
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): March 6, 2023

ENTRADA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

**Delaware
(State or other jurisdiction
of incorporation)**

**001-40969
(Commission
File Number)**

**81-3983399
(I.R.S. Employer
Identification No.)**

**6 Tide Street
Boston, MA**
(Address of principal
executive offices)

02210
(Zip Code)

Registrant's telephone number, including area code: (857) 520-9158

**Not Applicable
(Former name or former address, if changed since last report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	TRDA	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On March 6, 2023, Entrada Therapeutics, Inc. announced its financial results for the year ended December 31, 2022 and other corporate updates. A copy of the press release in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit relating to Item 2.02 of this Current Report on Form 8-K shall be deemed furnished and not filed:

99.1 [Press Release issued by Entrada Therapeutics, Inc. on March 6, 2023](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Entrada Therapeutics, Inc.

Date: March 6, 2023

/s/ Dipal Doshi

Dipal Doshi

President and Chief Executive Officer

Entrada Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results

- *Established a transformative collaboration with Vertex to discover and develop intracellular Endosomal Escape Vehicle-therapeutics for myotonic dystrophy type 1 -*
- *Actively working to resolve the clinical hold on its IND application for ENTR-601-44 -*
- *Selected ENTR-601-45, expanding the Company's commitment to include a potential therapy for people living with Duchenne who are amenable to exon 45 skipping -*
- *Cash runway extended into 2H 2025 following the closing of the collaboration with Vertex -*

BOSTON, March 6, 2023 -- Entrada Therapeutics, Inc. (Nasdaq: TRDA), a biopharmaceutical company aiming to transform the lives of patients by establishing intracellular Endosomal Escape Vehicle (EEV™) therapeutics as a new class of medicines, today reported financial results for the fourth quarter and full year ending December 31, 2022 and highlighted recent business updates.

"We made significant progress executing on our strategic initiatives in 2022, highlighted by the expansion of our pipeline, establishing a global, transformative collaboration with Vertex focused on discovering and developing intracellular EEV-therapeutics for myotonic dystrophy type 1 and strengthening our balance sheet," said Dipal Doshi, President and Chief Executive Officer of Entrada Therapeutics. "We are working diligently to address FDA's concerns regarding our IND for ENTR-601-44 and remain very confident in achieving our goal of initiating a healthy volunteer trial in 2023. Fundamentally, we believe we are well-positioned to advance our pipeline in the year ahead to create value for patients and shareholders."

Recent Corporate Highlights

- In December 2022, the U.S. Food and Drug Administration (FDA) placed the Investigational New Drug (IND) application on hold for ENTR-601-44 for the potential treatment of people living with Duchenne who are amenable to exon 44 skipping, requesting that the Company gather and submit additional information. The Company is actively working to resolve the clinical hold as quickly as possible. Given the extraordinary unmet medical need, Entrada is simultaneously pursuing global opportunities with the continued goal of initiating a healthy volunteer trial in 2023.
- In December 2022, the U.S. FDA Office of Orphan Products Development (OOPD) granted orphan drug designation for ENTR-601-44 for the treatment of Duchenne muscular dystrophy.
- In January 2023, Entrada selected the second clinical candidate within its Duchenne franchise, ENTR-601-45, for the potential treatment of people living with Duchenne who are exon 45 skipping amenable. The Company plans to submit an IND application in the fourth quarter of 2024.
- In February 2023, Entrada announced the closing of its strategic collaboration and license agreement with Vertex for the discovery and development of intracellular EEV-therapeutics for myotonic dystrophy type 1 (DM1). The collaboration includes ENTR-701, which is in late-stage preclinical development. Under the terms of the agreement, Entrada received an upfront payment of \$224 million, as well as an equity investment of \$26 million in February 2023. Entrada is eligible to receive up to \$485 million 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 the collaboration agreement.

Upcoming Events

The Company will present at the following events during the first quarter of 2023:

- Cowen 43rd Annual Health Care Conference in Boston, MA. Dipal Doshi will join the Neuromuscular and Bone Corporate Panel on March 8, 2023 at 2:10 p.m. EST.
- Muscular Dystrophy Association (MDA) Clinical & Scientific Conference 2023 in Dallas, TX from March 19-22, 2023.

Fourth Quarter and Full Year 2022 Financial Results

Cash Position: Cash, cash equivalents and marketable securities were \$188.7 million as of December 31, 2022, compared to \$215.6 million as of September 30, 2022 and \$291.1 million as of December 31, 2021. The Company anticipates that its existing cash, cash equivalents and marketable securities, together with the proceeds received under the Vertex Agreement, ongoing research support and the anticipated achievement of certain near-term milestones under the Vertex Agreement will be sufficient to extend our cash runway into the second half of 2025, supporting the Company's expansion and continued development of EEV-therapeutic candidates targeting Duchenne as well as other indications beyond neuromuscular diseases.

Research & Development (R&D) Expenses: R&D expenses were \$15.7 million for the fourth quarter of 2022 and \$66.6 million for the full year of 2022, compared to \$12.4 million and \$35.9 million for the same periods in 2021, respectively. This increase was primarily due to additional investment in preclinical studies to support future clinical trials and higher personnel costs (including non-cash stock-based compensation).

General & Administrative (G&A) Expenses: G&A expenses were \$9.9 million for the fourth quarter of 2022 and \$30.6 million for the full year of 2022, compared to \$6.1 million and \$15.2 million for the same periods in 2021, respectively. This increase was primarily due to higher personnel costs (including non-cash stock-based compensation), legal costs and other costs associated with Entrada operating as a public company.

Net Loss: Net loss was \$24.6 million for the fourth quarter of 2022 and \$94.6 million for the full year of 2022, compared to net loss of \$18.4 million and \$51.2 million for the same periods of 2021, respectively.

About Entrada Therapeutics

Entrada Therapeutics is a biopharmaceutical company aiming to transform the lives of patients by establishing a new class of medicines, Endosomal Escape Vehicle (EEV[™])-therapeutics, to engage intracellular targets that have long been considered inaccessible and undruggable. The Company's 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 its proprietary, highly versatile and modular EEV platform, Entrada is building a robust development portfolio of RNA-, antibody- and enzyme-based programs for the potential treatment of neuromuscular, immunological, ocular and metabolic diseases, among others. The Company's lead oligonucleotide programs include ENTR-601-44 and ENTR-601-45 for the potential treatment of people living with Duchenne who are exon 44 and 45 skipping amenable, respectively, as well as our partnered candidate ENTR-701 targeting myotonic dystrophy type 1 (DM1).

For more information about Entrada, please visit our website, www.entradatx.com, and follow us on [Twitter](#) and [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, express or implied statements regarding the clinical hold on the IND for ENTR-601-44, expectations regarding the timing and outcome of the Company's discussions with the FDA regarding the clinical hold on the IND for ENTR-601-44, the Company's ability to address the FDA's concerns regarding its IND for ENTR-601-44, the timing of the Company's Phase 1 single ascending dose trial for

ENTR-601-44 and initial clinical readout for such trial, the ability to enroll patients and achieve successful results in ENTR-601-44 clinical trials, the potential benefits and results that may be achieved through Entrada's collaboration with Vertex, Entrada's expectations of the use of proceeds from its collaboration with Vertex, expectations regarding the findings from preclinical data of the Company's therapeutic candidates, the continued development and advancement of ENTR-601-44 and ENTR-601-45 for the treatment of Duchenne and ENTR-701 for the treatment of DM1, including the Investigational New Drug (IND) application-enabling studies, the timing of Entrada's planned regulatory filings regarding its development programs, including the planned IND submission for ENTR-601-45, the ability to develop additional exon skipping programs, the potential therapeutic benefits of its EEV candidates, and the sufficiency of its cash resources into the second half of 2025, 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; the timing of and Entrada's ability to submit and obtain regulatory clearance for IND applications and initiate 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,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 15,685	\$ 12,362	\$ 66,609	\$ 35,926
General and administrative	9,894	6,098	30,639	15,201
Total operating expenses	25,579	18,460	97,248	51,127
Loss from operations	(25,579)	(18,460)	(97,248)	(51,127)
Other income (expense):				
Interest and other income (expense), net	950	13	2,632	(31)
Total other income (expense), net	950	13	2,632	(31)
Net loss	\$ (24,629)	\$ (18,447)	\$ (94,616)	\$ (51,158)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.79)	\$ (0.89)	\$ (3.02)	\$ (8.16)
Weighted-average common shares outstanding, basic and diluted	31,351,770	20,779,674	31,293,312	6,267,776

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

	December 31, 2022	December 31, 2021
Cash and cash equivalents	\$ 45,157	\$ 291,064
Marketable securities	143,555	—
Total assets	252,056	305,833
Total liabilities	39,502	7,115
Total stockholders' equity	212,554	298,718

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