

**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): July 19, 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 (Address of Principal Executive Offices)		33131 (Zip Code)

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(s)	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 Unveils Additional Preclinical Success

MIRA Pharmaceuticals, Inc. (the "Company") recently received the results of new preclinical testing data for its novel oral ketamine analog, Ketamir-2. Ketamir-2 is under investigation for its potential in treating neurological and neuropsychiatric disorders, including depression, treatment-resistant depression (TRD), and post-traumatic stress disorder (PTSD).

The Company plan to use this data as it works towards its goal of submitting an Investigational New Drug application to the U.S. Food and Drug Administration by the end of this year which, if granted, would allow for human testing of Ketamir-2.

The data highlights Ketamir-2's potential for superior brain penetration and reduced drug resistance compared to traditional ketamine. Ketamir-2 demonstrated *in vitro* studies that it is not a substrate for interaction with P-glycoprotein (P-gp), a membrane protein that typically pumps many drugs out of cells, including cells located in the brain. This characteristic might allow Ketamir-2 to have a better oral absorption and to penetrate the blood-brain barrier more effectively than traditional ketamine, which is a substrate of P-gp.

The Company previously announced that Ketamir-2's oral bioavailability is predicted to be around 80%, significantly higher than traditional ketamine's less than 30%. Additionally, preclinical studies have shown that while oral Ketamir-2 has been shown to be safe at high doses and is effective in several anti-depressant and anxiolytic models, and it does not appear to induce hyper-locomotor activity, a common side effect of traditional ketamine. Moreover, Ketamir-2 has shown no interaction with the mu-opioid receptor, unlike traditional ketamine. This could potentially mean a reduced risk of opioid-related side effects and dependency.

Building on these promising preclinical results, the Company has additional ongoing preclinical studies to demonstrate Ketamir-2's potential efficacy in treating

chemotherapy-induced depression and cancer-related neuropathic pain. Due to its novel chemical profile, the Company is exploring options for orphan drug indications such as multiple sclerosis-induced depression and Huntington's disease-induced depression. Models are being developed to validate these designations and ongoing studies have been designed to help support these efforts.

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. Readers are cautioned that actual future results related to Ketamir-2 may deviate materially and adversely from the forward-looking statements regarding 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.

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 PHARMACEUTICALS, INC.

Date: July 19, 2024

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