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, 2024**

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, 2024, Fortress Biotech, Inc. issued a press release to provide a corporate update and to announce its financial results for the quarter ended September 30, 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 November 14, 2024
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, 2024

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 2024 Financial Results and Recent Corporate Highlights

Emrosi approved by FDA on November 4 for the treatment of inflammatory lesions of rosacea in adults

Cosibelimab PDUFA goal date of December 28 for potential approval to treat metastatic or locally advanced cutaneous squamous cell carcinoma

Miami, FL – November 14, 2024 – 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 third quarter ended September 30, 2024.

Lindsay A. Rosenwald, M.D., Fortress ' Chairman, President and Chief Executive Officer, said, "We are thrilled to have received U.S. Food and Drug Administration ("FDA") approval for Emrosi™, a potential best-in-class treatment for inflammatory lesions of rosacea in adults, which is a tremendous milestone for Fortress and our partner company, Journey Medical Corporation ("Journey Medical"). This marks the first FDA approval across the Fortress portfolio, and demonstrates our ability to successfully in-license a clinical stage program and develop it through commercialization. We could achieve up to two more U.S. FDA approvals in the next nine months, and our next anticipated PDUFA goal date is December 28, 2024, for cosibelimab, an anti-PD-L1 antibody, for the treatment of metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC"). We have an exciting late-stage pipeline with many upcoming value creation opportunities, and we are focused on attaining our long-term strategy of building shareholder value, while bringing innovative treatment options to patients with unmet medical needs."

Recent Corporate Highlights[1]:

Regulatory Updates

- In November 2024, the FDA approved Emrosi (Minocycline Hydrochloride Extended-Release Capsules, 40mg), also known as DFD-29. Emrosi has the potential to be the new treatment paradigm for the millions of patients suffering from inflammatory lesions of rosacea. The treatment is expected to launch late in the first quarter or early in the second quarter of 2025 by our partner company, Journey Medical (Nasdaq: DERM).
- In July 2024, the FDA accepted the Biologics License Application ("BLA") resubmission for cosibelimab, our investigational anti-PD-L1 antibody, as a treatment for patients with metastatic or locally advanced cSCC who are not candidates for curative surgery or radiation and set a PDUFA goal date of December 28, 2024. Cosibelimab is currently in development at our partner company, Checkpoint Therapeutics (Nasdaq: CKPT) ("Checkpoint").

[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.

- In December 2023, we completed the asset transfer of CUTX-101 (copper histidinate for Menkes disease) to Sentynl Therapeutics ("Sentynl"), a wholly owned subsidiary of Zydus Lifesciences Ltd. Sentynl completed the rolling submission of the New Drug Application for CUTX-101 in the fourth quarter of 2024. Cyprium Therapeutics ("Cyprium"), our subsidiary company that developed CUTX-101, will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101.

Clinical Updates

- 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 our pivotal trial of cosibelimab in locally advanced and metastatic cSCC during the European Society for Medical Oncology ("ESMO") Congress 2024. The longer-term results for cosibelimab demonstrate a deepening of response over time, with higher objective response and complete response rates than initially observed at the primary analyses.

Other Updates

- In July 2024, we announced a collaboration to explore the combined therapeutic potential of cosibelimab with GC Cell's Immuncell-LC, an innovative autologous Cytokine Induced Killer ("CIK") T cell therapy composed of cytotoxic T lymphocytes and natural killer T cells.
- Also 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 securitized 3% royalty on future net sales of dotinurad.

Commercial Product Updates

- Journey Medical's net product revenues for the third quarter ended September 30, 2024 were $14.6 million, compared to net product revenues of $14.9 million for the second quarter ended June 30, 2024.

General Corporate:

- In July 2024, Checkpoint raised $12 million in a registered direct offering priced at-the-market under Nasdaq rules.
- 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. The Company believes pausing the dividend is in the best interest of the Company and its stakeholders to maintain financial flexibility ahead of potentially significant inflection points. 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 suspension 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.

- In September 2024, Fortress raised $8 million in a registered direct offering and concurrent private placements.
- In October 2024, Mustang Bio raised $4 million in gross proceeds from the exercise of existing warrants.
- In November 2024, Checkpoint received $9.2 million in gross proceeds through the exercise of existing warrants.

Financial Results:

- As of September 30, 2024, Fortress' consolidated cash and cash equivalents totaled $58.9 million, compared to $76.2 million as of June 30, 2024, and compared to $80.9 million as of December 31, 2023, a decrease of $17.3 million during the quarter and a decrease of $22.0 million year-to-date.
- Fortress' consolidated cash and cash equivalents, totaling $58.9 million as of September 30, 2024, includes $25.6 million attributable to Fortress and the private subsidiaries, $2.6 million attributable to Avenue, $4.7 million attributable to Checkpoint, $3.5 million attributable to Mustang Bio and $22.5 million attributable to Journey Medical.
    - Fortress' consolidated cash and cash equivalents totaled $80.9 million as of December 31, 2023, which included $40.6 million attributable to Fortress and private subsidiaries, $1.8 million attributable to Avenue, $4.9 million attributable to Checkpoint, $6.2 million attributable to Mustang Bio and $27.4 million attributable to Journey Medical.
- Fortress' consolidated net revenue totaled $14.6 million for the third quarter ended September 30, 2024, all of which was generated from our marketed dermatology products. This compares to consolidated revenue totaling $34.8 million for the third quarter of 2023, which included $15.3 million in revenue generated from our marketed dermatology products and an upfront license agreement payment of $19 million.
- Consolidated research and development expenses including license acquisitions totaled $9.4 million for the third quarter ended September 30, 2024, compared to $20.3 million for the third quarter ended September 30, 2023.
- Consolidated selling, general and administrative costs were $22.0 million for the third quarter ended September 30, 2024, compared to $21.7 million for the third quarter ended September 30, 2023.
- Consolidated net loss attributable to common stockholders was $(15.0) million, or $(0.76) per share, for the third quarter ended September 30, 2024, compared to net loss attributable to common stockholders of $(7.1) million, or $(0.94) per share for the third quarter ended September 30, 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 seven 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; 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)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 58,853	$ 80,927
Accounts receivable, net	10,671	15,222
Inventory	11,788	10,206
Other receivables - related party	174	167
Prepaid expenses and other current assets	2,583	10,500
Assets held for sale	2,209	—
Total current assets	86,278	117,022
Property, plant and equipment, net	3,403	6,505
Operating lease right-of-use asset, net	14,152	16,990
Restricted cash	2,063	2,438
Intangible assets, net	17,844	20,287
Other assets	3,345	4,284
Total assets	**$ 127,085**	**$ 167,526**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued expenses	$ 64,499	$ 73,562
Income taxes payable	850	843
Common stock warrant liabilities	154	886
Operating lease liabilities, short-term	2,514	2,523
Partner company convertible preferred shares, short-term, net	—	3,931
Partner company installment payments - licenses, short-term	1,250	3,000
Other short-term liabilities	1,038	163
Total current liabilities	70,305	84,908
Notes payable, long-term, net	52,473	60,856
Operating lease liabilities, long-term	15,292	18,282
Other long-term liabilities	1,753	1,893
Total liabilities	**139,823**	**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 September 30, 2024 and December 31, 2023, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 27,584,600 and 15,093,053 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	28	15
Additional paid-in-capital	755,229	717,396
Accumulated deficit	(734,102)	(694,870)
Total stockholders' equity attributed to the Company	21,158	22,544
Non-controlling interests	(33,896)	(20,957)
Total stockholders' equity (deficit)	(12,738)	1,587
Total liabilities and stockholders' equity (deficit)	**$ 127,085**	**$ 167,526**

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,	
	2024	2023	2024	2023
Revenue				
Product revenue, net	$ 14,629	$ 15,279	$ 42,514	$ 44,405
Collaboration revenue	—	182	—	546
Revenue - related party	—	31	41	97
Other revenue	—	19,260	—	19,519
Net revenue	14,629	34,752	42,555	64,567
Operating expenses				
Cost of goods sold - product revenue	5,285	6,429	18,642	20,645
Research and development	9,446	20,288	46,941	87,702
Research and development - licenses acquired	—	60	—	4,293
Selling, general and administrative	21,993	21,733	60,867	71,512
Asset impairment	—	—	2,649	3,143
Total operating expenses	36,724	48,510	129,099	187,295
Loss from operations	(22,095)	(13,758)	(86,544)	(122,728)
Other income (expense)				
Interest income	589	547	2,157	2,296
Interest expense and financing fee	(6,209)	(2,534)	(10,933)	(13,255)
Gain (loss) on common stock warrant liabilities	19	4,542	(578)	10,708
Other income (expense)	1,071	620	1,334	(2,049)
Total other income (expense)	(4,530)	3,175	(8,020)	(2,300)
Loss before income tax expense	(26,625)	(10,583)	(94,564)	(125,028)
Income tax expense (refund)	69	141	(24)	142
Net loss	**(26,694)**	**(10,724)**	**(94,540)**	**(125,170)**
Net loss attributable to non-controlling interests	13,827	5,679	55,308	73,812
Net loss attributable to Fortress	**$ (12,867)**	**$ (5,045)**	**$ (39,232)**	**$ (51,358)**
Preferred A dividends declared and paid and/or cumulated, and Fortress' share of subsidiary deemed dividends	(2,173)	(2,008)	(7,006)	(6,024)
Net loss attributable to common stockholders	**$ (15,040)**	**$ (7,053)**	**$ (46,238)**	**$ (57,382)**
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.76)	$ (0.94)	$ (2.43)	$ (7.94)
Weighted average common shares outstanding - basic and diluted	19,697,290	7,498,653	19,041,590	7,231,004