
**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 16, 2021**

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	FBIOF	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 16, 2021, Fortress Biotech, Inc. issued a press release to announce financial results and recent corporate highlights for the quarter ended June 30, 2021. A copy of such press release is being furnished as Exhibit 99.1 to this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit Number	Description
<u>99.1</u> 104	<u>Press Release issued by Fortress Biotech, Inc., dated August 16, 2021.</u> 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: August 16, 2021

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



Fortress Biotech Reports Record Second Quarter 2021 Financial Results and Recent Corporate Highlights

Net revenue for second quarter of 2021 increased 89% year-over-year to \$17.8 million, a quarterly record

Rolling NDA submission for CUTX-101 for the treatment of Menkes disease expected to begin in the second half of 2021

On track to report top-line results from registration-enabling study of cosibelimab in metastatic cutaneous squamous cell carcinoma by year-end 2021

New York, NY – August 16, 2021 – Fortress Biotech, Inc. (NASDAQ: FBIO) (“Fortress”), an innovative biopharmaceutical company focused on acquiring, developing and commercializing or monetizing promising biopharmaceutical products and product candidates cost-effectively, today announced financial results and recent corporate highlights for the second quarter ended June 30, 2021.

Lindsay A. Rosenwald, M.D., Fortress’ Chairman, President and Chief Executive Officer, said, “We generated significant sales momentum in the second quarter, recording quarterly record net revenues of \$17.8 million, an 89% increase year-over-year. We also successfully acquired and recently launched QBREXZA® to further expand our portfolio of marketed products, as well as in-licensed Dotinurad, DFD-29, and a novel CAR T technology, which enhance our robust pipeline of drug candidates. In addition, we presented compelling clinical data for CAEL-101 for the treatment of AL amyloidosis and MB-106 for relapsed or refractory B-cell non-Hodgkin lymphomas (“B-NHL”) and chronic lymphocytic leukemia (“CLL”) at the European Hematology Association 2021 Virtual Congress (“EHA2021”). Looking ahead, we anticipate several additional regulatory and clinical catalysts throughout the remainder of 2021, including the availability of pivotal data from cosibelimab for the treatment of metastatic cutaneous squamous cell carcinoma. We also expect to begin the rolling New Drug Application (“NDA”) submission for CUTX-101 for the treatment of Menkes disease in the second half of 2021.”

Dr. Rosenwald continued, “We have an expanding portfolio of seven marketed dermatology products and more than 25 product candidates across our partner companies, including 18 clinical programs and 24 clinical trials, of which four are pivotal clinical trials, and up to four more could potentially be pivotal soon. Our diversified business model is supported by a world-class business development team. Fortress and our partner companies are well-positioned to achieve an array of milestones over the next year and into the future with the objective of providing new treatment options to patients in need, while creating significant long-term value for our shareholders.”

Recent Corporate Highlights¹:

Marketed Dermatology Products and Product Candidates

- Our seven dermatology products are marketed by our partner company, Journey Medical Corporation (“Journey”).

¹ Includes product candidates in development at Fortress, majority-owned and controlled partners and partners 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 and partners, as dictated by context.

- Our products generated net revenues of \$15.3 million for the second quarter of 2021, compared to second quarter 2020 net revenues of \$9.4 million.
- In July 2021, Journey completed its final closing under the Cumulative Convertible Class A Preferred Stock Offering (the “Preferred Offering”). In connection with the Preferred Offering, Journey issued an aggregate of 750,680 preferred shares at a price of \$25.00 per share, and after deducting commissions, fees and expenses, for a total of approximately \$16.8 million in net proceeds across the various closings.
- In June 2021, Journey entered into a definitive agreement with Dr. Reddy’s Laboratories Ltd. to develop and commercialize DFD-29 (modified release minocycline capsules) for the treatment of rosacea. Journey and Dr. Reddy’s Laboratories Ltd. intend to conduct two Phase 3 clinical trials to assess the efficacy, safety and tolerability of DFD-29 for regulatory approval.
- In May 2021, Journey acquired and recently launched its seventh prescription dermatology product, QBREXZA®.
- In April 2021, Journey entered into an agreement with East West Bank (“EWB”) in which EWB provided a \$7.5 million working capital line of credit.
- Journey intends to launch one additional prescription product in the second half of this year.

CUTX-101 (Copper Histidinate for Menkes disease)

- We intend to begin the rolling submission of the NDA for CUTX-101 to the U.S. Food and Drug Administration (“FDA”) in the second half of 2021.
- CUTX-101 was sourced by Fortress and is currently in development at our partner company, Cyprium Therapeutics, Inc.

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

- Caelum Biosciences, Inc. (“Caelum”) has two ongoing Phase 3 studies of CAEL-101 for AL amyloidosis.
- Caelum formed a collaboration with Alexion Pharmaceuticals, Inc. (“Alexion”) in 2019, which included an option to acquire Caelum. AstraZeneca completed its acquisition of Alexion on July 21, 2021. The period during which AstraZeneca/Alexion must now decide whether or not to exercise their option to purchase Caelum expires in January 2022. Fortress would receive approximately 43 percent of the proceeds from a potential AstraZeneca transaction.
- In June 2021, we announced that CAEL-101 clinical data were presented at EHA2021. The data, presented in two e-posters, strengthen the safety and tolerability profile of CAEL-101 to further support the dose selection for the ongoing Phase 3 study, and suggest possible cardiac and renal response.
- Also in June 2021, the FDA granted Fast Track designation to CAEL-101 for the treatment of light chain AL amyloidosis.
- CAEL-101 was sourced by Fortress and is currently in development at Caelum Biosciences, Inc., a company founded by Fortress in 2017 and in which Fortress maintains a minority position.

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

- The registration-enabling study in metastatic cutaneous squamous cell carcinoma is fully enrolled and we are on track to report top-line results by year-end 2021. Upon a successful outcome, Checkpoint Therapeutics, Inc. (“Checkpoint”) intends to submit a Biologics License Application (“BLA”) for cosibelimab in 2022, followed shortly thereafter by a Marketing Authorization Application submission in Europe. 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 \$25 billion and growing PD-(L)1 class.
 - A Phase 3 registration-enabling trial is planned to begin in first-line metastatic non-small cell lung cancer (“NSCLC”) in the second half of 2021.
 - Cosibelimab was sourced by Fortress and is currently in development at our partner company, Checkpoint.
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Olafertinib (formerly CK-101, a third-generation epidermal growth factor receptor (“EGFR”) inhibitor)

- During the second quarter, we had productive interactions with the FDA regarding our development program for olafertinib (formerly CK-101), our third-generation EGFR inhibitor being evaluated by our partner in an ongoing double-blind, randomized Phase 3 study in China. We intend to utilize the Phase 3 study, if successful, to support an NDA submission for olafertinib as a potential first-line treatment for patients with NSCLC whose tumors have certain types of EGFR mutations.
- Olafertinib was sourced by Fortress and is currently in development at our partner company, Checkpoint.

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

- In May 2021, we announced that the FDA approved Mustang Bio Inc.’s (“Mustang Bio”) Investigational New Drug (“IND”) application to initiate a multicenter Phase 1/2 clinical trial investigating the safety and efficacy of MB-106, a CD20-targeted CAR T for relapsed or refractory B-NHL and CLL.
- In June 2021, we announced that MB-106 CD20-targeted CAR T data were presented at EHA2021. Dr. Mazyar Shadman of Fred Hutchinson Cancer Research Center presented updated interim data from the ongoing Phase 1/2 clinical trial for B-NHL and CLL, which showed a favorable safety profile and compelling clinical activity, with a 93% overall response rate and 67% complete response rate in patients treated with the modified cell manufacturing process.
- Also in June 2021, we hosted a key opinion leader webinar featuring a presentation from Dr. Shadman, who discussed interim results from the ongoing Phase 1/2 clinical trial investigating the safety and efficacy of MB-106 CD20-targeted CAR T for B-NHL and CLL. A replay of the webinar can be found [here](#).
- MB-106 was sourced by Fortress and is currently in development at our partner company, Mustang Bio.

MB-107 and MB-207 (Lentiviral Gene Therapies for X-linked Severe Combined Immunodeficiency (“XSCID”))

- Earlier this month, we announced that the European Medicines Agency (“EMA”) granted Priority Medicines (“PRIME”) designation to MB-107, a lentiviral gene therapy for the treatment of XSCID in newly diagnosed infants, also known as bubble boy disease.
- Later this quarter, we expect to enroll the first patient in the MB-107 pivotal multicenter Phase 2 clinical trial under Mustang Bio’s IND and to file an IND for our pivotal multicenter Phase 2 clinical trial of MB-207.
- MB-107 and MB-207 were sourced by Fortress and are currently in development at our partner company, Mustang Bio.

MB-101 (IL13Ra2-targeted CAR T Cell Therapy)

- In May 2021, we announced that the first patient was dosed at City of Hope in a clinical trial to establish the safety and feasibility of administering MB-101 (autologous IL13Ra2-targeted CAR T cells) to patients with leptomeningeal brain tumors (e.g., glioblastoma, ependymoma or medulloblastoma).
- MB-101 was sourced by Fortress and is currently in development at our partner company, Mustang Bio.

Novel CAR T Technology

- In August 2021, we announced an exclusive license agreement with Mayo Clinic for a novel technology that may be able to transform the administration of CAR T therapies and has the potential to be used as an off-the-shelf therapy.
- The novel CAR T technology was sourced by Fortress and is currently in development at our partner company, 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, Europe, United Kingdom and Canada. Dotinurad is a potential best-in-class urate transporter (URAT1) inhibitor for gout and possibly other hyperuricemic indications, including chronic kidney disease 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.
 - Dotinurad was sourced by Fortress and is currently in development at our partner company, FBIO Acquisition Corp. VIII.
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Financial Results:

To assist our stockholders in understanding our company, we have prepared non-GAAP financial results for the three months ended June 30, 2021 and 2020. These results exclude the operations of our three public partner companies: Avenue, Checkpoint and Mustang Bio. The goal in providing these non-GAAP financial metrics is to highlight the financial results of Fortress’ core operations, which are comprised of our commercial-stage business, our privately held development-stage entities, as well as our business development and finance functions.

- As of June 30, 2021, Fortress’ consolidated cash, cash equivalents and restricted cash totaled \$276.6 million, compared to \$235.0 million as of December 31, 2020, an increase of \$41.6 million year-to-date.
- On a GAAP basis, Fortress’ net revenue totaled \$17.8 million for the second quarter of 2021, which included \$15.3 million in net revenue generated from our marketed dermatology products. This compares to net revenue totaling \$9.5 million for the second quarter of 2020, which included \$9.4 million in net revenue generated from our marketed dermatology products.
- On a GAAP basis, consolidated research and development expenses, including license acquisitions of \$11.0 million, were \$33.8 million for the second quarter of 2021, compared to consolidated research and development expenses, including license acquisitions of \$1.6 million, totaling \$17.3 million for the second quarter of 2020. On a non-GAAP basis, research and development expenses including license acquisitions of \$10.0 million, were \$14.5 million for the second quarter of 2021, compared to research and development expenses, including license acquisitions of \$0.3 million, totaling \$4.8 million for second quarter of 2020.
- On a GAAP basis, consolidated selling, general and administrative expenses were \$19.4 million for the second quarter of 2021, compared to \$14.5 million for the second quarter of 2020. On a non-GAAP basis, consolidated selling, general and administrative expenses were \$14.9 million, of which \$7.6 million is attributed to Journey, for the second quarter of 2021, compared to \$10.4 million, of which \$4.7 million is attributed to Journey, for the second quarter of 2020.
- On a GAAP basis, consolidated net loss attributable to common stockholders was \$3.5 million, or \$0.04 per share, for the second quarter of 2021, compared to consolidated net loss attributable to common stockholders of \$13.3 million, or \$0.19 per share for the second quarter of 2020.
- Fortress’ non-GAAP loss attributable to common stockholders was \$14.1 million, which includes \$10 million related to Journey’s acquisition of DFD-29 and excludes the change in fair value of Fortress’ investment in Caelum, or \$0.17 per share, for the second quarter of 2021, compared to Fortress’ non-GAAP loss attributable to common stockholders of \$3.7 million, or \$0.05 per share, for the second quarter of 2020.

The tables below have more information.

Use of Non-GAAP Measures:

In addition to the GAAP financial measures as presented in our Form 10-Q that will be filed with the Securities and Exchange Commission ("SEC") on August 16, 2021, the Company has, in this press release, included certain non-GAAP measurements. The non-GAAP net income (loss) attributable to common stockholders is defined by the Company as GAAP net income (loss) attributable to common stockholders, less net losses attributable to common stockholders from our public partner companies Avenue, Checkpoint and Mustang Bio. 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 income (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, Qbrexza inventory step-up and depreciation expense.

Management believes use 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 results. However, non-GAAP income (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,		For the six months ended June 30,	
	2021	2020	2021	2020
Net loss attributable to common stockholders	\$ (3,535)	\$ (13,314)	\$ (12,357)	\$ (25,684)
Net loss attributable to common stockholders - Avenue ¹	(215)	(431)	(440)	(718)
Net loss attributable to common stockholders - Checkpoint ²	(1,711)	(1,045)	(2,869)	(1,798)
Net loss attributable to common stockholders - Mustang Bio ³	(2,496)	(3,732)	(5,414)	(7,332)
Non-GAAP net income (loss) attributable to common stockholders	\$ 887	\$ (8,106)	\$ (3,634)	\$ (15,836)
Stock based compensation	2,921	1,844	4,811	3,584
Non-cash interest	497	1,713	707	2,482
Amortization of licenses	741	355	1,325	710
Amortization of debt discount	595	390	903	878
Depreciation	137	151	278	305
Increase in fair value of investment ⁴	(25,005)	-	(30,918)	-
Change in fair value of derivative liabilities ⁵	3,925	-	344	-
Qbrexza inventory step-up ⁶	1,238	-	1,238	-
Fortress non-GAAP loss attributable to common stockholders	\$ (14,064)	\$ (3,653)	\$ (24,946)	\$ (7,877)
Per common share - basic and diluted:				
Net income (loss) attributable to common stockholders (GAAP)	\$ (0.04)	\$ (0.19)	\$ (0.15)	\$ (0.39)
Non-GAAP net income (loss) attributable to common stockholders	\$ 0.01	\$ (0.12)	\$ (0.04)	\$ (0.24)
Fortress non-GAAP loss attributable to common stockholders	\$ (0.17)	\$ (0.05)	\$ (0.31)	\$ (0.12)
Weighted average common shares outstanding - basic and diluted	80,962,994	68,550,494	80,907,671	66,023,367

- Avenue net loss from their external SEC report for the three months ended June 30, 2021 and 2020 of \$0.9 million and \$1.9 million, respectively, net of non-controlling interest of \$0.7 million and \$1.4 million, respectively. Avenue net loss from their external SEC report for the six months ended June 30, 2021 and 2020 of \$2.0 million and \$3.1 million, respectively, net of non-controlling interest of \$1.5 million and \$2.4 million, respectively.
- Checkpoint net loss from their external SEC report of \$9.1 million net of non-controlling interest of \$7.1 million, MSA fee to Fortress of \$0.1 million and financing fee to Fortress of \$0.3 million for the quarter ended June 30, 2021; and net loss of \$4.6 million net of non-controlling interest of \$3.4 million, less MSA fee to Fortress of \$0.1 million and financing fee to Fortress of \$0.1 million for the quarter ended June 30, 2020. Checkpoint net loss from their external SEC report of \$15.6 million net of non-controlling interest of \$11.6 million, MSA fee to Fortress of \$0.1 million and financing fee to Fortress of \$0.9 million for the six months ended June 30, 2021; and net loss of \$7.9 million net of non-controlling interest of \$5.8 million, less MSA fee to Fortress of \$0.3 million and financing fee to Fortress of \$0.1 million for the six months ended June 30, 2020.
- Mustang Bio net loss from their external SEC report of \$14.4 million net of non-controlling interest of \$11.3 million, MSA fee to Fortress of \$0.1 million and financing fee to Fortress of \$0.4 million for the quarter ended June 30, 2021; and net loss of \$14.6 million net of non-controlling interest of \$9.7 million, MSA fee to Fortress of \$0.1 million and financing fee to Fortress of \$1.0 million for the quarter ended June 30, 2020. Mustang Bio net loss from their external SEC report of \$29.3 million net of non-controlling interest of \$22.1 million, MSA fee to Fortress of \$0.3 million and financing fee to Fortress of \$1.6 million for the six months ended June 30, 2021; and net loss of \$26.5 million net of non-controlling interest of \$17.7 million, MSA fee to Fortress of \$0.3 million and financing fee to Fortress of \$1.1 million for the six months ended June 30, 2020.

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

5. Increase in fair value of derivative liabilities of Journey Medical Corporation for the quarter and six months ended June 30, 2021.

6. Step-up related to FV of Qbrexza inventory sold and recorded in COGS for the quarter and six months ended June 30, 2021.

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

(\$ in thousands)	For the quarter ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Research and development ¹	\$ 33,834	\$ 17,273	\$ 53,988	\$ 32,390
Less:				
Research and development Avenue	328	1,219	586	1,916
Research and development Checkpoint	7,198	3,029	11,411	5,664
Research and development Mustang Bio ²	11,840	9,771	23,395	19,023
Non-GAAP research and development costs	\$ 14,468	\$ 3,254	\$ 18,596	\$ 5,787
Selling, general and administrative	\$ 19,382	\$ 14,456	\$ 36,924	\$ 29,975
Less:				
Selling, general and administrative Avenue	623	684	1,366	1,261
Selling, general and administrative Checkpoint ³	1,736	1,496	3,350	3,049
Selling, general and administrative Mustang Bio ⁴	2,086	1,917	4,296	3,685
Non-GAAP selling, general and administrative costs	\$ 14,937	\$ 10,359	\$ 27,912	\$ 21,980

1. Includes Research and development expense and Research and development - licenses acquired expense for the quarter and six month ended June 30, 2021 and 2020, respectively.
2. Excludes \$0.1 million and \$0.1 million of Fortress MSA expense for the quarter ended June 30, 2021 and 2020, respectively and \$0.1 million and \$0.1 million for the six months ended June 30, 2021 and 2020, respectively.
3. Excludes \$0.1 million of Fortress MSA expense and \$0.3 million Fortress financing fee for the quarter ended June 30, 2021; and \$0.1 million of Fortress MSA expense and \$0.1 million Fortress financing fee for the quarter ended June 30, 2020. Excludes \$0.3 million of Fortress MSA expense and \$0.9 million Fortress financing fee for the six months ended June 30, 2021; and \$0.3 million of Fortress MSA expense and \$0.1 million Fortress financing fee for the six months ended June 30, 2020.
4. Excludes \$0.1 million of Fortress MSA expense and \$0.4 million Fortress financing fee for the quarter ended June 30, 2021; and \$0.1 million of Fortress MSA expense and \$1.0 million Fortress financing fee for the quarter ended June 30, 2020. Excludes \$0.1 million of Fortress MSA expense and \$1.6 million Fortress financing fee for the six months ended June 30, 2021; and \$0.1 million of Fortress MSA expense and \$1.1 million Fortress financing fee for the six months ended June 30, 2020.

About Fortress Biotech

Fortress Biotech, Inc. ("Fortress") is an innovative biopharmaceutical company that was ranked in Deloitte's 2019 and 2020 Technology Fast 500™, annual rankings of the fastest-growing North American companies in the technology, media, telecommunications, life sciences and energy tech sectors, based on percentages of fiscal year revenue growth over three-year periods. Fortress is focused on acquiring, developing and commercializing high-potential marketed and development-stage drugs and drug candidates. The company has seven marketed prescription pharmaceutical products and over 25 programs in development at Fortress, at its majority-owned and majority-controlled partners and at partners 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 Alexion Pharmaceuticals, Inc., AstraZeneca, 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 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; 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. 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 Contacts:

Jaclyn Jaffe and Bill Begien
Fortress Biotech, Inc.
(781) 652-4500
ir@fortressbiotech.com

Investor Relations Contact:

Daniel Ferry
LifeSci Advisors, LLC
(617) 430-7576
daniel@lifesciadvisors.com

Media Relations Contact:

Tony Plohoros
6 Degrees
(908) 591-2839
tplohoros@6degreespr.com

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(\$ in thousands except for share and per share amounts)

	June 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	\$ 274,992	\$ 233,351
Accounts receivable, net	26,193	23,928
Inventory	14,315	1,404
Other receivables - related party	842	744
Prepaid expenses and other current assets	4,003	6,723
Total current assets	<u>320,345</u>	<u>266,150</u>
Property and equipment, net	13,126	11,923
Operating lease right-of-use asset, net	19,731	20,487
Restricted cash	1,645	1,645
Long-term investment, at fair value	48,484	17,566
Intangible asset, net	13,701	14,629
Other assets	1,126	1,013
Total assets	<u>\$ 418,158</u>	<u>\$ 333,413</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 59,906	\$ 45,389
Deferred revenue	4,800	—
Operating lease liabilities, short-term	2,035	1,849
Partner company installment payments - licenses, short-term (net of imputed interest of \$639 and \$778 at June 30, 2021 and December 31, 2020, respectively)	3,861	4,522
Total current liabilities	<u>70,602</u>	<u>51,760</u>
Notes payable, long-term (net of debt discount of \$7,737 and \$8,323 at June 30, 2021 and December 31, 2020, respectively)	52,263	51,677
Operating lease liabilities, long-term	21,906	22,891
Partner company installment payments - licenses, long-term (net of imputed interest of \$565 and \$863 at June 30, 2021 and December 31, 2020, respectively)	6,435	8,137
Partner company convertible preferred shares (net of debt discount of \$1,824 at June 30, 2021)	12,508	—
Partner company derivative warrant liabilities	4,287	—
Other long-term liabilities	1,856	1,949
Total liabilities	<u>169,857</u>	<u>136,414</u>
Commitments and contingencies		
Stockholders' equity		
Cumulative redeemable perpetual preferred stock, \$.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively, liquidation value of \$25.00 per share	3	3
Common stock, \$.001 par value, 170,000,000 shares authorized, 97,495,244 shares issued and outstanding as of June 30, 2021; 150,000,000 shares authorized, 94,877,492 shares issued and outstanding as of December 31, 2020, respectively	97	95
Common stock issuable, 78,671 and 0 shares as of June 30, 2021 and December 31, 2020, respectively	263	—
Additional paid-in-capital	603,035	583,000
Accumulated deficit	(495,117)	(482,760)
Total stockholders' equity attributed to the Company	<u>108,281</u>	<u>100,338</u>
Non-controlling interests	140,020	96,661
Total stockholders' equity	<u>248,301</u>	<u>196,999</u>
Total liabilities and stockholders' equity	<u>\$ 418,158</u>	<u>\$ 333,413</u>

FORTRESS BIOTECH, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(\$ in thousands except for share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue				
Product revenue, net	\$ 15,288	\$ 9,415	\$ 26,007	\$ 21,361
Collaboration revenue	2,400	—	3,200	—

Revenue - related party	155	42	223	1,014
Net revenue	<u>17,843</u>	<u>9,457</u>	<u>29,430</u>	<u>22,375</u>
Operating expenses				
Cost of goods sold - product revenue	7,484	3,124	11,392	6,934
Research and development	22,831	15,703	42,859	30,570
Research and development - licenses acquired	11,003	1,570	11,129	1,820
Selling, general and administrative	19,382	14,456	36,924	29,975
Total operating expenses	<u>60,700</u>	<u>34,853</u>	<u>102,304</u>	<u>69,299</u>
Loss from operations	(42,857)	(25,396)	(72,874)	(46,924)
Other income (expense)				
Interest income	146	336	373	963
Interest expense and financing fee	(2,760)	(3,059)	(4,949)	(6,184)
Change in fair value of investments	25,005	—	30,918	—
Change in fair value of derivative liability	(3,925)	(344)	(3,925)	(386)
Total other income (expense)	<u>18,466</u>	<u>(3,067)</u>	<u>22,417</u>	<u>(5,607)</u>
Net loss	<u>(24,391)</u>	<u>(28,463)</u>	<u>(50,457)</u>	<u>(52,531)</u>
Less: net loss attributable to non-controlling interests	20,856	15,149	38,100	26,847
Net loss attributable to common stockholders	<u>\$ (3,535)</u>	<u>\$ (13,314)</u>	<u>\$ (12,357)</u>	<u>\$ (25,684)</u>
Net loss per common share - basic and diluted	\$ (0.30)	\$ (0.42)	\$ (0.62)	\$ (0.80)
Net loss per common share attributable to non - controlling interests - basic and diluted	\$ (0.26)	\$ (0.22)	\$ (0.47)	\$ (0.41)
Net loss per common share attributable to common stockholders - basic and diluted	\$ (0.04)	\$ (0.19)	\$ (0.15)	\$ (0.39)
Weighted average common shares outstanding - basic and diluted	80,962,994	68,550,494	80,907,671	66,023,367