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

DIVISION OF
CORPORATION FINANCE

October 8, 2020

David Baker
Chief Executive Officer
Vallon Pharmaceuticals, Inc.
Two Logan Square
100 N. 18th Street, Suite 300
Philadelphia, PA 19103

Re: Vallon Pharmaceuticals, Inc.
Draft Registration Statement on Form S-1
Submitted September 11, 2020
CIK No. 0001824293

Dear Mr. Baker:

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

Company Overview, page 1

1. We refer to your statements that you intend to pursue a section 505(b)(2) approval pathway, and that this path may expedite the development of your programs. Please expand your explanation of this process so that investors understand the steps necessary to achieve FDA approval using this process. Please similarly revise the pipeline table to identify the steps necessary for regulatory approval. Additionally, identify and describe the studies and results you intend to rely on, including the identification of the parties that performed the studies. Please also disclose whether the FDA has given any indication that you may use such pathway for ADAIR.

2. We note your statements that you completed a pivotal bioequivalence study of ADAIR as well as a food effect study and a proof-of-concept intranasal human abuse potential study. Please clarify whether these were clinical studies and if so, the phase of clinical testing to which these studies correlate. Please also disclose the number of patients that participated in each study and each study's primary endpoints.

3. Please disclose the value of the 33,750,000 shares of common stock that were exchanged for the ADAIR assets.

The Offering, page 6

4. You indicate at the top of page seven that unless otherwise indicated, all information in this prospectus reflects or assumes a reverse stock split of your common stock to be effected prior to the closing of this offering. Please address the following:
   - To the extent you intend to effect the split prior to the effectiveness of your registration statement, we remind you that you must revise your financial statements presented to reflect the stock split in accordance with ASC 260-10-55-12 and SAB Topic 4C. Also, ensure your auditor revises its report on page F-2 to reference the stock split and dual-date its opinion in accordance with PCAOB AU 530.05; and
   - If the reverse stock split will occur after effectiveness of your registration statement but prior to the consummation of this offering, please expand your pro forma earnings per share information in your Summary and Selected Financial Data to clarify the nature of this pro forma information.

Use of Proceeds, page 53

5. Please revise your disclosure in this section to specify which candidates will be advanced with the proceeds of the offering and which clinical trials will be funded. Please indicate how far you expect the proceeds from the offering will allow you to proceed in the clinical development of your product candidates. If the anticipated proceeds from your offering will not be sufficient to complete those trials, please disclose the amount and sources of other funds needed.

Controls and Procedures, page 74

6. We note your disclosures regarding disclosure controls and procedures and internal controls over financial reporting. Please expand your disclosures and related risk factors to address the following:
   - Disclose the fact that you are not currently required to provide these assessments;
   - Revise to clarify, if true, that you performed an assessment of your internal control over financial reporting which is a separate assessment from disclosure controls and procedures; and
   - Identify the version of the COSO framework you used to evaluate the effectiveness of your internal control over financial reporting, if you performed one.

Business
ADHD Condition and Impact, page 80

7. Please revise to disclose the bases for the figures in the table at the top of page 81.

Existing Treatment Options, page 81

8. In the table on page 81, please provide the percentage of prescriptions that are immediate-release and extended-release tablets and capsules. Please also disclosure what portion of the $9 billion U.S. market for ADHD treatment was immediate-release ADHD treatments that your products are targeting.

Our Solutions, page 85

9. We note the disclosure in the financial statement footnotes that you have completed three Phase 1 clinical trials. Please disclose the specific results from all prior and ongoing trials, including the duration of each trial, the number of subjects or patients in such trials, how the drug candidates were administered, who conducted and/or sponsored the trials, the dosages used, and all serious adverse events that were experienced, including the number of patients that experienced such SAEs. With respect to the disclosure of each such trial, state the primary and secondary endpoints and whether they were met.

Intellectual Property, page 93

10. With respect to those patents that have been issued, please indicate the type of patent protection in each instance, be it composition of matter, use, or process.

Medice License Agreement, page 93

11. We note your reference here to low double-digit royalties. Please revise your disclosure to narrow the royalty range to no more than ten percentage points (for example, between twenty and thirty percent). Also disclose the duration of the royalty obligation and discuss the termination provisions of the license agreement.

Whitaker Consulting Agreement, page 104

12. Please disclose the terms on the options to purchase common stock that were granted to Dr. Whitaker in October 2018 and May 2020.

Principal Stockholders, page 110

13. We note that members of the board of directors and management will control approximately 58.4% of the voting power. Please tell us whether you may be a controlled company under applicable exchange listing standards, and, if so, whether you will use related exemptions to governance rules under those standards.

Notes to Financial Statements
June 30, 2020 and 2019 (unaudited)
Note B - Summary of SIgnificant Accounting Policies
2 - Revenue recognition, page F-26

14. You have determined that Medice is a related party and that the License Agreement was transacted at arm's-length with the consideration therein determined to be at fair value. Please tell us how the representation as to arm's length fair value was substantiated. Refer to ASC 850-10-50-5.

General

15. 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.

16. The graphic that precedes the table of contents suggests that ADAIR is an approved reformulation that is clinically effective. Please revise to remove any statements that suggest the safety and efficacy of your candidates, as these determinations are the exclusive authority of the FDA or other regulators. In addition, the graphic includes a large amount of text. Text in this context should be used only to the extent necessary to explain briefly the visuals in the presentation and should not overwhelm the visual presentation. Also, the graphics should not include extensive narrative text that repeats information already contained in the summary or business sections. For guidance, refer to Question 101.02 of Compliance Disclosure of our Securities Act Forms Compliance and Disclosure Interpretations and revise accordingly.

17. We note your cautionary statements concerning the representations, warranties and covenants made in agreements filed as exhibits to the registration statement. Disclosure regarding an agreement's representations, warranties and covenants in a registration statement (whether through incorporation by reference or direct inclusion) constitutes a disclosure to investors, and you are required to consider whether additional disclosure is necessary in order to put the information contained in, or otherwise incorporated into that publication, into context so that such information is not misleading. Please refer to Report of Investigation Pursuant to Section 21(a) of the Securities Exchange Act of 1934 and Commission Statement on potential Exchange Act Section 10(b) and Section 14(a) liability, Exchange Act Release No. 51283 (Mar. 1, 2005). If you continue to use these cautionary statements in your registration statement, please revise them to remove any implication that the agreements do not constitute disclosure under the federal securities laws and to clarify that you will provide additional disclosure to the extent that you are or become aware of the existence of any material facts that are required to be disclosed under the federal securities laws and that might otherwise contradict the representations, warranties and covenants contained in the agreements and will update such disclosure as

required by federal securities laws.

You may contact Gary Newberry at 202-551-3761 or Jeanne Baker at 202-551-3691 if you have questions regarding comments on the financial statements and related matters. Please contact Chris Edwards at 202-551-6761 or Mary Beth Breslin at 202-551-3625 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Kaoru C. Suzuki, Esq.