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

DIVISION OF
CORPORATION FINANCE

December 8, 2023

Mark S. Shearman, Ph.D.
Chief Executive Officer
APRINOIA Therapeutics Inc.
245 Main Street, 2nd Floor
Cambridge, MA 02142

Re: APRINOIA Therapeutics Inc.
Draft Registration Statement on Form F-1
Submitted November 13, 2023
CIK No. 0001998311

Dear Mark S. Shearman:

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 F-1 submitted November 13, 2023

Cover Page

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

Prospectus Summary
Overview, page 1

2. Your prospectus summary should include a balanced discussion of your company and your business, including any associated weaknesses and challenges you currently face and may face in the future. Please balance your discussion of your advantages and competitive strengths with an equally prominent discussion of any detriments. By way of example only, please revise throughout where you discuss potential uses for your product candidates to clarify that the outcomes of clinical trials are inherently uncertain

and that if your product candidates do not perform as anticipated in clinical trials, they may not secure marketing approval and your business could be adversely affected.

3. Please revise where you discuss the Orphan Drug Designation for APN-1607 to clarify, if true, that such a designation neither shortens the development time or regulatory review time of your diagnostic nor increases the likelihood that the FDA will approve it. Revise to state how you can "leverage" the Orphan Drug Designation to submit results from a single Phase 3 trial as a basis for regulatory approval.

4. We note your statement that you have initiated a Phase 2 clinical trial of APN-1607 in AD in the United States, Japan and Taiwan. Please revise to reflect your disclosure on page 96 that this trial is not recruiting and disclose when the most recent subject was enrolled.

5. We note your disclosure that you plan to file an IND with the FDA to launch a Phase 3 trial of APN-1607 in subjects suspected to have PSP and your disclosure on page 96 that you intend to enroll the first patient in this trial in the fourth quarter of 2023. Please revise your disclosure to clarify when you intend to file the IND for this clinical trial.

Our Pipeline, page 3

6. Please revise your pipeline table so there is only one progress arrow for your Alzheimer's indication depicting its overall current stage of clinical development. You may include a footnote disclosing the Phase 2 clinical trial.

7. Please revise your pipeline table to clearly disclose the licensing and collaboration agreements related to your product candidates.

Therapeutics Pipeline, page 4

8. We note your statement that APNmAb005 recognizes a three-dimensional conformation-dependent epitope that is only present in tau abnormal aggregates but not in normal tau protein, thus showing the potential to achieve a high level of specificity. Please revise here and on page 98 to clarify if this capability has been demonstrated in a clinical trial that was powered for statistical significance. Please also remove your statement here and on page 98 that APNmAb005 may offer a superior therapeutic strategy over other anti-tau antibody programs as this statement appears to be premature given your current stage of development.

9. Your pipeline table indicates that your Phase 1 trial of APNmAb005 is not recruiting. Please revise this section to disclose the current status of this trial.

10. We note your statements here and on page 100 that you plan to launch a POC study of APNmAb005 in the second half of 2024. To the extent that your Phase 1 trial remains ongoing and you have not submitted an IND for your POC trial, please remove your statements regarding when you plan to launch future clinical trials. You may state when you anticipate completing your Phase 1 clinical trial.

Risk Factors
Risks Related to Our Operations, page 26

11. We note that your disclosure elsewhere throughout the prospectus indicates that you have an exclusive license to develop and commercialize APN-1607, except for mainland China where you have granted Yitai an exclusive sublicense. Please revise this section of your prospectus to discuss risks related to conducting business in the People's Republic of China (PRC) including the possibility, if true, that the PRC government could interfere in, or exercise control over, Yitai's operations.

General Risk Factors
Our amended and restated articles of association to be in effect prior to the completion of this offering . . . ., page 56

12. We note your Federal Forum Provision states “the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.” Please revise to state that there is uncertainty as to whether a court would enforce such provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. In that regard, we note that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

Use of Proceeds, page 60

13. Please revise page 60 to state how far into the Phase 3 clinical trial of APN-1607 you expect to reach with the proceeds from this offering.

Capitalization, page 62

14. Please revise your capitalization table to separate the line-item "cash" with a double underline to clearly separate it from your capitalization.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies, Judgments and Estimates
Share-Based Compensation, page 80

15. 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. Please discuss with the staff how to submit your response.

Market, Industry and Other Data, page 82

16. We note your statement that you have not independently verified the accuracy or completeness of any third-party information. This statement may imply an inappropriate disclaimer of responsibility with respect to such information. Please either delete this statement or specifically state that you are liable for such information that appears in the prospectus.

Business
Our Next-Generation Diagnostics Pipeline, page 89

17. We note your statement that APN-1607 has generated imaging data that has demonstrated statistically significant correlation with disease severity in AD and PSP patients, as measured by clinically relevant scales. Please revise your discussion of APN-1607, where appropriate, to clearly describe the clinical trials in which these observations were made including the number of enrollees, the primary and secondary endpoints, adverse events and whether the trials met their endpoints.

Our Preclinical-Stage Diagnostic Pipeline, page 96

18. Please revise to identify the collaborator for your 18F-APN-1701+ tracer program. For each of your 18F-APN-1701+ and -Syn PET tracer programs, disclose whether the parties have executed collaboration agreements. To the extent they have, revise to disclose the material terms and file the agreements as exhibits to your registration statement.

Our Therapeutic Product Candidates, page 98

19. Please remove your disclosure on page 98 stating your toxicology studies demonstrated “APNmAb005 is safe according to the efficacious dosage used in rTg4510” as the FDA or similar foreign regulators have the sole discretion for making safety and efficacy determinations. Please similarly revise your statement referencing the "efficacy" of your lead degraders on pages 2 and 84.

License Agreements and Collaborations
License Agreement with National Institutes for Quantum Science and Technology, page 102

20. Please revise here to disclose the aggregate payments made to date, potential future milestone payments to be paid and royalty rate within a ten-point range or less pursuant to the license agreement with QST. Please also revise to disclose whether you renewed the QST License Agreement in October 2023 or advise.

Intellectual Property, page 104

21. Please revise to disclose the other jurisdictions where you have pending patents for each patent family.

Facilities, page 106

22. Please revise this section to disclose the locations of your offices and facilities outside of the United States and to disclose the approximate number of employees at each of your locations.

Description of Share Capital
Registration Rights, page 139

23. Please quantify the number of ordinary shares that will have registration rights following the offering.

Underwriting, page 147

24. We note your statement that if all of the shares are not sold at the initial offering price, the underwriters may change the offering price and the other selling terms. Please delete this statement and confirm in your response letter that the shares will be sold at a fixed price for the duration of the offering.

Exhibits

25. We note your disclosure on page 123 stating you "have entered into employment agreements with each of [y]our executive officers." Please file these agreements as exhibits or advise.

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 Eric Atallah at 202-551-3663 or Lynn Dicker at 202-551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Daniel Crawford at 202-551-7767 or Alan Campbell at 202-551-4224 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Will H. Cai, Esq.