



DIVISION OF  
CORPORATION FINANCE

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

September 27, 2023

Zhengbin (Bing) Yao, Ph.D.  
Chief Executive Officer  
ArriVent Biopharma, Inc.  
18 Campus Boulevard, Suite 100  
Newtown Square, PA 19073

**Re: ArriVent Biopharma, Inc.**  
**Draft Registration Statement on Form S-1**  
**Submitted August 25, 2023**  
**CIK 0001868279**

Dear Zhengbin (Bing) Yao:

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

Prospectus Summary

Overview, page 1

1. We note that furmonertinib is currently approved in China to treat classical EGFRm NSCLC. Please revise to clarify all statements related to safety and efficacy to clarify that they only relate to classical EGFRm NSCLC and are based on NMPA's authority to approve biopharmaceutical products in China. Remove all other statements related to safety and efficacy from your registration statement. Such conclusions are within the sole authority of the FDA or equivalent foreign regulator. Such statements include, but are not limited to, the following:
  - "Furmonertinib. . .has demonstrated compelling efficacy and safety results in clinical

trials in NSCLC patients across a broader set of EGFR mutations (EGFRm) than are currently served by approved AGFR TKKIs." (pages 1 and 95);

- "In clinical trials to date, across a patient population of over 700 patients, furmonertinib has demonstrated compelling activity against a broad range of EGFRm NSCLC, including both classical and uncommon EGFRm. . ." (page 2);
- "Furmonertinib retains many of the key advantages of third-generation EGFR TKIs compared to first- and second-generation EGFR TKIs including overcoming T790M mutations that confer resistance, while also targeting a broader set of EGFRm." (page 108);
- "Furmonertinib is potentially differentiated from third-generation EGFR TKIs approved for classic EGFRm NSCLC by its observed clinical activity against exon 20 insertions in FAVOUR clinical trial and compelling preclinical data against PACC mutations." (page 108).

You may reference your trial observations that are described in more detail elsewhere without drawing a conclusion that a product candidate that has not yet been approved is effective.

2. Please revise the description of clinical trials to describe the objective results, rather than your conclusions. For example, rather than indicating that the FAVOUR trial demonstrated a 79% overall response rate, identify the clinical endpoints that lead you or Allist to conclude that it was a positive response and indicate the number of such observations. For instance, was the overall response rate intended to indicate an elimination of all tumors, a reduction in the number of tumors, a reduction in size of the tumors, a decline in growth in the number of size of tumors, or some other measure?
3. Please balance your discussion of the results of the ongoing Phase 1b clinical trial (the FAVOUR trial) with disclosure that these are interim results are subject to change. We note disclosure to this effect on pages 24 and 121.
4. We note your reference to "compelling" safety results. It is inappropriate to state or imply that a product that is still in clinical trials is safe. Generally, we will allow statements that there have been no serious adverse events. However, we note your disclosure indicating that there were treatment-related adverse events that resulted in trial participants discontinuing their participation in the FAVOUR trial; 5.6% of FURLONG trial participants experienced Grade 3 treatment-related adverse events; and 6 FAVOUR trial participants experiencing serious adverse events and 12 participants experiencing Grade 3 or higher treatment-related events. We note that Grade 3 events are generally defined as severe or medically significant, requiring hospitalization or prolongation of hospitalization, or disabling. A serious adverse event is generally defined as one resulting in death, life threatening situation, hospitalization (initial or prolonged), disability or permanent damage. Please revise your summary to quantify the number of events that met the definition of serious adverse events and quantify the number of occurrences. Similarly, revise your risk factor titled "Use of furmonertinib or any future product candidates could be associated with adverse side events or other safety risks, which could

delay or preclude regulatory approval..." appearing on page 21 to describe the number of events that meet the definition of serious adverse event, including all events that require hospitalization or result in a prolonged hospitalization, and the number of each type of event, and quantify the number of participants who discontinued their participation due to treatment-related adverse events.

Our Pipeline, page 2

5. We note your pipeline table currently indicates you have completed Phase 1 and Phase 2 clinical trials for 1L NSCLC EGFR Exon 20 INS Mutations. However, it appears that the FURTHER and FAVOUR clinical trials are Phase 1b trials for Exon 20 and PACC. Additionally, there is no disclosure of your Phase 2 trial for 1L NSCLC EGFR Exon 20 Ins Mutations. Please explain why you believe the table reflects the current status of your development of 1L NSCLC EGFR Exon 20 Ins Mutations. If you have conducted a Phase 2 trial, please describe it and the objective results of the trial.

Our Furmonertinib Development Initiative, page 3

6. The sub-heading states that this is "[y]our Furmonertinib Development Initiative" and that you "have designed a robust global clinical development plan[]," but we note that the table includes clinical trials sponsored by third-parties Allist and InnoCare that appear unrelated to your current pipeline. Please clarify how these clinical trials related to your furmonertinib programs. To the extent they relate to separate Allist and Innocare programs, unrelated your current pipeline, explain why they are part of your development initiative and why it is appropriate for you to include them in this table. Alternatively, remove them from the clinical trial table. Please also define the terms "1L" and "2L+" used in the table included in this section.
7. Additionally, explain what additional information this table provides. It appears the table is largely redundant of your pipeline table, but in a different format. For example, with respect to your Furvent trial, your pipeline table already indicates you are in Phase 3 trials related to the treatment of 1L NSCLC EGFR Exon 20 Ins Mutations, and your next milestone is topline data. With respect to the additional data, such as the information about the FURLONG trial, it is not clear how it relates to your candidates in development.

Our Team and Approach , page 4

8. Please limit the disclosure of specific investors on this page to those identified in the Principal Stockholder table on page 173. Unlike the other investors mentioned on this page, General Catalyst does not appear to be included in the Principal Stockholder table.

Risk Factors

Several of the ongoing clinical trials for our lead product candidate, furmonertinib, are being conducted outside the United States. . . , page 23

9. Please specify which ongoing clinical trials for furmonertinib are being conducted outside of the United States.

If we are required by the FDA to obtain approval of a companion diagnostic in connection with approval of any of our product candidates..., page 36

10. To the extent you have any reason to believe the approval of a companion diagnostic device will be required in connection with any of your product candidates, please expand your disclosure to discuss the circumstances. For example, given that many of your programs are studying the efficacy of furmonertinib for NSCLC in patients with specific mutations, is it likely that a companion diagnostic will be required to determine whether a patient has the specific mutation or a diagnostic test to make such a determination readily available?

Use of Proceeds, page 87

11. As you are advancing your development of furmonertinib for three different NSCLC indications, please revise your use of proceeds to discuss the proceeds you intend to use to advance each of these programs and specify how far in the clinical development process you expect to reach with the proceeds of this offering.
12. We note that you intend to devote proceeds from the offering to pre-commercial and commercial activities of furmonertinib. Please clarify if this use is with respect to furmonertinib 1L NSCLC EGFR Exon m20 Ins Mutations. Additionally, clarify that these activities are contingent on successful completion of Phase 3 trials. Clarify that any commercial activities are contingent on receiving regulatory approval.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Results of Operations

Research and Development, page 98

13. You disclose here that you track outsourced clinical and preclinical study costs and other external research and development costs associated with your lead product candidate, furmonertinib. You also disclose elsewhere that furmonertinib is currently being evaluated in multiple clinical trials across a range of epidermal growth factor receptor (EGFR) mutations in non-small cell lung cancer (NSCLC), including a pivotal Phase 3 clinical trial in exon 20 insertion mutations. Please revise to further disclose the research and development expenses you tracked for furmonertinib by each individual clinical indication, or if you do not track by indication, disclose that fact. Please also expand your fluctuation disclosures here to provide more robust quantitative or qualitative discussions about change drivers, trend and uncertainties. Refer to Item 303(b)(2) of Regulation S-X.

Liquidity and Capital Resources

Cash Flows, page 102

14. You disclose here that your net cash used in operating activities for 2021 includes a \$42.9 million *non-cash* charge for acquired in-process research and development related to the Allist License Agreement. Since \$40.0 million of the \$42.9 million was a cash payment, revise to quantify the amount of cash versus non-cash payments in the total.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Determination of Fair Value of Our Common Stock, page 104

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.

Overview, page 107

16. Delete your statement that furmonertinib has the potential to become the standard of care in first-line EGFRm NSCLC patients with PACC mutations given preclinical activity observed against these mutations together with its safety results in clinical trials. Such statements inappropriately assume regulatory approval and results relative to alternative treatments.

Our Furmonertinib Development Initiative, page 109

17. Please clarify whether anti-tumor activity is a reduction in tumors or no growth in tumors. Additionally, quantify the low rate of discontinuation due to treatment-related adverse events.

Our Strategy, page 111

18. We note your statement that "the data obtained as of June 15, 2023 in your Phase 1b FAVOUR clinical trial. . .supports the use of furmonertinib as a first line therapy." We also note that, according to your table appearing on pages 3 and 109, this Phase 1b is still ongoing, is intended to be a proof of concept trial, and the use of furmonertinib has not yet been approved for exon 20. Please delete this statement and all similar statements of efficacy.

FAVOUR - Ongoing Phase 1b Clinical Trial in NSCLC Patients with EGFR Exon 20 Insertion Mutations, page 120

19. Please explain the meaning of the following:
- "ORR per RECIST 1.1 by BICR;" and
  - "OS."
- Additionally, quantify the secondary end points and provide data from the trials so that a reader will be able to determine if the end points were met.
20. Please clarify the meaning of ECOG in the table on page 121.

FURLONG - Completed Phase 3 Clinical Trial in Classical EGFRm First-Line NSCLC Patients, page 125

21. With respect to the FURLONG clinical trial in China, please confirm the trial was a head-to-head trial with gefitinib. Alternatively, remove the comparisons to gefitinib.

Licenses, Partnerships and Collaborations, page 128

22. Please revise this section to include your collaboration with Beijing InnoCare Pharma Co., Ltd. This disclosure should:
- describe the collaboration goal(s);
  - identify the pipeline assets related to the collaboration, and;
  - describe and quantify the benefits and obligations under any collaboration agreement, including quantifying payments made to date, aggregate potential milestone payments, royalty rates or applicable ranges, and term and termination provisions.
- If there is a written agreement underlying this collaboration, please file this agreement as an exhibit to the registration statement. Refer to Item 601(b)(10) of Regulation S-K.
23. Please clarify when your obligation to pay royalties for all licensed products expires.

Aarvik Research Collaboration Agreement, page 130

24. Please clarify how the research agreement is funded.
25. Please quantify the amount of the "one-time non-refundable payment," that you would need to make to Aarvik if you exercised the Option.
26. Disclose when the obligation to pay royalties will expire if you exercise the Option.

Manufacturing, page 131

27. Please specify whether your two third-party contract manufacturers, Zhejiang Raybow Pharmaceutical Company, Ltd. and WuXi SynTheAll Pharmaceutical company, Ltd., are located in China.

Principal Stockholders, page 173

28. Please identify in a footnote to the table all natural persons who have voting and/or investment power over the shares held by LAV Fund VI, L.P. and the entities affiliated with Octagon Capital Advisors LP and Hillhouse Investment Management, Ltd.

Financial Statements

Note 7. Convertible Preferred Stock and Common Stock

Convertible Preferred Stock, page F-12

29. You report the Series A and B convertible preferred stocks as permanent equity. Please respond to the following comments:
- Provide us with your analysis of the applicable guidance to support your conclusion that these convertible preferred stocks should not be classified as temporary equity following ASC 480-10-S99-3A. In that regard, we note your Certificate of Incorporation as filed under Exhibit 3.1 includes redemption clauses under situations including deemed liquidation.
  - Revise to expand your disclosures to include all key terms for these convertible preferred stocks, including any redemption features, as well as any adjusting mechanism for their conversion price.
  - Revise to disclose in the equity section of the statement of financial position the aggregate amount of liquidation preference of these convertible preferred stocks if considerably in excess of the par or stated value of the shares. Refer to ASC 505-10-50-4.

Note 11. Allist License Agreement, page F-17

30. Please revise to address the following:
- Revise this section and elsewhere as appropriate to disclose the financial arrangements under the Joint Clinical Collaboration Agreement, including how costs and profit are shared between parties.
  - Tell us your consideration whether the agreement is subject to ASC 808, *Collaborative Arrangements*.
  - If so, please revise to provide all the required disclosures under ASC 808-10-50, including any profit sharing arrangement.
  - For the research and development expenses related to the Clinical Collaboration with Allist as you disclosed here, please also revise to disclose the nature of the costs and their related global clinical studies.

Zhengbin (Bing) Yao, Ph.D.  
ArriVent Biopharma, Inc.  
September 27, 2023  
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General

31. 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.

You may contact Li Xiao at 202-551-4391 or Kevin Vaughn at 202-551-3494 if you have questions regarding comments on the financial statements and related matters. Please contact Dillon Hagius at 202-551-7967 or Suzanne Hayes at 202-551-3675 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: John Rudy