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

DIVISION OF
CORPORATION FINANCE

September 15, 2022

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

Re: Coya Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted August 19, 2022
CIK No. 0001835022

Dear Dr. Berman:

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

Cover Page

1. We note your disclosure on page 41 that after this offering, certain of your current stockholders will continue to own a significant percentage of the company "for the foreseeable future, including the outcome of matters requiring stockholder approval." If you will be a "controlled company" as defined under the relevant Nasdaq listing rules, please disclose that on your cover page and disclose whether you intend to rely on any exemptions as a controlled company. If applicable, please include risk factor disclosure that discusses the effect, risks and uncertainties of being designated a controlled company including, but not limited to, the result that you may elect not to comply with certain corporate governance requirements.

Prospectus Summary, page 1

2. Please clarify the meaning of scientific or technical terms the first time they are used in order to ensure that lay readers will understand the disclosure. For example, please briefly explain what you mean by autologous, allogeneic, exosomes, self-tolerance, and CD4+CD25high hFOXP3+ cells. Please also clarify the meaning of scientific or technical terms the first time they are used in the Business section, such as leukapheresis and mesenchymal cell derived exosomes.

3. We refer to your disclosure on page F-15 relating to certain milestone requirements pursuant to the Methodist License agreement that are triggered upon the completion of the Phase 2a clinical trial and a successful end-of-Phase 2 meeting with the FDA. Please clarify in the Summary when you completed your Phase 1 and 2a clinical trials for your COYA 101 product candidate and conducted an end-of-Phase 2 meeting with the FDA, as applicable. Please also revise to disclose that you have received Orphan Drug Designation for your COYA 101 product candidate as disclosed on page 21.

4. We note your disclosure here and elsewhere in the prospectus that you are currently seeking non-dilutive funding sources in the form of a government grant or through a partnership with an established pharmaceutical company to advance your COYA 101 product candidate into Phase 2b clinical trial for the treatment of ALS. You also state on page 16 that if you are unable to receive such non-dilutive funding, you may delay or terminate the clinical development of COYA 101. We also refer to your disclosure on page 48 that you will only allocate proceeds from this offering if you successfully receive non-dilutive funding. Please expand your disclosure, where appropriate, to discuss the reasons for seeking non-dilutive funding for your COYA 101 product candidate, your decision to make allocations of net proceeds of this offering to COYA 101 contingent upon receipt of non-dilutive funding, and whether you have applied to any government grants or strategic partnerships to date.

5. We refer to your references to COYA 300 as your lead product candidate, for which you are currently conducting IND-enabling studies. We also note that COYA 101 is your most clinically advanced product candidate to date. Please expand your disclosure, where appropriate, to discuss your designation of COYA 300 as your lead product candidate. In this regard, we note that for the Phase 2a study for COYA 101, your Treg cell therapy required taking Tregs from patients and growing those cells out to "produce at least 2 billion Treg cells from each study participant." If the cost or scalability of your manufacturing process is a barrier to further studies for COYA 101 with a larger number of participants, please include a brief discussion of that, or any other material challenges, in an appropriate location in your prospectus.

6. Please revise the Summary to provide clear descriptions of the primary endpoints for your preclinical and clinical trials and whether any serious adverse events were observed. We refer to your disclosure on page 20 relating to fatalities observed in your preclinical mouse models. Please revise your disclosure here, page 20 and the Business section to clarify for which product candidate the fatalities were observed.

7. We note on page 6 that you will effect a stock split on xx, 2022. If the stock split will occur prior to effectiveness of the registration statement, please revise your historical financial statements to reflect the stock split based upon the guidance in ASC 260-10-55-12 and SAB Topic 4(C). This also applies to your capitalization table on page 50. Please also note the need for your independent auditor to reference and dual-date their audit opinion for the aforementioned stock split.

Our Pipeline, page 2

8. Please revise your pipeline table here and on page 66 to include a separate column for Phase 3 trial. In addition, we note the inclusion of your COYA 206 program in the fifth row of your pipeline table. Given the status of development and the undisclosed target, please explain why this program is sufficiently material to your business to warrant inclusion in your Summary pipeline table. If it is material, please expand your disclosure in your Business section to provide a more fulsome discussion of this program, including a description of preclinical studies or development activities conducted. Alternatively, remove any programs that are not currently material from your pipeline table.

Risks Associated with our Business, page 2

9. We note your disclosure on page 17 that you do not currently own, lease or operate a principal laboratory, research and development or manufacturing facility of your own and currently collaborate with various research institutions to perform research and development for your products, including The Methodist Hospital. Please highlight this risk in your summary risk factors.

Utilizing Treg cells represents a novel approach to the treatment of neurodegenerative and auto immune diseases..., page 15

10. We note your reference in the second bullet point of this risk factor to your planned solid tumor trial. Please expand your disclosure elsewhere to disclose the material aspects of this planned trial or revise your disclosure as appropriate.

We may not identify or discover other product candidates and may fail to capitalize on programs or product candidates..., page 22

11. We note your reference to your "NK cell manufacturing platform." Please define NK.

We rely on third parties to manufacture our product candidates..., page 33

12. We note your disclosure on page 33 that you do not currently have any agreements with third-party manufacturers of your product candidates. Please also disclose whether you are dependent on any single or limited number of suppliers for your raw materials. If so, please expand your disclosure to discuss your sources, including the names of any principal suppliers. See Item 101(h)(4)(v) of Regulation S-K. To the extent you have experienced shortages of any raw materials, please expand your discussion to discuss the specific circumstances and the impact on your operations.

If our license agreement with The Methodist Hospital is terminated, we could lose our rights..., page 34

13. We note your disclosure on page 34 relating to the termination provisions and the single-digit royalty payments you make under the Methodist License Agreement. However, we refer to your disclosure on page F-15 that Methodist also has the right to terminate the license agreement or convert the license to a non-exclusive license if you do not achieve certain milestones. You also disclose on page F-15 that you are required to make tiered royalty payments ranging from high single-digit to low double-digit percentages of annual worldwide net sales and single-digit royalty payments for certain licensed services. Please revise your risk factor disclosure and page 76 accordingly.

If securities or industry analysts do not publish research or reports about our business..., page 44

14. Your disclosure indicates that you currently have limited research coverage by analysts. Please confirm if you currently are covered by analysts. If you are not currently covered, please revise your disclosure to indicate that you may not obtain analyst coverage.

Our Amended Charter will provide that the Court of Chancery of the State of Delaware..., page 45

15. We note your disclosure on page 45 that the forum selection in your amended charter may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with you and may discourage such lawsuits. Please revise to disclose that there is also a risk that your forum selection provision may result in increased costs for investors to bring a claim.

Use of Proceeds, page 48

16. We note that one use of proceeds for your offering will be to advance COYA 101 towards a Phase 2 trial in the event you are successful in receiving non-dilutive funding from government grants or from a strategic partner. If known, please quantify, or provide a range, of the non-dilutive funding you would need to receive before advancing COYA 101 towards a Phase 2 trial.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations, page 57

17. We note the statement on page 55 that you do not track internal research and development expenses by product candidate or by platform. However, on page 57 you have provided the expenses by therapeutic program. Please revise the statement on page 55 to clarify how you track these expenses and correct the apparent inconsistency in these disclosures.

18. In this regard, given the importance of your research and development expenses to your operations, please revise to also include disaggregated quantified disclosure by the nature of expense for each period presented.

Critical Accounting Policies
Stock-Based Compensation, page 61

19. 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.

COYA 300, page 68

20. We refer to your disclosure on page 68 relating to the data from the FTD development program and preclinical *in vitro* and *in vivo* testing to support the development of your COYA 300 product candidate. Please expand your disclosure to discuss the design, scope, primary endpoints of your preclinical trials, as applicable, and whether any adverse events were observed. Please also clarify whether the preclinical *in vitro* and *in vivo* data generated to date also supports the development of your COYA 202 product candidate, and if so, please revise your disclosure accordingly.

Our Treg-Derived Exosomes Technology Platform, page 68

21. We note your disclosure on page 68 that your strategy is to simultaneously develop both COYA 300 and COYA 202 for the treatment of FTD and you also state that you expect to initiate the Phase 1 trial for COYA 300 in the first half of 2023. Please also clarify when you intend to conduct a Phase 1 trial for COYA 202.

22. We note your disclosure relating to preclinical studies you are currently conducting for your COYA 204 and 205 product candidates. Please expand your disclosure of the design and scope of your preclinical studies.

23. We note your disclosure that Treg exosomes contain different types of cargo, such as proteins, lipids and nucleic acid. If you may use a variety of substances as a product candidate and there would be challenges to your obtaining intellectual property rights covering such substances or combinations thereof, such as composition of matter patents, please include appropriate risk factor disclosure.

COYA 101, page 71

24. Please clearly disclose the primary and secondary endpoints of your Phase 1 clinical study in ALS patients, as applicable. We also refer to your disclosure on pages 72 and 73 that you received constructive feedback from a pre-IND meeting with the FDA, which provided a clear path for the planning and implementation of the clinical product manufacturing. Please expand your disclosure to discuss the feedback you received from the FDA.

25. If you have graphical representations of the data from your studies that would be material to investors, please present them in this section.

Competition, page 75

26. We note your disclosure on pages 23 and 75 that many of your competitors have similar products that focus on the same diseases and conditions that your current and future pipeline product candidates address and may address in the future. Please expand your disclosure to identify your existing competitors and their products and disclose whether any of your competitors are also developing Treg therapies, Treg-derived exosomes and/or biologics for the treatment of various neurodegenerative diseases.

Methodist License Agreement, page 76

27. Please revise your disclosure relating to the Methodist License Agreement to specify the amount of the annual license maintenance fee, the termination provisions, when the last-to-expire licensed patent is scheduled to expire and the aggregate amounts paid to date (including the payment of any up-front or execution fees), as well as expanded disclosure of the milestone requirements. We also note your disclosure on page 64 of tiered royalties ranging from high-single to low-double digit percentages. Please revise your disclosure to provide the number of tiers and a reasonable idea of the amount of the royalty rates that does not exceed ten percentage points.

Government Regulation, page 77

28. We note your disclosure on page 32 concerning the risks related to the use and handling of hazardous materials and compliance with environmental regulation. Please include a discussion of material regulation applicable to your business and plans. Refer to Item 101(h)(4)(ix) and (xi) of Regulation S-K.

Patent Rights, page 77

29. For each patent listed, please revise to clarify whether each such patent is owned or licensed and the applicable jurisdiction. Please ensure that the type of patent protection (such as composition of matter, use or process) is clearly identified for each patent. For example, the type of patent protection is not clearly disclosed for the third patent under the COYA 101 and the COYA 206 Intellectual Property Portfolios.

30. We note your disclosure on page 77 of six patent rights. However, we refer to your disclosure on pages 35 and 76 that your patent estate includes two pending U.S. provisional patent applications, one U.S. non-provisional patent application, five foreign patent applications and four pending PCT applications. Please advise whether disclosure of these twelve pending patent applications are disclosed in this section or revise your disclosure accordingly.

Management, page 89

31. The disclosure throughout your prospectus indicates that you have a scientific advisory board. If material, please include disclosure in an appropriate location that describes the role or function of your scientific advisory board, identifies each member, and indicates whether there are any rules of procedures governing this board. Please also disclose how members of the scientific advisory board are compensated.

Summary of the 2021 Equity Incentive Plan, page 95

32. We note your disclosure on page 96 that the plan administrator of the 2021 Equity Incentive Plan has the authority to modify (reprice) the purchase price or the exercise price of any outstanding award. Please disclose if repricings could be implemented without stockholder approval. If so, please include appropriate risk factor disclosure, including whether proxy advisory firms could find such repricing without stockholder approval contrary to a performance-based pay philosophy.

Policies and Procedures for Related Party Transactions, page 104

33. Please disclose the standards that will be applied in determining whether to approve any of the transactions described in this section. Refer to Item 404(b)(1)(ii) of Regulation S-K.

License Agreement, page F-15

34. We note that certain milestone requirements under the Methodist License refer to "the effective date" on page F-15. Please revise your disclosure to clarify the meaning of the "effective date" for such milestones.

Exhibit Index, page II-3

35. We note your disclosure that you acquired Nicoya Health, Inc. in December 2020. Please file the merger agreement as an exhibit or tell us why such agreement is not required to be filed. See Item 601(b)(2) and (10) of Regulation S-K.

General

36. 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 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.