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

DIVISION OF
CORPORATION FINANCE

February 5, 2020

Roni Mamluk
Chief Executive Officer
Ayala Pharmaceuticals, Inc.
Oppenheimer 4
Rehovot 7670104, Israel

Re: Ayala Pharmaceuticals, Inc.
Draft Registration Statement on Form S-1
Submitted January 8, 2020
CIK No. 0001797336

Dear Dr. Mamluk:

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, page 1

1. We note your statements indicating that your small molecule therapeutics are potentially “best-in-class". This term suggests that your product candidates are effective, likely to be approved and favorable as compared to competitive products and product candidates. Given the status of development, it is premature and inappropriate for you to make such statements or implications at this time. Accordingly, please delete all references in your registration statement to your product candidates being potentially “best-in-class".

2. We note the inclusion of your collaboration program with Novartis in your pipeline table. Given the status of development and the limited disclosure on pages 115-116 concerning the program, it is premature to highlight this program prominently in your Summary

pipeline table. Accordingly, please revise to remove this program from the Summary table.

3. Please revise your disclosures on pages 2-3 concerning clinical trial results to indicate whether the reported results are statistically significant.

4. For each study where you report results concerning efficacy, please revise to indicate whether the trials were powered to assess statistical significance for any endpoints.

5. Revise to explain briefly key measures you cite in this section, including terms such as "disease control rate" and "overall response rate." Also, please ensure that you provide a balanced presentation of results. In this regard, we note that your discussion of the interim Phase 2 ACCURACY trial results highlights the percentage of patients displaying "partial responses" and "stable disease" but it does not indicate whether any patients displayed a "complete response."

6. We note that your disclosures on page 4 highlight your strategy to rapidly advance your clinical development of three programs. With reference to your disclosures on pages 22 and 102, please revise to highlight in the Summary the risk that you may not be able to identify a sufficient number of patients to initiate and complete your clinical trials in a timely manner, including with respect to your on-going Phase 2 ACCURACY Trial.

Risk Factors, page 11

7. You may not disclaim responsibility for your disclosures, particularly as it relates to interpretations of trial data that you present throughout the prospectus. Accordingly, please revise to remove this risk factor. Alternatively, please explain to us why this risk factor disclosure is appropriate and discuss your consideration of Rule 436(a).

8. Please revise the disclosure on page 22 to clarify which "trial" you may not be able to initiate by the target date and identify such date.

Use of Proceeds, page 74

9. Please revise to disclose the approximate amount of proceeds that you intend to allocate toward the development of each AL101 and AL102 program that you identify in the Summary pipeline table. For each program, disclose the trial phase or phases that you intend to fund with the proceeds and indicate whether your plans call for additional funding to complete that phase or phases. Also tell us whether a material portion of the offering proceeds is intended to be allocated to the development of companion diagnostics.

Management's Discussion and Analysis
Research and Development Expenses, page 84

10. You disclosed multiple drug candidates with multiple indications and that research and development is a significant aspect of your business. Please expand to provide more

detail for your research and development expenses during each period presented, including but not limited to, by drug candidates and/or by indications, as well as by the nature of the expenses.

Critical Accounting Policies and Use of Estimates, page 87

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 IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances, including stock compensation.

Contractual Obligations, page 91

12. Please tell us what consideration was given to including the future payments you may be obligated to pay under the BMS License Agreement in your contractual obligations table. Refer to Item 303(a)(5) of Regulation S-K.

Business, page 93

13. For each clinical trial you discuss, please disclose whether there were treatment-related serious adverse events and, if so, identify them.

14. Given the status of your clinical development programs, please tell us the basis for your claim on page 98 that your GSIs are “highly potent and selective.”

15. Please reconcile your disclosure in the final sentence on page 99 with the two footnotes on page 100 which indicate that two of the three third-party drug candidates are not under active development.

16. Please revise the discussion that accompanies the first table on page 100 to clarify how these results demonstrate the relative inhibitory potency of your product candidates and also discuss why the levels achieved support continued clinical development. Also, briefly discuss the term “PDX model” and clarify whether this relates to a mouse model.

Expanding Our Addressable Patient Population, page 99

17. We note you have entered into a collaboration agreement with ArcherDX, Inc. Please revise to discuss the terms of the collaboration and file the agreement as an exhibit or explain why it is not a material contract.

License Agreements, page 116

18. For each of your license agreements, please revise to clarify the term of the agreement and the duration of the royalty obligations.

Choice of Forum, page 157

19. We note that your forum selection provision identifies the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain litigation, including any "derivative action." Please disclose whether this provision applies to actions arising under the Securities Act or Exchange Act. In that regard, we note that Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, and 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. If the provision applies to Securities Act claims, please also revise your prospectus 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.

Financial Statements
Note 2. Significant Accounting Policies
Consolidated Financial Statements in U.S. Dollars, page F-8

20. You disclose that the functional and reporting currency of the company is the U.S dollar, while also disclose that a substantial portion of your subsidiary's expenses are paid in new Israeli shekels. Please tell us and revise if necessary what you consider to be the functional currency for your subsidiary. Refer to ASC 830-10-45-2, which requires that the assets, liabilities, and operations of a foreign entity shall be measured using the functional currency of that entity.

Note 5. Commitments and Contingent Liabilites, page F-16

21. Please expand your disclosures related to your BMS License Agreement to clarify the following:
    - You disclose that in November 2017 you entered into the BMS License Agreement under which BMS granted you a license related to BMS Licensed Products. In light of the fact that you issued the shares of Series A Preferred stock in 2018, disclose when the license was transferred and, if applicable, why the license was transferred before the shares were issued. Supplementally support your basis for the timing of your recognition of the related research and development expense; and
    - Separately quantify the amount of the fixed upfront payment and the value of the Series A convertible preferred shares issued to BMS.

Note 11. Net Loss per Share, page F-26

22. Please revise to disclose the securities that could potentially dilute basic EPS in the future that were not included in the computation of diluted EPS because to do so would have been antidilutive for the periods presented as required by ASC 260-10-50-1.

General

23. Please supplementally 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.

You may contact Li Xiao at 202-551-4391 or Jeanne Baker at 202-551-3691 if you have questions regarding comments on the financial statements and related matters. Please contact William Mastrianna at 202-551-3778 or Joseph McCann at 202-551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences