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

DIVISION OF
CORPORATION FINANCE

November 21, 2024

Tien-Li Lee, M.D.
Chief Executive Officer
Aardvark Therapeutics, Inc.
4370 La Jolla Village Drive, Suite 1050
San Diego, CA 92122

Re: Aardvark Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted October 24, 2024
CIK No. 0001774857

Dear Tien-Li Lee M.D.:

We have reviewed your draft registration statement and have the following comments.

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 a comment applies 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 this letter and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1 submitted October 24, 2024

Prospectus Summary, page 2

1. Please provide balancing disclosure in the Prospectus Summary concerning the following:
   - your history of net losses and accumulated deficit, quantifying each;
   - your ability to continue as a going concern; and
   - the current competitive landscape surrounding the treatment of obesity and obesity-related conditions, relevant to your development of ARD-201.
2. Please revise or remove statements both here and throughout the prospectus implying that your product candidates are or may be determined to be safe and/or effective. Examples of such statements include, but are not limited to, the following:

- that you have "observed promising clinical benefit with an encouraging tolerability profile";
- that you believe your product candidates can "offer enhanced efficacy, tolerability and convenience over existing therapies to provide superior benefits to patients";
- that you have "successfully" completed certain clinical trials; and
- your statement that "ARD-201's full potential remains to be discovered in future trials, with enhanced potency through combination with a DPP-4 inhibitor, and without the constraints in the Phase 2a clinical trial design".

Note that conclusions of safety and efficacy are within the sole purview of the FDA. Given the fact that your products candidates have not yet been approved by the FDA, it is premature to state or imply that your product candidates are safe and/or effective. Rather than including conclusory statements, you may include information regarding data observed in trials to date. In addition, based on the uncertainty surrounding the timing of clinical trials, please remove your statement that you plan to pursue "accelerated development" of ARD-101.

3. We note your statement that the administration of CCK may significantly reduce food consumption in patients with hyperphagia associated with HO. Please cite the specific literature mentioned as the source for this claim.

4. We note your references both here and elsewhere to a "potentially pivotal Phase 3 clinical trial" for ARD-101. We also note your statements on page 25 that you have not previously conducted any later stage or pivotal clinical trials and that in order to do so, you "will need to expand [y]our clinical management and regulatory capabilities." Please provided more detail regarding the steps needed to be taken prior to conducting this trial in each instance where the "potentially pivotal Phase 3" is discussed.

We plan to conduct certain clinical trials for our product candidates outside the . . ., page 26

5. We note your statement that you plan to conduct certain clinical trials of ARD-101 and ARD-201 outside the U.S., including, but not limited to, in "the EU, Australia and Asia". Please expand this disclosure to clarify the specific countries in which the company has already conducted clinical trials, specifying the trial, and where the company currently plans to conduct trials in the future.

An active and liquid trading market for our common stock may not develop..., page 76

6. We note your statement in the above entitled risk factor that there is no assurance that your application to list your common stock on the Nasdaq Global Market will be approved. We also note your statement on the cover page and pages 194 and 204 that the offering is contingent upon obtaining approval of such listing. Please reconcile these statements.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations
Comparison of the Six Months Ended June 30, 2023 and 2024
Research and Development Expenses, page 105

7. You disclose on page 3 that you are pursuing two indications for ARD-101 and one indication for ARD-201. For each significant research and development project, please disclose the costs incurred during each period. If the company does not track research and development costs by individual project, please clarify in the filing.

Critical Accounting Estimates
Stock-Based Compensation Expense, page 111

8. 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.

Our Strategy, page 118

9. We note your statements throughout the prospectus indicating you believe that ARD-201 has "the potential to address the gaps associated with GLP-1 treatments", which include weight regain post-withdrawal and the loss of lean body mass. Please revise your disclosure to explain why you do not believe these will be issues with ARD-201 and provide data supporting your statements.

ARD-101 Preclinical Data Summary, page 123

10. Please define "tachyphylaxis" where first used on page 123.

ARD-101, page 125

11. Please revise Figure 3 and other figures, as appropriate, to provide a clear key for the colors used in the bar graph representations.

Government Regulations, page 136

12. Please update the disclosure in your Government Regulations section to disclose how the regulatory framework for your fixed-dose combination of the ARD-201 product candidate may differ from your other product candidates in development or otherwise advise. Also, revise your risk factor disclosure to include a discussion of any material risks arising from your development of a fixed-dose combination product candidate.

Intellectual Property, page 136

13. Please revise your intellectual property disclosure to clearly describe for each material individual or patent family the type of patent protection (e.g., composition of matter, use or process), the product candidate(s) dependent on each patent or patent family,

the expiration dates of each patent or patent family discussed, and the jurisdiction of each. In this regard, it may be useful to provide this disclosure in tabular form to support the narrative already included.

Statements of Cash Flows, page F-6

14. Please explain to us why you have classified your payment made in exchange for related party convertible promissory notes as a financing activity. Refer to ASC 230-10-45-15.

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.

Please contact Eric Atallah at 202-551-3663 or Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Tamika Sheppard at 202-551-8346 or Laura Crotty at 202-551-7614 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Jeff Hartlin