

**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 24, 2024

MIRA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

<u>Florida</u> (State or Other Jurisdiction of Incorporation)	<u>001-41765</u> (Commission File Number)	<u>85-3354547</u> (IRS Employer Identification No.)
<u>1200 Brickell Avenue, Suite 1950 #1183, Miami, Florida</u> (Address of Principal Executive Offices)		<u>33131</u> (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

Additional Positive Discovery of Ketamir-2's Selective NMDA Binding Mechanism of Action

MIRA Pharmaceuticals, Inc. (the "Company") is disclosing new insights garnered from additional, recently received preclinical study data regarding the mechanism of action and toxicology data for its novel oral ketamine analog, Ketamir-2. Ketamir-2 is under preclinical investigation for its potential in treating neurological and neuropsychiatric disorders, including depression, treatment-resistant depression (TRD), and post-traumatic stress disorder (PTSD).

The latest preclinical data reveals that Ketamir-2 is a selective inhibitor of the NMDA receptor of glutamate, the primary excitatory neurotransmitter in the human brain, specifically interacting at the PCP-binding site of the NMDA complex. Ketamir-2 has a 30-50-fold lower affinity to the PCP site compared with ketamine. The lower affinity is important because at high affinity, compounds may affect neurobehavioral functions, potentially leading to side effects such as dissociation and hallucinations. Unlike traditional ketamine, which also affects several other sites on the NMDA receptor and interacts with opioid receptors, dopamine and serotonin transporters, and various acetylcholine receptors, Ketamir-2 exhibits unique selectivity and does not interact with these additional receptor sites. This selectivity is notable as it may contribute to a distinct pharmacological profile for Ketamir-2, potentially reducing the risk of side effects associated with these other interactions.

The potential benefits of Ketamir-2's selective binding also include:

1. **Reduced Side Effects:** By targeting only the NMDA receptor at the PCP-binding site, Ketamir-2 appears to avoid the broader spectrum of ketamine interactions with other receptors and transporters. This specificity may help minimize unwanted side effects, such as dissociation, hallucinations, and addictive potential, often observed with ketamine use.

2. **Improved Safety Profile:** The selective inhibition allows for a cleaner pharmacological profile, potentially leading to better tolerability and fewer adverse reactions in patients. These advantages could enhance patient compliance and overall treatment outcomes.

3. **Enhanced Therapeutic Effectiveness:** With a selective mechanism of action, Ketamir-2 could potentially deliver more consistent and predictable therapeutic effects, which may be particularly beneficial in treating conditions like depression, TRD and PTSD.

Complementing its novel mechanism, recently conducted toxicology studies in rats and dogs have shown no toxicity at very high doses of Ketamir-2. These findings underscore Ketamir-2's excellent safety margin, further supported by its pronounced antidepressant and anxiolytic activities observed at oral doses five to tenfold lower than those tested in the toxicology studies. The substantial therapeutic window of Ketamir-2 offers promising potential for safe and effective use in human therapies.

The new preclinical study results disclosed above are the latest in a string of positive research developments which are progressing the Company's goal of submitting an Investigational New Drug Application to the U.S. Food and Drug Administration for Ketamir-2 later this year.

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 24, 2024

By: */s/ Erez Aminov*

Erez Aminov
Chief Executive Officer
