# 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): **January 13, 2026**

# Fortress Biotech, Inc.
(Exact Name of Registrant as Specified in Charter)

| **Delaware** | **001-35366** | **20-5157386** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**1111 Kane Concourse, Suite 301**
**Bay Harbor Islands, FL 33154**
(Address of Principal Executive Offices)

**(781) 652-4500**
(Registrant's telephone number, including area code)

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.

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act.

☐ Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.

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

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 | FBIO | Nasdaq Capital Market |
| 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock | FBIOP | Nasdaq Capital 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). ☐

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 January 13, 2026, Fortress Biotech, Inc. (the "**Company**") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") approved ZYCUBO® (copper histidinate, formerly known as CUTX-101) for the treatment of Menkes disease in pediatric patients. A Rare Pediatric Disease Priority Review Voucher ("PRV") was issued in connection with the FDA approval and will be transferred to Cyprium Therapeutics, Inc. ("Cyprium"), a majority-owned subsidiary of the Company. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

The following exhibit is furnished herewith:

| **Exhibit Number** | **Description** |
|---|---|
| 99.1 | Press Release of Fortress Biotech, Inc. dated January 13, 2026 |
| 104 | Cover Page Interactive Data File (the cover page XBRL tags are imbedded in the Inline XBRL document) |

**SIGNATURES**

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

**Fortress Biotech, Inc.**
(Registrant)

Date: January 13, 2026

By: /s/ David Jin
David Jin
Chief Financial Officer

**Exhibit 99.1**

**Fortress Biotech and Cyprium Therapeutics Announce U.S. FDA Approval of ZYCUBO® (copper histidinate), the First and Only Approved Treatment for Menkes Disease in the United States**

*Rare Pediatric Disease Priority Review Voucher (PRV) granted by FDA at approval to be transferred from Sentynl Therapeutics to Cyprium*

*Cyprium eligible to receive tiered royalties and up to $129 million in aggregate development and sales milestones from Sentynl Therapeutics*

**Miami, FL – January 13, 2026** – Fortress Biotech, Inc. (Nasdaq: FBIO) ("Fortress") and its majority-owned subsidiary, Cyprium Therapeutics, Inc. ("Cyprium"), today announced that the U.S. Food and Drug Administration ("FDA") has approved ZYCUBO® (copper histidinate, formerly known as CUTX-101) for the treatment of Menkes disease in pediatric patients.

In December 2023, Sentynl Therapeutics, Inc. ("Sentynl"), a U.S.-based biopharmaceutical company wholly-owned by Zydus Lifesciences Limited ("Zydus Group"), assumed full responsibility for the development and commercialization of CUTX-101 from Cyprium. A Rare Pediatric Disease Priority Review Voucher (PRV) was issued in connection with FDA approval and, pursuant to the transaction with Sentynl, will be transferred to Cyprium. Cyprium is also eligible to receive tiered royalties on net sales of ZYCUBO and up to $129 million in aggregate development and sales milestones from Sentynl.

Menkes disease is a rare X-linked recessive pediatric disease caused by mutations of the copper transporter ATP7A encoded by the *ATP7A* gene. Patients with Menkes disease are born with the inability to absorb dietary copper and subsequently have impaired copper transport across the blood-brain barrier, and, until now, there has been no approved treatment in the United States. ZYCUBO® is a subcutaneous injectable formulation of copper histidinate that restores copper homeostasis and maintains copper levels in patients with Menkes disease.

"The approval of ZYCUBO is a pivotal milestone for our company and patients suffering from Menkes Disease, as it is the first and only FDA-approved treatment for this rare, often fatal, pediatric disease. In connection with FDA approval, ZYCUBO was granted a Rare Pediatric Disease Voucher which will be transferred from Sentynl to our majority-owned subsidiary Cyprium," said Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer and Cyprium's Chairman. "With three FDA approvals received in the last 15 months, for Emrosi™, UNLOXCYT™ (cosibelimab-ipdl), and now ZYCUBO, along with the recent sale of Checkpoint Therapeutics to Sun Pharma for approximately $28 million upfront to Fortress, plus the potential for an additional contingent value right (CVR) payment and ongoing royalties on future sales of UNLOXCYT, we believe that our business model has demonstrated measurable success and continued execution across the portfolio. We look forward to the potential achievement of

additional upcoming milestones across our extensive pipeline of commercial and clinical-stage assets."

"The development and approval of ZYCUBO are the culmination of more than three decades of hard work and dedication by many people, including the team members at Cyprium, Fortress and Sentynl," stated Lung S. Yam, M.D., Ph.D., Cyprium's President and Chief Executive Officer. "We would like to express our gratitude to the Menkes disease patients and their families who participated in the clinical studies and helped advance our understanding of this devastating disease."

The approval is supported by positive topline clinical efficacy results for ZYCUBO, demonstrating statistically significant improvement in overall survival for Menkes disease subjects who received early treatment ("**ET**") with ZYCUBO, compared to an untreated contemporaneous external control ("**EC**") cohort, with a nearly 80% reduction in the risk of death. Median overall survival ("**OS**") was 177.1 months for ZYCUBO ET cohort compared to 17.6 months for the EC cohort.

The most common adverse reactions (incidence ≥7%) were pneumonia, viral infection, respiratory failure, seizure, bacterial infection, hemorrhage, hypotension, vomiting, tachycardia, pyrexia, volume depletion, fracture, dyspnea, transaminases elevation, diarrhea, fungal infection, anemia, and local administration reaction.

ZYCUBO has received Breakthrough Therapy, Fast Track, Rare Pediatric Disease, and Orphan Drug Designation from the FDA. Copper histidinate has also been granted Orphan Designation by the European Medicines Agency.

**About Menkes Disease**
Menkes disease is a rare X-linked recessive pediatric disease caused by gene mutations of the copper transporter ATP7A. The minimum birth prevalence for Menkes disease is believed to be 1 in 34,810 live male births, and potentially as high as 1 in 8,664 live male births, based on recent genome-based ascertainment. The condition is characterized by distinctive clinical features, including sparse and depigmented hair ("kinky hair"), connective tissue problems, and severe neurological symptoms such as seizures, hypotonia, failure to thrive, and neurodevelopmental delays. Mortality is high in untreated Menkes disease, with many patients dying between 2-3 years of age. Milder versions of *ATP7A* mutations are associated with conditions other than Menkes Disease, such as Occipital Horn Syndrome and *ATP7A*-related Distal Motor Neuropathy.

**About ZYCUBO® (copper histidinate)**
ZYCUBO® is the first and only FDA-approved, bioavailable copper replacement therapy for the treatment of Menkes disease, a copper transport deficiency caused by mutations in *ATP7A*. ZYCUBO is a subcutaneous injectable formulation of copper histidinate that is given daily to deliver elemental copper to the body. In a pooled analysis of two open label, single-arm clinical trials, early treatment with ZYCUBO (ZYCUBO-ET) demonstrated significant improvement in overall survival for Menkes disease patients with a nearly 80% reduction in the risk of death compared to the overall survival of patients in the untreated contemporaneous external control cohort. For more information, visit https://zycubo.com.

**INDICATIONS AND USAGE**

ZYCUBO is indicated for the treatment of Menkes disease in pediatric patients.

Limitations of Use

ZYCUBO is not indicated for the treatment of Occipital Horn Syndrome.

**IMPORTANT SAFETY INFORMATION**

**Contraindications**

None.

**Warnings and Precautions**

Copper Accumulation and Risk of Toxicity

Impaired copper transport in patients with Menkes disease can lead to copper accumulation and organ impairment in the kidneys, liver, and hematopoietic system. Treatment with ZYCUBO may lead to further copper accumulation and related toxicity, especially in the first two years of life given renal and hepatic immaturity.

***Renal Dysfunction***

Kidney injury has been reported in patients taking ZYCUBO. In patients with Menkes disease, kidney dysfunction may already be present from the accumulation of copper in the kidneys. This may be worsened from the administration of copper in ZYCUBO. The healthcare team will monitor your child's kidney function through periodic laboratory tests before and during ZYCUBO administration. The dose of ZYCUBO may be adjusted as appropriate based on the results of the laboratory tests.

***Liver Dysfunction***

Copper accumulation can result in liver dysfunction. The healthcare team will monitor your child's liver function through periodic laboratory tests before and during ZYCUBO administration. The dose of ZYCUBO may be adjusted as appropriate based on the results of the laboratory tests.

***Hematological Abnormalities***

Copper accumulation with ZYCUBO can result in spleen and bone marrow dysfunction as well as interference with iron metabolism. Anemia has been reported in patients taking ZYCUBO for Menkes disease. The healthcare team will perform periodic laboratory tests (complete blood count) before and during ZYCUBO administration. The dose of ZYCUBO may be adjusted as appropriate based on the results of the laboratory tests.

**Adverse Reactions**

The most common adverse reactions (≥7%) were pneumonia (30%), viral infection (27%), respiratory failure[1] (23%) (including cardiopulmonary failure (9%)), seizure (23%), bacterial infection[2] (20%) (including renal and urinary tract infection (9%)), hemorrhage (18%), hypotension (16%), vomiting (15%), tachycardia (12%), pyrexia (12%), volume depletion (12%), fracture (12%), dyspnea (12%), transaminases elevation (10%), diarrhea (10%), fungal infection (9%), anemia (9%), and local administration reaction (7%).

**Use in Specific Populations**

***Pregnancy***

Risk Summary

There are no available data on ZYCUBO use during pregnancy to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Animal reproduction studies have not been conducted with ZYCUBO.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defects, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%-4% and 15%-20%, respectively.

***Lactation***

Risk Summary

There are no available data on the presence of ZYCUBO in either human or animal breast milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ZYCUBO and any potential adverse effects on the breastfed infant from ZYCUBO or from the underlying maternal condition.

***Pediatric Use***

The safety and effectiveness of ZYCUBO for the treatment of Menkes disease have been established in pediatric patients. Use of ZYCUBO for this indication is supported by evidence from two clinical trials. Data from patients in these two trials were compared to data from an untreated contemporaneous external control cohort.

***Geriatric Use***

Menkes disease is a disease of pediatric patients. Clinical trials of ZYCUBO did not include patients 65 years of age and older.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

**Please see full U.S. Prescribing Information including Instructions for Use (IFU) for ZYCUBO® at https://zycubo.com.**

[1] Respiratory failure consists of multiple similar terms including cardiopulmonary failure.
[2] Bacterial infection consists of multiple similar terms including renal and urinary tract infection.

**About Cyprium Therapeutics**
Cyprium Therapeutics, Inc. ("Cyprium") is focused on the development of novel therapies for the treatment of Menkes disease and related copper metabolism disorders. In March 2017, Cyprium entered into a Cooperative Research and Development Agreement with the Eunice Kennedy Shriver National Institute of Child Health and Human Development ("NICHD"), part of the NIH, to advance the clinical development of CUTX-101 (Copper Histidinate injection) for the treatment

of Menkes disease. In 2023, Cyprium completed the transfer of its proprietary rights and assigned its FDA documents pertaining to CUTX-101 to Sentynl Therapeutics, Inc. ZYCUBO (formerly CUTX-101) was U.S. FDA-approved in 2026 to treat patients with Menkes disease. Cyprium and NICHD also have an ongoing worldwide, exclusive license agreement to develop and commercialize adeno-associated virus (AAV)-based gene therapy, called AAV-ATP7A, to deliver working copies of the copper transporter that is defective in patients with Menkes disease, and to be used in combination with CUTX-101; AAV-ATP7A gene therapy is currently in pre-clinical development and has received FDA Orphan Drug Designation. Cyprium was founded by, and is a majority-owned subsidiary of, Fortress Biotech, Inc. (Nasdaq: FBIO). For more information, visit www.cypriumtx.com.

**About Fortress Biotech**

Fortress Biotech, Inc. ("Fortress") is an innovative biopharmaceutical company focused on acquiring and advancing assets to enhance long-term value for shareholders through product revenue, equity holdings and dividend and royalty income. The company has eight marketed prescription pharmaceutical products and multiple programs in development at Fortress, at its majority-owned and majority-controlled partners and subsidiaries and at partners and subsidiaries it founded and in which it holds significant minority ownership positions. Fortress' portfolio is being commercialized and developed for various therapeutic areas including oncology, dermatology, and rare diseases. Fortress' model is focused on leveraging its significant biopharmaceutical industry expertise and network to further expand and advance the company's portfolio of product opportunities. Fortress has established partnerships with some of the world's leading academic research institutions and biopharmaceutical companies to maximize each opportunity to its full potential, including AstraZeneca, City of Hope, Fred Hutchinson Cancer Center, Nationwide Children's Hospital, Columbia University, Dana Farber Cancer Center and Sentynl Therapeutics. For more information, visit www.fortressbiotech.com.

**Forward-Looking Statements**

Statements in this press release that are not descriptions of historical facts are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. The words "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "might," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other comparable terminology are generally intended to identify forward-looking statements. These forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include risks relating to: the relatively small universe of potential buyers for a PRV; if we decide to sell the PRV and are able to find a buyer, the possibility that we are unable to do so on economic terms, or during a timeframe, that we deem favorable; our growth strategy, financing and strategic agreements and relationships; our need for substantial additional funds and uncertainties relating to financings; uncertainty related to the timing and amounts expected to be realized from future milestone, contingent value right, royalty or similar future revenue streams, if at all; our ability to identify, acquire, close and integrate product candidates successfully and on a timely basis; our ability to attract, integrate and retain key personnel; the early stage of products under development; the results of research and development activities; uncertainties relating to preclinical and clinical testing; our ability to obtain regulatory approval for products under development; our ability to successfully commercialize products or other marketable assets for which we receive regulatory approval; our ability to secure and maintain third-party manufacturing, marketing and distribution of our and our partner companies' products and product candidates; government regulation; patent and intellectual property

matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this press release should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

**Company Contact:**
Jaclyn Jaffe
Fortress Biotech, Inc.
(781) 652-4500
ir@fortressbiotech.com

**Media Relations Contact:**
Tony Plohoros
6 Degrees
(908) 591-2839
tplohoros@6degreespr.com