

**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): **May 12, 2025**

ARRIVENT BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-41929
(Commission File Number)

86-3336099
(IRS Employer
Identification No.)

18 Campus Boulevard, Suite 100
Newtown Square, PA
(Address of principal executive offices)

19073
(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 2.02 Results of Operations and Financial Condition.

On May 12, 2025, ArriVent BioPharma, Inc. (the “Company”) issued a press release announcing its financial results for the first quarter ended March 31, 2025. A copy of the press release is furnished as Exhibit 99.1 hereto.

The information contained in this Item 2.02 and in the press release furnished as Exhibit 99.1 hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, or incorporated by reference in any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit No. | Description |
|--------------------|--|
| 99.1 | Press Release dated May 12, 2025. |
| 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

Winston Kung

Chief Financial Officer and Treasurer

Date: May 12, 2025

ArriVent BioPharma Reports First Quarter 2025 Financial Results

- *Completed enrollment in global pivotal Phase 3 study for firmonertinib monotherapy in first-line NSCLC harboring EGFR exon 20 insertion mutations*
- *Planned update for development of firmonertinib in first-line NSCLC PACC mutations in Q2 2025*
- *First IND for ARR-217 (MRG007), an antibody drug conjugate (ADC) targeting CDH17, submitted in China*
- *Cash, cash equivalents and marketable securities of \$205.5 million as of March 31, 2025*

NEWTOWN SQUARE, PA, May 12, 2025 (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 reported financial results for the first quarter ended March 31, 2025, and highlighted recent Company progress.

“We continued our strong execution across our oncology-focused pipeline and are preparing for several near-term milestones. Importantly, our late-stage firmonertinib program continues to show differentiated potential to address unmet needs across EGFR-mutant non-small cell lung cancer (NSCLC),” said Bing Yao, Chairman and Chief Executive Officer of ArriVent. “ARR-217 (MRG007), our recently acquired antibody drug conjugate (ADC) targeting the gastrointestinal marker CDH17 with best-in-class potential, is expected to be the first ADC from our pipeline to enter the clinic.”

Dr. Yao continued, “In the year ahead, we plan to present updated data for firmonertinib in first line EGFR PACC mutant NSCLC, including Progression Free Survival (PFS) and duration of response, and provide our clinical development plan on the PACC program in the second quarter of 2025. We expect topline data in 2025 in our event-driven global pivotal Phase 3 study for firmonertinib monotherapy in first-line NSCLC harboring EGFR exon 20 insertion mutations.”

First Quarter 2025 and Recent Highlights

Firmonertinib

- **Completed enrollment for pivotal trial.** During the first quarter of 2025, we completed enrollment in the the global pivotal Phase 3 FURVENT study of firmonertinib monotherapy in first-line NSCLC EGFR exon 20 insertion mutations (NCT05607550). Firmonertinib, an oral, highly brain-penetrant, and broadly active mutation-selective epidermal growth factor receptor (EGFR) inhibitor, received FDA Breakthrough Therapy Designation in this patient population.

Pipeline

- **Expanded our pipeline to include ARR-217 (MRG007).** In January 2025, ArriVent entered into a collaboration agreement with Lepu Biopharma for ARR-217, a CDH17-targeted ADC with the potential to treat gastrointestinal cancers. Under the agreement, ArriVent obtained the exclusive rights to develop and commercialize ARR-217 worldwide outside of greater China. In March 2025, our first IND was submitted in China with an initial clinical development focus in colorectal, pancreatic and other GI cancers. Pre-clinical data presented recently at the American Association
-

of Cancer Research (AACR) annual meeting in April 2025 demonstrated compelling antitumor activity in multiple GI cancer models and a favorable safety profile.

Upcoming Milestones

- **EGFR PACC plans.** Data from the FURTHER Phase 1b (NCT05364043) trial continues to mature for first-line firmonertinib monotherapy in NSCLC patients with EGFR PACC mutations. ArriVent expects to provide an update on our plans to develop firmonertinib in EGFR PACC mutant NSCLC in Q2 2025.
- **Topline pivotal Phase 3 firmonertinib data.** ArriVent anticipates having topline firmonertinib monotherapy data from the event-driven global pivotal FURVENT Phase 3 (NCT05607550) study in 2025 and expects to provide an update on timing of the topline Phase 3 data release in Q2 2025.

Corporate Updates

- **Appointed Merdad Parsey, M.D., Ph.D., to the Board of Directors.** In April 2025, ArriVent announced the appointment of Merdad Parsey to the ArriVent Board of Directors. Dr. Parsey brings decades of executive experience leading global clinical development in the biopharmaceutical industry, most recently serving as Chief Medical Officer and Executive Vice President of Gilead Sciences, Inc. He currently serves on the Board of Directors of Sagimet Biosciences, Inc., formerly 3-V Biosciences, Inc. following his tenure as President and Chief Executive Officer.

2025 Financial Results

- As of March 31, 2025, the Company had cash, cash equivalents and marketable securities of \$205.5 million, which is expected to fund operations into the second half of 2026. Net cash used in operations was \$68.0 million and \$18.6 million for the quarters ended March 31, 2025 and 2024, respectively. The increase in net cash used in operations in the first quarter of 2025 was primarily driven by the one-time upfront payment of \$40 million made to Lepu Biopharma.
- Research and development expenses were \$61.3 million and \$17.0 million for the quarters ended March 31, 2025 and 2024, respectively. The increase in expense was primarily due to an one-time upfront payment made to Lepu Biopharma for our collaboration that began in January 2025, along with increased headcount and clinical expense related to firmonertinib.
- General and administrative expenses were \$5.5 million and \$3.7 million for the quarters ended March 31, 2025 and 2024, respectively. The increase in expense was primarily due to expenses related to expanding the infrastructure necessary for operating as a public company.
- Net loss was \$64.4 million and \$17.4 million for the quarters ended March 31, 2025 and 2024, respectively.

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 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 U.S. FDA Orphan Drug Designation for the treatment of NSCLC with 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; NCT05364043). 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.

About EGFR PACC mutations

P-loop and α C-helix compressing (PACC) EGFR mutations are a distinct set of approximately 70 mostly missense activating mutations within the kinase domain of EGFR. They are similar to Exon 20 insertion mutations in narrowing the drug binding pocket to affect tyrosine kinase inhibitor activity. PACC mutations are diagnosed through commercially available NGS and most PCR tests. Patients with PACC mutations have limited treatment options, and there is no broadly utilized standard of care treatment for first-line PACC mutant patients.

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, cash runway, differentiation of firmonertinib, activity of firmonertinib compared to available therapies, the timing of anticipated near-term clinical milestones, the timing of our planned update of data of firmonertinib in first-line NSCLC PACC mutations and corresponding clinical development plan for a potential pivotal study of firmonertinib in patients with NSCLC EGFR PACC mutations, the timing of top-line pivotal Phase 3 data for firmonertinib in previously untreated NSCLC patients whose tumors contain EGFR exon 20 insertion mutations, the differentiation of ARR-217 compared to other members of the same class, and the timing of ARR-217’s planned entry into the clinic, 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, 2024, to be filed with the Securities and Exchange Commission on March 3, 2025 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.

ARRIVENT BIOPHARMA, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and per share data)
(Unaudited)

| | March 31, 2025 | December 31, 2024 |
|---|-------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 49,865 | \$ 74,293 |
| Short-term investments | 126,212 | 144,570 |
| Prepaid expenses and other current assets | 9,708 | 8,116 |
| Total current assets | 185,785 | 226,979 |
| Long-term investments | 29,414 | 47,683 |
| Right of use assets – operating leases | 120 | 154 |
| Other assets | 176 | 126 |
| Total assets | <u>\$ 215,495</u> | <u>\$ 274,942</u> |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 4,364 | \$ 3,782 |
| Accrued expenses | 8,451 | 13,330 |
| Operating lease liabilities | 138 | 162 |
| Total current liabilities | 12,953 | 17,274 |
| Operating lease liabilities, net of current amount | — | 14 |
| Total liabilities | <u>12,953</u> | <u>17,288</u> |
| Stockholders' equity: | | |
| Preferred stock \$0.0001 par value, 10,000,000 shares authorized; no shares issued and outstanding | — | — |
| Common stock \$0.0001 par value, 200,000,000 shares authorized; 34,040,996 and 33,706,765 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively | 4 | 3 |
| Additional paid-in capital | 505,275 | 496,195 |
| Accumulated deficit | (302,720) | (238,333) |
| Accumulated other comprehensive loss | (17) | (211) |
| Total stockholders' equity | <u>202,542</u> | <u>257,654</u> |
| Total liabilities and stockholders' equity | <u>\$ 215,495</u> | <u>\$ 274,942</u> |

ARRIVENT BIOPHARMA, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)
(Unaudited)

| | Three Months Ended | |
|---|--------------------|-------------|
| | March 31, | |
| | 2025 | 2024 |
| Operating expenses: | | |
| Research and development | \$ 61,289 | \$ 16,975 |
| General and administrative | 5,483 | 3,699 |
| Total operating expenses | 66,772 | 20,674 |
| Operating loss | (66,772) | (20,674) |
| Interest and investment income | 2,385 | 3,257 |
| Net loss | (64,387) | (17,417) |
| Unrealized gain on marketable securities | 194 | — |
| Total other comprehensive gain | 194 | — |
| Total comprehensive loss | \$ (64,193) | \$ (17,417) |
| Share information: | | |
| Net loss per share attributable to common stockholders, basic and diluted | \$ (1.90) | \$ (0.70) |
| Weighted-average shares of common stock outstanding, basic and diluted | 33,898,870 | 25,046,531 |

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