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): **August 11, 2022**

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 August 11, 2022, Fortress Biotech, Inc. issued a press release to announce financial results and recent corporate highlights for the quarter ended June 30, 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 August 11, 2022.
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: August 11, 2022

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

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

Net revenue for the first half of 2022 increased 45.5% period-over-period to $42.8 million

Positive results from registration-enabling study of cosibelimab in metastatic cutaneous squamous cell carcinoma presented at ASCO in June 2022; BLA submission expected YE 2022

Miami, FL – August 11, 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 second quarter ended June 30, 2022.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "Fortress ended the first half of 2022 with $42.8 million in net revenue, which is a 45.5% increase over the same period last year. We currently have nine marketed prescription products and a growing portfolio of 20 clinical programs in over 30 ongoing clinical trials. We anticipate multiple important late-stage regulatory and clinical inflection points including the submission of a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for cosibelimab for the treatment of metastatic cutaneous squamous cell carcinoma ("cSCC") and the continued rolling submission of Cyprium Therapeutics's CUTX-101 New Drug Application ("NDA"). CUTX-101 is eligible for a priority review voucher upon FDA approval."

Dr. Rosenwald continued, "We believe that our business is well-positioned for growth in the coming months. Our business development team is targeting potentially exciting clinical stage medicines with proof-of-concept data in areas of unmet need. We 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."

Recent Corporate Highlights[1]:

Marketed Dermatology Products and Product Candidates

- Journey Medical Corporation ("Journey Medical"), a Fortress partner company, currently has nine prescription dermatology products.
- Journey Medical generated net revenues of $18.3 million in the second quarter of 2022, compared to second quarter 2021 net revenues of $15.3 million, representing growth of 20%.
- 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 half of 2023 with an NDA filing expected in the second half of 2023.
- In May 2022, Journey Medical announced that it entered into a settlement agreement with Padagis US LLC ("Padagis") pertaining to the patents protecting QBREXZA®, the first and only prescription cloth towelette for the treatment of primary axillary hyperhidrosis, AMZEEQ®, the first and only topical minocycline product for the

[1] 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.

treatment of acne, and ZILXI®, the first and only topical minocycline product for the treatment of rosacea. Under terms of the paragraph IV settlement agreement, Padagis will not be allowed to launch generic versions of QBREXZA, AMZEEQ and ZILXI until August 15, 2030, July 1, 2031, and April 1, 2027, respectively.

- Journey Medical intends to launch an additional prescription product in the second half of 2022.

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

- On October 5, 2021, 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).
- 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)

- In May 2022, we announced that Checkpoint Therapeutics, Inc. ("Checkpoint") received Pediatric Investigation Plan ("PIP") product-specific waivers from the European Medicines Agency ("EMA") and the U.K. Medicines & Healthcare products Regulatory Agency ("MHRA") for cosibelimab in cSCC. The waivers remove the requirement to conduct pediatric clinical studies to support cosibelimab marketing authorization applications in Europe.
- In June 2022, we announced that the top-line results of our pivotal trial of cosibelimab in metastatic cSCC were presented at the 2022 American Society of Clinical Oncology Annual Meeting. Data highlights presented include confirmed objective response rate ("ORR") by independent central review in the modified intent-to-treat population of 48.7% (95% CI, 37.0-60.4) and 13.2% of patients achieved a complete response in target lesions. Cosibelimab was generally well tolerated with no unexpected safety signals. Checkpoint intends to submit a BLA to the FDA by the end of this year based on data from this pivotal cohort.
- Also in June 2022, we announced positive interim results from our pivotal trial of cosibelimab in locally advanced cSCC. As of the March 2022 data cutoff, the confirmed ORR by independent central review in 31 patients was 54.8% (95% CI: 36.0, 72.7), substantially exceeding a clinically meaningful lower bound of the 95% two-sided confidence interval. Based on these positive results, Checkpoint intends to continue discussions with the FDA on the potential addition of locally advanced cSCC as a second indication in the planned BLA targeted for submission at year-end.
- Cosibelimab was sourced by Fortress and is currently in development at our partner company, Checkpoint.

CUTX-101 (Copper Histidinate for Menkes disease)

- In December 2021, we initiated the rolling submission of an NDA to the FDA for CUTX-101. The rolling submission of the NDA for CUTX-101 is ongoing.
- Cyprium is currently in a dispute with its contract manufacturing organization ("the CMO"), regarding the CMO's attempt to terminate a Master Services Agreement ("MSA") between Cyprium and the CMO. Additional details regarding the status of this dispute will be contained within the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2022.
- CUTX-101 is currently in development at Cyprium Therapeutics, Inc.

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 ("B-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 ORR of 96% and a complete response ("CR") rate of 72% were observed in all patients across all dose levels.

- Also in April 2022, MB-106 data focused on CLL were presented at the 4th International Workshop on CAR-T and Immunotherapies.
- In June 2022, we announced that MB-106 data were presented in an oral session at the European Hematology Association 2022 Hybrid Congress. Dr. Mazyar Shadman of Fred Hutch presented updated interim data from the ongoing Phase 1/2 clinical trial for B-NHL and CLL. Data presented include a 94% ORR and 78% CR rate in patients with FL. Overall, for the 26 patients treated on the trial, there was a 96% ORR and 73% CR, including complete responses in both DLBCL patients, both WM patients, and both patients previously treated with CD19-targeted CAR-T therapy (1 DLBCL patient and 1 FL patient).
- Also in June 2022, we announced that the FDA granted Orphan Drug Designation to MB-106 for the treatment of WM, a rare type of B-NHL.
- A Mustang Bio-sponsored multicenter Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106 for relapsed or refractory B-NHL and CLL is enrolling patients, and dosing of the first patient is expected within the next 60 days.
- 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 presented in an oral presentation during the Clinical Trials Spotlight Symposium at the American Society of Gene & Cell Therapy 25th Annual Meeting. The presentation included 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. All 23 treated patients were alive at 2.6-year median follow-up without evidence of malignant transformation.
- In 2023, 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 FDA, Mustang Bio expects to enroll the first patient in a pivotal multicenter Phase 2 clinical trial in 2023.
- MB-107 and MB-207 were sourced by Fortress and are currently in development at Mustang Bio.

Triplex (Cytomegalovirus ("CMV") Vaccine)

- Earlier today we announced that Triplex received a grant from the National Institute of Allergy and Infectious Diseases of the National Institutes of Health ("NIAID/NIH") that could provide over $20 million in non-dilutive funding. This competitive award will fund a multi-center, placebo-controlled, randomized Phase 2 study of Triplex for control of CMV in patients undergoing liver transplantation.
- Triplex was sourced by Fortress and is currently in development at our subsidiary company, Helocyte.

Dotinurad (Urate Transporter (URAT1) Inhibitor)

- In June 2022, we initiated a Phase 1 clinical trial to evaluate Dotinurad in healthy volunteers in the United States. Dotinurad is in development for the treatment of gout. We anticipate topline data from the Phase 1 trial in the

second half of 2022. 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.

- Dotinurad was sourced by Fortress and is currently in development at our subsidiary company, UR-1 Therapeutics.

MB-110 (Lentiviral Gene Therapy for RAG1 Severe Combined Immunodeficiency (RAG1-SCID))

- In July 2022, we announced that the first patient successfully received LV-RAG1 *ex vivo* lentiviral gene therapy to treat recombinase-activating gene-1 ("RAG1") severe combined immunodeficiency ("RAG1-SCID"), in an ongoing Phase 1/2 multicenter clinical trial taking place in Europe. LV-RAG1 is exclusively licensed by Mustang Bio for the development of MB-110, a first-in-class *ex vivo* lentiviral gene therapy for the treatment of RAG1-SCID.
- MB-110 was sourced by Fortress and is currently in development at Mustang Bio.

MB-109 (MB-101 IL13Rα2-targeted CAR T Cell Therapy + MB-108 C134 Oncolytic Virus)

- In April 2022, we announced interim data from two ongoing investigator-sponsored Phase 1 clinical trials evaluating two clinical candidates, MB-101 (IL13Rα2-targeted CAR T cell therapy licensed from City of Hope) and MB-108 (herpes simplex virus type 1 oncolytic virus licensed from Nationwide Children's Hospital) for the treatment of recurrent glioblastoma ("rGBM"). The data were 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. Mustang expects to file an IND in 2023 to initiate an MB-109 Phase 1 clinical trial.
- MB-101 and MB-108 were sourced by Fortress and they are currently in development at Mustang Bio.

General Corporate

- In July 2022, we announced that David Jin, who has served as Head of Corporate Development since May 2020, was also appointed as Chief Financial Officer effective August 16, 2022.

Financial Results:

To assist our stockholders in understanding our company, we have prepared non-GAAP financial results for the three months ended June 30, 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 June 30, 2022, Fortress' consolidated cash, cash equivalents and restricted cash totaled $251.0 million[2], compared to $289.7 million as of March 31, 2022 and $308.0 million as of December 31, 2021, a decrease of $38.7 million during the prior quarter and a decrease of $57.0 million year-to-date.
- On a GAAP basis, Fortress' net revenue totaled $18.9 million for the second quarter of 2022, which included $18.2 million in net revenue generated from our marketed dermatology products. This compares to net revenue totaling $17.8 million for the second quarter of 2021, which included $15.3 million in net revenue generated from our marketed dermatology products.
- On a GAAP basis, consolidated research and development expenses including license acquisitions were $33.1 million for the second quarter of 2022, compared to $33.8 million for the second quarter of 2021. On a non-GAAP basis, Fortress research and development expenses were $3.3 million for the second quarter of 2022, compared to $0.7 million for second quarter of 2021.

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[2] At June 30, 2022, we had cash and cash equivalents of $248.8 million, of which $71.5 million relates to Fortress and the private partner companies, primarily funded by Fortress, $30.9 million relates to Checkpoint, $107.4 million relates to Mustang Bio, $38.1 million relates to Journey Medical, and $0.9 million relates to Avenue. Restricted cash related to our leases was $2.2 million, of which $1.2 million relates to Fortress and $1.0 million relates to Mustang Bio.

- On a GAAP basis, consolidated selling, general and administrative expenses were $29.0 million for the second quarter of 2022, compared to $19.4 million for the second quarter of 2021. On a non-GAAP basis, Fortress selling, general and administrative expenses were $8.5 million, for the second quarter of 2022, compared to $7.1 million for the second quarter of 2021.
- On a GAAP basis, consolidated net loss attributable to common stockholders was $21.4 million, or $0.24 per share, for the second quarter of 2022, compared to consolidated net loss attributable to common stockholders of $3.5 million, or $0.04 per share for the second quarter of 2021.
- Fortress' non-GAAP loss attributable to common stockholders was $8.9 million, or $0.10 per share, for the second quarter of 2022, compared to Fortress' non-GAAP loss attributable to common stockholders of $6.4 million, or $0.08 per share, for the second 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 for the second quarter of 2022 to be filed with the Securities and Exchange Commission ("SEC"), 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:

($ in thousands except for share and per share amounts)	For the three months ended June 30, 2022	For the three months ended June 30, 2021[1]	For the six months ended June 30, 2022	For the six months ended June 30, 2021[1]
Net loss attributable to common stockholders	$ (21,356)	$ (3,535)	$ (37,116)	$ (12,357)
Net loss attributable to common stockholders – Avenue [2]	$ (354)	$ (215)	$ (889)	$ (440)
Net loss attributable to common stockholders – Checkpoint [3]	$ (2,596)	$ (1,711)	$ (5,520)	$ (2,869)
Net loss attributable to common stockholders - Journey Medical [4]	$ (4,747)	$ (14,071)	$ (5,564)	$ (13,741)
Net loss attributable to common stockholders - Mustang Bio [5]	$ (1,374)	$ (2,496)	$ (3,916)	$ (5,414)
Non-GAAP (loss) income attributable to common stockholders	$ (12,285)	$ 14,958	$ (21,227)	$ 10,107
Stockbased compensation	$ 2,884	$ 2,910	$ 5,665	$ 4,777
Non-cash interest	$ 4	$ 14	$ 8	$ 23
Amortization of debt discount	$ 404	$ 594	$ 761	$ 903
Depreciation	$ 98	$ 137	$ 198	$ 278
Increase in fair value of investment in Caelum [6]	$ —	$ (25,005)	$ —	$ (30,918)
Fortress non-GAAP loss attributable to common stockholders	$ (8,895)	$ (6,392)	$ (14,595)	$ (14,830)
Per common share - basic and diluted:				
Net loss attributable to common stockholders (GAAP)	$ (0.24)	$ (0.04)	$ (0.42)	$ (0.15)
Non-GAAP net loss attributable to common stockholders	$ (0.14)	$ 0.18	$ (0.24)	$ 0.12
Fortress non-GAAP loss attributable to common stockholders	$ (0.1)	$ (0.08)	$ (0.17)	$ (0.18)
Weighted average common shares outstanding - basic and diluted	$ 88,743,457	$ 80,962,994	$ 87,593,952	$ 80,907,671

1. Results for the three and six months ended June 30, 2021 have been adjusted to present Journey Medical separately as a public entity.

2. Avenue net loss for the three months ended June 30, 2022 and 2021 of $0.6 million and $0.9 million, respectively, net of non-controlling interest of $0.3 million and $0.8 million, respectively. Avenue net loss for the six months ended June 30, 2022 and 2021 of $3.5 million and $1.9 million, respectively, net of non-controlling interest of $2.6 million and $1.5 million, respectively.

3. Checkpoint net loss of $14.1 million net of non-controlling interest of $11.4 million, Fortress management services agreement ("MSA") fee of $0.1 million for the three months ended June 30, 2022; and net loss of $9.1.0 million net of non-controlling interest of $7.1 million, Fortress MSA fee of $0.1 million, and Fortress financing fee of $0.3 million for the three months ended June 30, 2021; net loss of $31.0 million net of non-controlling interest of $25.0 million, Fortress MSA fee of $0.3 million, and Fortress financing fee of $0.2 million for the six months ended June 30, 2022; and net loss of $15.6 million net of non-controlling interest of $11.6 million, Fortress MSA fee of $0.3 million, and Fortress financing fee of $0.9 million for the three months ended June 30, 2021.

4. Journey Medical net loss for the three months ended June 30, 2022 of $7.5 million net of non-controlling interest of $2.8 million and tax benefit recognized on a stand-alone basis of $0.1 million; and net loss for the three months ended June 30, 2021 of $11.9 million, net non-controlling interest of approximately $1.2 million and tax benefit recognized on a stand-alone basis of $3.4 million; and net loss of $8.9 million net of non-controlling interest of $3.3 million and tax expense recognized on a stand-alone basis of $40,000 for the 6 months ended June 30, 2022, and net loss of $11.6 million net non-controlling interest of $1.2 million and tax benefit recognized on a stand-alone basis of $3.3 million for the six months ended June 30, 2021.

5. Mustang Bio net loss of $19.1 million net of non-controlling interest of $17.4 million, Fortress MSA fee of $0.3 million and Fortress financing fee of $0.1 million for the three months ended June 30, 2022; and net loss of $14.4 million net of non-controlling interest of $11.3 million, Fortress MSA fee of $0.1 million and Fortress financing fee of $0.4 million for the three months ended June 30, 2021; and net loss of $38.9 million net of non-controlling interest of $33.6 million, Fortress MSA fee of $0.5 million and Fortress financing fee of $0.9 million for the six months ended June 30, 2022; and net loss of $29.3 million net of non-controlling interest of $22.0 million, Fortress financing fee of $0.3 million and Fortress financing fee of $1.6 million for the six month period ended June 30, 2021.

6. Increase in fair value of investment in Caelum Biosciences for the quarter and six months ended June 30, 2021.

($ in thousands)	For the quarter ended June 30, 2022	For the quarter ended June 30, 2021[1]	For the six months ended June 30, 2022	For the six months ended June 30, 2021[1]
Research and development[2]	**$ 33,131**	**$ 33,834**	**$ 69,853**	**$ 53,988**
Less:				
Research and development - Avenue	151	328	1,959	586
Research and development - Checkpoint	12,053	7,198	26,723	11,411
Research and development - Journey Medical	2,609	13,772	3,875	13,772
Research and development - Mustang Bio[3]	15,039	11,840	31,203	23,395
Non-GAAP research and development costs	**$ 3,279**	**$ 697**	**$ 6,093**	**$ 4,824**
Selling, general and administrative	**$ 29,048**	**$ 19,382**	**$ 55,318**	**$ 36,924**
Less:				
General and administrative - Avenue	454	623	1,509	1,336
General and administrative – Checkpoint[4]	1,987	1,736	3,909	3,350
Selling, general and administrative - Journey Medical	15,191	7,795	29,906	14,021
General and administrative - Mustang Bio[5]	2,876	2,086	5,278	4,296
Non-GAAP selling, general and administrative costs	**$ 8,540**	**$ 7,142**	**$ 14,716**	**$ 13,891**

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

1. Results for the three and six months ended June 30, 2021 have been adjusted to present Journey Medical separately as a public entity.

2. Includes Research and development expense and Research and development - licenses acquired expense for the periods presented.

3. Excludes $0.1 million of Fortress MSA expense for the three months ended June 30, 2022 and 2021; $0.3 million of Fortress MSA expense for the six months ended June 30, 2022, and $0.1 million of Fortress MSA for the six months ended June 30, 2021.

4. Excludes $0.1 million of Fortress MSA expense for the three months ended June 30, 2022; and $0.1 million of Fortress MSA expense and $0.3 million Fortress financing fee for the three months ended June 30, 2021; and excludes $0.3 million Fortress MSA expense and $0.2 million Fortress financing fee for the six months ended June 30, 2022, and $0.3 million Fortress MSA expense and $0.9 million Fortress financing fee for the six months ended June 30, 2021.

5. Excludes $0.1 million of Fortress MSA expense and $0.1 million Fortress financing fee for the three months ended June 30, 2022; and $0.1 million of Fortress MSA expense and $0.4 million Fortress financing fee for the three months ended June 30, 2021; and excludes $0.3 million of Fortress MSA expense and $0.9 million Fortress financing fee for the six months ended June 30, 2022; and $0.1 million of Fortress MSA expense and $1.6 million Fortress financing fee for the six months ended June 30, 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 Sentynl 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 treat 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)

	June 30, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 248,771	$ 305,744
Accounts receivable, net	28,671	23,112
Inventory	16,053	9,862
Other receivables - related party	376	678
Prepaid expenses and other current assets	5,120	7,066
Total current assets	298,991	346,462
Property, plant and equipment, net	14,021	15,066
Operating lease right-of-use asset, net	18,116	19,005
Restricted cash	2,220	2,220
Intangible asset, net	29,440	12,552
Other assets	1,167	1,198
Total assets	**$ 363,955**	**$ 396,503**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 93,540	$ 90,660
Deferred revenue	1,457	2,611
Income taxes payable	345	345
Operating lease liabilities, short-term	2,092	2,104
Partner company line of credit	—	812
Partner company installment payments - licenses, short-term, net	7,487	4,510
Total current liabilities	104,921	101,042
Notes payable, long-term, net	85,611	42,937
Operating lease liabilities, long-term	19,973	20,987
Partner company installment payments - licenses, long-term, net	3,808	3,627
Other long-term liabilities	1,940	2,033
Total liabilities	**216,253**	**170,626**
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 June30, 2022 and December 31, 2021, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 107,717,647 shares issued and outstanding as of June 30, 2022; 170,000,000 shares authorized, 101,435,505 shares issued and outstanding as of December 31, 2021, respectively	108	101
Additional paid-in-capital	661,691	656,033
Accumulated deficit	(584,579)	(547,463)
Total stockholders' equity attributed to the Company	77,223	108,674
Non-controlling interests	70,479	117,203
Total stockholders' equity	147,702	225,877
Total liabilities and stockholders' equity	**$ 363,955**	**$ 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue				
Product revenue, net	$ 18,235	$ 15,288	$ 39,031	$ 26,007
Collaboration revenue	577	2,400	1,154	3,200
Revenue - related party	18	155	70	223
Other revenue	56	—	2,556	—
Net revenue	18,886	17,843	42,811	29,430
Operating expenses				
Cost of goods sold - product revenue	7,633	7,484	15,836	11,392
Research and development	33,130	22,831	69,852	42,859
Research and development - licenses acquired	1	11,003	1	11,129
Selling, general and administrative	29,048	19,382	55,318	36,924
Total operating expenses	69,812	60,700	141,007	102,304
Loss from operations	(50,926)	(42,857)	(98,196)	(72,874)
Other income (expense)				
Interest income	150	146	292	373
Interest expense and financing fee	(3,154)	(2,760)	(5,504)	(4,949)
Change in fair value of investments	—	25,005	—	30,918
Change in fair value of derivative liability	—	(3,925)	—	(3,925)
Total other income (expense)	(3,004)	18,466	(5,212)	22,417
Net loss	**(53,930)**	**(24,391)**	**(103,408)**	**(50,457)**
Net loss attributable to non-controlling interests	32,574	20,856	66,292	38,100
Net loss attributable to common stockholders	**$ (21,356)**	**$ (3,535)**	**$ (37,116)**	**$ (12,357)**
Net loss per common share - basic and diluted	$ (0.61)	$ (0.30)	$ (1.18)	$ (0.62)
Net loss per common share attributable to non - controlling interests - basic and diluted	$ (0.37)	$ (0.26)	$ (0.76)	$ (0.47)
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.24)	$ (0.04)	$ (0.42)	$ (0.15)
Weighted average common shares outstanding - basic and diluted	88,743,457	80,962,994	87,593,952	80,907,671