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): **December 3, 2021**

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.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(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 December 3, 2021, Fortress Biotech, Inc. partner company Cyprium Therapeutics, Inc. ("Cyprium") initiated the rolling submission of a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for CUTX-101, Cyprium's copper histidinate product candidate, for the treatment of Menkes disease.

As previously disclosed, Cyprium is party to an asset purchase agreement with Sentynl Therapeutics, Inc. ("Sentynl") a wholly owned subsidiary of Cadila Healthcare Limited, pursuant to which Cyprium retains development responsibility of CUTX-101 through NDA approval, and Sentynl will be responsible for commercialization of CUTX-101 thereafter, as well as newborn screening activities.

Cyprium is eligible to receive up to $20 million in development and regulatory cash milestones under such agreement, as well as potential sales milestones totaling up to $255 million. Royalties on CUTX-101 net sales are also payable, with 6% due on that portion of annual net sales up to $75 million, 17.5% due on that portion of annual net sales between $75 million and $100 million, and 25% due on that portion of annual net sales over $100 million. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101.

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: December 7, 2021

By: /s/ Lindsay A. Rosenwald, M.D.
Lindsay A. Rosenwald, M.D.
Chairman, President and Chief Executive Officer
