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May 15, 2024

Submitted pursuant to a
Request for Confidential Treatment
Pursuant to 17 C.F.R. 200.83

FOIA Confidential Treatment Request

The entity requesting confidential treatment is
Zenas BioPharma, Inc.
1000 Winter Street, North Building, Suite 1200
Waltham, MA 02451
Attention: Leon O. Moulder, Jr.
Chief Executive Officer
Phone: (857) 271-2954

Certain confidential information in this letter has been omitted and provided separately to the Securities and Exchange Commission. Confidential treatment has been requested by Zenas BioPharma, Inc. with respect to the omitted portions, which are identified in this letter by the mark "[***]."

VIA EDGAR AND SECURE FILE TRANSFER

U.S. Securities and Exchange Commission
Division of Corporation Finance, Office of Life Sciences
100 F Street, N.E. Washington, D.C. 20549
Attention: Tyler Howes and Chris Edwards
Re: Zenas BioPharma, Inc.
Draft Registration Statement on Form S-1
Submitted January 25, 2024
CIK No. 0001953926

Ladies and Gentlemen:

On behalf of Zenas BioPharma, Inc. ("Zenas" or the "Company"), we hereby confidentially submit to the U.S. Securities and Exchange Commission (the "Commission"), via EDGAR, Amendment No. 1 ("Amendment No. 1") to the above-referenced draft registration statement (the "Draft Registration Statement"). Amendment No. 1 reflects revisions to the Draft Registration Statement made in response to the comment letter from the staff of the Division of Corporation Finance (the "Staff") of the Commission dated February 21, 2024 regarding the Draft Registration Statement, as well as certain other updated information. Marked copies showing changes from the Draft Registration Statement confidentially submitted on January 25, 2024 are being furnished supplementally for the convenience of the Staff.

May 15, 2024

In addition, we are providing the following responses to the Staff's comments. To assist your review, we have presented the text of the Staff's comments in italics below and the Company's responses set forth in this letter are numbered to correspond to the numbered comments from the Staff's letter. The responses and information described below are based upon information provided to us by the Company and all terms used but not defined herein have the meanings assigned to such terms in Amendment No. 1.

CONFIDENTIAL TREATMENT REQUESTED BY ZENAS BIOPHARMA, INC. UNDER 17 C.F.R. §200.83 FOR REQUEST NO. 1

May 15, 2024

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.*

Response to Comment 1: In response to the Staff's comment, the Company has revised the disclosure on pages 1, 2, 81, 82, 84 and 101 of Amendment No. 1.

Prospectus Summary
Overview, page 1

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.*

Response to Comment 2: In response to the Staff's comment, the Company has revised the disclosure throughout Amendment No. 1 to remove statements that obexelimab is "safer" or "more effective" than other therapies.

Prospectus Summary
Overview, page 1

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.*

Response to Comment 3: In response to the Staff's comment, the Company has revised the disclosure on pages 1-2 of Amendment No. 1 to include a brief description of IgG4-RD, wAIHA, MS and SLE.

Prospectus Summary
Overview, page 1

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.*

Response to Comment 4: In response to the Staff's comment, the Company has revised the disclosure on pages 1, 3, 5, 81, 101, 102, 104, 106, 108, 114, 115, 121 and 123 of Amendment No. 1.

Prospectus Summary
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.*

Response to Comment 5: The Company has revised the disclosure in the Company's pipeline table to remove each of ZB002 and ZB004 and revised the disclosure in the Business section accordingly. The Company respectfully advises the Staff that it intends to continue development and ultimately commercialize ZB002 and ZB004 with partners.

Prospectus Summary
Our Pipeline, page 2

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

Response to Comment 6: The Company acknowledges the Staff's comment and confirms that the Company filed an IND in the first half of 2024 and, once cleared, plan to advance obexelimab in a Phase 2 study in patients with MS.

Prospectus Summary
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.*

Response to Comment 7: In response to the Staff's comment, the Company has revised the discussion on pages 4 and 112 of Amendment No. 1 to clarify that B cell targeting agents developed by other companies, rather than obexelimab, have demonstrated the role of B cells in the pathogenesis of MS.

Prospectus Summary
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.*

Response to Comment 8: In response to the Staff's comment, the Company has revised the disclosure on page 5 of Amendment No. 1 to state that the primary endpoint for the completed Phase 2 double-blind, randomized trial of obexelimab in SLE did not achieve statistical significance.

Prospectus Summary
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.*

Response to Comment 9: In response to the Staff's comment, the Company has revised the disclosure on page 121 of Amendment No. 1 to clarify that ZB002 has been tested in a preclinical head-to-head study against adalimumab.

Prospectus Summary
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.*

Response to Comment 10: In response to the Staff's comment, the Company has revised the disclosure in the Prospectus Summary and Business section of Amendment No. 1 accordingly.

Prospectus Summary
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 different risk tolerances than investors in this offering and paid significantly less per share than the price at which these shares are being offered.*

Response to Comment 11: The Company acknowledges the Staff's comment and intends to limit any discussion of pre-IPO investors in the prospectus to investors disclosed in the Principal Stockholders table. Further, in response to the Staff's comment, the Company has revised the disclosure on pages 6 and 104 of Amendment No. 1 to disclose that potential investors should not consider investments made by its existing investors as a factor when making a decision to purchase shares in this offering since existing investors may have different risk tolerances and paid less per share than the price at which the shares are being offered in this offering.

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.*

Response to Comment 12: In response to the Staff's comment, the Company has revised the disclosure on pages 58, 59 and 131 of Amendment No. 1 to identify WuXi Biologics as its single third-party manufacturer of clinical supply of our product candidates and to disclose the material terms of the master services agreement between the Company and WuXi Biologics (the "WuXi Agreement").

Further, the Company respectfully advises the Staff that the WuXi Agreement is not a material contract within the meaning of Item 601 of Regulation S-K. Third-party manufacturing agreements such as the WuXi Agreement are such as ordinarily accompany the kind of business conducted by the Company. Such an agreement would be a material agreement according to Item 601(b)(10)(ii)(B) if the contract is one upon which the Company's business is substantially dependent. The Company respectfully submits that the WuXi Agreement is not an agreement upon which the Company is substantially dependent. Pursuant to the WuXi Agreement, WuXi Biologics provides the Company with a clinical supply of its product candidates pursuant to individual statements of work. The WuXi Agreement is terminable by the Company and WuXi for convenience, except in the case of WuXi Biologics' termination with respect to any ongoing statement of work. Currently, WuXi Biologics is contracted to provide clinical trial materials. The Company orders drug substance and drug product on a rolling basis. Currently, the Company has an inventory of drug substance and drug product that is sufficient to complete the ongoing studies of obexelimab in IgG4-RD (INDIGO), to initiate the Phase 2 trials in MS and SLE and to complete the ongoing Phase 2 trial in wAIHA. Furthermore, the Company is currently manufacturing obexelimab drug substance and drug product and expects to have inventory sufficient to complete each of these studies by the end of the third quarter of 2024. Finally, all drug product for non-China clinical sites is shipped out of China and stored in the United States promptly following the completion of manufacturing. While the termination of the WuXi Agreement and any reduction or halt in supply of clinical product candidates from WuXi Biologics could limit the Company's ability to develop its product candidates until a replacement contract manufacturing organization is identified and qualified, the Company believes that it has sufficient supply to support its current clinical trial programs and that it could find a new manufacturer without a material delay to its overall development plans. In addition, the Company is actively evaluating and expects to select replacement contract manufacturing organizations in the United States or European Union for drug substance, drug product and analytical testing in the second quarter of 2024. Accordingly, the Company believes it is not substantially dependent on the WuXi Agreement at this time.

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.*

Response to Comment 13: The Company acknowledges the Staff's comment and confirms that the Company will revise the disclosure in a future amendment to the Draft Registration Statement to specify the Company's expectation of how far the proceeds from the offering will enable the Company 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.*

Response to Comment 14: In response to the Staff's comment, the Company has revised the disclosure on page 76 of Amendment No. 1 to include the Company's convertible notes outstanding in its total capitalization.

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.*

Response to Comment 15: The Company acknowledges the Staff's comment and confirms that, once it has an estimated offering price range, it will supplementally provide an explanation to the Staff of the reasons for any differences between recent valuations of its common stock leading up to the planned initial public offering and the midpoint of its estimated offering price range.

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.*

Response to Comment 16*:* In response to the Staff's comment, the Company has revised the disclosure on pages 106-107 of Amendment No. 1 to disclose the primary and secondary endpoints for each trial, where each trial was conducted, which of the Company's trials were powered for statistical significance and if any serious adverse events were observed while conducting each trial.

May 15, 2024

Business
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.*

Response to Comment 17: The Company acknowledges the Staff's comment and intends to address the status of enrollment in the INDIGO and SApHiAre trials in a future amendment to the Draft Registration Statement.

Business
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.*

Response to Comment 18: In response to the Staff's comment, the Company has revised the disclosure on pages 125, 126 and 128 of Amendment No. 1.

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.*

Response to Comment 19: The Company acknowledges the Staff's comment and respectfully advises the Staff that none of the Dianthus Agreements or the Viridian Agreements is material to the Company's business or a material contract within the meaning of Item 601 of Regulation S-K, because the Company is not substantially dependent on any of these agreements. The Company included disclosure regarding the agreements with Dianthus and Viridian in the Draft Registration Statement to clarify the Company's relationship with each such party and the source of certain of the Company's expenses.

The Company does not believe that any of the Dianthus Agreements or the Viridian Agreements is material to its business because these agreements relate to the in-license of rights to develop certain monoclonal antibodies in greater China, and such development is not material to the Company's business strategy. Specifically, as disclosed on pages 81, 101 and 121 of Amendment No. 1, following the initial clinical development of each product candidate, the Company intends to seek to enter into an agreement with a third party who could complete the clinical development work, obtain regulatory approval and ultimately, if approved, commercialize these programs in greater China. The Company does not plan to itself develop or commercialize any product candidate, including ZB001 and ZB005, in greater China. Furthermore, each of these agreements did not require the Company to incur material expense during the three months ended March 31, 2024 or the year ended December 31, 2023. Specifically, the Company incurred expenses of $1.0 million and no expense for the three months ended March 31, 2024 pursuant to the Dianthus Agreements and Viridian Agreements, respectively, compared to $22.6 million of total Company research and development expenses for the period, accounting for approximately 4.4% of such research and development expenses. Additionally, the Company incurred expenses of $3.0 million and $0.1 million for the year ended December 31, 2023 pursuant to the Dianthus Agreements and the Viridian Agreements, respectively, compared to $60.0 million of total Company research and development expenses for the year, which means that the Dianthus Agreements and Viridian Agreements together only accounted for approximately 5% of the Company's research and development expenses in 2023. Further, the Company anticipates that expenses related to these agreements will decrease relative to the Company's overall research and development expenses, particularly given the Company's development plans for obexelimab.

The Company does not expect to receive significant payments pursuant to these agreements. The only near-term payment that the Company expects to receive from Dianthus or Viridian is pursuant to the Company's agreement to support Viridian as it conducts its Phase 3 THRIVE-2 and Global Safety Trials in China. Specifically, the Company will conduct clinical operations activities in China and Viridian will reimburse the Company for the costs incurred. These pass through costs may be accounted for by the Company as revenue, but such payments are not expected to be material to the Company. The Company does not otherwise derive revenue from these assets currently, nor does it expect to do so in the near term, and, as discussed earlier, the Company does not expect either to be a material part of the Company's development plans.

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.*

CONFIDENTIAL TREATMENT REQUESTED BY ZENAS BIOPHARMA, INC. UNDER 17 C.F.R. §200.83 FOR REQUEST NO. 1

Response to Comment 20: In response to the Staff's comment, the Company has revised the disclosures on pages F-21-F-22 of Amendment No. 1 and has provided the below additional analysis with regard to the Staff's comment.

The Company's agreement with Bristol Myers Squibb ("BMS") allows for BMS to participate in global studies that the Company intends to perform. Global studies are defined as clinical studies that are designed to obtain regulatory approval of obexelimab in multiple jurisdictions. Currently, the Company's only global study is the Phase 3 clinical trial for IgG4-RD. Additional global studies related to obexelimab, if any, would also be subject to the terms of the agreement. A Joint Steering Committee ("JSC") that includes equal representation of the parties, was formed to oversee the parties' activities under the agreement, including performance of any joint global studies (those studies in which BMS elects to participate). With regard to any joint global studies (including the IgG4-RD Phase 3 clinical trial), both the Company and BMS are active participants with specific roles and responsibilities assigned to each party, and these joint activities will benefit both the Company and BMS and will be used by the parties to obtain regulatory approval in their respective jurisdictions. The Company is the global study sponsor and provides study design and protocol. As the sponsor, Zenas will be responsible for all planning, management and oversight of the study as well as research plan development. Outside of the BMS Territory, the Company will lead local regulatory interactions, have oversight of study management and operations, lead interactions with investigators and ethics boards, and oversee third parties that perform development activities. BMS is the sponsor within the BMS Territory, and will lead local regulatory interactions, has oversight of study management and operations, and will lead interactions with investigators and ethics boards. BMS is part of the global study team and has the right to review and comment on the study design and protocol and has input into vendor and clinical trial site selection. Both parties also are required to share data related to the study.

ASC 606-10-15-3 defines a customer as "*a party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities in exchange for consideration*." The Company also considered the FASB and IASB basis for conclusions for ASC 606, in particular paragraph BC54, which indicates in part that "*The Boards observed that in many arrangements highlighted by respondents, an entity would need to consider all relevant facts and circumstances, such as the purpose of the activities undertaken by the counterparty, to determine whether the counterparty is a customer. Examples of arrangements in which an entity would need to make that assessment are as follows: a. Collaborative research and development efforts between biotechnology and pharmaceutical entities or similar arrangements in the aerospace and defense, technology, and healthcare industries, or in higher education.*"

In applying the guidance above, the Company first considered the overall purpose of the collaboration on the joint global studies, and in particular the IgG4-RD Phase 3 clinical trial, which is to work together toward the common goal of successful completion of the trial, facilitating commercialization in the respective territories. The activities performed pursuant to the agreement are defined between the parties and overseen by the JSC. Further, the costs of the IgG4-RD Phase 3 clinical trial are shared between the parties with each party responsible for its proportionate share up to a cap [***] based on patient enrollment in the BMS Territory. Accordingly, the structure of the arrangement is to collaborate and share the costs of the study rather than Zenas performing specified services, the output of which are transferred to BMS. Both parties share in the risks and benefits of the study, which is representative of a collaborative arrangement rather than that of a vendor-customer. Zenas chose to partner with BMS in a strategic partnership, as BMS is an established global pharmaceutical company that has extensive experience running clinical trials globally, and especially in the Territory, which will provide Zenas with valuable knowledge and support, while facilitating the successful completion of the study. While certain of the activities specified above are those that the Company regularly performs to complete its own research and development efforts, in this case, the Company is performing them jointly with another party such that each party benefits from the collective efforts of both. This structure and separation of the responsibility for research and development activities is not consistent with Zenas' ordinary activities. Accordingly, the Company concluded that this is not indicative of BMS receiving the output of the Company's ordinary activities, and is consistent with the guidance contained in ASC 606-10-15-3.

During the development stage (including the IgG4-RD Phase 3 clinical trial and any other global studies deemed to be part of the collaboration), both parties will incur significant costs to support the development in their respective territories. The risk will be shared by both parties with each party bearing a portion of the costs in proportion to its own territory enrollment. During the commercial stage, BMS will bear all costs and receive all profits associated with commercial sales in the BMS Territory, and will owe milestones and royalties to the Company. The Company will bear all costs and receive all profits outside of the BMS Territory, plus milestones and royalties due from the BMS Territory. There is no limit on the reward to either party, and as such, both parties share in the risks and rewards of the arrangement.

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.*

Response to Comment 21: In response to the Staff's comment, the Company has revised the disclosures throughout Amendment No. 1 to quantify the extent of the Company's operations in China.

General

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.*

Response to Comment 22: The Company advises the Staff that it will supplementally provide all written communications that are provided to potential investors in reliance on Section 5(d) of the Securities Act, if any.

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Please do not hesitate to call me at (617) 235-4961 or Nicholas Roper at (617) 951-7116 with any questions or further comments you may have regarding this filing or if you wish to discuss the above responses.

Sincerely,

/s/ Thomas J. Danielski

cc. Leon O. Moulder, Jr. (Zenas BioPharma, Inc.)
cc. Joseph Farmer (Zenas BioPharma, Inc.)
cc. Nicholas Roper (Ropes & Gray LLP)
cc. Richard Segal (Cooley LLP)
cc. Denny Won (Cooley LLP)