
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): **October 1, 2025**

Fortress Biotech, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35366
(Commission File Number)

20-5157386
(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	FBIO-P	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 October 1, 2025, Fortress Biotech, Inc. issued a press release announcing that the U.S. Food and Drug Administration issued a complete response letter for CUTX-101 (copper histidinate). 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
<u>99.1</u>	<u>Press release of Fortress Biotech, Inc., dated October 1, 2025.</u>
104	Cover Page Interactive Data File (embedded within 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: October 1, 2025

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



Fortress Biotech and Cyprium Therapeutics Announce an Update on the NDA for CUTX-101

Miami, FL – October 1, 2025 – 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 issued a Complete Response Letter (“CRL”) relating to the New Drug Application (“NDA”) for CUTX-101 (copper histidinate), intended to treat Menkes disease in pediatric patients.

In December 2023, Sentynl Therapeutics, Inc. (“Sentynl”), a U.S.-based biopharmaceutical company wholly-owned by Zydus Lifesciences, Ltd. (“Zydus Group”) assumed full responsibility for the development and commercialization of CUTX-101 from Cyprium. Cyprium expects its partner, Sentynl, will work expeditiously to address the FDA’s concerns and pursue resubmission promptly.

The CRL noted cGMP deficiencies had been observed at the facility where CUTX-101 is manufactured. The facility recently provided responses to the FDA’s September 2025 re-inspection of the facility, and Sentynl expects to request a meeting with the FDA to discuss the CRL and resubmission of the CUTX-101 NDA. The CRL did not cite any other approvability concerns, nor did it identify any deficiencies in CUTX-101’s efficacy and safety data.

Pursuant to the transaction with Sentynl, Sentynl will transfer to Cyprium, if issued upon approval, a Rare Pediatric Disease Priority Review Voucher (“PRV”), and Cyprium will also be eligible to receive royalties on net sales of CUTX-101 and up to \$129 million in aggregate development and sales milestones from Sentynl.

The CUTX-101 NDA was initially granted Priority Review by the FDA and is supported by positive topline clinical efficacy results for CUTX-101, demonstrating significant improvement in overall survival for Menkes disease subjects who received early treatment with CUTX-101.

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 (Kaler SG, Ferreira CR, Yam LS. Estimated birth prevalence of Menkes disease and *ATP7A*-related disorders based on the Genome Aggregation Database (gnomAD). *Molecular Genetics and Metabolism Reports* 2020 June 5;24:100602). 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 other conditions, including Occipital Horn Syndrome and *ATP7A*-related Distal Motor Neuropathy. Currently, there is no FDA-approved treatment for Menkes disease and its variants.

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. CUTX-101 is an investigational drug currently under FDA review to treat patients with Menkes disease. In 2023, Cyprium completed the transfer of its proprietary rights and assigned its FDA documents pertaining to CUTX-101 to Sentyln Therapeutics, Inc. 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, Nationwide Children’s Hospital, Columbia University, Dana Farber Cancer Center and Sentyln 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: whether the CUTX-101 NDA is approved in a timely manner, or at all, and whether a PRV is granted in connection therewith; 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 or receive royalties or other distributions from third parties; 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.

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