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): **March 31, 2021**

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.)

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	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 March 31, 2021, 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, 2020. 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
99.1	Press Release issued by Fortress Biotech, Inc., dated March 31, 2021.

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: March 31, 2021

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

Exhibit 99.1

Fortress Biotech Reports Record 2020 Financial Results and Recent Corporate Highlights

Revenue from marketed dermatology products increased 28% for full-year 2020 compared to 2019

Our partner company, Cyprium Therapeutics, and Sentynl Therapeutics, a wholly-owned subsidiary of the Zydus Group, 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 begin in the second half of 2021

New York, NY – March 31, 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 full-year ended December 31, 2020.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "We are delighted with our continued progress, and achievement of significant milestones throughout 2020 and in recent months. Notably, our partner company, Cyprium Therapeutics ("Cyprium"), and Sentynl Therapeutics, a wholly-owned subsidiary of the Zydus Group, signed a Development and Asset Purchase Agreement for CUTX-101 for the treatment of Menkes disease, in February 2021. Also, our full-year 28% revenue growth during the pandemic shows the resilience of the Fortress business model. Since the company's management took over in 2014, Fortress and our partner companies have built a growing portfolio of six marketed dermatologic pharmaceutical products and more than 25 product candidates in our pipeline across multiple therapeutic categories, including oncology, gene therapy, dermatology, and rare diseases. We are on track to submit our second New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") later this year."

Dr. Rosenwald continued, "As we look ahead to 2021, Fortress expects to deliver further top-line growth through a diversified, long-term revenue stream, and we and our partner companies anticipate multiple key value-creating milestones throughout the year. We have four product candidates in five ongoing pivotal clinical trials, with multiple other earlier-stage clinical trials progressing as well. Additionally, we intend to continue to in-license promising drugs and drug candidates, and to seek partners for late-stage programs to maximize each opportunity to its full potential. We continue to demonstrate the ability of our business model to generate meaningful value creation opportunities with the potential to produce life-changing therapies for people in need."

2020 and Recent Corporate Highlights[1]:

Marketed Dermatology Products

- Our six 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 $44.5 million for full-year 2020, compared to full-year 2019 net revenues of $34.9 million, representing growth of 28%. Our products generated $13.7 million in revenues in the fourth quarter of 2020, compared to $11.1 million in the fourth quarter of 2019, representing growth of 23%. While we generated revenue growth year-over-year in 2020, sales of our products were impacted by the COVID-19 pandemic, which caused a temporary supply shortage and impacted the ability of our sales force to make in person calls, due to states slowly re-opening.
- We in-licensed and recently launched our sixth prescription dermatology product.
- We intend to launch up to two additional new prescription products this year and expect to generate further sales growth in 2021.
- We currently have 42 sales representatives dedicated to the dermatology product portfolio and we expect that number to continue to grow this year.

CUTX-101 (Copper Histidinate for Menkes disease)

- In January 2020, the FDA granted Rare Pediatric Disease Designation to CUTX-101 for the treatment of Menkes disease.
- In June 2020, we announced the publication of a study, "Estimated birth prevalence of Menkes disease and ATP7A-related disorders based on the Genome Aggregation Database (gnomAD)," in *Molecular Genetics and Metabolism Reports*. Assuming Hardy-Weinberg genetic equilibrium, the allelic frequency of loss-of-function variants suggests a minimum birth prevalence for Menkes disease of 1 in 34,810 males, higher than previously recognized. If likely pathogenic missense variants are included, the estimated birth prevalence could potentially be as high as 1 in 8,664 live male births. The study can be accessed here.
- In July 2020, we announced the publication of a study, "Targeted Next Generation Sequencing for Newborn Screening of Menkes Disease" in *Molecular Genetics and Metabolism Reports*. The study assessed the analytic validity of an ATP7A targeted next generation DNA sequencing assay as a potential newborn screen for Menkes disease. The study can be accessed here.
- In July 2020, we announced that the European Medicines Agency ("EMA") Committee for Orphan Medicinal Products issued a positive opinion on our application for Orphan Drug Designation for CUTX-101 for the treatment of Menkes disease. In August 2020, the European Commission granted Orphan Drug Designation to CUTX-101. EMA Orphan Drug Designation provides companies with certain benefits and incentives, including clinical protocol assistance, differentiated evaluation procedures for Health Technology Assessments in certain countries, access to a centralized marketing authorization procedure valid in all EU member states, reduced regulatory fees and 10 years of market exclusivity.
- In August 2020, we reported positive top-line clinical efficacy results for CUTX-101. The study demonstrated statistically significant improvement in overall survival for Menkes disease subjects who received early treatment (ET) with CUTX-101, compared to an untreated historical control (HC) cohort, with a nearly 80% reduction in the risk of death (Hazard Ratio = 0.21, $p<0.0001$). Median survival for the ET cohort was 14.8 years (177.1 months), compared to 1.3 years (15.9 months) for the untreated HC cohort.
- In September 2020, we raised net proceeds of approximately $7.1 million in a private offering of Cyprium's 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock.
- In December 2020, the FDA granted Breakthrough Therapy Designation to CUTX-101 for the treatment of Menkes disease.

- In February 2021, our partner company, Cyprium, and Sentynl Therapeutics, a wholly-owned subsidiary of the Zydus Group, signed a Development and Asset Purchase Agreement 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 through NDA approval, 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 Sentynl will be responsible for commercialization of CUTX-101, as well as progressing newborn screening activities.

- We intend to begin the rolling submission of the NDA for CUTX-101 to the FDA in the second half of 2021.
- CUTX-101 is currently in development at our partner company, Cyprium Therapeutics, Inc.

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

- In 2020, Caelum Biosciences, Inc.'s ("Caelum") Phase 2 dose selection clinical trial of CAEL-101, a light chain fibril-reactive monoclonal antibody for the treatment of AL amyloidosis, met its primary objective, supporting the initiation of two parallel Phase 3 studies that will enroll approximately 370 AL amyloidosis patients.
- In September 2020, Caelum announced the initiation of two Phase 3 studies of CAEL-101 for AL amyloidosis.
- Also in September 2020, positive long-term Phase 1a/1b data were presented at the International Symposium on Amyloidosis (ISA) 2020. The data demonstrated prolonged overall survival (78% at 37 months) and durable organ response.
- In December 2020, CAEL-101 Phase 2 data were selected for oral and poster presentations at the 62nd American Society of Hematology Annual Meeting, which was held virtually in December 2020. Links to the abstracts can be found here: oral presentation and poster presentation.
- Caelum formed a collaboration with Alexion Pharmaceuticals, Inc. in 2019, which includes an option to acquire Caelum. AstraZeneca announced the execution of a definitive agreement to purchase Alexion Pharmaceuticals, Inc.; in event of the closing of such transaction, the timeline for a potential exercise of the option to purchase Caelum will be accelerated to six months following the date of acquisition closing.
- CAEL-101 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)

- In January 2020, we announced confirmation of the registration path for cosibelimab in metastatic cutaneous squamous cell carcinoma ("mCSCC"). FDA feedback supports the plan to submit a Biologics License Application ("BLA") based on data from the ongoing Phase 1 clinical trial.
- In April 2020, we announced that the U.S. Patent and Trademark Office issued a composition of matter patent for cosibelimab. U.S. Patent No. 10,590,199 specifically covers the antibody, cosibelimab, or a fragment thereof, providing protection through at least May 2038, exclusive of any additional patent-term extensions that might become available.
- In September 2020, at the European Society for Medical Oncology Virtual Congress 2020, we announced updated interim results from the ongoing global, open-label, multicohort, Phase 1 clinical trial of cosibelimab in patients with advanced cancers, including the registration-enabling cohort of patients with mCSCC. Cosibelimab demonstrated a 51.4% objective response rate ("ORR") and 13.5% complete response rate, which is nearly double the complete response rate observed at the time of previous analysis.
- The registration-enabling study in mCSCC is approximately 90% enrolled and we are on track to report full top-line results in the second half of 2021. With a potentially favorable safety profile 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.
- In November 2020, we announced the expansion of a long-term manufacturing partnership for cosibelimab with Samsung Biologics. Building upon an existing contract manufacturing agreement entered into in 2017, Samsung Biologics will provide additional commercial-scale drug substance manufacturing for cosibelimab.
- Also in November 2020, we announced updated interim results from the ongoing global, open-label, multicohort Phase 1 clinical trial of cosibelimab in patients with advanced cancers, including a cohort of patients with previously untreated high PD-L1 expressing advanced non-small cell lung cancer ("NSCLC"). The updated interim results were presented in a poster presentation at the Society for Immunotherapy of Cancer 35th Anniversary Annual Meeting. Cosibelimab demonstrated a 44.0% objective response rate and 10.3-month median progression-free survival in the NSCLC cohort. A Phase 3 registration-enabling trial is planned to begin in first-line metastatic NSCLC in mid-2021.
- Cosibelimab is currently in development at our partner company, Checkpoint Therapeutics, Inc. ("Checkpoint").

CK-101 (Third-generation Epidermal Growth Factor Receptor ("EGFR") Inhibitor)

- In November 2020, Checkpoint's collaboration partner in Asia for CK-101, Neupharma Inc., initiated a Phase 3, registration-enabling study of CK-101 in first-line, EGFR mutation-positive locally advanced or metastatic NSCLC. We plan to meet with the FDA to discuss the ongoing Phase 3 study design and its potential use, upon a successful study, to support a new drug application submission in the United States.
- CK-101 is currently in development at our partner company, Checkpoint.

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

- In April 2020, we announced that the EMA granted Advanced Therapy Medicinal Product classification to MB-107, a lentiviral gene therapy for the treatment of newly diagnosed infants with X-linked severe combined immunodeficiency ("XSCID"), also known as bubble boy disease.
- In the second quarter of 2020, we submitted an IND application with the FDA to initiate a multi-center pivotal Phase 2 trial of MB-107 in newly diagnosed infants with XSCID who are under the age of two. The trial is expected to enroll 10 patients who, together with patients enrolled in the current multicenter trial led by St. Jude Children's Research Hospital, will be compared with 25 matched historical control patients who have undergone hematopoietic stem cell transplant ("HSCT"). The primary efficacy endpoint will be event-free survival. On January 28, 2021, the FDA removed a CMC hold on the MB-107 Phase 2 clinical trial IND application after reviewing a comprehensive CMC package that was submitted in December 2020. We expect to enroll the first patient in this pivotal multicenter trial in the second quarter of 2021 and are targeting top-line data from the trial in the second half of 2022.
- We further expect to file an IND in the second quarter of 2021 for a pivotal multi-center Phase 2 clinical trial of MB-207, our lentiviral gene therapy in previously transplanted XSCID patients who received prior treatment with HSCT and for whom re-treatment is indicated. We anticipate enrolling 20 patients and we are targeting topline data for this trial in the first half of 2023.
- In August 2020, we announced that the FDA granted Rare Pediatric Disease Designations to MB-107 for the treatment of XSCID in newly diagnosed infants and to MB-207 for the treatment of XSCID in patients who were previously treated with HSCT and for whom re-treatment is indicated.
- In September 2020, we announced that the FDA granted Orphan Drug Designations to MB-107 for the treatment of XSCID in newly diagnosed infants and to MB-207 for the treatment of XSCID in patients who were previously treated with HSCT and for whom re-treatment is indicated.
- In October 2020, we in-licensed LentiBOOST™ technology from SIRION Biotech GmbH for the development of MB-207.

- In November 2020, we signed an agreement with Minaris Regenerative Medicine GmbH to enable technology transfer and GMP clinical manufacturing of the MB-107 lentiviral gene therapy program for the treatment of XSCID in Europe.
- Also in November 2020, we announced that the European Commission issued a positive opinion on our application for Orphan Drug Designation for the MB-107 lentiviral gene therapy for the treatment of XSCID.
- MB-107 and MB-207 are currently in development at our partner company, Mustang Bio, Inc. ("Mustang Bio").

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

- In February 2020, we announced that the first subject treated with the modified MB-106 (CD20-targeted, autologous CAR T cell therapy) manufacturing process, developed in a collaboration between Mustang Bio and the Fred Hutchinson Cancer Research Center ("Fred Hutch"), achieved a complete response at the lowest starting dose in an ongoing Phase 1/2 clinical trial. The trial is evaluating the safety and efficacy of MB-106 in subjects with relapsed or refractory B-cell non-Hodgkin lymphomas ("NHL") and chronic lymphocytic leukemia ("CLL").
- In December 2020, we announced positive interim Phase 1/2 data on MB-106 for patients with relapsed or refractory B-cell non-Hodgkin lymphomas, which were presented at the 62nd American Society of Hematology Annual Meeting. Data presented showed a favorable safety profile and clinical activity with an 89% ORR and 44% complete response rate over 4 dose levels in 9 patients treated with the modified cell manufacturing process.
- In the second quarter of 2021, we expect to announce follow up data from the Fred Hutch trial in NHL and initial data in CLL.
- MB-106 is currently in development at our partner company, Mustang Bio.

MB-102 (CD123-targeted CAR T Cell Therapy)

- In October 2020, we announced that the first patient was dosed in a Mustang Bio-sponsored, open-label, multicenter Phase 1/2 clinical trial to evaluate the safety and efficacy of MB-102 (CD123-targeted CAR T cell therapy) in patients with relapsed or refractory blastic plasmacytoid dendritic cell neoplasm.
- MB-102 is currently in development at our partner company, Mustang Bio.

MB-101 (IL13Rα2-targeted CAR T Cell Therapy)

- In December 2020, we announced that a Phase 1 single-center, two-arm clinical trial was initiated to establish the safety and feasibility of administering MB-101 to patients with leptomeningeal brain tumors (e.g., glioblastoma, ependymoma or medulloblastoma).
- MB-101 is currently in development at our partner company, Mustang Bio.

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

- In October 2020, we announced that initial Phase 1 data on MB-105, a PSCA-targeted CAR T administered systemically to patients with PSCA-positive metastatic castration-resistant prostate cancer (mCRPC), were presented by City of Hope at the virtual 27th Annual Prostate Cancer Foundation Scientific Retreat. A 73-year-old male patient with PSCA-positive mCRPC was treated with MB-105 and lymphodepletion (a standard CAR T pre-conditioning regimen) after failing eight prior therapies. On day 28 of the patient's treatment, MB-105 demonstrated a 94% reduction in prostate-specific antigen, near complete reduction of measurable soft tissue metastasis by computerized tomography, and improvement in bone metastases by magnetic resonance imaging.
- MB-105 is currently in development at our partner company, Mustang Bio.

MB-104 (CS1-targeted CAR T Cell Therapy)

- In May 2020, City of Hope presented two posters pertaining to MB-104, an innovative CS1 CAR T cell therapy, at the virtual 23rd Annual Meeting of the American Society of Gene & Cell Therapy.
- MB-104 is currently in development at our partner company, Mustang Bio.

IV Tramadol

- In October 2020, Avenue Therapeutics ("Avenue") announced that it had received a Complete Response Letter ("CRL") from the FDA regarding Avenue's NDA for IV tramadol. The FDA held a Type A meeting with Avenue in November 2020 to discuss the issues outlined in the CRL. On February 12, 2021, Avenue resubmitted its NDA to the FDA for IV tramadol. The NDA resubmission followed the receipt of the official minutes from Avenue's Type A meeting with the FDA. The NDA resubmission included revised language relating to the proposed product label and a report relating to terminal sterilization validation. On February 26, 2021, Avenue received an acknowledgement letter from the FDA that Avenue's resubmission of its NDA is a complete, class 1 response to the CRL, and a PDUFA goal date was set for April 12, 2021.
- Also in October 2020, Invagen Pharmaceuticals Inc. ("InvaGen") communicated to Avenue that it believes a Material Adverse Event (as defined in the Stock Purchase and Merger Agreement entered into on November 12, 2018 between Avenue, InvaGen and Madison Pharmaceuticals Inc., a newly formed, wholly-owned subsidiary of InvaGen) has occurred due to the impact of the COVID-19 pandemic on potential commercialization and projected sales of IV tramadol. Additionally, in connection with the resubmission of Avenue's NDA in February 2021, InvaGen communicated to Avenue that it believes the proposed label for IV tramadol would also constitute a Material Adverse Event on the purported basis that the proposed label under certain circumstances would make the product commercially unviable, and in addition that the indication that the FDA approves may fail to satisfy a condition precedent to InvaGen's obligation to consummate the second stage closing of the Avenue SPMA. While Avenue disagrees with InvaGen's assertions, it is possible InvaGen could attempt to avoid its obligation to consummate the merger, terminate the Stock Purchase and Merger Agreement, and/or pursue monetary claims against Avenue and/or Fortress.
- IV tramadol is currently in development at our partner company, Avenue.

ONCOlogues (proprietary platform technology using PNA oligonucleotides)

- In May 2020, we entered into an exclusive worldwide licensing agreement with Columbia University to develop novel oligonucleotides for the treatment of genetically driven cancers. The proprietary platform produces oligomers, known as "ONCOlogues," which are capable of binding gene sequences 1,000 times more effectively than complementary native DNA.
- In addition, we are exploring the potential of the platform to treat novel coronaviruses, such as COVID-19. We are also evaluating the platform to treat Huntington's disease and myotonic dystrophy.
- The ONCOlogues platform is currently in development at our partner company, Oncogenuity, Inc.

General Corporate

- From February to August 2020, we closed on a gross total of approximately $39 million in underwritten public offerings of our 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock (FBIOP).

- In June 2020, Fortress and Avenue were added to the Russell 3000® index.
- Also in August 2020, we announced a $60 million long-term debt refinancing agreement with Oaktree Capital Management, replacing $60 million of existing debt that was due over the subsequent seven quarters, with the debt now due in August 2025.
- In November 2020, Fortress ranked in Deloitte's Technology Fast 500™ for the second year in a row. Deloitte's Technology Fast 500™ is an annual ranking of the fastest-growing North American companies in the technology, media, telecommunications, life sciences and energy tech sectors. Fortress' 874 percent revenue growth based on the increase in net product sales from 2016 to 2019 secured its spot in the rankings.

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, 2020 and 2019. These results exclude the operations of our three public partner companies: Avenue Therapeutics, Inc. ("Avenue"), Checkpoint Therapeutics, Inc. ("Checkpoint") and Mustang Bio, Inc. ("Mustang"), as well as any one-time, non-recurring, non-cash transactions, such as the gain of $18.4 million we recorded in the first quarter of 2019 resulting from the deconsolidation of Caelum Biosciences, Inc. ("Caelum"). 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 December 31, 2020, Fortress' consolidated cash, cash equivalents, short-term investments (certificates of deposit) and restricted cash totaled $235.0 million, compared to $220.0 million as of September 30, 2020, and $153.4 million as of December 31, 2019, an increase of $15.0 million for the fourth quarter and an increase of $81.6 million for the full year.
- On a GAAP basis, Fortress' net revenue totaled $45.6 million for the full year ended December 31, 2020, which included $44.5 million in net revenue generated from our marketed dermatology products. This compares to net revenue totaling $36.6 million for the full year ended 2019, which included $34.9 million in net revenue generated from our marketed dermatology products. Fortress expects to achieve year-over-year revenue growth in 2021; however, it continues to monitor the spread of COVID-19 and assess the impact it may have on 2021 revenues.

- On a GAAP basis, consolidated research and development expenses including license acquisitions totaled $64.1 million for the full year ended December 31, 2020, compared to $81.3 million for the full year ended December 31, 2019. On a non-GAAP basis, research and development expenses including research and development license acquisitions totaled $10.0 million for the full year ended December 31, 2020, compared to $11.2 million for the full year ended December 31, 2019.
- On a GAAP basis, consolidated selling, general and administrative expenses were $61.2 million for the full year ended December 31, 2020, compared to $55.6 million for the full year ended December 31, 2019. On a non-GAAP basis, selling, general and administrative expenses were $45.5 million, of which $22.1 million is attributed to Journey, for the full year ended December 31, 2020, compared to $38.9 million, of which $19.7 million is attributed to Journey, for the full year ended December 31, 2019.
- On a GAAP basis, consolidated net loss attributable to common stockholders was $46.5 million, or $0.65 per share, for the full year ended December 31, 2020, compared to net loss attributable to common stockholders of $40.0 million, or $0.73 per share for the full year ended December 31, 2019.
- Fortress' non-GAAP loss attributable to common stockholders was $13.3 million, or $0.18 per share, for the full year ended December 31, 2020, compared to Fortress' non-GAAP loss attributable to common stockholders of $14.7 million, or $0.27 per share, for the full year ended December 31, 2019.

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 31, 2021, 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, and Mustang, as well as 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.

Management believes 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 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)	For the year ended December 31, 2020	2019
Net income (loss) attributable to common stockholders	$ (46,526)	$ (39,960)
Net (Loss) income attributable to common stockholders - Avenue[1]	(1,177)	(6,897)
Net (Loss) income attributable to common stockholders - Checkpoint[2]	(3,798)	(6,280)
Net (Loss) income attributable to common stockholders - Mustang[3]	(13,065)	(13,578)
Deconsolidation of Caelum Biosciences	-	18,476
Non-GAAP net loss attributable to common stockholders	$ (28,486)	$ (31,681)
Stock based compensation	6,974	5,564
Non-cash interest	8,099	7,007
Amortization of licenses	1,420	1,174
Amortization of debt discount	3,301	2,611
Depreciation	603	664
Increase in fair value of investment[4]	(6,418)	-
Change in fair value of derivative liability[5]	1,189	-

Fortress non-GAAP loss attributable to common stockholders	$ (13,318)	$ (14,661)
Per common share - basic and diluted:		
Net income (loss) attributable to common stockholders (GAAP)	$ (0.65)	$ (0.73)
Non-GAAP net loss attributable to common stockholders	$ (0.40)	$ (0.58)
Fortress non-GAAP loss attributable to common stockholders	$ (0.18)	$ (0.27)
Weighted average common shares outstanding - basic and diluted	72,005,181	54,711,838

1. Avenue net loss from their external SEC report for the years ended December 31, 2020 and 2019 of $5.2 million and $25.9 million, respectively, net of non-controlling interest of $4.0 million and $19.0 million, respectively.

2. Checkpoint net loss from their external SEC report of $23.1 million net of non-controlling interest of $13.3 million, PIK dividend of $4.6 million, MSA fee to Fortress of $0.5 million and financing fee to Fortress of $0.9 million for the year ended December 31, 2020; and net loss of $24.7 million net of non-controlling interest of $14.7 million, PIK dividend of $2.5 million, MSA fee to Fortress of $0.5 million and financing fee to Fortress of $0.7 million for the year ended December 31, 2019.

3. Mustang net loss from their external SEC report of $60.0 million net of non-controlling interest of $36.4 million, PIK dividend of $7.6 million, MSA fee to Fortress of $0.5 million and financing fee to Fortress of $2.4 million for the year ended December 31, 2020; and net loss of $46.4 million net of non-controlling interest of $25.7 million, PIK dividend of $4.9 million, MSA fee to Fortress of $0.5 million and financing fee to Fortress of $1.7 million for the year ended December 31, 2019.

4. Increase in fair value of investment in Caelum Biosciences for the year ended December 31, 2020.

5. Related to issuance of Cyprium warrant in connection with 2018 Venture Debt for the year ended December 31, 2020.

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

	For the year ended December 31,	
($ in thousands)	**2020**	**2019**
Research and development[1]	**$ 64,108**	**$ 81,326**
Less:		
Research and development Avenue	2,866	22,194
Research and development Checkpoint[2]	11,735	16,815
Research and development Mustang[3]	39,475	31,142
Non-GAAP research and development costs	**$ 10,032**	**$ 11,175**
Selling, general and administrative	**$ 61,166**	**$ 55,590**
Less:		
General and administrative Avenue	2,347	3,071
General and administrative Checkpoint[4]	6,518	5,996
General and administrative Mustang[5]	6,810	7,659
Non-GAAP selling, general and administrative costs	**$ 45,491**	**$ 38,864**

1. Includes Research and development expense and Research and development - licenses acquired expense for the years ended December 31, 2020 and December 31, 2019, respectively.

2. Excludes $4.6 million and $2.5 million PIK Dividend for the years ended December 31, 2020 and 2019, respectively.

3. Excludes $0.3 million for Fortress MSA and $7.6 million PIK Dividend for the year ended December 31, 2020; excludes $0.3 million for Fortress MSA and $4.9 million PIK dividend for the year ended December 31, 2019.

4. Excludes $0.5 million of Fortress MSA expense and $0.9 million Fortress financing fee for the year ended December 31, 2020; and $0.5 million of Fortress MSA expense and $0.7 million Fortress financing fee for the year ended December 31, 2019.

5. Excludes $0.3 million of Fortress MSA expense and $2.4 million Fortress financing fee for the year ended December 31, 2020; and $0.3 million of Fortress MSA expense and $1.7 million Fortress financing fee for the year ended December 31, 2019.

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 six 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 and Nationwide Children’s Hospital. 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 William 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
Consolidated Balance Sheets
($ in thousands except for share and per share amounts)

	December 31, 2020	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 233,351	$ 136,858
Accounts receivable, net	19,349	13,539
Inventory	1,404	857
Other receivables - related party	744	865
Prepaid expenses and other current assets	6,723	4,133
Total current assets	261,571	156,252
Property and equipment, net	11,923	12,433
Operating lease right -of-use asset, net	20,487	21,480
Restricted cash	1,645	16,574
Long-term investment, at fair value	17,566	11,148
Intangible asset, net	14,629	7,377
Other assets	1,013	1,158
Total assets	**$ 328,834**	**$ 226,422**
LIABILITIES AND STO CKHO LDERS’ EQ UITY		
Current liabilities		
Accounts payable and accrued expenses	$ 40,674	$ 35,451
Interest payable	—	1,042
Interest payable - related party	—	92
Income taxes payable	136	—
Notes payable, short -term	—	7,220
Operating lease liabilities, short -term	1,849	1,784
Derivative warrant liability	—	27
Partner company note payable, short -term	5,300	—
Total current liabilities	47,959	45,616
Notes payable, long-term (net of debt discount of $8,323 and $5,086 at December 31, 2020 and December 31, 2019, respectively)	51,677	77,436
Operating lease liabilities, long-term	22,891	23,712
Partner company note payable, long-term	7,359	4,990
Other long-term liabilities	1,949	2,136
Total liabilities	**131,835**	**153,890**
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 and 1,341,167 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively; liquidation value of $25.00 per share	3	1
Common stock, $.001 par value, 150,000,000 and 100,000,000 shares authorized, 94,877,492 and 74,027,425 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	95	74
Common stock issuable, 0 and 251,337 shares as of December 31, 2020 and December 31, 2019, respectively	—	500
Additional paid-in-capital	583,000	461,874
Accumulated deficit	(482,760)	(436,234)
Total stockholders' equity attributed to the Company	100,338	26,215
Non-controlling interests	96,661	46,317
Total stockholders' equity	196,999	72,532
Total liabilities and stockholders' equity	**$ 328,834**	**$ 226,422**

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

	Year Ended December 31,	
	2020	**2019**
Revenue		
Product revenue, net	$ 44,531	$ 34,921
Revenue - related party	1,068	1,708
Net revenue	45,599	36,629
Operating expenses		
Cost of goods sold - product revenue	14,594	10,532
Research and development	61,275	75,236
Research and development - licenses acquired	2,834	6,090
Selling, general and administrative	61,166	55,590
Total operating expenses	139,869	147,448
Loss from operations	(94,270)	(110,819)
Other income (expense)		
Interest income	1,518	2,559
Interest expense and financing fee	(15,326)	(11,849)
Change in fair value of derivative liability	(1,189)	(27)
Change in fair value of investments	6,418	—
Gain on deconsolidation of Caelum	—	18,476
Total other income (expense)	(8,579)	9,159
Loss before income tax expense	(102,849)	(101,660)
Income tax expense	136	—
Net loss	**(102,985)**	**(101,660)**
Less: net loss attributable to non-controlling interests	56,459	61,700
Net loss attributable to common stockholders	**$ (46,526)**	**$ (39,960)**
Net loss per common share - basic and diluted	$ (1.43)	$ (1.86)
Net loss per common share attributable to non - controlling interests - basic and diluted	$ (0.78)	$ (1.13)
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.65)	$ (0.73)
Weighted average common shares outstanding - basic and diluted	72,005,181	54,711,838