



DIVISION OF
CORPORATION FINANCE

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

May 30, 2024

Fred Aslan
Chief Executive Officer
Artiva Biotherapeutics, Inc.
5505 Morehouse Drive, Suite 100
San Diego, CA 92121

Re: Artiva Biotherapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted May 3, 2024
CIK No. 0001817241

Dear Fred Aslan:

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

Cover Page

1. We note your disclosure on page 70 that there will be a concentration of ownership post-offering, such that certain stockholders will have the ability to control or significantly influence all matters submitted to stockholders for approval. Please tell us whether you will be considered a "controlled company" within the meaning of Nasdaq listing standards post-offering. If so:
 - Provide appropriate disclosure of your controlled company status on the prospectus cover page and revise the prospectus where appropriate throughout to indicate that you will be a "controlled company" and the implications of such status, including whether you plan to utilize any of the exemptions available to you.
 - Also revise the Prospectus Summary to address the risks of being a shareholder in a controlled company, and include information regarding the controlling shareholders and their ability to impact your company and its stated business strategies.

Overview, page 1

2. We note your statement that you are developing "allogeneic, off-the-shelf, natural killer (NK) cell-based therapies." Please revise your disclosure here to clarify, at first use, what you mean by "allogeneic" and "off-the-shelf."
3. We refer to your statements on pages 1,108, and 113 that you believe your "critical first mover advances, supported by [y]our rapid and strategic execution, will solidify [y]our leadership in multiple autoimmune diseases with high unmet need." Please balance your disclosure by clarifying that the receipt of INDs or FDA designations does not guarantee that a product candidate will successfully complete the regulatory approval process and highlight that Artiva has yet to develop an approved product. In addition, please clarify what you mean when you state your first mover advances are supported by "rapid and strategic execution."
4. We note that your lead product candidate, AlloNK, is being investigated in a basket investigator-initiated trial (IIT) in multiple autoimmune indications. Please expand your disclosure here and throughout as appropriate to:
 - Briefly clarify the nature of a basket trial;
 - Identify the investigator(s) in the IIT; and
 - Explain how an IIT differs from a trial sponsored by your company, and your role/responsibility, if any, in "supporting" the IIT.

In addition, in an appropriate place in the Business section, please describe the material terms of any agreement(s) with the investigator(s) so that investors understand the nature of your rights or obligations in relation to the IIT. File the agreements as exhibits to your registration statement if required by Item 601 of Regulation S-K, or advise.

B-Cell Driven Autoimmune Disease Background, Prevalence and Unmet Need, page 2

5. Please revise your disclosure throughout your prospectus to remove or revise statements that state, conclude, or imply the safety or efficacy of your product candidates or treatment approach, as determinations of safety and efficacy are solely within the authority of the FDA and comparable regulatory bodies. You may provide a summary of the objective observations from your trials without stating your conclusions or predictions. Please refer to the following non-exhaustive list by way of example only:
 - "Autoimmune disease treatment approach validated through scientific publications and our ongoing clinical trial" (pages 4 and 112). In this regard, we note that your approach to the development of NK cell-based product candidates for the treatment of any disease is unproven, your products are in an early development stage, and you may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials.
 - "Conversely, safety data results for AlloNK in combination with rituximab, as of April 8, 2024, have demonstrated the ability of AlloNK to be administered and managed in an outpatient setting, with limited risk of required hospitalization."

- (pages 2, 109, and 114).
 - "Once safety is determined, AlloNK will be given at four billion total cells per dose..." (page 124).
6. Please revise to explain the basis for assuming a treatment regimen of six billion AlloNK cells total per patient or otherwise advise.

AlloNK Overview, page 3

7. You disclose that AlloNK in combination with rituximab or obinutuzumab for patients with class III or IV LN has been granted Fast Track designation by the FDA, as has AlloNK for intravenous (IV) infusion in combination with rituximab for the treatment of relapsed or refractory B-NHL. Please expand your disclosure here and elsewhere as appropriate to explicitly state that Fast Track designation does not guarantee a faster development process, regulatory review, or approval as compared to the conventional FDA review process.

Manufacturing Capabilities, page 4

8. We note statements here and throughout the registration statement that your proprietary manufacturing process is designed to allow for the production of NK cell therapy candidates at a "massive scale," that the scalability of your process creates potential to expand treatment access "to the hundreds of thousands of autoimmune patients," that AlloNK can be manufactured at scale, or that your processes "allow for scalable and cost effective AlloNK production." Throughout, please revise to qualify these and any similar statements. In this regard we contrast certain of your other disclosures that:
- the manufacture of cell therapy products is novel and complex;
 - the manufacturing processes for certain of your CAR-NK cell product candidates have not been tested at full scale;
 - you have not yet demonstrated an ability to manufacture product at a commercial scale; and
 - your cost of goods production is at an early stage.

Capitalization, page 84

9. Please revise to incorporate the SAFE liability as part of your capitalization and include bold double lines under the cash, cash equivalents and short-term investments amounts to clearly distinguish them from your capitalization.

Merck Exclusive License and Collaboration Agreement, page 93

10. Please revise your disclosure to clarify who terminated the Merck Collaboration Agreement in October 2023, describe the material terms of the termination and clarify the status of the programs that were under development or otherwise advise.

Critical Accounting Policies and Significant Judgments and Estimates

Stock-Based Compensation Expense
Common Stock Valuation, page 105

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 and beneficial conversion features. Please discuss with the staff how to submit your response.

Business, page 108

12. Throughout this section where appropriate, please revise your discussion of the clinical trials of your material product candidates that you have conducted, are currently conducting, or plan to conduct to disclose the primary and secondary endpoints of such trials, as well as the results as they relate to those endpoints.
13. We note that you discuss preclinical trials in this section without providing proper context for your observations. For each material pre-clinical trial discussed, please briefly describe how the tests were conducted, the number of animal models used, the number of tests conducted, the range of results or effects observed in these tests and how such results were measured.

Our Strengths, page 112

14. We note that your disclosures in this section and elsewhere throughout reference terms such as "overall response rate," "complete response", "partial response," "ongoing response," "durable response," "stable disease" and "progressive disease." Please revise to explain the meaning of these terms and how responses were measured.

Clinical Responses in B-NHL, page 119

15. Your clinical trial results or your product candidate's performance in such trials should not be compared to alternative trials and technologies unless head to head studies were conducted. In this regard, please remove the third paragraph in this section referencing the JULIET, ZUMA-1, and TRANSCEND trials of auto CAR-T cell therapies in B-cell lymphoma patients, as the inclusion of this information appears to assume or imply that AlloNK is more effective than other products. Similarly, please remove the following statement from your discussion of drug-related hospitalization days following dosing of AlloNK on page 121: "In the study of CD19 auto-CAR-T led by Schett, ten days mandatory hospitalization was required for all patients."

AlloNK Patient Journey, page 120

16. Please revise the graphic on page 121 and any other tables or graphics throughout your filing to ensure that the text in each, including subscript or other notations, are clearly

legible without need for magnification.

AlloNK, page 122

17. You state that you have completed enrollment in your Phase 1/2 trial exploring AlloNK in patients with relapsed or refractory B-NHL, and that you have deprioritized further development of AlloNK in B-NHL but will continue to follow patients to assess duration of responses. Please revise to explain the reason(s) for this deprioritization or otherwise advise.

Preliminary Safety Data, page 127

18. Please revise this section to describe all serious adverse events that occurred in your clinical trials and quantify the number of occurrences, if any.

Intellectual Property, page 133

19. In relation to the company's material patents, please revise your intellectual property disclosure to clearly describe on an individual or patent family basis the jurisdiction, including any foreign jurisdiction, of each material pending or issued patent.

Collaboration and License Agreements, page 135

20. We note your disclosure that the Core Agreement and the AB-101, AB-201 and AB-205 license agreements will remain in effect until the expiration of the last-to-expire royalty term. For each agreement, please revise to clarify when the patents underlying the royalty term are expected to expire.

Corporate Philanthropy, page 157

21. You state that you have joined the Pledge 1% Movement, and as such, your board of directors approved the reservation of shares of common stock that you may issue to or for the benefit of a charitable foundation established by you or other charities in equal installments over five years following this offering. As appropriate, please add risk factor disclosure related to your participation in the Pledge 1% Movement, including but not limited to disclosing, if true, that the donation of such shares may dilute shareholders' ownership of the company's common stock.

Notes to Financial Statements

8. Collaboration, Option, and License Agreements

Option and License Agreement with GC Cell, page F-18

22. On page F-19 you state that you have exercised your rights to license four option candidates, one of which is AB-202, under the GC Cell license agreement. Please include a discussion with regards to the AB-202 selected product agreement or explain why a discussion is not provided.

Fred Aslan
Artiva Biotherapeutics, Inc.
May 30, 2024
Page 6

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, have presented or expect to 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 Sasha Parikh at 202-551-3627 or Lynn Dicker at 202-551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Lauren Hamill at 303-844-1008 or Jason Drory at 202-551-8342 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences