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): May 15, 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)	(I.R.S. Employer Identification No.)

1111 Kane Concourse, Suite 301
Bay Harbor Islands, FL 33154
(Address of principal executive offices)

Registrant's telephone number, including area code: **(781) 652-4500**

Check the appropriate box below if the Form 8-K 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 (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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	The Nasdaq Capital Market
9.375% Series A Cumulative Redeemable Perpetual Preferred Stock	FBIOP	The 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).

Emerging growth company ☐

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 May 15, 2024, Fortress Biotech, Inc. issued a press release to provide a corporate update and to announce its financial results for the three months ended March 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 exhibits are furnished herewith:

Exhibit Number	**Description**
99.1	Press release issued by Fortress Biotech, Inc., dated May 15, 2024.
104	Cover Page Interactive Data File, formatted in Inline Extensible Business Reporting Language (iXBRL).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Fortress Biotech, Inc.
(Registrant)

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

Date: May 15, 2024

Exhibit 99.1

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

Fortress' late-stage pipeline continues to advance and may generate up to three regulatory approvals on NDAs and BLAs in the next 12 months and potentially a fourth BLA filing as early as 2025

FDA accepted New Drug Application filing for DFD-29 to treat inflammatory lesions and erythema of rosacea in adults; PDUFA goal date of November 4, 2024

Miami, FL – May 15, 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 first quarter ended March 31, 2024.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "We achieved first quarter year-over-year product revenue growth of 7%, which was driven by greater than 20% year-over-year growth in our flagship products, Qbrexza® and Accutane®. In the first quarter of 2024, the U.S. Food and Drug Administration ("FDA") accepted the New Drug Application ("NDA") filing for DFD-29 and set a Prescription Drug User Fee Act ("PDUFA") goal date of November 4, 2024. If approved, DFD-29 has the potential to be the only oral, systemic therapy to address inflammatory lesions and erythema (redness) from rosacea, differentiating it as a potential best-in-class solution for the millions of patients suffering from rosacea. We also dosed the first patient in a multi-center Phase 2 study for Triplex for control of cytomegalovirus ("CMV") in patients undergoing liver transplantation and received grant funding from the National Institutes of Health ("NIH") to further advance cell and gene therapy candidates for the potential treatment of adults living with HIV and children with Menkes disease. Looking ahead, our expansive portfolio of development-stage programs across multiple areas, including oncology, dermatology, and rare diseases, holds the potential for up to three NDA and Biologics License Application ("BLA") regulatory approvals within the next 12 months and potentially a fourth BLA filing as early as 2025. Additionally, we anticipate multiple data readouts this year, including topline data from the Phase 1b/2a clinical trial of AJ201 to treat spinal and bulbar muscular atrophy ("SBMA"), data from the Phase 1b clinical trial of dotinurad for the treatment of gout and hyperuricemia and topline Phase 2 clinical data of Triplex, a CMV vaccine for adults co-infected with HIV and CMV. This sustained progress underscores the strength of Fortress' business model, centered on acquiring and advancing assets that address unmet medical needs and enhance long-term value for shareholders through product revenues, equity holdings and royalties."

Recent Corporate Highlights[1]:

Regulatory Milestones and 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. We submitted the NDA to the FDA seeking approval for DFD-29 for the treatment of inflammatory lesions and erythema of rosacea in adults in January 2024. 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 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").
- The CUTX-101 rolling NDA submission is ongoing and is expected to be completed by our partner, Sentynl Therapeutics, Inc. in 2024. 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.
- We submitted a BLA to the FDA for cosibelimab, our investigational anti-PD-L1 antibody, as a treatment for patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or radiation, in January 2023. In December 2023, the FDA issued a complete response letter ("CRL") for the cosibelimab BLA. The CRL solely cited findings that arose during a multi-sponsor inspection of a third-party contract manufacturing organization as approvability issues to address in a resubmission. The CRL did not state any concerns about the clinical data package, safety or labeling for the approvability of cosibelimab. We intend to seek to address the feedback in a potential BLA resubmission, which is currently targeted for mid-year. Cosibelimab is currently in development at our partner company, Checkpoint Therapeutics, Inc. (Nasdaq: CKPT) ("Checkpoint").
- Based on its public statements, AstraZeneca plc has estimated that it expects the FDA to accept its BLA submission of CAEL-101 (anselamimab) to treat AL amyloidosis for review as early as 2025.

Clinical Updates

- The Phase 2 clinical trial of Triplex, a CMV vaccine, for adults co-infected with 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.
- In May 2024, we announced that the first patient was dosed in a multi-center, placebo-controlled, randomized Phase 2 study of Triplex for control of CMV in patients undergoing liver transplantation. The trial is funded by a grant from the NIH's National Institute of Allergy and Infectious Diseases of the (NIH/NIAID) that could provide over $20 million in non-dilutive funding. Triplex is currently in development at our subsidiary company, Helocyte, Inc.
- A Phase 1b clinical trial in patients with gout and hyperuricemia is ongoing in the U.S. to confirm the comparability of U.S. patients' response to dotinurad (urate transporter (URAT1) inhibitor) with data generated in Japan, and to assess drug-drug interactions, if any, with allopurinol. We expect to announce data from this trial in mid-2024. Dotinurad is currently in development at our subsidiary company, Urica Therapeutics, Inc. ("Urica").

Commercial Product Updates

- Journey Medical's total revenues for the first quarter ended March 31, 2024 were $13.0 million, an increase of $0.8 million, or 7%, compared to total net revenues of $12.2 million for the first quarter ended March 31, 2023.

[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.

General Corporate:

- In January 2024, Fortress raised gross proceeds of approximately $11.0 million in a registered direct offering priced at-the-market under Nasdaq rules.
- In January 2024, Checkpoint raised gross proceeds of approximately $14.0 million in a registered direct offering, and Avenue raised approximately $5.0 million gross proceeds from warrant exercise transactions.

Financial Results:

- As of March 31, 2024, Fortress' consolidated cash, cash equivalents and restricted cash totaled $85.8 million, compared to $83.4 million as of December 31, 2023, an increase of $2.5 million during the quarter.
- Fortress' consolidated cash, cash equivalents and restricted cash, totaling $85.8 million as of March 31, 2024, includes $45.6 million attributable to Fortress and the private subsidiaries, $3.2 million attributable to Avenue, $11.2 million attributable to Checkpoint, $1.7 million attributable to Mustang Bio and $24.1 million attributable to Journey Medical.
    - Fortress' consolidated cash, cash equivalents and restricted cash, totaled $83.4 million as of December 31, 2023, which included $42.2 million attributable to Fortress and private subsidiaries, $1.8 million attributable to Avenue, $4.9 million attributable to Checkpoint, $7.0 million attributable to Mustang Bio and $27.4 million attributable to Journey Medical.
- Subsequent to the end of the first quarter, in May 2024, Avenue raised approximately $4.4 million in gross proceeds from warrant exercise transactions and Mustang raised approximately $4.0 million in gross proceeds from a public offering of common stock and warrants.
- Fortress' consolidated net revenue totaled $13.0 million for the first quarter ended March 31, 2024, all of which was generated from our marketed dermatology products. This compares to consolidated revenue totaling $12.4 million for the first quarter of 2023, which included $12.2 million in revenue generated from our marketed dermatology products.
- Consolidated research and development expenses including license acquisitions totaled $24.8 million for the first quarter ended March 31, 2024, compared to $39.5 million for the first quarter ended March 31, 2023.
- Consolidated selling, general and administrative costs were $17.9 million for the first quarter ended March 31, 2024, compared to $25.3 million for the first quarter ended March 31, 2023.
- Consolidated net loss attributable to common stockholders was $(17.7) million, or $(1.03) per share, for the first quarter ended March 31, 2024, compared to net loss attributable to common stockholders of $(23.5) million, or $(3.47) per share for the first quarter ended March 31, 2023.
- All share and per share information has been retroactively adjusted to give effect to the Company's October 2023 1-for-15 reverse stock split for all periods presented, unless otherwise indicated.

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; 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)

	March 31, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 83,774	$ 80,927
Accounts receivable, net	9,799	15,222
Inventory	10,580	10,206
Other receivables - related party	324	167
Prepaid expenses and other current assets	12,071	10,500
Total current assets	116,548	117,022
Property, plant and equipment, net	6,128	6,505
Operating lease right-of-use asset, net	16,462	16,990
Restricted cash	2,063	2,438
Intangible assets, net	19,473	20,287
Other assets	3,971	4,284
Total assets	**$ 164,645**	**$ 167,526**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued expenses	$ 76,379	$ 73,562
Income taxes payable	843	843
Common stock warrant liabilities	689	886
Operating lease liabilities, short-term	2,601	2,523
Partner company convertible preferred shares, short-term, net	4,021	3,931
Partner company installment payments - licenses, short-term, net	3,000	3,000
Other short-term liabilities	163	163
Total current liabilities	87,696	84,908
Notes payable, long-term, net	61,420	60,856
Operating lease liabilities, long-term	17,619	18,282
Other long-term liabilities	1,847	1,893
Total liabilities	**168,582**	**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 March 31, 2024 and December 31, 2023, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 19,375,343 and 15,093,053 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	19	15
Additional paid-in-capital	733,290	717,396
Accumulated deficit	(710,287)	(694,870)
Total stockholders' equity attributed to the Company	23,025	22,544
Non-controlling interests	(26,962)	(20,957)
Total stockholders' equity (deficit)	(3,937)	1,587
Total liabilities and stockholders' equity (deficit)	**$ 164,645**	**$ 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 March 31,	
	2024	2023
Revenue		
Product revenue, net	$ 13,030	$ 12,165
Collaboration revenue	—	181
Revenue - related party	—	35
Other revenue	—	48

Net revenue	13,030	12,429
Operating expenses		
Cost of goods sold - product revenue	6,816	6,449
Research and development	24,839	35,276
Research and development - licenses acquired	—	4,230
Selling, general and administrative	17,941	25,341
Total operating expenses	49,596	71,296
Loss from operations	(36,566)	(58,867)
Other income (expense)		
Interest income	833	1,036
Interest expense and financing fee	(2,602)	(4,296)
Gain (loss) on common stock warrant liabilities	(667)	6,678
Other income (expense)	(21)	304
Total other income (expense)	(2,457)	3,722
Net loss	**(39,023)**	**(55,145)**
Net loss attributable to non-controlling interests	23,606	33,608
Net loss attributable to Fortress	**$ (15,417)**	**$ (21,537)**
Net loss attributable to common stockholders	**$ (17,731)**	**$ (23,545)**
Net loss per common share attributable to common stockholders - basic and diluted	$ (1.03)	$ (3.47)
Weighted average common shares outstanding - basic and diluted	17,151,945	6,792,376