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): November 22, 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**	**02210**
(Address of principal executive offices)	(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 November 22, 2023, Entrada Therapeutics, Inc. (the "Company") issued a press release providing an update on ENTR-601-44, its lead product candidate that is being developed for patients with Duchenne muscular dystrophy. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Form 8-K (including Exhibit 99.1) 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 a filing.

Item 8.01. Other Events.

Update on ENTR-601-44

On November 22, 2023, the Company provided an update on ENTR-601-44, its lead product candidate that is being developed for patients with Duchenne muscular dystrophy. The Company announced the completion of dosing for the first and second cohorts of its Phase 1 clinical trial, ENTR-601-44-101. The Company plans to announce data from ENTR-601-44-101 in the second half of 2024.

The primary objective of the Company's double-blind, single ascending dose Phase 1 clinical trial, which is expected to enroll approximately 40 participants, is to evaluate the safety and tolerability of a single dose of ENTR-601-44 in healthy male volunteers. ENTR-601-44-101 will also evaluate pharmacokinetics and target engagement, as measured by exon skipping in the skeletal muscle.

Update on ENTR-601-44 Investigational New Drug ("IND") Application

The Company was previously notified by the FDA ("FDA" or the "Agency") that the IND for the Phase 1 clinical trial of ENTR-601-44 had been placed on clinical hold. Despite providing additional information to the FDA, the Company was informed that the Agency declined to lift the clinical hold. Importantly, the information that was submitted to the FDA supported the initiation of the Phase 1 clinical trial in the United Kingdom in September 2023.

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 the Company's strategy, future operations, prospects and plans, objectives of management, the Company's ability to continue to recruit for and complete its ENTR-601-44-101 Phase 1 clinical trial in the United Kingdom, expectations regarding the announcement of data from its ENTR-601-44-101 clinical trial in the second half of 2024, express or implied statements regarding the clinical hold on the IND for ENTR-601-44, the Company's ability to address the FDA's concerns regarding ENTR-601-44, the Company's ability to initiate and recruit for potential global clinical trials for ENTR-601-44 in patients with Duchenne muscular dystrophy (DMD) who are exon 44 skipping amenable, expectations regarding the safety and therapeutic benefits of ENTR-601-44, and the continued development and advancement of ENTR-601-44, 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. The Company 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 the Company's ability to submit and obtain regulatory clearance for INDs 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 the Company'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 the Company's filings with the Securities and Exchange Commission (the "SEC"), including the Company's most recent Form 10-K and in subsequent filings the Company may make with the SEC. In addition, the forward-looking statements included in this Form 8-K represent the Company's views as of the date of this Form 8-K. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company 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 the Company'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 November 22, 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: November 22, 2023

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

Exhibit 99.1

Entrada Therapeutics Announces Updates on ENTR-601-44 in Duchenne Muscular Dystrophy

– Company completes dosing of first and second cohorts in Phase 1 clinical trial, ENTR-601-44-101 –

– ENTR-601-44 clinical development program remains on track with data readout expected in second half of 2024 –

– U.S. FDA clinical hold on IND application remains in effect –

– Cash runway expected through 2025 –

Boston, November 22, 2023 – Entrada Therapeutics, Inc. (Nasdaq: TRDA), a clinical-stage 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 the completion of dosing for the first and second cohorts of its Phase 1 clinical trial, ENTR-601-44-101. Entrada plans to announce data from ENTR-601-44-101 in the second half of 2024.

“Our strategy has always been to run a single Phase 1 clinical trial for ENTR-601-44 and, notably, that trial is progressing in the United Kingdom. We are pleased to have completed dosing of the first and second cohorts of participants,” said Dipal Doshi, President and Chief Executive Officer at Entrada Therapeutics. “In parallel with the Phase 1 clinical trial, we continue to plan for the global development of ENTR-601-44 which will include clinical trials in patients with Duchenne who are exon 44 skipping amenable.”

The primary objective of Entrada’s double-blind, single ascending dose Phase 1 clinical trial, which is expected to enroll approximately 40 participants, is to evaluate the safety and tolerability of a single dose of ENTR-601-44 in healthy male volunteers. ENTR-601-44-101 will also evaluate pharmacokinetics and target engagement, as measured by exon skipping in the skeletal muscle.

Update on ENTR-601-44 Investigational New Drug (IND) Application
Entrada was previously notified by the FDA that the IND for the Phase 1 clinical trial of ENTR-601-44 had been placed on clinical hold. Despite providing additional information to the FDA, the Company was informed that the Agency declined to lift the clinical hold. Importantly, the information that was submitted to the FDA supported the initiation of the Phase 1 clinical trial in the United Kingdom in September 2023.

“We are disappointed that the U.S. clinical hold has not been lifted, especially given the strength of the data package submitted to the FDA. It’s important to emphasize that the ongoing ENTR-601-44 development program continues to progress, with ENTR-601-44-101 clinical data expected in the second half of 2024. We will re-engage the FDA to discuss next steps in due course,” concluded Mr. Doshi.

About ENTR-601-44
ENTR-601-44, a proprietary Endosomal Escape Vehicle (EEV™)-conjugated phosphorodiamidate morpholino oligomer (PMO), is the lead product candidate within Entrada’s Duchenne muscular dystrophy franchise from its 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 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, is being evaluated for its potential to restore the mRNA reading frame and allow for the translation of dystrophin protein that is slightly shortened but still functional.

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, 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, ENTR-601-45 and ENTR-601-50 for the potential treatment of people living with Duchenne who are exon 44, 45 and 50 skipping amenable, respectively, as well as our partnered candidate ENTR-701 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 news release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this news 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 ENTR-601-44-101 Phase 1 clinical trial in the United Kingdom, expectations regarding the announcement of data from its ENTR-601-44-101 clinical trial in the second half of 2024, express or implied statements regarding the clinical hold on the IND for ENTR-601-44, Entrada's ability to address the FDA's concerns regarding ENTR-601-44, Entrada's ability to initiate and recruit for potential global clinical trials for ENTR-601-44 in patients with Duchenne muscular dystrophy (DMD) who are exon 44 skipping amenable, expectations regarding the safety and 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 ENTR-701 for the treatment of myotonic dystrophy type 1 (DM1), 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 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 and clinical trials; the timing of and Entrada's ability to submit and obtain regulatory clearance for INDs 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 news release represent Entrada's views as of the date of this news 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 news release.

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