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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

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**FORM 8-K**

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**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, 2023**

**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	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.

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**Item 2.02. Results of Operations and Financial Condition.**

On November 14, 2023, Fortress Biotech, Inc. issued a press release to announce financial results and recent corporate highlights for the quarter ended September 30, 2023. 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:

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release issued by Fortress Biotech, Inc., dated November 14, 2023.</a>
104	Cover Page Interactive Data File (the cover page XBRL tags are imbedded in the Inline XBRL document)

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**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, 2023

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

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## Fortress Biotech Reports Third Quarter 2023 Financial Results and Recent Corporate Highlights

**Total consolidated net revenue was \$34.8 million in the third quarter of 2023, a 100% increase from total consolidated net revenue of \$17.4 million in the second quarter of 2023**

**Fortress is advancing several late-stage clinical assets with three potential NDA and BLA submissions to FDA through year-end of 2024 across our portfolio<sup>1</sup>, including a NDA submission for DFD-29 to treat rosacea, anticipated around year-end of 2023**

**Miami, FL – November 14, 2023** – Fortress Biotech, Inc. (Nasdaq: FBIO) (“Fortress”), an innovative biopharmaceutical company focused on efficiently acquiring, developing and commercializing or monetizing promising therapeutic products and product candidates, today announced financial results and recent corporate highlights for the third quarter ended September 30, 2023.

Lindsay A. Rosenwald, M.D., Fortress’ Chairman, President and Chief Executive Officer, said, “In the third quarter of 2023, Fortress and our partner companies and subsidiaries continued to advance our diverse portfolio of drug candidates. Our total consolidated net revenue this quarter was \$34.8 million, which includes an upfront payment of \$19 million that Journey Medical received upon entering into an exclusive license agreement with Maruho for commercialization of Qbrexza® in additional territories in Asia. We’re looking forward to multiple significant near-term milestones, including potentially up to four New Drug Application (“NDA”) and Biologics License Application (“BLA”) submissions to the U.S. Food and Drug Administration (“FDA”) between 2023 and 2025, one of which is a NDA for DFD-29 to treat rosacea around the end of this year. We are also anticipating the PDUFA goal date of January 3, 2024, for cosibelimab, our investigational anti-PD-L1 antibody, as a treatment for patients with metastatic or locally advanced cutaneous squamous cell carcinoma (“cSCC”).”

### Recent Corporate Highlights<sup>2</sup>:

#### Marketed Dermatology Products

- Journey Medical Corporation (Nasdaq: DERM) (“Journey Medical”), our partner company, primarily focuses on selling and marketing of prescription dermatology products.
- In September 2023, Journey Medical entered into an exclusive license agreement with Maruho Co., Ltd. (“Maruho”), a Japanese company specializing in dermatology as well as Journey’s exclusive licensing partner that developed and is commercializing Qbrexza® (Rapifort®) in Japan. Under the terms of the Agreement, Journey Medical received a \$19 million nonrefundable upfront payment

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<sup>1</sup> Includes CAEL-101, an asset in development at Caelum Biosciences (a former subsidiary now 100% owned by AstraZeneca’s Alexion) with respect to which Fortress remains eligible to receive substantial milestone payments.

<sup>2</sup> 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 which 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.

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and granted Maruho an exclusive license to develop and commercialize Qbrexza (glycopyrronium tosylate hydrate) for the treatment of hyperhidrosis in South Korea, Taiwan, Hong Kong, Macau, Thailand, Indonesia, Malaysia, Philippines, Singapore, Vietnam, Brunei, Cambodia, Myanmar and Laos (the "Territory"). Maruho is responsible for all development and commercialization costs for the program throughout the Territory.

- Journey Medical's total net revenues in the third quarter of 2023 were \$34.5 million, an increase of \$18.4 million, or 114%, compared to total net revenues of \$16.1 million in the third quarter of 2022.
- Journey Medical's total product net revenues were \$15.3 million for the third quarter of 2023, compared to third quarter 2022 total product net revenues of \$16.0 million.

**Fortress, through its subsidiaries, partner companies and partners, has a broad and diverse pipeline of clinical-stage programs being evaluated in over 20 ongoing clinical trials. We look forward to potential filings of up to four NDA and BLA submissions from 2023 through 2025, including:**

- DFD-29 – modified release oral minocycline for rosacea
- Cosibelimab – anti-PD-L1 antibody for solid tumors
- CUTX-101 – copper histidinate for Menkes disease
- CAEL-101 – light chain fibril-reactive monoclonal antibody for AL amyloidosis

**We also expect to continue to advance our early-to-mid-clinical-stage candidates, some of which may begin pivotal trials during the next twelve to eighteen months, including:**

- Dotinurad – urate transporter (URAT1) inhibitor for gout and hyperuricemia
- IV tramadol – intravenous small molecule for acute post-operative pain
- MB-106 – CD20-targeted CAR-T cell therapy for hematologic malignancies
- Triplex – multi-antigen, modified vaccinia Ankara-based (MVA) vaccine for cytomegalovirus (CMV)
- MB-117 – ex vivo lentiviral gene therapy for newborns with XSCID (X-linked severe combined immunodeficiency)
- MB-217 – ex vivo lentiviral gene therapy for previously transplanted children and young adults with XSCID
- AJ201 – Nrf1 and Nrf2 activator, androgen receptor degradation enhancer for spinal and bulbar muscular atrophy (SBMA), also known as Kennedy's Disease
- BAER-101 – GABAA  $\alpha 2/3$  positive allosteric modulator for refractory epilepsies
- MB-109 – IL13R $\alpha 2$ -targeted CAR-T cell therapy combined with HSV-1 oncolytic virus for recurrent glioblastoma and high-grade astrocytomas

#### **General Corporate:**

- In November 2023, Fortress raised approximately \$10.0 million in gross proceeds in a public offering.
- In October 2023, Fortress effected a 1-for-15 reverse stock split of its issued and outstanding common stock to bring the Company into compliance with Nasdaq's minimum bid price requirement for continued listing.

#### **Financial Results:**

- As of September 30, 2023, Fortress' consolidated cash, cash equivalents and restricted cash totaled \$74.7 million, compared to \$89.2 million as of June 30, 2023, a decrease of \$14.5 million during the quarter.
  - Fortress' consolidated cash, cash equivalents and restricted cash, totaling \$74.7 million as of September 30, 2023, includes \$37.7 million attributable to Fortress and private subsidiaries, \$0.2
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million attributable to Avenue, \$1.8 million attributable to Checkpoint, \$10.3 million attributable to Mustang Bio and \$24.7 million attributable to Journey Medical.

- Subsequent to the end of the third quarter, in November 2023, Fortress raised approximately \$10.0 million in gross proceeds in a public offering and Avenue raised approximately \$5.0 million in gross proceeds in a public offering. In addition, in October 2023, Checkpoint raised approximately \$11.1 million in gross proceeds from the exercise of warrants and Mustang Bio raised approximately \$4.4 million in gross proceeds in a registered direct offering.
- Fortress' consolidated net revenue totaled \$34.8 million for the third quarter of 2023, which included \$15.3 million in net product revenue generated from our marketed dermatology products. This compares to consolidated net revenue totaling \$16.5 million for the third quarter of 2022, which included \$16.0 million in net product revenue generated from our marketed dermatology products.
- Consolidated research and development expenses including license acquisitions were \$20.3 million for the third quarter of 2023, compared to \$29.9 million for the third quarter of 2022.
- Consolidated selling, general and administrative expenses were \$21.7 million for the third quarter of 2023, compared to \$30.1 million for the third quarter of 2022.
- Consolidated net loss attributable to common stockholders was \$7.1 million, or \$0.94 per share, for the third quarter of 2023, compared to consolidated net loss attributable to common stockholders of \$24.5 million, or \$4.11 per share for the third quarter of 2022.

### **About Fortress Biotech**

Fortress Biotech, Inc. ("Fortress") is an innovative biopharmaceutical company focused on efficiently acquiring, developing and commercializing or monetizing promising therapeutic products and product candidates. The company has eight marketed prescription pharmaceutical products and over 25 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. Such product candidates span six large-market areas, including oncology, rare diseases and gene therapy, which allow it to create value for shareholders. Fortress advances its diversified pipeline through a streamlined operating structure that fosters efficient drug development. The Fortress model is focused on leveraging its significant biopharmaceutical industry expertise and network to further expand 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, St. Jude Children's Research Hospital, Nationwide Children's Hospital and Sentyln. For more information, visit [www.fortressbiotech.com](http://www.fortressbiotech.com).

### **Forward-Looking Statements**

This press release may contain "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. As used below and throughout this press release, the words "we", "us" and "our" may refer to Fortress individually or together with one or more partner companies, as dictated by context. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs, ability to generate shareholder value, ability of our products to receive necessary approvals, including FDA approval, ability of our products and therapies to help patients and any other statements that are not historical facts. 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 uncertainty 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; risks relating to the timing of starting and completing clinical trials; the 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

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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)

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 72,307	\$ 178,266
Accounts receivable, net	7,989	28,208
Inventory	11,024	14,159
Other receivables - related party	165	138
Prepaid expenses and other current assets	6,341	9,661
Total current assets	97,826	230,432
Property, plant and equipment, net	6,854	13,020
Operating lease right-of-use asset, net	17,507	19,991
Restricted cash	2,438	2,688
Intangible asset, net	21,102	27,197
Other assets	4,822	973
<b>Total assets</b>	<b>\$ 150,549</b>	<b>\$ 294,301</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 81,406	\$ 97,446
Income taxes payable	84	—
Common stock warrant liabilities	5,430	13,869
Operating lease liabilities, short-term	2,413	2,447
Partner company convertible preferred shares, short-term, net	3,797	2,052
Partner company line of credit	—	2,948
Partner company installment payments - licenses, short-term, net	3,000	7,235
Other short-term liabilities	1,221	1,718
Total current liabilities	97,351	127,715
Notes payable, long-term, net	45,791	91,730
Operating lease liabilities, long-term	18,944	21,572
Partner company installment payments - licenses, long-term, net	—	1,412
Other long-term liabilities	1,706	1,847
<b>Total liabilities</b>	<b>163,792</b>	<b>244,276</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity (deficit)</b>		
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, 2023 and December 31, 2022, respectively, liquidation value of \$25.00 per share	3	3
Common stock, \$0.001 par value, 200,000,000 shares authorized, 8,937,587 and 7,366,283 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	9	7
Additional paid-in-capital	702,253	675,944
Accumulated deficit	(685,591)	(634,233)
Total stockholders' equity attributed to the Company	16,674	41,721
Non-controlling interests	(29,917)	8,304
Total stockholders' equity (deficit)	(13,243)	50,025
<b>Total liabilities and stockholders' equity (deficit)</b>	<b>\$ 150,549</b>	<b>\$ 294,301</b>



**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,	
	2023	2022	2023	2022
<b>Revenue</b>				
Product revenue, net	\$ 15,279	\$ 16,043	\$ 44,405	\$ 55,074
Collaboration revenue	182	364	546	1,518
Revenue - related party	31	48	97	118
Other revenue	19,260	73	19,519	2,629
Net revenue	<u>34,752</u>	<u>16,528</u>	<u>64,567</u>	<u>59,339</u>
<b>Operating expenses</b>				
Cost of goods sold - product revenue	6,429	7,221	20,645	23,057
Research and development	20,288	29,855	87,702	99,707
Research and development - licenses acquired	60	47	4,293	48
Selling, general and administrative	21,733	30,139	71,512	85,457
Asset impairment	—	—	3,143	—
Total operating expenses	<u>48,510</u>	<u>67,262</u>	<u>187,295</u>	<u>208,269</u>
Loss from operations	(13,758)	(50,734)	(122,728)	(148,930)
<b>Other income (expense)</b>				
Interest income	547	419	2,296	711
Interest expense and financing fee	(2,534)	(3,393)	(13,255)	(8,897)
Change in fair value of warrant liabilities	4,542	—	10,708	—
Other income (expense)	620	648	(2,049)	648
Total other income (expense)	<u>3,175</u>	<u>(2,326)</u>	<u>(2,300)</u>	<u>(7,538)</u>
Loss before income tax expense	(10,583)	(53,060)	(125,028)	(156,468)
Income tax expense	141	—	142	—
<b>Net loss</b>	<u><b>(10,724)</b></u>	<u><b>(53,060)</b></u>	<u><b>(125,170)</b></u>	<u><b>(156,468)</b></u>
Net loss attributable to non-controlling interests	5,679	30,549	73,812	96,841
<b>Net loss attributable to Fortress</b>	<u><b>(5,045)</b></u>	<u><b>(22,511)</b></u>	<u><b>(51,358)</b></u>	<u><b>(59,627)</b></u>
Preferred A dividends declared and paid	(2,008)	(2,008)	(6,024)	(6,024)
<b>Net loss attributable to common stockholders</b>	<u><b>\$ (7,053)</b></u>	<u><b>\$ (24,519)</b></u>	<u><b>\$ (57,382)</b></u>	<u><b>\$ (65,651)</b></u>
Net loss per common share attributable to common stockholders - basic and diluted	\$ (0.94)	\$ (4.11)	\$ (7.94)	\$ (11.15)
Weighted average common shares outstanding - basic and diluted	7,498,653	5,961,663	7,231,004	5,886,131