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, 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 March 31, 2025, Fortress Biotech, Inc. issued a press release to provide a corporate update and to announce its financial results for the year ended December 31, 2024. 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, 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: March 31, 2025

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

Fortress Biotech Reports 2024 Financial Results and Recent Corporate Highlights

Emrosi™ approved by FDA for the treatment of inflammatory lesions of rosacea in adults, with commercial launch underway; initial distribution ongoing and first prescriptions filled

Fortress subsidiary Checkpoint Therapeutics to be acquired by Sun Pharma; Checkpoint's lead product, UNLOXCYT™, approved by FDA for the treatment of metastatic or locally advanced cutaneous squamous cell carcinoma

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

Miami, FL – March 31, 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 full-year ended December 31, 2024.

Lindsay A. Rosenwald, M.D., Fortress ' Chairman, President and Chief Executive Officer, said, "The fourth quarter of 2024 was transformational for Fortress, marked by two FDA approvals — Emrosi™ and UNLOXCYT™ — as well as the FDAs' recent acceptance of the New Drug Application for CUTX-101. Additionally, we congratulate Fortress-founded partner company, Checkpoint Therapeutics, Inc. ("Checkpoint"), as earlier this month they signed an exciting agreement that delivers FDA approved UNLOXCYT into the capable and established global commercial organization at Sun Pharma, which is expected to expedite patient access. This transaction is also a successful milestone for Fortress as we expect to receive approximately $28 million at closing in addition to a 2.5% royalty on net sales of UNLOXCYT, and up to an additional $4.8 million if the contingent value right (CVR) is achieved. These milestones continue to validate the Fortress business model. We aim to acquire and advance assets to their full potential, in this specific case, with an exit strategy that benefits patients and maximizes value for our shareholders."

Dr. Rosenwald continued, "Looking ahead, we are focused on our next key milestone: the September 30, 2025, Prescription Drug User Fee Act ("PDUFA") goal date for CUTX-101. Upon approval of the New Drug Application, our majority-owned subsidiary, Cyprium Therapeutics, may be eligible for a Priority Review Voucher. The commercial launch of Emrosi for inflammatory lesions of rosacea is underway with first prescriptions filled, and we expect continued revenue growth, portfolio milestone achievements and additional future monetization opportunities given our significant pipeline of late clinical-stage candidates and recently approved products. This is an exciting time for Fortress, and we remain committed to building shareholder value while delivering innovative treatment options to patients with unmet medical needs."

Recent Corporate Highlights[1]:

Monetization Updates

- 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 for a 2.5% royalty on future sales of UNLOXCYT (cosibelimab-ipdl), 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 contingent value rights agreement. The transaction is expected to be completed in the second quarter of 2025. The transaction is subject to customary closing conditions, including required regulatory approvals and approval by the holders of a majority of the voting power of outstanding shares of Checkpoint common stock, and by the holders of a majority of the shares of Checkpoint common stock that are not held by Fortress or by certain other affiliates of Checkpoint. In connection with the transaction, Fortress, which holds a majority of Checkpoint's outstanding voting power, has agreed to vote in favor of the transaction.
- In July 2024, our majority-owned and controlled subsidiary company Urica Therapeutics ("Urica"), entered into an asset purchase agreement, royalty agreement and related agreements with Crystalys Therapeutics ("Crystalys"). Urica transferred rights to dotinurad, its URAT1 inhibitor product candidate in development for the treatment of gout, and related intellectual property, licenses and agreements to Crystalys. In return, Crystalys issued to Urica shares of its common stock equal to 35% of Crystalys' outstanding equity and granted Urica a secured 3% royalty on future net sales of dotinurad.

Regulatory Updates

- In November 2024, the U.S. Food and Drug Administration ("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 February 2025, we hosted a webcast to discuss the U.S. commercial launch plan for Emrosi, and 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 recently accepted the New Drug Application ("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.

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[1] The development programs depicted in this press release include product candidates in development at Fortress, at Fortress' private subsidiaries (referred to herein as "subsidiaries"), at Fortress' public subsidiaries (referred to herein as "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.

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 Minocycline Hydrochloride Extended Release Capsules, 40 mg ("DFD-29" or "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.
- In October 2024, clinical data were presented at the 44th Fall Clinical Dermatology Conference assessing the dermal and systemic pharmacokinetics of Emrosi versus oral doxycycline 40 mg capsules (Oracea®) in healthy subjects. With its extended-release formulation, Emrosi provides higher dermal concentration than doxycycline from day 1 onward at a similar dose, expected to translate into a clinically meaningful impact for treating patients with rosacea, and as demonstrated in Emrosi's Phase 3 clinical trials.
- In September 2024, we presented longer-term data from Checkpoint's pivotal trial of UNLOXCYT in locally advanced and metastatic cSCC during the European Society for Medical Oncology Congress 2024. The longer-term results for UNLOXCYT demonstrate a deepening of response over time, with higher objective response and complete response rates than initially observed at the primary analyses.
- In May 2024, we announced that the first patient was dosed in a multicenter, placebo-controlled, randomized Phase 2 study of Triplex in patients undergoing liver transplantation. The trial will enroll up to 416 CMV seronegative prospective liver transplant recipients and will be conducted across up to 20 nationally recognized transplant centers in the U.S. The trial is funded by a grant from the National Institute of Allergy and Infectious Diseases of the National Institutes of Health that could provide over $20 million in non-dilutive funding. We believe this data set could ultimately be used to support the approval of Triplex in this setting.

Commercial Product Updates

- Journey Medical's net product revenues for the full year ended December 31, 2024, were $55.1 million, compared to net product revenues of $59.7 million for the full year ended December 31, 2023.

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.
- Throughout 2024, Fortress raised total net proceeds of approximately $21.1 million through equity offerings.
- Throughout 2024, Checkpoint raised total net proceeds of approximately $32.8 million through equity offerings and the exercise of existing warrants.
- Throughout 2024, our partner Mustang Bio, Inc. ("Mustang") raised total net proceeds of approximately $11.2 million through equity offerings and the exercise of existing warrants. Subsequently, Mustang raised net proceeds of $6.9 million in a public offering in February 2025.
- Throughout 2024, our partner Avenue Therapeutics, Inc. ("Avenue") raised total net proceeds of approximately $9.8 million through equity offerings and the exercise of existing warrants.
- Throughout 2024, Journey Medical raised total net proceeds of approximately $7.9 million through equity offerings.

- In July 2024, Fortress' Board of Directors paused the payment of dividends on the Company's 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock (the "Series A Preferred Stock") until further notice. Dividends on the Series A Preferred Stock accrue in accordance with their terms; the pausing of these dividends will defer approximately $0.7 million in cash dividend payments each month. The Board intends to revisit its decision regarding the monthly dividend regularly and will assess the profitability and cash flow of the Company to determine whether and when the pause should be lifted.
- Also in July 2024, Fortress reduced its total debt by entering into a new loan agreement maturing in July 2027 with funds managed by Oaktree Capital Management, L.P. ("Oaktree"), a leading global investment firm. The Company received an initial tranche of $35 million and is eligible to draw an additional $15 million with Oaktree's consent. In connection with the new loan agreement, the Company repaid its prior term loan with Oaktree of $50 million resulting in an outstanding debt reduction of approximately $15 million of debt excluding accrued interest and prepayment fees.

Financial Results:

- As of December 31, 2024, Fortress' consolidated cash and cash equivalents totaled $57.3 million, compared to $58.9 million as of September 30, 2024, and $80.9 million as of December 31, 2023, a decrease of $1.6 million for the fourth quarter and a decrease of $23.6 million for the full year.
- Fortress' consolidated cash and cash equivalents totaled $57.3 million as of December 31, 2024, and includes $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 revenue totaled $57.7 million for the full year ended December 31, 2024, which included $55.1 million in net revenue generated from our marketed dermatology products. This compares to consolidated net revenue totaling $84.5 million for the full year ended 2023, which included $59.7 million in net revenue generated from our marketed dermatology products.
- Consolidated research and development expenses including license acquisitions totaled $56.9 million for the full year ended December 31, 2024, compared to $106.1 million for the full year ended December 31, 2023.
- Consolidated selling, general and administrative costs were $87.7 million for the full year ended December 31, 2024, compared to $91.0 million for the full year ended December 31, 2023.
- Consolidated net loss attributable to common stockholders was $(55.9) million, or $(2.69) per share, for the full year ended December 31, 2024, compared to net loss attributable to common stockholders of $(68.7) million, or $(8.47) per share for the full year ended December 31, 2023.

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.

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

	December 31, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 57,263	$ 80,927
Accounts receivable, net	10,231	15,222
Inventory	14,431	10,206
Other receivables - related party	171	167
Prepaid expenses and other current assets	7,110	10,500
Assets held for sale	1,165	—
Total current assets	90,371	117,022
Property, plant and equipment, net	3,260	6,505
Operating lease right-of-use asset, net	13,861	16,990
Restricted cash	1,552	2,438
Intangible assets, net	31,863	20,287
Other assets	3,316	4,284
Total assets	**$ 144,223**	**$ 167,526**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued expenses	$ 65,501	$ 73,562
Income taxes payable	932	843
Common stock warrant liabilities	214	886
Operating lease liabilities, short-term	2,623	2,523
Partner company convertible preferred shares, short-term, net	—	3,931
Partner company installment payments - licenses, short-term	625	3,000
Other current liabilities	1,504	163
Total current liabilities	71,399	84,908
Notes payable, long-term, net	57,962	60,856
Operating lease liabilities, long-term	14,750	18,282
Other long-term liabilities	1,756	1,893
Total liabilities	**145,867**	**165,939**
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, 2024 and December 31, 2023, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 27,908,839 and 15,093,053 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	28	15
Additional paid-in-capital	763,573	717,396
Accumulated deficit	(740,867)	(694,870)
Total stockholders' equity attributed to the Company	22,737	22,544
Non-controlling interests	(24,381)	(20,957)
Total stockholders' equity (deficit)	(1,644)	1,587
Total liabilities and stockholders' equity (deficit)	**$ 144,223**	**$ 167,526**

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

	Year Ended December 31,	
	2024	**2023**
Revenue		
Product revenue, net	$ 55,134	$ 59,662
Collaboration revenue	1,500	5,229
Revenue - related party	41	103
Other revenue	1,000	19,519
Net revenue	57,675	84,513
Operating expenses		
Cost of goods sold - product revenue	20,879	22,893
Amortization of acquired intangible assets	3,424	3,767
Research and development	56,629	101,747
Research and development - licenses acquired	252	4,324
Selling, general and administrative	87,731	90,981
Loss recovery	(4,553)	—
Asset impairment	3,692	3,143
Total operating expenses	168,054	226,855
Loss from operations	(110,379)	(142,342)
Other income (expense)		
Interest income	2,683	3,003
Interest expense and financing fee	(13,527)	(15,315)
Gain (loss) on common stock warrant liabilities	(638)	4,424
Other income (expense)	1,318	(3,403)
Total other income (expense)	(10,164)	(11,291)
Loss before income tax expense	(120,543)	(153,633)
Income tax expense	312	521
Net loss	**(120,855)**	**(154,154)**
Net loss attributable to non-controlling interests	74,858	93,517
Net loss attributable to Fortress	**(45,997)**	**$ (60,637)**
Preferred A dividends declared and paid and/or cumulated, and Fortress' share of subsidiary deemed dividends	(9,893)	(8,032)
Net loss attributable to common stockholders	**$ (55,890)**	**$ (68,669)**
Net loss per common share attributable to common stockholders - basic and diluted	$ (2.69)	$ (8.47)
Weighted average common shares outstanding - basic and diluted	20,784,334	8,110,906