

**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): October 21, 2024

MIRA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Florida
(State or Other Jurisdiction
of Incorporation)

001-41765
(Commission
File Number)

85-3354547
(IRS Employer
Identification No.)

1200 Brickell Avenue, Suite 1950 #1183
Miami, Florida 33131
(Address of Principal Executive Offices)

Registrant's telephone number, including area code: (737) 289-0835

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 | Name of each exchange on which registered |
|--|----------------|---|
| Common Stock, \$0.0001 par value per share | MIRA | The Nasdaq Capital 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

MIRA Pharmaceuticals Reports Ketamir-2 Outperforms Current FDA-Approved Neuropathic Pain Treatments in Preclinical Study

MIRA Pharmaceuticals, Inc. (NASDAQ: MIRA) announces that in a recent study, its oral ketamine analog, Ketamir-2, demonstrated significantly greater efficacy than FDA-approved treatments Gabapentin (Neurontin) and Pregabalin (Lyrica) in recent preclinical models of neuropathic pain.

The Company is actively conducting additional studies focused on chemotherapy-induced and diabetic neuropathy. These studies are part of the broader development program, which also includes plans to initiate PTSD trials. Notably, MIRA Pharmaceuticals is exploring government funding opportunities to support the PTSD program.

The Company remains on track to submit an Investigational New Drug (IND) application by the end of 2024, with Phase I clinical trials expected to begin in Q1 2025. Phase II trials are projected to start by late 2025.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such forward-looking statements are characterized by future or conditional verbs such as "may," "will," "expect," "intend," "plans," "anticipate," "believe," "estimate," "continue" and similar words. Such statements are only predictions and actual events or results may differ materially from those anticipated in these forward-looking statements. You should not place undue reliance on any forward-looking statements. In this report, such forward-looking statements relate to the anticipated benefits of the Company's preclinical testing results for, and the time for regulatory filings related to, Ketamir-2 or Nor-Ketamir-2. Readers are cautioned that actual future results related to Ketamir-2 or Nor-Ketamir-2 may deviate materially and adversely from the forward-looking statements regarding Ketamir-2 and Nor-Ketamir-2 contained

herein. The Company does not assume any obligation to update forward-looking statements as circumstances change, except as required by securities laws. These and other risks concerning the Company's programs and operations are described in additional detail in Annual Report on Form 10-K for the year ended December 31, 2023, and other SEC filings, which are on file with the SEC at www.sec.gov and the Company's website at <https://www.mirapharmaceuticals.com/investors/sec-filings>. The Company explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

SIGNATURES

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.

MIRA PHARMACUTICALS, INC.

Dated: October 21, 2024

By: /s/ Erez Aminov
Name: Erez Aminov
Title: Chief Executive Officer
