
**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 7, 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.)

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 x

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. o

Item 2.02 Results of Operations and Financial Condition

On November 7, 2023, Entrada Therapeutics, Inc. announced its financial results for the quarter ended September 30, 2023 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 Form 8-K shall be deemed to be furnished and not filed:

99.1 [Press Release issued by Entrada Therapeutics, Inc. on November 7, 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 7, 2023

/s/ Dipal Doshi

Dipal Doshi

President and Chief Executive Officer

Entrada Therapeutics Reports Third Quarter 2023 Financial Results

- *Initiated a Phase 1 clinical trial of ENTR-601-44 for the potential treatment of Duchenne muscular dystrophy, marking Entrada's transition to a clinical-stage company –*
- *Expanded the Company's Duchenne franchise with the selection of its third clinical candidate, ENTR-601-50, for the potential treatment of people living with Duchenne who are exon 50 skipping amenable –*
- *Cash runway expected through 2025 with \$354 million in cash, cash equivalents and marketable securities as of September 30, 2023 –*

BOSTON, Nov. 07, 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 reported financial results for the third quarter ending September 30, 2023, and highlighted recent business updates.

"The third quarter marked an important milestone for Entrada, as we transitioned into a clinical-stage company, with the initiation of the Phase 1 clinical trial in healthy volunteers for our lead Duchenne product candidate, ENTR-601-44. Duchenne muscular dystrophy is a relentlessly progressive neurodegenerative disease, and we are committed to bringing forward potential new therapeutic options for people living with Duchenne who have mutations that are amenable to particular exon skipping therapies," said Dipal Doshi, President and Chief Executive Officer of Entrada Therapeutics. "We are well-positioned to embark upon our next phase of growth, as we further advance our Duchenne franchise and progress indications beyond neuromuscular diseases."

Recent Corporate Highlights

- In September 2023, Entrada dosed the first participant in its Phase 1 clinical trial evaluating ENTR-601-44 for the potential treatment of individuals with Duchenne muscular dystrophy (DMD) who are exon 44 skipping amenable. The primary objective of Entrada's Phase 1 clinical trial, which is being conducted in the United Kingdom, is to evaluate the safety and tolerability of a single dose of ENTR-601-44 in healthy male volunteers, with a target enrollment of approximately 40 participants. The trial will also evaluate pharmacokinetics and target engagement, as measured by exon skipping in skeletal muscle. Entrada expects to report data from the Phase 1 clinical trial in the second half of 2024.

The Company will provide an update on the clinical hold on its Investigational New Drug (IND) application for ENTR-601-44 with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2023.

- Entrada announced the selection of a third clinical candidate within its Duchenne franchise, ENTR-601-50, for the potential treatment of people living with Duchenne who are exon 50 skipping amenable. The selection of ENTR-601-50 is based on *in vivo* preclinical data demonstrating robust exon 50 skipping and dystrophin production across cardiac and skeletal muscle groups. Entrada expects to present these preclinical data in the first half of 2024 and plans to submit a Clinical Trial Application (CTA)/IND submission to initiate clinical development for ENTR-601-50 in 2025.
- In October 2023, the Company achieved a milestone pursuant to the Vertex Agreement related to preclinical IND-enabling GLP toxicology studies of ENTR-701 that triggered a \$17.5 million milestone payment, which the Company expects to receive in the fourth quarter of 2023.
- In July 2023, Entrada entered into a license agreement to advance the development of ENTR-501 with Pierrepont Therapeutics, Inc., a mitochondrial disease-focused company. ENTR-501 is an intracellular thymidine phosphorylase enzyme

replacement therapy in development for the treatment of mitochondrial neurogastrointestinal encephalomyopathy (MNGIE). MNGIE is a slowly progressive and fatal, ultra rare disease for which there are no treatment options available.

Third Quarter 2023 Financial Results

Cash Position: Cash, cash equivalents and marketable securities were \$353.6 million as of September 30, 2023, compared to \$188.7 million as of December 31, 2022. Entrada anticipates that its cash, cash equivalents and marketable securities as of September 30, 2023, together with Vertex collaboration ongoing research support and the anticipated achievement of certain milestones, will be sufficient to fund the Company's operating expenses and capital expenditure requirements through 2025.

Collaboration Revenue: Collaboration revenue was \$43.7 million for the third quarter of 2023. There was no collaboration revenue in the third quarter of 2022.

Research & Development (R&D) Expenses: R&D expenses were \$22.2 million for the third quarter of 2023, compared to \$19.0 million for the same period in 2022. This increase was primarily due to the initiation of the ENTR-601-44 Phase 1 clinical trial, additional investment in IND-enabling 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 \$7.5 million for the third quarter of 2023, compared to \$7.0 million for the same period in 2022. This increase was primarily due to higher personnel costs, including non-cash, stock-based compensation, legal costs and other costs to support its ongoing clinical trial and continued research and development activities.

Net Income (Loss): Net income was \$35.5 million for the third quarter of 2023, compared to a net loss of \$(25.1) million for the same period in 2022.

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 the potential treatment of 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

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 a healthy volunteer trial for ENTR-601-44 in the United Kingdom, expectations regarding the timing of data from its Phase 1 trial for ENTR-601-44 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 its IND for ENTR-601-44, expectations regarding the timing and content of any update expected in the fourth quarter of 2023 concerning the clinical hold on the IND for ENTR-601-44, expectations regarding the therapeutic benefits of

ENTR-601-44, expectations regarding the timing of preclinical data results and planned CTA/IND submission for ENTR-601-50, the continued development and advancement of ENTR-601-44, ENTR-601-45 and ENTR-601-50 for the treatment of DMD, ENTR-501 for the treatment of MNGIE, and ENTR-701 for the treatment of DM1, including the IND-enabling studies, expectations regarding the expected timing, progress and success of our collaboration with Vertex, including 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, statements regarding any future payments Entrada may receive under the Vertex Agreement, 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 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 September 30, | | Nine Months Ended September 30, | |
|---|----------------------------------|------------|---------------------------------|------------|
| | 2023 | 2022 | 2023 | 2022 |
| Collaboration revenue | 43,735 | — | 87,165 | — |
| Operating expenses: | | | | |
| Research and development | 22,191 | 18,958 | 71,593 | 50,924 |
| General and administrative | 7,532 | 6,978 | 23,639 | 20,745 |
| Total operating expenses | 29,723 | 25,936 | 95,232 | 71,669 |
| Income (loss) from operations | 14,012 | (25,936) | (8,067) | (71,669) |
| Other income: | | | | |
| Interest and other income | 4,051 | 799 | 10,926 | 1,682 |
| Total other income | 4,051 | 799 | 10,926 | 1,682 |
| Income (loss) before benefit from income taxes | 18,063 | (25,137) | 2,859 | (69,987) |
| Benefit from income taxes | 17,398 | — | — | — |
| Net income (loss) | 35,461 | (25,137) | 2,859 | (69,987) |
| Net income (loss) per share, basic | \$ 1.07 | \$ (0.80) | \$ 0.09 | \$ (2.24) |
| Net income (loss) per share, diluted | \$ 1.02 | \$ (0.80) | \$ 0.08 | \$ (2.24) |
| Weighted-average common shares outstanding, basic | 33,281,287 | 31,298,052 | 32,942,958 | 31,273,612 |
| Weighted-average common shares outstanding, diluted | 34,775,451 | 31,298,052 | 34,289,411 | 31,273,612 |

ENTRADA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheet Data (Unaudited)

(In thousands)

| | September 30, 2023 | December 31, 2022 |
|--|-----------------------|----------------------|
| Cash, cash equivalents and marketable securities | \$ 353,578 | \$ 188,712 |
| Total assets | 485,033 | 252,056 |
| Total liabilities | 238,370 | 39,502 |
| Total stockholders' equity | 246,663 | 212,554 |

Investor and Media Contact

Karla MacDonald
Chief Corporate Affairs Officer
kmacdonald@entrdatx.com