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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): **August 10, 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 August 10, 2020, Fortress Biotech, Inc. issued a press release to provide a corporate update and to announce its financial results for the second quarter ended June 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 August 10, 2020.</a>
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

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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.

Date: August 10, 2020

**Fortress Biotech, Inc.**  
(Registrant)

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 Second Quarter 2020 Financial Results and Recent Corporate Highlights

*Product revenue for the first six months of 2020 increased 50% year-over-year to \$21.4 million*

*Agreement executed with Columbia University to develop novel oligonucleotide platform for the treatment of genetically driven cancers, including KRAS-driven cancers, and coronaviruses*

**New York, NY – August 10, 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 second quarter ended June 30, 2020.

Lindsay A. Rosenwald, M.D., Fortress’ Chairman, President and Chief Executive Officer, said, “Fortress has continued to efficiently and effectively execute on its growth objectives due to our unique business model. We are proud to have generated total net revenue of \$21.4 million from our five marketed pharmaceutical products in the first half of 2020, a year-over-year increase of 50%, despite this unprecedented time. Moreover, during the second quarter, we acquired a broad platform technology from Columbia University to effectively deliver novel, proprietary oligonucleotides for the treatment of genetically driven cancers, with an initial target of KRAS-driven cancers. We are also exploring the potential of the platform to treat novel coronaviruses, such as COVID-19.”

Dr. Rosenwald continued, “Additionally, we continue to work with our partner companies to steadily build and advance our growing portfolio of commercial and development-stage product candidates. Our goal is to increase intrinsic value for our shareholders. In the second half of 2020, we look forward to a multitude of key inflection points, including: additional data from our registration-enabling clinical trial of cosibelimab in patients with metastatic cutaneous squamous cell carcinoma (“mCSCC”), the PDUFA date for IV tramadol in October and 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. We also anticipate the potential launch of four more registration-enabling clinical trials this year, two CAEL-101 pivotal trials for AL amyloidosis and two MB-107 and MB-207 lentiviral gene therapy clinical trials for newly diagnosed infants and previously transplanted patients with X-linked severe combined immunodeficiency (“XSCID”).”

### **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 \$21.4 million in revenues in the first half of 2020, compared to \$14.3 million in the first half of 2019, representing growth of 50% year-over-year. Our products generated second quarter 2020 net revenues of \$9.4 million, compared to second quarter 2019 net revenues of \$8.2 million, a 15% increase. Second quarter sales were below expectations due to COVID-19.
- We intend to acquire up to two new prescription products 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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#### IV Tramadol

- In April 2020, Avenue Therapeutics (“Avenue”) announced that two e-posters highlighting efficacy and safety results from its Phase 3 program are available for online viewing from the cancelled Annual Regional Anesthesiology and Acute Pain Medicine Meeting hosted by the American Society of Regional Anesthesia and Pain Medicine (“ASRA”).
  - o The e-poster (816), titled, “Intravenous Tramadol is Effective in Management of Postoperative Pain Following Abdominoplasty: A 3-arm Randomized Controlled Trial,” includes data from the Phase 3 abdominoplasty study and can be found [here](#).
  - o The e-poster (1001), titled, “IV tramadol – A New Treatment Option for Management of Post-Operative Pain: A Safety Trial Including Various Types of Surgery,” includes data from the Phase 3 safety study and can be found [here](#).
- In June 2020, Avenue announced the following clinical study publications in peer-reviewed journals.
  - o “Intravenous Tramadol is Effective in the Management of Postoperative Pain Following Abdominoplasty: A Three-Arm Randomized Placebo- and Active-Controlled Trial,” was published in *Drugs in R&D* and can be accessed [here](#).
  - o “IV Tramadol – A New Treatment Option for Management of Post-Operative Pain in the U.S.: An Open-Label, Single-Arm, Safety Trial Including Various Types of Surgery,” was published in *Journal of Pain Research* and can be accessed [here](#).
- In July 2020, Avenue announced the following publication of its Phase 3 bunionectomy study.
  - o “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,” was published in *Pain and Therapy* and can be accessed [here](#).
- The FDA assigned IV tramadol a PDUFA date of October 10, 2020.
- IV tramadol is currently in development at our partner company, Avenue.

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

- In June 2020, we announced the publication of a study, “Estimated birth prevalence of Menkes disease and ATP7A-related disorders based on the Genome Aggregation Database (gnomAD),” in *Molecular Genetics and Metabolism Reports*. Assuming Hardy-Weinberg genetic equilibrium, the allelic frequency of loss-of-function variants suggests a minimum birth prevalence for Menkes disease of 1 in 34,810 males, higher than previously recognized. If likely pathogenic missense variants are included, the estimated birth prevalence could potentially be as high as 1 in 8,664 live male births. The study can be accessed [here](#).
  - 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, a potential treatment for Menkes disease. EMA Orphan Drug Designation provides companies with certain benefits and incentives, including clinical protocol assistance, differentiated evaluation procedures for Health Technology Assessments in certain countries, access to a centralized marketing authorization procedure valid in all EU member states, reduced regulatory fees and 10 years of market exclusivity. The FDA previously granted Orphan Drug, Fast Track and Rare Pediatric Disease Designations to CUTX-101 for the treatment of Menkes disease.
  - We intend to begin the rolling submission of the NDA for CUTX-101 to the FDA in the fourth quarter of 2020.
  - CUTX-101 is currently in development at our partner company, Cyprium Therapeutics, Inc.
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**Cosibelimab (anti-PD-L1 antibody)**

- In April 2020, we announced that the U.S. Patent and Trademark Office issued a composition of matter patent for cosibelimab. U.S. Patent No. 10,590,199 specifically covers the antibody, cosibelimab, or a fragment thereof, providing protection through at least May 2038, exclusive of any additional patent-term extensions that might become available.
- In July 2020, we announced that an abstract highlighting updated interim safety and efficacy data from the ongoing registration-enabling clinical trial of cosibelimab in patients with mCSCC was accepted for e-poster presentation at the European Society for Medical Oncology (ESMO) Virtual Congress 2020, to be held September 19-21, 2020.
- The registration-enabling study in mCSCC is currently over 50% enrolled, with full enrollment anticipated around year-end. With a potentially favorable safety profile and a plan to commercialize at a substantially lower price, we believe cosibelimab can be a market disruptive product in the \$25 billion and growing PD-(L)1 class.
- Cosibelimab is currently in development at our partner company, Checkpoint Therapeutics, Inc.

**CAEL-101 (light chain fibril-reactive monoclonal antibody for AL amyloidosis)**

- Dosing is complete in the Phase 2 dose selection portion of the program; the Phase 3 portion of the pivotal program is planned to begin in the third quarter of 2020, pending dose selection.
- CAEL-101 is currently in development at Caelum Biosciences, Inc.

**MB-107 and MB-207 (lentiviral gene therapies for XSCID)**

- In April 2020, we announced that the EMA granted Advanced Therapy Medicinal Product (“ATMP”) classification to MB-107, a lentiviral gene therapy for the treatment of XSCID, also known as bubble boy disease.
- In May 2020, Mustang Bio, Inc. (“Mustang”) submitted an Investigational New Drug (“IND”) application to the FDA to initiate a multi-center Phase 2 clinical trial of MB-107 in newly diagnosed infants with XSCID who are under the age of two. The trial is expected to enroll 10 patients who, together with 15 patients enrolled in the current multicenter trial led by St. Jude Children’s Research Hospital, will be compared to 25 matched historical control patients who have undergone hematopoietic stem cell transplant (“HSCT”). The primary efficacy endpoint will be event-free survival. The initiation of this trial is currently on hold pending CMC clearance by the FDA, which is expected in early Q4 2020. Mustang is targeting top-line data from the trial in the second half of 2022.
- Mustang further expects to file an IND in the fourth quarter of 2020 for a registrational multi-center Phase 2 clinical trial of its lentiviral gene therapy in previously transplanted XSCID patients. This product will be designated MB-207. Mustang anticipates enrolling 20 patients and evaluating those subjects in comparison to matched historical control patients who have undergone a second HSCT. Mustang is targeting top-line data from this trial in the second half of 2022.
- MB-107 and MB-207 are currently in development at our partner company, Mustang.

**MB-104 (CS1-targeted CAR T cell therapy)**

- In May 2020, City of Hope presented two posters pertaining to MB-104, an innovative CS1 CAR T cell therapy, at the virtual 23<sup>d</sup> Annual Meeting of the American Society of Gene & Cell Therapy (“ASGCT”).
- MB-104 is currently in development at our partner company, Mustang.

**ONCOlogues (proprietary platform technology using PNA oligonucleotides)**

- In May 2020, we entered into an exclusive worldwide licensing agreement with Columbia University to develop novel oligonucleotides for the treatment of genetically driven cancers. The proprietary platform produces oligomers, known as “ONCOlogues,” which are capable of binding gene sequences 1,000 times more effectively than complementary native DNA.
    - ONCOlogues invade a DNA double helix and displace native mutated strands. This may prevent the mRNA that antisense binds to from ever being created. It is active higher upstream than traditional antisense approaches, as well as potentially more potent and broader in its utility.
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- In addition, we are exploring the potential of the platform to treat novel coronaviruses, such as COVID-19.
- The “Suppression of KRAS-G12D and BRAF-V600E Oncogene Transcription with PNA Conjugates,” data presentation from the ESMO Congress in 2019 can be found [here](#).
- The ONCOlogues platform is currently in development at our partner company, Oncogenity, Inc.

#### **General Corporate**

- In May 2020, we closed on a gross total of approximately \$11.5 million in an underwritten public offering of our 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock.
- In June 2020, Fortress and Avenue were added to the Russell 3000® index.

#### **Financial Results:**

To assist our stockholders in understanding our company, we have prepared non-GAAP financial results for the three months and six months ended June 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 de-consolidation 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 June 30, 2020, Fortress’ consolidated cash, cash equivalents and restricted cash totaled \$199.9 million, compared to \$152.5 million as of March 31, 2020 and \$153.4 million as of December 31, 2019.
- Fortress’ net revenue totaled \$9.5 million for the second quarter of 2020, which included \$9.4 million in net revenue generated from our marketed dermatology products. This compares to net revenue totaling \$9.3 million for the second quarter of 2019, which included \$8.2 million in net revenue generated from our marketed dermatology products.
- On a GAAP basis, consolidated research and development expenses were \$15.7 million for the second quarter of 2020, compared to \$18.5 million for the second quarter of 2019. On a non-GAAP basis, research and development expenses were \$1.7 million for the second quarter of 2020, compared to \$1.2 million for second quarter of 2019.
- On a GAAP basis, consolidated research and development expenses from license acquisitions totaled \$1.6 million for the second quarter of 2020, compared to \$0.2 million for the second quarter of 2019.
- On a GAAP basis, consolidated general and administrative expenses were \$14.5 million for the second quarter of 2020, compared to \$13.4 million for the second quarter of 2019. On a non-GAAP basis, general and administrative expenses were \$10.4 million, of which \$4.8 million is attributed to Journey, for the second quarter of 2020, compared to \$9.4 million, of which \$4.9 million is attributed to Journey, for the second quarter of 2019.
- On a GAAP basis, consolidated net loss attributable to common stockholders was \$13.3 million, or \$0.19 per share, for the second quarter of 2020, compared to net loss attributable to common stockholders of \$13.1 million, or \$0.24 per share for the second quarter of 2019.
- Fortress’ non-GAAP loss attributable to common stockholders was \$3.7 million, or \$0.05 per share, for the second quarter of 2020, compared to Fortress’ non-GAAP loss attributable to common stockholders of \$2.4 million, or \$0.04 per share, for the second quarter of 2019.

#### **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 August 10, 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.

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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:

	For the three months ended June 30,		For the six months ended June 30,	
	2020	2019	2020	2019
<b>Net income (loss) attributable to common stockholders</b>	\$ (13,314)	\$ (13,098)	\$ (25,684)	\$ (11,706)
<b>Net (Loss) income attributable to common stockholders - Avenue<sup>1</sup></b>	(431)	(1,810)	(718)	(5,079)
<b>Net (Loss) income attributable to common stockholders - Checkpoint<sup>2</sup></b>	(1,045)	(1,433)	(1,798)	(3,257)
<b>Net (Loss) income attributable to common stockholders - Mustang<sup>3</sup></b>	(3,732)	(3,144)	(7,332)	(6,838)
<b>Net (Loss) income attributable to common stockholders - Caelum<sup>4</sup></b>	-	137	-	18,521
<b>Non-GAAP net loss attributable to common stockholders</b>	\$ (8,106)	\$ (6,848)	\$ (15,836)	\$ (15,053)
<b>Stock based compensation</b>	1,844	1,403	3,584	2,731
<b>Non-cash interest</b>	1,713	2,057	2,482	2,793
<b>Amortization of licenses</b>	355	212	710	446
<b>Amortization of debt discount</b>	390	667	878	1,289
<b>Depreciation</b>	151	157	305	350
<b>Fortress non-GAAP loss attributable to common stockholders</b>	\$ (3,653)	\$ (2,352)	\$ (7,877)	\$ (7,444)
<b>GAAP net loss</b>	\$ (0.19)	\$ (0.24)	\$ (0.39)	\$ (0.23)
<b>Non-GAAP net loss</b>	\$ (0.12)	\$ (0.13)	\$ (0.24)	\$ (0.29)
<b>FBIO non-GAAP</b>	\$ (0.05)	\$ (0.04)	\$ (0.12)	\$ (0.15)
<b>WASO</b>	68,550,494	53,726,125	66,023,367	51,130,977

1. Avenue net loss from their external SEC report for the three months ended June 30, 2020 and 2019 of \$1.9 million and \$7.0 million, respectively, net of non-controlling interest of \$1.4 million and \$5.2 million, respectively. Avenue net loss from their external SEC report for the six months ended June 30, 2020 and 2019 of \$3.1 million and \$18.3 million, respectively, net of non-controlling interest of \$2.4 million and \$13.2 million, respectively.
2. Checkpoint net loss from their external SEC report of \$4.6 million net of non-controlling interest of \$3.4 million, MSA fee to Fortress of \$0.1 million and financing fee to Fortress of \$0.1 million for the three months ended June 30, 2020; and net loss of \$4.8 million net of non-controlling interest of \$3.1 million, MSA fee to Fortress of \$0.1 million and financing fee to Fortress of \$0.1 million for the three months ended June 30, 2019. Checkpoint net loss from their external SEC report of \$7.9 million net of non-controlling interest of \$5.8 million, MSA fee to Fortress of \$0.3 million and financing fee to Fortress of \$0.1 million for the six months ended June 30, 2020; and net loss of \$10.7 million net of non-controlling interest of \$7.1 million, MSA fee to Fortress of \$0.3 million and financing fee to Fortress of \$0.1 million for the six months ended June 30, 2019.
3. Mustang net loss from their external SEC report of \$14.6 million net of non-controlling interest of \$9.7 million, MSA fee to Fortress of \$0.1 million and financing fee to Fortress of \$1.0 million for the three months ended June 30, 2020; and net loss of \$10.4 million net of non-controlling interest of \$5.8 million, MSA fee to Fortress of \$0.1 million and financing fee to Fortress of \$1.3 million for the three months ended June 30, 2019. Mustang net loss from their external SEC report of \$26.5 million net of non-controlling interest of \$17.7 million, MSA fee to Fortress of \$0.3 million and financing fee to Fortress of \$1.1 million for the six months ended June 30, 2020; and net loss of \$20.0 million net of non-controlling interest of \$11.3 million, MSA fee to Fortress of \$0.3 million and financing fee to Fortress of \$1.7 million for the six months ended June 30, 2019.
4. Caelum's one-time gain from de-consolidation recorded in January 2019.



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

(\$ in thousands)	For the three months ended June 30,		For the six months ended June 30,	
	2020	2019	2020	2019
<b>Research and development</b>	\$ 15,703	\$ 18,511	\$ 30,570	\$ 41,784
Less:				
Research and development Avenue	1,219	6,392	1,916	16,633
Research and development Checkpoint	3,029	4,120	5,664	8,701
Research and development Mustang <sup>1</sup>	9,771	6,761	19,023	13,659
<b>Non-GAAP research and development costs</b>	<u>\$ 1,684</u>	<u>\$ 1,238</u>	<u>\$ 3,967</u>	<u>\$ 2,791</u>
<b>General and administrative</b>	\$ 14,456	\$ 13,443	\$ 29,975	\$ 26,921
Less:				
General and administrative Avenue	684	716	1,261	1,835
General and administrative Checkpoint <sup>2</sup>	1,496	1,536	3,049	3,105
General and administrative Mustang <sup>3</sup>	1,917	1,841	3,685	4,122
<b>Non-GAAP general and administrative costs</b>	<u>\$ 10,359</u>	<u>\$ 9,350</u>	<u>\$ 21,980</u>	<u>\$ 17,859</u>

1. Excludes \$62,500 and \$62,500 of Fortress MSA expense for the three months ended June 30, 2020 and 2019, respectively, and \$0.1 million and \$0.1 million for the six months ended June 30, 2020 and 2019, respectively.
2. Excludes \$0.1 million of Fortress MSA expense and \$0.1 million Fortress financing fee for the three months ended June 30, 2020; and \$0.1 million of Fortress MSA expense and \$0.1 million Fortress financing fee for the three months ended June 30, 2019. Excludes \$0.3 million of Fortress MSA expense and \$0.1 million Fortress financing fee for the six months ended June 30, 2020; and \$0.3 million of Fortress MSA expense and \$0.1 million Fortress financing fee for the six months ended June 30, 2019.
3. Excludes \$62,500 of Fortress MSA expense and \$1.0 million Fortress financing fee for the three months ended June 30, 2020; and \$62,500 of Fortress MSA expense and \$1.3 million Fortress financing fee for the three months ended June 30, 2019. Excludes \$0.3 million of Fortress MSA expense and \$1.1 million Fortress financing fee for the six months ended June 30, 2020; and \$0.3 million of Fortress MSA expense and \$1.7 million Fortress financing fee for the six months ended June 30, 2019.

## **About Fortress Biotech**

Fortress Biotech, Inc. (“Fortress”) is an innovative biopharmaceutical company that was recently 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. 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)

	June 30, 2020 (Unaudited)	December 31, 2019
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 183,278	\$ 136,858
Accounts receivable (net of allowance for doubtful accounts of \$176 and \$100 at June 30, 2020 and December 31, 2019, respectively)	11,173	13,539
Inventory	1,209	857
Other receivables - related party	936	865
Prepaid expenses and other current assets	3,203	4,133
Total current assets	199,799	156,252
Property and equipment, net	12,360	12,433
Operating lease right-of-use asset, net	20,675	21,480
Restricted cash	16,574	16,574
Long-term investment, at fair value	11,148	11,148
Intangible asset, net	6,667	7,377
Other assets	1,350	1,158
<b>Total assets</b>	<b>\$ 268,573</b>	<b>\$ 226,422</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 31,836	\$ 35,451
Interest payable	1,093	1,042
Interest payable - related party	52	92
Notes payable, short-term (net of debt discount of \$0 at June 30, 2020 and December 31, 2019)	21,823	7,220
Operating lease liabilities - short-term	1,752	1,784
Derivative warrant liability	413	27
Total current liabilities	56,969	45,616
Notes payable, long-term (net of debt discount of \$3,762 and \$5,086 at June 30, 2020 and December 31, 2019, respectively)	64,157	77,436
Operating lease liabilities - long-term	23,251	23,712
Other long-term liabilities	7,338	7,126
<b>Total liabilities</b>	<b>151,715</b>	<b>153,890</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, 2,693,806 and 1,341,167 shares issued and outstanding as of June 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, 86,113,331 and 74,027,425 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	86	74
Common stock issuable, 311,499 and 251,337 shares as of June 30, 2020 and December 31, 2019, respectively	813	500
Additional paid-in-capital	521,493	461,874
Accumulated deficit	(461,918)	(436,234)
Total stockholders' equity attributed to the Company	60,477	26,215
Non-controlling interests	56,381	46,317
Total stockholders' equity	116,858	72,532
<b>Total liabilities and stockholders' equity</b>	<b>\$ 268,573</b>	<b>\$ 226,422</b>

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
<b>Revenue</b>				
Product revenue, net	\$ 9,415	\$ 8,199	\$ 21,361	\$ 14,324
Revenue - related party	42	1,051	1,014	1,403
Net revenue	<u>9,457</u>	<u>9,250</u>	<u>22,375</u>	<u>15,727</u>
<b>Operating expenses</b>				
Cost of goods sold - product revenue	3,124	2,386	6,934	4,270
Research and development	15,703	18,511	30,570	41,784
Research and development – licenses acquired	1,570	200	1,820	650
General and administrative	14,456	13,443	29,975	26,921
Total operating expenses	<u>34,853</u>	<u>34,540</u>	<u>69,299</u>	<u>73,625</u>
Loss from operations	(25,396)	(25,290)	(46,924)	(57,898)
Other income (expense)				
Interest income	336	779	963	1,217
Interest expense and financing fee	(3,059)	(3,106)	(6,184)	(5,575)
Change in fair value of derivative liability	(344)	-	(386)	-
Gain on deconsolidation of Caelum	-	137	-	18,521
Total other (expense) income	<u>(3,067)</u>	<u>(2,190)</u>	<u>(5,607)</u>	<u>14,163</u>
<b>Net loss</b>	<b><u>(28,463)</u></b>	<b><u>(27,480)</u></b>	<b><u>(52,531)</u></b>	<b><u>(43,735)</u></b>
Less: net loss attributable to non-controlling interests	15,149	14,382	26,847	32,029
<b>Net loss attributable to common stockholders</b>	<b><u>\$ (13,314)</u></b>	<b><u>\$ (13,098)</u></b>	<b><u>\$ (25,684)</u></b>	<b><u>\$ (11,706)</u></b>
Net loss per common share - basic and diluted	\$ (0.42)	\$ (0.51)	\$ (0.80)	\$ (0.86)
Net loss per common share attributable to non-controlling interests - basic and diluted	\$ (0.22)	\$ (0.27)	\$ (0.41)	\$ (0.63)
Net loss per common share attributable to common stockholders - basic and diluted	\$ (0.19)	\$ (0.24)	\$ (0.39)	\$ (0.23)
Weighted average common shares outstanding - basic and diluted	68,550,494	53,726,125	66,023,367	51,130,977