Dyne Therapeutics Reports Third Quarter 2021 Financial Results and Business Highlights

November 4, 2021

- Robust In Vivo Data Presented at Scientific Meetings Support Advancement of Dyne's Co-lead Candidates into the Clinic -

- Investigational New Drug (IND) Submissions Anticipated for DYNE-251 in DMD During the Fourth Quarter of 2021 and for DYNE-101 in DM1 During the First Quarter of 2022 -

WALTHAM, Mass., Nov. 04, 2021 (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 third quarter of 2021 and business highlights.

"We made tremendous progress during the third quarter and are now preparing to advance Dyne's two co-lead programs into the clinic, with the IND submission for DYNE-251 in DMD anticipated during the fourth quarter of 2021, followed by the IND submission for DYNE-101 in DM1 expected in the first quarter of 2022," said Joshua Brumm, president and chief executive officer of Dyne. "As we highlighted at our recent R&D Day and presentations at the World Muscle Society and Muscle Study Group meetings, we have generated robust *in vivo* data for these programs. The team has also done extensive work to engage with multiple stakeholders, including thought leaders, regulators, advocacy groups and patients to prepare to move both candidates into the clinic. The FORCE™ platform is exhibiting powerful potential to address these rare muscle diseases where patients have few or no therapeutic options, and I'm proud that the Dyne team remains fully focused on urgently delivering on our mission."

Recent Highlights

- Dyne presented new *in vivo* data during the World Muscle Society 2021 Virtual Congress in September 2021 demonstrating the ability of DYNE-101 in myotonic dystrophy type 1 (DM1) to target the nucleus and achieve knockdown of toxic *DMPK* RNA, foci reduction and correction of splicing in muscle tissues in the novel hTfR1/DMSXL mouse model. DYNE-101 was also well tolerated in a non-GLP toxicology dose-range finding study in non-human primates (NHPs).

- The Company presented new *in vivo* data on October 1, 2021 during the 2021 Muscle Study Group Annual Scientific Meeting for its Duchenne muscular dystrophy (DMD) program, showing dystrophin restoration of 90% of wild-type levels in the diaphragm and 78% in the heart with approximately 80% dystrophin-positive fibers following a single dose of FORCE in the *mdx* mouse model. Its candidate, DYNE-251, also achieved exon 51 skipping of 52% in the diaphragm and 43% in the heart in NHPs and was well tolerated in a GLP toxicology study.

- Dyne held its inaugural R&D Day on October 13, 2021, highlighting preclinical data and clinical development plans for DYNE-251 in DMD and DYNE-101 in DM1. Following the IND submissions and review with regulators, the Company plans to initiate global, placebo-controlled multiple ascending dose (MAD) clinical trials for each of these candidates, evaluating safety, key disease markers and muscle function in patients with DMD and DM1, with the intention of dosing patients in both trials by the middle of 2022. The R&D Day also featured presentations and commentary by leading neuromuscular disease experts, Valeria Sansone, M.D., Ph.D. and John Day, M.D., Ph.D. A replay is available at https://investors.dyne-tx.com/events/event-details/dyne-rd-day.

Upcoming Events and Milestones

- IND submission for DYNE-251 in DMD is planned during the fourth quarter of 2021.

- IND submission for DYNE-101 in DM1 is anticipated in the first quarter of 2022.

- IND submission for DYNE-301 in facioscapulohumeral muscular dystrophy (FSHD) is expected in the second half of 2022.

- Dyne management is scheduled to participate in fireside chats during three upcoming investor conferences. The event webcasts and replays (available for 90 days) can be accessed in the Investors & Media section of Dyne's website at https://investors.dyne-tx.com/news-and-events/events-and-presentations:
  - Stifel 2021 Virtual Healthcare Conference on November 15, 2021 at 8:00 a.m. ET
  - Jefferies London Healthcare Conference, pre-recorded and available on November 18, 2021 beginning at 8:00 a.m. GMT / 3:00 a.m. ET.
  - Piper Sandler 33rd Annual Virtual Healthcare Conference, pre-recorded and available on November 22, 2021 beginning at 10:00 a.m. ET.

Third Quarter 2021 Financial Results

Cash position: Cash, cash equivalents and marketable securities were $407.5 million as of September 30, 2021, which is anticipated to fund operations into the second half of 2024.

Research and development (R&D) expenses: R&D expenses were $36.5 million for the third quarter of 2021 compared to $9.7 million for the third quarter of 2020.

General and administrative (G&A) expenses: G&A expenses were $6.3 million during the third quarter of 2021 compared to $3.8 million for the third quarter of 2020.

Net loss: Net loss was $42.6 million or $0.83 per share of common stock for the third quarter of 2021 compared to $13.9 million, or $2.01 per share of common stock for the third 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 has a broad portfolio of therapeutic candidates for serious muscle diseases, including 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 investigational new drug applications 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; the timing of and Dyne's ability to submit and obtain regulatory clearance for investigational new drug applications and initiate clinical trials; 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 September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 36,510	$ 9,679	$ 79,007	$ 23,102
General and administrative	6,256	3,841	19,058	6,945
Total operating expenses	**42,766**	**13,520**	**98,065**	**30,047**
Loss from operations	(42,766)	(13,520)	(98,065)	(30,047)
Other (expense) income, net	184	(400)	560	(741)
Net loss	**$ (42,582)**	**$ (13,920)**	**$ (97,505)**	**$ (30,788)**
Net loss per share—basic and diluted	$ (0.83)	$ (2.01)	$ (1.92)	$ (7.51)
Weighted-average common shares outstanding used in net loss per share—basic and diluted	51,320,940	6,920,008	50,676,668	4,100,504

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

	September 30, 2021	December 31, 2020
Assets		
Cash, cash equivalents and marketable securities	$ 407,523	$ 345,314
Other assets	59,355	8,020
Total assets	**$ 466,878**	**$ 353,334**
Liabilities and Stockholders' Equity		
Liabilities	52,762	10,967
Stockholders' equity	414,116	342,367
Total liabilities and stockholders' equity	**$ 466,878**	**$ 353,334**

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