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): **November 14, 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 November 14, 2025, Fortress Biotech, Inc. issued a press release to provide a corporate update and to announce its financial results for the quarter ended September 30, 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 November 14, 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: November 14, 2025

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

Exhibit 99.1

Fortress Biotech Reports Third Quarter 2025 Financial Results and Recent Corporate Highlights

Total net revenue increased 20.5% to $17.6 million for third quarter of 2025 compared to the third quarter of 2024

Fortress subsidiary Checkpoint Therapeutics acquired by Sun Pharma; Fortress received ~$28 million at closing and is eligible to receive up to an additional $4.8 million under a contingent value right (CVR), plus a 2.5% royalty on future net sales of UNLOXCYT™ (cosibelimab-ipdl)

Dotinurad, a next-generation URAT1 inhibitor, is advancing in two Phase 3 clinical trials with potential for best-in-class safety and efficacy following Crystalys Therapeutics' $205 million Series A financing

Miami, FL – November 14, 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 income, today announced financial results and recent corporate highlights for the third quarter ended September 30, 2025.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "Fortress has achieved several strategic milestones that reinforce the strength of our diversified business model and our continued ability to enhance shareholder value across our portfolio. The acquisition of two subsidiaries this year, Checkpoint Therapeutics, Inc. ("Checkpoint"), by Sun Pharma and Baergic Bio, Inc. ("Baergic") by Axsome Therapeutics ("Axsome"), are both strategic exits that represent validation of our approach. The sale of Checkpoint generated approximately $28 million in upfront consideration, with the potential for additional contingent value right (CVR) payments and future royalty income from sales of UNLOXCYT™ (cosibelimab-ipdl) to Fortress. We also anticipate the resubmission of the New Drug Application ("NDA") for CUTX-101, which, upon approval, may qualify for a Priority Review Voucher—further demonstrating the potential embedded value in our pipeline. Journey Medical Corporation ("Journey Medical") continues to deliver strong operational execution, highlighted by the successful launch of Emrosi™ and accelerating commercial performance, supported by expanded payer coverage and new pooled Phase 3 data analysis presented at Fall Clinical demonstrating Emrosi's statistical and clinical superiority over Oracea® and placebo for the treatment of rosacea. Additionally, our late-stage pipeline continues to progress meaningfully, with dotinurad advancing in two Phase 3 trials for the treatment of gout. The $205 million Series A financing announced by Crystalys Therapeutics, Inc. ("Crystalys") underscores the market's confidence in dotinurad's best-in-class potential for safety and efficacy. Urica Therapeutics' ("Urica") strategic sale of dotinurad to Crystalys last year, in exchange for equity and a 3% royalty on future net sales, further positions Fortress to participate in long-term value creation. As we move forward, Fortress remains focused on disciplined execution, optimizing our capital allocation, and advancing high-impact assets that drive sustainable growth and deliver innovative treatments to patients worldwide."

Recent Corporate Highlights[1]:

Monetization Updates

- In November 2025, Avenue Therapeutics, Inc. ("Avenue") announced the acquisition of its subsidiary Baergic by Axsome. Under the terms of the purchase agreement, Baergic shareholders will receive 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) and $1.5 million for each indication thereafter, up to $79 million in potential sales-based milestones, and a tiered mid-to-high single-digit royalty on potential global net sales of AXS-17. Avenue is eligible to receive ~74% of all future payments and royalties payable under the agreement. Avenue is a subsidiary of Fortress.
- 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 CVR, of which Fortress received approximately $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) to Fortress.

Clinical Updates

- In October 2025, the first patients were dosed in 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.
- Also in October 2025, we presented efficacy data from a pooled analysis of the two Phase 3 multicenter, randomized, double-blind, parallel-group, active-comparator and placebo-controlled clinical trials, Minocycline Versus Oracea® in Rosacea-1 and Minocycline Versus Oracea in Rosacea-2, evaluating DFD-29 (40 mg Minocycline Hydrochloride Modified-Release Capsules, 10 mg immediate release and 30 mg extended release) (or "Emrosi™") for the treatment of inflammatory lesions of rosacea in adults, at the 2025 Fall Clinical Dermatology Conference. DFD-29 demonstrated superior efficacy in Investigator's Global Assessment ("IGA") treatment success rates and inflammatory lesion counts versus both placebo and doxycycline ($P<0.001$ for all comparisons).
- 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 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 with regulatory authorities.

Regulatory Updates

- In December 2023, we completed the asset transfer of CUTX-101 to Sentynl Therapeutics ("Sentynl"), a wholly owned subsidiary of Zydus Lifesciences Ltd. Pursuant to the transaction with Sentynl, Sentynl will transfer to Cyprium, if issued upon approval, a Rare Pediatric Disease Priority Review Voucher ("PRV"), and Cyprium will also be eligible to receive royalties on net sales of CUTX-101 and up to $129 million in aggregate development and sales milestones from Sentynl. On September 30, 2025, the FDA issued a Complete Response Letter ("CRL") relating to the NDA for CUTX-101 (copper histidinate), intended to treat Menkes disease in pediatric patients. The CRL noted cGMP deficiencies had been observed at the facility where CUTX-101 is manufactured, and Sentynl expects to resubmit the CUTX-101 NDA shortly. The CRL did not cite any other approvability concerns, nor did it identify any deficiencies in CUTX-101's efficacy and safety data.

[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 July 2025, the FDA granted Orphan Drug Designation to Mustang Bio, Inc. ("Mustang Bio") for MB-101 (IL13Ra2-targeted CAR T-cells) for the treatment of recurrent diffuse and anaplastic astrocytoma and glioblastoma. MB-101 received Orphan Drug Designation on time and with a designation that is broader than the indication proposed. We intend to advance MB-101, in combination with MB-108, as a potential treatment option. Our novel therapeutic strategy, combining our MB-101 CAR-T cell therapy with our MB-108 oncolytic virus, leverages MB-108 to reshape the tumor microenvironment ("TME") to make cold tumors "hot," thereby potentially improving the efficacy of MB-101 CAR-T cell therapy.

Commercial Product Updates

- Journey Medical's net product revenues for the third quarter ended September 30, 2025, were $17.0 million, compared to net product revenues of $14.6 million for the third quarter ended September 30, 2024.
- In July 2025, Journey Medical announced expanded payer access with over 100 million commercial lives in the United States for Emrosi (40mg Minocycline Hydrochloride Modified-Release Capsules, 10mg immediate release and 30mg extended release), the Company's recently launched treatment for the inflammatory lesions of rosacea in adults. This compares to 54 million commercial lives in May 2025.

General Corporate:

- In the third quarter of 2025, Crystalys, in which Urica Therapeutics, Inc. ("Urica") maintains an equity position, announced a $205 million Series A financing to support the advancement of global Phase 3 clinical studies evaluating dotinurad for the treatment of gout. In addition, Urica is eligible to receive a 3% royalty on future net sales of dotinurad. Urica is a majority-owned and controlled subsidiary of Fortress.

Financial Results:

- As of September 30, 2025, Fortress' consolidated cash and cash equivalents totaled $86.2 million, compared to $57.3 million as of December 31, 2024, an increase of $28.9 million year-to-date.
- Fortress' consolidated cash and cash equivalents, totaling $86.2 million as of September 30, 2025, includes $38.6 million attributable to Fortress and the private subsidiaries, $3.7 million attributable to Avenue, $19.0 million attributable to Mustang Bio and $24.9 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 Bio and $20.3 million attributable to Journey Medical. Checkpoint was acquired by Sun Pharma in May 2025.
- Fortress' consolidated net revenue totaled $17.6 million for the third quarter ended September 30, 2025, $17.0 million of which was generated from our marketed dermatology products. This compares to consolidated net revenue totaling $14.6 million for the third quarter of 2024, all of which was generated from our marketed dermatology products.
- Consolidated research and development expenses totaled $0.2 million for the third quarter ended September 30, 2025, compared to $9.4 million for the third quarter ended September 30, 2024.
- Consolidated selling, general and administrative costs were $17.4 million for the third quarter ended September 30, 2025, compared to $22.0 million for the third quarter ended September 30, 2024.
- Consolidated net income attributable to common stockholders was $3.7 million, or $0.13 per share basic, and $0.11 per share diluted, for the third quarter ended September 30, 2025, compared to net loss attributable to common stockholders of $(15.0) million, or $(0.76) per share basic and diluted, for the third quarter ended September 30, 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 eight marketed prescription pharmaceutical products and multiple 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 Sentynl 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 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
Condensed Consolidated Balance Sheets
($ in thousands except for share and per share amounts)

	September 30, 2025	December 31, 2024
ASSETS	*(Unaudited)*	
Current assets		
Cash and cash equivalents	$ 86,218	$ 57,263
Accounts receivable, net	17,983	10,231
Inventory	11,818	14,431
Other receivables - related party	142	171
Prepaid expenses and other current assets	2,342	7,110
Assets held for sale	—	1,165
Total current assets	118,503	90,371
Property, plant and equipment, net	2,611	3,260
Operating lease right-of-use asset, net	12,321	13,861
Restricted cash	1,220	1,552
Intangible assets, net	28,670	31,863
Other assets	18,082	3,316
Total assets	**$ 181,407**	**$ 144,223**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued expenses	$ 45,171	$ 65,501
Income taxes payable	1,005	932
Common stock warrant liabilities	2	214
Operating lease liabilities, short-term	2,129	2,623
Partner company notes payable, short-term	5,625	—
Partner company installment payments - licenses, short-term	—	625
Other current liabilities	135	1,504
Total current liabilities	54,067	71,399
Notes payable, long-term, net	47,774	57,962
Operating lease liabilities, long-term	12,765	14,750
Other long-term liabilities	1,616	1,756
Total liabilities	**116,222**	**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 September 30, 2025 and December 31, 2024, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 31,005,170 and 27,908,839 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	31	28
Additional paid-in-capital	785,943	763,573
Accumulated deficit	(730,115)	(740,867)
Total stockholders' equity attributed to the Company	55,862	22,737
Non-controlling interests	9,323	(24,381)
Total stockholders' equity (deficit)	65,185	(1,644)
Total liabilities and stockholders' equity (deficit)	**$ 181,407**	**$ 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue				
Product revenue, net	$ 17,025	$ 14,629	$ 45,173	$ 42,514
Revenue - related party	—	—	—	41
Other revenue	606	—	2,010	—
Net revenue	17,631	14,629	47,183	42,555
Operating expenses				
Cost of goods - (excluding amortization of acquired intangible assets)	5,755	4,471	15,484	16,199
Amortization of acquired intangible assets	1,064	814	3,193	2,443
Research and development	208	9,446	12,268	46,941
Selling, general and administrative	17,415	21,993	81,670	60,867
Asset impairment	—	—	—	2,649
Total operating expenses	24,442	36,724	112,615	129,099
Loss from operations	(6,811)	(22,095)	(65,432)	(86,544)
Other income (expense)				
Interest income	736	589	1,848	2,157
Interest expense and financing fee	(2,742)	(6,209)	(8,065)	(10,933)
Gain (loss) on common stock warrant liabilities	(2)	19	(399)	(578)
Gain from deconsolidation of subsidiary	—	—	27,127	—
Other income	17,672	1,071	17,599	1,334
Total other income (expense)	15,664	(4,530)	38,110	(8,020)
Income (loss) before income tax expense	8,853	(26,625)	(27,322)	(94,564)
Income tax expense (refund)	26	69	196	(24)
Net income (loss)	**8,827**	**(26,694)**	**(27,518)**	**(94,540)**
Attributable to non-controlling interests	(2,977)	13,827	38,270	55,308
Net income (loss) attributable to Fortress	**$ 5,850**	**$ (12,867)**	**$ 10,752**	**$ (39,232)**
Preferred A dividends declared and paid and/or cumulated, and Fortress' share of subsidiary deemed dividends	(2,174)	(2,173)	(6,436)	(7,006)
Net income (loss) attributable to common stockholders	**$ 3,675**	**$ (15,040)**	**$ 4,316**	**$ (46,238)**
Net income (loss) per common share attributable to common stockholders - basic	$ 0.13	$ (0.76)	$ 0.16	$ (2.43)
Net income (loss) per common share attributable to common stockholders - diluted	$ 0.11	$ (0.76)	$ 0.14	$ (2.43)
Weighted average common shares outstanding - basic	27,244,474	19,697,290	27,075,216	19,041,590
Weighted average common shares outstanding - diluted	33,100,961	19,697,290	30,695,996	19,041,590