

**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 12, 2024 (July 8, 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 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On July 8, 2024, MIRA Pharmaceuticals, Inc. (the "Company") received a written notice (the "Notice") from the Listing Qualifications Staff of the Nasdaq Stock Market ("Nasdaq") indicating that, because the closing bid price for the Company's common stock has fallen below \$1.00 per share for 30 consecutive business days (May 22, 2024 through July 5, 2024), the Company no longer complies with the minimum bid price requirement for continued listing on the Nasdaq Capital Market under Rule 5550(a) (2) of the Nasdaq Listing Rules (the "Minimum Bid Requirement").

The Notice has no immediate effect on the listing of the Company's common stock on the Nasdaq Capital Market. Pursuant to Nasdaq Marketplace Rule 5810(c)(3) (A), the Company has been provided with a compliance period of 180 calendar days, or until January 6, 2025 (the next business day after the 180th calendar day from the date of the Notice), to regain compliance with the Minimum Bid Requirement. To regain compliance, the closing bid price of the Company's common stock must meet or exceed \$1.00 per share for a minimum of 10 consecutive business days prior to January 6, 2025.

Steps to Regain Compliance

The Company is proactively progressing its business towards the goal of achieving several significant upcoming milestones that the Company believes will support the Company's efforts to achieve both near and long-term shareholder value growth and regain compliance with the Minimum Bid Requirement:

- **IND Submission for Ketamir-2:** The Company remains on track to submit an Investigational New Drug application (IND) to the U.S. Food and Drug Administration (FDA) for its novel ketamine-analog compound, Ketamir-2, by the end of this year.

- **Preparation for Human Clinical Trials:** The Company is preparing to initiate human clinical trials of Ketamir-2 in the first quarter of next year (assuming the FDA grants the Company's Ketamir-2 IND).
- **Consistent Positive Preclinical Results:** The Company's pre-clinical research continues to yield consistent positive results, demonstrating the potential of the Company's compounds (see Item 8.01 below for a description of new positive preclinical study results for the Company's MIRA-55 compound).
- **Exploring Strategic Partnerships:** The Company is actively exploring potential licensing, development and other business collaborations to de-risk its clinical and regulatory pathway and enhance the Company's financial stability.
- **Enhanced Investor Relations Efforts:** The Company is improving its investor relations efforts to increase visibility and attract new investors.

If the Company does not regain compliance by January 6, 2025, the Company may be eligible for an additional grace period. To qualify, the Company would be required to meet the continued listing requirements for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the Minimum Bid Requirement, and provide written notice of its intention to cure the Minimum Bid Requirement deficiency during the second compliance period. If the Company meets these requirements, the Nasdaq staff would be expected to grant an additional 180 calendar days for the Company to regain compliance with the Minimum Bid Requirement. If the Nasdaq staff determines that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible for such additional compliance period, Nasdaq will provide notice that the Company's common stock will be subject to delisting. The Company would have the right to appeal the determination to delist its common stock, and the common stock would remain listed on the Nasdaq Capital Market until the completion of the appeal process. There can be no assurance that the Company will regain compliance with the Minimum Bid Requirement during the 180-day compliance period, secure a second period of 180 days to regain compliance or maintain compliance with the other Nasdaq listing requirements.

Item 8.01 Other Events

Positive Preclinical Findings for MIRA-55

The Company recently achieved additional positive preclinical study findings related to its novel oral pharmaceutical marijuana analog, MIRA-55, which is being studied in anxiety and cognitive decline, often associated with early-stage dementia

As previously disclosed by the Company in a Form 8-K filing on March 7, 2024, in late 2023, the Company, based on discussions with its contract manufacturers, began to suspect that the pharmaceutical marijuana analog compound it believed was being used in its initial preclinical studies (called MIRA1a) was in fact a new molecule with a distinct chemical structure, which the Company named "MIRA-55". This discovery led to the filing by the Company of a global provisional patent application for MIRA-55 in March 2024. At that time, the Company indicated its belief that MIRA-55 displayed enhanced potency and potential for efficacy over MIRA1a, but that additional testing was required to confirm the Company's preliminary beliefs.

The Company has conducted such additional preclinical testing on MIRA-55 utilizing in vitro testing and a mouse model. The results demonstrate that MIRA-55 offers significant potential advantages over THC, the main psychoactive component of marijuana:

- **Enhanced Efficacy:** MIRA-55 shows significantly improved efficacy over THC at both the CB1 and CB2 cannabinoid receptors, with stronger and more sustained activity.
- **Consistent Anxiolytic Effects:** MIRA-55 consistently reduces anxiety-like behaviors, outperforming THC in the Open Field and Elevated Plus Maze tests.
- **Stability and Balance:** Unlike THC, MIRA-55 maintains efficacy across a broader range of doses without losing effectiveness.
- **Reduced Side Effects:** MIRA-55 demonstrated a promising toxicological profile, indicating a potential safer profile for therapeutic use.

The Company believes these findings represent a significant advancement in developing treatments for neurological and neuropsychiatric disorders, positioning MIRA-55 as a promising candidate for further clinical development.

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: (i) the Company's efforts to maintain ongoing compliance with the Minimum Bid Requirement and (ii) the Company's testing and potential benefits of MIRA-55. There can be no assurance that the Company will be able to achieve or maintain such compliance, and the inability of the Company to maintain such compliance could lead to the delisting of the Company from Nasdaq. Moreover, actual future results related to MIRA-55 may deviate materially and adversely from the forward-looking statements regarding MIRA-55 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 12, 2024

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