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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **March 28, 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.)

**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	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.

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

On March 28, 2022, Fortress Biotech, Inc. issued a press release to announce financial results and recent corporate highlights for the fourth quarter and full year ended December 31, 2021. A copy of such press release is being furnished as Exhibit 99.1 to this report.

The information, including Exhibit 99.1, in this Form 8-K is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Form 8-K shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall otherwise be expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

The following exhibit is furnished herewith:

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press Release issued by Fortress Biotech, Inc., dated March 28, 2022.</a>
104	Cover Page Interactive Data File (formatted as 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.

Date: March 28, 2022

**Fortress Biotech, Inc.**  
(Registrant)

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



## Fortress Biotech Reports Record 2021 Financial Results and Recent Corporate Highlights

*Record 2021: Net revenue of \$68.8 million and proceeds from the successful monetization of our investment in Caelum Biosciences of \$56.9 million<sup>1</sup>*

*2021 net loss attributable to common stockholders on a GAAP basis was \$(64.7) million or \$(0.79) per share; 2021 non-GAAP income attributable to common stockholders of \$25.5 million or \$0.25 per share, as per the non-GAAP tables below*

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

*Cyprium Therapeutics, a Fortress subsidiary, and Sentynl Therapeutics, a wholly owned subsidiary of Zydus Lifesciences Ltd., signed a Development and Asset Purchase Agreement for CUTX-101 for the treatment of Menkes disease*

*Rolling NDA submission for CUTX-101 for the treatment of Menkes disease is expected to be completed in mid-2022*

*Journey Medical Corporation, a Fortress partner company, completed an initial public offering yielding net proceeds of \$30.6 million*

**Miami, FL – March 28, 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 full-year ended December 31, 2021.

Lindsay A. Rosenwald, M.D., Fortress’ Chairman, President and Chief Executive Officer, said, “Fortress and its partner companies had an exceptional year in 2021, generating a record-setting annual net revenue of \$68.8 million, representing more than 50% growth over 2020. We also began to realize the value of our monetization strategy when AstraZeneca acquired Caelum Biosciences (“Caelum”), a company founded by Fortress, during the fourth quarter of 2021, when we received a \$56.9 million payment for our investment in Caelum. Fortress has the potential to receive up to an additional approximately \$155 million in future milestone payments from the transaction, which includes proceeds from the release of escrow funds. Our subsidiary Cyprium Therapeutics (“Cyprium”) executed an agreement with Sentynl Therapeutics to commit development funding for and contingently acquire Cyprium’s proprietary rights to CUTX-101, its Copper Histidinate product candidate for the treatment of Menkes disease, upon FDA approval. Also of note, Journey Medical Corporation (“Journey Medical”) completed its \$30.6 million initial public offering (“IPO”), net of discounts and other offering costs, launched Accutane® (isotretinoin), acquired Qbrexza® (glycopyrronium) from Dermira, Inc. and entered into a collaboration agreement with Dr. Reddy’s Laboratories Ltd. to develop and commercialize DFD-29 (minocycline modified release capsules 40 mg) for the treatment of rosacea.”

<sup>1</sup> Figure is net of miscellaneous transaction expenses and a 10% holdback for an indemnification escrow.

Dr. Rosenwald continued, “Looking ahead in 2022, we anticipate continued progress and growth from our nine marketed prescription pharmaceutical products and over 30 product candidates in development. We have 30 ongoing clinical trials, including four product candidates in seven<sup>2</sup> ongoing pivotal clinical trials. We expect the rolling submission of the New Drug Application (“NDA”) for CUTX-101 to be complete in mid-2022. After announcing positive top-line results from the registration-enabling study of cosibelimab in metastatic cutaneous squamous cell carcinoma (“cSCC”) in January, our partner company Checkpoint Therapeutics, Inc. (“Checkpoint”) intends to submit a Biologics License Application (“BLA”) for cosibelimab in 2022, followed thereafter by a Marketing Authorization Application submission in Europe. Mustang Bio, Inc. (“Mustang Bio”), another one of our partner companies, plans to initiate a multicenter Phase 1/2 clinical trial investigating the safety and efficacy of MB-106, a CD20-targeted, autologous CAR T cell therapy for relapsed or refractory B-cell non-Hodgkin lymphomas (“B-NHL”) and chronic lymphocytic leukemia (“CLL”) in the first half of 2022. Mustang Bio also plans to enroll the first patient in a pivotal multicenter Phase 2 clinical trial to evaluate MB-107, a lentiviral gene therapy for the treatment of infants under the age of two with X-linked severe combined immunodeficiency (“XSCID”) in the second half of 2022. This ongoing advancement showcases the ability of Fortress’ business model to generate value for our shareholders and develop innovative therapies to help patients with unmet needs across multiple disease areas.”

### 2021 and Recent Corporate Highlights<sup>3</sup>:

#### Marketed Dermatology Products and Product Candidates

- Journey Medical currently has nine prescription dermatology products. In 2021 and early 2022, Journey Medical acquired and launched four prescription dermatology products including Accutane®, Qbrexza®, Amzeeq® and Zilxi®, and two product candidates, DFD-29 and FCD105.
- Our products generated net revenues of \$63.1 million for full-year 2021, compared to full-year 2020 net revenues of \$44.5 million, representing growth of 42%.
- 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 is anticipated in the first quarter of 2023 with an NDA filing expected in the second half of 2023.
- In February 2022, Journey Medical received notice from its exclusive licensing partner in Japan, Maruho Co., Ltd. (“Maruho”), that Japan’s Ministry of Health, Labor and Welfare (“MHLW”) approved Rapifort® Wipes 2.5% (glycopyrronium tosylate hydrate) for the treatment of primary axillary hyperhidrosis. This approval triggered a milestone payment of \$10 million to Journey Medical, of which \$7.5 million will be 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.
- In November 2021, Journey Medical completed its IPO of common stock of 3,520,000 shares at a public offering price of \$10.00 per share, for net proceeds of \$30.6 million, after deducting underwriting discounts and offering expenses. All of the shares of common stock were offered by Journey Medical.
- In July 2021, Journey Medical completed its final private placements under the 8% Cumulative Convertible Class A Preferred Stock Offering (the “Preferred Offering”), issuing an aggregate of 758,680 preferred shares at a price of \$25.00 per share, raising approximately \$19.0 million in gross proceeds and, after deducting commissions, fees and expenses, receiving approximately \$17.0 million in net proceeds. These shares converted into Journey Medical common stock upon the IPO.
- On April 1, 2021, Journey Medical entered into an agreement with East West Bank (“EWB”) in which EWB provided a \$7.5 million working capital line of credit. In January 2022, Journey Medical expanded the borrowing capacity of the EWB credit agreement to \$30.0 million, which includes an increase to the working capital line of credit to \$10.0 million and a \$20.0 million term loan.

- We intend to launch an additional prescription product this year in the first half of 2022.

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<sup>2</sup> Includes two trials at partner company Caelum Biosciences, which was sold to AstraZeneca in October 2021 and with respect to which Fortress remains eligible to receive up to approximately \$155 million in future milestone payments from the transaction.

<sup>3</sup> 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, as dictated by context.

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#### **CUTX-101 (Copper Histidinate for Menkes disease)**

- In February 2021, our subsidiary Cyprium signed a Development and Asset Purchase Agreement with Sentyln Therapeutics, a wholly owned subsidiary of Zydus Lifesciences Ltd., for CUTX-101 for the treatment of Menkes disease. Under the terms of the agreement, Cyprium received \$8 million upfront to fund the development of CUTX-101 and could receive up to \$12 million in regulatory milestone payments related to the NDA submission and approval process and is eligible to receive sales milestones plus royalties. Royalties start from mid-single digits, scaling up to 25% on sales exceeding \$100 million annually. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101. Cyprium is responsible for the development of CUTX-101 through approval of the NDA by the FDA, and Sentyln will be responsible for commercialization of CUTX-101, as well as progressing newborn screening activities.
- In October 2021, we announced positive results from an efficacy and safety analysis of data integrated from two completed pivotal studies in patients with Menkes disease treated with CUTX-101, copper histidinate (CuHis). These data were presented as a [virtual poster](#) at the 2021 American Academy of Pediatrics National Conference & Exhibition. Overall, a 79% reduction in risk of death was observed in patients treated within four weeks of birth compared with an untreated historical control cohort of patients and median overall survival (OS) was 177.1 and 16.1 months, respectively, with a hazard ratio (HR) of (95% CI) = 0.208 (0.094, 0.463)  $p < 0.0001$ . A 75% reduction in the risk of death was also observed in patients treated after four weeks of birth compared with untreated historical control subjects and median OS was 62.4 and 17.6 months, respectively; HR (95% CI) = 0.253 (0.119, 0.537);  $p < 0.0001$ .
- In December 2021, we initiated the rolling submission of an NDA to the U.S. Food and Drug Administration (“FDA”) for CUTX-101. We intend to complete the rolling submission of the NDA for CUTX-101 in mid-2022.
- In March 2022, 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 was sourced by Fortress and is currently in development at Cyprium.

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

- On October 5, 2021, AstraZeneca plc as successor-in-interest to Alexion Pharmaceuticals, Inc. (“Alexion”) 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 the \$6.4 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](#))
- In December 2021, CAEL-101 data were presented at the American Society of Hematology Annual Meeting (“ASH2021”). Abstracts can be viewed online through the ASH2021 website [here](#).
- In June 2021, Caelum announced that CAEL-101 clinical data were presented at the European Hematology Association 2021 Virtual Congress (“EHA2021”). The data, presented in two e-posters, demonstrates 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 was developed by Caelum until Caelum was acquired by AstraZeneca.

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

- In December 2021, we announced the initiation of the CONTERNO study, a global, randomized Phase 3 trial of cosibelimab in combination with pemetrexed and platinum chemotherapy for the first-line treatment of patients with non-squamous non-small cell lung cancer.
- 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. 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.
- Cosibelimab was sourced by Fortress and is currently in development at our partner company, Checkpoint.

#### **Olafertinib (formerly CK-101, a third-generation epidermal growth factor receptor (“EGFR”) inhibitor)**

- During the second quarter of 2021, we had productive interactions with the FDA regarding Checkpoint’s ongoing 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.
- 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’s 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, autologous CAR T cell therapy for relapsed or refractory B-NHL and CLL. We intend to dose the first patient in that trial in the first half of 2022.

- 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.
  - In November 2021, we announced that Mustang Bio was awarded a grant of approximately \$2 million from the National Cancer Institute of the National Institutes of Health. This two-year award will partially fund the Mustang Bio-sponsored multicenter trial to assess the safety, tolerability and efficacy of MB-106, a CD20-targeted, autologous CAR T cell therapy for patients with relapsed or refractory B- NHL or CLL.
  - In December 2021, we announced that MB-106 data were presented at ASH2021. Dr. Mazyar Shadman of Fred Hutchinson Cancer Research Center presented updated interim data showing a 95% overall response rate, 65% complete response rate and favorable safety profile from the ongoing Phase 1/2 clinical trial for B-NHL and CLL. A copy of the poster can be viewed online [here](#).
  - Also in December 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](#).
  - In January 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 NHL and CLL, were selected for a poster presentation 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, rescheduled to take place April 23-26, 2022, in Salt Lake City, Utah. A copy of the abstract can be viewed on the meeting website [here](#).
  - MB-106 was sourced by Fortress and is currently in development at our partner company, Mustang Bio.
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#### **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.
- Dotinurad was sourced by Fortress and is currently in development at our subsidiary company, UR1 Therapeutics.

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

- In February 2021, we announced encouraging MB-107 and MB-207 clinical updates from our XSCID investigator-IND trials, as well as additional consistent safety and efficacy data.
- In August 2021, 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.
- 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 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 (“HSCT”) 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 our partner company, Mustang Bio.

#### **Triplex (Cytomegalovirus (“CMV”) vaccine)**

- In December 2021, we announced that a Phase 2 double-blind, randomized, placebo-controlled clinical trial was initiated to evaluate the safety and efficacy of Triplex, a cytomegalovirus (“CMV”) vaccine, in eliciting a CMV-specific immune response and reducing CMV replication in people living with HIV. The trial is being conducted by the AIDS Clinical Trials Group and is funded by the National Institute of Allergy and Infectious Disease, part of the National Institutes of Health.
- Triplex was sourced by Fortress and is currently in development at our subsidiary company, Helocyte, Inc.

#### **MB-101 (IL13Rα2-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 IL13Rα2-directed CAR T cells) to patients with leptomeningeal brain tumors (e.g., glioblastoma, ependymoma or medulloblastoma).
  - In October 2021, Christine Brown, Ph.D., Deputy Director, T Cell Therapeutics Research Laboratory Professor, Departments of Hematology & Hematopoietic Cell Transplantation and Immuno-Oncology and The Heritage Provider Network Professor in Immunotherapy at City of Hope, presented updated Phase 1 clinical data regarding MB-101 (IL13Rα2-targeted CAR T cells) for the treatment of glioblastoma at two scientific conferences, the First Annual Conference on CNS Clinical Trials, co-sponsored by the Society for Neuro-Oncology and American Society of Clinical Oncology, and the American Association for Cancer Research Virtual Special Conference: Brain Cancer.
  - MB-101 was sourced by Fortress and is currently in development at our partner company, Mustang Bio.
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#### **MB-105 (PSCA-targeted CAR T Cell Therapy)**

- In February 2022, Phase 1 data on MB-105, a 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 results indicated that PSCA-CAR T-cell therapy is feasible in patients with mCRPC with dose limiting toxicity of cystitis and show 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 can proceed in the trial.
- MB-105 was sourced by Fortress and is currently in development at our partner company, Mustang Bio.

#### **MB-109 (MB-101 (IL13Rα2-targeted CAR T Cell Therapy) + MB-108 oncolytic virus)**

- In March 2022, we announced that an abstract reporting on Phase 1 trials being conducted at the University of Alabama at Birmingham (UAB) and City of Hope of Mustang Bio's exclusively licensed oncolytic viral and CAR T-cell therapies for the treatment of patients with glioblastoma (GBM) was selected as a late-breaking poster presentation at the American Association for Cancer Research (AACR) Annual Meeting 2022, taking place April 8 – 13, 2022, in New Orleans, Louisiana. The abstract will also be published in the online *Proceedings of the AACR*.

#### Novel CAR T Technology

- In August 2021, we announced an exclusive license agreement with Mayo Clinic for a novel technology to create *in vivo* CAR T cells 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.

#### Ex Vivo Lentiviral Gene Therapy for RAG1 Severe Combined Immunodeficiency (“RAG1-SCID”)

- In November 2021, we announced the execution of an exclusive license agreement with Leiden University Medical Centre for a first-in-class *ex vivo* lentiviral gene therapy for the treatment of RAG1-SCID.
- The *ex vivo* lentiviral gene therapy was sourced by Fortress and is currently in development at Mustang Bio.

#### Financial Results:

To assist our stockholders in understanding our company, we have prepared non-GAAP financial results for the three months and twelve months ended December 31, 2021 and 2020. 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.

- As of December 31, 2021, Fortress' consolidated cash, cash equivalents and restricted cash totaled \$308.0 million, compared to \$254.4 million as of September 30, 2021, and \$235.0 million as of December 31, 2020, an increase of \$53.6 million for the fourth quarter and an increase of \$73.0 million for the full year.

- On a GAAP basis, Fortress' net revenue totaled \$68.8 million for the full year ended December 31, 2021, which included \$63.1 million in net revenue generated from our marketed dermatology products. This compares to net revenue totaling \$45.6 million for the full year ended 2020, which included \$44.5 million in net revenue generated from our marketed dermatology products.
- On a GAAP basis, consolidated research and development expenses including license acquisitions totaled \$128.9 million for the full year ended December 31, 2021, compared to \$64.1 million for the full year ended December 31, 2020. On a non-GAAP basis, research and development costs including research and development license acquisitions totaled \$18.0 million for the full year ended December 31, 2021, compared to \$10.0 million for the full year ended December 31, 2020.
- On a GAAP basis, consolidated selling, general and administrative costs were \$86.8 million for the full year ended December 31, 2021, compared to \$61.2 million for the full year ended December 31, 2020. On a non-GAAP basis, selling, general and administrative expenses were \$28.6 million for the full year ended December 31, 2021, compared to \$23.4 for the full year ended December 31, 2020.
- On a GAAP basis, consolidated net loss attributable to common stockholders was \$(64.7) million, or \$(0.79) per share, for the full year ended December 31, 2021, compared to net loss attributable to common stockholders of \$(46.5) million, or \$(0.65) per share for the full year ended December 31, 2020.
- Fortress' non-GAAP income attributable to common stockholders was \$25.5 million, or \$0.31 per share basic and \$0.25 per share diluted, for the full year ended December 31, 2021, compared to Fortress' non-GAAP loss attributable to common stockholders of \$(30.8) million, or \$(0.43) per share basic and diluted, for the full year ended December 31, 2020.

#### Use of Non-GAAP Measures:

In addition to the GAAP financial measures as presented in our Form 10-K filed with the Securities and Exchange Commission (“SEC”) on March 28, 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 costs, defined as GAAP research and development costs, less research and development costs of our public partner companies and non-GAAP selling, general and administrative costs, defined as GAAP selling, general and administrative costs, less selling, general and administrative costs of our public partner companies.

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

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

(\$ in thousands except for share and per share amounts)	For the year ended	
	December 31,	
	2021	2020 <sup>1</sup>
<b>Net loss attributable to common stockholders</b>	\$ (64,703)	\$ (46,526)
Net loss attributable to common stockholders - Avenue <sup>2</sup>	(822)	(1,177)
Net loss attributable to common stockholders - Checkpoint <sup>3</sup>	(9,313)	(3,798)
Net (loss) income attributable to common stockholders - Journey Medical <sup>4</sup>	(36,708)	6,662

Net loss attributable to common stockholders - Mustang <sup>5</sup>	(11,256)	(13,066)
<b>Non-GAAP loss attributable to common stockholders</b>	<b>\$ (6,605)</b>	<b>\$ (35,147)</b>
Stock based compensation	10,133	6,821
Amortization of debt discount	3,914	3,301
Depreciation	462	603
Increase in fair value of investment in Caelum	(39,294)	(6,418)
Realization in Caelum investment <sup>6</sup>	56,860	-
<b>Fortress non-GAAP income (loss) attributable to common stockholders</b>	<b>\$ 25,469</b>	<b>\$ (30,840)</b>
Per common share - basic and diluted:		
Net loss attributable to common stockholders (GAAP)	\$ (0.79)	\$ (0.65)
Non-GAAP net loss attributable to common stockholders	\$ (0.08)	\$ (0.49)
Fortress non-GAAP income (loss) attributable to common stockholders - basic	\$ 0.31	\$ (0.43)
Fortress non-GAAP income (loss) attributable to common stockholders - diluted	\$ 0.25	n/a
Weighted average common shares outstanding - basic	81,700,220	72,005,181
Weighted average common shares outstanding - diluted	103,604,466	72,005,181

- Results for the year ended December 31, 2020 have been adjusted to remove Journey Medical as a public entity due to its IPO in November, 2021.
- Avenue net loss for the years ended December 31, 2021 and 2020 of \$3.7 million and \$5.2 million, respectively, net of non-controlling interest of \$2.9 million and \$4.0 million, respectively.
- Checkpoint net loss for the year ended December 31, 2021 of \$56.7 million net of non-controlling interest of \$39.2 million, Master Services Agreement (“MSA”) fee to Fortress of \$0.5 million, financing fee and payment-in-kind (“PIK”) dividend to Fortress of \$1.0 million and \$6.6 million, respectively; and net loss for the year ended December 31, 2020 of \$23.1 million net of non-controlling interest of \$13.3 million, MSA fee to Fortress of \$0.5 million, financing fee and PIK dividend to Fortress of \$0.9 million and \$4.6 million, respectively.
- Journey Medical net loss for the year ended December 31, 2021 of \$44.0 million net of non-controlling interest of \$5.7 million and tax expense recognized on a stand-alone basis of \$1.6 million; and net income for the year ended December 31, 2020 of \$5.3 million, net non-controlling interest of \$0.5 million and stand-alone tax expense of \$1.9 million.
- Mustang net loss of \$66.4 million net of non-controlling interest of \$48.5 million, MSA fee to Fortress of \$0.5 million and financing fee and PIK dividend to Fortress of \$1.9 million and \$4.2 million, respectively, for the year ended December 31, 2021; and net loss of \$60.0 million net of non-controlling interest of \$36.4 million, MSA fee to Fortress of \$0.5 million and financing fee and PIK dividend to Fortress of \$2.4 million and \$7.6 million, respectively, for the year ended December 31, 2020.
- Proceeds received from AstraZeneca plc acquisition of Caelum Biosciences, Inc. in October 2021.

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

(\$ in thousands)	For the year ended	
	December 31, 2021	December 31, 2020
<b>Research and development<sup>1</sup></b>	<b>\$ 128,864</b>	<b>\$ 64,108</b>
Less:		
Research and development - Avenue	1,254	2,866
Research and development - Checkpoint <sup>2</sup>	41,855	11,735
Research and development - Journey Medical	16,558	-
Research and development - Mustang <sup>3</sup>	51,244	39,475
<b>Non-GAAP research and development costs</b>	<b>\$ 17,953</b>	<b>\$ 10,032</b>
<b>Selling, general and administrative<sup>4</sup></b>	<b>\$ 96,384</b>	<b>\$ 61,166</b>
Less:		
General and administrative - Avenue	2,484	2,347
General and administrative - Checkpoint <sup>5</sup>	7,005	6,518
Selling, general and administrative - Journey Medical	49,373	22,086
General and administrative - Mustang <sup>6</sup>	8,883	6,810
<b>Non-GAAP selling, general and administrative costs</b>	<b>\$ 28,639</b>	<b>\$ 23,405</b>

- Includes Research and development expense and Research and development - licenses acquired expense for the years ended December 31, 2021 and 2020, respectively.
- Excludes \$6.6 million and \$4.6 million of PIK dividend payable to Fortress for the year ended December 31, 2021 and 2020, respectively.
- Excludes \$0.3 million of Fortress MSA expense and \$4.2 million PIK dividend payable to Fortress for the year ended December 31, 2021; and excludes \$0.3 million of Fortress MSA expense and \$7.6 million PIK dividend payable to Fortress for the year ended December 31, 2020.
- Includes Selling, general and administrative expenses and wire transfer fraud loss for the year ended December 31, 2021.
- Excludes \$0.5 million of Fortress MSA expense and \$1.0 million Fortress financing fee for the year ended December 31, 2021; and \$0.5 million of Fortress MSA expense and \$0.9 million Fortress financing fee for the year ended December 31, 2020.
- Excludes \$0.3 million of Fortress MSA expense and \$1.9 million Fortress financing fee for the year ended December 31, 2021; and \$0.3 million of Fortress MSA expense and \$2.4 million Fortress financing fee for the year ended December 31, 2020.

**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](http://www.fortressbiotech.com).

## Forward-Looking Statements

This press release may contain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. As used below and throughout this press release, the words “we”, “us” and “our” may refer to Fortress individually or together with one or more partner companies, as dictated by context. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs, ability to generate shareholder value, ability of our products 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. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this press release should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

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

	December 31, 2021	December 31, 2020
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 305,744	\$ 233,351
Accounts receivable, net	23,112	23,928
Inventory	9,862	1,404
Other receivables - related party	678	744
Prepaid expenses and other current assets	7,066	6,723
Total current assets	346,462	266,150
Property and equipment, net	15,066	11,923
Operating lease right-of-use asset, net	19,005	20,487
Restricted cash	2,220	1,645
Long-term investment, at fair value	—	17,566
Intangible asset, net	12,552	14,629
Other assets	1,198	1,013
<b>Total assets</b>	<b>\$ 396,503</b>	<b>\$ 333,413</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 90,660	\$ 45,389
Deferred revenue	2,611	—
Income taxes payable	345	—
Operating lease liabilities, short-term	2,104	1,849
Partner company line of credit	812	—



Partner company installment payments - licenses, short-term (net of imputed interest of \$490 and \$778 as of December 31, 2021 and December 31, 2020, respectively)	4,510	4,522
Total current liabilities	101,042	51,760
Notes payable, long-term (net of debt discount of \$7,063 and \$8,323 as of December 31, 2021 and December 31, 2020, respectively)	42,937	51,677
Operating lease liabilities, long-term	20,987	22,891
Partner company installment payments - licenses, long-term (net of imputed interest of \$373 and \$863 as of December 31, 2021 and December 31, 2020, respectively)	3,627	8,137
Other long-term liabilities	2,033	1,949
<b>Total liabilities</b>	<b>170,626</b>	<b>136,414</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
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 December 31, 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, 101,435,505 shares issued and outstanding as of December 31, 2021; 150,000,000 shares authorized, 94,877,492 shares issued and outstanding as of December 31, 2020, respectively	101	95
Additional paid-in-capital	656,033	583,000
Accumulated deficit	(547,463)	(482,760)
Total stockholders' equity attributed to the Company	108,674	100,338
Non-controlling interests	117,203	96,661
Total stockholders' equity	225,877	196,999
<b>Total liabilities and stockholders' equity</b>	<b>\$ 396,503</b>	<b>\$ 333,413</b>

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

	Year Ended December 31,	
	2021	2020
<b>Revenue</b>		
Product revenue, net	\$ 63,134	\$ 44,531
Collaboration revenue	5,389	—
Revenue - related party	268	1,068
Net revenue	68,791	45,599
<b>Operating expenses</b>		
Cost of goods sold - product revenue	32,084	14,594
Research and development	113,240	61,275
Research and development - licenses acquired	15,625	2,834
Selling, general and administrative	86,843	61,166
Wire transfer fraud loss	9,540	—
Total operating expenses	257,332	139,869
Loss from operations	(188,541)	(94,270)
Other income (expense)		
Interest income	649	1,518
Interest expense and financing fee	(15,308)	(15,326)
Change in fair value of investments	39,294	6,418
Change in fair value of derivative liability	(447)	(1,189)
Total other income (expense)	24,188	(8,579)
Loss before income tax expense	(164,353)	(102,849)
Income tax expense	473	136
<b>Net loss</b>	<b>(164,826)</b>	<b>(102,985)</b>
Net loss attributable to non-controlling interests	100,123	56,459
<b>Net loss attributable to common stockholders</b>	<b>\$ (64,703)</b>	<b>\$ (46,526)</b>
Net loss per common share - basic and diluted	\$ (2.02)	\$ (1.43)
Net loss per common share attributable to non - controlling interests - basic and diluted	\$ (1.23)	\$ (0.78)
Net loss per common share attributable to common stockholders - basic and diluted	\$ (0.79)	\$ (0.65)
Weighted average common shares outstanding - basic and diluted	81,700,220	72,005,181