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 15, 2021**

Fortress Biotech, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-35366**	**20-5157386**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(Address of Principal Executive Offices)

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

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

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

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	FBIO	Nasdaq Capital Market
9.375% Series A Cumulative Redeemable Perpetual Preferred Stock	FBIOP	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 15, 2021, Fortress Biotech, Inc. issued a press release to announce financial results and recent corporate highlights for the quarter ended September 30, 2021. A copy of such press release is being furnished as Exhibit 99.1 to this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit Number	Description
99.1	Press Release issued by Fortress Biotech, Inc., dated November 15, 2021.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Fortress Biotech, Inc.
(Registrant)

Date: November 15, 2021

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

Exhibit 99.1

Fortress Biotech Reports Record Third Quarter 2021 Financial Results and Recent Corporate Highlights

Net revenue for third quarter of 2021 increased 123% year-over-year to $21.1 million, a quarterly record

Journey Medical Corporation, a Fortress partner company, launched its $35.2 million initial public offering

AstraZeneca acquired Caelum Biosciences; Fortress received $56.9 million upfront[1]

Rolling NDA submission for CUTX-101 for the treatment of Menkes disease is expected to be initiated in the fourth quarter of 2021

Top-line results from registration-enabling study of cosibelimab in metastatic cutaneous squamous cell carcinoma expected around year-end 2021

New York, NY – November 15, 2021 – Fortress Biotech, Inc. (NASDAQ: FBIO) ("Fortress"), an innovative biopharmaceutical company focused on acquiring, developing and commercializing or monetizing promising biopharmaceutical products and product candidates cost-effectively, today announced financial results and recent corporate highlights for the third quarter ended September 30, 2021.

Lindsay A. Rosenwald, M.D., Fortress' Chairman and Chief Executive Officer, said, "Fortress and our partner companies continue to achieve significant clinical and corporate milestones as we develop new treatment options for patients in need and create long-term value for our shareholders. We attained a new quarterly record for net revenue, $21.1 million, which is an increase of 123% year-over-year. Journey Medical Corporation ("Journey"), our partner company, launched its initial public offering ("IPO") of 3,520,000 shares at $10.00 per share for gross proceeds of $35.2 million. Additionally, AstraZeneca's Alexion acquired Caelum Biosciences, Inc. ("Caelum") a company founded by Fortress, for an upfront payment of approximately $150 million paid to Caelum shareholders, of which approximately $56.9 million was paid to Fortress.[1] The agreement also provides for additional contingent payments to Caelum stockholders totaling up to $350 million, payable upon the achievement of regulatory and commercial milestones. Fortress is eligible to receive 42.4% of all proceeds from the transaction, totaling up to approximately $212 million. Our CAR T cell therapy portfolio continues to advance, with a $2 million grant awarded by the National Cancer Institute ("NCI") to partially fund our Mustang Bio, Inc. ("Mustang Bio")-sponsored Phase 1/2 trial of MB-106, a CD20-targeted, autologous CAR T cell therapy for patients with relapsed or refractory B-cell non-Hodgkin lymphomas ("NHL") or chronic lymphocytic leukemia ("CLL"). Finally, we announced positive data from two completed pivotal studies in patients with Menkes disease treated with CUTX-101 at the 2021 American Academy of Pediatrics National Conference & Exhibition."

Dr. Rosenwald continued, "Looking ahead, we anticipate continued regulatory and clinical progress including initiating the rolling submission of the new drug application ("NDA") for CUTX-101 for the treatment of Menkes disease to the U.S. Food and Drug Administration ("FDA") later this quarter and reporting top-line results from the registration-enabling study of cosibelimab in metastatic cutaneous squamous cell carcinoma around year-end. We also look forward to the upcoming data presentations of MB-106 and AL amyloidosis treatment CAEL-101 at the American Society of Hematology Annual Meeting ("ASH2021")."

[1] In each case, figures are net of miscellaneous transcation expenses and a 10% holdback for an indemnification escrow.

Recent Corporate Highlights[2]:

Marketed Dermatology Products and Product Candidates

- Journey, our partner company, markets seven prescription dermatology products.
- Our products generated net revenues of $19.6 million for the third quarter of 2021, compared to net revenues of $9.4 million for the third quarter of 2020.
- In July 2021, Journey completed its final closings under the Cumulative Convertible Class A Preferred Stock Offering (the "Preferred Offering"), issuing an aggregate of 758,680 preferred shares at a price of $25.00 per share, raising approximately $19.0 million in gross proceeds, and after deducting commissions, fees and expenses, receiving approximately $17.0 million in net proceeds. These shares converted into Journey common stock upon the IPO.
- On November 12, 2021, Journey launched its IPO of 3,520,000 shares of its common stock at $10.00 per share, totaling $35.2 million in gross proceeds, and, after deducting underwriting discounts, and estimated fees and expenses, is expected to receive approximately $31.4 million in net proceeds. Journey Medical's common stock began trading on the Nasdaq Capital Market on November 12, 2021, under the ticker symbol "DERM." The IPO is expected to close on November 16, 2021, subject to customary closing conditions.
- Journey intends to initiate the Phase 3 clinical program for DFD-29 for the treatment of rosacea in the fourth quarter of 2021.
- Journey intends to launch one additional prescription product in the first half of 2022.

CUTX-101 (Copper Histidinate for Menkes disease)

- We expect to initiate the rolling submission of the NDA, under its Breakthrough Designation, for CUTX-101 to the FDA this quarter.
- In October 2021, we announced positive results from an efficacy and safety analysis of data integrated from two completed pivotal studies in patients with Menkes disease treated with CUTX-101, copper histidinate (CuHis). These data were presented as a virtual poster at the 2021 American Academy of Pediatrics National Conference & Exhibition.
- CUTX-101 was sourced by Fortress and is currently in development at our partner company, Cyprium Therapeutics, Inc.

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

- On October 5, 2021, AstraZeneca's Alexion acquired Caelum, a company founded by Fortress, for an upfront payment of approximately $150 million paid to Caelum shareholders, of which approximately $56.9 million was paid to Fortress, net of the ten percent, 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 proceeds of the transaction, totaling up to approximately $212 million.

- CAEL-101 data were selected for presentation at ASH2021 scheduled to take place in December of 2021. Abstracts can be viewed online through the ASH2021 website here.
- There are two ongoing Phase 3 studies of CAEL-101 for AL amyloidosis.
- CAEL-101 was sourced by Fortress in 2017 and was developed by Caelum until Caelum was acquired by AstraZeneca on October 5, 2021.

[2] Includes product candidates in development at Fortress, majority-owned and controlled partners and partners in which Fortress holds significant minority ownership positions. As used herein, the words "we", "us" and "our" may refer to Fortress individually or together with our affiliates and partners, as dictated by context.

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

- The registration-enabling study in metastatic cutaneous squamous cell carcinoma is fully enrolled, and we are on track to report top-line results around year-end 2021. Upon a successful outcome, Checkpoint Therapeutics, Inc. ("Checkpoint") intends to submit a Biologics License Application ("BLA")
- for cosibelimab in 2022, followed shortly thereafter by a Marketing Authorization Application submission in Europe. With a potentially favorable safety profile versus anti-PD-1 therapy and a plan to commercialize at a substantially lower price, we believe cosibelimab has the potential to be a market disruptive product in the $25 billion and growing PD-(L)1 class.
- A Phase 3 registration-enabling trial is planned to begin in first-line metastatic non-small cell lung cancer ("NSCLC") in the fourth quarter of 2021.
- Cosibelimab was sourced by Fortress and is currently in development at our partner company, Checkpoint.

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

- In November 2021, we announced that MB-106 data were selected for presentation at ASH2021 scheduled to take place in December 2021. Dr. Mazyar Shadman of Fred Hutchinson Cancer Research Center will present updated interim data from the ongoing Phase 1/2 clinical trial for NHL and CLL. A copy of the abstract can be viewed online through the ASH2021 website here.
- Also in November 2021, we announced that Mustang Bio was awarded a grant of approximately $2 million from NCI of the National Institutes of Health. This two-year award will partially fund the Mustang-sponsored multicenter trial to assess the safety, tolerability and efficacy of MB-106, a CD20-targeted, autologous CAR T cell therapy for patients with relapsed or refractory B-cell NHL or CLL.
- MB-106 was sourced by Fortress and is currently in development at our partner company, Mustang Bio.

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

- In October 2021, Christine Brown, Ph.D., Deputy Director, T Cell Therapeutics Research Laboratory and The Heritage Provider Network Professor in Immunotherapy at City of Hope, presented updated Phase 1 clinical data regarding MB-101 (IL13Rα2-targeted CAR T cells) for the treatment of glioblastoma at two scientific conferences, the First Annual Conference on CNS Clinical Trials, co-sponsored by the Society for Neuro-Oncology and American Society of Clinical Oncology and the American Association for Cancer Research Virtual Special Conference: Brain Cancer.
- MB-101 was sourced by Fortress and is currently in development at our partner company, Mustang Bio.

Novel CAR T Technology

- In August 2021, we announced an exclusive license agreement with Mayo Clinic for a novel technology to create *in vivo* CAR T cells that may be able to transform the administration of CAR T therapies and has the potential to be used as an off-the-shelf therapy.
- The novel CAR T technology was sourced by Fortress and is currently in development at our partner company, Mustang Bio.

MB-107 and MB-207 (Lentiviral Gene Therapies for X-linked Severe Combined Immunodeficiency ("XSCID"))

- In August 2021, we announced that the European Medicines Agency ("EMA") granted Priority Medicines ("PRIME") designation to MB-107, a lentiviral gene therapy for the treatment of XSCID in newly diagnosed infants, also known as bubble boy disease.
- MB-107 and MB-207 were sourced by Fortress and are currently in development at our partner company, Mustang Bio.

***Ex Vivo* Lentiviral Gene Therapy for RAG1 Severe Combined Immunodeficiency ("RAG1-SCID")**

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

Financial Results:

To assist our stockholders in understanding our company, we have prepared non-GAAP financial results for the three months ended September 30, 2021 and 2020. These results exclude the operations of our three partner companies that were public at September 30, 2021: Avenue, Checkpoint and Mustang Bio. The goal in providing these non-GAAP financial metrics is to highlight the financial results of Fortress' core operations, which comprise our commercial-stage business, our privately held development-stage entities, as well as our business development and finance functions.

- As of September 30, 2021, Fortress' consolidated cash, cash equivalents and restricted cash totaled $254.4 million, compared to $235.0 million as of December 31, 2020, an increase of $19.4 million year-to-date.
- On a GAAP basis, Fortress' net revenue totaled $21.1 million for the third quarter of 2021, which included $19.6 million in net revenue generated from our marketed dermatology products. This compares to net revenue totaling $9.5 million for the third quarter of 2020, which included $9.4 million in net revenue generated from our marketed dermatology products.
- On a GAAP basis, consolidated research and development expenses, including license acquisitions of $0.7 million, were $28.1 million for the third quarter of 2021, compared to consolidated research and development expenses, including license acquisitions of $0.5 million, totaling $13.8 million for the third quarter of 2020. On a non-GAAP basis, research and development expenses including license acquisitions were $3.8 million for the third quarter of 2021, compared to research and development expenses including license acquisitions totaling $2.8 million for third quarter of 2020.

- On a GAAP basis, consolidated selling, general and administrative expenses were $22.2 million for the third quarter of 2021, compared to $15.4 million for the third quarter of 2020. On a non-GAAP basis, consolidated selling, general and administrative expenses were $17.6 million, of which $10.8 million is attributed to Journey, for the third quarter of 2021, compared to $11.6 million, of which $5.8 million is attributed to Journey, for the third quarter of 2020.
- On a GAAP basis, consolidated net loss attributable to common stockholders was $(20.8) million, or $(0.26) per share, for the third quarter of 2021, compared to consolidated net loss attributable to common stockholders of $(15.5) million, or $(0.20) per share for the third quarter of 2020.
- Fortress' non-GAAP income attributable to common stockholders was $43.7 million, which includes the partial realization of Fortress' investment in Caelum, or $0.54 per share, for the third quarter of 2021, compared to Fortress' non-GAAP loss attributable to common stockholders of $(5.2) million, or $(0.07) per share, for the third quarter of 2020.
- The tables below have more information.

Use of Non-GAAP Measures:

In addition to the GAAP financial measures as presented in our Form 10-Q that will be filed with the Securities and Exchange Commission ("SEC") on November 15, 2021, the Company has, in this press release, included certain non-GAAP measurements. The non-GAAP net income (loss) attributable to common stockholders is defined by the Company as GAAP net income (loss) attributable to common stockholders, less net losses attributable to common stockholders from our public partner companies Avenue, Checkpoint and Mustang Bio. 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 income (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, Qbrexza inventory step-up and depreciation expense. The Company included the partial realization of gain in connection with the exercise of the Caelum option.

Management believes use 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 results. However, non-GAAP income (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 September 30,		For the nine months ended September 30,	
($ in thousands except for share and per share amounts)	2021	2020	2021	2020
Net loss attributable to common stockholders	$ (20,781)	$ (15,547)	$ (33,138)	$ (41,231)
Net loss attributable to common stockholders - Avenue[1]	(196)	(234)	(636)	(718)
Net loss attributable to common stockholders - Checkpoint[2]	(2,126)	(886)	(4,995)	(1,798)
Net loss attributable to common stockholders - Mustang[3]	(3,085)	(3,082)	(8,499)	(7,332)
Non-GAAP net income (loss) attributable to common stockholders	$ (15,374)	$ (11,345)	$ (19,007)	$ (31,383)
Stock based compensation	2,594	1,678	7,404	5,264
Non-cash interest	2,037	1,662	2,745	1,154
Amortization of licenses	658	355	1,983	1,065
Amortization of debt discount	720	2,120	1,623	5,238
Depreciation	1,590	148	1,868	(645)
Increase in fair value of investment[4]	(8,376)	(575)	(39,294)	(575)
Change in fair value of derivative liabilities[5]	2	803	184	1,189
Qbrexza inventory step-up[6]	3,001	-	4,239	-
Realization in Caelum investment[7]	56,860	-	56,860	-
Fortress non-GAAP income (loss) attributable to common stockholders	$ 43,711	$ (5,154)	$ 18,603	$ (19,882)
Per common share - basic and diluted:				
Net income (loss) attributable to common stockholders (GAAP)	$ (0.26)	$ (0.20)	$ (0.41)	$ (0.59)
Non-GAAP net income (loss) attributable to common stockholders	$ (0.19)	$ (0.15)	$ (0.23)	$ (0.45)
Fortress non-GAAP income (loss) attributable to common stockholders	$ 0.54	$ (0.07)	$ 0.23	$ (0.29)
Weighted average common shares outstanding - basic and diluted	81,348,243	76,093,211	81,056,165	69,404,499

1. Avenue net loss from their external SEC report for the three months ended September 30, 2021 and 2020 of $0.9 million and $1.0 million, respectively, net of non-controlling interest of $0.7 million and $0.8 million, respectively. Avenue net loss from their external SEC report for the nine months ended September 30, 2021 and 2020 of $2.8 million and $4.2 million, respectively, net of non-controlling interest of $2.2 million and $3.2 million, respectively.

2. Checkpoint net loss from their external SEC report of $11.3 million net of non-controlling interest of $9.0 million, MSA fee to Fortress of $0.1 million and financing fee to Fortress of approximately $39,000 for the quarter ended September 30, 2021; and net loss of $4.9 million net of non-controlling interest of $3.2 million, less MSA fee to Fortress of $0.1 million and financing fee to Fortress of $0.7 million for the quarter ended September 30, 2020. Checkpoint net loss from their external SEC report of $26.9 million net of non-controlling interest of $20.6 million, MSA fee to Fortress of $0.4 million and financing fee to Fortress of $0.9 million for the nine months ended September 30, 2021; and net loss of $12.9 million net of non-controlling interest of $9.0 million, less MSA fee to Fortress of $0.4 million and financing fee to Fortress of $0.8 million for the nine months ended September 30, 2020.

3. Mustang net loss from their external SEC report of $17.0 million net of non-controlling interest of $13.7 million, MSA fee to Fortress of $0.1 million and financing fee to Fortress of $0.1 million for the quarter ended September 30, 2021; and net loss of $13.0 million net of non-controlling interest of $9.3 million, MSA fee to Fortress of $0.1 million and financing fee to Fortress of $0.4 million for the quarter ended September 30, 2020. Mustang net loss from their external SEC report of $46.3 million net of non-controlling interest of $35.8 million, MSA fee to Fortress of $0.4 million and financing fee to Fortress of $1.7 million for the nine months ended September 30, 2021; and net loss of $39.4 million net of non-controlling interest of $27.0 million, MSA fee to Fortress of $0.4 million and financing fee to Fortress of $1.6 million for the nine months ended September 30, 2020.

4. Increase in fair value of investment in Caelum Biosciences for the quarter and nine months ended September 30, 2021.

5. Increase in fair value of derivative liabilities of Journey Medical Corporation for the quarter and nine months ended September 30, 2021.

6. Step-up related to FV of Qbrexza inventory recorded in COGS for the quarter and nine months ended September 30, 2021.

7. Partial realization of gain in connection with the exercise of the Caelum option. The Company backed out of Fortress non-GAAP income (loss) attributable to stockholders until actual realization of gain due to exercise of option.

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

	For the quarter ended September 30,		For the nine months ended September 30,	
($ in thousands)	2021	2020	2021	2020
Research and development[1]	**$ 28,080**	**$ 13,756**	**$ 85,811**	**$ 46,146**
Less:				
Research and development Avenue	278	466	864	2,382
Research and development Checkpoint	9,384	2,543	20,795	8,207
Research and development Mustang [2]	14,651	7,925	38,046	26,948
Non-GAAP research and development costs	**$ 3,767**	**$ 2,822**	**$ 26,108**	**$ 8,609**
Selling, general and administrative	**$ 22,221**	**$ 15,383**	**$ 59,145**	**$ 45,358**
Less:				
Selling, general and administrative Avenue	594	571	1,960	1,832
Selling, general and administrative Checkpoint [3]	1,759	1,573	5,109	4,622
Selling, general and administrative Mustang [4]	2,226	1,640	6,522	5,325
Non-GAAP selling, general and administrative costs	**$ 17,641**	**$ 11,599**	**$ 45,553**	**$ 33,579**

1. Includes Research and development expense and Research and development - licenses acquired expense for the quarter and nine months ended September 30, 2021 and 2020, respectively.

2. Excludes $0.1 million and $0.1 million of Fortress MSA expense for the quarter ended September 30, 2021 and 2020, respectively, and $0.2 million and $0.2 million for the nine months ended September 30, 2021 and 2020, respectively.

3. Excludes $0.1 million of Fortress MSA expense and approximately 39,000 of Fortress financing fee for the quarter ended September 30, 2021; and $0.1 million of Fortress MSA expense and $0.7 million Fortress financing fee for the quarter ended September 30, 2020. Excludes $0.4 million of Fortress MSA expense and $0.9 million Fortress financing fee for the nine months ended September 30, 2021; and $0.4 million of Fortress MSA expense and $0.8 million Fortress financing fee for the nine months ended September 30, 2020.

4. Excludes $0.1 million of Fortress MSA expense and $0.1 million Fortress financing fee for the quarter ended September 30, 2021; and $0.1 million of Fortress MSA expense and $0.4 million Fortress financing fee for the quarter ended September 30, 2020. Excludes $0.2 million of Fortress MSA expense and $1.7 million Fortress financing fee for the nine months ended September 30, 2021; and $0.2 million of Fortress MSA expense and $1.6 million Fortress financing fee for the nine months ended September 30, 2020.

About Fortress Biotech

Fortress Biotech, Inc. (“Fortress”) is an innovative biopharmaceutical company that was ranked in Deloitte’s 2019 and 2020 Technology Fast 500™, annual rankings of the fastest-growing North American companies in the technology, media, telecommunications, life sciences and energy tech sectors, based on percentages of fiscal year revenue growth over three-year periods. Fortress is focused on acquiring, developing and commercializing high-potential marketed and development-stage drugs and drug candidates. The company has seven marketed prescription pharmaceutical products and over 25 programs in development at Fortress, at its majority-owned and majority-controlled partners and at partners it founded and in which it holds significant minority ownership positions. Such product candidates span six large-market areas, including oncology, rare diseases and gene therapy, which allow it to create value for shareholders. Fortress advances its diversified pipeline through a streamlined operating structure that fosters efficient drug development. The Fortress model is driven by a world-class business development team that is focused on leveraging its significant biopharmaceutical industry expertise to further expand the company’s portfolio of product opportunities. Fortress has established partnerships with some of the world’s leading academic research institutions and biopharmaceutical companies to maximize each opportunity to its full potential, including 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 and any other statements that are not historical facts. Forward-looking statements are based on management’s current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; risks relating to the timing of starting and completing clinical trials; our dependence on third-party suppliers; risks relating to the COVID-19 outbreak and its potential impact on our employees’ and consultants’ ability to complete work in a timely manner and on our ability to obtain additional financing on favorable terms or at all; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this press release should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

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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, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 252,721	$ 233,351
Accounts receivable, net	31,738	23,928
Inventory	11,614	1,404
Other receivables - related party	947	744
Prepaid expenses and other current assets	4,167	6,723
Total current assets	301,187	266,150
Property and equipment, net	13,975	11,923
Operating lease right-of-use asset, net	19,415	20,487
Restricted cash	1,645	1,645
Long-term investment, at fair value	56,860	17,566
Intangible asset, net	13,043	14,629
Other assets	1,708	1,013
Total assets	**$ 407,833**	**$ 333,413**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 82,855	$ 45,389
Accounts payable - related party	74	—
Deferred revenue	3,354	—
Operating lease liabilities, short-term	2,047	1,849
Notes payable, short-term	10,450	—
Partner company installment payments - licenses, short-term (net of imputed interest of $567 and $778 as of September 30, 2021 and December 31, 2020, respectively)	4,433	4,522
Total current liabilities	103,213	51,760
Notes payable, long-term (net of debt discount of $7,431 and $8,323 as of September 30, 2021 and December 31, 2020, respectively)	42,569	51,677
Operating lease liabilities, long-term	21,522	22,891
Partner company installment payments - licenses, long-term (net of imputed interest of $461 and $863 as of September 30, 2021 and December 31, 2020, respectively)	3,539	8,137
Partner company convertible preferred shares, short-term (net of debt discount of $1,923 as of September 30, 2021)	18,078	—
Partner company derivative warrant liabilities	4,365	—
Other long-term liabilities	2,079	1,949
Total liabilities	**195,365**	**136,414**
Commitments and contingencies		
Stockholders' equity		
Cumulative redeemable perpetual preferred stock, $.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively, liquidation value of $25.00 per share	3	3
Common stock, $.001 par value, 170,000,000 shares authorized, 98,714,222 shares issued and outstanding as of September 30, 2021; 150,000,000 shares authorized, 94,877,492 shares issued and outstanding as of December 31, 2020, respectively	99	95
Common stock issuable, 116,866 and 0 shares as of September 30, 2021 and December 31, 2020, respectively	365	—
Additional paid-in-capital	608,089	583,000
Accumulated deficit	(515,898)	(482,760)
Total stockholders' equity attributed to the Company	92,658	100,338
Non-controlling interests	119,810	96,661
Total stockholders' equity	212,468	196,999
Total liabilities and stockholders' equity	**$ 407,833**	**$ 333,413**

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,	
	2021	**2020**	**2021**	**2020**
Revenue				
Product revenue, net	$ 19,610	$ 9,447	$ 45,617	$ 30,808
Collaboration revenue	1,446	—	4,646	—
Revenue - related party	29	28	252	1,042
Net revenue	21,085	9,475	50,515	31,850
Operating expenses				
Cost of goods sold - product revenue	11,167	3,379	22,559	10,313
Research and development	27,367	13,298	70,226	43,868
Research and development - licenses acquired	713	458	15,585	2,278
Selling, general and administrative	22,221	15,383	59,145	45,358
Wire transfer fraud loss	9,540	—	9,540	—
Total operating expenses	71,008	32,518	177,055	101,817
Loss from operations	(49,923)	(23,043)	(126,540)	(69,967)
Other income (expense)				
Interest income	132	265	505	1,228
Interest expense and financing fee	(4,444)	(6,958)	(9,393)	(13,142)
Change in fair value of investments	8,376	575	39,294	575
Change in fair value of derivative liability	(2)	(803)	(184)	(1,189)
Total other income (expense)	4,062	(6,921)	30,222	(12,528)
Loss before income tax expense	(45,861)	(29,964)	(96,318)	(82,495)
Income tax expense	—	—	—	—
Net loss	**(45,861)**	**(29,964)**	**(96,318)**	**(82,495)**
Net loss attributable to non-controlling interests	25,080	14,417	63,180	41,264
Net loss attributable to common stockholders	**$ (20,781)**	**$ (15,547)**	**$ (33,138)**	**$ (41,231)**
Net loss per common share - basic and diluted	$ (0.56)	$ (0.39)	$ (1.19)	$ (1.19)
Net loss per common share attributable to non - controlling interests - basic and diluted	$ (0.31)	$ (0.19)	$ (0.78)	$ (0.59)
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.26)	$ (0.20)	$ (0.41)	$ (0.59)
Weighted average common shares outstanding - basic and diluted	81,348,243	76,093,211	81,056,165	69,404,499