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 24, 2023**

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.

Nasdaq Bid Price Requirement

On October 24, 2023, Fortress Biotech, Inc. (the "**Company**" or "**Fortress**") was formally notified by The Nasdaq Stock Market LLC ("**Nasdaq**") that the Company has evidenced compliance with the $1.00 bid price requirement for continued listing on The Nasdaq Capital Market, as set forth in Nasdaq Listing Rules 5550(a)(2), and that accordingly, the listing matter has been closed.

Cyprium CUTX-101 Development Transfer

As previously disclosed, on February 24, 2021, Cyprium Therapeutics, Inc. ("**Cyprium**"), a private subsidiary of Fortress, entered into a development and asset purchase agreement (the "**Agreement**") with Sentynl Therapeutics, Inc. ("**Sentynl**"), a U.S.-based specialty pharmaceutical company owned by the Zydus Group. Under the Agreement, Sentynl provided certain development funding for Cyprium's CUTX-101 program, with Cyprium remaining in control of development of such program; upon approval of the New Drug Application ("**NDA**") for CUTX-101 by the U.S. Food and Drug Administration ("**FDA**"), Cyprium is obligated to assign the NDA and certain other assets pertaining to the CUTX-101 program to Sentynl, after which point Sentynl will commercialize the drug and owe Cyprium royalties and regulatory and sales milestones.

As also previously disclosed, the Agreement contains an alternative "Approval Deadline Transfer" mechanism pursuant to which, in the event that CUTX-101 NDA approval has not been obtained by September 30, 2023, then Sentynl may elect, during the subsequent 45-day period, to assume control over development of CUTX-101. Following such election, Sentynl will be obligated under the Agreement to use commercially reasonable efforts to develop and commercialize CUTX-101, including the funding of the same. Additionally, following such election, Cyprium remains eligible to receive up to $133.5 million in aggregate development and sales milestones under the Agreement and royalties on net sales of CUTX-101 as follows: (i) 3% of annual net sales up to $75 million; (ii) 8.75% of annual net sales between $75 million and $100 million; and (iii) 12.5% of annual net sales in excess of $100 million.

The Company has received notice of Sentynl's election to effect the Approval Deadline Transfer, with closing of such transfer anticipated to occur in November 2023. Cyprium expects the Approval Deadline Transfer will result in a reduction in its development-related spending on the CUTX-101 program. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains "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. As used below and throughout this Current Report on Form 8-K, the words "we", "us" and "our" may refer to Fortress individually or together with one or more partner companies, as dictated by context. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs, ability to generate shareholder value, ability of our products to receive necessary approvals, including FDA approval, ability of our products and therapies to help patients, expectations related to future revenue, expenses related to Cyprium and any other statements that are not historical facts. 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 our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; risks relating to the timing of starting and completing clinical trials, including disruptions that may result from hostilities in Europe; our dependence on third-party suppliers; risks relating to the COVID-19 outbreak and its potential impact on our employees' and consultants' ability to complete work in a timely manner and on our ability to obtain additional financing on favorable terms or at all; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; 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 Current Report on Form 8-K should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

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 26, 2023

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