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

DIVISION OF
CORPORATION FINANCE

December 1, 2022

Jon Congleton
Chief Executive Officer
Mineralys Therapeutics, Inc.
150 N. Radnor Chester Road, Suite F200
Radnor, PA 19087

Re: Mineralys Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted November 4, 2022
CIK No. 0001933414

Dear Jon Congleton:

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 filed November 4, 2022

Cover Page

1. Please disclose whether your offering is contingent upon final approval of your NASDAQ listing on your cover page. Please ensure the disclosure is consistent with your underwriting agreements.

Prospectus Summary
Overview, page 2

2. We note your references to your Phase 2 clinical trial evaluating subjects with uHTN and rHTN where MLS-101 was well tolerated with "favorable safety data". Please revise the references to "favorable safety data", here and throughout the prospectus, as such phrase

implies a conclusion regarding safety of the product candidate, which determination is within the sole authority of the FDA and comparable foreign regulators.

3. You state that multiple large-scale studies have demonstrated that patients who fail to achieve their BP goal have a significantly elevated risk of developing heart disease, stroke, and kidney disease. Please revise your disclosure to cite the referenced studies, where appropriate.

Our Product Candidate, MLS-101, page 3

4. We note your statement that Mitsubishi Tanabe Pharmaceutical Company progressed MLS-101 through Phase 1 clinical development. Please add footnotes to your pipeline table to show which columns relate to work conducted by the company and which relate to the work of Mitsubishi Tanabe. In addition, please disclose where Mitsubishi Tanabe conducted the Phase 1 clinical trial and discuss, where appropriate, any interaction the company has had with the FDA regarding its ability to rely on such trial data in the event the trial was not conducted in the United States.

5. You state that you intend to use the observations from MLS-101's complete Phase 1 trial in healthy volunteers and Phase 2 in uHTN and rHTN to inform the development of MLS-101 in uHTN related to obesity and obstructive sleep apnea. You also state that you intend to develop MLS-101 for the treatment of chronic kidney disease. We note that your pipeline table shows completion of Phase 1 for both the use of MLS-101 in uHTN related to obesity and obstructive sleep apnea and chronic kidney disease. Please revise your disclosure to clearly state, if true, that you may rely on the Phase 1 data obtained by Mitsubishi Tanabe for these additional indications.

6. We note the use of p-values on page 4. At first use, please explain how "p-value" is used to measure statistical significance and the relevance of statistical significance to the FDA's evidentiary standards for drug approval.

Our Team and Investors, page 5

7. Please limit the disclosure of specific investors to those identified in the Principal Shareholder table on page 144. Additionally, indicate that prospective investors should not rely on the named investors' investment decision, that these investors may have different risk tolerances and the recent offering was conducted as a significant discount to the IPO price.

Summary of Risks Associated with Our Business, page 6

8. We note your summarized risk factor regarding your exclusive license with Mitsubishi Tanabe, which if terminated would cause you to lose the right to develop and commercialize MLS-101. Please also include the effects this would have on the business as you have done on page 24.

Implications of Being an Emerging Growth Company, page 7

9. Your disclosure here and on the cover page indicates that you have elected not to avail yourselves of the extended transition period for complying with new or revised accounting standards. Your risk factor disclosure on page 67, discussion of the JOBS Act on page 90, and Emerging Growth Company status on page F-8, however, indicates the opposite. Please revise to address this apparent inconsistency.

Risk Factors
We intend to conduct some of our clinical trials for MLS-101 outside of the United States..., page 22

10. We note the above listed risk factor. Please revise your disclosure to indicate the countries in which you intend to conduct clinical trials and discuss whether or not the equivalency standards that you reference in this risk factor will be implicated.

Use of Proceeds, page 75

11. We note your statement that you will require substantial additional capital in order to advance MLS-101 through clinical trials, regulatory approval and commercialization. In accordance with Item 504 of Regulation S-K, please revise your disclosure on page 75 to clarify where the company intends to obtain such additional capital, as you have done on page 14, or provide an appropriate cross-reference.

Intellectual Property, page 109

12. Please revise your disclosure regarding your patent portfolio to clarify the ownership status of each patent where referenced. In this regard it may be useful to provide tabular disclosure.

General

13. Please provide us with supplemental 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, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of those communications.

You may contact Gary Newberry at 202-551-3761 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Doris Stacey Gama at 202-551-3188 or Laura Crotty at 202-551-7614 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Matt Bush, Esq.