



DIVISION OF
CORPORATION FINANCE

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

October 19, 2022

Howard Berman, Ph.D.
Chief Executive Officer
Coya Therapeutics, Inc.
5850 San Felipe St. Suite 500
Houston, TX 77057

**Re: Coya Therapeutics, Inc.
Amendment No. 1 to
Draft Registration Statement on Form S-1
Submitted October 7, 2022
CIK No. 0001835022**

Dear Howard Berman:

We have reviewed your amended 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.

Amendment 1 to Form S-1 Draft Registration Statement Submitted on October 7, 2022

Prospectus Summary, page 1

1. We note your revised disclosure in response to prior comment 6 that death in certain animals was observed at the highest dose for your COYA 201 product candidate. Please revise here and elsewhere in the prospectus to specify the number of deaths observed in your preclinical mouse study. Please also clarify whether the primary endpoints for your preclinical and clinical trials were met, as applicable.

Our Pipeline, page 3

2. We note your response to prior comment 8, which we reissue in part. Please revise your pipeline table here and on page 67 to include a separate column for Phase 3 trial.

We rely on third parties to manufacture our product candidates...., page 34

3. We acknowledge your revised disclosure in response to prior comment 12. We note that you have entered into a material transfer agreement with ThermoFisher Scientific to manufacture your autologous Treg cell therapy. Please expand your disclosure on the materiality of your arrangement with ThermoFisher Scientific. If material, please disclose the material terms of the agreement and file such agreement as an exhibit to the registration statement or provide analysis as to why it would not be required under Item 601(b)(10) of Regulation S-K. Please also identify the foreign pharmaceutical manufacture for the supply of the antibody for the COYA 302 product candidate.

If securities or industry analysts do not publish research or reports...., page 45

4. We note your revised disclosure in response to prior comment 14, which we reissue in part. Please revise your disclosure to indicate that you may not obtain analyst coverage.

COYA 302, page 70

5. We note your response to prior comment 20, which we reissue in part. We refer to your disclosure on page 70 relating to preclinical in vitro and proof of concept human clinical studies conducted by Dr. Appel for your COYA 302 product candidate, which showed "adequate tolerability" and "promising clinical activity" in patients with neurodegenerative diseases. Please expand your disclosure to discuss the design, scope, primary endpoints and whether any adverse events were observed; whether the studies were powered to show statistical significance; and revise your characterizations of the preclinical trials to discuss the data, rather than drawing conclusions from the results.

COYA 101, page 73

6. We note the deleted reference to constructive feedback from the FDA on page 74 in response to prior comment 24, which we reissue in part. We note two remaining references to recommendations made by the FDA relating to your Phase 1 study on page 76. Please revise accordingly or expand your disclosure to discuss the feedback received from the FDA.
7. We note your expanded disclosure of the Phase 1 and Phase 2a studies of your COYA 101 product candidate, which include references to standard deviations. Please expand your disclosure to address related statistical significance and/or p-values. Please also discuss the meaning of the asterisks, where appropriate, in the graphics on page 77.

Howard Berman, Ph.D.
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Page 3

Methodist License Agreement, page 80

8. We note your revised disclosure in response to prior comment 27, which we reissue in part. We refer to your disclosure on page 81 of royalties equal to high-single digit to "low-double digit" percentages of annual worldwide net sales of such licensed product. Please revise your disclosure to give investors a reasonable idea of the amount of the royalty rate that does not exceed ten percentage points.

ARScience Biotherapeutics, Inc. License Agreement, page 81

9. We note your disclosure of your license agreement with ARScience Biotherapeutics, Inc. Please revise your disclosure on page 81 to disclose the upfront fee and the aggregate amounts paid to date under the agreement.

You may contact Tara Harkins at 202-551-3639 or Kevin Kuhar at 202-551-3662 if you have questions regarding comments on the financial statements and related matters. Please contact Jane Park at 202-551-7439 or Tim Buchmiller at 202-551-3635 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Steven M. Skolnick, Esq.