United States securities and exchange commission logo

October 18, 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.
Amended Draft Registration Statement on Form S-1
Submitted October 4, 2023
CIK 0001868279

Dear Zhengbin (Bing) Yao:

We have reviewed your amended draft registration statement and have the following comment(s).

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.

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

Prospectus Summary
Overview, page 1

1. 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." (pages 1, 95 and 107);

furmonertinib 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.

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

3. 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.

4. 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.

Our Pipeline, page 2

5. 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.

Furmonertinib Development Initiative, page 3

6. 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.
7. 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?
8. Explain the meaning of the term "Gated" future planned study in 1L.
Our Strategy, page 3

9. 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.
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. 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.
Our Strategy, page 112

11. 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.
Licenses, Partnerships and Collaborations, page 128

12. 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.
Aarvik Research Collaboration Agreement, page 130

13. 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.
Financial Statements
Note 7. Convertible Preferred Stock and Common Stock
Convertible Preferred Stocks, page F-12

14. 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.

Please 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,

FirstName LastNameZhengbin (Bing) Yao, Ph.D.

Division of
Corporation Finance

Comapany NameArriVent Biopharma, Inc.

Office of Life
Sciences

cc: John Rudy