
**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 12, 2022**

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.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(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 12, 2022, Fortress Biotech, Inc. issued a press release to announce financial results and recent corporate highlights for the quarter ended March 31, 2022. 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 12, 2022.
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

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 12, 2022

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



Fortress Biotech Reports First Quarter 2022 Financial Results and Recent Corporate Highlights

Net revenue for first quarter of 2022 increased 106% period-over-period to \$23.9 million, a company quarterly record

Positive topline results from registration-enabling study of cosibelimab in metastatic cutaneous squamous cell carcinoma announced in January 2022; BLA submission expected in 2022

Rolling NDA submission for CUTX-101 for the treatment of Menkes disease expected to be completed in mid-2022; CUTX-101 is eligible for a priority review voucher upon FDA approval

Ended first quarter 2022 with \$289.7 million in consolidated cash, cash equivalents and restricted cash

Miami, FL – May 12, 2022 – 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, 2022.

Lindsay A. Rosenwald, M.D., Fortress’ Chairman, President and Chief Executive Officer, said, “Together with our subsidiaries and partner companies, Fortress had an exciting start to the year with the acquisition and commercial launch of two dermatology products, Amzeeq® and Zilxi®, bringing our total number of marketed prescription products to nine. Fortress also has a growing portfolio of 30 product candidates across our partner companies, including 20 separate clinical programs in 30 ongoing clinical trials. Four product candidates are in seven¹ ongoing pivotal clinical trials. We were pleased to announce positive topline results from the registration-enabling study of cosibelimab in metastatic cutaneous squamous cell carcinoma (“cSCC”) in January 2022. Throughout the remainder of 2022 we anticipate multiple key regulatory and clinical inflection points, such as the submission of a Biologics License Application (“BLA”) to the U.S. Food and Drug Administration (“FDA”) for cosibelimab and the completion of Cyprium’s CUTX-101 rolling submission of its New Drug Application (“NDA”). CUTX-101 is eligible for a priority review voucher upon FDA approval. Moreover, we expect the availability of clinical data from many product candidates in ongoing clinical trials including MB-106, MB-107, cosibelimab and Dotinurad.”

Dr. Rosenwald continued, “We ended the first quarter with \$289.7 million in consolidated cash, cash equivalents and restricted cash. Additionally, we attained a new company quarterly record for net revenue, \$23.9 million, which is an increase of 106% period-over-period. We believe that we are well-positioned for success with multiple product candidates and remain focused on creating long-term shareholder value through asset monetizations, equity holdings/appreciation in our subsidiaries and partner companies, annual equity dividends and royalty revenues.”

¹ Includes two trials at our partner company Caelum Biosciences, Inc. (“Caelum”) which was sold to AstraZeneca PLC as successor-in-interest to Alexion Pharmaceuticals, Inc. in October 2021. Fortress remains eligible to receive up to approximately \$155 million in future milestone payments from the transaction.

Recent Corporate Highlights²:

Marketed Dermatology Products and Product Candidates

- Journey Medical Corporation (“Journey Medical”), a Fortress partner company, currently has nine prescription dermatology products.
- Our products generated net revenues of \$20.8 million in the first quarter of 2022, compared to first quarter 2021 net revenues of \$10.7 million, representing growth of 94%.
- In March 2022, Journey Medical dosed the first patient in the Phase 3 clinical program of DFD-29 for the treatment of papulopustular rosacea. Topline data are anticipated in the first quarter of 2023 with an NDA filing expected in the second half of 2023.
- In January 2022, Journey Medical received notice from its exclusive licensing partner in Japan, Maruho Co., Ltd., that Japan's Ministry of Health, Labor and Welfare approved Rapifort® Wipes 2.5% (glycopyrronium tosylate hydrate) for the treatment of primary axillary hyperhidrosis. This approval triggered a milestone payment of \$10.0 million to Journey Medical, of which \$7.5 million was paid to Dermira, Inc. (“Dermira”), a wholly owned subsidiary of Eli Lilly and Company, pursuant to the terms of the Asset Purchase Agreement between Journey Medical and Dermira, with net proceeds of \$2.5 million to Journey Medical.
- Also in January 2022, Journey Medical entered into a definitive agreement with VYNE Therapeutics, Inc. to acquire two FDA-approved topical minocycline products, Amzeeq® and Zilxi®, and a Molecule Stabilizing Technology™ platform for an upfront payment of \$20.0 million and an additional \$5.0 million on the one (1)-year anniversary of the closing of the transaction in January 2023.
- Additionally, in January 2022, Journey Medical expanded the borrowing capacity of the East West Bank credit agreement to \$30.0 million, which includes an increase to the working capital line of credit to \$10.0 million and the addition of a \$20.0 million term loan.
- We intend to launch an additional prescription product in the second half of 2022.

CUTX-101 (Copper Histidinate for Menkes disease)

- In December 2021, we initiated the rolling submission of an NDA to the FDA for CUTX-101. We intend to complete the rolling submission of the NDA for CUTX-101 in mid-2022.
- In March 2022, our subsidiary company, Cyprium Therapeutics, Inc (“Cyprium”) announced positive data on CUTX-101 were presented as a “Top-Rated Abstract” and Poster at the 2022 American College of Medical Genetics and Genomics Clinical Genetics Meeting. The abstract can be viewed here.
- CUTX-101 is currently in development at Cyprium.

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

- On October 5, 2021, AstraZeneca acquired 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, totaling up to approximately \$212 million.
- There are two ongoing Phase 3 studies of CAEL-101 for AL amyloidosis. (ClinicalTrials.gov Identifiers: NCT04512235 and NCT04504825).
- CAEL-101 was sourced by Fortress and was developed by Caelum until the acquisition by AstraZeneca in October 2021 .

Cosibelimab (formerly CK-301, an anti-PD-L1 antibody)

² Includes product candidates in development at Fortress, majority-owned and controlled partners and/or subsidiaries, and partners and/or subsidiaries in which Fortress holds significant minority ownership positions. As used herein, the words “we”, “us” and “our” may refer to Fortress individually or together with our affiliates, subsidiaries, and partners, and the word “partner” refers to either entities that are publicly traded and in which we own or control a majority of the ownership position or third party entities with whom we have a significant business relationship, each as dictated by context.

- In January 2022, we announced positive topline results from our registration-enabling clinical trial evaluating the safety and efficacy of our anti-PD-L1 antibody, cosibelimab, administered as a fixed dose of 800 mg every two weeks in patients with metastatic cSCC. The study met its primary endpoint, with cosibelimab demonstrating a confirmed objective response rate of 47.4% (95% CI: 36.0, 59.1) based on independent central review of 78 patients enrolled in the metastatic cSCC cohort using Response Evaluation Criteria in Solid Tumors version 1.1 criteria. Our partner company, Checkpoint Therapeutics, Inc. (“Checkpoint”) intends to submit a BLA for cosibelimab in 2022, followed by a Marketing Authorization Application submission in Europe and other territories worldwide. With a potentially favorable safety profile versus anti-PD-1 therapy and a plan to commercialize at a substantially lower price, we believe cosibelimab has the potential to be a market disruptive product in the \$30 billion and growing PD-(L)1 class.
- In April 2022, we announced that the results of our pivotal trial of cosibelimab in cSCC were selected for poster presentation at the 2022 American Society of Clinical Oncology Annual Meeting, to be held at McCormick Place, in Chicago, June 3-7, 2022.
- Cosibelimab was sourced by Fortress and is currently in development at Checkpoint.

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

- In April 2022, we announced that interim Phase 1/2 data on MB-106, a CD20-targeted, autologous CAR T cell therapy for patients with relapsed or refractory B-cell non-Hodgkin lymphomas (“NHL”) and chronic lymphocytic leukemia (“CLL”), were presented at the 2022 Tandem Meetings I Transplantation & Cellular Therapy Meetings of the American Society of Transplantation and Cellular Therapy and Center for International Blood & Marrow Transplant Research. Data demonstrated high efficacy and a very favorable safety profile in all patients (n=25). Five dose levels were used during the study, and complete responses were observed at all dose levels. Durable responses were observed in a wide range of hematologic malignancies including follicular lymphoma (“FL”), CLL, diffuse large B-cell lymphoma (“DLBCL”), and Waldenstrom macroglobulinemia (“WM”). An overall response rate (“ORR”) of 96% and complete response (“CR”) rate of 72% was observed in all patients across all dose levels. Additionally, two patients had been previously treated with CD19-directed CAR T therapy and subsequently relapsed, and both responded to treatment, one patient with FL with a CR and the other with DLBCL with a partial response. We expect to dose the first patient in a Mustang-sponsored multicenter Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106 for relapsed or refractory B-NHL and CLL in the second quarter of this year. A copy of the abstract can be viewed on the meeting website here.
- Also in April 2022, MB-106 data focused on CLL were presented at the 4th International Workshop on CAR-T and Immunotherapies.
- In May 2022, we announced that MB-106 CD20-targeted CAR T therapy data were selected for an oral presentation at the European Hematology Association 2022 (“EHA2022”) Hybrid Congress scheduled to take place in June. Dr. Mazyar Shadman of Fred Hutch will present updated interim data from the ongoing Phase 1/2 clinical trial for B-NHL and CLL. A copy of the abstract can be viewed online through the EHA2022 website here.
- MB-106 was sourced by Fortress and is currently in development at our partner company, Mustang Bio, Inc. (“Mustang Bio”).

MB-107 and MB-207 (Lentiviral Gene Therapies for XSCID)

- In May 2022, we announced that interim Phase 1/2 data on treatment with the same lentiviral vector used in MB-107, Mustang Bio’s lentiviral gene therapy for X-linked severe combined immunodeficiency (“XSCID”), also known as bubble boy disease, in newly diagnosed infants under the age of two, were selected for an oral presentation during the Clinical Trials Spotlight Symposium at the American Society of Gene & Cell Therapy 25th Annual Meeting taking place May 16-19, 2022, both virtually and in Washington, D.C. The presentation will include updated data from a multicenter Phase 1/2 clinical trial for XSCID in newly diagnosed infants under the age of two at St. Jude Children’s Research Hospital, UCSF Benioff Children’s Hospital in San Francisco and Seattle Children’s Hospital. The abstract can be viewed on the meeting website here. Information on such website is not part of this release.
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- In the second half of 2022, we expect to enroll the first patient in a pivotal multicenter Phase 2 clinical trial under Mustang Bio's Investigational New Product Drug Application ("IND") to evaluate MB-107, a lentiviral gene therapy for the treatment of infants under the age of two with XSCID.
- Mustang Bio filed an IND application in December 2021 for its pivotal multicenter Phase 2 clinical trial of MB-207, a lentiviral gene therapy for the treatment of patients with XSCID who have been previously treated with a hematopoietic stem cell transplantation and for whom re-treatment is indicated. The trial is currently on hold pending CMC clearance from the FDA, and based on feedback from the Agency, Mustang Bio expects to enroll the first patient in a pivotal multicenter Phase 2 clinical trial in the first quarter of 2023.
- MB-107 and MB-207 were sourced by Fortress and are currently in development at Mustang Bio.

Dotinurad (Urate Transporter (URAT1) Inhibitor)

- In May 2021, we announced an exclusive license agreement with Fuji Yakuhin Co. Ltd. to develop Dotinurad in North America and Europe. Dotinurad is a potential best-in-class urate transporter (URAT1) inhibitor for gout and possibly other hyperuricemic indications including chronic kidney disease (CKD) and heart failure. 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. Over 1,000 Japanese patients have been treated safely with this drug.
- In December 2021, we filed an IND with the FDA. We expect to initiate a Phase 1 clinical trial to evaluate Dotinurad for the treatment of gout in the first half of 2022. We anticipate topline data from the Phase 1 trial in the second half of 2022.
- Dotinurad was sourced by Fortress and is currently in development at our subsidiary company, UR-1 Therapeutics.

MB-105 (PSCA-targeted CAR T Cell Therapy)

- In February 2022, Phase 1 data on MB-105, a prostate stem cell antigen ("PSCA")-targeted CAR T cell therapy administered systemically to patients with PSCA-positive metastatic castration-resistant prostate cancer ("mCRPC"), were presented by City of Hope at the 2022 American Society of Clinical Oncology Genitourinary Cancers Symposium. The data indicated that PSCA-targeted CAR T-cell therapy is feasible in patients with mCRPC with dose-limiting toxicity of cystitis and is associated with preliminary anti-tumor effect at a dose of 100 million cells plus lymphodepletion. It was concluded that escalation up to the next dose level of 300 million cells plus modified lymphodepletion can proceed in the trial.
- MB-105 was sourced by Fortress and is currently in development at Mustang Bio.

MB-109 (MB-101 (IL13R α 2-targeted CAR T Cell Therapy) + MB-108 Oncolytic Virus)

- In April 2022, we announced our plan to file an IND in the second half of 2022 to initiate a Phase 1 clinical trial combining CAR T cells and an oncolytic virus for the treatment of recurrent glioblastoma ("rGBM"), supported by interim data from two ongoing investigator-sponsored Phase 1 clinical trials evaluating two clinical candidates, MB-101 (IL13R α 2-targeted CAR T cell therapy licensed from City of Hope) and MB-108 (C134 oncolytic virus licensed from Nationwide Children's Hospital). The data are from a late-breaking poster presented at the American Association for Cancer Research Annual Meeting 2022. Preclinical data also presented support the safety of administering these two therapies sequentially to optimize treatment in a regimen designated as MB-109.
- MB-101 and MB-108 were sourced by Fortress and they are currently in development at Mustang Bio.

General Corporate

- In April 2022, Fortress participated in a two-day summit hosted by the B. Riley Securities' Healthcare Equity Research team that featured multiple programs from Fortress' diversified pipeline. Webcast replays are available on Fortress' website here.

Financial Results:

To assist our stockholders in understanding our company, we have prepared non-GAAP financial results for the three months ended March 31, 2022 and 2021. These results exclude the operations of our four public partner companies: Avenue Therapeutics, Inc. (“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 are comprised of our privately held development-stage entities, as well as our business development and finance functions. See “Use of Non-GAAP Measures” below.

- As of March 31, 2022, Fortress’ consolidated cash, cash equivalents and restricted cash totaled \$289.7 million, compared to \$308.0 million as of December 31, 2021, a decrease of \$18.3 million during the quarter.
- On a GAAP basis, Fortress’ net revenue totaled \$23.9 million for the first quarter of 2022, which included \$20.8 million in net revenue generated from our marketed dermatology products. This compares to net revenue totaling \$11.6 million for the first quarter of 2021, which included \$10.7 million in net revenue generated from our marketed dermatology products.
- On a GAAP basis, consolidated research and development expenses including license acquisitions were \$36.7 million for the first quarter of 2022, compared to \$20.2 million for the first quarter of 2021. On a non-GAAP basis, Fortress research and development expenses were \$2.8 million for the first quarter of 2022, compared to \$4.1 million for first quarter of 2021.
- On a GAAP basis, consolidated selling, general and administrative expenses were \$26.3 million for the first quarter of 2022, compared to \$17.5 million for the first quarter of 2021. On a non-GAAP basis, Fortress selling, general and administrative expenses were \$6.2 million, for the first quarter of 2022, compared to \$6.7 million for the first quarter of 2021.
- On a GAAP basis, consolidated net loss attributable to common stockholders was \$15.8 million, or \$0.18 per share, for the first quarter of 2022, compared to consolidated net loss attributable to common stockholders of \$8.8 million, or \$0.11 per share for the first quarter of 2021.
- Fortress’ non-GAAP loss attributable to common stockholders was \$5.7 million, or \$0.07 per share, for the first quarter of 2022, compared to Fortress’ non-GAAP loss attributable to common stockholders of \$8.5 million, or \$0.11 per share, for the first quarter of 2021.

Use of Non-GAAP Measures:

In addition to the GAAP financial measures as presented in this press release and that will be presented in our Form 10-Q to be filed with the Securities and Exchange Commission (“SEC”) on May 12, 2022, 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 expenses including license acquisitions, defined as GAAP research and development costs, less research and development costs of our public partner companies and non-GAAP consolidated selling, general and administrative expenses, defined as GAAP selling, general and administrative expenses, 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:

<i>(Sin thousands except for share and per share amounts)</i>	For the three months ended March 31,	
	2022	2021¹
Net loss attributable to common stockholders	\$ (15,760)	\$ (8,822)
Net loss attributable to common stockholders - Avenue ²	(535)	(225)
Net loss attributable to common stockholders - Checkpoint ³	(2,924)	(1,158)
Net (loss) income attributable to common stockholders - Journey Medical ⁴	(817)	233
Net loss attributable to common stockholders - Mustang Bio ⁵	(2,541)	(2,773)
Non-GAAP loss attributable to common stockholders	\$ (8,943)	\$ (4,899)
Stock based compensation	2,782	1,866
Amortization of debt discount	357	309
Depreciation	100	141
Increase in fair value of investment in Caelum	-	(5,913)
Fortress non-GAAP loss attributable to common stockholders	\$ (5,705)	\$ (8,496)
Per common share - basic and diluted:		
Net loss attributable to common stockholders (GAAP)	\$ (0.18)	\$ (0.11)
Non-GAAP net loss attributable to common stockholders	\$ (0.10)	\$ (0.06)
Fortress non-GAAP loss attributable to common stockholders	\$ (0.07)	\$ (0.11)
Weighted average common shares outstanding - basic and diluted	86,255,142	80,851,671

- Results for the three months ended March 31, 2021 have been adjusted to present Journey Medical separately as a public entity.
- Avenue net loss for the three months ended March 31, 2022 and 2021 of \$2.9 million and \$1.0 million, respectively, net of non-controlling interest of \$2.4 million and \$0.8 million, respectively.
- Checkpoint net loss of \$16.8 million net of non-controlling interest of \$13.6 million, Fortress MSA fee of \$0.1 million, and Fortress financing fee of \$0.2 million for the three months ended March 31, 2022; and net loss of \$6.5 million net of non-controlling interest of \$4.6 million, Fortress MSA fee of \$0.1 million, and Fortress financing fee of \$0.6 million for the three months ended March 31, 2021.
- Journey Medical net loss for the three months ended March 31, 2022 of \$1.4 million net of non-controlling interest of \$0.5 million and tax expense recognized on a stand-alone basis of \$0.1 million; and net income for the three months ended March 31, 2021 of \$0.3 million, net non-controlling interest of approximately \$35,000.
- Mustang Bio net loss of \$19.8 million net of non-controlling interest of \$16.2 million, Fortress MSA fee of \$0.3 million and Fortress financing fee of \$0.8 million for the three months ended March 31, 2022; and net loss of \$15.0 million net of non-controlling interest of \$10.9 million, Fortress MSA fee of \$0.1 million and Fortress financing fee of \$1.2 million for the three months ended March 31, 2021.

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

<i>(Sin thousands)</i>	For the three months ended March 31,	
	2022	2021¹
Research and development¹	\$ 36,722	\$ 20,154
Less:		
Research and development - Avenue	1,808	258
Research and development - Checkpoint	14,670	4,213
Research and development - Journey Medical	1,266	-
Research and development - Mustang Bio ²	16,164	11,556
Non-GAAP research and development costs	\$ 2,814	\$ 4,127
Selling, general and administrative	\$ 26,270	\$ 17,542
Less:		
General and administrative - Avenue	1,055	743
General and administrative - Checkpoint ³	1,922	1,615
Selling, general and administrative - Journey Medical	14,715	6,226
General and administrative - Mustang Bio ⁴	2,402	2,210
Non-GAAP selling, general and administrative costs	\$ 6,177	\$ 6,748

1. Includes Research and development expense and Research and development - licenses acquired expense for the three months ended March 31, 2021.
2. Excludes \$0.1 million of Fortress MSA expense for each of the three months ended March 31, 2022 and 2021.
3. Excludes \$0.1 million of Fortress MSA expense and \$0.2 million Fortress financing fee for the three months ended March 31, 2022; and \$0.1 million of Fortress MSA expense and \$0.6 million Fortress financing fee for the three months ended March 31, 2021.
4. Excludes \$0.1 million of Fortress MSA expense and \$0.8 million Fortress financing fee for the three months ended March 31, 2022; and \$0.1 million of Fortress MSA expense and \$1.2 million Fortress financing fee for the three months ended March 31, 2021.

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 nine 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 plc, City of Hope, Fred Hutchinson Cancer Research Center, St. Jude Children’s Research Hospital, Nationwide Children’s Hospital and Sentyln Therapeutics, Inc. 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, 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; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to 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, including disruptions that may result from hostilities in Europe; our dependence on third-party suppliers; risks relating to the COVID-19 outbreak and its potential impact on our employees’ and consultants’ ability to complete work in a timely manner and on our ability to obtain additional financing on favorable terms or at all; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; 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.

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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, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	\$ 287,511	\$ 305,744
Accounts receivable, net	31,183	23,112
Inventory	16,137	9,862
Other receivables - related party	631	678
Prepaid expenses and other current assets	5,724	7,066
Total current assets	341,186	346,462
Property, plant and equipment, net	14,430	15,066
Operating lease right-of-use asset, net	18,565	19,005
Restricted cash	2,220	2,220
Intangible asset, net	30,457	12,552
Other assets	1,072	1,198
Total assets	\$ 407,930	\$ 396,503
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 91,268	\$ 90,660
Deferred revenue	2,034	2,611
Income taxes payable	346	345
Operating lease liabilities, short-term	2,129	2,104
Partner company line of credit	—	812
Partner company installment payments - licenses, short-term (net of imputed interest of \$637 and \$490 as of March 31, 2022 and December 31, 2021, respectively)	7,363	4,510
Total current liabilities	103,140	101,042
Notes payable, long-term (net of debt discount of \$10,994 and \$7,063 as of March 31, 2022 and December 31, 2021, respectively)	85,056	42,937
Operating lease liabilities, long-term	20,454	20,987
Partner company installment payments - licenses, long-term (net of imputed interest of \$284 and \$373 as of March 31, 2022 and December 31, 2021, respectively)	3,716	3,627
Other long-term liabilities	1,986	2,033
Total liabilities	214,352	170,626
Commitments and contingencies		
Stockholders' equity		
Cumulative redeemable perpetual preferred stock, \$0.01 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively, liquidation value of \$25.00 per share	3	3
Common stock, \$0.01 par value, 170,000,000 shares authorized, 106,321,875 and 101,435,505 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	106	101
Additional paid-in-capital	660,973	656,033
Accumulated deficit	(563,223)	(547,463)
Total stockholders' equity attributed to the Company	97,859	108,674
Non-controlling interests	95,719	117,203
Total stockholders' equity	193,578	225,877
Total liabilities and stockholders' equity	\$ 407,930	\$ 396,503

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,	
	2022	2021
Revenue		
Product revenue, net	\$ 20,796	\$ 10,719
Collaboration revenue	577	800
Revenue - related party	52	68
Other revenue	2,500	—
Net revenue	<u>23,925</u>	<u>11,587</u>
Operating expenses		
Cost of goods sold - product revenue	8,203	3,908
Research and development	36,722	20,028
Research and development - licenses acquired	—	126
Selling, general and administrative	26,270	17,542
Total operating expenses	<u>71,195</u>	<u>41,604</u>
Loss from operations	(47,270)	(30,017)
Other income (expense)		
Interest income	142	227
Interest expense and financing fee	(2,350)	(2,189)
Change in fair value of investments	—	5,913
Total other income (expense)	<u>(2,208)</u>	<u>3,951</u>
Net loss	<u>(49,478)</u>	<u>(26,066)</u>
Net loss attributable to non-controlling interests	33,718	17,244
Net loss attributable to common stockholders	\$ <u>(15,760)</u>	\$ <u>(8,822)</u>
Net loss per common share - basic and diluted	\$ (0.57)	\$ (0.32)
Net loss per common share attributable to non - controlling interests - basic and diluted	\$ (0.39)	\$ (0.21)
Net loss per common share attributable to common stockholders - basic and diluted	\$ (0.18)	\$ (0.11)
Weighted average common shares outstanding - basic and diluted	86,255,142	80,851,671