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): August 1, 2023

ENTRADA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-40969**	**81-3983399**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

One Design Center Place **Suite 17-500** **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 7.01. Regulation FD Disclosure.

On August 1, 2023, Entrada Therapeutics, Inc. (the "Company") issued a press release titled "Entrada Therapeutics Receives Authorization in the United Kingdom to Initiate Phase 1 Clinical Trial of ENTR-601-44 for the Potential Treatment of Duchenne Muscular Dystrophy." A copy of the press release is furnished hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 7.01 of Form 8-K, including the accompanying Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liability of such section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of the general incorporation language of such filing, except as shall be expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On August 1, 2023, the Company announced the receipt of authorization from the United Kingdom Medicines and Healthcare Products Regulatory Agency and Research Ethics Committee for its Clinical Trial of an Investigational Medicinal Product for a Phase 1 clinical trial in healthy volunteers for ENTR-601-44. ENTR-601-44 is Entrada's lead product candidate within its Duchenne franchise and is being developed for the potential treatment of individuals with Duchenne who are exon 44 skipping amenable.

The Phase 1 trial's primary objective is to evaluate the safety of a single dose of ENTR-601-44 in healthy volunteers, with a target enrollment of approximately 40 participants. The trial will also evaluate tolerability, pharmacokinetics and target engagement as measured by exon skipping in the skeletal muscle. The first participant is expected to be dosed in September of this year with data anticipated in the second half of 2024.

Forward-Looking Statements

This Form 8-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Form 8-K, including statements regarding Entrada's strategy, future operations, prospects and plans, objectives of management, ability to initiate and recruit for a healthy volunteer trial for ENTR-601-44 in the United Kingdom with the first subject dosed in September 2023, expectations regarding the timing of data from its Phase 1 trial for ENTR-601-44 in the second half of 2024, expectations regarding the safety and therapeutic benefits of ENTR-601-44, the potential of its EEV product candidates and EEV platform, the continued development and advancement of ENTR-601-44 and ENTR-601-45 for the treatment of Duchenne, and the sufficiency of its cash resources through 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 and clinical 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 (the "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 Form 8-K represent Entrada's views as of the date of this Form 8-K. 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 Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release issued by Entrada Therapeutics, Inc. on August 1, 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: August 1, 2023

By: /s/ Dipal Doshi
Dipal Doshi
President and Chief Executive Officer

Exhibit 99.1

Entrada Therapeutics Receives Authorization in the United Kingdom to Initiate Phase 1 Clinical Trial of ENTR-601-44 for the Potential Treatment of Duchenne Muscular Dystrophy

– First participant is expected to be dosed in September 2023 with data anticipated in the second half of 2024 –

– Cash runway extended through the end of 2025 –

BOSTON, August 1, 2023 (GLOBE NEWSWIRE) -- 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 announced that it has received authorization from the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) and Research Ethics Committee (REC) for its CTIMP (Clinical Trial of an Investigational Medicinal Product) for a Phase 1 clinical trial in healthy volunteers for ENTR-601-44. ENTR-601-44 is Entrada's lead product candidate within its Duchenne franchise and is being developed for the potential treatment of individuals with Duchenne who are exon 44 skipping amenable.

"We are looking forward to this important next step in advancing ENTR-601-44 for the potential treatment of people with exon 44 skipping amenable Duchenne muscular dystrophy, where there exists a profound unmet medical need," said Dipal Doshi, President and Chief Executive Officer of Entrada Therapeutics. "This milestone, coupled with the extension of our cash runway through the end of 2025, positions Entrada to advance our Duchenne franchise while broadening the potential of our intracellular therapeutics across serious diseases."

The Phase 1 trial's primary objective is to evaluate the safety of a single dose of ENTR-601-44 in healthy volunteers, with a target enrollment of approximately 40 participants. The trial will also evaluate tolerability, pharmacokinetics and target engagement as measured by exon skipping in the skeletal muscle. The first participant is expected to be dosed in September of this year with data anticipated in the second half of 2024.

About ENTR-601-44

ENTR-601-44, a proprietary Endosomal Escape Vehicle (EEV™)-conjugated phosphorodiamidate morpholino oligomer (PMO), is the lead product candidate within its Duchenne franchise from Entrada's growing pipeline of EEV-therapeutics. Each EEV-PMO therapeutic candidate has an oligonucleotide sequence designed and optimized for the specific subpopulation of interest. ENTR-601-44 is designed to address the underlying cause of Duchenne muscular dystrophy due to mutated or missing exons in the *DMD* gene. ENTR-601-44, an investigational therapy for the potential treatment of people living with Duchenne who are exon 44 skipping amenable, has the potential to restore the mRNA reading frame and allow for the translation of dystrophin protein that is slightly shortened but still functional.

About Duchenne Muscular Dystrophy

Duchenne muscular dystrophy is a rare genetic disease that causes progressive muscle degeneration and weakness throughout the body. Duchenne is caused by mutations in the *DMD* gene, which leads to inadequate production of dystrophin, a protein essential to maintaining the structural integrity and function of muscle cells. Duchenne causes progressive loss of muscle function throughout the body, which limits mobility and causes heart and respiratory complications in the later stages of the disease. Currently approved therapies for Duchenne seek to improve dystrophin production, but to date, the clinical benefits of these products have not been confirmed.

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 LinkedIn.

Forward-Looking Statements

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