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 14, 2025**

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).

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.

As previously disclosed, on October 1, 2025, Fortress Biotech, Inc. (the "**Company**") and its majority-owned subsidiary, Cyprium Therapeutics, Inc. ("**Cyprium**"), announced that the U.S. Food and Drug Administration (the "**FDA**") had issued a Complete Response Letter 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., assumed full responsibility for the development and commercialization of CUTX-101 from Cyprium.

On November 14, 2025, Sentynl notified Cyprium that Sentynl had resubmitted the NDA for CUTX-101 to the FDA.Cyprium will retain ownership over any Priority Review Voucher that may be issued upon NDA approval and is eligible to receive royalties and up to $129 million in aggregate development and sales milestones.

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: November 17, 2025

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