

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

June 15, 2023

Erez Aminov Chief Executive Officer MIRA Pharmaceuticals, Inc. 900 West Platt Street, Suite 200 Tampa, FL 33606-2173

Re: MIRA Pharmaceuticals, Inc.
Amendment No. 2 to
Draft Registration Statement on Form S-1
Submitted June 8, 2023
CIK No. 0001904286

Dear Erez Aminov:

We have reviewed your amended draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Amendment No. 2 to Draft Registration Statement on Form S-1

<u>Prospectus Summary</u>
<u>Our Product Candidate in Development</u>
<u>Our Clinical Development Program, page 6</u>

1. We note your response to prior comment 11 and revised disclosure on pages 6 and 53. Please provide your basis for your belief that an "overlapping (hybrid) Phase I and II can be designed" for your product candidate or otherwise advise. We note your disclosure that you have not had any discussions with the FDA regarding a hybrid trial design and you disclose elsewhere that "[a]fter the Phase I trial is complete, a Phase II trial will be considered."

Erez Aminov MIRA Pharmaceuticals, Inc. June 15, 2023 Page 2

#### **Risk Factors**

Certain of our directors and officers may have actual or potential conflicts of interest because of their positions with MyMD, page 14

2. We note your response to prior comment 13, including that Dr. Adam Kaplin, your President and Chief Scientific Officer, will continue to serve as the Chief Scientific Officer of MyMD. In light of Dr. Kaplin's other business commitments, please disclose how much time Dr. Kaplin devotes to your operations.

#### **Business**

## Mechanism of Action of MIRA1a, page 47

- 3. We note your response to prior comment 5 and reissue in part. We note you continue to describe MIRA1a as "more efficacious" and "more potent anti-inflammatory, anti-seizure, anticancer properties." In addition, we note your disclosure that "the expected safety and toxicity profile of MIRA1a should provide it with an edge over existing medicines." Please revise these disclosures and similar statements that imply that your product candidate is safe and effective or likely to be approved. You may present objective data resulting from your preclinical and clinical testing without concluding efficacy.
- 4. We note your graphic at the top of page 48 appears to depict "% Efficacy" on the y-axis. Please revise your disclosure to clarify what this means or otherwise advise.
- 5. We note your statement that "[b]ased on preliminary results of [y]our GPCR biosensor assays, the CB2 receptor agonistic effects of MIRA1a are 8-fold more potent than THC and 30-fold more potent than CBD." Please update your disclosure to clarify how your assays measured the CB2 receptor agonistic effects or otherwise advise.
- 6. We note your updated disclosure on pages 50-52, including your description of the "Thermal Sensitivity Model of Pain," "Trace Fear Conditioning Model of Cognition" and "Psychomotor Vigilance Test" performed. For each study, please revise your disclosure to describe the material details of each study, including, for example, who performed the study and the number of subjects studied.

### Our Market Advantage, page 54

7. We note your response to prior comment 18 and reissue in part. We note your disclosure states that "MIRA1a is the first cannabinoid that has demonstrated the ability to rapidly and significantly improve cognitive performance with acute use." Please provide us your basis for claim that MIRA1a is the "first." In addition, please include balancing disclosure here when you refer to the figures on page 4 and 51 to clarify that the study preformed was a non-human study that was not powered for statistical significance.

Erez Aminov MIRA Pharmaceuticals, Inc. June 15, 2023 Page 3

## Amended and Restated Limited License Agreement with MyMD Pharmaceuticals, page 76

8. We note your response to prior comment 18 and re-issue in part. Please disclose the termination provisions of the license agreement with MyMD Pharmaceuticals or otherwise advise.

#### General

9. We note your response to comment 28 and re-issue. At first use, please define abbreviations throughout your amended draft registration statement. For example only, we note "THC" and "CBD" on page 1 and "cAMP" on page 48 do not appear to be defined.

You may contact Sasha Parikh at 202-551-3627 or Kevin Vaughn at 202-551-3494 if you have questions regarding comments on the financial statements and related matters. Please contact Jimmy McNamara at 202-551-7349 or Jason Drory at 202-551-8342 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Curt Creely