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): **July 14, 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.

As previously reported, on October 12, 2020, Fortress' partner company Avenue Therapeutics, Inc. ("Avenue") announced that it had received a Complete Response Letter (the "First CRL") from the U.S. Food and Drug Administration (the "FDA") regarding Avenue's New Drug Application ("NDA") seeking approval for IV tramadol for the management of post-operative pain. The First CRL cited deficiencies related to the terminal sterilization validation and stated that IV tramadol, intended to treat patients in acute pain who require an opioid, is not safe for the intended patient population. In particular, the First CRL stated that, if a patient required an analgesic between the first dose of IV tramadol and the onset of analgesia, the prescribed rescue analgesic would likely be another opioid, which would result in opioid "stacking" and increase the likelihood of opioid-related adverse effects, including respiratory depression.

On February 12, 2021, Avenue resubmitted to the FDA Avenue's NDA for IV tramadol. The NDA resubmission followed the receipt of official minutes from a Type A meeting with the FDA. The resubmission included revised language relating to the proposed product label in an attempt to address the FDA's concerns, and a report relating to terminal sterilization validation. The FDA assigned a Prescription Drug User Fee Act goal date of April 12, 2021. On April 13, 2021, Avenue announced that the FDA was still reviewing Avenue's NDA for IV tramadol and had not provided a decision regarding that NDA.

On June 14, 2021, Avenue announced that it had received a second Complete Response Letter (the "Second CRL") from the FDA regarding Avenue's NDA for IV tramadol. The Second CRL stated that the delayed and unpredictable onset of analgesia with IV tramadol does not support its benefit as a monotherapy to treat patients in acute pain and that there is insufficient information to support that IV tramadol in combination with other analgesics is safe and effective for the intended patient population. In particular, the Second CRL stated that, while the primary endpoint was met in two efficacy studies, meaningful pain relief was delayed (accounting for the use of rescue medication, e.g., ibuprofen), and some patients never achieved pain relief.

At this time, Avenue intends to continue to pursue regulatory approval for IV tramadol and in connection therewith has a Type A meeting currently scheduled with the FDA for late July. Avenue does not believe that the FDA will deviate in such meeting from any of the positions the FDA previously took in the First CRL and the Second CRL, and therefore Avenue currently expects to submit a formal dispute resolution request ("FDRR") with the FDA following such meeting. Avenue is targeting a submission of such FDRR in the third quarter of 2021.

By submitting a FDRR with respect to the Second CRL, Avenue would be availing itself of the FDA's established appeal process whereby disagreements with conclusions reached by a reviewing Division within the FDA are reviewed above such Division level. FDA guidance provides timelines for the appeals process, but those timelines may be extended by the FDA, which can prolong the appeals process.

If Avenue's FDRR is denied at the first appeal level, it can appeal the same matter to the next higher appeal level, through a fourth and final appeal. Avenue expects that the ultimate outcome of this process, if it decides to (and is financially able to) exhaust all such appeals (if necessary) and if none of the timelines provided in the FDA's guidance is extended, could be known by the fourth quarter of 2022. If Avenue's appeal is ultimately granted, it would then be required to resubmit the NDA for IV tramadol to the Division for label renegotiation.

There can be no assurance that any FDRR(s) pursued by Avenue will be completed within the timelines provided in the FDA's guidance for its dispute resolution process and no assurance that any such FDRR(s) will be successful. Avenue may discontinue the pursuit of the FDRR process and regulatory approval of IV tramadol at any point if it determines that the risk/benefit ratio no longer justifies its continued expenditure of resources for such purpose, if its corporate resources are depleted at such point, if the assistance of certain key personnel supporting the approval process comes to an end, or upon the occurrence of certain other events identified as risks in Avenue's public filings.

Avenue's ability to potentially commercialize IV Tramadol, and the timing of any potential commercialization, are dependent on the FDA's review of Avenue's appeal of the FDA's determinations with regard to Avenue's NDA for IV Tramadol, whether or not the FDA ultimately approves IV Tramadol, and on whether or not Avenue is able to successfully procure additional capital to pursue the FDRR(s), for which no assurances can be given.

Under the Stock Purchase and Merger Agreement (the "Avenue SPMA") with InvaGen Pharmaceuticals Inc. ("InvaGen"), and Madison Pharmaceuticals Inc., dated November 12, 2018, consummation of the second stage closing at which InvaGen would acquire the remaining shares of Avenue's common stock for $180 million (the "Merger Transaction') is conditioned upon, among other things, FDA approval of IV tramadol, its labeling and scheduling, and the absence of certain other restrictions in effect with respect to IV tramadol. Pursuant to the Avenue SPMA, if FDA approval of IV tramadol was not obtained on or before April 30, 2021, InvaGen would not be subject to the mandatory closing obligations set forth in the Avenue SPMA with respect to the Merger Transaction. As noted, as of the date of this report, Avenue has not received approval from the FDA for IV tramadol. As a result, InvaGen is no longer subject to the mandatory closing obligations under the Avenue SPMA and has the right to terminate the Avenue SPMA at any time. In addition, InvaGen retains an option to complete the Merger Transaction at their sole discretion until October 31, 2021. Until the option is exercised, expires or is terminated, certain restrictions relating to Avenue's ability to raise capital and explore strategic alternatives, among other things, will apply.

Furthermore, in the event of termination of the Avenue SPMA, InvaGen will retain certain rights pursuant to the Stockholder's Agreement entered into on November 12, 2018 between Avenue and InvaGen. These rights exist as long as InvaGen maintains at least 75% of the common shares acquired in the Stock Purchase Transaction, and include, among other things, the right to restrict Avenue from certain equity issuances and changes to Avenue's capital stock without obtaining InvaGen's prior written consent.

Accordingly, there can be no assurance that the Merger Transaction will be completed, and if it is completed no assurance can be given that it will be consummated on the terms contemplated in the original Avenue SPMA.

It is also possible InvaGen could attempt to pursue monetary claims against Avenue and/or Fortress, regardless of whether or not the Merger Transaction is consummated.

The FDA appeals process is an inherently uncertain one, and the majority of drug candidates that are the subject of FDRR proceedings never obtain regulatory approval. There can be no assurance that the FDA will ever ultimately grant approval for IV tramadol or that Avenue will continue to pursue the appeals process, whether for financial reasons or for other reasons at the discretion of Avenue.

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: July 14, 2021

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