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, 2023**

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 May 15, 2023, Fortress Biotech, Inc. issued a press release to announce financial results and recent corporate highlights for the quarter ended March 31, 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:

Exhibit Number	Description
99.1	Press Release issued by Fortress Biotech, Inc., dated May 15, 2023.
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 15, 2023

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

Fortress Biotech Reports First Quarter 2023 Financial Results and Recent Corporate Highlights

Fortress is advancing several late-stage clinical assets with two NDA submissions anticipated in second half of 2023

PDUFA goal date of January 3, 2024 set by FDA for cosibelimab to treat metastatic or locally advanced cutaneous squamous cell carcinoma

Miami, FL – May 15, 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 first quarter ended March 31, 2023.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "Fortress and our subsidiaries and partner companies continued advancing our promising clinical-stage drug candidates for a wide range of diseases during the first quarter of 2023. We expect data updates from multiple clinical programs in the coming months, including Phase 3 topline results for DFD-29 to treat papulopustular rosacea ("PPR") in June of 2023. We also expect to report dose escalation and response data for MB-106, a CD20-targeted, autologous CAR T cell therapy to treat relapsed or refractory B-cell non-Hodgkin lymphomas ("B-NHL") and chronic lymphocytic leukemia ("CLL"), throughout the year. Dotinurad for the treatment of gout and Triplex for the treatment of cytomegalovirus continue to advance in clinical trials and we anticipate a dotinurad Phase 1 topline data readout in U.S. healthy volunteers in the second quarter of this year."

Dr. Rosenwald continued, "On the regulatory front, we expect the rolling New Drug Application ("NDA") submission for CUTX-101 to treat Menkes disease to be complete by the end of 2023. We also anticipate filing an NDA for DFD-29 in the second half of 2023 and look forward to the January 3, 2024, Prescription Drug User Fee Act ("PDUFA") goal date for cosibelimab to treat patients with metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC"). Overall, it is an exciting time for Fortress as we advance potential treatments for patients in need while focusing on increasing shareholder value."

Recent Corporate Highlights[1]:

Cosibelimab (Anti PD-L1 antibody)

- Our partner company, Checkpoint Therapeutics, Inc. (Nasdaq: CKPT) ("Checkpoint"), submitted a Biologics License Application ("BLA") to the FDA for cosibelimab, its 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, in January 2023. In March 2023, the FDA accepted the BLA filing for cosibelimab and set a PDUFA goal date of January 3, 2024. In its BLA filing acceptance letter, the FDA indicated that no potential filing review issues have been identified, and that an advisory committee

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 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.

meeting to discuss the application is not currently planned. According to U.S. prescription claims data, in 2021, approximately 11,000 cSCC patients were treated with systemic therapies. As PD-1 inhibitors comprised less than half of patient prescriptions, cSCC remains a disease with a need for more effective and tolerable treatment options, particularly for the significant number of cSCC patients with immunosuppressive conditions or autoimmune diseases. With its unique mechanism of action and compelling safety profile, we believe cosibelimab, if approved, would be uniquely positioned to provide an important new treatment option for cSCC patients that are currently underserved by available therapies.

- Cosibelimab was sourced by Fortress and is currently in development at Checkpoint.

Dotinurad (Urate Transporter (URAT1) Inhibitor)

- Dotinurad is in development for the treatment of gout. We anticipate topline data from the Phase 1 trial to evaluate dotinurad in healthy volunteers in the United States in the second quarter of 2023 and expect to begin pivotal clinical trials in early 2024.
- Dotinurad (URECE® tablet) was approved in Japan in 2020 as a once-daily oral therapy for gout and hyperuricemia. Dotinurad was efficacious and well-tolerated in more than 500 Japanese patients treated for up to 58 weeks in Phase 3 clinical trials. The clinical program supporting approval included over 1,000 patients.
- Dotinurad was sourced by Fortress and is currently in development at Urica.

MB-106 (CD20-targeted CAR T Cell Therapy)

- Mustang Bio, Inc.'s (Nasdaq: MBIO) ("Mustang Bio") lead clinical candidate is MB-106, a CD20-targeted, autologous CAR T cell therapy to treat relapsed or refractory B-NHL and CLL. MB-106 data to date include an overall response rate of 96% and complete response rate of 75% in a wide range of hematologic malignancies, including Waldenstrom macroglobulinemia ("WM"), in a clinical trial conducted by Mustang Bio's collaborators at Fred Hutch. In parallel, Mustang Bio's multicenter, open-label, non-randomized Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106 continues to accrue, and Mustang Bio anticipates escalation to the final dose level in the Phase 1 indolent lymphoma arm in the third quarter of this year. The FDA granted Orphan Drug Designation to MB-106 for the treatment of WM, and Mustang Bio has treated the first WM patient in the indolent lymphoma arm of the trial. Results from this arm are expected to support an accelerated Phase 2 registration strategy for WM, with the first pivotal Phase 2 WM patient potentially to be treated in the first quarter of 2024. In the second quarter of this year, Mustang Bio plans to report safety and efficacy data from the indolent lymphoma arm.
- Phase 1/2 data from the Fred Hutch clinical trial on MB-106, a CD20-targeted, autologous CAR T cell therapy for patients with relapsed or refractory B-NHL and CLL, will be presented at the European Hematology Association Hybrid Congress ("EHA2023") taking place June 8-11, 2023, in Frankfurt, Germany and at the International Conference on Malignant Lymphoma ("ICML") taking place June 13-17, 2023, in Lugano, Switzerland. Data from the WM cohort were selected for poster presentation at EHA2023 and outpatient treatment of follicular lymphoma was selected for oral presentation at ICML.
- MB-106 was sourced by Fortress and is currently in development at Mustang Bio.

CUTX-101 (Copper Histidinate for Menkes disease)

- Our subsidiary, Cyprium Therapeutics, Inc. ("Cyprium") has completed two pivotal studies in patients with Menkes disease treated with CUTX-101, copper histidinate (CuHis). In a pre-specified analysis of the studies, a 79% reduction in the risk of death was observed in patients treated within four weeks of birth, compared with a historical control cohort of untreated patients, and median overall survival (OS) was 177.1 months for CUTX-101 compared to 16.1 months for historical control, with a hazard ratio (HR) of (95% CI) = 0.208 (0.094, 0.463) $p<0.0001$. A 75% reduction in the risk of death was observed in patients treated after four weeks of birth, compared with untreated historical control subjects, and median OS was 62.4 and 17.6 months, respectively; HR (95% CI) = 0.253 (0.119, 0.537); $p<0.0001$.

- In 2021, Cyprium signed a Development and Asset Purchase Agreement with Sentynl Therapeutics, Inc. ("Sentynl"), a wholly owned subsidiary of Zydus Lifesciences Ltd., for CUTX-101 to treat Menkes disease. Cyprium is responsible for the development of CUTX-101, and Sentynl will be responsible for commercialization of CUTX-101, as well as progressing newborn screening activities.
- In December 2021, Cyprium initiated the rolling submission of an NDA to the FDA for CUTX-101, which is ongoing and expected to be completed by the end of 2023.
- Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval of CUTX-101.
- CUTX-101 was sourced by Fortress and is currently in development at Cyprium.

CAEL-101 (Light Chain Fibril-reactive Monoclonal Antibody for AL Amyloidosis)

- On October 5, 2021, AstraZeneca plc ("AstraZeneca") acquired Caelum Biosciences, Inc. ("Caelum") for an upfront payment of approximately $150 million paid to Caelum shareholders, of which approximately $56.9 million was paid to Fortress, net of Fortress' $6.4 million portion of the $15 million, 24-month escrow holdback amount and other miscellaneous transaction expenses. The agreement also provides for additional potential payments to Caelum shareholders totaling up to $350 million, payable upon the achievement of regulatory and commercial milestones. Fortress is eligible to receive 42.4% of all potential milestone payments, which, together with the upfront payment, would total up to approximately $212 million.
- There are two ongoing Phase 3 studies of CAEL-101 for AL amyloidosis. (ClinicalTrials.gov identifiers: NCT04512235 and NCT04504825).[2]
- AstraZeneca has estimated that it expects the FDA to accept its BLA submission for review during calendar year 2024.
- CAEL-101 (anselamimab) was sourced by Fortress and was developed by Caelum (founded by Fortress) until its acquisition by AstraZeneca in October 2021.

Triplex (Cytomegalovirus ("CMV") vaccine)

- We expect that the Phase 2 clinical trial of Triplex for adults co-infected with HIV and CMV will complete enrollment in the second half of 2023 with topline data anticipated in 2024. The study aims to show potential reduction in intensity of highly active antiretroviral therapy treatment, which is used in up to 1.7 million treated HIV patients.
- Triplex received a grant from the National Institute of Allergy and Infectious Diseases that could provide over $20 million in non-dilutive funding. This will fund a 420 patient multi-center, placebo-controlled, randomized Phase 2 study of Triplex for control of CMV in patients undergoing liver transplantation and is expected to begin enrollment this year. We believe this data set could ultimately be used to support approval of Triplex in this setting.
- Triplex is currently the subject of three ongoing clinical trials including: pediatric patients undergoing stem cell transplant; adults co-infected with CMV and HIV; and in combination with a CAR T cell therapy for adults with NHL.
- Triplex was sourced by Fortress and is currently in development at our subsidiary, Helocyte, Inc.

AJ201

- In March 2023, we announced that our partner company, Avenue Therapeutics, Inc. (Nasdaq: ATXI) ("Avenue"), entered into an exclusive license agreement with AnnJi Pharmaceutical Co., Ltd. for intellectual property related to AJ201, a first-in-class clinical asset currently in a Phase 1b/2a study in the U.S. for the treatment of spinal and bulbar muscular atrophy, also known as Kennedy's Disease. Kennedy's Disease is a debilitating rare genetic neuromuscular disease primarily affecting men.

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2 Information on clinicaltrials.gov does not constitute part of this release.

Although there is a range of cited prevalence rates in the literature, a recent study used genetic analysis to estimate disease prevalence of 1:6,887 males[3].

- AJ201 was sourced by Fortress and is currently in development at Avenue.

IV Tramadol

- In March 2023, Avenue participated in a Type C meeting with the FDA to discuss the proposed study protocol to assess the risk of respiratory depression related to opioid stacking on IV Tramadol compared to IV morphine. The Type C meeting minutes from the FDA indicate that the FDA and Avenue are in agreement with a majority of the proposed protocol items and are in active discussion about remaining open items. The minutes indicate that the FDA also agrees that a successful study will support the submission of a complete response to the second Complete Response Letter for IV Tramadol pending final agreement on a statistical analysis plan and a full review of the submitted data in the complete response as well as concurrence from the Division of Anesthesia, Analgesia and Addiction Products.
- IV Tramadol was sourced by Fortress and is currently in development at Avenue.

***In vivo* CAR T Platform Technology**

- We continue to collaborate with the Mayo Clinic to potentially revolutionize the delivery of CAR T in patients. The technology has the potential to generate CAR T cells within the patient's body after two outpatient injections, without the need for traditional *ex vivo* allogeneic or autologous CAR T cell processing wait time and expense.
- We anticipate the publication of proof-of-concept research from *in vivo* animal studies in 2023.
- The novel CAR T technology was sourced by Fortress and is currently in development at Mustang Bio.

Marketed Dermatology Products and Product Candidates

- Journey Medical Corporation (Nasdaq: DERM) ("Journey Medical"), our partner company, markets prescription dermatology products.
- In January 2023, Journey Medical completed enrollment in its DFD-29 Phase 3 clinical program for the treatment of papulopustular rosacea and achieved the "Last Patient Out" milestone in May 2023. Topline data from the DFD-29 Phase 3 clinical studies are expected in June of 2023. Journey Medical plans to submit its NDA for DFD-29 in the second half of 2023, and an FDA approval decision is anticipated in the second half of 2024.
    - In the Phase 2 clinical trials, DFD-29 (40mg) demonstrated nearly double the efficacy when compared to Oraycea® (European equivalent of Oracea®) on both co-primary endpoints. For the first co-primary endpoint, Investigator's Global Assessment ("IGA") treatment success, Oraycea had a 33.33% IGA treatment success rate, while DFD-29 achieved a 66.04% IGA treatment success rate. For the second co-primary endpoint, the change in total inflammatory lesion count, Oraycea had a 10.5 reduction in inflammatory lesions, while DFD-29 achieved a 19.2 reduction in inflammatory lesions.
- Journey Medical's total product net revenues were $12.2 million for the first quarter of 2023, compared to first quarter 2022 total product net revenues of $20.8 million. Compared to the prior year period, net sales were primarily impacted by Targadox® generic competition and gross-to-net deductions for Targadox and Ximino®, including returns and managed care rebates. Higher unit sales were seen in Accutane®, Amzeeq®, Zilxi® and Exelderm®, while Qbrexza® volume decreased but was offset by pricing increases.

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3 M. Zanovello et al., Unexpected frequency of the pathogenic *AR*CAG repeat 2 expansion in the general population. Brain, *in press* (2023).

General Corporate:

Fortress

- In February 2023, Fortress completed aregistered direct offering priced at-the-market under Nasdaq rules for total gross proceeds of approximately $13.9 million, and a concurrent private placement with investors in the registered direct offering for the pro rata rights to acquire, in the aggregate, securities exercisable into common stock in certain future operating subsidiaries that consummate a specified corporate development transaction within the next five years.

Financial Results:

To assist our stockholders in understanding our company, we have prepared non-GAAP financial metrics for the three months ended March 31, 2023 and 2022. These metrics exclude the operations of our four public partner companies: Avenue, Checkpoint, Journey Medical and Mustang Bio, as well as any one-time, non-recurring, non-cash transactions. The goal in providing these non-GAAP financial metrics is to highlight the financial results of Fortress' core operations, which comprise our privately held development-stage entities, as well as our business development and finance functions.

- As of March 31,2023, Fortress' consolidated cash, cash equivalents and restricted cash totaled $154.9 million, compared to $181.0 million as of December 31, 2022, a decrease of $26.1 million during the quarter.
- On a GAAP basis, Fortress' net revenue totaled $12.4 million for the first quarter of 2023, which included $12.2 million in net revenue generated from our marketed dermatology products. This compares to net revenue totaling $23.9 million for the first quarter of 2022, which included $20.8 million in net revenue generated from our marketed dermatology products.
- On a GAAP basis, consolidated research and development expenses including license acquisitions were $39.5 million for the first quarter of 2023, compared to $36.7 million for the first quarter of 2022. On a non-GAAP basis, Fortress research and development expenses were $2.3 million for the first quarter of 2023, compared to $2.8 million for first quarter of 2022.
- On a GAAP basis, consolidated selling, general and administrative expenses were $25.3 million for the first quarter of 2023, compared to $26.3 million for the first quarter of 2022. On a non-GAAP basis, Fortress selling, general and administrative expenses were $7.0 million, for the first quarter of 2023, compared to $6.2 million for the first quarter of 2022.
- On a GAAP basis, consolidated net loss attributable to common stockholders was $21.5 million, or $0.21 per share, for the first quarter of 2023, compared to consolidated net loss attributable to common stockholders of $15.8 million, or $0.18 per share for the first quarter of 2022.
- Fortress' non-GAAP loss attributable to common stockholders was $6.5 million, or $0.06 per share, for the first quarter of 2023, compared to Fortress' non-GAAP loss attributable to common stockholders of $5.7 million, or $0.07 per share, for the first quarter of 2022.

Use of Non-GAAP Measures:

In addition to the GAAP financial measures as presented in our filings with the Securities and Exchange Commission ("SEC"), including our Form 10-Q to be filed on May 15, 2023, the Company, in this press release, has included certain non-GAAP measurements. The non-GAAP net loss attributable to common stockholders is defined by the Company as GAAP net loss attributable to common stockholders, less net losses attributable to common stockholders from our public partner companies Avenue, Checkpoint, Journey Medical and Mustang Bio ("public partner companies"), as well as our former subsidiary, Caelum. In addition, the Company has also provided a Fortress non-GAAP loss attributable to common stockholders which is a modified EBITDA calculation that starts with the non-GAAP loss attributable to common stockholders and removes stock-based compensation expense, non-cash interest expense, amortization of licenses and debt discount, changes in fair values of investment, changes in fair value of derivative liability, and depreciation expense. The Company also provides non-GAAP research and development costs, defined as GAAP research and development costs, less research and development costs of our public partner companies and non-GAAP selling, general and

administrative costs, defined as GAAP selling, general and administrative costs, less selling, general and administrative costs of our public partner companies.

Management believes each of these non-GAAP measures provide meaningful supplemental information regarding the Company's performance because (i) it allows for greater transparency with respect to key measures used by management in its financial and operational decision-making; (ii) it excludes the impact of non-cash or, when specified, non-recurring items that are not directly attributable to the Company's core operating performance and that may obscure trends in the Company's core operating performance; and (iii) it is used by institutional investors and the analyst community to help analyze the Company's standalone results separate from the results of its public partner companies. However, non-GAAP loss attributable to common stockholders and any other non-GAAP financial measures should be considered as a supplement to, and not as a substitute for, or superior to, the corresponding measures calculated in accordance with GAAP. Further, non-GAAP financial measures used by the Company and the manner in which they are calculated may differ from the non-GAAP financial measures or the calculations of the same non-GAAP financial measures used by other companies, including the Company's competitors.

The tables below provide a reconciliation from GAAP to non-GAAP measures:

($ in thousands except for share and per share amounts)	For the three months ended March 31, 2023	2022
Net loss attributable to common stockholders	$ (21,537)	$ (15,760)
Net loss attributable to common stockholders - Avenue[1]	(949)	(535)
Net loss attributable to common stockholders - Checkpoint[2]	(1,768)	(2,924)
Net loss attributable to common stockholders - Journey Medical[3]	(5,733)	(817)
Net loss attributable to common stockholders - Mustang Bio[4]	(3,166)	(2,541)
Non-GAAP (loss) attributable to common stockholders	$ (9,921)	$ (8,943)
Stock based compensation	2,870	2,782
Amortization of debt discount	484	357
Depreciation	93	100
Fortress non-GAAP (loss) income attributable to common stockholders	$ (6,474)	$ (5,705)
Per common share - basic and diluted:		
Net loss attributable to common stockholders (GAAP)	$ (0.21)	$ (0.18)
Non-GAAP net loss attributable to common stockholders	$ (0.10)	$ (0.10)
Fortress non-GAAP (loss) income attributable to common stockholders	$ (0.06)	$ (0.07)
Fortress non-GAAP (loss) income attributable to common stockholders - diluted		
Weighted average common shares outstanding - basic and diluted	101,885,648	86,255,142

1. Avenue net loss for the three months ended March 31, 2023 of $7.5 million net of non-controlling interest ("NCI") of $6.4 million, Master Services Agreement ("MSA") fee to Fortress of $0.1 million, and financing fee to Fortress of $0.1 million; net loss for the three months ended March 31, 2022 of $2.9 million, net of NCI of $2.4 million.
2. Checkpoint net loss for the three months ended March 31, 2023 of $10.5 million net of NCI of $8.4 million, MSA fee to Fortress of $0.1 million, and financing fee to Fortress of $0.2 million; net loss for the three months ended March 31, 2022 of $16.8 million net of NCI of $13.6 million, MSA fee to Fortress of $0.1 million, and financing fee to Fortress of $0.2 million.
3. Journey Medical net loss for the three months ended March 31, 2023 of $10.1 million net of NCI of $4.4 million; net loss for the three months ended March 31, 2022 of $1.4 million net of NCI of $0.5 million and tax expense recognized on a stand-alone basis of $0.1 million.
4. Mustang Bio net loss for the three months ended March 31, 2023 of $16.7 million net of NCI of $13.3 million, Fortress MSA fee of $0.1 million, and Fortress financing fee of $0.1 million; net loss for the three months ended March 31, 2022 of $19.8 million net of NCI of $16.2 million, MSA fee to Fortress of $0.3 million and financing fee to Fortress of $0.8 million.

Reconciliation to non-GAAP research and development costs and non-GAAP selling, general and administrative costs:

($ in thousands)	For the three months ended March 31, 2023	2022
Research and development[1]	**$ 39,506**	**$ 36,722**
Less:		
Research and development - Avenue[2]	5,383	1,808
Research and development - Checkpoint	15,826	14,670
Research and development - Journey Medical	2,033	1,266
Research and development - Mustang Bio[3]	13,938	16,164
Non-GAAP research and development costs	**$ 2,327**	**$ 2,814**
Selling, general and administrative	**$ 25,341**	**$ 26,270**
Less:		
General and administrative - Avenue[4]	849	1,055
General and administrative - Checkpoint[5]	2,011	1,922
Selling, general and administrative - Journey Medical	13,292	14,715
General and administrative - Mustang Bio[6]	2,150	2,402
Non-GAAP selling, general and administrative costs	**$ 7,039**	**$ 6,177**

1. Includes Research and development expense and Research and development - licenses acquired expense for the periods presented.
2. Excludes $0.1 million of Fortress MSA expense payable to Fortress for the three months ended March 31, 2023.
3. Excludes $0.1 million of Fortress MSA expense payable to Fortress for the each of the three months ended March 31, 2023 and 2022, respectively.
4. Excludes $0.1 million of Fortress MSA expense and $0.1 million financing fee payable to Fortress for the three months ended March 31, 2023.
5. Excludes $0.1 million of Fortress MSA expense and $0.2 million Fortress financing fee for the three months ended March 31, 2023; and excludes $0.1 million of Fortress MSA expense and $0.2 million Fortress financing fee for the three months ended March 31, 2022.
6. Excludes $0.1 million of Fortress MSA expense and $0.1 million Fortress financing fee for the three months ended March 31, 2023; and $0.1 million of Fortress MSA expense and $0.9 million Fortress financing fee for the three months ended March 31, 2022.

About Fortress Biotech

Fortress Biotech, Inc. (“Fortress”) is an innovative biopharmaceutical company focused on acquiring, developing and commercializing high-potential marketed and development-stage drugs and drug candidates. The company has eight marketed prescription pharmaceutical products and over 30 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 driven by a world-class business development team that is focused on leveraging its significant biopharmaceutical industry expertise 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 Sentynl. For more information, visit 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 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)

	March 31, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 152,483	$ 178,266
Accounts receivable, net	27,616	28,208
Inventory	13,278	14,159
Other receivables - related party	636	138
Prepaid expenses and other current assets	8,368	9,661
Total current assets	202,381	230,432
Property, plant and equipment, net	12,194	13,020
Operating lease right-of-use asset, net	19,467	19,991
Restricted cash	2,438	2,688
Intangible asset, net	26,128	27,197
Other assets	943	973
Total assets	**$ 263,551**	**$ 294,301**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 105,419	$ 97,446
Deferred revenue	547	728
Income taxes payable	722	722
Common stock warrant liabilities	9,459	13,869
Operating lease liabilities, short-term	2,515	2,447
Partner company term loan, short-term, net	2,318	—
Partner company convertible preferred shares, short-term, net	2,937	2,052
Partner company line of credit	3,000	2,948
Partner company installment payments - licenses, short-term, net	2,288	7,235
Other short-term liabilities	268	268
Total current liabilities	129,473	127,715
Notes payable, long-term, net	89,996	91,730
Operating lease liabilities, long-term	21,026	21,572
Partner company installment payments - licenses, long-term, net	1,450	1,412
Other long-term liabilities	1,800	1,847
Total liabilities	**243,745**	**244,276**
Commitments and contingencies		
Stockholders' equity		
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, 2023 and December 31, 2022, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 130,417,161 and 110,494,245 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	130	110
Additional paid-in-capital	693,433	675,841
Accumulated deficit	(655,770)	(634,233)
Total stockholders' equity attributed to the Company	37,796	41,721
Non-controlling interests	(17,990)	8,304
Total stockholders' equity	19,806	50,025
Total liabilities and stockholders' equity	**$ 263,551**	**$ 294,301**

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,	
	2023	2022
Revenue		
Product revenue, net	$ 12,165	$ 20,796
Collaboration revenue	181	577
Revenue - related party	35	52
Other revenue	48	2,500
Net revenue	12,429	23,925
Operating expenses		
Cost of goods sold - product revenue	6,449	8,203
Research and development	35,276	36,722
Research and development - licenses acquired	4,230	—
Selling, general and administrative	25,341	26,270
Total operating expenses	71,296	71,195
Loss from operations	(58,867)	(47,270)
Other income (expense)		
Interest income	1,036	142
Interest expense and financing fee	(4,296)	(2,350)
Foreign exchange loss	(47)	—
Change in fair value of warrant liabilities	6,678	—
Grant income	351	—
Total other income (expense)	3,722	(2,208)
Net loss	**(55,145)**	**(49,478)**
Net loss attributable to non-controlling interests	33,608	33,718
Net loss attributable to common stockholders	**$ (21,537)**	**$ (15,760)**
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.21)	$ (0.18)
Weighted average common shares outstanding - basic and diluted	101,885,648	86,255,142