
**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 14, 2026**

Fortress Biotech, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35366
(Commission File Number)

20-5157386
(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	FBIO-P	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 May 14, 2026, Fortress Biotech, Inc. issued a press release to provide a corporate update and to announce its financial results for the quarter ended March 31, 2026. 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 May 14, 2026
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: May 14, 2026

By: /s/ David Jin
David Jin
Chief Financial Officer



Fortress Biotech Reports First Quarter 2026 Financial Results and Recent Corporate Highlights

ZYCUBO® approved by FDA to treat Menkes disease in the United States; Fortress subsidiary Cyprium Therapeutics closed the sale of its Rare Pediatric Disease Priority Review Voucher (PRV) for \$205 million

Fortress' consolidated net income attributable to common stockholders for the first quarter of 2026 was \$108.4 million, or \$3.44 per common share (basic) and \$2.82 per common share (diluted)

Miami, FL – May 14, 2026 – 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 first quarter ended March 31, 2026.

Lindsay A. Rosenwald, M.D., Fortress’ Chairman, President and Chief Executive Officer, said, “The first quarter of 2026 marked a pivotal period for Fortress, highlighted by significant execution across our portfolio and meaningful progress in enhancing long-term shareholder value. The FDA approval of ZYCUBO® for Menkes disease and the subsequent monetization of Cyprium’s PRV for \$205 million represent important validation of our business model. We deployed a portion of these proceeds to strengthen our balance sheet through debt reduction, lowering our outstanding principal with Oaktree to \$15.0 million. We also continued to expand our pipeline through business development, including Avenue’s acquisition of ATX-04 from Duke University, a clinically validated program with the potential to address significant unmet need in Pompe disease.”

Dr. Rosenwald added, “Looking ahead, we expect to generate increasing royalty revenue from ZYCUBO® and UNLOXCYT™, along with potential milestone payments across our portfolio. In parallel, AstraZeneca’s regulatory submissions in the EU and Japan for anselamimab (formerly known as CAEL-101), underscore the continued optionality within our partnered assets for potential future sales milestones for Fortress and approval milestones in the U.S. We have a diversified portfolio of commercial, late-stage, and development-stage programs and Fortress is well positioned to advance strategic initiatives and drive long-term value for our shareholders.”

Recent Corporate Highlights¹:

Regulatory and Monetization Updates

- **ZYCUBO® Approved for Menkes Disease; Cyprium Sold PRV for \$205 Million.** In January 2026, the FDA approved ZYCUBO® (copper histidinate, formerly known as CUTX-101) for the treatment of Menkes disease in pediatric patients. A PRV was issued at approval and transferred to Cyprium under its agreement with Sentyln Therapeutics, Inc. (“Sentyln”). In March 2026, Cyprium closed the sale of the PRV for gross proceeds of \$205 million. Cyprium is also eligible to receive tiered royalties on net sales of ZYCUBO® and up to approximately \$128 million in aggregate sales milestones from Sentyln.

¹ This press release references products being developed or commercialized by Fortress, by Fortress’ private or public subsidiaries (referred to herein as “subsidiaries” or “partner companies”) and by 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 connection with the sale of the PRV, Cyprium redeemed all outstanding shares of its 9.375% Perpetual Preferred Stock pursuant to the previously disclosed terms of such securities.
- **Checkpoint Acquired by Sun Pharma; Fortress Establishes Long-Term Royalty Stream.** In May 2025, Fortress' subsidiary, Checkpoint, was acquired by Sun Pharmaceutical Industries, Inc. (together with its subsidiaries and/or associated companies, "Sun Pharma"). Pursuant to the acquisition, Fortress received ~\$28 million upfront, with the potential for an additional contingent value right payment of up to \$4.8 million and a 2.5% royalty on future net sales of UNLOXCYT™ (cosibelimab-ipdl). UNLOXCYT™ was approved by the FDA in December 2024 to treat metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC") in patients who are not candidates for curative surgery or radiation and was commercially launched in January 2026.

Commercial Portfolio Updates

- **Journey Medical Expands Payer Access for Emrosi®.** At the end of March 2025, our partner company Journey Medical Corporation ("Journey Medical") commercially launched Emrosi® (40mg Minocycline Hydrochloride Modified-Release Capsules, consisting of 10mg immediate release and 30mg extended release pellets), also known as DFD-29, for inflammatory lesions of rosacea. Emrosi® was approved by the FDA in November 2024 and is available by prescription at specialty pharmacy chains. In April 2026, Journey Medical announced that it secured a contract with a third major group purchasing organization (GPO) for Emrosi®. As such, payer access for Emrosi® expanded to over 150 million commercial lives as of April 1, 2026, which equates to approximately 85% of all commercial lives in the United States that have access to Emrosi®. Journey Medical reported net product revenues of \$15.9 million for the first quarter of 2026, compared to net product revenues of \$13.1 million for the first quarter ended March 31, 2025.
- **Royalties.** In the first quarter of 2026, Cyprium recognized \$0.1 million in royalty revenue on net sales of ZYCUBO®.

Clinical Updates

- **Phase 3 CARES Results for Anselamimab (CAEL-101); Regulatory Submission of Prespecified Subgroup Analysis Planned.** 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 to regulatory authorities and disclosed regulatory submissions in the EU and Japan.

General Corporate:

- In March 2026, Fortress made aggregate prepayments on its loan with Oaktree, including a prepayment in connection with the sale of the PRV, reducing the outstanding principal balance to \$15.0 million.
- In February 2026, Avenue entered into an exclusive worldwide license agreement with Duke University to acquire patent and know-how rights pertaining to ATX-04 (clenbuterol), a well-characterized small-molecule β 2-adrenergic agonist, in clinical development for the treatment of Pompe disease. ATX-04 is a selective β 2-adrenergic agonist with human proof-of-concept data demonstrating improved muscle function and enhanced response to enzyme replacement therapy. Avenue anticipates meeting with the FDA in 2026 to discuss and align on the design of a potential single pivotal trial for ATX-04 for Pompe disease.

Financial Results:

- As of March 31, 2026, Fortress' consolidated cash and cash equivalents totaled \$255.8 million, compared to \$79.4 million as of December 31, 2025, an increase of \$176.5 million during the quarter.
 - Fortress' consolidated cash and cash equivalents totaling \$255.8 million as of March 31, 2026, includes \$209.9 million attributable to Fortress and the private subsidiaries, \$2.4 million attributable to Avenue, \$16.3 million attributable to Mustang Bio and \$27.2 million attributable to Journey Medical.
 - Fortress' consolidated cash and cash equivalents totaled \$79.4 million as of December 31, 2025, and includes \$35.2 million attributable to Fortress and private subsidiaries, \$2.9 million attributable to Avenue, \$17.3 million attributable to Mustang and \$24.1 million attributable to Journey Medical.
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- Fortress' consolidated net revenue totaled \$16.0 million for the first quarter ended March 31, 2026, of which \$15.9 million is generated from Journey Medical's marketed dermatology products. This compares to consolidated revenue totaling \$13.1 million for the first quarter of 2025.
- Consolidated research and development expenses totaled \$0.5 million for the first quarter ended March 31, 2026, compared to \$3.9 million for the first quarter ended March 31, 2025.
- Consolidated selling, general and administrative costs were \$15.9 million for the first quarter ended March 31, 2026, compared to \$25.7 million for the first quarter ended March 31, 2025.
- Consolidated net income attributable to common stockholders was \$108.4 million, or \$3.44 per share (basic) and \$2.82 per share (diluted), for the first quarter ended March 31, 2026, compared to net loss attributable to common stockholders of \$(12.7) million, or \$(0.48) per share basic and diluted for the first quarter ended March 31, 2025.

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 a portfolio of multiple marketed prescription pharmaceutical products and 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 Sentyln 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 product candidates 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)

	March 31, 2026	December 31, 2025
ASSETS		
Current assets		
Cash and cash equivalents	\$ 255,841	\$ 79,381
Accounts receivable, net	24,992	29,783
Inventory	9,292	9,624
Other receivables - related party	516	158
Prepaid expenses and other current assets	4,839	4,895
Total current assets	295,480	123,841
Property, plant and equipment, net	2,426	2,519
Operating lease right-of-use asset, net	11,822	12,302
Restricted cash	1,220	1,220
Equity investments, at fair value	18,707	17,660
Intangible assets, net	26,479	27,605
Other assets	740	401
Total assets	\$ 356,874	\$ 185,548
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 92,986	\$ 47,125
Income taxes payable	5,418	356
Common stock warrant liabilities	—	1
Operating lease liabilities, short-term	2,221	2,127
Partner company notes payable, short-term	2,500	—
Other current liabilities	268	135
Total current liabilities	103,393	49,744
Notes payable, long-term, net	36,878	52,417
Operating lease liabilities, long-term	12,028	12,672
Partner company redeemable perpetual preferred liability	—	7,085
Other long-term liabilities	2,201	1,447
Total liabilities	154,500	123,365
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, 2026 and December 31, 2025, respectively, liquidation value of \$25.00 per share	3	3
Common stock, \$0.001 par value, 200,000,000 shares authorized, 33,186,671 and 31,364,094 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	33	31
Additional paid-in-capital	785,851	783,891
Accumulated deficit	(623,679)	(734,052)
Total stockholders' equity attributed to the Company	162,208	49,873
Non-controlling interests	40,166	12,310
Total stockholders' equity	202,374	62,183
Total liabilities and stockholders' equity	\$ 356,874	\$ 185,548

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,	
	2026	2025
Revenue		
Product revenue, net	\$ 15,921	\$ 13,139
Other revenue	117	—
Net revenue	<u>16,038</u>	<u>13,139</u>
Operating expenses		
Cost of goods - (excluding amortization of acquired intangible assets)	6,218	4,790
Amortization of acquired intangible assets	1,126	1,065
Research and development	540	3,938
Selling, general and administrative	15,893	25,663
Total operating expenses	<u>23,777</u>	<u>35,456</u>
Loss from operations	(7,739)	(22,317)
Other income (expense)		
Interest income	570	490
Interest expense and financing fee	(3,368)	(2,805)
Gain on sale of priority review voucher, net of expenses	158,873	—
Change in fair value of partner company derivative liability	(7,085)	—
Gain (loss) on common stock warrant liabilities	1	(47)
Other income (expense)	1,042	(12)
Total other income (expense)	<u>150,033</u>	<u>(2,374)</u>
Income (loss) before income tax expense	142,294	(24,691)
Income tax expense	5,132	—
Net income (loss)	<u><u>137,162</u></u>	<u><u>(24,691)</u></u>
Attributable to non-controlling interests	(26,789)	14,107
Net income (loss) attributable to Fortress	<u><u>\$ 110,373</u></u>	<u><u>\$ (10,584)</u></u>
Preferred A dividends declared and paid and/or cumulated, and Fortress' share of subsidiary deemed dividends	(2,008)	(2,131)
Net income (loss) attributable to common stockholders	<u><u>\$ 108,365</u></u>	<u><u>\$ (12,715)</u></u>
Net income (loss) per common share attributable to common stockholders - basic	\$ 3.44	\$ (0.48)
Net income (loss) per common share attributable to common stockholders - diluted	\$ 2.82	\$ (0.48)
Weighted average common shares outstanding - basic	31,540,595	26,450,218
Weighted average common shares outstanding - diluted	38,412,716	26,450,218