March 30, 2023

Fortress Biotech Reports Record 2022 Financial Results and Recent Corporate Highlights

Fortress expects to file a total of three new drug applications in 2023

Record consolidated net revenue of $75.7 million for full-year 2022

FDA accepted for filing the Biologics License Application for cosibelimab in patients with metastatic or locally advanced cutaneous squamous cell carcinoma; PDUFA goal date of January 3, 2024

Rolling NDA submission for CUTX-101 for the treatment of Menkes disease is expected to be completed in 2023

Topline results from the Phase 3 clinical program of DFD-29 to treat papulopustular rosacea expected in the first half of 2023; NDA submission expected in the second half of 2023

MIAMI, March 30, 2023 (GLOBE NEWSWIRE) -- 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, 2022.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "In 2022, we continued to advance our extensive portfolio of multiple clinical-stage programs, several of which are late-stage and pivotal. We also generated record consolidated net revenues of $75.7 million, much of which came from the sales of our eight marketed dermatology products. Our growth continues in 2023, as the U.S. Food and Drug Administration ("FDA") accepted for filing the Biologics License Application ("BLA") for cosibelimab earlier this month and we expect to have two New Drug Applications ("NDA") submitted to the FDA for CUTX-101 for Menkes disease and DFD-29 for rosacea this year. We also anticipate multiple clinical trial initiations, data readouts and regulatory filings across our other development-stage programs. Fortress has also established 25 acquisition companies with expert opinion leaders in multiple therapeutic areas over the past year. These expert opinion leaders will continue to work with our business development team to identify, evaluate and acquire potential best-in-class therapies to form the bases of these

new companies. We are focused on licensing assets with proof-of-concept clinical data available in areas with high unmet medical need, which potentially lowers the development uncertainty and associated risk. Our pipeline and structure allow for flexibility and diversified exposure with many product candidates and potentially long-term revenue streams. We expect to achieve multiple milestones this year, and we are confident in our long-term growth prospects as we continue to scale."

2022 and Recent Corporate Highlights[1]:

Marketed Dermatology Products and Product Candidates

- Journey Medical Corporation (Nasdaq: DERM) ("Journey Medical"), our partner company, currently markets eight prescription dermatology products.
- Journey Medical's total net revenues were $73.7 million for the full-year 2022, which includes $71.0 million from their commercial portfolio, compared to full-year 2021 total net revenues of $63.1 million, representing growth of 17%.
- In January 2023, Journey Medical completed enrollment in its DFD-29 Phase 3 clinical program for the treatment of papulopustular rosacea. Topline data from the two DFD-29 Phase 3 clinical studies are expected to be announced in the first half of 2023. Journey Medical plans to submit the NDA for DFD-29 in the second half of 2023 and an FDA approval decision is anticipated in the second half of 2024.
    - In the Phase 2 clinical trials, DFD-29 (40mg) demonstrated nearly double the efficacy when compared against Oraycea® (European equivalent of Oracea®) on both co-primary endpoints. For the first co-primary endpoint, Investigator's Global Assessment ("IGA") treatment success, Oraycea had a 33.33% IGA treatment success rate, while DFD-29 achieved a 66.04% IGA treatment success rate. For the second co-primary endpoint, the change in total inflammatory lesion count, Oraycea had a 10.5 reduction in inflammatory lesions, while DFD-29 achieved a 19.2 reduction in inflammatory lesions.

Cosibelimab (Anti PD-L1 antibody)

- Our partner company, Checkpoint Therapeutics, Inc. (Nasdaq: CKPT) ("Checkpoint"), submitted a BLA to the FDA for cosibelimab, its investigational anti-PD-L1 antibody, as a treatment for patients with metastatic or locally advanced cutaneous squamous cell carcinoma ("cSCC") who are not candidates for curative surgery or radiation, in January 2023. In March 2023, the FDA accepted for filing the BLA for cosibelimab and set a Prescription Drug User Fee Act ("PDUFA") goal date of January 3, 2024. In its BLA filing acceptance letter, the FDA indicated that no potential filing review issues have been identified, and that an advisory committee meeting to discuss the application is not currently planned. According to U.S. prescription claims data, in 2021, approximately 11,000 cSCC patients were treated with systemic therapies. As PD-1 inhibitors comprised less than half of patient prescriptions, cSCC remains a disease with a need for more effective and tolerable treatment options, particularly for the significant number of cSCC patients with immunosuppressive conditions or autoimmune diseases. With its unique mechanism of action and compelling safety profile, we believe cosibelimab, if approved, would be uniquely positioned to provide an important new treatment option for cSCC patients that are currently underserved by available therapies.

- In January 2022, Checkpoint announced positive topline results from its registration-enabling clinical trial evaluating the safety and efficacy of the 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 ("ORR") 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.
- In June 2022, we announced that the topline results of Checkpoint's pivotal trial of cosibelimab in metastatic cSCC were presented at the 2022 American Society of Clinical Oncology Annual Meeting. Data highlights included confirmed ORR by independent central review in the modified intent-to-treat population of 48.7% (95% CI, 37.0-60.4) and 13.2% of patients achieved a complete response in target lesions. Cosibelimab was generally well tolerated with no unexpected safety signals.
- Also in June 2022, we announced positive interim results from Checkpoint's pivotal trial of cosibelimab in locally advanced cSCC. As of the March 2022 data cutoff, the confirmed ORR by independent central review in 31 patients was 54.8% (95% CI: 36.0, 72.7).
- In July 2022, Checkpoint successfully completed two pre-BLA meetings with the FDA (chemistry, manufacturing and controls ("CMC") and clinical/non-clinical). Based upon favorable interactions with the agency, the January 2023 BLA submission included both the metastatic and locally advanced cSCC indications.
- Cosibelimab was sourced by Fortress and is currently in development at Checkpoint.

Dotinurad (Urate Transporter (URAT1) Inhibitor)

- In May 2022, our subsidiary company Urica Therapeutics, Inc. ("Urica'") initiated a Phase 1 clinical trial to evaluate dotinurad in healthy volunteers in the United States. Dotinurad is in development for the treatment of gout. We anticipate topline data from the Phase 1 trial in the first half of 2023 and expect to be in pivotal clinical trials in early 2024.
- 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. The clinical program supporting approval included over 1,000 patients.
- In October 2022, Urica strengthened its leadership team by appointing Jay D. Kranzler, M.D., Ph.D., as Chairman and Chief Executive Officer, and Vibeke Strand, M.D., MACR, FACP, Adjunct Clinical Professor, Division of Immunology/Rheumatology, Stanford University, to Urica's Board of Directors.
- In December 2022, Urica expanded its exclusive license agreement with Fuji Yakuhin Co. Ltd. ("Fuji") for the development of dotinurad to include the Middle East and North Africa and Turkey territories. The agreement builds upon the exclusive license agreement between Urica and Fuji previously announced in May 2021 to develop dotinurad in the United States, United Kingdom, European Union and Canada.
- Dotinurad was sourced by Fortress and is currently in development at Urica.

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

- In June 2022, we announced that the FDA granted Orphan Drug Designation to MB-106 for the treatment of Waldenstrom macroglobulinemia ("WM"), a rare type of B-cell

non-Hodgkin lymphoma (“B-NHL”). Our partner company Mustang Bio, Inc. (Nasdaq: MBIO) (“Mustang Bio”), which is developing MB-106, plans to treat additional WM patients in the Mustang Bio-sponsored Phase 1 portion of its multicenter trial to potentially support an accelerated Phase 2 strategy for WM.

- In October 2022, we announced that the first patient was treated in Mustang Bio’s multicenter, open-label, non-randomized Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106, for the treatment of relapsed or refractory B-NHL and chronic lymphocytic leukemia (“CLL”). In 2023, Mustang Bio anticipates dose escalation and reporting response data at major medical meetings.
- Additionally, in October 2022, we shared interim data from 28 patients treated in the ongoing Phase 1/2 investigator-sponsored clinical trial at Fred Hutch.
    - An ORR of 96% and complete response (“CR”) rate of 75% were observed in a wide range of hematologic malignancies including follicular lymphoma, CLL, diffuse large B-cell lymphoma and WM. Twelve patients have experienced CR for more than 12 months (10 ongoing), including four patients with CR for more than two years and the longest patient with CR at 33 months. Six patients with initial partial response at 28 days post-treatment improved to CR and all remain in ongoing CR. All three patients previously treated with CD19 CAR T cell therapy responded to treatment with MB-106.
    - A favorable safety profile for MB-106 as an outpatient therapy remains, with no cytokine release syndrome or immune effector cell-associated neurotoxicity syndrome ≥ Grade 3 reported to date on this trial.
- MB-106 continues to generate compelling safety and efficacy data, and the product profile of this autologous CD20-directed CAR T is favorable compared to the approved autologous CD19-directed CAR Ts, which are generating an annualized run rate of $3 billion in net sales, based on reported sales in the third quarter of 2022.
- MB-106 was sourced by Fortress and is currently in development at Mustang Bio.

CUTX-101 (Copper Histidinate for Menkes disease)

- Our subsidiary, Cyprium Therapeutics, Inc. (“Cyprium) has completed two pivotal studies in patients with Menkes disease treated with CUTX-101, copper histidinate (CuHis). In the studies, 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 for CUTX-101 compared to 16.1 months historical control, 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 2021, Cyprium signed a Development and Asset Purchase Agreement with Sentynl Therapeutics, Inc. (“Sentynl”), a wholly owned subsidiary of Zydus Lifesciences Ltd., for CUTX-101 to treat Menkes disease. Cyprium is responsible for the development of CUTX-101 and Sentynl will be responsible for commercialization of CUTX-101, as well as progressing newborn screening activities.
- In December 2021, Cyprium initiated the rolling submission of an NDA to the FDA for CUTX-101, which is ongoing and expected to be completed in 2023.
- 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.
- Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101.
- 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 ("AstraZeneca") acquired Caelum Biosciences, Inc. ("Caelum") for an upfront payment of approximately $150 million paid to Caelum shareholders, of which approximately $56.9 million was paid to Fortress, net of Fortress' $6.4 million portion of the $15 million, 24-month escrow holdback amount and other miscellaneous transaction expenses. The agreement also provides for additional potential payments to Caelum shareholders totaling up to $350 million, payable upon the achievement of regulatory and commercial milestones. Fortress is eligible to receive 42.4% of all potential milestone payments, which together with the upfront payment, would total up to approximately $212 million.
- There are two ongoing Phase 3 studies of CAEL-101 for AL amyloidosis. (ClinicalTrials.gov identifiers: NCT04512235 and NCT04504825).[2]
- AstraZeneca has estimated that it expects the FDA to accept its BLA submission for review during calendar year 2024.
- CAEL-101 (anselamimab) was sourced by Fortress and was developed by Caelum (founded by Fortress) until its acquisition by AstraZeneca in October 2021.

Triplex (Cytomegalovirus ("CMV") vaccine)

- We expect that the Phase 2 clinical trial of Triplex for adults co-infected with HIV and CMV will complete enrollment in the second half of 2023 with topline data anticipated in 2024. The study aims to show potential reduction in intensity of highly active antiretroviral therapy treatment (HAART) which is used in up to 1.7 million treated HIV patients.
- In August 2022, we announced that Triplex received a grant from the National Institute of Allergy and Infectious Diseases that could provide over $20 million in non-dilutive funding. This will fund a 420 patient multi-center, placebo-controlled, randomized Phase 2 study of Triplex for control of CMV in patients undergoing liver transplantation and is expected to begin enrollment this year. The company believes this data set could ultimately be used to support approval of Triplex in this setting.
- Triplex is currently the subject of four clinical trials including: adults undergoing stem cell transplant; adults co-infected with CMV and HIV; and in combination with a CAR T cell therapy for adults with NHL.
- Triplex was sourced by Fortress and is currently in development at our subsidiary company, Helocyte, Inc.

AJ201

- In March 2023, we announced that our partner company, Avenue Therapeutics, Inc. (Nasdaq: ATXI) ("Avenue"), entered into an exclusive license agreement with AnnJi Pharmaceutical Co., Ltd. for intellectual property related to AJ201, a first-in-class clinical asset currently in a Phase 1b/2a study in the U.S. for the treatment of spinal and bulbar muscular atrophy ("SBMA"), also known as Kennedy's Disease. Kennedy's Disease is a debilitating rare genetic neuromuscular disease primarily affecting men.

Although there is a range of cited prevalence rates in the literature, a recent study used genetic analysis to estimate disease prevalence of *1:6,887* males[3].
- AJ201 was sourced by Fortress and is currently in development at Avenue.

IV Tramadol

- In September 2022, our partner company Avenue received the official meeting minutes from the FDA regarding a meeting conducted in August 2022, for IV Tramadol. At the meeting, Avenue presented a study design for a single safety clinical trial that Avenue believes could address the concerns regarding risks related to opioid stacking. The FDA stated that the proposed study design appears reasonable and agreed on various study design aspects with the expectation that additional feedback would be provided to Avenue upon review of a more detailed study protocol. Avenue incorporated the FDA's suggestions from the meeting minutes and submitted a detailed study protocol that could form the basis for the submission of a complete response to the second Complete Response Letter for IV Tramadol.
- In March 2023, Avenue participated in a Type C meeting with the FDA to discuss the proposed study protocol to assess the risk of respiratory depression related to opioid stacking on IV Tramadol relative to an approved opioid analgesic.
- IV Tramadol was sourced by Fortress and is currently in development at Avenue.

***In vivo* CAR T Platform Technology**

- We continue to collaborate with the Mayo Clinic to potentially revolutionize the delivery of CAR T in patients. The technology has the potential to generate CAR T cells within the patient's body after two outpatient injections, without the need for traditional *ex vivo* allogeneic or autologous CAR T cell processing wait time and expense.
- We anticipate the publication of proof-of-concept research from *in vivo* animal studies in 2023.
- The novel CAR T technology was sourced by Fortress and is currently in development at Mustang Bio.

General Corporate:

Fortress

- In April 2022, Fortress participated in a two-day summit hosted by the B. Riley Securities' Healthcare Equity Research team that featured multiple programs from Fortress' diversified pipeline. Webcast replays are available on Fortress' website here. Information on our website does not constitute part of this press release.
- In July 2022, we announced that David Jin, who has served as Vice President of Corporate Development since May 2020, was also appointed as Chief Financial Officer effective August 16, 2022.
- In December 2022, Fortress appointed Lucy Lu to its Board of Directors.
- In February 2023, Fortress completed a registered direct offering priced At-the-Market under Nasdaq rules for total gross proceeds of approximately $13.9 million, and a concurrent private placement with investors in the registered direct offering for the pro rata rights to acquire, in the aggregate, securities exercisable into common stock in certain future operating subsidiaries that consummate a specified corporate development transaction within the next five years.

Financial Results:

To assist our stockholders in understanding our company, we have prepared non-GAAP financial metrics for the three months and 12 months ended December 31, 2022 and 2021. These metrics exclude the operations of our four public partner companies: 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, 2022, Fortress' consolidated cash, cash equivalents and restricted cash totaled $181.0 million, compared to $210.6 million as of September 30, 2022, and $308.0 million as of December 31, 2021, a decrease of $29.6 million for the fourth quarter and a decrease of $127.0 million for the full year.
- On a GAAP basis, Fortress' net revenue totaled $75.7 million for the full year ended December 31, 2022, which included $71.0 million in net revenue generated from our marketed dermatology products. This compares to net revenue totaling $68.8 million for the full year ended 2021, which included $63.1 million in net revenue generated from our marketed dermatology products.
- On a GAAP basis, consolidated research and development expenses including license acquisitions totaled $134.9 million for the full year ended December 31, 2022, compared to $128.9 million for the full year ended December 31, 2021. On a non-GAAP basis, research and development costs including research and development license acquisitions totaled $11.3 million for the full year ended December 31, 2022, compared to $18.0 million for the full year ended December 31, 2021.
- On a GAAP basis, consolidated selling, general and administrative costs were $113.7 million for the full year ended December 31, 2022, compared to $86.8 million for the full year ended December 31, 2021. On a non-GAAP basis, selling, general and administrative expenses were $30.6 million for the full year ended December 31, 2022, compared to $28.6 for the full year ended December 31, 2021.
- On a GAAP basis, consolidated net loss attributable to common stockholders was $(86.6) million, or $(0.97) per share, for the full year ended December 31, 2022, compared to net loss attributable to common stockholders of $(64.7) million, or $(0.79) per share for the full year ended December 31, 2021.
- Fortress' non-GAAP loss attributable to common stockholders was $(29.2) million, or $(0.33) per share, for the full year ended December 31, 2022, compared to Fortress' non-GAAP income attributable to common stockholders of $25.5 million, or $0.31 per share basic and $0.25 per share diluted, for the full year ended December 31, 2021. In 2021, Fortress received initial proceeds from the AstraZeneca acquisition of Caelum.

Use of Non-GAAP Measures:

In addition to the GAAP financial measures as presented in our filings with the Securities and Exchange Commission ("SEC"), including our Form 10-K to be filed on March 31, 2023, 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, 2022	2021
Net loss attributable to common stockholders	$ (86,575)	$ (64,703)
Net loss attributable to common stockholders - Avenue[1]	(587)	(822)
Net loss attributable to common stockholders - Checkpoint[2]	(11,415)	(9,313)
Net loss attributable to common stockholders - Journey Medical[3]	(17,107)	(36,708)
Net loss attributable to common stockholders - Mustang Bio[4]	(13,680)	(11,256)
Non-GAAP (loss) attributable to common stockholders	$ (43,786)	$ (6,605)
Stock based compensation	12,706	10,133
Amortization of debt discount	1,532	3,914
Depreciation	385	462
Increase in fair value of investment in Caelum	-	(39,294)
Realization in Caelum investment[5]	-	56,860
Fortress non-GAAP (loss) income attributable to common stockholders	$ (29,163)	$ 25,469
Per common share - basic and diluted:		
Net loss attributable to common stockholders (GAAP)	$ (0.97)	$ (0.79)
Non-GAAP net loss attributable to common stockholders	$ (0.49)	$ (0.08)
Fortress non-GAAP (loss) income attributable to common stockholders	$ (0.33)	$ 0.31
Fortress non-GAAP (loss) income attributable to common stockholders - diluted	$ (0.33)	$ 0.25
Weighted average common shares outstanding - basic	88,874,519	81,700,220
Weighted average common shares outstanding - diluted	88,874,519	103,604,466

1. Avenue net loss for the year ended December 31, 2022 of $3.6 million net of non-controlling interest of $2.4 million, Master Services Agreement ("MSA") fee to Fortress of $0.1 million, financing fee and payment-in-kind ("PIK") dividend to Fortress of $0.3 million and $0.3 million, respectively; net loss for the year ended December 31, 2021 of $3.7 million, net of non-controlling interest of $2.9 million.
2. Checkpoint net loss of $62.6 million net of NCI of $48.4 million, MSA fee to Fortress of $0.5 million, financing fee and PIK dividend to Fortress of $0.4 million and $1.9 million, respectively, for the year ended December 31, 2022; and net loss of $56.7 million net of NCI of $39.2 million, MSA fee to Fortress of $0.5 million, financing fee and PIK dividend to Fortress of $1.0 million and $6.6 million, respectively, for the year ended December 31, 2021.
3. Journey Medical net loss for the year ended December 31, 2022 of $29.6 million net of NCI of $12.5 million and tax expense recognized on a stand-alone basis of $0.1 million; and net loss for the year ended December 31, 2021 of $44.0 million net of NCI of $5.7 million and tax expense recognized on a stand-alone basis of $1.6 million.
4. Mustang Bio net loss of $77.5 million net of NCI of $60.8 million, Fortress MSA fee of $1.0 million, and Fortress financing fee and PIK dividend of $0.9 million and $1.1 million, respectively, for the year ended December 31, 2022; and net loss of $66.4 million net of NCI 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.
5. 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, 2022	2021
Research and development[1]	**$ 134,877**	**$ 128,864**
Less:		
Research and development - Avenue[2]	2,388	1,254
Research and development - Checkpoint[3]	47,940	41,855
Research and development - Journey Medical	10,943	16,558
Research and development - Mustang Bio[4]	62,340	51,244
Non-GAAP research and development costs	**$ 11,266**	**$ 17,953**
Selling, general and administrative[5]	**$ 113,656**	**$ 96,384**
Less:		
General and administrative - Avenue[6]	5,045	2,484
General and administrative - Checkpoint[7]	7,782	7,005
Selling, general and administrative - Journey Medical	59,468	49,373
General and administrative - Mustang Bio[8]	10,795	8,883
Non-GAAP selling, general and administrative costs	**$ 30,566**	**$ 28,639**

1. Includes Research and development expense and Research and development - licenses acquired expense for the periods presented.
2. Excludes $42,000 of Fortress MSA expense and $0.3 million PIK dividend payable to

Fortress for the year ended December 31, 2022.

3. Excludes $1.9 million and $6.6 million of PIK dividend payable to Fortress for the year ended December 31, 2022 and 2021, respectively.
4. Excludes $0.5 million of Fortress MSA expense and $1.1 million PIK dividend payable to Fortress for the year ended December 31, 2022; and excludes $0.3 million of Fortress MSA expense and $4.2 million PIK dividend payable to Fortress for the year ended December 31, 2021.
5. Includes Selling, general and administrative expenses and wire transfer fraud loss for the year ended December 31, 2021.
6. Excludes $42,000 of Fortress MSA expense and $0.3 million of Fortress financing fee for the year ended December 31, 2022.
7. Excludes $0.5 million of Fortress MSA expense and $0.4 million Fortress financing fee for the year ended December 31, 2022; and $0.5 million of Fortress MSA expense and $1.0 million Fortress financing fee for the year ended December 31, 2021.
8. Excludes $0.5 million of Fortress MSA expense and $0.9 million Fortress financing fee for the year ended December 31, 2022; and $0.3 million of Fortress MSA expense and $1.9 million Fortress financing fee for the year ended December 31, 2021.

About Fortress Biotech

Fortress Biotech, Inc. (“Fortress”) is an innovative biopharmaceutical company focused on acquiring, developing and commercializing high-potential marketed and development-stage drugs and drug candidates. The company has eight 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, City of Hope, Fred Hutchinson Cancer Center, St. Jude Children’s Research Hospital, Nationwide Children’s Hospital and Sentynl. For more information, visit www.fortressbiotech.com.

Forward-Looking Statements

This press release may contain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. As used below and throughout this press release, the words “we”, “us” and “our” may refer to Fortress individually or together with one or more partner companies, as dictated by context. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs, ability to generate shareholder value, ability of our products to receive necessary approvals, including FDA approval, 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; financing and strategic agreements and relationships; our need for substantial additional funds and uncertainty relating to financings; our ability to identify, acquire, close and integrate product candidates successfully and on a timely basis; our ability to attract, integrate and retain key personnel; the early stage of products under development; 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; the ability to secure and maintain third-party manufacturing, marketing and distribution of our and our partner companies' products and product candidates; 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, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 178,266	$ 305,744
Accounts receivable, net	28,208	23,112
Inventory	14,159	9,862
Other receivables - related party	138	678
Prepaid expenses and other current assets	9,661	7,066
Total current assets	230,432	346,462
Property, plant and equipment, net	13,020	15,066
Operating lease right-of-use asset, net	19,991	19,005
Restricted cash	2,688	2,220
Intangible asset, net	27,197	12,552
Other assets	973	1,198
Total assets	**$ 294,301**	**$ 396,503**

LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 97,446	$ 90,660
Deferred revenue	728	2,611
Income taxes payable	722	345
Common stock warrant liabilities	13,869	—
Operating lease liabilities, short-term	2,447	2,104
Partner company convertible preferred shares, short-term, net	2,052	—
Partner company line of credit	2,948	812
Partner company installment payments - licenses, short-term, net	7,235	4,510
Other short-term liabilities	268	—
Total current liabilities	127,715	101,042
Notes payable, long-term, net	91,730	42,937
Operating lease liabilities, long-term	21,572	20,987
Partner company installment payments - licenses, long-term, net	1,412	3,627
Other long-term liabilities	1,847	2,033
Total liabilities	**244,276**	**170,626**
Commitments and contingencies		
Stockholders' equity		
Cumulative redeemable perpetual preferred stock, $0.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 110,494,245 shares issued and outstanding as of December 31, 2022; 170,000,000 shares authorized, 101,435,505 shares issued and outstanding as of December 31, 2021, respectively	110	101
Additional paid-in-capital	675,841	656,033
Accumulated deficit	(634,233)	(547,463)
Total stockholders' equity attributed to the Company	41,721	108,674
Non-controlling interests	8,304	117,203
Total stockholders' equity	50,025	225,877
Total liabilities and stockholders' equity	**$ 294,301**	**$ 396,503**

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

	Year Ended December 31,	
	2022	**2021**
Revenue		
Product revenue, net	$ 70,995	$ 63,134
Collaboration revenue	1,882	5,389
Revenue - related party	192	268
Other revenue	2,674	—
Net revenue	75,743	68,791
Operating expenses		
Cost of goods sold - product revenue	30,775	32,084
Research and development	134,199	113,240
Research and development - licenses acquired	677	15,625
Selling, general and administrative	113,656	86,843
Wire transfer fraud loss	—	9,540
Total operating expenses	279,307	257,332
Loss from operations	(203,564)	(188,541)

Other income (expense)		
Interest income	1,398	649
Interest expense and financing fee	(13,642)	(15,308)
Foreign exchange loss	(89)	—
Change in fair value of investments	—	39,294
Change in fair value of warrant liabilities	1,129	(447)
Grant income	1,304	—
Total other income (expense)	(9,900)	24,188
Loss before income tax expense	(213,464)	(164,353)
Income tax expense	449	473
Net loss	**(213,913)**	**(164,826)**
Net loss attributable to non-controlling interests	127,338	100,123
Net loss attributable to common stockholders	**$ (86,575)**	**$ (64,703)**
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.97)	$ (0.79)
Weighted average common shares outstanding - basic and diluted	88,874,519	81,700,220

[1] The development programs depicted in this press release include product candidates in development at Fortress, at Fortress' private subsidiaries (referred to herein as "subsidiaries"), at Fortress' public subsidiaries (referred to herein as "partner companies") and at entities with whom one of the foregoing parties has a significant business relationship, such as an exclusive license or an ongoing product-related payment obligation (such entities referred to herein as "partners"). The words "we", "us" and "our" may refer to Fortress individually, to one or more of our subsidiaries and/or partner companies, or to all such entities as a group, as dictated by context.

[2] Information on clinicaltrials.gov does not constitute part of this release.

[3] M. Zanovello et al., Unexpected frequency of the pathogenic*AR*CAG repeat 2 expansion in the general population. Brain, *in press* (2023).

Source: Fortress Biotech, Inc.