



DIVISION OF
CORPORATION FINANCE

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

August 8, 2019

Christian Schade
Chief Executive Officer
Aprea Therapeutics, Inc.
535 Boylston Street
Boston, MA 02116

Re: Aprea Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted July 12, 2019
CIK No. 0001781983

Dear Mr. Schade:

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

Prospectus Summary

Aprea Therapeutics overview, page 1

1. Please delete your reference to "first-in-class" throughout your registration statement as it implies the product candidate will be approved by the FDA or foreign regulatory body.
2. We note your disclosure on page 1 that your Phase 3 clinical trial is supported by data from an ongoing "investigator initiated" clinical trial and your disclosure in your chart on page 2 that indicates two "investigator initiated" trials. Please identify the investigators in these trials here, and expand your disclosure to explain how an "investigator initiated clinical trial" differs from a trial sponsored by the company. Also, on page 4, you state that you are "supporting" investigator initiated clinical trials. Please describe the

material terms of your agreements with the investigators so that investors understand the nature of your support, and file the agreements as exhibits to your registration statement if required by Item 601 of Regulation S-K.

3. We note your disclosure on page 1 that you are seeking approval for APR-246 from the EMA as well as the FDA. Please revise your chart to indicate which trials are being conducted pursuant to an IND with the FDA and which are being conducted in connection with seeking approval from the EMA.
4. We note your disclosure on page 2 regarding results from preclinical studies of APR-246. As APR-246 is in clinical trials, please limit the prospectus summary discussion of your results to a description of the clinical trials. To the extent that you do discuss preclinical studies in your prospectus summary, please disclose a summary of the number and types of tests conducted as well as quantitative information regarding the range of results observed.

Implications of being an emerging growth company, page 6

5. Please 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.

Risk Factors

Risks related to the discovery, development and commercialization of our product candidates
If serious adverse or unacceptable side effects are identified, page 16

6. We note your disclosure on page 17 that "[m]ultiple patients . . . have experienced adverse events." Please clarify whether any of these adverse events are serious adverse events, and, if so, the number and percentage of patients that experienced such serious adverse events.

Risks related to our intellectual property

Our proprietary position for APR-246 depends upon patents that consist of method-of-use, page 35

7. We note your disclosure on page 35 that the chemical structure of APR-246 is in the public domain and that you do not own or license and will not in the future own or license any composition of matter patents claiming the compound of APR-246. Please revise your prospectus summary to state that APR-246 is in the public domain and provide a summary of the potential effect this could have on your business.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies..., page 69

8. You disclose that the JOBS Act provides for the option for emerging growth companies (EGCs) to delay adopting certain accounting guidance. Please revise this section, as well as your disclosure about being an EGC elsewhere in your document including page 7, to definitively confirm whether you have elected to avail yourself of this option. If you have elected to avail yourself of that delay, revise this risk factor to discuss the implications.

Risks related to our common stock and this offering

Our certificate of incorporation that will become effective, page 72

9. We note your disclosure here and on page 171 that your certificate of incorporation will contain an exclusive forum provision. Please disclose whether this provision applies to actions arising under the Securities Act or Exchange Act. If these provisions do not apply to actions arising under the Securities Act or the Exchange Act, please ensure that the exclusive forum provision in the certificate of incorporation and your disclosure regarding the provision in the prospectus state this clearly. If the provision does apply to actions arising under the federal securities laws, please disclose that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. In addition, file a copy of your certificate of incorporation with your next amendment or tell us when you plan to do so. Note that we may have further comment after review of this document and your revised disclosure.

Use of Proceeds, page 75

10. Please disclose the amount of the proceeds you intend to use for each of the specified purposes as well as how far in the specified clinical trials, the research related to APR-246 and the research related to your platform and other programs the proceeds will allow you to reach. If you do not believe that the anticipated proceeds will be sufficient to complete all of the proposed purposes, please disclose an estimate of the additional funds needed and the sources of such funds.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Stock-based compensation, page 89

11. 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.

Business

Our approach

Our approach to re-activating p53, page 102

12. Please remove conclusory statements regarding the results of your preclinical studies here and throughout the prospectus. Instead, when disclosing observed results of your preclinical studies, please disclose the range of results observed, how the studies and tests were conducted, including the number of animals tested. For example, we note your disclosure on page 103 that states that "[i]n vitro and in vivo experiments have shown that [y]our lead p53 re-activating product candidate, APR-246, via MQ, impairs tumor cells' capacity to respond to oxidative stress," and your disclosure on page 104 that states that you have observed preclinical anti-tumor activity with APR-246 in a wide variety of hematological and solid tumors models and cell lines, including MDS, AML, and several solid tumors including ovarian cancer and esophageal cancer. Similarly, include detailed descriptions of clinical trials, including the number of patients tested, the endpoints of the trials, whether the results were statistically significant and the p-valued used to determine significance. For example, on page 115 you state that, in the CALYPSO trial, PFS was reported as 11.3 months and OS as 30.7 months, but you do not describe how the study was conducted.

Our lead product candidate, APR-246

AEs reported in > 1 patient during APR-246 monotherapy lead-in phase (n=12), page 109

13. Please clarify which of the adverse events disclosed on page 109 are serious adverse events. Similarly, on page 114 identify all serious adverse events experienced in your Phase 1b clinical trial of APR-246 in Platinum Sensitive Ovarian Cancer.

Clinical development in solid tumors, page 114

14. We note your disclosure that your Phase 1b trial did not indicate "significant safety concerns" of combining APR-246 with carboplatin and PLD. Statements regarding safety are a determination that only the FDA and foreign government equivalent regulators have the authority to make. Please revise your disclosure to eliminate any suggestions that your product candidates have been or will ultimately be determined safe. Similarly, please revise your disclosure that your "lead product candidate, APR-246, reactivates p53 for the treatment of various cancers" as your product has not yet been approved by the FDA or a foreign government equivalent regulator, and this statement suggests that it will be approved.

Clinical developments in solid tumors

Phase 1b/2 Clinical Trial of APR-246 in Platinum-Sensitive Ovarian Cancer, or PiSARRO, page 114

15. Please disclose, on page 114, the number of patients evaluable for radiological response

according to RECIST 1.1 in your Phase 1b trial and the number of patients evaluable for CA-125 response. In addition, explain what you mean by "stable disease" on page 114.

Phase 2 clinical trial of APR-246 in platinum-resistant ovarian cancer, or PiSARRO-R, page 115

16. Please disclose the observed results of the Phase 2 clinical trial, including any serious adverse events, the number of patients that experienced serious adverse events and the number of patients that received a 4500 mg/d fixed dose of APR-246 as a 6 hour intravenous infusion as well as the number that received the same or lower fixed dose over 3 or 4 hours for four consecutive days.

Our second product candidate, APR-548, page 116

17. We note your disclosure on page 116 that in preclinical testing you have observed potency with APR-548 that is superior to that of APR-246 in the cell lines that you have tested and that you have provided an example of one such test. Please include disclosure regarding the other preclinical studies, and, for all of the preclinical studies discussed in this section, please disclose the number of times you conducted the tests, the number of animals tested, the doses used in the tests, when the results were measured and the range of results observed. Similarly, we note your disclosure regarding your xenograft study on page 116. Please disclose the number of mice tested in this study.

Consolidated Financial Statements

Note 2: Summary of significant accounting policies

Unaudited pro forma financial information, page F-8

18. Once the corporate reorganization described has been consummated, revise your disclosure in a pre-effective amendment to clearly confirm the completed terms of the reorganization transaction.
19. Revise your description of the pro forma amounts to more clearly describe here the shares exchanged in the corporate reorganization transaction as well as the automatic conversion in a manner that allows the reader to be able to easily recalculate the pro forma equity balances. More clearly identify here the triggers for the conversion, including the specific conversion terms of each class of the preferred shares of the registrant that will be outstanding after the corporate reorganization, which will be automatically converted into the common stock of the registrant.

General

20. Please provide us mockups of any pages that include any additional pictures or graphics to be presented, including any accompanying captions. Please keep in mind, in scheduling your printing and distribution of the preliminary prospectus, that we may have comments after our review of these materials.

You may contact Keira Nakada at 202-551-3659 or Kevin Vaughn at 202-551-3494 if

Christian Schade
Aprea Therapeutics, Inc.
August 8, 2019
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you have questions regarding comments on the financial statements and related matters. Please contact Sonia Bednarowski at 202-551-3666 or Dietrich King at 202-551-8071 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Healthcare & Insurance