

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): December 19, 2022

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 8.01 Other Events.

On December 19, 2022, Entrada Therapeutics, Inc. announced that it received a clinical hold notice from the U.S. Food and Drug Administration regarding the Investigational New Drug application for ENTR-601-44 for the potential treatment of Duchenne muscular dystrophy. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

[99.1](#) [Press Release issued by Entrada Therapeutics, Inc. on December 19, 2022.](#)

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: December 19, 2022

/s/ Dipal Doshi

Dipal Doshi

President and Chief Executive Officer



Entrada Therapeutics Announces Clinical Hold on IND Application for ENTR-601-44 in Duchenne Muscular Dystrophy

BOSTON, Monday, December 19, 2022 (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 the Company received a clinical hold notice from the U.S. Food and Drug Administration (FDA) regarding their Investigational New Drug Application (IND) for ENTR-601-44 for the potential treatment of Duchenne muscular dystrophy. The FDA indicated they will provide an official Clinical Hold letter to Entrada within 30 days. The Company plans to share additional updates pending further communications with the Agency.

“The clinical hold on our ENTR-601-44 program is disappointing and we will work to address the FDA’s concerns regarding the IND,” said Dipal Doshi, President and Chief Executive Officer of Entrada Therapeutics. “There are no approved Duchenne therapies for people with exon 44 skippable mutations and we are eager to resolve this hold and continue down the treatment development pathway.”

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 oligonucleotide-, antibody- and enzyme-based programs for the potential treatment of neuromuscular diseases, immunology, oncology and diseases of the central nervous system. The Company’s lead oligonucleotide programs include ENTR-601-44 targeting Duchenne muscular dystrophy (DMD) and 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, 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, expectations regarding the findings from preclinical data of the Company's therapeutic candidates, expectations regarding the continued development, advancement and the potential therapeutic benefits of ENTR-601-44 for the treatment of Duchenne, the timing of Entrada's planned regulatory filings regarding its development programs, and the potential therapeutic benefits of its EEV candidates, 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; uncertainties associated with the impact of the ongoing COVID-19 pandemic on Entrada's business and operations; 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 Investor/Media Contact

Karla MacDonald
Chief Corporate Affairs Officer
kmacdonald@entradatx.com
