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

DIVISION OF
CORPORATION FINANCE

May 29, 2023

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

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

Dear Erez Aminov:

We have reviewed your 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.

Draft Registration Statement on Form S-1

Cover Page

1. Please disclose, if accurate, that the closing of this offering is contingent upon a Nasdaq Listing, or otherwise advise. Please ensure the disclosure is consistent with your underwriting agreement.

2. We note that you have checked the Rule 415 box on your outside cover page, yet disclosures elsewhere indicate that this is a firm commitment, underwritten offering. Please advise or revise.

Prospectus Summary, page 1

3. The disclosure in the summary should be a balanced presentation of your business. Please balance your prospectus summary by including disclosure regarding your limited operating history and your history of net losses.

4. We note your disclosure in reference to “studies” suggesting that MIRA1a may be capable of unmasking positive therapeutic effects not previously seen with THC. Please specify that these are preclinical studies, or otherwise advise.

5. We note that disclosures here, and elsewhere in the prospectus, include statements or implications that your product candidates are safe and/or effective. Please revise these statements, as safety and efficacy determinations are in the exclusive purview of the FDA or other regulators. For example only, the following statements improperly state or imply that your product candidates are safe or effective:
   - On page 2, your product candidate is "likely much more efficacious as a potential therapeutic for inflammatory, autoimmune, and neurodegenerative conditions."
   - On page 2, that you found MIRA1a has “potent” anti-anxiety effects.
   - On page 7, your belief that MIRA1a’s expected “safety and toxicity profile” should provide an edge over existing medicines categories.
   - On page 7, that you will be "using a safe, effective and FDA-approved treatment option."

Pre-Clinical Developments and Studies, page 2

6. We note your disclosure of pre-clinical trials relating to your product candidate throughout this section. Please revise to clarify whether each trial was powered for statistical significance. In addition, if a trial was powered for statistical significance please provide p-values for the results of each trial.

7. At the top of page 3 you have a table of pre-clinical tests. Please revise your disclosure to clarify what "Group 1" and "Group 2" actually mean. In addition, we note that you include descriptions, including the results, of only some of your pre-clinical studies completed to date. If a pre-clinical study is material, please expand your disclosure in your Business section to provide a more fulsome discussion of the study design as well as the objective results.

Market Opportunity, page 6

8. We note your statistics on page 6 reference the global market for “medicines” as well as the United States market. We also note your disclosure on page 1 that your treatment is geared towards a particular demographic, namely, adult patients with anxiety and cognitive decline typically associated with early-stage dementia, as well as those with chronic pain. Please revise your disclosure or otherwise provide additional context on why the global and domestic statistics for all medicines is relevant given your current product candidate's apparent more narrow potential indications.

9. We note your reference on page 6 to an IQVIA Report that specifies statistics about the "global" CNS market, and that anxiety is worth between approximately $20 billion and $25 billion in annual sales. We also note your disclosure on page 7 that you currently have no plans to develop the MIRA1a compound for approval and commercialization outside of the United States, and that your license is for research and development activities as well as for commercial uses in the United States. Please tell us whether the global statistic is an accurate depiction of the market opportunity for your Company, particularly in light of the geographic scope of your current license, or otherwise advise.

10. We note your disclosure that another "key market will be the traditional pain market, which the IQVIA Report estimates will be worth $42 billion in 2027 and grow between three and six percent during the forecast period." Please specify whether the estimates are for a domestic or global market, or otherwise advise.

Our Clinical Development Program, page 6

11. We note your disclosure on page 6, and elsewhere, that an overlapping (hybrid) Phase I and Phase II can be designed and allowed to proceed by the FDA, allowing you to "accelerate" the development of MIRA1a. Please provide balancing disclosure here, and elsewhere, that there is no guarantee the FDA will provide such approval and disclose whether you or your representatives have had any conversations with the FDA regarding an "overlapping" trial design. Finally, please revise this statement and any similar disclosure to remove any implication that you will be successful in developing your product candidate in a rapid or accelerated manner as such statements are speculative.

12. We note your statement on page 6 that a Phase II trial for your first IND application "is planned to commence by the end of the fourth quarter of 2024" and a "Phase II trial will begin in the third quarter of 2026" for your second IND application. Given the lengthy timeline and uncertainty with regard to clinical development, please remove these statements as it appears to be premature and speculative given your stage of development.

Risk Factors, page 14

13. In light of your relationship with MyMD, please consider including a risk factor discussing risk resulting from any conflicts of interest or the appearance of conflicts of interest. In this regard, we note that certain of your executive officers are also senior management within MyMD. We also note your disclosures on page F-9 that "[t]he Company and MYMD have similar members of the Board, as well as officers from the respective companies."

Use of Proceeds, page 39

14. We note your disclosure that you cannot specify with certainty the particular uses of the net proceeds that you will receive from this offering. Please revise your use of proceeds disclosure to provide more granularity regarding the first bullet point, namely how far in

the development process you estimate that the proceeds will enable you to reach, including specific phases of clinical trials, if applicable. In this regard, we note your disclosure on page 22 that you have significant and increasing liquidity needs and may require additional funding.

Capitalization, page 41

15. Please include debt in the capitalization table as a component to determining your total capitalization.

Management's Discussion and Analysis and Results of Operations
Results of Operations, page 44

16. For each of the periods presented, please quantify each factor identified for the increase/decrease in each of your expense line items. As part of your response, please address the following:
    - Please revise your results of operations to provide a quantified breakdown of your research and development expense by nature or type of expense, and discuss each component, as applicable.
    - Disclose how much of your $1.3 million in stock compensation expense was applicable to general and administrative expense and research and development expense.

Business
Market Opportunity, page 53

17. We note your graphic disclosure depicting the total addressable population on page 54. Please identify the referenced “published literature,” and provide a more detailed discussion of the underlying assumptions used in your calculations.

Our Market Advantage, page 54

18. We note your disclosures that "MIRA1a is the first cannabinoid that has demonstrated the ability to improve cognitive performance in pre-clinical studies." Please provide your basis for this statement. In addition, we note your disclosures on page 17 that conclusions based on your pre-clinical data may prove inaccurate, and are not necessarily predictive indicators of future results. Please provide balancing disclosure here, and elsewhere, regarding any conclusions and predictions you make based on preclinical studies.

19. We note your disclosure regarding the DEA’s determination and your belief that MIRA1a has a distinct competitive advantage by being poised to move through the regulatory approval process at a “faster pace” than that of competing scheduled product candidates. Please remove this statement as the DEA’s determination may not lead to a faster development or regulatory process, and also does not increase the likelihood that the product candidate will receive approval by the FDA. We further note your disclosure that your Company is positioned to enjoy market exclusivity in the United States “upon

receiving regulatory approval." Please remove this statement as there is no guarantee that your product candidates will receive regulatory approval by the FDA or similar regulatory body.

Intellectual Property, page 56

20. We note your disclosure here that you own U.S. Patent 10,787,675 B2. Please disclose the expiration date of the patent.

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

21. We note your disclosure on page 7, and elsewhere, regarding the perpetual license you have with MyMD Pharmaceuticals, Inc. to use MyMD's Supera-CBD as a synthetic intermediate in the manufacture of MIRA1a for research and development activities as well as for commercial uses in the United States. We also note your disclosure on F-9 that you have entered into a non-exclusive, royalty-free license to use MYMD's Supera-CBD as a synthetic intermediate in the manufacture of MIRA1a for research and development activities relating to your planned pre-clinical and clinical studies. Please disclose, if accurate, that this is a non-exclusive license, or otherwise advise. In addition, please disclose the material terms of the agreement, including amounts paid to date, future potential payments, royalty provisions, and termination provisions or otherwise advise. We note the agreement appears to cover "commercial uses" in addition to research and development activities.

22. We note your disclosure that you have the "right to use MyMD's Supera-CBD as a synthetic intermediate in the manufacture of MIRA1a for research and development activities as well as for commercial uses in the United States." Please clarify whether there are other third parties or other "synthetic intermediates" for which you could use to manufacture your product candidate, MIRA1a. To the extent MyMD is your sole supplier for your "synthetic intermediate" in the manufacture of MIRA1a, please disclose the risk relating your reliance on a sole-supplier and please disclose whether you believe alternate sources of the "synthetic intermediate" are available, or otherwise advise.

Certain Relationships and Related Party Transactions
Line of Credit and Promissory Note with the Bay Shore Trust, page 76

23. Please tell us your accounting analysis with regards to the common stock purchase warrant issued to Bay Shore Trust citing supportive, authoritative accounting guidance, and revise to disclose your accounting for the warrant, providing quantification as applicable.

Note 5. Related party transactions, page F-7

24. Confirm, if true, that all related party transactions are separately quantified on the face of your statement of operations.

Notes to the Financial Statements
Note 1. Description of business and summary of significant accounting policies
Research and Development Expenses, page F-7

25. You disclose on page 44 that legal costs included in your general and administrative expense line item include patent costs. However, you also disclose on page F-7 that your research and development expenses include patent-related costs. Please address the following:
    - Revise to reconcile the apparent inconsistency between these disclosures.
    - Further, tell us how you considered the guidance of ASC 730-10-55-2(i), which outlines the type of patent costs that must be excluded from research and development expenses.

Note 8. Stockholders' Equity
Stock Based Compensation, page F-12

26. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features. Please discuss with the staff how to submit your response.

General

27. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

28. At first use, please define abbreviations throughout your draft registration statement. For example only, we note that "MTD/7D" and "DRF" on page 5, which do not appear to be defined.

29. Please ensure the writing is legible in the visual depictions throughout your draft registration statement. For example only, your visual at the top of page 2, contains legends and text on the y-axis that are not legible and with respect to the “Pain Reduction” Thermal Sensitivity visual on page 4, the writing above and below the yellow bar is not legible.

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