# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d)**
**of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **September 9, 2024**

# ARRIVENT BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **001-41929** | **86-3336099** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **18 Campus Boulevard, Suite 100**<br>**Newtown Square, PA** | **19073** |
|---|---|
| (Address of principal executive offices) | (zip code) |

Registrant's telephone number, including area code: **(628) 277-4836**

**N/A**
**(Former name or former address, if changed since last report.)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| **Common Stock, $0.0001 par value per share** | **AVBP** | **The Nasdaq Stock Market LLC** |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging Growth Company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 7.01 Regulation FD Disclosure.**

September 9, 2024, ArriVent BioPharma, Inc. (the "Company") issued a press release announcing positive proof-of-concept global Phase 1b interim data for firmonertinib monotherapy in first-line EGFR PACC mutant non-small cell lung cancer at the 2024 World Conference on Lung Cancer. A copy of the press release is furnished as Exhibit 99.1 hereto.

The information set forth in this Item 7.01 and Exhibit 99.1 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 8.01 Other Events.**

On September 9, 2024, the Company announced positive interim proof of concept data for firmonertinib monotherapy from a global study of firmonertinib in first-line epidermal growth factor receptor (EGFR) mutant non-small cell lung cancer (NSCLC) patients with P-loop and-alpha-c-helix compressing (PACC) mutations, which the Company believes represents the first clinical dataset of an EGFR inhibitor being tested in a randomized defined population of EGFR PACC mutant NSCLC. In this interim readout, 81.8% of patients treated in first-line at 240mg and 47.8% of patients treated in first-line at 160mg as of June 20, 2024 were observed to experience a reduction in tumor size of at least 30% from the baseline in a patient without evidence of progression as measured by blinded independent central review (BICR) utilizing Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 criteria, which measurement of reduction is the threshold in this trial for a partial response and for inclusion in determination of the overall response rate (ORR). In this interim readout, 63.6% of patients treated in first-line at 240mg and 34.8% of patients treated in first-line at 160mg were observed to experience a confirmed response as measured by BICR utilizing RECIST 1.1 criteria as of June 20, 2024. Median duration of response had not yet been reached, with 90.9% (n = 20/22) of patients with confirmed responses remaining on study. In addition, 46.2% (n = 6/13) of first line patients with brain metastases at baseline were observed to experience a confirmed response utilizing modified RECIST 1.1 by BICR as of June 20, 2024. Firmonertinib was generally well-tolerated with interim safety results as of July 5, 2024 consistent with prior firmonertinib data, and the most frequent treatment-related adverse events (TRAEs) in the study were diarrhea, rash, dry skin, stomatitis, and hepatic enzyme elevation. No Grade 4 or 5 TRAEs were observed, and there were no treatment discontinuations due to TRAEs. The Company believes firmonertinib showed promising dose-dependent activity in NSCLC patients across a broad range of EGFR PACC mutations in the first-line metastatic setting and includes central nervous system antitumor activity consistent with its high brain penetrance.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated September 9, 2024. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**ARRIVENT BIOPHARMA, INC.**

By: /s/ Winston Kung, MBA
Winston Kung, MBA
Chief Financial Officer and Treasurer

Date: September 9, 2024

**Exhibit 99.1**

**Arrivent Announces Positive Proof-Of-Concept Global Phase 1b Interim Data for Firmonertinib Monotherapy In First-Line EGFR PACC Mutant Non-Small Cell Lung Cancer At The 2024 World Conference On Lung Cancer**

*81.8% ORR by BICR and 63.6% confirmed ORR by BICR at the 240 mg dose; 46.2% confirmed ORR in CNS Metastases*

*90.9% (n = 20/22) of patients with confirmed responses remained on study with a median duration of response not yet reached at time of analysis*

*ArriVent to host virtual webinar on these interim analyses of Phase 1b data for firmonertinib in EGFR PACC mutant NSCLC on September 9, 2024 at 4:30 pm ET*

NEWTOWN SQUARE, PA, September 9, 2024 (GLOBE NEWSWIRE) -- ArriVent BioPharma, Inc. (Company or ArriVent) (Nasdaq: AVBP), a clinical-stage company dedicated to accelerating the global development of innovative biopharmaceutical therapeutics, today announced positive proof-of-concept randomized global Phase 1b FURTHER interim data for first-line firmonertinib monotherapy in patients with non-small cell lung cancer (NSCLC) harboring EGFR PACC mutations at a Presidential Symposium Presentation at the IASCLC 2024 annual World Conference on Lung Cancer (WCLC), in San Diego, California. ArriVent plans to host a virtual webinar on September 9, 2024 at 4:30 pm ET. To register for the event, please click here.

“These compelling dose-dependent interim data are the first to demonstrate robust systemic and CNS anti-tumor activity for firmonertinib in a PACC mutant population,” said Bing Yao, Chairman and Chief Executive Officer of ArriVent. “We believe that the generally well-tolerated safety profile and response duration seen to date reinforce the therapeutic potential of firmonertinib to be an effective oral, chemotherapy-free treatment for this underserved patient population. Importantly, these data add to the clinical body of evidence supporting firmonertinib as a potentially effective option across EGFR mutation types and lines of non-small cell lung cancer therapy.”

**Presidential Symposium Presentation Highlights**

Current standards of care have improved outcomes for classical EGFR mutations but have been less effective against uncommon EGFR mutation types including PACC and exon 20 insertion mutations which represent approximately 12% and 9% of NSCLC EGFR mutations, respectively. Firmonertinib, an oral, once-daily, highly brain-penetrant EGFR inhibitor with broad activity across EGFR mutations, was evaluated for interim clinical proof-of-concept data in first-line EGFR PACC mutant NSCLC as part of the Phase 1b FURTHER trial. **Select clinical activity and safety results from FURTHER interim data analysis include:**

- First clinical dataset from an EGFR inhibitor being tested in a randomized defined population of EGFR PACC mutant NSCLC
- Robust systemic and central nervous system (CNS) responses across patients observed as of June 20, 2024 (data cut):

- 81.8% at 240mg and 47.8% at 160mg overall response rate (ORR) by blinded independent central review (BICR)
- 63.6% and 34.8% confirmed ORR by BICR at 240mg and 160mg dose levels, respectively. One unconfirmed partial response pending confirmation at each of the 160mg and 240mg dose levels.
- Median duration of response had not yet been reached; 90.9% (n = 20/22) patients with confirmed responses remain on study
- 46.2% (n = 6/13) CNS confirmed ORR by modified Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 by BICR in first-line patients with brain metastases at baseline

· Generally well-tolerated with a profile consistent with prior firmonertinib data

- Most frequent treatment-related adverse events (TRAEs) were diarrhea, rash, dry skin, stomatitis, and hepatic enzyme elevation
- No treatment discontinuation due to TRAEs was observed

· Firmonertinib showed promising dose-dependent activity in NSCLC patients across a broad range of EGFR PACC mutations in the first-line metastatic setting and includes CNS antitumor activity consistent with its high brain penetrance.

Dr. Xiuning Le, Associate Professor of Thoracic Head and Neck Medical Oncology at MD Anderson Cancer Center and the lead Principal Investigator added, “Treating lung cancer patients with EGFR uncommon mutation lung cancer, including PACC mutations and exon 20 insertion mutations, remains a clinical challenge, as we need more potent and better tolerated EGFR inhibitors. These encouraging randomized data for firmonertinib suggest rapid and robust anti-tumor activity across PACC mutations which is similar to that observed for firmonertinib in exon 20 insertion mutations. Moreover, the apparent high CNS activity points to firmonertinib as a promising potential new therapy for frontline patients with PACC mutations including those with CNS disease.

**About ArriVent**

ArriVent is a clinical-stage biopharmaceutical company dedicated to the identification, development, and commercialization of differentiated medicines to address the unmet medical needs of patients with cancers. ArriVent seeks to utilize its team’s deep drug development experience to maximize the potential of its lead development candidate, firmonertinib, and advance a pipeline of novel therapeutics, such as next-generation antibody drug conjugates, through approval and commercialization.

**About Firmonertinib**

Firmonertinib (formerly furmonertinib) is an oral, highly brain-penetrant, and broadly active mutation-selective epidermal growth factor receptor (EGFR) inhibitor active against both classical and uncommon EGFR mutations, including PACC and exon 20 insertion mutations. In March 2021, firmonertinib was approved in China for first-line advanced non-small-cell lung cancer (NSCLC) with EGFR exon 19 deletion or L858R mutations and for patients with previously treated locally advanced or metastatic NSCLC with EGFR T790M mutation, otherwise known as EGFR classical mutations.

Firmonertinib was granted U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation for the treatment of patients with previously untreated, locally advanced or metastatic non-squamous NSCLC with EGFR exon 20 insertion mutations. Firmonertinib was also granted FDA Orphan Drug Designation for the treatment of non-small cell lung cancer with epidermal growth factor receptor (EGFR) mutations or human epidermal growth factor receptor 2 (HER2) mutations or HER4 mutations.

Firmonertinib is currently being studied in a global Phase 3 trial for first-line NSCLC patients with EGFR exon 20 insertion mutations (FURVENT; NCT05607550) and in a global Phase 1b study, which includes a cohort evaluating firmonertinib in patients with EGFR PACC mutations (FURTHER; NCT05364073). In addition, firmonertinib is also being studied in a clinical combination study targeting advanced or metastatic NSCLC patients with EGFR classical mutations, in partnership with Beijing InnoCare Pharma Tech Co., Ltd.

**About EGFR mutant NSCLC**

Globally, lung cancer is the leading cause of cancer-related deaths among men and women. NSCLC is the predominant subtype of lung cancer, accounting for approximately 85% of all cases. Mutational activation of the EGFR is a frequent and early event in the development of NSCLC. EGFR mutations are divided into classical and uncommon. EGFR exon 20 insertion mutations are a group of uncommon EGFR mutations and constitute approximately 9% of all EGFR mutations. PACC mutations are another group of uncommon EGFR mutations and represent approximately 12% of all EGFR mutations. Patients with NSCLC whose tumors harbor uncommon EGFR mutations have significantly lower life expectancy with available therapies and represent an area of unmet medical need.

**Forward-Looking Statements**

This press release includes certain disclosures that contain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this press release, including statements regarding our future results of operations or financial condition, business strategy and plans, activity of firmonertinib compared to available therapies, anticipated clinical milestones, including proof of concept data for firmonertinib in patients with NSCLC EGFR PACC mutations, top-line pivotal Phase 3 data for firmonertinib in previously untreated NSCLC patients whose tumors contain EGFR exon 20 insertion mutations, and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” or the negative of these words or other similar terms or expressions. Forward-looking statements are based on ArriVent’s current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, risks and uncertainties that are described more fully in the section titled “Risk Factors” in our annual report on Form 10-K for the fiscal year ended December 31, 2023, filed with the Securities and Exchange Commission on March 28, 2024 and our other filings with the Securities and Exchange Commission. Forward-looking statements contained in this press release are made as of this date, and ArriVent undertakes no duty to update such information except as required under applicable law.

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