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 13, 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 August 13, 2024, Fortress Biotech, Inc. issued a press release to provide a corporate update and to announce its financial results for the quarter ended June 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 August 13, 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: August 13, 2024

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

Fortress Biotech Reports Second Quarter 2024 Financial Results and Recent Corporate Highlights

PDUFA goal date of November 4, 2024 for DFD-29 for the treatment of inflammatory lesions and erythema of rosacea in adults

FDA accepted Biologics License Application resubmission for cosibelimab to treat metastatic or locally advanced cutaneous squamous cell carcinoma; PDUFA goal date of December 28, 2024

Miami, FL – August 13, 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 second quarter ended June 30, 2024.

Lindsay A. Rosenwald, M.D., Fortress ' Chairman, President and Chief Executive Officer, said, "We had a very productive first half of the year and we anticipate an exciting second half, as we have a New Drug Application ("NDA") and a Biologics License Application ("BLA") on file with the U.S. Food and Drug Administration ("FDA") from our diversified portfolio, both with PDUFA goal dates in the fourth quarter, including DFD-29 for rosacea and cosibelimab for metastatic and locally advanced cutaneous squamous cell carcinoma ("cSCC"). Our late-stage candidates could generate up to three regulatory approvals in the next 12 months and a potential fourth BLA submission as early as 2025. Additionally, we had a solid second quarter 2024 of product revenue from our marketed dermatology products of $14.9 million, representing growth of approximately 15% compared to first quarter 2024 product revenues of $13.0 million. We continue to prioritize the development of our candidates and the expansion of our business for long-term success. This involves business development efforts and the growth of additional revenue streams, all aimed at benefiting our shareholders. Our business model provides the potential for significant growth as we acquire new assets and our subsidiary and partner companies grow in value, allowing for the opportunity to collect diversified cashflows such as royalties, milestones, product revenues, cash and stock dividends and through meaningful monetizations."

Recent Corporate Highlights[1]:

Regulatory Updates

- In March 2024, the FDA accepted the NDA for DFD-29 (Minocycline Hydrochloride Modified Release Capsules, 40 mg) and set a PDUFA goal date of November 4, 2024. If approved, DFD-29 has the potential to be the new treatment paradigm for the millions of patients suffering from inflammatory lesions and erythema of rosacea. Both double blinded, randomized controlled DFD-29 Phase 3 clinical trials achieved their co-primary and all secondary endpoints with subjects completing the 16-week treatment with no significant safety issues. DFD-29 demonstrated statistical superiority compared to both Oracea capsules and placebo for Investigator's Global Assessment (IGA) treatment success and

[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.

the reduction in the total inflammatory lesion count in both clinical trials. Additionally, DFD-29 showed significantly superior reduction in Clinicians Erythema Assessment compared to placebo in both of the Phase 3 clinical trials. DFD-29 is currently in development at our partner company, Journey Medical Corporation (Nasdaq: DERM) ("Journey Medical").

- In July 2024, the FDA accepted the 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. In June 2024, we reached alignment with the FDA on our BLA resubmission strategy for cosibelimab and announced the resubmission of the BLA in July 2024. Cosibelimab is currently in development at our partner company, Checkpoint Therapeutics, Inc. (Nasdaq: CKPT) ("Checkpoint").

Clinical Updates

- In May 2024, we announced that the last patient had completed dosing in a Phase 1b/2a study evaluating AJ201 in the U.S. for the treatment of spinal and bulbar muscular atrophy ("SBMA"), also known as Kennedy's Disease. SBMA is a debilitating rare genetic neuromuscular disease primarily affecting men. Topline data for the Phase 1b/2a clinical trial of AJ201 to treat SBMA are currently expected in the second half of 2024. A webcast replay of the Key Opinion Leader event that took place in April 2024 highlighting expert perspectives on SBMA is available on the Events page of Avenue's website at https://avenuetx.com/. AJ201 is currently in development at our partner company, Avenue Therapeutics, Inc. (Nasdaq: ATXI) ("Avenue").
- The Phase 2 clinical trial of Triplex, a cytomegalovirus vaccine, for adults co-infected with Human Immunodeficiency Virus ("HIV") and CMV is now fully enrolled with topline data anticipated in the fourth quarter of 2024. The study aims to show that vaccination with Triplex can safely elicit a CMV-specific immune response and reduce asymptomatic CMV replication in a population of people with HIV on suppressive antiretroviral therapy. The study will also evaluate whether this intervention might reduce chronic inflammation and immune activation, as compared to placebo, and thus, potentially reduce related mortality and morbidity. Triplex is currently in development at our subsidiary company, Helocyte, Inc.
- In May 2024, we announced that the first patient was dosed in a multi-center, placebo-controlled, randomized Phase 2 study of Triplex, a vaccine for control of CMV, 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.

Other Updates

- In July 2024, we announced a collaboration to explore the combined therapeutic potential of cosibelimab, our anti-PD-L1 antibody, 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.
- In July 2024, our majority owned and controlled subsidiary company, Urica Therapeutics, Inc. ("Urica"), entered into an asset purchase agreement, royalty agreement, and related agreements (collectively, the "Transaction Documents") with Crystalys Therapeutics, Inc. ("Crystalys"). Crystalys is a Delaware corporation incorporated in 2022 and seeded by leading life sciences institutional investors. Under the Transaction Documents, Urica transferred rights to its URAT1 inhibitor product candidate in development for the treatment of gout, dotinurad, 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. The Transaction Documents also grant Urica a securitized three percent (3%) royalty on future net sales of dotinurad to be paid by Crystalys, as well as the right to receive nominal cash reimbursement payments for certain clinical and development costs incurred by Urica related to dotinurad.
- In October 2023, we announced an exclusive worldwide option agreement with City of Hope ("COH") to license certain intellectual property relating to a CMV/HIV bi-specific Chimeric Antigen Receptor

("CAR") (collectively, CMV/HIV-CAR) T cell program for the treatment of adults living with HIV, optionally in combination with Triplex. Additionally, the California Institute for Regenerative Medicine awarded a $11.3 million grant to COH to fund a Phase 1 clinical trial involving the CMV/HIV-CAR T. In preclinical studies, administration of the bi-specific CAR T cells followed by administration of a CMV vaccine successfully eradicated HIV, including from latent reservoirs.

Commercial Product Updates

- Journey Medical's total net revenues for the second quarter ended June 30, 2024 were $14.9 million, compared to total net revenues of $13.0 million for the first quarter ended March 31, 2024.

General Corporate:

- In April 2024, Avenue announced the exercise of warrants for $4.4 million in gross proceeds and a 1-for-75 reverse split of its issued and outstanding common stock.
- In May and June 2024, Mustang Bio raised approximately $6.5 million across two offerings of its common stock and warrants.
- 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 a net paydown of $15 million of debt excluding accrued interest and prepayment fees.

Financial Results:

- As of June 30, 2024, Fortress' consolidated cash and cash equivalents totaled $76.2 million, compared to $83.8 million as of March 31, 2024 and compared to $80.9 million as of December 31, 2023, a decrease of $7.6 million during the quarter and a decrease of $4.7 million year-to-date.
- Fortress' consolidated cash and cash equivalents, totaling $76.2 million as of June 30, 2024, includes $38.2 million attributable to Fortress and the private subsidiaries, $4.9 million attributable to Avenue, $5.0 million attributable to Checkpoint, $4.3 million attributable to Mustang Bio and $23.9 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 $14.9 million for the second quarter ended June 30, 2024, most of which was generated from our marketed dermatology products. This compares to consolidated revenue totaling $17.4 million for the second quarter of 2023, which included $17.0 million in revenue generated from our marketed dermatology products.
- Consolidated research and development expenses including license acquisitions totaled $12.7 million for the second quarter ended June 30, 2024, compared to $32.1 million for the second quarter ended June 30, 2023.

- Consolidated selling, general and administrative costs were $20.8 million for the second quarter ended June 30, 2024, compared to $24.4 million for the second quarter ended June 30, 2023.
- Consolidated net loss attributable to common stockholders was $(13.3) million, or $(0.73) per share, for the second quarter ended June 30, 2024, compared to net loss attributable to common stockholders of $(26.9) million, or $(3.65) per share for the second quarter ended June 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; the ongoing UTRF litigation and our indemnification of Caelum in connection therewith; 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.

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
Unaudited Condensed Consolidated Balance Sheets
($ in thousands except for share and per share amounts)

	June 30, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 76,201	$ 80,927
Accounts receivable, net	10,465	15,222
Inventory	9,687	10,206
Other receivables - related party	224	167
Prepaid expenses and other current assets	4,649	10,500
Assets held for sale	2,209	—
Total current assets	103,435	117,022
Property, plant and equipment, net	3,546	6,505
Operating lease right-of-use asset, net	14,626	16,990
Restricted cash	2,063	2,438
Intangible assets, net	18,658	20,287
Other assets	3,357	4,284
Total assets	**$ 145,685**	**$ 167,526**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued expenses	$ 68,921	$ 73,562
Income taxes payable	806	843
Common stock warrant liabilities	172	886
Operating lease liabilities, short-term	2,481	2,523
Partner company convertible preferred shares, short-term, net	—	3,931
Partner company installment payments - licenses, short-term, net	3,000	3,000
Other short-term liabilities	163	163
Total current liabilities	75,543	84,908
Notes payable, long-term, net	67,007	60,856
Operating lease liabilities, long-term	15,934	18,282
Other long-term liabilities	1,799	1,893
Total liabilities	**160,283**	**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 June 30, 2024 and December 31, 2023, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 22,587,038 and 15,093,053 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	23	15
Additional paid-in-capital	739,086	717,396
Accumulated deficit	(721,235)	(694,870)
Total stockholders' equity attributed to the Company	17,877	22,544
Non-controlling interests	(32,475)	(20,957)
Total stockholders' equity (deficit)	(14,598)	1,587
Total liabilities and stockholders' equity (deficit)	**$ 145,685**	**$ 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue				
Product revenue, net	$ 14,855	$ 16,961	$ 27,885	$ 29,126
Collaboration revenue	—	183	—	364
Revenue - related party	41	31	41	66
Other revenue	—	211	—	259
Net revenue	14,896	17,386	27,926	29,815
Operating expenses				
Cost of goods sold - product revenue	6,541	7,767	13,357	14,216
Research and development	12,671	32,139	37,495	67,415
Research and development - licenses acquired	—	3	—	4,233
Selling, general and administrative	20,823	24,439	38,777	49,780
Asset impairment	2,649	3,143	2,649	3,143
Total operating expenses	42,684	67,491	92,278	138,787
Loss from operations	(27,788)	(50,105)	(64,352)	(108,972)
Other income (expense)				
Interest income	734	715	1,567	1,751
Interest expense and financing fee	(2,122)	(6,425)	(4,724)	(10,721)
Change in fair value of warrant liabilities	—	(512)	—	6,166
Gain (loss) on common stock warrant liabilities	70	—	(597)	—
Loss from deconsolidation of subsidiaries	—	(3,369)	—	(3,369)
Other income (expense)	282	395	260	699
Total other income (expense)	(1,036)	(9,196)	(3,494)	(5,474)
Net loss	**(28,824)**	**(59,301)**	**(67,846)**	**(114,446)**
Net loss attributable to non-controlling interests	17,876	34,525	41,481	68,133
Net loss attributable to Fortress	**$ (10,948)**	**$ (24,776)**	**$ (26,365)**	**$ (46,313)**
Net loss attributable to common stockholders	**$ (13,339)**	**$ (26,917)**	**$ (31,199)**	**$ (50,595)**
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.73)	$ (3.65)	$ (1.76)	$ (7.14)
Weighted average common shares outstanding - basic and diluted	18,316,874	7,377,332	17,736,299	7,086,482