

August 14, 2023



Fortress Biotech Reports Second Quarter 2023 Financial Results and Recent Corporate Highlights

Total net revenue was \$17.4 million in the second quarter of 2023, a 40% increase from \$12.4 million in the first quarter of 2023

Positive topline results from two Phase 3 clinical trials evaluating DFD-29 demonstrated achievement of co-primary and all secondary endpoints versus placebo and Oracea® (doxycycline) with no significant safety issues

Fortress is advancing several late-stage clinical assets with two NDA submissions anticipated in the second half of 2023 for DFD-29 and CUTX-101

Cosibelimab longer-term results demonstrated substantial increases in complete response rates in advanced cutaneous squamous cell carcinoma

PDUFA goal date of January 3, 2024, set by FDA for cosibelimab to treat metastatic or locally advanced cutaneous squamous cell carcinoma

MIAMI, Aug. 14, 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 second quarter ended June 30, 2023.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "Fortress, along with our partner companies and subsidiaries, demonstrated meaningful progress in the second quarter of 2023 and subsequent months, including:

- Our revenue numbers remain strong for the second quarter, totaling \$17.4 million, which represents a 40% growth rate over the first quarter of 2023.
- Additionally, we are excited by all of the positive data milestones recently achieved, notably:
 - Positive topline results from our two Phase 3 DFD-29 clinical trials for papulopustular rosacea;
 - Positive data from our Phase 1/2 single center clinical trial of our CAR T cell therapy, MB-106, to treat a wide range of hematologic malignancies;

- Positive data from the Phase 1 dotinurad clinical trial in healthy volunteers in the U.S.;
- Excellent longer-term positive Phase 3 cosibelimab data demonstrating substantial increases in complete response rates in advanced cutaneous squamous cell carcinoma (“cSCC”);
- New pharmacokinetic (“PK”) modeling data for cosibelimab supporting the extension to an every-three-week dosing regimen; and
- Positive preclinical data in the BAER-101 trial supporting a Phase 2 study in epilepsy.
- On the regulatory front:
 - We reached agreement with the U.S. Food and Drug Administration (“FDA”) on key elements of the Phase 3 safety study, including the primary endpoint and statistical analysis approach, for intravenous (“IV”) tramadol, which is in development for the treatment of acute post-operative pain in a medically supervised setting. We believe that a positive study outcome could result in the FDA approval of IV tramadol.
 - By the end of 2023, we expect to have two additional New Drug Applications (“NDA”) on file with the FDA for CUTX-101 and DFD-29.
 - There is a Prescription Drug User Fee Act (“PDUFA”) goal date of January 3, 2024, for cosibelimab to treat metastatic or locally advanced cSCC.”

Dr. Rosenwald continued, “With an expanding portfolio of marketed dermatology products, more than 25 drug candidates across our partner companies, and the potential for multiple FDA approvals over the next two years, we believe that our business is well-positioned for continued growth. Our strategy is focused on targeting exciting clinical-stage medicines with proof-of-concept data in areas of unmet need. Fortress and our partner companies are poised to achieve our collective objective of providing new treatment options to patients in need, while creating significant long-term value for our shareholders through our equity interests and royalties.”

Recent Corporate Highlights¹:

Marketed Dermatology Products and Product Candidates

- Journey Medical Corporation (Nasdaq: DERM) (“Journey Medical”), our partner company, primarily focuses on selling and marketing of prescription dermatology products.
- Journey Medical’s total product net revenues were \$17.0 million for the second quarter of 2023, compared to second quarter 2022 total product net revenues of \$18.2 million, and showed sequential growth compared to \$12.2 million total product net revenues in the first quarter of 2023.
- In July 2023, Journey Medical announced positive topline data from the two DFD-29 (Minocycline Hydrochloride Modified Release Capsules, 40 mg) Phase 3 clinical trials for the treatment of rosacea and achieved the co-primary and all secondary endpoints with subjects completing the 16-week treatment with no significant safety issues. DFD-29 demonstrated statistical superiority compared to both Oracea capsules and placebo for Investigator’s Global Assessment treatment success and the reduction in the total inflammatory lesion count in both studies. Journey Medical plans to file its NDA for DFD-29 in the second half of 2023 and expects potential approval from the FDA in the

second half of 2024.

- In June 2023, Journey Medical announced positive topline data from the Phase 1 clinical trial assessing the impact of DFD-29 on the microbial flora of healthy adults and also evaluated the safety and tolerability of DFD-29. The study achieved all primary objectives and no significant safety issues were noted during the study. The results indicate that DFD-29 can be safely used for up to 16 weeks with no significant risk of microbiota suppression or development of resistance.

Cosibelimab (Anti PD-L1 antibody)

- Our partner company, Checkpoint Therapeutics, Inc. (Nasdaq: CKPT) (“Checkpoint”), submitted a Biologics License Application (“BLA”) to the FDA for cosibelimab, its investigational anti-PD-L1 antibody, as a treatment for patients with metastatic or locally advanced cSCC who are not candidates for curative surgery or radiation, in January 2023. In March 2023, the FDA accepted the BLA filing for cosibelimab and set a 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 patients with cSCC were treated with systemic therapies. As checkpoint inhibitors comprised less than half of U.S. 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 patients with cSCC who are currently underserved by available therapies.
- In July 2023, Checkpoint announced new, longer-term data for cosibelimab from its pivotal studies in locally advanced and metastatic cutaneous squamous cell carcinoma (“cSCC”). These results demonstrate a deepening of response over time, resulting in substantially higher complete response rates than previously reported (55% objective response rate; 23% complete response rate in locally advanced cSCC and 50% objective response rate; 13% complete response rate in metastatic cSCC). Furthermore, responses continue to remain durable over time with the median duration of response not yet reached in either group.
- In June 2023, Checkpoint announced that new PK modeling data on cosibelimab supporting the extension to an every-three-week dosing regimen were presented at the Population Approach Group Europe 2023 annual meeting. Results support comparability of cosibelimab 800 mg every-two-week and 1200 mg every-three-week dosing regimens.
- Cosibelimab was sourced by Fortress and is currently in development at Checkpoint.

Dotinurad (Urate Transporter (URAT1) Inhibitor)

- Dotinurad is in development for the treatment of gout. Data announced in June 2023 from the Phase 1 clinical trial in healthy volunteers showed comparable pharmacokinetic, pharmacodynamic and safety profile between U.S. and Japanese healthy subjects. We plan to initiate a Phase 1b clinical trial in gout patients in the U.S. in the third quarter of 2023 to confirm the comparability of Japanese and U.S. subjects’ response to dotinurad and we expect to begin 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.
- Dotinurad was sourced by Fortress and is currently in development at Urica.

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

- Mustang Bio, Inc.'s (Nasdaq: MBIO) ("Mustang Bio") lead clinical candidate is MB-106, a CD20-targeted, autologous CAR T cell therapy to treat a wide range of hematologic malignancies, including Waldenstrom macroglobulinemia ("WM") and follicular lymphoma ("FL"). MB-106 continues to demonstrate a favorable safety and efficacy profile in both the Fred Hutch single institution and Mustang Bio multicenter Phase 1/2 clinical trials.
- Phase 1/2 data from the WM cohort in the Fred Hutch clinical trial for MB-106 were presented in a poster session at the European Hematology Association Hybrid Congress. All six patients in the WM cohort in the study were previously treated with Bruton's tyrosine kinase inhibitors ("BTKi"), and their disease continued to progress while on BTKis. 83% (5/6) of the WM cohort patients treated with MB-106 responded to treatment, including 2 complete responses ("CR"), 1 very good partial response ("VGPR"), 1 partial response ("PR"), and 1 minor response, with the remaining patient experiencing stable disease. One of the patients who achieved a CR has remained in remission for 22 months. From a safety perspective, cytokine release syndrome ("CRS") occurred in five patients with no grade 3 or 4 CRS observed, and one patient experienced grade 1 immune effector cell-associated neurotoxicity syndrome ("ICANS") with no grade 2, 3 or 4 ICANS observed.
- Fred Hutch also presented MB-106 data from the FL cohort of their clinical trial in an oral presentation at the International Conference on Malignant Lymphoma. A total of 20 patients with relapsed FL with confirmed CD20 expression participated in the study and had day 28 assessment. Median age was 63 years (range: 44 – 81), and median prior lines of treatment was 4 (range: 1 – 12). High-risk features included patients with progression of disease within 24 months of first-line chemoimmunotherapy (POD24) (n=15, 75%), history of histologic transformation (n=4, 20%), prior treatment with a CD19 target CAR T (n=1, 5%). Overall response rate ("ORR") was 95% (19/20), and CR rate was 80% (16/20). Patients who received higher dose levels had an ORR of 100% and a CR rate of 91%. Ten patients are in remission over one year, seven of whom are in remission over two years. One patient, previously treated with a CD19-targeted CAR T-cell therapy, achieved a CR and remains in remission after 18 months. From a safety profile perspective, all CRS events were grade 1 (n=5, 25%) or grade 2 (n=1, 5%), with no grade ≥ 3 CRS events and there was no occurrence of ICANS of any grade.
- In parallel, Mustang Bio's multicenter, open-label, non-randomized Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106 continues to accrue, and Mustang Bio anticipates escalation to the final dose level in the Phase 1 indolent lymphoma arm in the third quarter of this year. The FDA granted Orphan Drug Designation to MB-106 for the treatment of WM, and results from this arm are expected to support an accelerated Phase 2 registration strategy for WM, with the first pivotal Phase 2 patient with WM to be treated potentially in the first quarter of 2024. Mustang Bio plans to report initial safety and efficacy data from the multicenter trial shortly, with additional

safety and efficacy data from the trial expected in the fourth quarter. Finally, Mustang Bio expects to initiate a pivotal phase 2 trial in at least one additional B-cell malignancy later in 2024.

- 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 a pre-specified analysis of the studies, a 79% reduction in the risk of death was observed in patients treated within four weeks of birth, compared with a historical control cohort of untreated patients, and median overall survival (OS) was 177.1 months for CUTX-101 compared to 16.1 months for the 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 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 by the end of 2023.
- Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval of 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
- Based on its public statements, AstraZeneca has estimated that it expects the FDA to accept its BLA submission for review in the second half of 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)

- In June 2023, we announced that the National Cancer Institute awarded a \$3.2 million grant to City of Hope for clinical studies of Triplex, a CMV vaccine being developed by

Helocyte and City of Hope. This competitive award will fund two planned multicenter, placebo-controlled, randomized Phase 2 studies to evaluate the potential safety and immunological response of Triplex and its ability to enhance CMV-specific T cell immunity in stem cell donors to reduce the risk of CMV events in recipients of allogeneic hematopoietic cell transplant.

- 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 that vaccination with Triplex can potentially reduce the dose of highly active antiretroviral therapy treatment required to control HIV, which is used in up to 1.7 million treated patients with HIV.
- 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 multicenter, 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. We believe this data set could ultimately be used to support approval of Triplex in this setting.
- Triplex is currently the subject of three ongoing clinical trials including: pediatric patients undergoing stem cell transplant; adults co-infected with CMV and HIV; and in combination with a CAR T cell therapy for adults with non-Hodgkin lymphoma.
- Triplex was sourced by Fortress and is currently in development at our subsidiary, Helocyte, Inc.

AJ201

- In July 2023, we announced that our partner company, Avenue Therapeutics, Inc. (Nasdaq: ATXI) ("Avenue"), dosed the first patient in a Phase 1b/2a study, which is evaluating AJ201 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 males³. Topline data for the Phase 1b/2a clinical trial of AJ201 in SBMA are expected in the first half of 2024.
- AJ201 was sourced by Fortress and is currently in development at Avenue.

BAER-101

- In August 2023, Avenue reported preclinical results for BAER-101, a potentially best in class GABA-A $\alpha 2,3$ positive allosteric modulator, demonstrating it significantly suppressed seizures in a translational animal model of absence epilepsy. In an *in vivo* evaluation using the SynapCell's Genetic Absence Epilepsy Rat from Strasbourg ("GAERS") model of absence epilepsy, BAER-101 fully suppressed seizure activity with a minimal effective dose of 0.3 mg/kg, PO. The effect was fast in onset and stable throughout the duration of testing. The detailed preclinical results will be presented at an upcoming scientific meeting. The combination of safety and tolerability in hundreds of patients and the preclinical efficacy data support BAER-101's continued development in a Phase 2a trial, which the Company plans to initiate in 2024.
- BAER-101 was sourced by Fortress and is currently in development at Baergic Bio, a subsidiary of Avenue.

IV Tramadol

- In July 2023, Avenue reached an agreement with the FDA on key elements of the Phase 3 safety study, including the primary endpoint and statistical analysis approach, for intravenous (“IV”) tramadol, which is in development for the treatment of acute post-operative pain in a medically supervised setting. The agreed upon non-inferiority study is designed to assess the theoretical risk of opioid-induced respiratory depression related to opioid stacking on IV tramadol compared to IV morphine. Avenue expects to initiate the Phase 3 safety study this year, subject to obtaining the necessary financing which could be provided through a strategic partnership. We expect that a positive study outcome could result in the FDA approval of IV tramadol.
- 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:

- In July 2023, Mustang Bio announced that it amended its previously announced asset purchase agreement with uBriGene (Boston) Biosciences Inc. (“uBriGene”), the U.S. subsidiary of uBriGene Group, a leading cell and gene therapy contract development and manufacturing organization (“CDMO”), and closed the transaction. Per the terms of the amended asset purchase agreement, at closing, uBriGene acquired all of Mustang Bio’s assets primarily relating to the manufacturing and production of cell and gene therapies at Mustang Bio’s state-of-the-art clinical- and commercial-scale cell and gene therapy manufacturing facility in Worcester, Massachusetts, for upfront consideration of \$6 million in cash. An additional \$5 million contingent payment will be payable to Mustang Bio upon (i) Mustang Bio’s raising \$10 million in gross proceeds from equity raises following the closing of the transaction and (ii) completion of the assignment of Mustang Bio’s lease to uBriGene, which remains subject to landlord’s approval, within two years of the closing. Until the lease is transferred to uBriGene, Mustang Bio will retain its facility lease and facility personnel, and will continue to occupy the leasehold premises and manufacture there its lead product candidate, MB-106.
- In April 2023, Aevitas Therapeutics, Inc. (“Aevitas”), Fortress’ subsidiary company, and 4D Molecular Therapeutics (“4DMT”) announced the execution of an asset purchase agreement for 4DMT to acquire Aevitas’ proprietary rights to its short-form human complement factor H (“sCFH”) asset for the treatment of complement-mediated diseases. Under the terms of the agreement, 4DMT will make cash payments to Aevitas totaling up to ~\$140 million in potential late-stage development, regulatory and sales milestones. A range of single-digit royalties on net sales are also payable. The aforementioned payments are payable solely to Aevitas, and 4DMT will be responsible

for license payment obligations to University of Pennsylvania, where the sCFH technology was co-invented and co-developed.

Financial Results:

To assist our stockholders in understanding our company, we have prepared non-GAAP financial metrics for the three months ended June 30, 2023 and 2022. 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 comprise our privately held development-stage entities, as well as our business development and finance functions.

- As of June 30, 2023, Fortress' consolidated cash, cash equivalents and restricted cash totaled \$89.2 million, compared to \$154.9 million as of March 31, 2023 and \$181.0 million as of December 31, 2022, a decrease of \$65.7 million during the quarter and a decrease of \$91.8 million year-to-date.
- On a GAAP basis, Fortress' net revenue totaled \$17.4 million for the second quarter of 2023, which included \$17.0 million in net revenue generated from our marketed dermatology products. This compares to net revenue totaling \$18.9 million for the second quarter of 2022, which included \$18.2 million in net revenue generated from our marketed dermatology products.
- On a GAAP basis, consolidated research and development expenses including license acquisitions were \$32.1 million for the second quarter of 2023, compared to \$33.1 million for the second quarter of 2022. On a non-GAAP basis, Fortress research and development expenses were \$2.7 million for the second quarter of 2023, compared to \$3.3 million for second quarter of 2022.
- On a GAAP basis, consolidated selling, general and administrative expenses were \$24.4 million for the second quarter of 2023, compared to \$29.0 million for the second quarter of 2022. On a non-GAAP basis, Fortress selling, general and administrative expenses were \$6.8 million, for the second quarter of 2023, compared to \$8.5 million for the second quarter of 2022.
- On a GAAP basis, consolidated net loss attributable to common stockholders was \$26.8 million, or \$0.24 per share, for the second quarter of 2023, compared to consolidated net loss attributable to common stockholders of \$23.4 million, or \$0.26 per share for the second quarter of 2022.
- Fortress' non-GAAP loss attributable to common stockholders was \$8.0 million, or \$0.07 per share, for the second quarter of 2023, compared to Fortress' non-GAAP loss attributable to common stockholders of \$10.9 million, or \$0.12 per share, for the second quarter of 2022.

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-Q to be filed on August 14, 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"). 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 debt discount, changes in fair value of derivative liability, loss on deconsolidation of subsidiary, 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:

	For the three months ended June 30,		For the six months ended June 30,	
(\$ in thousands except for share and per share amounts)	2023	2022	2023	2022
Net loss attributable to common stockholders¹	\$ (26,784)	\$ (23,364)	\$ (50,329)	\$ (41,132)
Net loss attributable to common stockholders - Avenue ²	(339)	(354)	(1,361)	(889)
Net loss attributable to common stockholders - Checkpoint ³	(2,441)	(2,596)	(4,208)	(5,520)
Net loss attributable to common stockholders - Journey Medical ⁴	(4,662)	(4,747)	(10,395)	(5,564)
Net loss attributable to common stockholders - Mustang Bio ⁵	(3,276)	(1,374)	(6,550)	(3,916)
Non-GAAP loss attributable to common stockholders	\$ (16,066)	\$ (14,293)	\$ (27,815)	\$ (25,243)
Stock based compensation	2,705	2,884	5,574	5,665
Non-cash interest	391	4	836	8
Amortization of debt discount	970	404	1,454	761
Depreciation	92	98	185	198
Change in fair value of warrant liabilities	512	-	(6,166)	-
Loss on deconsolidation of Aevitas	3,369	-	3,369	-
Fortress non-GAAP loss attributable to common stockholders	\$ (8,027)	\$ (10,903)	\$ (22,563)	\$ (18,611)
Per common share - basic and diluted:				
Net loss attributable to common stockholders (GAAP)	\$ (0.24)	\$ (0.26)	\$ (0.47)	\$ (0.47)
Non-GAAP net loss attributable to common stockholders	\$ (0.15)	\$ (0.16)	\$ (0.26)	\$ (0.29)

Fortress non-GAAP loss attributable to common stockholders	\$	(0.07)	\$	(0.12)	\$	(0.21)	\$	(0.21)
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Weighted average common shares outstanding - basic and diluted	110,659,985	88,743,457	106,297,241	87,593,952
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1. Net loss attributable to common stockholders reflects the Series A Preferred dividends for all periods presented.
2. Avenue net loss for the three months ended June 30, 2023 of \$4.0 million net of non-controlling interest ("NCI") of \$3.5 million, Fortress management services agreement ("MSA") fee of \$0.1 million and financing fee to Fortress of \$0.1 million; net loss for the three months ended June 30, 2022 of \$0.6 million net of NCI of \$0.3 million; net loss for the six months ended June 30, 2023 of \$11.5 million net of NCI of \$9.9 million, Fortress MSA fee of \$0.3 million, and Fortress financing fee of \$0.1 million; and net loss for the six months ended June 30, 2022 of \$3.5 million net of NCI of \$2.6 million.
3. Checkpoint net loss for the three months ended June 30, 2023 of \$16.5 million net of NCI of \$13.6 million, Fortress MSA fee of \$0.1 million and financing fee to Fortress of \$0.4 million; net loss for the three months ended June 30, 2022 of \$14.1 million net of NCI of \$11.4 million, Fortress MSA fee of \$0.1 million; net loss for the six months ended June 30, 2023 of \$27.0 million net of NCI of \$22.0 million, Fortress MSA fee of \$0.3 million, and Fortress financing fee of \$0.6 million; and net loss for the six months ended June 30, 2022 of \$31.0 million net of NCI of \$25.0 million, Fortress MSA fee of \$0.3 million, and Fortress financing fee of \$0.2 million.
4. Journey Medical net loss for the three months ended June 30, 2023 of \$8.4 million net of NCI of \$3.7 million; and net loss for the three months ended June 30, 2022 of \$7.5 million, net of NCI of approximately \$2.8 million and tax benefit recognized on a stand-alone basis of \$0.1 million; and net loss of \$18.5 million net of non-controlling interest of \$8.1 million for the 6 months ended June 30, 2023, and net loss of \$8.9 million net non-controlling interest of \$3.3 million for the six months ended June 30, 2022.
5. Mustang Bio net loss for the three months ended June 30, 2023 of \$16.2 million net of NCI of \$12.8 million, Fortress MSA fee of \$0.1 million; net loss for the three months ended June 30, 2022 of \$19.1 million net of NCI of \$17.4 million; net loss for the six months ended June 30, 2023 of \$32.9 million net of non-controlling interest of \$26.1 million and Fortress MSA fee of \$0.3 million; and net loss for the six months ended June 30, 2022 of \$38.9 million net of NCI of \$31.5 million, Fortress MSA of \$0.5 million and Fortress financing fee of \$0.9 million.

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

	For the three months ended June 30,		For the six months ended June 30,	
(\$ in thousands)	2023	2022	2023	2022
Research and development¹	\$ 32,141	\$ 33,131	\$ 71,647	\$ 69,853
Less:				
Research and development - Avenue ²	2,965	151	8,347	1,959
Research and development - Checkpoint	13,945	12,053	29,771	26,723
Research and development - Journey Medical	1,774	2,609	3,807	3,875
Research and development - Mustang Bio ³	10,773	15,039	24,711	31,203
Non-GAAP research and development costs	\$ 2,684	\$ 3,279	\$ 5,011	\$ 6,093

Selling, general and administrative	\$	24,439	\$	29,048	\$	49,780	\$	55,318
Less:								
General and administrative - Avenue ⁴		761		454		1,683		1,509
General and administrative - Checkpoint ⁵		1,753		1,987		3,764		3,909
Selling, general and administrative - Journey Medical		12,141		15,191		25,433		29,906
General and administrative - Mustang Bio ⁶		2,993		2,876		5,251		5,278
Non-GAAP selling, general and administrative costs	\$	6,791	\$	8,540	\$	13,649	\$	14,716

1. Includes Research and development expense and Research and development - licenses acquired expense for the periods presented.
2. Excludes \$0.1 million of Fortress MSA expense payable to Fortress for the three and six months ended June 30, 2023.
3. Excludes \$0.1 million of Fortress MSA expense for the three months ended June 30, 2023; \$0.1 million of Fortress MSA expense for the three months ended June 30, 2022; \$0.1 million Fortress MSA expense for the six months ended June 30, 2023; and \$0.3 million Fortress MSA expense for the six months ended June 30, 2022.
4. Excludes \$0.1 million of Fortress MSA expense and \$0.1 million financing fee payable to Fortress for the three months ended June 31, 2023 and \$0.3 million of Fortress MSA expense and \$0.1 million financing fee payable to Fortress for the six months ended June 31, 2023.
5. Excludes \$0.1 million of Fortress MSA expense and \$0.4 million Fortress financing fee for the three months ended June 30, 2023; \$0.1 million of Fortress MSA expense for the three months ended June 30, 2022; \$0.3 million Fortress MSA expense and \$0.6 million Fortress financing fee for the six months ended June 30, 2023; and \$0.3 million Fortress MSA expense and \$0.2 million Fortress financing fee for the six months ended June 30, 2022.
6. Excludes \$0.1 million of Fortress MSA expense for the three months ended June 30, 2023; \$0.1 million of Fortress MSA expense and \$0.1 million Fortress financing fee for the three months ended June 30, 2022; \$0.1 million Fortress MSA expense for the six months ended June 30, 2023; and \$0.3 million Fortress MSA expense and \$0.9 million Fortress financing fee for the six months ended June 30, 2022.

About Fortress Biotech

Fortress Biotech, Inc. ("Fortress") is an innovative biopharmaceutical company focused on efficiently acquiring, developing and commercializing or monetizing promising therapeutic products and product candidates. The company has eight marketed prescription pharmaceutical products and over 25 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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Unaudited Condensed Consolidated Balance Sheets
(\$ in thousands except for share and per share amounts)

	June 30, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	\$ 78,022	\$ 178,266
Accounts receivable, net	16,737	28,208
Inventory	12,166	14,159
Other receivables - related party	273	138
Prepaid expenses and other current assets	7,315	9,661
Restricted cash	8,750	—
Assets held for sale	4,348	—
Total current assets	127,611	230,432
Property, plant and equipment, net	7,230	13,020
Operating lease right-of-use asset, net	17,951	19,991
Restricted cash	2,438	2,688
Intangible asset, net	21,916	27,197
Other assets	3,573	973
Total assets	\$ 180,719	\$ 294,301
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued expenses	\$ 99,162	\$ 97,446
Common stock warrant liabilities	9,971	13,869
Operating lease liabilities, short-term	2,329	2,447
Partner company term loan, short-term, net	9,942	—
Partner company convertible preferred shares, short-term, net	3,491	2,052
Partner company line of credit	—	2,948
Partner company installment payments - licenses, short-term, net	2,333	7,235
Other short-term liabilities	1,355	1,718
Total current liabilities	128,583	127,715
Notes payable, long-term, net	45,333	91,730
Operating lease liabilities, long-term	19,502	21,572
Partner company installment payments - licenses, long-term, net	1,490	1,412
Other long-term liabilities	1,754	1,847
Total liabilities	196,662	244,276
Commitments and contingencies		
Stockholders' equity (deficit)		
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 June 30, 2023 and December 31, 2022, respectively, liquidation value of \$25.00 per share	3	3
Common stock, \$0.001 par value, 200,000,000 shares authorized, 131,657,369 and 110,494,245 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	132	110
Common stock issuable, 39,595 and 0 shares as of June 30, 2023 and December 31, 2022	23	—
Additional paid-in-capital	698,897	675,841
Accumulated deficit	(680,546)	(634,233)
Total stockholders' equity attributed to the Company	18,509	41,721
Non-controlling interests	(34,452)	8,304
Total stockholders' equity (deficit)	(15,943)	50,025
Total liabilities and stockholders' equity (deficit)	\$ 180,719	\$ 294,301

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue				
Product revenue, net	\$ 16,961	\$ 18,235	\$ 29,126	\$ 39,031
Collaboration revenue	183	577	364	1,154
Revenue - related party	31	18	66	70
Other revenue	211	56	259	2,556
Net revenue	<u>17,386</u>	<u>18,886</u>	<u>29,815</u>	<u>42,811</u>
Operating expenses				
Cost of goods sold - product revenue	7,767	7,633	14,216	15,836
Research and development	32,139	33,130	67,415	69,852
Research and development - licenses acquired	3	1	4,233	1
Selling, general and administrative	24,439	29,048	49,780	55,318
Asset impairment	3,143	—	3,143	—
Total operating expenses	<u>67,491</u>	<u>69,812</u>	<u>138,787</u>	<u>141,007</u>
Loss from operations	(50,105)	(50,926)	(108,972)	(98,196)
Other income (expense)				
Interest income	715	150	1,751	292
Interest expense and financing fee	(6,425)	(3,154)	(10,721)	(5,504)
Change in fair value of warrant liabilities	(512)	—	6,166	—
Loss from deconsolidation of Aevitas	(3,369)	—	(3,369)	—
Other income	395	—	699	—
Total other expense	<u>(9,196)</u>	<u>(3,004)</u>	<u>(5,474)</u>	<u>(5,212)</u>
Net loss	(59,301)	(53,930)	(114,446)	(103,408)
Net loss attributable to non-controlling interests	<u>34,525</u>	<u>32,574</u>	<u>68,133</u>	<u>66,292</u>
Net loss attributable to Fortress	(24,776)	(21,356)	(46,313)	(37,116)
Preferred A dividends declared and paid	<u>(2,008)</u>	<u>(2,008)</u>	<u>(4,016)</u>	<u>(4,016)</u>
Net loss attributable to common stockholders	\$ (26,784)	\$ (23,364)	\$ (50,329)	\$ (41,132)
Net loss per common share attributable to common stockholders - basic and diluted	\$ (0.24)	\$ (0.26)	\$ (0.47)	\$ (0.47)
Weighted average common shares outstanding - basic and diluted	110,659,985	88,743,457	106,297,241	87,593,952

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 which 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 *ARCAG* repeat 2 expansion in the general population. *Brain*, *in press* (2023).



Source: Fortress Biotech, Inc.