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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**FORM 8-K**

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**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 9, 2020**

**Fortress Biotech, Inc.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-35366**  
(Commission File Number)

**20-5157386**  
(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	FBIOF	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.

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**Item 2.02. Results of Operations and Financial Condition.**

On November 9, 2020, Fortress Biotech, Inc. issued a press release to provide a corporate update and to announce its financial results for the third quarter ended September 30, 2020. A copy of such press release is being furnished as Exhibit 99.1 to this report.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

The following exhibit is furnished herewith:

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press release issued by Fortress Biotech, Inc., dated November 9, 2020.</a>

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**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 9, 2020

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

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## Fortress Biotech Reports Third Quarter 2020 Financial Results and Recent Corporate Highlights

*Product revenue for the first nine months of 2020 increased 29% year-over-year to \$30.8 million*

*Rolling submission of the New Drug Application for CUTX-101 is expected to begin in the first quarter of 2021 and be completed by the end of the second quarter of 2021*

**New York, NY – November 9, 2020** – Fortress Biotech, Inc. (NASDAQ: FBIO) (“Fortress”), an innovative revenue-generating 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, 2020.

“The third quarter was highlighted by multiple transactions that strengthened our balance sheet. First, we received gross proceeds of approximately \$12 million through our Series A perpetual preferred stock offering. Later in the quarter, we signed a \$60 million refinancing agreement with Oaktree Capital Management. Moreover, we demonstrated significant top-line growth, as our net product revenue for the first nine months of 2020 increased 29% year-over-year to \$30.8 million,” said Lindsay A. Rosenwald, M.D., Fortress’ Chairman, President and Chief Executive Officer. “Based on the potential for multiple additional commercial product opportunities over the next few years, Fortress is well-positioned to drive further meaningful growth in our business.”

Dr. Rosenwald continued, “The Fortress business model, including five revenue-generating marketed products and a pipeline of over 25 development-stage programs, is uniquely structured to provide a multitude of significant catalysts in the near- and long-term. We are pleased with the ongoing momentum in each of our partnered programs, notably the positive late-stage clinical data recently reported for cosibelimab and CUTX-101, as well as promising data reported for CAEL-101 and MB-105. As we look ahead to the remainder of 2020 and early 2021, we look forward to multiple data presentations at the 62<sup>nd</sup> American Society of Hematology (“ASH”) Annual Meeting, initiating the rolling submission of the New Drug Application (“NDA”) to the U.S. Food and Drug Administration (“FDA”) for CUTX-101 for the treatment of Menkes disease, and the potential to further expand our portfolio of products and product candidates.”

### **Recent Corporate Highlights<sup>1</sup>:**

#### **Marketed Dermatology Products**

- Our dermatology products are marketed by our partner company, Journey Medical Corporation (“Journey”).
- Our products generated \$30.8 million in revenues in the first nine months of 2020, compared to \$23.8 million in the first nine months of 2019, representing growth of 29% year-over-year. Our products generated net revenues of \$9.4 million in the third quarter of 2020, compared to third quarter 2019 net revenues of \$9.5 million. Sales of our products in the third quarter of 2020 were impacted by the COVID-19 pandemic. The COVID-19 pandemic caused a temporary supply shortage and impacted the ability of our sales force to make in person calls, due to states slowly opening in the third quarter of 2020.
- We expect to generate record revenues in 2020.

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<sup>1</sup> 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.

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#### **CUTX-101 (Copper Histidinate for Menkes disease)**

- In July 2020, we announced the publication of a study, “Targeted Next Generation Sequencing for Newborn Screening of Menkes Disease” in *Molecular Genetics and Metabolism Reports*. The study assessed the analytic validity of an ATP7A targeted next generation DNA sequencing assay as a potential newborn screen for Menkes disease, an X-linked recessive disorder of copper metabolism caused by mutations in ATP7A, an evolutionarily conserved copper-transporting ATPase. The study can be accessed [here](#).
- In July 2020, we announced that the European Medicines Agency (“EMA”) Committee for Orphan Medicinal Products issued a positive opinion on Cyprium Therapeutics’ application for Orphan Drug Designation for Copper Histidinate, also referred to as CUTX-101.
- In August 2020, we reported positive top-line clinical efficacy results for CUTX-101. The study demonstrated statistically significant improvement in overall survival for Menkes disease subjects who received early treatment (ET) with CUTX-101, compared to an untreated historical control (HC) cohort, with a nearly 80% reduction in the risk of death (Hazard Ratio = 0.21, p<0.0001). Median survival for the ET cohort was 14.8 years (177.1 months) compared to 1.3 years (15.9 months) for the untreated HC cohort.
- In September 2020, we raised net proceeds of approximately \$7.1 million in a private offering of Cyprium’s 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock.
- We intend to begin the rolling submission of the NDA for CUTX-101 to the FDA in the first quarter of 2021. The submission is expected to be completed by the end of the second quarter of 2021.
- CUTX-101 is currently in development at our partner company, Cyprium Therapeutics, Inc.

#### **Cosibelimab (Anti-PD-L1 antibody)**

- In September 2020, we announced updated positive interim results from the ongoing global, open-label, multicohort, Phase 1 clinical trial of our anti-PD-L1 antibody, cosibelimab, in patients with advanced cancers, including the registration-enabling cohort of patients with metastatic cutaneous squamous cell carcinoma (“mCSCC”). Cosibelimab demonstrated a 51.4% objective response rate (“ORR”) and 13.5% complete response rate, which is nearly double the complete response rate observed at the time of previous analysis.
  - The registration-enabling study in mCSCC is currently over 50% enrolled, with full enrollment anticipated in the first quarter of 2021. We are on track to report full top-line results in the second half of 2021. With a potentially favorable safety profile and a plan to commercialize at a substantially lower price, we believe cosibelimab has the potential to be a market disruptive product in the \$25 billion and growing PD-(L)1 class.
  - Earlier this month, we announced the expansion of a long-term manufacturing partnership for cosibelimab with Samsung Biologics. Building upon an existing contract manufacturing agreement entered into in 2017, Samsung Biologics will provide additional commercial-scale drug substance manufacturing for cosibelimab.
  - This morning, we announced updated interim results from the ongoing global, open-label, multicohort Phase 1 clinical trial of cosibelimab in patients with advanced cancers, including a cohort of patients with previously untreated high PD-L1 expressing advanced non-small cell lung cancer (“NSCLC”). The updated interim results are being presented in a poster presentation at the Society for Immunotherapy of Cancer (SITC) 35th Anniversary Annual Meeting being held virtually from November 9-14, 2020. Cosibelimab demonstrated a 44.0% objective response rate and 10.3-month median progression-free survival in the NSCLC cohort. A Phase 3 registration-enabling trial is planned in first-line metastatic NSCLC.
  - Cosibelimab is currently in development at our partner company, Checkpoint Therapeutics, Inc.
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#### **CAEL-101 (Light Chain Fibril-reactive Monoclonal Antibody for AL Amyloidosis)**

- In September 2020, we announced the initiation of two Phase 3 studies of CAEL-101 for AL amyloidosis.
  - o The Phase 2 study met its primary objective, supporting the initiation of two parallel Phase 3 studies that will enroll approximately 370 AL amyloidosis patients.
  - o Positive long-term Phase 1a/1b data presented at the International Symposium on Amyloidosis (ISA) 2020 demonstrated prolonged overall survival (78% at 37 months) and durable organ response.
- Earlier this month, we announced that CAEL-101 Phase 2 data were selected for oral and poster presentations at the 62<sup>nd</sup> ASH Annual Meeting, which is being held virtually from December 5 – 8, 2020. Links to the abstracts can be found here: [oral presentation](#) and [poster presentation](#).
- CAEL-101 is currently in development at Caelum Biosciences, Inc., a company founded by Fortress, in collaboration with Alexion Pharmaceuticals, Inc.

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

- In August 2020, we announced that the FDA granted Rare Pediatric Disease Designations to MB-107, a lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency (“XSCID”), also known as bubble boy disease, in newly diagnosed infants and MB-207, a lentiviral gene therapy for the treatment of patients with XSCID, who were previously treated with hematopoietic stem cell transplantation (“HSCT”) and for whom re-treatment is indicated.
- In September 2020, we announced that the FDA granted Orphan Drug Designations to MB-107 for the treatment of XSCID in newly diagnosed infants and to MB-207 for the treatment of patients with XSCID, who were previously treated with HSCT and for whom re-treatment is indicated.
- In October 2020, we in-licensed LentiBOOST™ technology from SIRION Biotech GmbH for the development of MB-207.
- MB-107 and MB-207 are currently in development at our partner company, Mustang Bio, Inc (“Mustang Bio”).

#### **MB-102 (CD123-targeted CAR T Cell therapy)**

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

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

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

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

- Earlier this month, we announced that interim Phase 1/2 data on MB-106, a CD20-targeted, autologous CAR T cell therapy for patients with relapsed or refractory B-cell non-Hodgkin lymphomas, were selected for a poster presentation at the 62<sup>nd</sup> ASH Annual Meeting. A link to the abstract can be found [here](#).
  - MB-106 is currently in development at our partner company, Mustang Bio.
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#### **IV Tramadol**

- In July 2020, Avenue Therapeutics (“Avenue”) announced that outcomes from its Phase 3 bunionectomy study were published in *Pain and Therapy*. “Efficacy and Safety of Intravenously Administered Tramadol in Patients with Moderate to Severe Pain Following Bunionectomy: A Randomized, Double-Blind, Placebo-Controlled, Dose-Finding Study” can be accessed here.
- In October 2020, Avenue announced that it had received a Complete Response Letter (“CRL”) from the FDA regarding Avenue’s NDA for IV tramadol. Avenue has a meeting scheduled in the fourth quarter of 2020 with the FDA to discuss the issues outlined in the CRL.
- IV tramadol is currently in development at our partner company, Avenue.

#### **General Corporate**

- In August 2020, we raised a gross total of approximately \$12 million in an underwritten public offering of our 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock.
- Also in August 2020, we announced a \$60 million long-term debt refinancing agreement with Oaktree Capital Management, replacing \$60 million due over the next six quarters, with the debt due in August 2025.

#### **Financial Results:**

To assist our stockholders in understanding our company, we have prepared non-GAAP financial results for the three months and nine months ended September 30, 2020 and 2019. These results exclude the operations of our three public partner companies: Avenue Therapeutics, Inc. (“Avenue”), Checkpoint Therapeutics, Inc. (“Checkpoint”) and Mustang Bio, Inc. (“Mustang”), as well as any one-time, non-recurring, non-cash transactions, such as the gain of \$18.4 million we recorded in the first quarter of 2019 resulting from the deconsolidation of Caelum Biosciences, Inc. (“Caelum”). The goal in providing these non-GAAP financial metrics is to highlight the financial results of Fortress’ core operations, which are comprised of our commercial-stage business, our privately held development-stage entities, as well as our business development and finance functions.

- As of September 30, 2020, Fortress’ consolidated cash, cash equivalents and restricted cash totaled \$220.0 million, compared to \$199.9 million as of June 30, 2020 and \$153.4 million as of December 31, 2019.
  - Fortress’ net revenue totaled \$9.5 million for the third quarter of 2020, which included \$9.4 million in net revenue generated from our marketed dermatology products. This compares to net revenue totaling \$9.8 million for the third quarter of 2019, which included \$9.5 million in net revenue generated from our marketed dermatology products. Fortress is on track to achieve quarter-over-quarter revenue growth in the fourth quarter of 2020, however, it continues to monitor the spread of COVID-19 and assess the impact it may have on the fourth quarter of 2020.
  - On a GAAP basis, consolidated research and development expenses were \$13.3 million for the third quarter of 2020, compared to \$14.6 million for the third quarter of 2019. On a non-GAAP basis, research and development expenses were \$2.4 million for the third quarter of 2020, compared to \$1.7 million for third quarter of 2019.
  - On a GAAP basis, consolidated research and development expenses from license acquisitions totaled \$0.5 million for the third quarter of 2020, compared to \$0.7 million for the third quarter of 2019.
  - On a GAAP basis, consolidated general and administrative expenses were \$15.4 million for the third quarter of 2020, compared to \$14.3 million for the third quarter of 2019. On a non-GAAP basis, general and administrative expenses were \$11.6 million, of which \$5.8 million is attributed to Journey, for the third quarter of 2020, compared to \$10.4 million, of which \$5.0 million is attributed to Journey, for the third quarter of 2019.
  - On a GAAP basis, consolidated net loss attributable to common stockholders was \$15.5 million, or \$0.20 per share, for the third quarter of 2020, compared to net loss attributable to common stockholders of \$12.8 million, or \$0.22 per share for the third quarter of 2019.
  - Fortress’ non-GAAP loss attributable to common stockholders was \$5.2 million, or \$0.07 per share, for the third quarter of 2020, compared to Fortress’ non-GAAP loss attributable to common stockholders of \$3.2 million, or \$0.06 per share, for the third quarter of 2019.
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### Use of Non-GAAP Measures:

In addition to the GAAP financial measures as presented in our Form 10-Q filed with the Securities and Exchange Commission (“SEC”) on November 9, 2020, the Company, in this press release, has included certain non-GAAP measurements. The non-GAAP loss attributable to common stockholders is defined by the Company as GAAP net loss attributable to common stockholders, less net losses from our public partner companies Avenue, Checkpoint, and Mustang, as well as Caelum. In addition, the Company has also provided a Fortress non-GAAP loss attributable to common stockholders which is a modified EBITDA calculation that starts with the non-GAAP loss attributable to common stockholders and removes stock-based compensation expense, non-cash interest expense, amortization of licenses and debt discount, and depreciation.

Management believes these non-GAAP measures provide meaningful supplemental information regarding the Company's performance because (i) it allows for greater transparency with respect to key measures used by management in its financial and operational decision-making; (ii) it excludes the impact of non-cash or, when specified, non-recurring items that are not directly attributable to the Company's core operating performance and that may obscure trends in the Company's core operating performance; and (iii) it is used by institutional investors and the analyst community to help analyze the Company's results. However, non-GAAP loss attributable to common stockholders and any other non-GAAP financial measures should be considered as a supplement to, and not as a substitute for, or superior to, the corresponding measures calculated in accordance with GAAP. Further, non-GAAP financial measures used by the Company and the manner in which they are calculated may differ from the non-GAAP financial measures or the calculations of the same non-GAAP financial measures used by other companies, including the Company's competitors.

The tables below provide a reconciliation from GAAP to non-GAAP measures:

(\$ in thousands)	For the three months ended September 30,		For the nine months ended September 30,	
	2020	2019	2020	2019
<b>Net income (loss) attributable to common stockholders</b>	\$ (15,547)	\$ (12,762)	\$ (41,231)	\$ (24,468)
Net (Loss) income attributable to common stockholders - Avenue <sup>1</sup>	(234)	(545)	(952)	(5,624)
Net (Loss) income attributable to common stockholders - Checkpoint <sup>2</sup>	(886)	(1,533)	(2,684)	(4,791)
Net (Loss) income attributable to common stockholders - Mustang <sup>3</sup>	(3,082)	(3,254)	(10,416)	(10,091)
Deconsolidation of Caelum Biosciences	-	-	-	18,521
<b>Non-GAAP net loss attributable to common stockholders</b>	\$ (11,345)	\$ (7,430)	\$ (27,180)	\$ (22,483)
Stock based compensation	1,678	1,490	5,264	4,220
Non-cash interest	1,662	1,508	4,145	4,301
Amortization of licenses	355	374	1,065	820
Amortization of debt discount	2,120	704	2,998	1,993
Depreciation	148	157	453	507
Increase in fair value of investment <sup>4</sup>	(575)	-	(575)	-
Change in fair value of derivative liability <sup>5</sup>	803	-	1,189	-
<b>Fortress non-GAAP loss attributable to common stockholders</b>	\$ (5,154)	\$ (3,197)	\$ (12,640)	\$ (10,642)
GAAP net loss	\$ (0.20)	\$ (0.22)	\$ (0.59)	\$ (0.46)
Non-GAAP net loss	\$ (0.15)	\$ (0.13)	\$ (0.39)	\$ (0.42)
FBIO non-GAAP	\$ (0.07)	\$ (0.06)	\$ (0.18)	\$ (0.20)
WASO	76,093,211	56,856,821	69,404,499	53,060,565

1. Avenue net loss from their external SEC report for the three months ended September 30, 2020 and 2019 of \$1.0 million and \$2.2 million, respectively, net of non-controlling interest of \$0.8 million and \$1.7 million, respectively. Avenue net loss from their external SEC report for the nine months ended September 30, 2020 and 2019 of \$4.2 million and \$20.5 million, respectively, net of non-controlling interest of \$3.2 million and \$14.9 million, respectively.



- Checkpoint net loss from their external SEC report of \$4.9 million net of non-controlling interest of \$3.2 million, MSA fee to Fortress of \$0.1 million and financing fee to Fortress of \$0.7 million for the three months ended September 30, 2020; and net loss of \$5.2 million net of non-controlling interest of \$3.5 million, MSA fee to Fortress of \$0.1 million and financing fee to Fortress of \$0.1 million for the three months ended September 30, 2019. Checkpoint net loss from their external SEC report of \$12.9 million net of non-controlling interest of \$9.0 million, 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; and net loss of \$15.9 million net of non-controlling interest of \$10.5 million, MSA fee to Fortress of \$0.4 million and financing fee to Fortress of \$0.2 million for the nine months ended September 30, 2019..
- Mustang net loss from their external SEC report 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 three months ended September 30, 2020; and net loss of \$10.2 million net of non-controlling interest of \$6.8 million, MSA fee to Fortress of \$0.1 million for the three months ended September 30, 2019. Mustang net loss from their external SEC report 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; and net loss of \$30.2 million net of non-controlling interest of \$18.1 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, 2019.
- Increase in fair value of investment in Caelum Biosciences for the three months and nine months ended September 30, 2020.
- Related to issuance of Cyprium warrant in connection with 2018 Venture Debt for the three months and nine months ended September 30, 2020.

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

<i>(\$ in thousands)</i>	For the three months ended September 30,		For the nine months ended September 30,	
	2020	2019	2020	2019
<b>Research and development</b>	\$ 13,298	\$ 14,571	\$ 43,868	\$ 56,355
Less:				
Research and development Avenue	466	1,706	2,382	18,339
Research and development Checkpoint	2,543	3,894	8,207	12,595
Research and development Mustang <sup>1</sup>	7,925	7,247	26,948	20,905
<b>Non-GAAP research and development costs</b>	\$ 2,364	\$ 1,724	\$ 6,331	\$ 4,516
<b>General and administrative</b>	\$ 15,383	\$ 14,339	\$ 45,358	\$ 41,260
Less:				
General and administrative Avenue	571	617	1,832	2,452
General and administrative Checkpoint <sup>2</sup>	1,573	1,403	4,622	4,508
General and administrative Mustang <sup>3</sup>	1,640	1,925	5,325	6,046
<b>Non-GAAP general and administrative costs</b>	\$ 11,599	\$ 10,394	\$ 33,579	\$ 28,254

- Excludes \$62,500 and \$62,500 of Fortress MSA expense for the three months ended September 30, 2020 and 2019, respectively, and \$0.2 million and \$0.2 million for the nine months ended September 30, 2020 and 2019, respectively.
- Excludes \$0.1 million of Fortress MSA expense and \$0.7 million Fortress financing fee for the three months ended September 30, 2020; and \$0.1 million of Fortress MSA expense and \$0.1 million Fortress financing fee for the three months ended September 30, 2019. Excludes \$0.4 million of Fortress MSA expense and \$0.8 million Fortress financing fee for the nine months ended September 30, 2020; and \$0.4 million of Fortress MSA expense and \$0.2 million Fortress financing fee for the nine months ended September 30, 2019.
- Excludes \$62,500 of Fortress MSA expense and \$0.4 million Fortress financing fee for the three months ended September 30, 2020; and \$62,500 of Fortress MSA expense for the three months ended September 30, 2019. Excludes \$0.2 million of Fortress MSA expense and \$1.6 million Fortress financing fee for the nine months ended September 30, 2020; and \$0.2 million of Fortress MSA expense and \$1.7 million Fortress financing fee for the nine months ended September 30, 2019.

## **About Fortress Biotech**

Fortress Biotech, Inc. (“Fortress”) is an innovative biopharmaceutical company that was ranked number 10 in Deloitte’s 2019 Technology Fast 500™, an annual ranking of the fastest-growing North American companies in the technology, media, telecommunications, life sciences and energy tech sectors, based on percentage of fiscal year revenue growth over a three-year period. Fortress is focused on acquiring, developing and commercializing high-potential marketed and development-stage drugs and drug candidates. The company has five marketed prescription pharmaceutical products and over 25 programs in development at Fortress, at its majority-owned and majority-controlled partners and at partners it founded and in which it holds significant minority ownership positions. Such product candidates span six large-market areas, including oncology, rare diseases and gene therapy, which allow it to create value for shareholders. Fortress advances its diversified pipeline through a streamlined operating structure that fosters efficient drug development. The Fortress model is driven by a world-class business development team that is focused on leveraging its significant biopharmaceutical industry expertise to further expand the company’s portfolio of product opportunities. Fortress has established partnerships with some of the world’s leading academic research institutions and biopharmaceutical companies to maximize each opportunity to its full potential, including Alexion Pharmaceuticals, Inc., AstraZeneca, City of Hope, Fred Hutchinson Cancer Research Center, InvaGen Pharmaceuticals Inc. (a subsidiary of Cipla Limited), St. Jude Children’s Research Hospital and Nationwide Children’s Hospital. For more information, visit [www.fortressbiotech.com](http://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**  
**Consolidated Balance Sheets**  
(\$ in thousands except for share and per share amounts)

	September 30, 2020 (Unaudited)	December 31, 2019
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 218,389	\$ 136,858
Accounts receivable (net of allowance for doubtful accounts of \$147 and \$100 at September 30, 2020 and December 31, 2019, respectively)	15,653	13,539
Inventory	1,052	857
Other receivables - related party	939	865
Prepaid expenses and other current assets	1,704	4,133
Total current assets	<u>237,737</u>	<u>156,252</u>
Property and equipment, net	12,114	12,433
Operating lease right-of-use asset, net	20,265	21,480
Restricted cash	1,645	16,574
Long-term investment, at fair value	11,723	11,148
Intangible asset, net	11,039	7,377
Other assets	1,356	1,158
<b>Total assets</b>	<b><u>\$ 295,879</u></b>	<b><u>\$ 226,422</u></b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 32,542	\$ 35,451
Accounts payable and accrued expenses - related party	19	—
Interest payable	23	1,042
Interest payable - related party	—	92
Notes payable, short-term	—	7,220
Operating lease liabilities – short-term	1,697	1,784
Derivative warrant liability	—	27
Other current liabilities	3,000	—
Total current liabilities	<u>37,281</u>	<u>45,616</u>
Notes payable, long-term (net of debt discount of \$8,607 and \$5,086 at September 30, 2020 and December 31, 2019, respectively)	51,393	77,436
Operating lease liabilities – long-term	22,855	23,712
Other long-term liabilities	8,205	7,126
<b>Total liabilities</b>	<b><u>119,734</u></b>	<b><u>153,890</u></b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Preferred stock, \$.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 3,427,138 and 1,341,167 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively; liquidation value of \$25.00 per share	3	1
Common stock, \$.001 par value, 150,000,000 shares authorized, 93,748,374 and 74,027,425 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	94	74
Common stock issuable, 5,451 and 251,337 shares as of September 30, 2020 and December 31, 2019, respectively	18	500
Additional paid-in-capital	574,461	461,874
Accumulated deficit	(477,465)	(436,234)
Total stockholders' equity attributed to the Company	<u>97,111</u>	<u>26,215</u>
Non-controlling interests	79,034	46,317
Total stockholders' equity	<u>176,145</u>	<u>72,532</u>
<b>Total liabilities and stockholders' equity</b>	<b><u>\$ 295,879</u></b>	<b><u>\$ 226,422</u></b>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
<b>Revenue</b>				
Product revenue, net	\$ 9,447	\$ 9,492	\$ 30,808	\$ 23,816
Revenue - related party	28	280	1,042	1,683
Net revenue	<u>9,475</u>	<u>9,772</u>	<u>31,850</u>	<u>25,499</u>
<b>Operating expenses</b>				
Cost of goods sold - product revenue	3,379	2,702	10,313	6,972
Research and development	13,298	14,571	43,868	56,355
Research and development - licenses acquired	458	700	2,278	1,350
General and administrative	15,383	14,339	45,358	41,260
Total operating expenses	<u>32,518</u>	<u>32,312</u>	<u>101,817</u>	<u>105,937</u>
Loss from operations	(23,043)	(22,540)	(69,967)	(80,438)
<b>Other income (expense)</b>				
Interest income	265	738	1,228	1,955
Interest expense and financing fee	(6,958)	(3,168)	(13,142)	(8,743)
Change in fair value of derivative liability	(803)	—	(1,189)	—
Change in fair value of investments	575	—	575	—
Gain on deconsolidation of Caelum	—	—	—	18,521
Total other income (expense)	<u>(6,921)</u>	<u>(2,430)</u>	<u>(12,528)</u>	<u>11,733</u>
<b>Net loss</b>	<b><u>(29,964)</u></b>	<b><u>(24,970)</u></b>	<b><u>(82,495)</u></b>	<b><u>(68,705)</u></b>
Less: net loss attributable to non-controlling interests	14,417	12,208	41,264	44,237
<b>Net loss attributable to common stockholders</b>	<b><u>\$ (15,547)</u></b>	<b><u>\$ (12,762)</u></b>	<b><u>\$ (41,231)</u></b>	<b><u>\$ (24,468)</u></b>
Net loss per common share - basic and diluted	\$ (0.39)	\$ (0.44)	\$ (1.19)	\$ (1.29)
Net loss per common share attributable to non - controlling interests - basic and diluted	\$ (0.19)	\$ (0.21)	\$ (0.59)	\$ (0.83)
Net loss per common share attributable to common stockholders - basic and diluted	\$ (0.20)	\$ (0.22)	\$ (0.59)	\$ (0.46)
Weighted average common shares outstanding - basic and diluted	76,093,211	56,856,821	69,404,499	53,060,565