluted	$ (0.88)	$ (1.09)	$ (3.37)	$ (3.95)
Weighted average common shares outstanding, basic and diluted	101,982,168	61,393,409	94,143,565	59,683,851

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

	December 31,	
	2024	**2023**
Assets		
Cash, cash equivalents and marketable securities	$ 642,268	$ 123,100
Other assets	48,966	41,982
Total Assets	**$ 691,234**	**$ 165,082**
Liabilities and Stockholders' Equity		
Liabilities	61,396	73,790
Stockholders' equity	629,838	91,292
Total liabilities and stockholders' equity	**$ 691,234**	**$ 165,082**

Contacts:

Investors

Mia Tobias
ir@dyne-tx.com
781-317-0353

Media
Stacy Nartker
snartker@dyne-tx.com
781-317-1938