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): **August 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 August 14, 2025, Fortress Biotech, Inc. issued a press release to provide a corporate update and to announce its financial results for the quarter ended June 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 August 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: August 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 Second Quarter 2025 Financial Results and Recent Corporate Highlights

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)

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

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

Miami, FL – August 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 revenue, today announced financial results and recent corporate highlights for the second quarter ended June 30, 2025.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "We achieved several key milestones in the second quarter that underscore the strength of Fortress's diversified business model and our ability to create value across our portfolio. The acquisition of our subsidiary Checkpoint Therapeutics by Sun Pharma marked a significant validation of our business model, delivering approximately $28 million upfront, plus the potential for an additional contingent value right (CVR) payment and ongoing royalties on future sales of UNLOXCYT™ (cosibelimab-ipdl). We also look forward to the PDUFA goal date for CUTX-101, which is rapidly approaching on September 30, 2025 and the potential Priority Review Voucher which may be issued upon approval."

Dr. Rosenwald continued, "In addition, Mustang Bio received Orphan Drug Designation for MB-101, reinforcing the promise of our combination strategy leveraging MB-101 and MB-108 to target high-grade gliomas. Journey Medical continues to execute well, with the launch of Emrosi™ and commercial uptake, including expanded payer coverage now reaching 65% of U.S. commercial lives. We remain focused on unlocking the value of our portfolio and delivering innovative treatments to patients in need."

Recent Corporate Highlights[1]:

Monetization Updates

- On May 30, 2025, Fortress' subsidiary, Checkpoint Therapeutics, Inc. ("Checkpoint"), was acquired by Sun Pharmaceutical Industries, Inc. (together with its subsidiaries and/or associated companies, "Sun Pharma"). Fortress received ~$28 million shortly after closing and is eligible to receive up to an

[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.

additional $4.8 million under a contingent value right (CVR), plus a 2.5% royalty on future net sales of UNLOXCYT™ (cosibelimab-ipdl).

Regulatory Updates

- The FDA accepted the NDA submission for CUTX-101 (copper histidinate for Menkes disease) for priority review with a Prescription Drug User Fee Act ("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. 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.
- In July 2025, the FDA granted Orphan Drug Designation to Mustang 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 second quarter ended June 30, 2025, were $15.0 million, compared to net product revenues of $14.9 million for the second quarter ended June 30, 2024.
- At the end of March 2025, Journey Medical announced initial distribution to pharmacies and first prescriptions filled for Emrosi for the treatment of inflammatory lesions of rosacea in adults. The full commercial launch began on April 7, 2025. Emrosi is available by prescription at specialty pharmacy chains.
- 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.

Clinical Updates

- In June 2025, we announced that 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 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 is continuing to evaluate the full results and plans to share the data with health authorities and at a medical meeting.

General Corporate:

- Journey Medical joined the small-cap Russell 2000® Index and the broad-market Russell 3000® Index, effective after the close of U.S. equity markets on June 27, 2025, as a result of the 2025 annual Russell Index reconstitution.

Financial Results:

- As of June 30, 2025, Fortress' consolidated cash and cash equivalents totaled $74.4 million, compared to $57.3 million as of December 31, 2024, an increase of $17.1 million year-to-date.
- Fortress' consolidated cash and cash equivalents, totaling $74.4 million as of June 30, 2025, includes $38.1 million attributable to Fortress and the private subsidiaries, $3.3 million attributable to Avenue, $12.7 million attributable to Mustang Bio and $20.3 million attributable to Journey Medical. Checkpoint was acquired by Sun Pharma in May 2025.
    - 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 revenue totaled $16.4 million for the second quarter ended June 30, 2025, $15.0 million of which was generated from our marketed dermatology products. This compares to consolidated net revenue totaling $14.9 million for the second quarter of 2024, most of which was generated from our marketed dermatology products.
- Consolidated research and development expenses totaled $8.1 million for the second quarter ended June 30, 2025, compared to $12.7 million for the second quarter ended June 30, 2024.
- Consolidated selling, general and administrative costs were $38.8 million for the second quarter ended June 30, 2025, compared to $20.8 million for the second quarter ended June 30, 2024.
- Consolidated net income attributable to common stockholders was $13.4 million, or $0.50 per share basic, and $0.45 per share diluted, for the second quarter ended June 30, 2025, compared to net loss attributable to common stockholders of $(13.3) million, or $(0.73) per share basic and diluted, for the second quarter ended June 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 revenue. 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, 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 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.

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

	June 30, 2025	December 31, 2024
ASSETS		
Current assets		
Cash and cash equivalents	$ 74,386	$ 57,263
Accounts receivable, net	15,644	10,231
Inventory	12,852	14,431
Other receivables - related party	558	171
Prepaid expenses and other current assets	6,956	7,110
Assets held for sale	—	1,165
Total current assets	110,396	90,371
Property, plant and equipment, net	2,704	3,260
Operating lease right-of-use asset, net	12,817	13,861
Restricted cash	1,220	1,552
Intangible assets, net	29,734	31,863
Other assets	3,024	3,316
Total assets	**$ 159,895**	**$ 144,223**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued expenses	$ 48,576	$ 65,501
Income taxes payable	984	932
Common stock warrant liabilities	—	214
Operating lease liabilities, short-term	2,140	2,623
Partner company notes payable, short-term	3,750	—
Partner company installment payments - licenses, short-term	—	625
Other current liabilities	2,071	1,504
Total current liabilities	57,521	71,399
Notes payable, long-term, net	50,026	57,962
Operating lease liabilities, long-term	13,303	14,750
Other long-term liabilities	1,662	1,756
Total liabilities	**122,512**	**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 June 30, 2025 and December 31, 2024, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 29,752,795 and 27,908,839 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	30	28
Additional paid-in-capital	779,856	763,573
Accumulated deficit	(735,965)	(740,867)
Total stockholders' equity attributed to the Company	43,924	22,737
Non-controlling interests	(6,541)	(24,381)
Total stockholders' equity (deficit)	37,383	(1,644)
Total liabilities and stockholders' equity (deficit)	**$ 159,895**	**$ 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue				
Product revenue, net	$ 15,009	$ 14,855	$ 28,148	$ 27,885
Revenue - related party	—	41	—	41
Other revenue	1,404	—	1,404	—
Net revenue	16,413	14,896	29,552	27,926
Operating expenses				
Cost of goods - (excluding amortization of acquired intangible assets)	4,939	5,727	9,729	11,728
Amortization of acquired intangible assets	1,064	814	2,129	1,629
Research and development	8,126	12,671	12,060	37,495
Selling, general and administrative	38,757	20,823	64,424	38,777
Asset impairment	—	2,649	—	2,649
Total operating expenses	52,886	42,684	88,342	92,278
Loss from operations	(36,473)	(27,788)	(58,790)	(64,352)
Other income (expense)				
Interest income	622	734	1,112	1,567
Interest expense and financing fee	(2,518)	(2,122)	(5,324)	(4,724)
Gain (loss) on common stock warrant liabilities	(350)	70	(397)	(597)
Gain from deconsolidation of subsidiary	27,127	—	27,127	—
Other income (expense)	(62)	282	(73)	260
Total other income (expense)	24,819	(1,036)	22,445	(3,494)
Net loss	**(11,654)**	**(28,824)**	**(36,345)**	**(67,846)**
Attributable to non-controlling interests	27,140	17,876	41,247	41,481
Net income (loss) attributable to Fortress	**$ 15,486**	**$ (10,948)**	**$ 4,902**	**$ (26,365)**
Net income (loss) attributable to common stockholders	**$ 13,355**	**$ (13,339)**	**$ 640**	**$ (31,199)**
Net income (loss) per common share attributable to common stockholders - basic	$ 0.50	$ (0.73)	$ 0.02	$ (1.76)
Net income (loss) per common share attributable to common stockholders - diluted	$ 0.45	$ (0.73)	$ 0.02	$ (1.76)
Weighted average common shares outstanding - basic	26,879,380	18,316,874	26,679,106	17,736,299
Weighted average common shares outstanding - diluted	29,824,182	18,316,874	29,182,033	17,736,299