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): **November 14, 2022**

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.)

1111 Kane Concourse, Suite 301
Bay Harbor Islands, FL 33154
(Address of Principal Executive Offices)

(781) 652-4500
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act.

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act.

☐ Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	FBIO	Nasdaq Capital Market
9.375% Series A Cumulative Redeemable Perpetual Preferred Stock	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 November 14, 2022, Fortress Biotech, Inc. issued a press release to announce financial results and recent corporate highlights for the quarter ended September 30, 2022. A copy of such press release is being furnished as Exhibit 99.1 to this report.

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

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit Number	Description
99.1	Press Release issued by Fortress Biotech, Inc., dated November 14, 2022.
104	Cover Page Interactive Data File (the cover page XBRL tags are imbedded in the Inline XBRL document)

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: November 14, 2022

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

Fortress Biotech Reports Third Quarter 2022 Financial Results and Recent Corporate Highlights

Net revenue for the nine months of 2022 increased 17.5% period-over-period to $59.3 million

Cosibelimab BLA submission for metastatic and locally advanced cutaneous squamous cell carcinoma expected to be submitted by January 2023

Miami, FL – November 14, 2022– Fortress Biotech, Inc. (Nasdaq: FBIO) ("Fortress" or "Company"), 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 third quarter ended September 30, 2022.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "Fortress' unique business model continues to provide value-creating events for our shareholders with a 17.5% net revenue increase for the first nine months of 2022, compared to the first nine months of 2021. We, along with our partner companies and subsidiaries, are focused on successfully advancing our 20 clinical-stage programs in 31 ongoing clinical trials, including seven[1] pivotal clinical trials. Additionally, we have eight marketed dermatology products in our portfolio."

Dr. Rosenwald continued, "Urica Therapeutics initiated a Phase 1 clinical trial of dotinurad, which we are developing for the treatment of gout and possibly other hyperuricemic conditions. Our cell and gene therapy partner company, Mustang Bio, announced that the first patient was treated in its multicenter Phase 1/2 clinical trial to evaluate the safety and efficacy of MB-106, a first-in-class CD20-targeted, autologous CAR T cell therapy for the treatment of relapsed or refractory B-cell non-Hodgkin lymphomas ("B-NHL") and chronic lymphocytic leukemia ("CLL"). Additionally, MB-106 data from the ongoing Phase 1/2 clinical trial underway at Fred Hutchinson Cancer Center ("Fred Hutch") continue to demonstrate a high rate of complete, durable responses and a favorable safety profile across a wide range of hematologic malignancies, including a 100% complete response rate in patients with Waldenstrom macroglobulinemia ("WM"), a rare form of B-NHL, for which we were granted Orphan Drug Designation. MB-106 also shows potential to treat patients in an outpatient setting and provides an option for patients treated previously with CD19-targeted CAR T cell therapy."

Dr. Rosenwald concluded, "Looking ahead, we have several near-term milestones planned including the announcement of early results from the Mustang Bio-sponsored Phase 1/2 clinical trial of MB-106 and Checkpoint Therapeutics' planned Biologics License Application ("BLA") submission of cosibelimab for both metastatic and locally advanced cutaneous squamous cell carcinoma indications. In the first half of 2023, we anticipate Phase 1 data from the dotinurad clinical trial and topline data from the two DFD-29 Phase 3 clinical trials for the treatment of papulopustular rosacea. In 2023, we also expect the first data publication of

[1] Includes two trials at Caelum Biosciences; AstraZeneca's Alexion acquired Caelum Biosciences, a company founded by Fortress, on 10/5/2021 for up to $500 million, including $150 million upfront and up to $350 million in future contingent milestone payments. Fortress received ~$56.9 million of such upfront amount and is eligible to receive ~42% of the proceeds from all future milestone payments.

Mustang's novel *in vivo* CAR T platform technology which has the potential to transform oncology therapy through our collaboration with the Mayo Clinic. Additionally, in 2023, we expect to complete the rolling submission of the New Drug Application ("NDA") for CUTX-101 for the treatment of Menkes disease. We believe this ongoing progress shows the efficiency of Fortress' model and its ability to advance potentially meaningful treatments while continuing to build long-term value for our shareholders."

Recent Corporate Highlights[2]:

Marketed Dermatology Products and Product Candidates

- Journey Medical Corporation ("Journey Medical"), a Fortress partner company, currently has eight marketed prescription dermatology products.
- Journey Medical generated total revenue of $57.7 million for the first nine months of 2022, compared to total revenue of $45.6 million for the first nine months of 2021; Journey Medical generated total revenue of $16.1 million in the third quarter of 2022, compared to total revenue of $19.6 million in the third quarter of 2021.
- To date, Journey Medical has achieved 75% enrollment in the Phase 3 clinical program of DFD-29 for the treatment of papulopustular rosacea. Topline data are anticipated in the first half of 2023 with a New Drug Application ("NDA") filing expected in the second half of 2023.
- In August 2022, an additional $5.0 million was drawn from Journey Medical's term loan facility with East West Bank as part of the operating plan for additional working capital.
- Journey Medical intends to launch an additional prescription product in the coming months.

Cosibelimab (Anti-PD-L1 Antibody for Solid Tumors)

- In July 2022, Checkpoint Therapeutics, Inc. ("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 planned BLA submission by January 2023 will include both the metastatic and locally advanced cutaneous squamous cell carcinoma indications. Checkpoint also reached agreement with the FDA on all key aspects discussed regarding the content of the upcoming BLA submission.
- Cosibelimab was sourced by Fortress and is currently in development at our partner company, Checkpoint.

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

- In October 2022, we announced that the first patient was treated in Mustang Bio, Inc.'s ("Mustang Bio") multicenter, open-label, non-randomized Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106, Mustang Bio's first-in-class CD20-targeted, autologous CAR T cell therapy for the treatment of relapsed or refractory B-NHL and CLL.
- Also in October 2022, we announced that results from the WM cohort and other interim data from the ongoing Phase 1/2 clinical trial of MB-106 at Fred Hutch were presented at the 11th International Workshop for Waldenstrom's Macroglobulinemia that took place in Madrid, Spain. Mustang Bio's MB-106 program was granted Orphan Drug Designation by the FDA for WM, and Mustang plans to treat additional WM patients in the Mustang Bio-sponsored Phase 1 portion of its multicenter trial in order to potentially support an accelerated Phase 2 strategy for this indication.
- Additionally, in October 2022, we shared interim data from 28 patients treated in the initial, ongoing Phase 1/2 investigator-sponsored clinical trial at Fred Hutch. These data continue to support MB-106 as a viable CAR T cell therapy for B-NHLs and CLL. An overall response rate of 96% and complete

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[2] Includes product candidates in development at Fortress, majority-owned and controlled partners and/or subsidiaries, and partners and/or subsidiaries in which Fortress holds significant minority ownership positions. As used herein, the words "we", "us" and "our" may refer to Fortress individually or together with our affiliates, subsidiaries and partners, and the word "partner" refers to either entities that are publicly traded and in which we own or control a majority of the ownership position or third-party entities with whom we have a significant business relationship, each as dictated by context.

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 (“PR”) at 28 days post-treatment improved to CR, presumably due to the demonstrated persistence of CAR T cells in these patients, 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.

- MB-106 continues to generate compelling safety and efficacy data and the CD20 CAR T’s product profile is favorable compared to the approved autologous 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.
- Early results from the Mustang Bio-sponsored multicenter MB-106 trial are expected to be announced later this quarter.
- MB-106 was sourced by Fortress and is currently in development at our partner company, Mustang Bio.

CUTX-101 (Copper Histidinate for Menkes disease)

- In December 2021, Cyprium Therapeutics, Inc. (“Cyprium”) initiated the rolling submission of an NDA to the FDA for CUTX-101. The rolling submission of the NDA for CUTX-101 is ongoing and is expected to be completed in 2023.
- Cyprium is currently in a dispute with its contract manufacturing organization (the “CMO”), regarding the CMO’s attempt to terminate a Master Services Agreement (together with related work orders, the “MSA”) between Cyprium and the CMO. Cyprium believes the CMO’s grounds for purporting to terminate the MSA are without merit and is currently availing itself of all appropriate legal remedies in efforts to ensure that the CMO abides by its obligations under the MSA and/or to pursue monetary damages claims against the CMO. To that end, Cyprium obtained a temporary restraining order in August 2022 and a preliminary injunction in September 2022 from a court in New York State; the injunction enjoined the CMO from terminating the MSA and prohibited the CMO from further attempts to terminate the MSA during the pendency of dispute resolution procedures.
- CUTX-101 was sourced by Fortress and is currently in development at our subsidiary company, Cyprium.

IV Tramadol

- In September 2022, Avenue Therapeutics, Inc. (“Avenue”) received the official meeting minutes from the FDA regarding a meeting conducted on August 9, 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 intends to incorporate the FDA’s suggestions from the meeting minutes and submit 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.
- IV Tramadol was sourced by Fortress and is currently in development at our partner company, Avenue.

Triplex (Cytomegalovirus (“CMV”) Vaccine)

- In August 2022, we announced that Triplex received a grant from the National Institute of Allergy and Infectious Diseases of the National Institutes of Health that could provide over $20 million in non-dilutive funding. This competitive award will fund a multi-center, placebo-controlled, randomized Phase 2 study of Triplex for control of CMV in patients undergoing liver transplantation. The company believes this data set could ultimately be used to support approval of Triplex in this setting.

- Triplex is currently the subject of five ongoing trials, funded by non-dilutive sources, in various clinical settings including: CMV control in stem cell and solid organ transplantation; the treatment of HIV; and in combination with a CAR T cell therapy for the treatment of NHL.
- Triplex was sourced by Fortress and is currently in development at our subsidiary company, Helocyte, Inc.

Dotinurad (Urate Transporter (URAT1) Inhibitor)

- In June 2022, we 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 early 2023.
- 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, our subsidiary company, Urica Therapeutics, Inc. ("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.
- Dotinurad was sourced by Fortress and is currently in development at Urica.

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

- On October 5, 2021, AstraZeneca plc 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).
- CAEL-101 was sourced by Fortress and was developed by Caelum (founded by Fortress) until its acquisition by AstraZeneca in October 2021.

MB-110 (Lentiviral Gene Therapy for RAG1 Severe Combined Immunodeficiency (RAG1-SCID))

- In July 2022, we announced that the first patient successfully received LV-RAG1 *ex vivo* lentiviral gene therapy to treat recombinase-activating gene-1 ("RAG1") severe combined immunodeficiency ("RAG1-SCID") in an ongoing Phase 1/2 multicenter clinical trial taking place in Europe. LV-RAG1 is exclusively licensed by Mustang Bio for the development of MB-110, a first-in-class *ex vivo* lentiviral gene therapy for the treatment of RAG1-SCID.
- MB-110 was sourced by Fortress and is currently in development at our partner company, Mustang Bio.

General Corporate:

- 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 September 2022, Avenue effected a 1-for-15 reverse stock split to bring the company in compliance with the minimum bid price listing requirements of The Nasdaq Capital Market.
- In October 2022, Avenue closed a $12 million underwritten public offering. Avenue received net proceeds of approximately $10.4 million at closing after deducting underwriting discounts and commissions and other expenses of the offering.
- Fortress' Board of Directors declared the regular monthly dividend of $0.1953125 per share of the Company's 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock (the "Series A Preferred Stock") for the months of October, November and December 2022. The dividend will be payable on the last day of each month (October 31, November 30 and December 31) to holders of record as of the close of business on the fifteenth of that same month (October 15, November 15, December 15). Dividends will be paid in cash. Going forward, future notifications related to dividends for the Series A Preferred Stock will be disclosed on the Fortress website in the Investors section on the FBIOP Announcements page under Resources, https://www.fortressbiotech.com/investors/resources/fbiop-announcements. In addition, investors will also be able to find Form 8937s related to FBIOP on the same page.
- On October 31, 2022, Fortress received a letter from the Listing Qualifications Staff of Nasdaq indicating that the bid price of the Company's common stock had closed below $1.00 per share for 30 consecutive business days and, as a result, Fortress is not in compliance with Nasdaq minimum bid price requirement. Nasdaq's notice has no immediate effect on the listing of the common stock on Nasdaq. The Company intends to closely monitor the closing bid price of the Common Stock and consider all available options to remedy the bid price deficiency, but no decision regarding any action has yet been made.
- In November 2022, Avenue announced the completion of the acquisition of Baergic Bio, Inc. from Fortress, pursuant to a Share Contribution Agreement.
- Also in November 2022, holders of a majority of the voting power of the capital stock of Checkpoint approved a 1-for-10 reverse stock split of Checkpoint's common stock. Checkpoint expects its common shares will begin trading on a split-adjusted basis on The Nasdaq Capital Market in December 2022. The Board of Directors determined the 1-for-10 ratio to be appropriate in order to improve the marketability and liquidity of Checkpoint's common stock and to remain in compliance with all of Nasdaq's continued listing requirements.

Financial Results:

To assist our stockholders in understanding our company, we have prepared non-GAAP financial results for the three months ended September 30, 2022 and 2021. These results 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. See "Use of Non-GAAP Measures" below.

- As of September 30, 2022, Fortress' consolidated cash, cash equivalents and restricted cash totaled $210.6 million[3], compared to $251.0 million[4] as of June 30, 2022 and $308.0 million as of December 31, 2021, a decrease of $40.4 million during the prior quarter and a decrease of $97.4 million year-to-date.
- On a GAAP basis, Fortress' net revenue totaled $16.5 million for the third quarter of 2022, which included $16.0 million in net revenue generated from our marketed dermatology products. This compares to net revenue totaling $21.1 million for the third quarter of 2021, which included $19.6 million in net revenue generated from our marketed dermatology products.
- On a GAAP basis, consolidated research and development expenses including license acquisitions were $29.9 million for the third quarter of 2022, compared to $28.1 million for the third quarter of 2021. On a non-GAAP basis, Fortress research and development expenses were $2.7 million for the third quarter of 2022, compared to $3.0 million for third quarter of 2021.
- On a GAAP basis, consolidated selling, general and administrative expenses were $30.1 million for the third quarter of 2022, compared to $22.2 million for the third quarter of 2021. On a non-GAAP basis, Fortress selling, general and administrative expenses were $9.2 million, for the third quarter of 2022, compared to $6.9 million for the third quarter of 2021.
- On a GAAP basis, consolidated net loss attributable to common stockholderswas $(22.5) million, or $(0.25) per share, for the third quarter of 2022, compared to consolidated net loss attributable to common stockholders of $(20.8) million, or $(0.26) per share for the third quarter of 2021.
- Fortress' non-GAAP loss attributable to common stockholderswas $(7.4) million, or $(0.08) per share, for the third quarter of 2022, compared to Fortress' non-GAAP income attributable to common stockholders of $48.7 million, or $0.60 per share, for the third quarter of 2021.

Use of Non-GAAP Measures:
In addition to the GAAP financial measures as presented in this press release and that will be presented in our Form 10-Q for the third quarter of 2022 to be filed with the Securities and Exchange Commission ("SEC"), 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 expenses including license acquisitions, defined as GAAP research and development costs, less research and development costs of our public partner companies and non-GAAP consolidated selling, general and administrative expenses, defined as GAAP selling, general and administrative expenses, 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

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[3] At September 30, 2022, we had cash and cash equivalents of $208.4 million, of which $61.2 million relates to Fortress and the private partner companies, primarily funded by Fortress, $20.5 million relates to Checkpoint, $91.4 million relates to Mustang Bio, $34.9 million relates to Journey Medical, and $0.2 million relates to Avenue. Restricted cash related to our leases was $2.2 million, of which $1.2 million relates to Fortress and $1.0 million relates to Mustang Bio.

[4] At June 30, 2022, we had cash and cash equivalents of $248.8 million, of which $71.5 million relates to Fortress and the private partner companies, primarily funded by Fortress, $30.9 million relates to Checkpoint, $107.4 million relates to Mustang Bio, $38.1 million relates to Journey Medical, and $0.9 million relates to Avenue. Restricted cash related to our leases was $2.2 million, of which $1.2 million relates to Fortress and $1.0 million relates to Mustang Bio.

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 three months ended September 30, 2,022	2021[1]	For the nine months ended September 30, 2022	2021[1]
Net loss attributable to common stockholders	$ (22,511)	$ (20,781)	$ (59,627)	$ (33,138)
Net loss attributable to common stockholders - Avenue [2]	(254)	(196)	(1,143)	(636)
Net loss attributable to common stockholders - Checkpoint [3]	(1,900)	(2,126)	(7,420)	(4,995)
Net loss attributable to common stockholders - Journey Medical [4]	(6,017)	(12,863)	(11,581)	(26,605)
Net loss attributable to common stockholders - Mustang Bio [5]	(2,365)	(3,085)	(6,281)	(8,499)
Non-GAAP (loss) income attributable to common stockholders	$ (11,975)	$ (2,511)	$ (33,202)	$ 7,597
Stock based compensation	4,096	2,587	9,763	7,363
Non-cash interest	4	14	12	37
Amortization of debt discount	364	72	1,125	975
Depreciation	93	78	291	356
Increase in fair value of investment in Caelum [6]	-	(8,376)	-	(39,294)
Realization in Caelum investment[6]	-	56,860	-	56,860
Fortress non-GAAP (loss) income attributable to common stockholders	$ (7,418)	$ 48,724	$ (22,011)	$ 33,894
Per common share - basic and diluted:				
Net loss attributable to common stockholders (GAAP)	$ (0.25)	$ (0.26)	$ (0.68)	$ (0.41)
Non-GAAP net loss attributable to common stockholders	$ (0.13)	$ (0.03)	$ (0.38)	$ 0.09
Fortress non-GAAP loss attributable to common stockholders	$ (0.08)	$ 0.60	$ (0.25)	$ 0.42
Weighted average common shares outstanding - basic and diluted	89,424,947	81,348,243	88,291,970	81,056,165

1. Results for the three and nine months ended September 30, 2021 have been adjusted to present Journey Medical separately as a public entity.
2. Avenue net loss for the three months ended September 30, 2022 and 2021 of $0.6 million and $0.9 million, respectively, net of non-controlling interest of $0.4 million and $0.7 million, respectively. Avenue net loss for the nine months ended September 30, 2022 and 2021 of $4.1 million and $2.8 million, respectively, net of non-controlling interest of $3.0 million and $2.2 million, respectively.
3. Checkpoint net loss of $10.6 million net of non-controlling interest of $8.6 million, Fortress management services agreement ("MSA") fee of $0.1 million, and Fortress financing fee of approximately $26,000 for the three months ended September 30, 2022; and net loss of $11.3 million net of non-controlling interest of $9.0 million, Fortress MSA fee of $0.1 million, and Fortress financing fee of approximately $39,000 for the three months ended September 30, 2021; net loss of $41.6 million net of non-controlling interest of $33.6 million, Fortress MSA fee of $0.4 million, and Fortress financing fee of $0.2 million for the nine months ended September 30, 2022; and net loss of $26.9 million net of non-controlling interest of $20.6 million, Fortress MSA fee of $0.4 million, and Fortress financing fee of $0.9 million for the nine months ended September 30, 2021.
4. Journey Medical net loss for the three months ended September 30, 2022 of $10.1 million net of non-controlling interest of $4.1 million and tax benefit recognized on a stand-alone basis of $10,000; and net loss for the three months ended September 30, 2021 of $10.6 million, net non-controlling interest of approximately $1.2 million and tax benefit recognized on a stand-alone basis of $3.4 million; and net loss of $19.0 million net of non-controlling interest of $7.4 million and tax expense recognized on a stand-alone

basis of $50,000 for the 9 months ended September 30, 2022, and net loss of $22.2 million net non-controlling interest of $2.3 million and tax benefit recognized on a stand-alone basis of $6.7 million for the nine months ended September 30, 2021.

5. Mustang Bio net loss of $19.0 million net of non-controlling interest of $16.4 million, Fortress MSA fee of $0.3 million and Fortress financing fee of $18,000 for the three months ended September 30, 2022; and net loss of $17.0 million net of non-controlling interest of $13.7 million, Fortress MSA fee of $0.1 million and Fortress financing fee of $0.1 million for the three months ended September 30, 2021; and net loss of $57.9 million net of non-controlling interest of $49.9 million, Fortress MSA fee of $0.8 million and Fortress financing fee of $0.9 million for the nine months ended September 30, 2022; and net loss of $46.3 million net of non-controlling interest of $35.8 million, Fortress financing fee of $0.4 million and Fortress financing fee of $1.7 million for the nine month period ended September 30, 2021.
6. On October 5, 2021, AstraZeneca plc (acquiror of Alexion) purchased 100% of our partner company Caelum Biosciences, Inc. ("Caelum") for approximately $150 million upfront and up to $350 million in contingent regulatory and sales milestone payments.

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

($ in thousands)	For the quarter ended September 30, 2022	For the quarter ended September 30, 2021[1]	For the nine months ended September 30, 2022	For the nine months ended September 30, 2021[1]
Research and development[2]	**$ 29,903**	**$ 28,080**	$ 99,755	**$ 85,811**
Less:				
Research and development - Avenue	194	278	2,153	864
Research and development - Checkpoint	8,866	9,384	35,589	20,795
Research and development - Journey Medical	2,812	794	6,687	14,566
Research and development - Mustang Bio[3]	15,334	14,651	46,537	38,046
Non-GAAP research and development costs	**$ 2,697**	**$ 2,973**	$ 8,789	**$ 11,540**
Selling, general and administrative	**$ 30,139**	**$ 22,221**	$ 85,457	**$ 59,145**
Less:				
General and administrative - Avenue	469	594	1,978	1,960
General and administrative - Checkpoint[4]	1,695	1,759	5,604	5,109
Selling, general and administrative - Journey Medical	15,575	10,755	45,481	24,776
General and administrative - Mustang Bio[5]	3,246	2,226	8,524	6,522
Non-GAAP selling, general and administrative costs	**$ 9,154**	**$ 6,887**	$ 23,870	**$ 20,778**

1. Results for the three and nine months ended September 30, 2021 have been adjusted to present Journey Medical separately as a public entity.

2. Includes Research and development expense and Research and development - licenses acquired expense for the periods presented.

3. Excludes $0.1 million of Fortress MSA expense for the three months ended September 30, 2022 and 2021; $0.4 million of Fortress MSA expense for the nine months ended September 30, 2022, and $0.2 million of Fortress MSA for the nine months ended September 30, 2021.

4. Excludes $0.1 million of Fortress MSA expense and $26,000 Fortress financing fee for the three months ended September 30, 2022; and $0.1 million of Fortress MSA expense and $39,000 Fortress financing fee for the three months ended September 30, 2021; and excludes $0.4 million Fortress MSA expense and $0.2 million Fortress financing fee for the nine months ended September 30, 2022, and $0.4 million Fortress MSA expense and $0.9 million Fortress financing fee for the nine months ended September 30, 2021.

5. Excludes $0.1 million of Fortress MSA expense and $18,000 Fortress financing fee for the three months ended September 30, 2022; and $0.1 million of Fortress MSA expense and $0.1 million Fortress financing fee for the three months ended September 30, 2021; and excludes $0.4 million of Fortress MSA expense

and $0.9 million Fortress financing fee for the nine months ended September 30, 2022; and $0.2 million of Fortress MSA expense and $1.7 million Fortress financing fee for the nine months ended September 30, 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 plc, City of Hope, Fred Hutchinson Cancer Research Center, St. Jude Children's Research Hospital, Nationwide Children's Hospital and Sentynl Therapeutics, Inc. For more information, visit www.fortressbiotech.com.

Forward-Looking Statements

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. As used below and throughout this press release, the words "we", "us" and "our" may refer to Fortress individually or together with one or more partner companies, as dictated by context. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs, ability to generate shareholder value, ability of our products to receive necessary approvals, including FDA, ability of our products and therapies to help treat patients and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; risks relating to the timing of starting and completing clinical trials, including disruptions that may result from hostilities in Europe; our dependence on third-party suppliers; risks relating to the COVID-19 outbreak and its potential impact on our employees' and consultants' ability to complete work in a timely manner and on our ability to obtain additional financing on favorable terms or at all; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; our compliance with applicable Nasdaq listing standards; 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.

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

	September 30, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 208,351	$ 305,744
Accounts receivable, net	28,533	23,112
Inventory	15,230	9,862
Other receivables - related party	153	678
Prepaid expenses and other current assets	5,727	7,066
Total current assets	257,994	346,462
Property, plant and equipment, net	13,773	15,066
Operating lease right-of-use asset, net	19,756	19,005
Restricted cash	2,220	2,220
Intangible asset, net	28,424	12,552
Other assets	1,394	1,198
Total assets	**$ 323,561**	**$ 396,503**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 93,817	$ 90,660
Deferred revenue	1,093	2,611
Income taxes payable	—	345
Operating lease liabilities, short-term	2,271	2,104
Partner company line of credit	—	812
Partner company installment payments - licenses, short-term, net	9,122	4,510
Total current liabilities	106,303	101,042
Notes payable, long-term, net	91,165	42,937
Operating lease liabilities, long-term	21,474	20,987
Partner company installment payments - licenses, long-term, net	1,374	3,627
Other long-term liabilities	1,893	2,033
Total liabilities	**222,209**	**170,626**
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 September 30, 2022 and December 31, 2021, respectively, liquidation value of $25.00 per share	3	3
Common stock, $0.001 par value, 200,000,000 shares authorized, 108,259,353 shares issued and outstanding as of September 30, 2022; 170,000,000 shares authorized, 101,435,505 shares issued and outstanding as of December 31, 2021, respectively	108	101
Additional paid-in-capital	668,650	656,033
Accumulated deficit	(607,090)	(547,463)
Total stockholders' equity attributed to the Company	61,671	108,674
Non-controlling interests	39,681	117,203
Total stockholders' equity	101,352	225,877
Total liabilities and stockholders' equity	**$ 323,561**	**$ 396,503**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue				
Product revenue, net	$ 16,043	$ 19,610	$ 55,074	$ 45,617
Collaboration revenue	364	1,446	1,518	4,646
Revenue - related party	48	29	118	252
Other revenue	73	—	2,629	—
Net revenue	16,528	21,085	59,339	50,515
Operating expenses				
Cost of goods sold - product revenue	7,221	11,167	23,057	22,559
Research and development	29,855	27,367	99,707	70,226
Research and development - licenses acquired	47	713	48	15,585
Selling, general and administrative	30,139	22,221	85,457	59,145
Wire transfer fraud loss	—	9,540	—	9,540
Total operating expenses	67,262	71,008	208,269	177,055
Loss from operations	(50,734)	(49,923)	(148,930)	(126,540)
Other income (expense)				
Interest income	419	132	711	505
Interest expense and financing fee	(3,393)	(4,444)	(8,897)	(9,393)
Foreign exchange loss	(21)	—	(21)	—
Change in fair value of investments	—	8,376	—	39,294
Change in fair value of derivative liability	—	(2)	—	(184)
Grant income	669	—	669	—
Total other income (expense)	(2,326)	4,062	(7,538)	30,222
Net loss	**(53,060)**	**(45,861)**	**(156,468)**	**(96,318)**
Net loss attributable to non-controlling interests	30,549	25,080	96,841	63,180
Net loss attributable to common stockholders	**$ (22,511)**	**$ (20,781)**	**$ (59,627)**	**$ (33,138)**
Net loss per common share - basic and diluted	$ (0.59)	$ (0.56)	$ (1.77)	$ (1.19)
Net loss per common share attributable to non - controlling interests - basic and diluted	$ (0.34)	$ (0.31)	$ (1.10)	$ (0.78)
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.25)	$ (0.26)	$ (0.68)	$ (0.41)
Weighted average common shares outstanding - basic and diluted	89,424,947	81,348,243	88,291,970	81,056,165