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 13, 2024**

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 December 13, 2024, Checkpoint Therapeutics ("**Checkpoint**"), a majority-controlled subsidiary of Fortress Biotech, Inc. (the "**Company**" or "**Fortress**"), announced that the U.S. Food and Drug Administration (the "**FDA**") approved UNLOXCYT™ (cosibelimab-ipdl) for the treatment of adults with metastatic or locally advanced cutaneous squamous cell carcinoma ("**cSCC**") who are not candidates for curative surgery or curative radiation. UNLOXCYT is the first and only programmed death ligand-1 (PD-L1) blocking antibody to receive FDA marketing approval for this indication.

The FDA approval for UNLOXCYT was granted based on clinically meaningful objective response rates and duration of response data, as assessed by an independent central review committee, from Study CK-301-101 (NCT03212404), a multicenter, multicohort, open-label study of UNLOXCYT in adults with advanced solid tumor cancers, including cSCC.

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 16, 2024

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