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

DIVISION OF
CORPORATION FINANCE

February 21, 2024

Leon O. Moulder, Jr.
Chief Executive Officer
Zenas BioPharma, Inc.
1000 Winter Street
North Building, Suite 1200
Waltham, MA 02451

Re: Zenas BioPharma, Inc.
Draft Registration Statement on Form S-1
Submitted January 25, 2024
CIK No. 0001953926

Dear Leon O. Moulder:

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

Prospectus Summary
Overview, page 1

1. Please revise this section to state that you are a clinical stage company with no product candidates approved for commercial sale in any country and that you have yet to generate any revenue from product sales.

2. We note statements here, and throughout the prospectus, claiming that obexelimab is "safer" and "more effective" than anti-CD20 or other anti-CD19 targeting therapies. Please note that conclusions of safety and efficacy are within the sole authority of the FDA and comparable foreign regulators. Qualifying language that statements of safety and efficacy are expressions of the company's beliefs or expectations do not address this concern. Please revise these statements or remove them.

3. Please include a brief description of IgG4-RD and wAIHA in the Summary section, including a statement related to the small patient population for each of these diseases.

4. We note your statement that obexelimab has shown "favorable clinical activity" and "promising tolerability" across five clinical trials. Please revise this statement, and any others like it, to instead present the objective data resulting from your clinical trials. In this regard, please also revise here to clarify the quantity and types of serious adverse events experienced by patients in these clinical trials.

Our Pipeline, page 2

5. Please disclose the autoimmune indications you are pursuing with your ZB002 and ZB004 programs in your pipeline table and revise your Business section to add corresponding narrative disclosure. If these indications have not yet been determined, please tell us why you believe these programs are sufficiently material to your business to warrant inclusion in your pipeline table. We also note that you are not using any proceeds from this offering to advance these programs.

6. Please revise the pipeline chart to reflect that you have not filed an IND for obexelimab for the treatment of MS.

Obexelimab for the Treatment of MS, page 4

7. Your statement that the role of B cells in the pathogenesis of MS has been "clinically validated" appears to indicate that obexelimab has already been proven effective. Based on your current disclosure, that you are planning to conduct clinical trials, we believe your use of this terminology is not appropriate. Please revise your discussion accordingly.

Obexelimab for the Treatment of SLE, page 5

8. Please disclose that the primary endpoint for the completed Phase 2 double-blind, randomized trial of obexelimab in SLE was not achieved with statistical significance.

Our ZB002 Program, page 5

9. Please clarify if you have tested your ZB002 candidate in a head-to-head study against adalimumab. To the extent you have not, please remove any statements comparing your product candidate to adalimumab.

Our ZB004 Program, page 5

10. Please remove your statement claiming ZB004 will have "increased potency" when compared to existing therapies as it is speculative in light of the current development status of this candidate.

Our Team and Investors, page 6

11. We note your statement here that you have raised over $159.0 million from certain pre-

IPO investors. Please limit any discussion of pre-IPO investors to the investors disclosed in your Principal Stockholders table on page 176. Please also disclose that potential investors should not consider investments made by these pre-IPO investors, which are likely to have have different risk tolerances than investors in this offering and paid significantly less per share than the price at which these shares are being offered.

Risk Factors

We rely on a single third-party manufacturer to supply our product candidates..., page 58

12. Please identify the single third-party manufacturer that you currently rely on to manufacture your clinical candidates. Please also clarify if they hold any of the necessary know-how required to manufacture your clinical candidates and if you have entered into any supply agreements with this manufacturer.

Use of Proceeds, page 74

13. Please revise to specify how far you expect the proceeds from this offering will enable you to reach in Phase 2 and 3 trials of obexelimab for each indication listed.

Capitalization, page 76

14. Please revise to include your convertible notes outstanding as part of your total capitalization and indebtedness.

Critical Accounting Policies and Significant Judgments and Estimates

Determination of Fair Value of Common Stock, page 97

15. 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.

Business

Clinical Development, page 105

16. Please revise the discussion of your clinical trials to disclose the primary and secondary endpoints for each trial, where the trials were conducted, which of your trials were powered for statistical significance and if any serious adverse events were observed while conducting each trial.

INDIGO Trial - Our Ongoing Phase 3 Trial in IgG4-RD, page 109

17. Please disclose the number of patients enrolled in the INDIGO trial to date. Please provide similar information for the SApHiAre Trial on page 111.

License Agreements
License Agreements with Xencor, page 123

18. Please revise to disclose the aggregate amounts you have paid or received to date under your licensing agreements with Xencor and Bristol-Myers Squib. Please also revise your disclosure of the Xencor agreements to disclose if the 2020 Xencor Agreement included any development or regulatory milestones and, if applicable, quantify them.

Certain Relationships and Related Party Transactions, page 172

19. Please revise to discuss the material terms of your agreements with Dianthus Therapeutics Inc. and Viridian Therapeutics Inc., including the aggregate amounts paid or received to date under these agreements, any regulatory or developmental milestones, and applicable royalty rates or royalty rate ranges not to exceed ten percentage points. Please also file these agreements as exhibits to your registration statement, or tell us why you believe such a filing is not required.

Notes to Condensed Consolidated Financial Statements for the Nine Months Ended September 30, 2023
7. Collaboration Revenue
Bristol Myers Squibb, page F-43

20. For your license agreement with Bristol Myers Squibb, please provide us an analysis how you have concluded that the global development activities under the agreement do not represent a transaction with a customer under ASC 606 and thus payments received by the Company for global development activities are accounted for as a reduction of the related research and development expenses. In your response, please explain how you determined that your contractual obligations with respect to the global development activities are not an output of your ordinary activities. Please also include more detailed descriptions for the rights and obligations (e.g. cost and profit sharing percentages) between the two parties, at their respective territories, with regard to the ongoing Phase 3 clinical trial for IgG4-RD as well as other future development. Revise your disclosures where necessary.

General

21. We note disclosure throughout your prospectus stating you have in-licensed the greater China rights for development, manufacturing and commercialization of certain of your preclinical candidates and that you have office space in Shanghai, China. Please revise, where appropriate, to quantify the extent of your operations in China. As an example only, disclose the portion of your development activities currently located in China.

22. 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 Li Xiao at 202-551-4391 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Tyler Howes at 202-551-3370 or Chris Edwards at 202-551-6761 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Nicholas Roper, Esq.