Entrada Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results

March 13, 2024

– Cash runway extended through the second quarter of 2026 –

– $352 million in cash, cash equivalents and marketable securities as of December 31, 2023 –

– Completed dosing for third cohort of Phase 1 clinical trial of ENTR-601-44 for the potential treatment of DMD with data readout on track for the second half of 2024 –

– Regulatory applications expected in the fourth quarter of 2024 for the global Phase 2 clinical development of ENTR-601-44 and ENTR-601-45 in people living with DMD –

BOSTON, March 13, 2024 (GLOBE NEWSWIRE) -- Entrada Therapeutics, Inc. (Nasdaq: TRDA) is a clinical-stage biopharmaceutical company aiming to transform the lives of patients by establishing a new class of medicines that engage intracellular targets that have long been considered inaccessible. The Company today reported financial results for the fourth quarter and full year ending December 31, 2023, and highlighted recent business updates.

“We continue to make significant progress advancing our growing pipeline of intracellular therapeutics,” said Dipal Doshi, Chief Executive Officer of Entrada Therapeutics. “We have an exciting year ahead in 2024, with several important clinical milestones within our Duchenne franchise, including the expected fourth quarter submissions of Phase 2 regulatory applications for the global development of ENTR-601-44 and ENTR-601-45. Clinical momentum is also building in our collaboration with Vertex, with the initiation of a Phase 1/2 clinical trial of VX-670 in patients with DM1. With the extension of our cash runway through the second quarter of 2026, we believe we are well positioned to progress our Duchenne franchise and broader pipeline to create value for patients and shareholders.”

Recent Corporate Highlights

- Completed dosing for the first three cohorts of its Phase 1 clinical trial, ENTR-601-44-101, for the potential treatment of individuals with Duchenne muscular dystrophy (DMD) who are exon 44 skipping amenable. Entrada plans to announce data from the clinical trial in the second half of 2024. Additionally, the Company expects to submit regulatory applications in the fourth quarter of 2024 for the separate global Phase 2 clinical development of ENTR-601-44 in Duchenne patients who are exon 44 skipping amenable and ENTR-601-45 in Duchenne patients who are exon 45 skipping amenable.
- Vertex Pharmaceuticals announced it received clearances from Health Canada and Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom for Clinical Trial Applications for VX-670 for patients with myotonic dystrophy type 1 (DM1). Vertex initiated the Phase 1/2 clinical trial in patients with DM1 in Canada and will initiate the study in the UK near-term.
- In January 2024, Entrada announced the promotion of Nathan Dowden, previously Chief Operating Officer of Entrada Therapeutics, to President and Chief Operating Officer. Mr. Dowden has played a critical role in developing Entrada’s strategic and operational capabilities. In February 2024, the Company appointed Kevin Healy, PhD, as Senior Vice President of Regulatory Affairs. Mr. Healy has extensive expertise in the development and commercialization of therapies for serious and rare diseases and has led or participated in more than 30 formal meetings with the FDA, EMA, and other global health authorities. In March 2024, Entrada appointed Marie Rosenfeld as Senior Vice President of Clinical Operations and Data Management. Ms. Rosenfeld has more than 20 years of experience in R&D at large and medium-size pharmaceutical companies and contract research organizations, with a proven track record of securing product regulatory approvals.

Fourth Quarter and Full Year 2023 Financial Results

Cash Position: Cash, cash equivalents and marketable securities were $352.0 million as of December 31, 2023, compared to $188.7 million as of December 31, 2022. This increase was primarily due to the proceeds received to date from the Vertex Agreement. Entrada anticipates that its cash, cash equivalents and marketable securities as of December 31, 2023, together with ongoing research support and the anticipated achievement of certain milestones pursuant to the Vertex collaboration, will be sufficient to fund the Company's operating expenses and capital expenditure requirements through the second quarter of 2026.

Collaboration Revenue: Collaboration revenue was $41.8 million for the fourth quarter of 2023 and $129.0 million for the full year of 2023. There was no collaboration revenue in the fourth quarter or full year of 2022.

Research & Development (R&D) Expenses: R&D expenses were $28.3 million for the fourth quarter of 2023 and $99.9 million for the full year of 2023, compared to $15.7 million and $66.6 million for the same periods in 2022, respectively. The increases were primarily due to the initiation of the ENTR-601-44 Phase 1 clinical trial, costs incurred for IND-enabling studies for ENTR-601-45 and ENTR-601-50 to support future clinical trials, additional platform investment, and higher personnel costs, including non-cash, stock-based compensation.

General & Administrative (G&A) Expenses: G&A expenses were $8.7 million for the fourth quarter of 2023 and $32.3 million for the full year of 2023, compared to $9.9 million and $30.6 million for the same periods in 2022, respectively. The G&A expenses in the fourth quarter of 2023 were lower than the fourth quarter of 2022 primarily due to a decrease in legal and consulting fees. The increase in the full year expense was primarily due to higher personnel costs (including non-cash stock-based compensation).

Net Income (Loss): Net loss was $9.5 million for the fourth quarter of 2023 and $6.7 million for the full year of 2023, compared to a net loss of $24.6 million and $94.6 million for the same periods in 2022, respectively.

About Entrada Therapeutics

Entrada Therapeutics is a clinical-stage biopharmaceutical company aiming to transform the lives of patients by establishing a new class of medicines that engage intracellular targets that have long been considered inaccessible. The Company's Endosomal Escape Vehicle (EEV™)-therapeutics are designed to enable the efficient intracellular delivery of a wide range of therapeutics into a variety of organs and tissues, resulting in an improved therapeutic index. Through this proprietary, versatile and modular approach, Entrada is advancing a robust development portfolio of RNA-, antibody- and enzyme-based programs for the potential treatment of neuromuscular, ocular, metabolic and immunological diseases, among others. The Company's lead oligonucleotide programs are in development for the potential treatment of people living with Duchenne who are exon 44, 45 and 50 skipping amenable. Entrada has partnered to develop a clinical-stage program, VX-670, for myotonic dystrophy type 1.

For more information about Entrada, please visit our website, www.entradatx.com, and follow us on LinkedIn.

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 Entrada's strategy, future operations, prospects and plans, objectives of management, Entrada's ability to continue to recruit for and complete its ongoing healthy volunteer trial for ENTR-601-44 in the United Kingdom with dosing complete through the third cohort, the ability of Entrada's partner Vertex to recruit for and complete its Phase 1/2 clinical trial in patients with DM1 in Canada and to initiate a Phase 1/2 clinical trial in patients with DM1 in the United Kingdom, expectations regarding the timing of data from its Phase 1 clinical trial for ENTR-601-44 in the second half of 2024, expectations regarding the therapeutic benefits of ENTR-601-44, the continued development and advancement of ENTR-601-44, ENTR-601-45 and ENTR-601-50 for the treatment of Duchenne and our partnered candidate VX-670 for the treatment of DM1, expectations regarding the expected timing, progress and success of our collaboration with Vertex, including any future payments we may receive under our collaboration and license agreements, the ability to develop additional therapeutic programs, including further exon skipping programs, the potential therapeutic benefits of its EEV candidates, and the sufficiency of its cash resources through the second quarter of 2026, 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. Entrada 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 Entrada's ability to submit and obtain regulatory clearance for IND or equivalent foreign applications and initiate or complete clinical trials; whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials; whether Entrada's cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; as well as the risks and uncertainties identified in Entrada's filings with the Securities and Exchange Commission (SEC), including the Company's most recent Form 10-K and in subsequent filings Entrada may make with the SEC. In addition, the forward-looking statements included in this press release represent Entrada's views as of the date of this press release. Entrada anticipates that subsequent events and developments will cause its views to change. However, while Entrada 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 Entrada's views as of any date subsequent to the date of this press release.

ENTRADA THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations (Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Collaboration revenue	$ 41,848	$ —	$ 129,013	$ —
Operating expenses:				
Research and development	28,291	15,685	99,884	66,609
General and administrative	8,652	9,894	32,291	30,639
Total operating expenses	36,943	25,579	132,175	97,248
Income (loss) from operations	4,905	(25,579)	(3,162)	(97,248)
Other income:				
Interest and other income	4,292	950	15,218	2,632
Total other income	4,292	950	15,218	2,632
Income (loss) before provision for income taxes	9,197	(24,629)	12,056	(94,616)
Provision for income taxes	(18,741)	—	(18,741)	—
Net loss	$ (9,544)	$ (24,629)	$ (6,685)	$ (94,616)

Net loss per share attributable to common stockholders, basic and diluted	$ (0.29)	$ (0.79)	$ (0.20)	$ (3.02)
Weighted-average common shares outstanding, basic and diluted	33,368,901	31,351,770	33,050,319	31,293,312

ENTRADA THERAPEUTICS, INC.
Condensed Consolidated Balance Sheet Data (Unaudited)
(In thousands)

	December 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 351,969	$ 188,712
Total assets	469,192	252,056
Total liabilities	226,832	39,502
Total stockholders' equity	242,360	212,554

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