# 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): **May 15, 2025**

# 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 2.02. Results of Operations and Financial Condition.**

On May 15, 2025, Fortress Biotech, Inc. issued a press release to provide a corporate update and to announce its financial results for the quarter ended March 31, 2025. A copy of such press release is being furnished as Exhibit 99.1 to this report.

The information, including Exhibit 99.1, in this Form 8-K is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Form 8-K shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall otherwise be expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

The following exhibit is furnished herewith:

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release, dated May 15, 2025 |
| 104 | Cover Page Interactive Data File (the cover page XBRL tags are imbedded in the Inline XBRL document) |

**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: May 15, 2025

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

**Fortress Biotech Reports First Quarter 2025 Financial Results and Recent Corporate Highlights**

*Emrosi™ commercial launch initiated for the treatment of inflammatory lesions of rosacea in adults*

*Fortress subsidiary Checkpoint Therapeutics to be acquired by Sun Pharma; special meeting of Checkpoint stockholders to approve the transaction to take place on May 28, 2025*

*FDA accepted New Drug Application filing for priority review of CUTX-101 to treat Menkes disease; PDUFA goal date of September 30, 2025*

**Miami, FL – May 15, 2025** – Fortress Biotech, Inc. (Nasdaq: FBIO) ("Fortress"), an innovative biopharmaceutical company focused on acquiring and advancing assets to enhance long-term value for shareholders through product revenue, equity holdings and dividend and royalty revenue, today announced financial results and recent corporate highlights for the first quarter ended March 31, 2025.

Lindsay A. Rosenwald, M.D., Fortress ' Chairman, President and Chief Executive Officer, said, " Fortress entered 2025 with strong momentum following a transformational fourth quarter marked by the U.S. Food and Drug Administration ("FDA") approvals of Emrosi™ and UNLOXCYT™, and the acceptance of the New Drug Application ("NDA") for CUTX-101. In the first quarter 2025, our Fortress-founded partner company, Checkpoint Therapeutics, Inc., ("Checkpoint"), signed a merger agreement with Sun Pharma providing for Checkpoint's acquisition by Sun Pharma, which we believe will enable broader patient access for Checkpoint's UNLOXCYT (cosibelimab-ipdl) product and trigger a significant monetization event for Fortress — including an expected ~$28 million at closing, future potential royalties, and a potential CVR payment. These outcomes continue to validate Fortress' business model — identifying, developing, and advancing innovative therapies with strategic optionality for value creation."

Dr. Rosenwald continued, "Looking ahead, we are focused on key value drivers, including the September 30, 2025 Prescription Drug User Fee Act ("PDUFA") action date for CUTX-101, which may also result in a Priority Review Voucher for our subsidiary, Cyprium Therapeutics, upon approval. Commercial launch of Emrosi is also underway with initial prescriptions filled at the end of March. Fortress' robust pipeline — including multiple late-stage programs and newly approved products — positions us for continued revenue growth, value-driving milestones, and additional monetization opportunities. We remain committed to delivering innovative therapies to patients while building long-term shareholder value."

**Recent Corporate Highlights[1]:**

*Monetization Updates*

[1] The development programs depicted in this press release include product candidates in development at Fortress, at Fortress' private or public subsidiaries (referred to herein as "subsidiaries" or "partner companies") and at entities with whom one of the foregoing parties has a significant business relationship, such as an exclusive license or an ongoing product-related payment obligation (such entities referred to herein as "partners"). The words "we", "us" and "our" may refer to Fortress individually, to one or more of our subsidiaries and/or partner companies, or to all such entities as a group, as dictated by context.

- In March 2025, our subsidiary Checkpoint entered into an agreement to be acquired by Sun Pharmaceutical Industries Limited (together with its subsidiaries and/or associated companies, "Sun Pharma"). Fortress owns approximately 6.9 million shares (including Class A Common on an as-converted basis) of Checkpoint's common stock and is eligible to receive a 2.5% royalty on future sales of UNLOXCYT, pursuant to a royalty agreement between Checkpoint, Sun Pharma and Fortress. Upon completion of the transaction, Sun Pharma will acquire all outstanding shares of Checkpoint, and Checkpoint stockholders will receive, for each share of common stock they hold, an upfront cash payment of $4.10, without interest, and a non-transferable contingent value right ("CVR") entitling the stockholder to receive up to an additional $0.70 in cash if cosibelimab is approved prior to certain deadlines in the European Union pursuant to the centralized approval procedure or in Germany, France, Italy, Spain or the United Kingdom, subject to the terms and conditions in the CVR agreement. The closing of the transaction is subject to various conditions including the approval by requisite majorities of holders of Checkpoint's shares at a special meeting of Checkpoint's stockholders on May 28, 2025. We expect the transaction to close shortly after the stockholder meeting, assuming the requisite votes are received, although there can be no assurance that the transaction closes in a timely manner, or at all.

*Regulatory Updates*

- In November 2024, the FDA approved Emrosi (Minocycline Hydrochloride Extended-Release Capsules, 40mg), also known as DFD-29. Emrosi has the potential to be the new treatment paradigm for the millions of patients suffering from inflammatory lesions of rosacea. In March 2025, we announced the launch of Emrosi by our partner company, Journey Medical Corporation ("Journey Medical") (Nasdaq: DERM).
- In December 2024, the FDA approved UNLOXCYT, also known as cosibelimab, our anti-PD-L1 antibody, as a treatment for patients with metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC") who are not candidates for curative surgery or radiation. UNLOXCYT was developed at our partner company, Checkpoint (Nasdaq: CKPT).
- The FDA accepted the NDA submission for CUTX-101 (copper histidinate for Menkes disease) for priority review with a PDUFA goal date of September 30, 2025. In December 2023, we completed the asset transfer of CUTX-101 to Sentynl Therapeutics ("Sentynl"), a wholly owned subsidiary of Zydus Lifesciences Ltd. Sentynl completed the rolling submission of the NDA for CUTX-101 in the fourth quarter of 2024. Cyprium Therapeutics, our subsidiary company that developed CUTX-101, will retain 100% ownership over any FDA Priority Review Voucher that may be issued at NDA approval.

*Commercial Product Updates*

- Journey Medical's net product revenues for the first quarter ended March 31, 2025, were $13.1 million, compared to net product revenues of $13.0 million for the first quarter ended March 31, 2024.
- At the end of March 2025, Journey Medical announced the launch of, and the first prescriptions filled for, Emrosi for the treatment of inflammatory lesions of rosacea in adults. Emrosi is available by prescription at specialty pharmacy chains.

*Clinical Updates*

- In March 2025, we announced that full results from two Phase 3 multicenter, randomized, double-blind, parallel-group, active-comparator and placebo-controlled clinical trials, Minocycline Versus Oracea® in Rosacea-1 ("MVOR-1") and Minocycline Versus Oracea in Rosacea-2 ("MVOR-2"), evaluating Emrosi for the treatment of moderate-to-severe papulopustular rosacea in adults, were published in the *Journal of the American Medical Association - Dermatology*. The results demonstrated the efficacy, safety and tolerability of oral DFD-29 in rosacea. The full publication is available at https://jamanetwork.com/journals/jamadermatology/article-abstract/2830693. Information on such website is not a part of this release.
- In January 2025, we announced that the first patient was dosed in a multicenter, placebo-controlled and randomized Phase 2 clinical trial to evaluate Triplex, a cytomegalovirus ("CMV") vaccine, when administered to human leukocyte antigen matched related stem cell donors to reduce CMV events in

patients undergoing hematopoietic stem cell transplantation. Triplex is currently in development at our subsidiary company, Helocyte, Inc.

**General Corporate:**

- In March 2025, Fortress entered into a strategic collaboration with Partex NV to identify and evaluate biopharmaceutical compounds using artificial intelligence for potential acquisition or licensing by Fortress.
- In February 2025, our partner company Mustang Bio, Inc. (“Mustang”) raised net proceeds of $6.8 million in a public offering.
- Also in February 2025, Mustang announced the exit of the lease for its manufacturing facility in Worcester, Massachusetts and concurrent divestment of certain fixed assets including furniture and equipment to AbbVie Bioresearch Center Inc. for $1.0 million.

**Financial Results:**

- As of March 31, 2025, Fortress’ consolidated cash and cash equivalents totaled $91.3 million, compared to $57.3 million as of December 31, 2024, an increase of $34.0 million during the quarter.
- Fortress’ consolidated cash and cash equivalents totaling $91.3 million as of March 31, 2025, includes $19.5 million attributable to Fortress and the private subsidiaries, $3.5 million attributable to Avenue, $33.0 million attributable to Checkpoint, $14.2 million attributable to Mustang Bio and $21.1 million attributable to Journey Medical.
    - Fortress’ consolidated cash and cash equivalents totaled $57.3 million as of December 31, 2024, and included $20.9 million attributable to Fortress and private subsidiaries, $2.6 million attributable to Avenue, $6.6 million attributable to Checkpoint, $6.8 million attributable to Mustang and $20.3 million attributable to Journey Medical.
- Fortress’ consolidated net product revenue totaled $13.1 million for the first quarter ended March 31, 2025, which is generated from Journey Medical’s marketed dermatology products. This compares to consolidated revenue totaling $13.0 million for the first quarter of 2024.
- Consolidated research and development expenses totaled $3.9 million for the first quarter ended March 31, 2025, compared to $24.8 million for the first quarter ended March 31, 2024.
- Consolidated selling, general and administrative costs were $25.7 million for the first quarter ended March 31, 2025, compared to $17.9 million for the first quarter ended March 31, 2024.
- Consolidated net loss attributable to common stockholders was $(12.7) million, or $(0.48) per share, for the first quarter ended March 31, 2025, compared to net loss attributable to common stockholders of $(17.9) million, or $(1.04) per share for the first quarter ended March 31, 2024.

**About Fortress Biotech**

Fortress Biotech, Inc. (“Fortress”) is an innovative biopharmaceutical company focused on acquiring and advancing assets to enhance long-term value for shareholders through product revenue, equity holdings and dividend and royalty revenue. The company has eight marketed prescription pharmaceutical products and over 20 programs in development at Fortress, at its majority-owned and majority-controlled partners and subsidiaries and at partners and subsidiaries it founded and in which it holds significant minority ownership positions. Fortress’ portfolio is being commercialized and developed for various therapeutic areas including oncology, dermatology, and rare diseases. Fortress’ model is focused on leveraging its significant biopharmaceutical industry expertise and network to further expand and advance the company’s portfolio of product opportunities. Fortress has established partnerships with some of the world’s leading academic research institutions and biopharmaceutical companies to maximize each opportunity to its full potential, including AstraZeneca, City of Hope, Fred Hutchinson Cancer Center, Nationwide Children’s Hospital and Sentynl. For more information, visit www.fortressbiotech.com.

**Forward-Looking Statements**

Statements in this press release 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: our growth strategy, financing and strategic agreements and relationships; our need for substantial additional funds and uncertainties relating to financings; uncertainty related to the timing and completion of the closing of the acquisition of Checkpoint by Sun Pharma and the failure to realize the anticipated benefits of the proposed transaction in the time frame expected, or at all; 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.

**Company Contact:**
Jaclyn Jaffe
Fortress Biotech, Inc.
(781) 652-4500
ir@fortressbiotech.com

**Media Relations Contact:**
Tony Plohoros
6 Degrees
(908) 591-2839
tplohoros@6degreespr.com

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Unaudited Condensed Consolidated Balance Sheets**
**($ in thousands except for share and per share amounts)**

| | March 31, 2025 | December 31, 2024 |
|---|---|---|
| **ASSETS** | | |
| Current assets | | |
| Cash and cash equivalents | $ 91,339 | $ 57,263 |
| Accounts receivable, net | 18,025 | 10,231 |
| Inventory | 12,496 | 14,431 |
| Other receivables - related party | 309 | 171 |
| Prepaid expenses and other current assets | 4,734 | 7,110 |
| Assets held for sale | — | 1,165 |
| Total current assets | 126,903 | 90,371 |
| | | |
| Property, plant and equipment, net | 2,796 | 3,260 |
| Operating lease right-of-use asset, net | 13,303 | 13,861 |
| Restricted cash | 1,220 | 1,552 |
| Intangible assets, net | 30,798 | 31,863 |
| Other assets | 3,051 | 3,316 |
| **Total assets** | **$ 178,071** | **$ 144,223** |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)** | | |
| Current liabilities | | |
| Accounts payable and accrued expenses | $ 66,286 | $ 65,501 |
| Income taxes payable | 952 | 932 |
| Common stock warrant liabilities | 261 | 214 |
| Operating lease liabilities, short-term | 2,159 | 2,623 |
| Partner company notes payable, short-term | 1,875 | — |
| Partner company installment payments - licenses, short-term | — | 625 |
| Other current liabilities | 2,141 | 1,504 |
| Total current liabilities | 73,674 | 71,399 |
| | | |
| Notes payable, long-term, net | 56,382 | 57,962 |
| Operating lease liabilities, long-term | 13,820 | 14,750 |
| Other long-term liabilities | 1,709 | 1,756 |
| **Total liabilities** | **145,585** | **145,867** |
| | | |
| **Commitments and contingencies** | | |
| | | |
| **Stockholders' equity (deficit)** | | |
| Cumulative redeemable perpetual preferred stock, $0.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively, liquidation value of $25.00 per share | 3 | 3 |
| Common stock, $0.001 par value, 200,000,000 shares authorized, 29,554,966 and 27,908,839 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively | 30 | 28 |
| Additional paid-in-capital | 773,668 | 763,573 |
| Accumulated deficit | (751,451) | (740,867) |
| Total stockholders' equity attributed to the Company | 22,250 | 22,737 |
| | | |
| Non-controlling interests | 10,236 | (24,381) |
| Total stockholders' equity (deficit) | 32,486 | (1,644) |
| **Total liabilities and stockholders' equity (deficit)** | **$ 178,071** | **$ 144,223** |

**FORTRESS BIOTECH, INC. AND SUBSIDIARIES**
**Unaudited Condensed Consolidated Statements of Operations**
**($ in thousands except for share and per share amounts)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2025** | **2024** |
| **Revenue** | | |
| Product revenue, net | $ 13,139 | $ 13,030 |
| | | |
| **Operating expenses** | | |
| Cost of goods - (excluding amortization of acquired intangible assets) | 4,790 | 6,002 |
| Amortization of acquired intangible assets | 1,065 | 814 |
| Research and development | 3,938 | 24,839 |
| Selling, general and administrative | 25,663 | 17,941 |
| Total operating expenses | 35,456 | 49,596 |
| Loss from operations | (22,317) | (36,566) |
| | | |
| Other income (expense) | | |
| Interest income | 490 | 833 |
| Interest expense and financing fee | (2,805) | (2,602) |
| Loss on common stock warrant liabilities | (47) | (667) |
| Other income (expense) | (12) | (21) |
| Total other income (expense) | (2,374) | (2,457) |
| **Net loss** | **(24,691)** | **(39,023)** |
| | | |
| Net loss attributable to non-controlling interests | 14,107 | 23,606 |
| **Net loss attributable to Fortress** | **$ (10,584)** | **$ (15,417)** |
| | | |
| Preferred A dividends declared and paid and/or cumulated, and Fortress' share of subsidiary deemed dividends | (2,131) | (2,442) |
| **Net loss attributable to common stockholders** | **$ (12,715)** | **$ (17,860)** |
| | | |
| Net loss per common share attributable to common stockholders - basic and diluted | $ (0.48) | $ (1.04) |
| | | |
| Weighted average common shares outstanding - basic and diluted | 26,450,218 | 17,151,945 |