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October 31, 2023

VIA EDGAR

Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Washington, D.C. 20549 Attention: Dillon Hagius and Suzanne Hayes, Office of Life Sciences

Re: ArriVent BioPharma, Inc. Amended Draft Registration Statement on Form S-1 Submitted October 4, 2023 CIK No. 0001868279 (the "Amended Draft Registration Statement")

Ladies and Gentlemen:

We are submitting this letter on behalf of ArriVent BioPharma, Inc. (the "**Company**") in response to comments from the staff (the "**Staff**") of the U.S. Securities and Exchange Commission (the "**Commission**") received by letter dated October 18, 2023 (the "**Comment Letter**") from the Division of Corporation Finance, Office of Life Sciences, to Zhengbin (Bing) Yao, Ph.D., President and Chief Executive Officer of the Company, relating to the above-referenced Amended Draft Registration Statement. In conjunction with this letter, the Company is confidentially submitting its Amendment No. 2 to its draft registration statement on Form S-1 (the "**Registration Statement**") with the Commission.

For reference, we have set forth below in italics each of the Staff's comments from the Comment Letter and have keyed the Company's responses to the numbering of the comments and the headings used in the Comment Letter. All of the responses are based on information provided to Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. by representatives of the Company. Where appropriate, the Company has responded to the Staff's comments by making changes to the disclosure in the Registration Statement. Page numbers referred to in the responses reference the applicable pages of the Registration Statement.

BOSTON LOS ANGELES NEW YORK SAN DIEGO SAN FRANCISCO TORONTO WASHINGTON MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.



Amendment No. 1 to Draft Registration Statement on Form S-1

Prospectus Summary Overview, page 1

<u>Comment 1</u>: We note your response to comments 1 and 2. However, you continue to make statements relating to safety and efficacy related to ongoing clinical trials of furmonertinib. Please note, we do not object to statements indicating that trial participants experienced a measured reduction in tumor size of at least 30%, but object to statements indicating that the trial demonstrated a 79% overall response rate. Your objective observations should not conclude that the results were due to your product candidate. Such a determination of efficacy is a determination that is within the sole authority of the FDA or equivalent foreign regulator. Please revise the following statements accordingly:

- "furmonertinib demonstrated a 79% (n=22 out of 28 patients) confirmed overall response rate ... and a 15.2 month median duration of response." (page 1, 95 and 107);
- furmonertnib demonstrated an ORR of 91% and progression free survival of 20.8 months in first generation EGFR TKI (page 108) and
- "Phase 1b FAVOUR clinical trial, in which furmonertinib demonstrated a reduction in tumor size of at least 30% from the baseline in 79% of the first-line patients..." (page 112)

Similarly remove all other statements of efficacy. You may replace them with objective information about the results from the trial without indicating the conclusion that the observed results "demonstrate" a cause and effective relationship between the product candidate and the observation.

<u>Response 1</u>: The Staff's comment is acknowledged, and the Company has revised the disclosure on pages 1, 97, 110, 115 and 120-126 of the Registration Statement.

Comment 2: Clearly state in the summary that the FDA has not approved furmonertinib for any use.

Response 2: The Staff's comment is acknowledged, and the Company has revised the disclosure on pages 1, 97, and 110 of the Registration Statement.

<u>Comment 3</u>: We note your response to comment 4 and re-issue the comment. With respect to the number of serious adverse events, please explain why adverse events at a Grade 3 or greater are not all serious adverse events, given the definition of Grade 3 treatment related adverse events as severe or medically significant, requiring hospitalization or prolongation of hospitalization, or disability. We note your FAVOUR trial results indicate 17 Grade 3 or higher treatment related adverse events and 6 adverse events. Please explain how an adverse event met the definition of Grade 3 without meeting the definition of serious adverse event. Additionally, balance your disclosure that furmonertinib "has been observed to be generally well tolerated" in multiple clinical trials with a description of all serious adverse events, as opposed to the most common events, and quantify the number of such events.

<u>Response 3</u>: The Staff's comment is acknowledged, and the Company has revised the disclosure on page 21 of the Registration Statement to define more clearly the distinct measures of adverse event severity (grades 1 through 5) and the definition of serious adverse event. The Company notes that "severe adverse event" and "serious adverse event" are not synonymous, which may result in certain severe adverse events (*i.e.*, those that are Grade 3) not also being deemed serious adverse events. The Company has also revised the disclosure on pages 2, 21, 127, and 130 to describe and quantify all of the treatment-related serious adverse events (TRSAEs) and treatment-emergent serious adverse events (TESAEs) for the clinical trials that are referenced. In addition, the Company has deleted statements that furmonertinib has been observed to be generally well tolerated except on pages 3, 4, 112, 115, and 127, where it is balanced by the expanded discussion of the TRSAEs and TESAEs on pages 2, 21, 127, and 131.

<u>Comment 4</u>: We note your disclosure that you selected furmonertinib for global development against nonclassical mutations based on "preliminary clinical activity" observed in exon 20 insertion mutations. Please revise to clarify the nature of this clinical activity (e.g., the clinical stage and number of subjects). If you are referring to clinical trials mentioned in the filing, please so specify.

<u>Response 4</u>: The Staff's comment is acknowledged, and the Company has revised the disclosure on pages 1, 2, 4, 97, 110, 111, and 115 of the Registration Statement.

Our Pipeline, page 2

<u>Comment 5</u>: We note your response to comment 5. However, we note that your Furmonertnib Development Initiative table on pages 3 and 109 indicates that the FAVOUR trial in an ongoing Phase 1b trial related to Exon 20 1L. While the FDA may have agreed that to your plan to proceed from your Phase 1 to your pivotal Phase 3 trial, it appears from the Development Initiative Table that all Phase 1 trials have not yet been completed. Please explain why your pipeline table indicates that Phase 1 trials have been completed when the Development Initiative table indicates that a 1b trial is ongoing or revise your pipeline table to clarify that you have not completed all Phase 1 trials.

<u>Response 5</u>: The Staff's comment is acknowledged, and the Company has revised the disclosure on pages 2 and 111 to specify that the pipeline table indicates the most advanced stage of development for each development program. Furthermore, the Company has revised the disclosure on pages 2, 97, 110, 111, and 112 to clarify the status of the clinical trials corresponding to the indications in the pipeline table.

Our Furmonertinib Development Initiative, page 3

<u>Comment 6</u>: We note you have included studies in your Development Initiative table that do not appear to correlate with items in your pipeline table. For example, the Development Initiative table indicates your FURTHER trial is a Phase 1b trial relating to second line treatment of Exon 20 and first and second line treatment of PACC. However, your pipeline table does not indicate the development of second line treatment for Exon and PACC. Similarly your disclosed intention to pursue Adjuvant trials is not related to a current pipeline program. Please limit the trials presented in the Development Initiative table to your currently material programs and move the information about your plans for trials related to future programs out of the Summary and into the Business section.

<u>Response 6</u>: The Staff's comment is acknowledged, and the Company has revised the disclosure on pages 2, 4, 111, 112, 115, including the addition of a footnote to the pipeline table on pages 3 and 112 of the Registration Statement, to clarify that the FURTHER trial also includes cohorts of second line patients with EGFR exon 20 insertion mutations and PACC mutations. This information is also included in the FURTHER trial description on pages 122 and 123 of the Registration Statement. As noted above in the response to Comment 5, the Company has also revised the disclosure on pages 2 and 111 to specify that the pipeline table indicates the most advanced stage of development for each development program and to clarify the status of the trials corresponding to the indications in the pipeline table. With respect to the planned clinical trial in the adjuvant setting, the Company has removed this trial from the Development Initiative table on pages 3 and 112 of the Registration Statement.

<u>Comment 7</u>: With respect to trials that relate to different EGFRm Patient Populations, please clarify whether you expect to perform one trial that will serve the needs of both indications or if you will conduct two separate trials. For example, with respect to Adjuvant, do you expect to conduct separate trials for Exon 20 and PACC or do you expect to conduct one trial for both Exon and PACC?

<u>Response 7</u>: The Staff's comment is acknowledged, and the Company has revised the disclosure on pages 4 and 129 of the Registration Statement to note that the Company currently believes that it will be possible to conduct a single clinical trial in the adjuvant setting comprising both EGFR Exon 20 and EGFR PACC patients.

Comment 8: Explain the meaning of the term "Gated" future planned study in 1L.

Response 8: The Staff's comment is acknowledged, and the Company has revised the disclosure on pages 3 and 112 of the Registration Statement.

Our Strategy, page 3

<u>Comment 9</u>: We note your disclosure on page 4 that you intend to initiate a Phase 3 clinical trial to investigate the potential benefit of furmonertinib in the adjuvant setting. We also note tabular disclosure concerning this "planned" Phase 3 trial on page 3 and disclosure on page 110 that you "intend to pursue an adjuvant study of furmonertinib in EGFRm NSCLC with uncommon mutations based on results obtained from currently ongoing clinical trials." Please tell us if you have discussed your plan to proceed directly to a Phase 3 trial. If you have not, please discuss the risks that the FDA may require earlier stage clinical trials prior to a Phase 3 trial.

<u>Response 9</u>: The Staff's comment is acknowledged, and the Company has revised the disclosure on pages 4, 17, and 116 to note that the Company has not yet sought alignment on the design of the planned adjuvant study with the FDA or comparable foreign regulatory authorities. As noted in the revised disclosure on pages 4, 17, and 116 such authorities may ask the Company to collect more clinical data prior to permitting the Company to initiate the planned global registrational Phase 3 clinical trial to investigate the potential benefit of furmonertinib in the adjuvant setting.

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

<u>Comment 10</u>: We note your response to comment 10. Given your disclosure on page 114 indicating that you are utilizing an NGS test for confirming mutations that already is approved and you believe it can be used if furmonertinib is approved. Please revise this risk factor to clarify the basis for your concern that the FDA may require you to obtain approval of a companion diagnostic and why it may object to any of the already approved tests for confirming mutations. To the extent the risk factor discussion applies to future product candidates, please clarify.

<u>Response 10:</u> The Staff's comment is acknowledged, and the Company has revised the disclosure on pages 37 and 117 to clarify that the Company is working with a diagnostics company to develop a diagnostic for FDA approval to identify patients with EGFR Exon 20 insertion mutations, that Company may be required to pursue a similar approach for EGFR PACC mutations, and that the risks identified in this risk factor discussion apply to these planned and potential diagnostics.

Our Strategy, page 112

<u>Comment 11</u>: We note your response to comment 18. However, your revised disclosure that "a 240 mg once-daily dose of furmonertinib demonstrated a reduction in tumor size of at least 30% from the baseline in 79% of first-line patients" inappropriately indicates that the furmonertineb is effective. You may indicate that 79% of the first line patients in the study who were taking a 240 mg once-daily dose of furmonertinib experienced a 30% reduction in tumor size, but you may not indicate your conclusions of cause and effect.

Response 11: The Staff's comment is acknowledged, and the Company has revised the disclosure on page 115 of the Registration Statement.

Licenses, Partnerships and Collaborations, page 128

<u>Comment 12</u>: We note your response to comment 22 and re-issue the comment. Please revise this section to include a discussion of your agreement with Beijing InnoCare Pharma Co., Ltd. Your discussion should describe the cost-sharing arrangement, including each party's rights and obligations including how much of the costs each party is obligated to fund and what rights, if any, each party will have to the data resulting from the trial. To the extent that Innocare, has any rights to furmontinib, as a result of any of your agreements with

Innocare or any agreements between Innocare and Allist, please describe such rights. Additionally, please remove or explain the references to Innocare as your "partner" or "collaboration partner" in the pipeline table and throughout your filing. Given our response indicating that your agreement with Innocare is primarily limited to a cost sharing arrangement, it does not appear appropriate to refer to it as a partner, collaborator or to indicate that you are developing furmonertinib with a SHP2 inhibitor ICP-189 with Innocare.

Additionally, provide us with an analysis supporting your conclusion that you are not substantially dependent on your cost sharing agreement with Innocare. Your analysis should address your ability to finance the clinical study on your own given your other financial obligations.

<u>Response 12</u>: The Staff's comment is acknowledged, and the Company has revised the disclosure on page 136 of the Registration Statement to describe the material terms of the Clinical Collaboration Agreement by and between the Company and Beijing InnoCare Pharma Co., Ltd. ("InnoCare" and the "InnoCare Collaboration Agreement") and has filed it as an exhibit to the Registration Statement pursuant to Item 601(b)(10) of Regulation S-K. In connection with description of the material terms of the InnoCare Collaboration Agreement and its filing as an exhibit to the Registration Statement pursuant to Item 601(b)(10) of Regulation S-K, the Company notes that the InnoCare Collaboration Agreement is necessary for the Company to be able to conduct a joint Phase 1b clinical trial to assess the combination of furmonertinib with ICP-189, a SHP2 inhibitor, in collaboration Agreement and as described in the Registration Statement, the Company respectfully informs the Staff that as provided for in the InnoCare Collaboration Agreement and as described in the Registration Statement, the Company's development of furmonertinib in combination with InnoCare's SHP2 inhibitor ICP-189 is a collaboration with InnoCare in which the clinical trial is being jointly conducted by InnoCare and the Company. As a result, the Company has continued to refer to InnoCare as a partner or collaboration partner of the Company in the Registration Statement.

Aarvik Research Collaboration Agreement, page 130

<u>Comment 13</u>: We note your responses to comments 24 and 25 and re-issue in part. Please quantify all amounts paid to Aarvik to date and explain how the amounts of your "certain research costs and expenses" will be determined, for example have you agreed to fund all research costs and expenses, 50% of such research costs and expenses or certain specific costs and expenses. Given that they are estimates, if such amounts have already been estimated, please quantify these amounts.

<u>Response 13</u>: The Staff's comment is acknowledged, and the Company has revised the disclosure on page 135 of the Registration Statement. As described in the Registration Statement, the amounts of research costs and expenses are set out in the statements of work attached as annexes to the agreement itself and the Registration Statement discloses on page 135 of the Registration Statement the maximum amount that the Company may owe pursuant to such statements of work.

<u>Financial Statements</u> <u>Note 7. Convertible Preferred Stock and Common Stock</u> <u>Convertible Preferred Stocks, page F-12</u>

<u>Comment 14</u>: Please address the following regarding your response to our prior comment 29 and the related revisions made in the financial statements:

- The exception discussed in ASC 480-10-S99-3A3(f) requires that all holders of equally and more subordinated equity instruments would always be entitled to also receive the same form of consideration. Tell us in detail how you evaluated whether there were other hypothetical situations in which the holders of all equity instruments might not receive the same form of consideration.
- Your conclusion that a Deemed Liquidation Event is solely within the control of the Company appears to be partially based on the assumption that an insufficient redemption amount would cause inherent conflict in economic interest between the Series A and Series B shareholders such that they would never be incentivized to act in concert against the interests of the common shareholders. Please further explain to us how you considered a hypothetical situation where a prospective buyer offers to buyout all your licenses (product candidates) for an amount just sufficient to redeem the full amount for both Series A and B shareholders. Note that under ASC 480-10-S99-3A paragraph 5, the possibility that any triggering event that is not solely within the control of the issuer could occur—without regard to probability—would require the instrument to be classified in temporary equity.



MINTZ

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<u>Response 14</u>: The Staff's comment is acknowledged. Based on further review of ASC 480-10-S99, the Company has assessed that the deemed liquidation events were not solely within the control of the Company subsequent to the second closing of the Series A convertible preferred stock in February 2022 and as of December 31, 2022 and, as a result, the Company has restated its December 31, 2022 financial statements to present the Series A and B convertible preferred stock as temporary equity. This restatement is described and/or disclosed:

- in the Report of Independent Registered Public Accounting Firm on page F-2 of the Registration Statement, which has been dual dated to reflect the restatement; and
- on the face of the balance sheet as of December 31, 2022 and the statements of convertible preferred stock and stockholders' equity (deficit) for the fiscal year ended December 31, 2022 and in Note 3(a) to those financial statements on pages F-3, F-7 and F-8 of the Registration Statement.

The Company has also noted the restatement in connection with the Company's description of its material weaknesses in it its internal controls on pages 6, 80, 81, 82, 108, and 109 of the Registration Statement. The Company has assessed that the occurrence of a deemed liquidation event is not currently probable and therefore the carrying values of the Series A and B convertible preferred stock are not being accreted to their redemption values.

With respect to the financial statements for the fiscal year ended December 31, 2021, prior to the second closing of the Series A convertible preferred stock in February 2022, the Series A investors could not control the vote of the board of directors through direct representation or through other rights. Prior to the second closing in February 2022, and as of December 31, 2021, the board of directors was contractually required to consist of, and did consist of:

- one director designated by VSUM VI Holdings Limited ("VSUM") for so long as VSUM continued to own beneficially an aggregate of at least 50% of the number of shares of Series A Preferred Stock originally issued to VSUM;
- one director designated by the holders of at least 55% of the shares of the Series A Preferred Stock, provided that such director is mutually and reasonable acceptable to each of Zhengbin Yao (the Chief Executive Officer of the Company and a common stockholder) and VSUM;
- one director designated by the holders of a majority of the shares of Common Stock outstanding; and
- Zhengbin Yao, the Chief Executive Officer of the Company and a common stockholder, who was also designated Chairman of the Board and was contractually provided with two votes for any matter before the Board, with the other directors possessing one vote.

As a result of the foregoing, the Series A investors had rights to only two of five board votes, with the common stockholders holding rights to the other three board votes. As such, the deemed liquidation events were solely within the control of the Company as of December 31, 2021 and, consequently, the Series A convertible preferred stock is presented within permanent equity as of December 31, 2021 in accordance with ASC 480-10-S99.

We hope that the above response will be acceptable to the Staff. Please do not hesitate to call me at (617) 348-3050 with any comments or questions regarding the proposed disclosure. We thank you for your time and attention.

Sincerely,

/s/ John T. Rudy John T. Rudy

cc: <u>Securities and Exchange Commission</u> Li Xiao Kevin Vaughn

> <u>ArriVent BioPharma, Inc.</u> Zhengbin (Bing) Yao, Ph.D. Robin LaChapelle James Kastenmayer

<u>Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.</u> Matthew T. Simpson

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