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

DIVISION OF
CORPORATION FINANCE

November 1, 2023

Peter Maag, Ph.D.
Chief Executive Officer
Kyverna Therapeutics, Inc.
5980 Horton St., STE 550
Emeryville, CA 94608

Re: Kyverna Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted October 5, 2023
CIK No. 0001994702

Dear Peter Maag:

We have reviewed your draft registration statement and have the following comments.

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 a comment applies 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 this letter and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1 submitted October 5, 2023

Prospectus Summary
Overview, page 1

1. We note your disclosure that you aim to bring transformational change to this field by applying your proprietary technology. We also note your disclosure on page 4 that the CAR T cells created with Hu19-CD828Z, the humanized CAR, used by the NCI in its clinical study is “the same CAR [you] use to create KYV-101.” Please revise to disclose what technology you have developed versus what technology you have in-licensed.

2. Please revise pages 1, 95 and 113 to describe the “several published case studies” supporting your conclusion that your “early insights and investments into the potential benefits of cell therapies in autoimmune diseases have been validated.” State whether the studies were conducted in relation to autoimmune diseases and disclose the number of patients in the case studies and whether statistically meaningful conclusions can be drawn

at this time. Revise your disclosure on pages 3 and 118 to remove the statement that recent publications using CD19 CAR T cells resulted in "robust and durable responses." You may disclose and discuss the data supporting your conclusions.

3. Please revise here and elsewhere as appropriate to describe your "patient-centered approach."

4. We note your disclosure on page 1 that KYV-101 was observed "to have improved tolerability in the clinic." Revise to disclose what KYV-101's tolerability was compared to and in what patient population. We also note your disclosure that KYV-101 was created using a CAR designed by the NIH to improve tolerability through the use of a fully human CD19 binding domain and optimized hinge and transmembrane domains. If this is the factor that improves tolerability, please disclose this upfront and revise to indicate any other factors that lead you to believe that KYV-101 may have improved tolerability.

5. We note your disclosure on page 1 that you believe lupus nephritis is an attractive lead indication in part because of "prior clinical validation of the potential of CD19 CAR T cells in this indication." Please revise to clarify the prior clinical validation that you are referring to and, in an appropriate location, include and discuss the objective data from previous clinical trials that support your conclusion.

KYV-201, an Allogeneic CD19 CAR T-cell Product Candidate, page 2

6. Please revise pages 2 and 132 to disclose the jurisdiction where you intend to file a CTA for KYV-201.

Our Solution - Cell Therapy for Autoimmune Disease Treatment, page 2

7. Please revise to remove your disclosure on pages 3 and 118 stating "the clinical and regulatory paths established in these indications highlight the breakthrough potential of cell therapies in autoimmune diseases" as it appears to be speculative.

Our Strategy, page 2

8. Please revise to remove your references to developing "best-in-class" product candidates appearing on page 2 and elsewhere in your Prospectus as such statements are speculative given your stage of development.

9. We note your reference to Gilead in the summary section. However, we note from your disclosure on page 137 that on November 30, 2022, after the completion of research activities under Program A and Program B, Gilead provided you with notice that Program A and Program B were terminated and that there are currently no other active programs under the Gilead Agreement. Although we note that your research-stage programs are focused on developing product candidates that you believe will be required to treat other autoimmune diseases, and that these programs include a suite of capabilities related to regulatory T cells, or T-regs, developed through your completed research collaboration with Gilead, these research programs do not appear to be material at this time. As such,

please remove your references to Gilead in the summary section or revise your disclosure to make clear how that completed collaboration and related programs are material at this time.

10. Please balance the disclosure in the fourth bullet point of this section to indicate, if true, that you do not expect to be able to use the results from any investigator initiated trials conducted with your product candidates in any regulatory submission for marketing approval.

Our Pipeline, page 3

11. Please make the following changes to your pipeline tables appearing on pages 3 and 120:
    - Add a Clinical Phase 3 column; and
    - Remove your “CAR T & Other Approaches” row as it appears immaterial given the minimal discussion of this program within your Prospectus. Alternatively, revise your Business section to provide additional detail about this program that supports why it is a material technology for purposes of inclusion in your pipeline tables and revise your pipeline tables to disclose the indication.

KYV-101, an Autologous CD19 CAR T-cell Product Candidate for Rheumatology and Neurology Indications, page 4

12. Please revise where you state on page 4 that there are “clinical results from individual patients treated with KYV-101” in MS to disclose the results of the clinical studies, the phase of clinical development, and whether the results are statistically significant.

13. We note your disclosure that Hu19-CD828Z "was found" to reduce the levels of cytokine release in a systematic comparison of CARs created with alternate domain structures, including the FMC63-CD28Z CAR used to create Yescarta®. Revise to clarify the data on which this finding was based, the statistical significance of that data and who made this finding. In this regard, we note your disclosure later on this page regarding twenty patients with B-cell lymphoma that had undergone four prior lines of therapy. If the finding you reference is based on this patient population, please include cautionary disclosure about the applicability of this finding in the context of the patient populations, prior treatments and indications you are pursuing.

KYV-101, Designed for Improved Efficacy and Safety, page 4

14. Please revise your headings on pages 4 and 121 stating KYV-101 is “designed for improved efficacy and safety” as they create an improper inference that your product candidate is safe, effective and superior to existing approved products.

Summary of KYV-101 Clinical Development, page 4

15. Please revise here to discuss the clinical development of KYV-101. Disclose the indications, phases of clinical development, regulatory jurisdictions where the trials are being conducted, trial design, number of patients, primary and secondary endpoints and when you started dosing patients.

Manufacturing Capabilities and Industrialization of Autologous CAR T-cell Therapies, page 5

16. We note your disclosure on pages 4 and 131 stating "five patients have consented to treatment and manufacturing of KYV-101 for these patients has initiated" appears to conflict with your disclosure on page 5 stating you "have successfully manufactured all needed clinical supply for clinical sites in both the United States and Germany." Please revise or otherwise advise. Revise to disclose the contract development and manufacturing organization that will generate KYV-101 for near-term clinical trials and disclose the "world-class organizations in cell therapy manufacturing" you partnered with for the Ingenui-T manufacturing process.

The Offering, page 9

17. Please revise page 9 and your Use of Proceeds Section to disclose how far through clinical development you expect to get using the proceeds from this offering for KYV-101 and KYV-201 in each indication.

Management's Discussion and Analysis of Financial Condition and Results of Operations, page 95
Results of Operations, page 103

18. Regarding the table of external costs by program on page 104, please revise to explain the nature of Other programs and research and development activities, which appears to be significant to your external research and development expense in each annual period.

Business
Overview, page 113

19. We note your disclosure that you believe your CAR T-cell therapies may present a significant advantage over current standard-of-care therapies by aiming to directly deplete B cells and potentially resetting disease-contributing B cells. In an appropriate location, please disclose your current understanding of the biological process that may lead to this potential for reset of the immune system and disclose whether the conclusions to be drawn from that understanding are based on statistically significant data at this time.

KYV-101 Clinical Development in Lupus Nephritis, page 126

20. Please revise to provide the material details and parameters of your current clinical trials for Lupus Nephritis, including primary and secondary endpoints, metrics utilized,

including the clinically meaningful improvements and objective clinical endpoints referred to on page 114.

Clinical Results of KYV-101 Treatment in MG, page 128

21. Please revise here to disclose the circumstance by which the patient was permitted to be treated with KYV-101.

Our Collaboration and License Agreements, page 134

22. For the "low double-digit percentage" for the sublicense royalty under the NIH Agreements, please revise to disclose the upper range of this percentage so that it is expressed at no greater than 10 percentage points. For the Kite Agreement, please revise to disclose aggregate payments made to date, the aggregate future milestone payments payable, and a range of no greater than 10 percentage points for the minimum annual royalty rates payable, under the Kite Agreement.

Gilead Collaboration, Option and License Agreement, page 136

23. You disclose that pursuant to the Gilead Agreement, you and Gilead will collaborate to develop potential cell-based therapy products. Given your disclosure that there are no current active programs under the Gilead Agreement, please provide an expected timeframe for these development activities or revise your disclosure as appropriate.

Intellectual Property, page 139

24. Please revise starting on page 139 to disclose, for each material patent family, the technologies to which the patents relate, whether the patents are owned or licensed, the type of patent protection, patent expiration dates, expected expiration dates for pending patent applications and jurisdictions.

Notes to Financial Statements
6. Significant Agreements
Kite License Agreement (Related Party), page F-17

25. You disclose that the current accrued license expense is based on when milestone payments under the Gilead Agreement will be due and a liability can be offset. Please tell us how you determined when the milestone payments will be due.

General

26. 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 Rule 163B of the Securities Act, whether or not you retained, or intend to retain, copies of those communications.

Please contact Jenn Do at 202-551-3743 or Vanessa Robertson at 202-551-3649 if you have questions regarding comments on the financial statements and related matters. Please contact Daniel Crawford at 202-551-7767 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Jeffrey T. Hartlin, Esq.