
**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 16, 2025**

Fortress Biotech, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35366
(Commission File Number)

20-5157386
(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	FBIO-P	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 6, 2021, AstraZeneca's Alexion Therapeutics, Inc. ("AstraZeneca") purchased 100% of the equity securities (the "Caelum Acquisition") of Caelum Biosciences, Inc. ("Caelum"), a privately held biopharmaceutical company founded by Fortress Biotech, Inc. ("Fortress"). As part of the Caelum Acquisition, AstraZeneca obtained all of Caelum's right and interest to CAEL-101, its proprietary product candidate for the treatment of light chain (AL) amyloidosis (formerly known as "CAEL-101" and now known as "anselamimab"). Fortress received approximately \$57 million upfront under the Caelum Acquisition and remains eligible to additionally receive up to approximately \$125 million of the up to \$295 million that is remunerable to all former stockholders of Caelum, upon the satisfaction of certain regulatory and sales milestones.

On July 16, 2025, AstraZeneca announced an update from its Cardiac Amyloid Reaching for Extended Survival ("CARES") Phase III clinical program showing that anselamimab did not achieve statistical significance for the primary endpoint compared to placebo in patients with Mayo stages IIIa and IIIb AL amyloidosis. The primary endpoint was defined as a hierarchical combination of time to all-cause mortality ("ACM") and frequency of cardiovascular hospitalizations ("CVH"). All patients in the clinical program received background standard of care for plasma cell dyscrasia.

AstraZeneca stated that anselamimab showed highly clinically meaningful improvement in time to ACM and frequency of CVH in a prespecified subgroup of patients, compared to placebo (although AstraZeneca did not further characterize this subgroup). AstraZeneca also reported that anselamimab was well tolerated, with the majority of events balanced between the anselamimab treatment arm and the placebo arm. AstraZeneca indicated that evaluation of full results from the CARES program is ongoing, in order to further characterize the efficacy and safety of anselamimab, and that the company plans to share these data with global health authorities and present them at a forthcoming medical meeting.

Forward-Looking Statements

Statements in this Current Report on Form 8-K that are not descriptions of historical facts are "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. The words "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "might," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other comparable terminology are generally intended to identify forward-looking statements. These 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: the difficulty of predicting the timing or outcome of regulatory interactions, approvals or actions, including those pertaining to the above-mentioned prespecified subgroup of patients identified by AstraZeneca in its CARES clinical program; our growth strategy, financing and strategic agreements and relationships; our need for substantial additional funds and uncertainties relating to financings; our ability to identify, acquire, close and integrate product candidates successfully and on a timely basis; our ability to attract, integrate and retain key personnel; the early stage of products under development; the results of research and development activities; uncertainties relating to preclinical and clinical testing; our ability to obtain regulatory approval for products under development; our ability to successfully commercialize products for which we receive regulatory approval or receive royalties or other distributions from third parties; our ability to secure and maintain third-party manufacturing, marketing and distribution of our and our partner companies' products and product candidates; 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 press release 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: July 16, 2025

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