Dyne Therapeutics Reports Second Quarter 2021 Financial Results and Business Highlights

August 5, 2021

- On Track to Submit INDs for DM1, DMD and FSHD Programs Between the Fourth Quarter of 2021 and the Fourth Quarter of 2022 -

- New In Vivo Data from DM1 and DMD Programs to be Presented at Scientific Meetings this Fall -

WALTHAM, Mass., Aug. 05, 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 second quarter 2021 and business highlights.

"We were pleased to present preclinical data from our DM1 and FSHD programs at scientific meetings during the quarter which further support our approach for addressing these devastating diseases, neither of which has any approved therapies," said Joshua Brumm, president and chief executive officer of Dyne. "We remain on track to submit INDs for all three of our programs – DM1, DMD and FSHD – between the fourth quarter of 2021 and the fourth quarter of 2022. We have an exceptional team and the right resources to transition Dyne into a clinical stage company focused on bringing potentially life-transforming therapies to patients."

Recent Highlights

- The Company presented preclinical data from its facioscapulohumeral muscular dystrophy (FSHD) program during the 28th Annual FSHD Society International Research Congress in June 2021. Data from *in vitro* studies in an FSHD patient cell line highlighted that Dyne's proprietary FORCE™ platform enabled targeted muscle delivery with its lead FSHD candidate demonstrating potent suppression of DUX4 transcriptome markers.
- Oxana Beskrovnaya, Ph.D., was appointed chief scientific officer in June 2021, after serving as Dyne's senior vice president, head of research since January 2020.
- The Company presented new preclinical data from its myotonic dystrophy type 1 (DM1) program, during the American Society of Gene & Cell Therapy (ASGCT) 24th Annual Meeting in May 2021.
    - To assess the ability of its lead DM1 candidate to reduce toxic human nuclear *DMPK* RNA, Dyne developed an innovative hTfR1/DMSXL mouse model that expresses the human TfR1 and carries a human *DMPK* gene that represents a severe DM1 phenotype with more than 1,000 CTG repeats. Dyne's lead DM1 candidate demonstrated sustained *DMPK* RNA knockdown at 4 weeks in multiple muscles after administration of a single, low 10 mg/kg dose.
    - The Company also reported new *in vitro* findings from DM1 patient cells with approximately 380 and 2,600 CTG repeats, where its candidate showed a robust, dose-dependent reduction in *DMPK* RNA, nuclear foci and correction of splicing defects as measured by BIN1 exon 11 inclusion.
    - Following the ASGCT presentations, Dyne hosted a webcast reviewing its DM1 program and preclinical data and featuring leading DM1 expert, Charles Thornton, M.D., the Saunders Distinguished Professor of Neuromuscular Research at the University of Rochester. A replay of the event is available at https://investors.dyne-tx.com/news-and-events/events-and-presentations.

Upcoming Events and Presentations

- Dyne plans to present additional *in vivo* data at scientific meetings this fall:
    - New data from its DM1 program during the World Muscle Society 2021 Virtual Congress taking place September 20-24
    - New data from its Duchenne muscular dystrophy (DMD) program during the 2021 Muscle Study Group Annual Scientific Meeting being held virtually October 1-3
- Dyne will host an R&D Day on October 13, 2021, beginning at 8:00 a.m. ET. The Company will review its programs in serious muscle diseases and be joined by key opinion leaders. Further details will be announced closer to the event.

Second Quarter 2021 Financial Results

Cash position: Cash, cash equivalents and marketable securities were $435.6 million as of June 30, 2021, which is anticipated to fund operations into the second half of 2024.
Research and development (R&D) expenses: R&D expenses were $23.9 million for the second quarter of 2021 compared to $7.3 million for the second quarter of 2020.
General and administrative (G&A) expenses: G&A expenses were $6.3 million during the second quarter of 2021 compared to $1.3 million for the second quarter of 2020.
Net loss: Net loss was $30.0 million or $0.58 per common share for the second quarter of 2021 compared to $9.0 million, or $3.31 per common share for the second 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's broad portfolio of therapeutic candidates for serious muscle diseases includes programs 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, plans, objectives of management, the expected timeline for submitting investigational new drug applications and achieving proof-of-concept data readouts 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 and clinical trials; the timing of and Dyne's ability to submit investigational new drug applications; whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials; uncertainties related to Dyne's ability to obtain sufficient cash resources to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements for the anticipated periods; 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.

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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,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 23,872	$ 7,334	$ 42,496	$ 13,423
General and administrative	6,293	1,341	12,802	3,105
Total operating expenses	**30,165**	**8,675**	**55,298**	**16,528**
Loss from operations	(30,165)	(8,675)	(55,298)	(16,528)
Other (expense) income, net	210	(307)	375	(340)
Net loss	**$ (29,955)**	**$ (8,982)**	**$ (54,923)**	**$ (16,868)**
Net loss per share—basic and diluted	$ (0.58)	$ (3.31)	$ (1.09)	$ (6.31)
Weighted-average common shares outstanding used in net loss per share—basic and diluted	51,216,254	2,710,556	50,349,193	2,675,260

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

	June 30, 2021	December 31, 2020
Assets		
Cash, cash equivalents and marketable securities	$ 435,589	$ 345,314
Other assets	31,558	8,020
Total assets	**$ 467,147**	**$ 353,334**
Liabilities and Stockholders' Equity		
Liabilities	14,551	10,967
Stockholders' equity	452,596	342,367
Total liabilities and stockholders' equity	**$ 467,147**	**$ 353,334**