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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **November 12, 2019**

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

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

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

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

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

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

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

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

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

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

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

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

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

Item 2.02 Results of Operations and Financial Condition.

On November 12, 2019, 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, 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 November 12, 2019.

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 12, 2019

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

Exhibit 99.1

Fortress Biotech Reports Third Quarter 2019 Financial Results and Recent Corporate Highlights

New York, NY – November 12, 2019 – Fortress Biotech, Inc. (NASDAQ: FBIO) ("Fortress"), an innovative biopharmaceutical company focused on identifying, in-licensing and developing high-potential marketed and development-stage drugs and drug candidates, today announced financial results and recent corporate highlights for the third quarter ended September 30, 2019.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "We are very pleased with the progress made during the third quarter of 2019 as we continue to focus on generating shareholder value in five distinct ways – through potential revenue and balance sheet growth, monetizations, priority review vouchers and future sales royalties. We recently acquired and launched Ximino®, the second prescription oral antibiotic for acne in our marketed dermatology portfolio, which we expect will enable us to continue to grow the commercial side of our business. The last quarter of 2019 is expected to be marked by the achievement of additional milestones, notably the anticipated filing of a New Drug Application ("NDA") for IV tramadol for post-surgical pain management."

Dr. Rosenwald continued, "We are also pleased that MB-107, the lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency ("XSCID"), also known as bubble boy disease, being developed by our partner company Mustang Bio, was granted the Regenerative Medicine Advanced Therapy ("RMAT") designation by the U.S. Food and Drug Administration ("FDA"). We look forward to the presentation of additional clinical data on MB-107 at the upcoming 61 st ASH Annual Meeting and hope to achieve regulatory agreement with the FDA later this year to potentially expedite the development and approval of this critically needed treatment option for XSCID (bubble boy) patients. In addition, positive interim data for cosibelimab, an anti-PD-L1 antibody, were presented at the European Society for Medical Oncology ("ESMO") Congress 2019. The ongoing Phase 1 clinical trial of cosibelimab could support the submission of an initial Biologics License Application ("BLA") to the FDA. We are proud of our achievements during the third quarter and are well positioned to build on the momentum in order to continue to execute on our business plan into 2020 and beyond."

Financial Results:

- As of September 30, 2019, Fortress' consolidated cash, cash equivalents, short-term investments (certificates of deposit), and restricted cash totaled $156.0 million, compared to $170.5 million as of June 30, 2019, and $99.2 million as of December 31, 2018, a decrease of $14.5 million for the quarter and an increase of $56.8 million year-to-date.
- Fortress' net revenue totaled $9.8 million for the third quarter of 2019, which includes $9.5 million in net revenue generated from our marketed dermatology products. This compares to a total of $5.2 million in net revenue for the third quarter of 2018.
- Research and development expenses were $14.6 million for the third quarter of 2019, of which $13.9 million was related to Fortress partner companies. This compares to $16.1 million for the third quarter of 2018, of which $15.1 million was related to Fortress partner companies. Non-cash, stock-based compensation expenses included in research and development were $1.2 million for the third quarter of 2019, compared to $1.8 million for the third quarter of 2018.

- Research and development expenses from license acquisitions totaled $0.7 million for the third quarter of 2019, compared to $3.7 million for the third quarter of 2018.
- General and administrative expenses were $14.3 million for the third quarter of 2019, of which $9.3 million was related to Fortress partner companies. This compares to $12.2 million for the third quarter of 2018, of which $7.4 million was related to Fortress partner companies. Non-cash, stock-based compensation expenses included in general and administrative expenses were $2.5 million for the third quarter of 2019, compared to $2.3 million for the third quarter of 2018.
- Net loss attributable to common stockholders was $12.8 million, or $0.22 per share, for the third quarter of 2019, compared to a net loss attributable to common stockholders of $16.6 million, or $0.37 per share, for the third quarter of 2018. For the first nine months of 2019, net loss attributable to common stockholders was $24.5 million or $0.46 per share, compared to $59.3 million or $1.36 per share for the first nine months of 2018.

Recent Corporate Highlights[1]:

Marketed Dermatology Products
- In the third quarter of 2019, our marketed products generated net revenue of $9.5 million, compared to $5.2 million in the third quarter of 2018.
- Also, in the third quarter of 2019, we launched Ximino®, a prescription oral antibiotic for acne.
- We anticipate 2019 annual net pharmaceutical revenues of approximately $30 million.
- We currently have 37 sales representatives dedicated to the dermatology product portfolio.
- We anticipate launching one to two new prescription products in 2020.
- Our dermatology products are marketed by our partner company, Journey Medical Corporation.

IV Tramadol
- In October 2019, an eAbstract was presented at ANESTHESIOLOGY® 2019, the Annual Meeting of the American Society of Anesthesiologists 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. As previously announced, IV tramadol 50 mg met the primary endpoint, as well as all of the key secondary endpoints. We expect an NDA for IV tramadol to be filed with the FDA by year-end 2019.
- We anticipate that the Avenue Therapeutics merger with InvaGen Pharmaceuticals Inc. will be completed in 2021, if the conditions of the Stock Purchase and Merger Agreement are met, resulting in a potential net distribution to Fortress of approximately $48 million plus potential future product royalties.
- 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.
- IV tramadol is currently in development at our partner company, Avenue Therapeutics, Inc.

MB-107 (Lentiviral Gene Therapy for XSCID)
- In August 2019, MB-107, a lentiviral gene therapy for the treatment of XSCID, also known as bubble boy disease, was granted 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 have been selected for oral and poster presentations at the 61st American Society of Hematology (ASH) Annual Meeting, which will be held December 7-10, 2019, at the Orange County Convention Center in Orlando, FL.
- MB-107 is currently in development at our partner company, Mustang Bio, Inc.

[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/or partners, as dictated by context.

CAEL-101

- In October 2019, the European Commission granted orphan drug designation to CAEL-101 for the treatment of AL amyloidosis. The U.S. Food and Drug Administration (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 the use of CAEL-101 as a radio-imaging agent in amyloidosis.
- We received feedback from the FDA that supports our initiating a pivotal Phase 2/3 program stratified by Mayo stage beginning in 1H2020.
- CAEL-101 is currently in development at Caelum Biosciences, Inc., with its partner Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN).

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

- In September 2019, positive interim results for cosibelimab were presented at the ESMO 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 cutaneous squamous cell carcinoma ("CSCC") and non-small cell lung cancer ("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.
- CSCC enrollment to support a potential initial BLA submission for cosibelimab is ongoing.
- In November 2019, we announced that pharmacokinetic and target occupancy modeling data for cosibelimab were presented at the Society for Immunotherapy of Cancer (SITC) 34th Annual Meeting. The poster, entitled, "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 demonstrate 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.
- Cosibelimab is currently in development at our partner company, Checkpoint Therapeutics, Inc.

MB-101 (IL13Rα2-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 (IL13Rα2-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 IL13Rα2-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-103 (HER2-targeted CAR T cell therapy)

- In August 2019, we announced that the California Institute for Regenerative Medicine ("CIRM") granted City of Hope $9.28 million 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 has begun to treat its first patients in a Phase 1 clinical trial of MB-105 (PSCA-targeted CAR T cell therapy) for the treatment of prostate cancer.
- MB-105 is currently in development at our partner company, Mustang Bio, Inc.

MB-106 (CD20-targeted CAR T cell therapy)

- Fred Hutchinson Cancer Research Center will present 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, which will be held December 7-10, 2019, at the Orange County Convention Center in Orlando, FL. The abstract is available here.
- MB-106 is currently in development at our partner company, Mustang Bio, Inc.

MB-108 (Oncolytic Virus C134)

- In October 2019, we announced that the first participant was dosed in a Phase 1 clinical trial to determine the safety and efficacy of MB-108 (oncolytic virus C134), an attenuated herpes simplex virus type 1, in recurrent glioblastoma multiforme.
- MB-108 is currently in development at our partner company, Mustang Bio, Inc.

General Corporate

- In August 2019, we announced the appointment of Kevin L. Lorenz, J.D., to our Board of Directors.

About Fortress Biotech

Fortress Biotech, Inc. ("Fortress") is an innovative biopharmaceutical company focused on identifying, in-licensing and developing 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) and St. Jude Children's Research 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; 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
Condensed Consolidated Balance Sheets
($ in thousands except for share and per share amounts)

	September 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 134,945	$ 65,508
Accounts receivable (net of allowance of $250 and $0 at September 30, 2019 and December 31, 2018, respectively)	5,137	5,498
Short-term investments (certificates of deposit)	5,000	17,604
Inventory	941	678
Other receivables - related party	1,243	2,095
Prepaid expenses and other current assets	4,117	6,735
Restricted cash, current	14,929	-
Current assets held for sale	-	13,089
Total current assets	166,312	111,207
Property and equipment, net	12,152	12,019
Operating lease right-of-use asset, net	21,876	-
Restricted cash	1,145	16,074
Long-term investment, at fair value	11,193	-
Intangible asset, net	7,731	1,417
Other assets	1,179	276
Total assets	**$ 221,588**	**$ 140,993**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 28,512	$ 34,067
Accounts payable and accrued expenses - related party	-	149
Interest payable	1,039	1,232
Interest payable - related party	89	97
Notes payable, short-term - related party (net of debt discount of $0 and $336 at September 30, 2019 and December 31, 2018, respectively)	15,472	9,164
Partner company convertible note, short-term, at fair value	-	9,914
Operating lease liabilities - short-term	1,741	-
Derivative warrant liability	-	991
Total current liabilities	46,853	55,614
Notes payable, long-term (net of debt discount of $5,728 and $4,567 at September 30, 2019 and December 31, 2018, respectively)	68,542	60,425
Operating lease liabilities - long-term	24,168	-
Other long-term liabilities	7,025	5,211
Total liabilities	**146,588**	**121,250**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 1,026,111 and 1,000,000 shares issued and outstanding as of September 30, 2019 and December 31, 2018; liquidation value of $25.00 per share	1	1
Common stock, $.001 par value, 100,000,000 shares authorized, 70,335,534 and 57,845,447 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	70	58
Common stock issuable, 307,486 and 744,322 shares as of September 30, 2019 and December 31, 2018, respectively	500	659
Additional paid-in-capital	445,966	397,408
Accumulated deficit	(420,742)	(396,274)
Total stockholders' equity attributed to the Company	25,795	1,852
Non-controlling interests	49,205	17,891
Total stockholders' equity	75,000	19,743
Total liabilities and stockholders' equity	**$ 221,588**	**$ 140,993**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenue				
Product revenue, net	$ 9,492	$ 5,168	$ 23,816	$ 17,366
Revenue - from a related party	280	5	1,683	525
Net revenue	9,772	5,173	25,499	17,891
Operating expenses				
Cost of goods sold - product revenue	2,702	1,406	6,972	4,546
Research and development	14,571	16,082	56,355	58,528
Research and development – licenses acquired	700	3,706	1,350	3,804
General and administrative	14,339	12,184	41,260	38,788
Total operating expenses	32,312	33,378	105,937	105,666
Loss from operations	(22,540)	(28,205)	(80,438)	(87,775)
Other income (expenses)				
Interest income	738	269	1,955	841
Interest expense and financing fee	(3,168)	(2,657)	(8,743)	(7,650)
Change in fair value of derivative liability	-	12	-	114
Change in fair value of subsidiary convertible note	-	(84)	-	26
Change in fair value of investments	-	(565)	-	(1,390)
Other loss	-	-	-	(333)
Gain on deconsolidation of Caelum	-	-	18,521	-
Total other income (expenses)	(2,430)	(3,025)	11,733	(8,392)
Loss from continuing operations	(24,970)	(31,230)	(68,705)	(96,167)
Discontinued operations:				
Income (loss) from discontinued operations, net of tax	-	2,643	-	(6,354)
Total income (loss) from discontinued operations	-	2,643	-	(6,354)
Net loss	**(24,970)**	**(28,587)**	**(68,705)**	**(102,521)**
Less: net loss attributable to non-controlling interests	12,208	11,949	44,237	43,254
Net loss attributable to common stockholders	**$ (12,762)**	**$ (16,638)**	**$ (24,468)**	**$ (59,267)**
Loss from continuing operations per common share - basic and diluted	$ (0.44)	$ (0.70)	$ (1.29)	$ (2.21)
Income (loss) from discontinued operations per common share - basic and diluted	$ -	$ 0.06	$ -	$ (0.15)
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.22)	$ (0.37)	$ (0.46)	$ (1.36)
Weighted average common shares outstanding - basic and diluted	56,856,821	44,818,186	53,060,565	43,578,763