
**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): **March 31, 2026**

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).

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 March 31, 2026, Fortress Biotech, Inc. issued a press release to provide a corporate update and to announce its financial results for the year ended December 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 March 31, 2026
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: March 31, 2026

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



Fortress Biotech Reports 2025 Financial Results and Recent Corporate Highlights

ZYCUBO® approved by FDA to treat Menkes disease in the United States; Fortress subsidiary Cyprium Therapeutics sold its Rare Pediatric Disease Priority Review Voucher (PRV) for gross proceeds of \$205 million; Cyprium is also eligible to receive tiered royalties and up to approximately \$128 million in aggregate sales milestones from Sentyln Therapeutics

Fortress subsidiary Checkpoint Therapeutics acquired by Sun Pharma; Fortress remains eligible to receive up to an additional \$4.8 million under a contingent value right (CVR), plus a 2.5% royalty on net sales of UNLOXCYT™ (cosibelimab-ipdl)

Miami, FL – March 31, 2026 – 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 income, today announced financial results and recent corporate highlights for the full-year ended December 31, 2025.

Lindsay A. Rosenwald, M.D., Fortress’ Chairman, President and Chief Executive Officer, said, “2025 and early 2026 reflect disciplined execution across our portfolio, including monetizing assets, achieving key regulatory approvals and advancing high-value clinical programs. The acquisition of Checkpoint Therapeutics, Inc. (“Checkpoint”) by Sun Pharma generated meaningful upfront capital and established a long-term royalty stream from UNLOXCYT™ (cosibelimab-ipdl), highlighting the strength of our business model. The FDA approval of ZYCUBO® for Menkes disease, followed by the recent sale of the Rare Pediatric Disease Priority Review Voucher (“PRV”) for \$205 million by our majority-owned subsidiary Cyprium Therapeutics, Inc. (“Cyprium”), demonstrates our continued ability to advance our portfolio toward value-generating approvals and corporate transactions. Additionally, the progression of dotinurad into Phase 3 by Crystalys Therapeutics, to which we transferred rights to dotinurad in exchange for equity in Crystalys and a 3% royalty on dotinurad sales, supported by its Series A \$205 million financing, further validates our strategy of building diversified revenue streams and creating long-term shareholder value.”

Recent Corporate Highlights¹:

Regulatory Updates

- **ZYCUBO® Approved for Menkes Disease; Cyprium Sold PRV for \$205 Million; Royalty and Milestone Participation Secured.** In January 2026, the FDA approved ZYCUBO® (copper histidinate, formerly known as CUTX-101) for the treatment of Menkes disease in pediatric patients. A PRV was issued at approval and transferred to Cyprium under its agreement with Sentyln Therapeutics, Inc. (“Sentyln”). In March 2026, Cyprium closed the sale of the PRV for gross proceeds of \$205 million. Cyprium is also eligible to receive tiered royalties on net sales of

¹ This press release references products being developed or commercialized by Fortress, by Fortress’ private or public subsidiaries (referred to herein as “subsidiaries” or “partner companies”) and by 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.

ZYCUBO® and up to approximately \$128 million in aggregate sales milestones from Sentyln. ZYCUBO® was commercially launched by Sentyln subsequent to approval.

- In connection with the sale of the PRV, Cyprium redeemed all outstanding shares of its 9.375% Perpetual Preferred Stock pursuant to the previously disclosed terms of such securities.
- In total, Fortress expects to receive an aggregate of at least \$100 million from Cyprium pursuant to potential future dividends and intercompany agreements, including amounts owed by Cyprium to Fortress through intercompany debt, interest and accrued expenses. The amount Fortress will receive is subject to change based on various considerations including, but not limited to, Cyprium's obligation to pay 20% of the proceeds from a PRV sale to an institute of the National Institutes of Health, Cyprium's tax obligations on the income received from the PRV sale, any future dividends that may be approved by Cyprium's Board of Directors, and Cyprium's outstanding and future obligations.

Monetization Updates

- **Checkpoint Acquired by Sun Pharma; Fortress Establishes Long-Term Royalty Stream.** In May 2025, Fortress' subsidiary, Checkpoint, was acquired by Sun Pharmaceutical Industries, Inc. (together with its subsidiaries and/or associated companies, "Sun Pharma"). Checkpoint was acquired for an aggregate upfront payment totaling ~\$355 million and ~\$60 million payable in a contingent value right ("CVR"), of which Fortress received ~\$28 million upfront, with the potential for an additional CVR payment of up to \$4.8 million and a 2.5% royalty on future net sales of UNLOXCYT™ (cosibelimab-ipdl). UNLOXCYT™ was approved by the FDA in December 2024 to treat metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC") in patients who are not candidates for curative surgery or radiation and was commercially launched in January 2026.
- **Avenue Therapeutics' Subsidiary Baergic Acquired by Axsome.** In November 2025, Avenue Therapeutics, Inc.'s ("Avenue") subsidiary Baergic Bio, Inc. ("Baergic") was acquired by Axsome Therapeutics ("Axsome"). Under the terms of the purchase agreement, Baergic shareholders received a \$0.3 million upfront payment (less transaction expenses) and are eligible to receive milestone payments of up to \$2.5 million upon the occurrence of certain development and regulatory events for the first indication for AXS-17 (formerly known as BAER-101). Avenue, a Fortress subsidiary, is eligible to receive approximately 74% of all future milestone and royalty payments under the agreement, including up to \$79 million in potential sales milestones and tiered mid-to-high single-digit royalties.
- **\$205 Million Series A Raised by Crystalys to Advance Dotinurad Phase 3 Program.** In the third quarter of 2025, Crystalys Therapeutics ("Crystalys"), in which our majority-owned and controlled subsidiary company Urica Therapeutics, Inc. ("Urica"), maintains an equity position, announced a \$205 million Series A financing to support two global Phase 3 clinical studies evaluating dotinurad for gout. Urica is eligible to receive a 3% royalty on future net sales of dotinurad. Urica entered into an asset purchase agreement, royalty agreement and related agreements with Crystalys in July 2024.

Commercial Product Updates

- **Journey Medical Expands Commercial Footprint of Emrosi™.** At the end of March 2025, our partner company Journey Medical Corporation ("Journey Medical"), commercially launched Emrosi™ (40mg Minocycline Hydrochloride Modified-Release Capsules, consisting of 10mg immediate release and 30mg extended release pellets), also known as DFD-29, for inflammatory lesions of rosacea. Emrosi™ was approved by the FDA in November 2024 and is available by prescription at specialty pharmacy chains. Journey Medical reported net product revenues of \$61.2 million for full-year 2025, compared to net product revenues of \$55.1 million for the full year ended December 31, 2024.

Clinical Updates

- **Dotinurad Enters Phase 3 Development.** In October 2025, the first patients were dosed in Crystalys' two randomized, double-blind, multicenter global Phase 3 trials evaluating dotinurad, a next-generation, once daily oral, URAT1 inhibitor with potential for best-in-class safety and efficacy for the treatment of gout.
 - **Phase 3 CARES Results for Anselamimab (CAEL-101); Regulatory Submission of Prespecified Subgroup Analysis Planned.** In July 2025, AstraZeneca announced that anselamimab (formerly known as CAEL-101) did not achieve statistical significance for the primary endpoint in its Phase III Cardiac Amyloid Reaching for Extended Survival ("CARES") clinical program for Mayo stages IIIa and IIIb AL amyloidosis patients. However, the drug showed
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clinically meaningful improvement in a prespecified subgroup and was well tolerated. AstraZeneca indicated that the company plans to submit the prespecified subgroup analysis from the CARES trials to regulatory authorities.

- **Emrosi™ Phase 3 Data Published in JAMA Dermatology and Journal of Drugs in Dermatology.** In March 2025, 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 December 2025, results from the Phase 1 clinical trial (DFD-29-CD-006) assessing the impact of low-dose oral minocycline (commercially known as Emrosi™) on skin, gastrointestinal (“GI”) and vaginal microflora in healthy adults were published in the *Journal of Drugs in Dermatology*. The clinical trial also assessed the safety and tolerability of the treatment. The results indicate that DFD-29 administration for 16 weeks had no detectable effects on skin, GI tract or vaginal microflora and it was well tolerated in healthy adults, supporting its use as a therapeutic option for patients with moderate-to-severe rosacea.
- **Emrosi™ Phase 3 Results Presented at Scientific Meetings.** In June 2025, a data analysis from the two Phase 3 multicenter clinical trials evaluating Emrosi™ for the treatment of moderate-to-severe papulopustular rosacea in adults was presented at the Society of Dermatology Physician Associates 2025 Summer Dermatology Conference. The analysis determined that differences in body weight did not affect the efficacy of Emrosi™ in the two Phase 3 trials, which supported its November 2024 FDA approval. In October 2025, efficacy data from a pooled analysis of the MVOR-1 and MVOR-2 trials were presented at the 2025 Fall Clinical Dermatology Conference and demonstrated superior efficacy in Investigator’s Global Assessment treatment success rates and inflammatory lesion counts versus both placebo and doxycycline (P<0.001 for all comparisons).
- **Triplex CMV Vaccine Phase 2 Update.** In January 2025, 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 being investigated in eight clinical trials and is currently in development at our subsidiary company, Helocyte, Inc.

General Corporate:

- In March 2026, Fortress made aggregate prepayments on its loan with Oaktree, including a prepayment in connection with the sale of the PRV, reducing the outstanding principal balance to \$15.0 million.
- In February 2026, Avenue entered into an exclusive worldwide license agreement with Duke University to acquire patent and know-how rights pertaining to ATX-04 (clenbuterol), a well-characterized small-molecule β2-adrenergic agonist, in clinical development for the treatment of Pompe disease. ATX-04 is a selective β2-adrenergic agonist with human proof-of-concept data demonstrating improved muscle function and enhanced response to enzyme replacement therapy. Avenue anticipates meeting with the FDA in 2026 to discuss and align on the design of a potential single pivotal trial for ATX-04 for Pompe disease.
- Journey Medical joined the small-cap Russell 2000® and the broad-market Russell 3000® Indexes, in June 2025.

Financial Results:

- As of December 31, 2025, Fortress’ consolidated cash and cash equivalents totaled \$79.4 million, compared to \$86.2 million as of September 30, 2025, and \$57.3 million as of December 31, 2024, a decrease of \$6.8 million for the fourth quarter and an increase of \$22.1 million for the full year.
 - Fortress’ consolidated cash and cash equivalents totaled \$79.4 million as of December 31, 2025, and includes \$35.2 million attributable to Fortress and private subsidiaries, \$2.9 million attributable to Avenue, \$17.3 million attributable to Mustang and \$24.1 million attributable to Journey Medical. Checkpoint was acquired by Sun Pharma in May 2025.
 - Fortress’ consolidated net revenue totaled \$63.3 million for the full year ended December 31, 2025, which included \$61.2 million in net revenue generated from our marketed dermatology products. This compares to
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consolidated net revenue totaling \$57.7 million for the full year ended 2024, which included \$55.1 million in net revenue generated from our marketed dermatology products.

- Consolidated research and development expenses including license acquisitions totaled \$11.9 million for the full year ended December 31, 2025, compared to \$56.9 million for the full year ended December 31, 2024.
- Consolidated selling, general and administrative costs were \$96.4 million for the full year ended December 31, 2025, compared to \$87.7 million for the full year ended December 31, 2024.
- Consolidated net loss attributable to common stockholders was \$(1.9) million, or \$(0.07) per share, for the full year ended December 31, 2025, compared to net loss attributable to common stockholders of \$(55.9) million, or \$(2.69) per share for the full year ended December 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 income. The company has a portfolio of multiple marketed prescription pharmaceutical products and 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, Nationwide Children’s Hospital, Columbia University, Dana-Farber Cancer Center and Sentyln Therapeutics. 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 amounts expected to be realized from future milestone, contingent value right, royalty or similar future revenue streams, if 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 product candidates 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.

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

	December 31, 2025	December 31, 2024
ASSETS		
Current assets		
Cash and cash equivalents	\$ 79,381	\$ 57,263
Accounts receivable, net	29,783	10,231
Inventory	9,624	14,431
Other receivables - related party	158	171
Prepaid expenses and other current assets	4,895	7,110
Assets held for sale	—	1,165
Total current assets	123,841	90,371
Property, plant and equipment, net	2,519	3,260
Operating lease right-of-use asset, net	12,302	13,861
Restricted cash	1,220	1,552
Equity investments, at fair value	17,660	2,585
Intangible assets, net	27,605	31,863
Other assets	401	731
Total assets	\$ 185,548	\$ 144,223
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued expenses	\$ 47,125	\$ 65,501
Income taxes payable	356	932
Common stock warrant liabilities	1	214
Operating lease liabilities, short-term	2,127	2,623
Partner company installment payments - licenses, short-term	—	625
Other current liabilities	135	1,504
Total current liabilities	49,744	71,399
Notes payable, long-term, net	52,417	57,962
Operating lease liabilities, long-term	12,672	14,750
Partner company redeemable perpetual preferred liability	7,085	—
Other long-term liabilities	1,447	1,756
Total liabilities	123,365	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 December 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, 31,364,094 and 27,908,839 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	31	28
Additional paid-in-capital	783,891	763,573
Accumulated deficit	(734,052)	(740,867)
Total stockholders' equity attributed to the Company	49,873	22,737
Non-controlling interests	12,310	(24,381)
Total stockholders' equity (deficit)	62,183	(1,644)
Total liabilities and stockholders' equity (deficit)	\$ 185,548	\$ 144,223

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

	Year Ended December 31,	
	2025	2024
Revenue		
Product revenue, net	\$ 61,239	\$ 55,134
Collaboration revenue	—	1,500
Revenue - related party	—	41
Other revenue	2,023	1,000
Net revenue	<u>63,262</u>	<u>57,675</u>
Operating expenses		
Cost of goods - (excluding amortization of acquired intangible assets)	20,924	20,879
Amortization of acquired intangible assets	4,258	3,424
Research and development	11,901	56,629
Research and development - licenses acquired	—	252
Selling, general and administrative	96,400	87,731
Loss recovery	—	(4,553)
Asset impairment	—	3,692
Total operating expenses	<u>133,483</u>	<u>168,054</u>
Loss from operations	(70,221)	(110,379)
Other income (expense)		
Interest income	2,485	2,683
Interest expense and financing fee	(10,106)	(13,527)
Loss on common stock warrant liabilities	(398)	(638)
Gain from deconsolidation of subsidiary	27,127	—
Other income	17,578	1,318
Total other income (expense)	<u>36,686</u>	<u>(10,164)</u>
Loss before income tax expense	(33,535)	(120,543)
Income tax expense (benefit)	(620)	312
Net loss	<u>(32,915)</u>	<u>(120,855)</u>
Attributable to non-controlling interests	39,730	74,858
Net income (loss) attributable to Fortress	<u>\$ 6,815</u>	<u>\$ (45,997)</u>
Preferred A dividends declared and paid and/or cumulated, and Fortress' share of subsidiary deemed dividends	(8,697)	(9,893)
Net loss attributable to common stockholders	<u>\$ (1,882)</u>	<u>\$ (55,890)</u>
Net loss per common share attributable to common stockholders - basic & diluted	\$ (0.07)	\$ (2.69)
Weighted average common shares outstanding - basic & diluted	27,901,889	20,784,334