
**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): **March 16, 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.

Item 2.02 Results of Operations and Financial Condition.

On March 16, 2020, Fortress Biotech, Inc. issued a press release to announce financial results and recent corporate highlights for the fourth quarter and full year ended December 31, 2019. 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 March 16, 2020.

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: March 16, 2020

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



Fortress Biotech Reports Record Fourth Quarter and Full-Year 2019 Financial Results and Recent Corporate Highlights

Revenue from marketed dermatology products increased 85% for fourth quarter 2019 and 49% for full-year 2019 compared to 2018

NDA for IV tramadol accepted for review by FDA; PDUFA date is set for October 10, 2020

Rolling NDA submission for CUTX-101 for the treatment of Menkes disease is on track to begin in the fourth quarter of 2020

New York, NY – March 16, 2020 – Fortress Biotech, Inc. (NASDAQ: FBIO) (“Fortress”), an innovative biopharmaceutical company, today announced financial results and recent corporate highlights for the fourth quarter and full year ended December 31, 2019.

Fortress achieved multiple key milestones in 2019 and early 2020, including:

- Our five marketed specialty dermatology products generated 2019 net revenues of \$34.9 million, representing growth of 49% compared to 2018. Fourth quarter 2019 revenues generated from our five marketed specialty dermatology products were \$11.1 million, representing 85% growth over fourth quarter 2018. The products are marketed by our partner company, Journey Medical Corporation.
 - We 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, given Fortress’ 8,463% revenue growth due to the increase in Journey Medical’s net product sales from 2015 to 2018.
 - We submitted a New Drug Application (“NDA”) for IV tramadol to the U.S. Food and Drug Administration (“FDA”) in December 2019, which represents our first NDA filing. The FDA accepted the NDA for review and assigned a Prescription Drug User Fee Act (“PDUFA”) goal action date of October 10, 2020. Shortly after NDA approval of IV tramadol, and pending our fulfillment of the criteria as defined in the Stock Purchase and Merger Agreement, we plan to close the second stage of the strategic transaction between InvaGen Pharmaceuticals Inc. (“InvaGen”) and our partner company Avenue Therapeutics, Inc. (“Avenue”), for an aggregate cash purchase of up to \$180 million payable to Avenue shareholders, including \$48 million to Fortress directly, as well as future contingent value rights.
 - The FDA granted Rare Pediatric Disease Designation to Copper Histidinate, also referred to as CUTX-101, for the treatment of Menkes disease. We intend to begin a rolling NDA submission for CUTX-101 to the FDA in the fourth quarter of 2020.
 - Caelum Biosciences, Inc. (“Caelum”) executed an agreement with Alexion Pharmaceuticals, Inc. (“Alexion”) to advance the development of CAEL-101. Under the terms of the agreement, Alexion purchased a 19.9% minority equity interest in Caelum for \$30 million. Additionally, Alexion agreed to make potential payments to Caelum upon the achievement of certain developmental milestones in exchange for which Alexion obtained a contingent exclusive option to acquire the remaining equity in the company.
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- We executed license agreements for several product candidates and FDA-approved products, including:
 - o Ximino®, a prescription oral antibiotic for acne, with Sun Pharma; the prescription run rate in December 2019 represents a 150% increase over the previous December with just four months of our sales effort;
 - o MB-108 (oncolytic virus C134) for the treatment of glioblastoma multiforme, with Nationwide Children’s Hospital; and
 - o AZD7325, now known as BAER-101, a novel $\alpha 2/3$ -subtype-selective GABA A positive allosteric modulator (“PAM”) for the treatment of select central nervous system (“CNS”) disorders, with AstraZeneca.
- We announced confirmation of the registration path for cosibelimab in metastatic cutaneous squamous cell carcinoma (“CSCC”). FDA feedback supports the plan to submit a Biologics License Application (“BLA”) based on data from the ongoing Phase 1 clinical trial. Over one-third of enrollment is complete in the cohort of patients with metastatic CSCC. There is potential for cosibelimab to be differentiated both clinically and as a lower-cost alternative to available anti-PD-1/L1 mAbs.
- We announced that the first patient treated with the optimized MB-106 (CD20-targeted, autologous CAR T cell therapy) manufacturing process achieved a complete response at the lowest starting dose in an ongoing Phase 1/2 clinical trial in patients with relapsed or refractory B-cell non-Hodgkin lymphomas.

Lindsay A. Rosenwald, M.D., Fortress’ Chairman, President and Chief Executive Officer, said, “We have generated significant momentum throughout 2019 and into early 2020. In order to drive our next phase of growth, our world-class business development team continues to identify and acquire high-potential marketed and development-stage assets to further expand our portfolio of product opportunities. Additionally, Fortress and our development partners continue to advance our clinical-stage programs across multiple therapeutic categories. With five commercial products and over 25 programs in development, we aim to continue to meaningfully increase value and decrease overall risk for Fortress shareholders. Looking ahead, we expect 2020 to be a record revenue-generating year and a transformational one for many of the development-stage programs across Fortress and our partner companies. Finally, we look forward to continued acquisitions of marketable dermatology drugs and in-licenses of development-stage drug candidates.”

2019 and Recent Corporate Highlights¹:

Marketed Dermatology Products

- Our dermatology products are marketed by our partner company, Journey Medical Corporation.
 - In 2019, our marketed products generated net revenue of \$34.9 million, including \$11.1 million generated in the fourth quarter of 2019. This compares to net revenue of \$23.4 million in 2018, including \$6.0 million generated in the fourth quarter of 2018, representing an increase of 49% year-over-year and an increase of 85% for the fourth quarter-over-quarter.
 - We launched Ximino®, a prescription oral antibiotic for acne, in the third quarter of 2019; the prescription run rate in December 2019 represents a 150% increase over the previous December. This impact occurred with only four months of our sales effort.
 - We expect to launch one to two new prescription drugs in 2020.
 - We currently have 41 sales representatives dedicated to the dermatology product portfolio and we expect that number to continue to grow this year.
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IV Tramadol

- The stock purchase stage of the strategic transaction between InvaGen and Avenue closed in February 2019. InvaGen acquired approximately 5.8 million shares of Avenue Therapeutics' common stock at \$6.00 per share for total gross consideration of \$35.0 million, representing a 33.3% stake in Avenue's capital stock on a fully-diluted basis. Avenue anticipates that the merger with InvaGen will be completed shortly after the Prescription Drug User Fee Act ("PFUDA") date of October 10, 2020, if IV tramadol is approved by the FDA and pending our fulfillment of the criteria as defined in the Stock Purchase and Merger Agreement, resulting in a potential net distribution to Fortress of approximately \$48 million, plus potential future product royalties.
- In June 2019, we announced that our second pivotal Phase 3 clinical trial of IV tramadol achieved the primary endpoint of a statistically significant improvement in Sum of Pain Intensity Difference over 24 hours ("SPID24") compared to placebo in patients with postoperative pain following abdominoplasty surgery. In addition, the trial met all of its key secondary endpoints. The trial also included a standard-of-care IV opioid, IV morphine 4 mg, as an active comparator. In this trial, IV tramadol also demonstrated similar efficacy and safety to that of IV morphine.
- In October 2019, an eAbstract was presented at ANESTHESIOLOGY 2019, the American Society of Anesthesiologists' annual meeting in Orlando, FL, highlighting the Phase 3 data for IV tramadol in the management of post-surgical pain in patients undergoing bunionectomy, an orthopedic model.
- Also in October 2019, IV tramadol Phase 1 clinical data were published in the peer-reviewed journal *Clinical Pharmacology in Drug Development*. The paper, titled "Comparing the Pharmacokinetics of 2 Novel Intravenous Tramadol Dosing Regimens to Oral Tramadol: A Randomized 3-Arm Crossover Study," can be accessed [here](#).
- In December 2019, we submitted our NDA to the FDA for IV tramadol for the management of moderate to moderately severe pain in adults in a medically supervised health care setting. The FDA accepted the NDA for review in February 2020 with a PDUFA goal action date of October 10, 2020.
- IV Tramadol is currently in development at our partner company, Avenue Therapeutics, Inc.

CUTX-101

- In January 2020, we announced that the FDA granted Rare Pediatric Disease Designation 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.

CAEL-101

- In January 2019, Caelum signed an agreement with Alexion to advance the development of CAEL-101. Under the terms of the agreement, Alexion purchased a 19.9% minority equity interest in Caelum for \$30 million. Additionally, Alexion agreed to make potential payments to Caelum upon the achievement of certain developmental milestones in exchange for which Alexion obtained a contingent exclusive option to acquire the remaining equity in the company.
 - In October 2019, the European Commission granted Orphan Drug Designation to CAEL-101 for the treatment of AL amyloidosis. The FDA had previously granted two orphan drug designations to CAEL-101 for the use of CAEL-101 as a therapeutic agent for patients with AL amyloidosis and a radio-imaging agent in amyloidosis.
 - Caelum received feedback from the FDA that supports initiating a pivotal Phase 2/3 program, which is expected to begin in the first half of 2020.
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MB-107 (Lentiviral Gene Therapy for XSCID)

- In April 2019, the *New England Journal of Medicine* published data from St. Jude Children's Research Hospital. The data are from a Phase 1/2 clinical trial of a lentiviral gene therapy, MB-107, for the treatment of newly diagnosed infants under two years old with X-linked severe combined immunodeficiency ("XSCID"), also known as bubble boy disease. Data demonstrate that MB-107 achieved normalization of T-cell numbers in all eight newly diagnosed infants with XSCID to date and disseminated infections resolved completely in all affected infants. Seven of the eight infants treated have developed normal IgM levels to date. Four of those seven infants have discontinued monthly infusions of intravenous immunoglobulin ("IVIG") therapy to date. Three of those four infants who discontinued monthly IVIG infusions have responded to vaccines to date.
- In August 2019, MB-107 was granted Regenerative Medicine Advanced Therapy ("RMAT") designation by the FDA.
- Also in August 2019, we entered into a license agreement with CSL Behring for the Cytegrity™ stable producer cell line, which will be used to produce the viral vector for the MB-107 lentiviral gene therapy program for the treatment of XSCID.
- Updated Phase 1/2 clinical data for MB-107 were selected for oral and poster presentations at the 61st American Society of Hematology ("ASH") Annual Meeting, which was held in December 2019. Data demonstrated that MB-107 preceded by low-dose busulfan conditioning continued to be well tolerated and resulted in development of a functional immune system both in newly diagnosed infants with XSCID, as well as in older patients with XSCID who had received prior hematopoietic stem cell transplantation ("HSCT"). Also, the enhanced transduction procedure demonstrated similar improvements in older patients with XSCID who had received prior HSCT, but with faster time to NK cell reconstitution, as well as faster time to resolution of chronic norovirus infections.
- MB-107 is currently in development at our partner company, Mustang Bio, Inc.

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

- In September 2019, positive interim results for cosibelimab were presented at the European Society for Medical Oncology Congress 2019 in Barcelona, Spain. The poster presentation provided updated interim efficacy and safety results from the ongoing multicenter Phase 1 clinical trial of cosibelimab, including expansion cohorts in CSCC and NSCLC. A 50% objective response rate was observed in CSCC, and a 40% objective response rate was observed in NSCLC. Cosibelimab appeared to be safe and well-tolerated with a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies.
 - In November 2019, pharmacokinetic and target occupancy modeling data for cosibelimab were presented at the Society for Immunotherapy of Cancer 34th Annual Meeting. The poster, titled "Semi-mechanistic PK and target-occupancy modeling to support dose justification for anti-PD-L1 clinical candidate CK-301 ("TG-1501") in oncology patients," compares pharmacokinetic and tumor target occupancy data at steady state under various dosing regimens of cosibelimab to those of three marketed anti-PD-L1 monoclonal antibodies: atezolizumab, durvalumab and avelumab. The results demonstrated that cosibelimab dosed at 800 mg and 1200 mg once every two weeks or every three weeks is expected to achieve over 99% PD-L1 target occupancy throughout the dosing interval, which is comparable to atezolizumab and durvalumab and higher than avelumab, at approved doses.
 - In January 2020, we announced confirmation of the registration path for cosibelimab in metastatic CSCC. FDA feedback supports the plan to submit a BLA based on data from the ongoing Phase 1 clinical trial. Over one-third of enrollment is complete in the cohort of patients with metastatic CSCC. There is potential for cosibelimab to be differentiated both clinically and as a lower-cost alternative to available anti-PD-1/L1 mAbs.
 - Cosibelimab is currently in development at our partner company, Checkpoint Therapeutics, Inc.
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CK-101 (third-generation EGFR inhibitor)

- In March 2019, we announced two new patent issuances by the U.S. Patent and Trademark Office and the European Patent Office for CK-101. The patents cover CK-101 in the U.S. and Europe through at least August 2034, not including any potential patent term extensions.
- CK-101 is currently in development at our partner company, Checkpoint Therapeutics, Inc.

MB-102 (CD123-targeted CAR T cell therapy)

- In July 2019, the FDA granted Orphan Drug Designation to MB-102 (CD123-targeted chimeric antigen receptor T ["CAR T"]) cell therapy for the treatment of acute myeloid leukemia ("AML").
- In August 2019, we announced that the FDA approved the Investigational New Drug application to initiate a multicenter Phase 1/2 clinical trial of MB-102 in AML, blastic plasmacytoid dendritic cell neoplasm and high-risk myelodysplastic syndrome.
- MB-102 is currently in development at our partner company, Mustang Bio, Inc.

MB-101 (IL13R α 2-targeted CAR T cell therapy)

- In October 2019, we announced that City of Hope received \$4.1 million in grant awards for a clinical trial of MB-101 (IL13R α 2-targeted CAR T cell therapy) in combination with nivolumab (commercial name: Opdivo®) and ipilimumab (commercial name: Yervoy®) in patients with recurrent malignant glioma. The trial, which is now enrolling patients, is the first human study to combine IL13R α 2-targeted CAR T cell therapy with checkpoint inhibitors, as well as the first to locally deliver CAR T cells with systemic nivolumab combination treatment.
- MB-101 is currently in development at our partner company, Mustang Bio, Inc.

MB-108 (Oncolytic Virus C134)

- In February 2019, we entered into an exclusive worldwide license agreement with Nationwide Children's Hospital to develop an oncolytic virus (C134), an attenuated herpes simplex virus type 1, for the treatment of glioblastoma multiforme. We intend to combine MB-108 with MB-101 (IL13R α 2-targeted CAR T cell therapy) to potentially enhance efficacy in treating glioblastoma multiforme.
- In May 2019, the FDA granted Orphan Drug Designation to MB-108 for the treatment of malignant glioma, a type of brain cancer with a median survival of less than 18 months.
- In October 2019, we announced that the first patient was dosed in a Phase 1 clinical trial to determine the safety and efficacy of MB-108 in recurrent glioblastoma multiforme.
- MB-108 is currently in development at our partner company, Mustang Bio, Inc.

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

- In May 2019, we announced that City of Hope began enrolling patients with relapsed or treatment-resistant multiple myeloma in an innovative CS1 CAR T cell therapy (MB-104) trial.
- MB-104 is currently in development at our partner company, Mustang Bio, Inc.

MB-103 (HER2-targeted CAR T cell therapy)

- In August 2019, we announced that the California Institute for Regenerative Medicine ("CIRM") granted \$9.3 million to City of Hope to fund an ongoing Phase 1 clinical trial of MB-103 (HER2-targeted CAR T cell therapy) for the treatment of HER2-positive breast cancer with brain metastases.
- MB-103 is currently in development at our partner company, Mustang Bio, Inc.

MB-105 (Prostate Stem Cell Antigen (PSCA)-targeted CAR T cell therapy)

- In September 2019, we announced that City of Hope opened and began to treat its first patients in a Phase 1 clinical trial of MB-105 (prostate stem cell antigen-targeted CAR T cell therapy) for the treatment of prostate cancer.
 - MB-105 is currently in development at our partner company, Mustang Bio, Inc.
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MB-106 (CD20-targeted CAR T cell therapy)

- Fred Hutchinson Cancer Research Center (“Fred Hutch”) presented a poster about the design of the ongoing Phase 1/2 clinical trial investigating the safety and efficacy of MB-106 (CD20-targeted CAR T cell therapy) for high-risk B-cell non-Hodgkin lymphomas at the 61st ASH Annual Meeting.
- In February 2020, we announced that the first subject treated with the optimized MB-106 (CD20-targeted, autologous CAR T cell therapy) manufacturing process, developed in collaboration between Mustang Bio and Fred Hutch, achieved a complete response at the lowest starting dose in an ongoing Phase 1/2 clinical trial. The trial is evaluating the safety and efficacy of MB-106 in subjects with relapsed or refractory B-cell non-Hodgkin lymphomas.
- MB-106 is currently in development at our partner company, Mustang Bio, Inc.

BAER-101 (novel $\alpha 2/3$ -subtype-selective GABA A positive allosteric modulator [“PAM”])

- In December 2019, we entered into an exclusive worldwide licensing agreement with AstraZeneca for AZD7325, now known as BAER-101, a novel $\alpha 2/3$ -subtype-selective GABA A PAM, as well as an agreement with Cincinnati Children’s Hospital Medical Center to advance clinical development in select CNS disorders.
- BAER-101 is currently in development at our partner company, Baergic Bio, Inc.

General Corporate

- In August 2019, we announced the appointment of Kevin L. Lorenz, J.D., to our Board of Directors.
- In November 2019, we announced that Fortress 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.
- In November 2019 and February 2020, we closed on a gross total of approximately \$20.4 million in two underwritten public offerings of our 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock.

Financial Results:

- As of December 31, 2019, Fortress’ consolidated cash, cash equivalents, short-term investments (certificates of deposit) and restricted cash totaled \$153.4 million, compared to \$156.0 million as of September 30, 2019, and \$99.2 million as of December 31, 2018, a decrease of \$2.6 million for the fourth quarter and an increase of \$54.2 million for the full year.
 - Fortress’ net revenue totaled \$36.6 million as of December 31, 2019, which includes \$34.9 million in net revenue generated from our marketed dermatology products, which represented growth of 49% year-over-year. This compares to a total of \$26.9 million in net revenue as of December 31, 2018.
 - Consolidated research and development expenses were \$75.2 million for the year ended December 31, 2019, of which \$72.6 million was related to partner companies. This compares to \$83.3 million for 2018, of which \$76.8 million was related to partner companies. Non-cash, stock-based compensation expenses included in research and development were \$2.8 million for the year ended December 31, 2019, compared to \$5.3 million for 2018.
 - Research and development expenses from license acquisitions totaled \$6.1 million for the year ended December 31, 2019, compared to \$4.1 million for 2018.
 - Consolidated general and administrative expenses were \$55.6 million for the year ended December 31, 2019, of which \$37.3 million was related to partner companies. This compares to \$53.4 million for 2018, of which \$33.0 million was related to partner companies. Non-cash, stock-based compensation expenses included in general and administrative expenses were \$10.4 million for the year ended December 31, 2019, compared to \$9.7 million for 2018.
 - Consolidated net loss attributable to common stockholders was \$40.0 million, or \$0.73 per share, for the year ended December 31, 2019, compared to a net loss attributable to common stockholders of \$84.1 million, or \$1.94 per share, for 2018.
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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 therapeutic areas, including oncology, rare diseases and gene therapy, which allow it to create value while mitigating risk 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., 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.

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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¹ 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.

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

	December 31,	
	2019	2018
ASSETS		
Current assets		
Cash and cash equivalents	\$ 136,858	\$ 65,508
Accounts receivable (net of allowance for doubtful accounts of \$100 and \$0 at December 31, 2019 and December 31, 2018, respectively)	13,539	5,498
Short-term investments (certificates of deposit)	-	17,604
Inventory	857	678
Other receivables - related party	865	2,095
Prepaid expenses and other current assets	4,133	6,735
Current assets held for sale	-	13,089
Total current assets	<u>156,252</u>	<u>111,207</u>
Property and equipment, net	12,433	12,019
Operating lease right-of-use asset, net	21,480	-
Restricted cash	16,574	16,074
Long-term investment, at fair value	11,148	-
Intangible asset, net	7,377	1,417
Other assets	1,158	276
Total assets	<u>\$ 226,422</u>	<u>\$ 140,993</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 35,451	\$ 34,067
Accounts payable and accrued expenses - related party	-	149
Interest payable	1,042	1,232
Interest payable - related party	92	97
Notes payable, short-term (net of debt discount of \$0 and \$336 at December 31, 2019 and December 31, 2018, respectively)	7,220	9,164
Partner company convertible note, short-term, at fair value	-	9,914
Operating lease liabilities - short-term	1,784	-
Derivative warrant liability	27	991
Total current liabilities	<u>45,616</u>	<u>55,614</u>
Notes payable, long-term (net of debt discount of \$5,086 and \$4,567 at December 31, 2019 and December 31, 2018, respectively)	77,436	60,425
Operating lease liabilities - long-term	23,712	-
Other long-term liabilities	7,126	5,211
Total liabilities	<u>153,890</u>	<u>121,250</u>
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 1,341,167 and 1,000,000 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively; liquidation value of \$25.00 per share	1	1
Common stock, \$.001 par value, 100,000,000 shares authorized, 74,027,425 and 57,845,447 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	74	58
Common stock issuable, 251,337 and 744,322 shares as of December 31, 2019 and December 31, 2018, respectively	500	659
Additional paid-in-capital	461,874	397,408
Accumulated deficit	(436,234)	(396,274)
Total stockholders' equity attributed to the Company	<u>26,215</u>	<u>1,852</u>
Non-controlling interests	46,317	17,891
Total stockholders' equity	<u>72,532</u>	<u>19,743</u>
Total liabilities and stockholders' equity	<u>\$ 226,422</u>	<u>\$ 140,993</u>

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

	For the Years Ended December 31,	
	2019	2018
Revenue		
Product revenue, net	\$ 34,921	\$ 23,376
Revenue - from a related party	1,708	3,506
Net revenue	<u>36,629</u>	<u>26,882</u>
Operating expenses		
Cost of goods sold - product revenue	10,532	6,125
Research and development	75,236	83,333
Research and development – licenses acquired	6,090	4,050
General and administrative	55,590	53,371
Total operating expenses	<u>147,448</u>	<u>146,879</u>
Loss from operations	(110,819)	(119,997)
Other income (expense)		
Interest income	2,559	1,104
Interest expense and financing fee	(11,849)	(10,340)
Change in fair value of derivative liability	(27)	(682)
Change in fair value of subsidiary convertible note	-	437
Change in fair value of investments	-	(1,390)
Gain on deconsolidation of Caelum	18,476	-
Other income	-	68
Total other income (expense)	<u>9,159</u>	<u>(10,803)</u>
Loss from continuing operations	(101,660)	(130,800)
Discontinued operations:		
Gain from disposal of National	-	2,333
Loss from discontinued operations, net of tax	-	(13,469)
Total loss from discontinued operations	<u>-</u>	<u>(11,136)</u>
Net loss	<u>(101,660)</u>	<u>(141,936)</u>
Less: net loss attributable to non-controlling interests	61,700	57,789
Net loss attributable to common stockholders	<u>\$ (39,960)</u>	<u>\$ (84,147)</u>
Loss from continuing operations per common share - basic and diluted	\$ (1.86)	\$ (3.01)
Loss from discontinued operations per common share - basic and diluted	\$ -	\$ (0.26)
Net loss per common share attributable to common stockholders - basic and diluted	\$ (0.73)	\$ (1.94)
Weighted average common shares outstanding - basic and diluted	54,711,838	43,461,978