Entrada Therapeutics Reports First Quarter 2024 Financial Results

May 7, 2024

– Initiated dosing of the fourth and final cohort of Phase 1 clinical trial of ENTR-601-44 for the potential treatment of DMD with data readout on track for October of 2024 –

– Achieved $75 million milestone payment from Vertex for the clinical advancement of its Phase 1/2 clinical trial of VX-670 for DM1 –

– Cash runway expected through the second quarter of 2026 with $327 million in cash, cash equivalents and marketable securities as of March 31, 2024 –

BOSTON, May 07, 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 first quarter ended March 31, 2024, and highlighted recent business updates.

"The first quarter of 2024 was a period of significant clinical progress for Entrada. We initiated dosing for the fourth and final cohort of our Phase 1 clinical trial of ENTR-601-44 for DMD and our partner Vertex announced that enrollment and dosing are underway in their global Phase 1/2 clinical trial of VX-670 for DM1," said Dipal Doshi, Chief Executive Officer of Entrada Therapeutics. "With two neuromuscular programs from Entrada's development pipeline now in the clinic and a cash runway expected through the second quarter of 2026, we believe we are well positioned to execute on several important clinical milestones across our pipeline of intracellular therapeutic candidates in 2024 and beyond."

Recent Corporate Highlights

- The Company completed dosing for the first three cohorts and has initiated dosing for the fourth and final cohort 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 expects to report data from the clinical trial in October of 2024.
- The Company is on track to submit regulatory applications in the fourth quarter of 2024 to initiate independent global Phase 2 clinical development studies for ENTR-601-44 in patients with DMD who are exon 44 skipping amenable and ENTR-601-45 in patients with DMD who are exon 45 skipping amenable.
- Vertex announced that its U.S. Investigational New Drug Application (IND) for the Phase 1/2 clinical trial of VX-670 in people with myotonic dystrophy type 1 (DM1) has cleared, as have the Clinical Trial Applications (CTAs) in Canada, the U.K. and the EU, and the Clinical Trials Notification (CTN) in Australia. Vertex further noted that enrollment and dosing are underway.
- In March 2024, Entrada achieved a milestone under its global collaboration with Vertex related to the clinical advancement of Vertex's Phase 1/2 clinical trial of VX-670, which triggered a $75 million payment. The Company expects to receive this payment in the second quarter of 2024. The Company is eligible to receive up to $485 million, inclusive of milestones achieved to date, for the successful achievement of certain research, development, regulatory and commercial milestones, and tiered royalties on future net sales for any products that may result from this collaboration agreement.

First Quarter 2024 Financial Results

Cash Position: Cash, cash equivalents and marketable securities were $327.4 million as of March 31, 2024, compared to $352.0 million as of December 31, 2023. Entrada anticipates that its cash, cash equivalents and marketable securities as of March 31, 2024, together with ongoing research support from Vertex and the clinical advancement milestone expected to be received in the second quarter of 2024, will be sufficient to extend its cash runway through the second quarter of 2026, supporting the Company's expansion and continued development of EEV therapeutic candidates targeting DMD and advance EEV-therapeutic candidates in indications beyond neuromuscular disease.

Collaboration Revenue: Collaboration revenue was $59.1 million for the first quarter of 2024, compared to $25.3 million for the same period in 2023. The increase was primarily a result of the clinical advancement milestone achieved in the first quarter of 2024.

Research & Development (R&D) Expenses: R&D expenses were $28.6 million for the first quarter of 2024, compared to $23.1 million for the same period in 2023. The increase was primarily due to the progression of the Company's 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 $9.4 million for the first quarter of 2024, compared to $7.9 million for the same period in 2023. The increase was primarily due to higher personnel costs (including non-cash, stock-based compensation).

Net Income (Loss): Net income was $23.5 million for the first quarter of 2024, compared to a net loss of $(6.7) million for the same period in 2023.

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 UK 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 US, the UK, the EU and Australia, expectations regarding the timing of data from its Phase 1 clinical trial for ENTR-601-44 in October of 2024, expectations regarding the submission of regulatory applications in the fourth quarter of 2024 for ENTR-601-44 in patients with DMD who are exon 44 skipping amenable and ENTR-601-45 in patients with DMD who are exon 45 skipping amenable, 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 DMD 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 the receipt of the $75 million milestone payment from Vertex and 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, express and implied statements regarding any future payments Entrada may receive under the Vertex Agreement, 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 March 31,	
	2024	2023
Collaboration revenue	$ 59,120	$ 25,260
Operating expenses:		
Research and development	28,608	23,102
General and administrative	9,399	7,938
Total operating expenses	38,007	31,040
Income (loss) from operations	21,113	(5,780)
Other income:		
Interest and other income	4,214	2,657
Total other income	4,214	2,657
Income (loss) before provision for income taxes	25,327	(3,123)
Provision for income taxes	(1,831)	(3,551)
Net income (loss)	$ 23,496	$ (6,674)
Net income (loss) per share, basic	$ 0.70	$ (0.21)
Net income (loss) per share, diluted	$ 0.68	$ (0.21)

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

	March 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 327,414	$ 351,969
Total assets	510,844	469,192
Total liabilities	241,477	226,832
Total stockholders' deficit	269,367	242,360

Investor and Media Contact
Karla MacDonald
Chief Corporate Affairs Officer
kmacdonald@entradatx.com