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): November 22, 2024

BridgeBio Pharma, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38959**	**84-1850815**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
3160 Porter Dr., Suite 250 **Palo Alto, CA** **(Address of Principal Executive Offices)**		**94304** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (650) 391-9740

Not Applicable
(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, par value $0.001 per share	BBIO	The Nasdaq Global Select Market

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

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 8.01. Other Events

On November 22, 2024, BridgeBio Pharma, Inc. ("BridgeBio" or the "Company") issued a press release titled "Attruby™ (acoramidis), a Near Complete TTR Stabilizer (≥90%), approved by FDA to Reduce Cardiovascular Death and Cardiovascular-related Hospitalization in ATTR-CM Patients." A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Attruby (acoramidis) will be available at a recommended dose of 712 mg (as two 356 mg tablets) taken twice daily. The list price for ATTRuby is $18,759.12 for a 28-day supply.

Forward-Looking Statements

This Current Report on Form 8-K and certain of the materials filed and furnished herewith contain forward-looking statements. Statements in this Current Report on Form 8-K or the materials furnished or filed herewith may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act, and Section 21E of the Exchange Act, which are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "will," and variations of such words or similar expressions. The Company intends these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act. These forward-looking statements, including express and implied statements regarding the significance of the FDA approval of ATTRuby, the safety, efficacy and mechanism of action of ATTRuby and other product characteristics, the availability, use, commercialization, cost and commercial and medical potential of ATTRuby, and the therapeutic potential of acoramidis for ATTR-CM, including the potential to significantly improve rates of mortality, cardiovascular-related hospitalization and quality of life, reflect the Company's current views about its plans, intentions, expectations and strategies, which are based on the information currently available to the Company and on assumptions it has made. Although the Company believes that its plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, it can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a number of risks, uncertainties and assumptions, including, but not limited to, risks that BridgeBio has only recently begun establishing its sales force and other commercialization capabilities and may not be able to successfully launch or commercialize ATTRuby, risks associated with BridgeBio's dependence on third parties for development, manufacture and commercialization activities related to ATTRuby, government and third-party payor actions, including relating to reimbursement and pricing, risks and uncertainties relating to competitive products and other changes that may limit demand for ATTRuby, the risks that regulatory authorities may require additional studies or data to support continued commercialization of ATTRuby, the risks that drug-related adverse events may be observed during commercialization or clinical development, data and results may not meet regulatory requirements or otherwise be sufficient for further development, regulatory review or approval, other regulatory agencies not agreeing with BridgeBio's regulatory approval strategies, components of BridgeBio's filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted, the continuing success of its collaborations, potential volatility in BridgeBio's share price, uncertainty regarding any impacts due to global health emergencies, including delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy, the impacts of current macroeconomic and geopolitical events, including changing conditions from hostilities in Ukraine and in Israel and the Gaza Strip, increasing rates of inflation and changing interest rates, on BridgeBio's business operations and expectations, as well as those risks set forth in the Risk Factors section of BridgeBio's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q and its other filings with the U.S. Securities and Exchange Commission. Moreover, the Company operates in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of the Company's management as of the date of this Current Report on Form 8-K, and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Except as required by applicable law, the Company assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release titled, "ATTRuby™ (acoramidis), a Near Complete TTR Stabilizer (> 90%), approved by FDA to Reduce Cardiovascular Death and Cardiovascular-related Hospitalization in ATTR-CM Patients"
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 hereunto duly authorized.

BridgeBio Pharma, Inc.

Date: November 22, 2024

By: /s/ Brian C. Stephenson
Brian C. Stephenson
Chief Financial Officer

Exhibit 99.1

Attruby™ (acoramidis), a Near Complete TTR Stabilizer (≥90%), approved by FDA to Reduce Cardiovascular Death and Cardiovascular-related Hospitalization in ATTR-CM Patients

- Attruby is the first and only approved product with a label specifying near-complete stabilization of TTR. Attruby has been shown to preserve the native function of TTR as a transport protein of thyroxine and vitamin A and to demonstrate benefit on cardiovascular outcomes

- Attruby demonstrated the most rapid benefit seen in any Phase 3 study of ATTR-CM to date:

- *In as few as 3 months, the time to first event (all-cause mortality (ACM) or cardiovascular-related hospitalizations (CVH)) durably separated relative to placebo*
- *A 42% reduction in composite ACM and recurrent CVH events relative to placebo at Month 30*
- *A 50% reduction in the cumulative frequency of CVH events relative to placebo at Month 30*

- To honor the courage of our U.S. clinical trial participants, BridgeBio will provide these patients Attruby free for life

- To learn about our extensive suite of programs to provide access to Attruby call 1-888-55-BRIDGE (1-888-552-7434)

- With this approval, BridgeBio will receive a $500 million payment under our royalty funding agreement

- BridgeBio will share management remarks on key aspects of the Attruby label and important access programs on Friday, November 22, 2024 at 8:00 pm ET

Palo Alto, CA – November 22, 2024 – BridgeBio Pharma, Inc. (Nasdaq: BBIO) (BridgeBio or the Company), a new type of biopharmaceutical company focused on genetic diseases, today announced that the U.S. Food and Drug Administration (FDA) approved Attruby™ (acoramidis), an orally-administered near-complete (≥90%) stabilizer of Transthyretin (TTR) for the treatment of adults with ATTR-CM to reduce cardiovascular death and cardiovascular-related hospitalization. The FDA approval is based on positive results seen in the ATTRibute-CM Phase 3 study, where Attruby significantly reduced death and cardiovascular-related hospitalization, and improved quality of life.

“We are excited to be part of the celebration for the FDA approval of Attruby. The need for more treatment options for patients living with ATTR-CM is crucial to achieving the goal of better outcomes and improved quality of life. Access to this new therapy means more hope and more opportunity to improve the lives of patients with amyloidosis,” said Muriel Finkel, President of Amyloidosis Support Groups, a non-profit organization dedicated to the support of amyloidosis patients and caregivers.

Attruby is the first and only approved product with a label specifying near-complete stabilization of TTR. Attruby was designed to mimic a naturally occurring “rescue mutation” of the TTR gene (T119M) that targets the root cause of ATTR-CM, destabilization of the native TTR tetramer. Through near-complete TTR stabilization, Attruby has been shown to preserve the native function of TTR as a transport protein of thyroxine and vitamin A and to demonstrate benefit on cardiovascular outcomes.

The ATTRibute-CM Phase 3 study enrolled 632 participants with symptomatic ATTR-CM, associated with either wild-type or variant TTR. Participants were randomized 2:1 to receive Attruby or placebo for 30 months. As published in The New England Journal of Medicine, the trial successfully met its primary endpoint of a 4-component composite endpoint of ACM, CVH, N-terminal prohormone of brain natriuretic peptide (NT-proBNP), and 6-minute walk distance with a Win Ratio of 1.8 ($p<0.0001$). Attruby demonstrated a statistically significant treatment effect at 30 months on the Kansas City Cardiomyopathy Questionnaire and 6-minute walk test. Additionally, the increase in NT-proBNP on treatment was about half that of placebo.

“Transthyretin cardiac amyloidosis is a progressive disease with a poor prognosis when left untreated. Having a new first line treatment option which provides excellent TTR stabilization and improves outcomes in this disease gives patients more options,” said Martha Grogan, M.D., of the Mayo Clinic. “Encouraging data suggests Attruby reduces all-cause mortality and cardiovascular hospitalization as early as three months after initiation of therapy. With continued advances in therapy, this previously fatal disease is becoming a manageable chronic cardiovascular condition. "

BridgeBio offers a patient support services program, ForgingBridges™, for people in the U.S. prescribed Attruby and their families to receive help accessing this new therapy. ForgingBridges includes insurance resources, financial assistance options and a dedicated support team to assist in the treatment journey. More information about BridgeBio’s patient support services program is available on ForgingBridges.com or by calling 1-888-55-BRIDGE (1-888-552-7434).

“With the landmark approval of Attruby, we gain the ability to serve patients with ATTR-CM. I’m grateful to each trial participant, their families, and the physicians, scientists and our team at BridgeBio who made this possible,” said Neil Kumar, Ph.D., founder and CEO. “Our journey is not over as we look to pursue approvals globally, next in Europe, Japan, and Brazil, and to continue exploring the full potential of this treatment. I am thrilled to extend our mission of ‘putting patients first’ with this third FDA approval in less than 10 years.”

BridgeBio submitted a Marketing Authorization Application to the European Medicines Agency, with a decision expected in 2025. BridgeBio has granted exclusive rights to Bayer to commercialize acoramidis for ATTR-CM in Europe.

Management Remarks on Attruby
BridgeBio will share management remarks on key aspects of the Attruby label and important access programs on Friday, November 22, 2024 at 8:00 pm ET. A link to the remarks may be accessed from the event calendar page of BridgeBio's website at **https://investor.bridgebio.com/news-and-events/event-calendar**. Remarks will be archived on the Company's website and will be available for at least 30 days following the event.

INDICATION
Attruby is a transthyretin stabilizer indicated for the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization.

IMPORTANT SAFETY INFORMATION
Adverse Reactions
Diarrhea (11.6% vs 7.6%) and upper abdominal pain (5.5% vs 1.4%) were reported in patients treated with Attruby versus placebo, respectively. The majority of these adverse reactions were mild and resolved without drug discontinuation.
Discontinuation rates due to adverse events were similar between patients treated with Attruby versus placebo (9.3% and 8.5%, respectively).

Laboratory Tests
Mean increase in serum creatinine of 0.2 and 0.0 mg/dL and a mean decrease in eGFR of 8.2 and 0.7 mL/min/1.73 m^2 was observed in the adults with ATTR-CM treated with Attruby versus placebo, respectively, at Day 28 and then stabilized. These changes were reversible after treatment discontinuation.

Use in Specific Populations
Pregnancy & Lactation: There are no data on the use of Attruby in pregnant women. Animal data have not shown developmental risk associated with the use of Attruby in pregnancy. There are no available data on the presence of Attruby in either human or animal milk or the effects of the drug on the breastfed infant or maternal milk production.

To report suspected adverse reactions, contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About Attruby™ (acoramidis)
Attruby is the only near-complete (≥90%) stabilizer of Transthyretin (TTR) approved in the U.S. for the treatment of adult patients with ATTR-CM to reduce cardiovascular death and cardiovascular-related hospitalization. Attruby was generally well-tolerated. The most common side effects were mild and included diarrhea and abdominal pain that were resolved without drug discontinuation. BridgeBio offers an extensive suite of programs to help patients access our medicines.

About BridgeBio Pharma, Inc.
BridgeBio Pharma, Inc. (BridgeBio) is a new type of biopharmaceutical company founded to discover, create, test, and deliver transformative medicines to treat patients who suffer from genetic diseases. BridgeBio's pipeline of development programs ranges from early science to advanced clinical trials. BridgeBio was founded in 2015 and its team of experienced drug discoverers, developers and innovators are committed to applying advances in genetic medicine to help patients as quickly as possible. For more information visit **bridgebio.com** and follow us on **LinkedIn, Twitter** and **Facebook**.

BridgeBio Pharma, Inc. Forward-Looking Statements
This press release contains forward-looking statements. Statements in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), which are usually identified by the use of words such as "anticipates," "believes," "continues," "estimates," "expects," "hopes," "intends," "may," "plans," "projects," "remains," "seeks," "should," "will," and variations of such words or similar expressions. BridgeBio intends these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act. These forward-looking statements, including statements relating to the impact of acoramidis on clinical outcomes, providing Attruby free for life to clinical trial patients; potential benefits of Attruby, including its efficacy and potential to improve the quality of life for patients, and the potential outcomes and expected timing of regulatory reviews and approvals in Europe, Japan and Brazil, reflect BridgeBio's current views about its plans, intentions, expectations and strategies, which are based on the information currently available to BridgeBio and on assumptions BridgeBio has made. Although BridgeBio believes that its plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, BridgeBio can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a number of risks, uncertainties and assumptions, including, but not limited to the risks that BridgeBio has only recently begun establishing its sales force and other commercialization capabilities and may not be able to successfully launch or commercialize Attruby, risks associated with BridgeBio's dependence on third parties for development, manufacture and commercialization activities related to Attruby, government and third-party payor actions, including relating to reimbursement and pricing, risks and uncertainties relating to competitive products and other changes that may limit demand for Attruby, the risks regulatory authorities may require additional studies or data to support continued commercialization of Attruby, the risks that drug-related adverse events may be observed during commercialization or clinical development, data and results may not meet regulatory requirements or otherwise be sufficient for further development, regulatory review or approval, other regulatory agencies not agreeing with BridgeBio's regulatory approval strategies, components of BridgeBio's filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted, the continuing success of its collaborations, potential volatility in BridgeBio's share price, uncertainty regarding any impacts due to global health emergencies, including delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy, the impacts of current macroeconomic and geopolitical events, including changing conditions from hostilities in Ukraine and in Israel and the Gaza Strip, increasing rates of inflation and changing interest rates, on BridgeBio's business operations and expectations, as well as those risks set forth in the Risk Factors section of BridgeBio's most recent Annual Report on Form 10-K and Quarterly Report on From 10-Q and its other filings with the U.S. Securities and Exchange Commission. Moreover, BridgeBio operates in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of BridgeBio's management as of the date of this press release, and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Except as required by applicable law, BridgeBio assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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