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): **May 10, 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, NY 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.

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).

Emerging growth company ☐

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. ☐

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

Title of Class	**Trading Symbol(s)**	**Exchange Name**
Common Stock	FBIO	Nasdaq Capital Market
9.375% Series A Cumulative Redeemable Perpetual Preferred Stock	FBIOP	Nasdaq Capital Market

Item 2.02. Results of Operations and Financial Condition.

On May 10, 2019, Fortress Biotech, Inc. issued a press release to provide a corporate update and to announce its financial results for the first quarter ended March 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 May 10, 2019.

SIGNATURE

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

Date: May 10, 2019

Fortress Biotech, Inc.
(Registrant)

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

Exhibit 99.1

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

New York, NY – May 10, 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 first quarter ended March 31, 2019.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "We enjoyed a strong start to 2019, with compelling data recently published in the *New England Journal of Medicine* pertaining to our partner company Mustang's lentiviral gene therapy for infants under the age of two diagnosed with X-linked severe combined immunodeficiency ("XSCID"), and the closing of two promising partnership deals with Alexion Pharmaceuticals and InvaGen Pharmaceuticals (a subsidiary of Cipla Limited) in the first quarter. These significant achievements demonstrate how our business model is designed to drive value for our shareholders. We have several opportunities to increase economics and decrease risk for our shareholders with multiple possible near-term revenue streams due to our specialty pharmaceutical business; large equity stakes in our partner companies; strategic, flexible potential exits; and potential royalties on product sales."

Dr. Rosenwald continued, "We look forward to advancing our and our partner companies' development programs and achieving numerous milestones during the remainder of 2019, including important data readouts and the potential for the first New Drug Application ("NDA") filing by a Fortress partner company later this year. Our sizable business development team continues to source and in-license high-potential marketed and development-stage programs to enhance the growing, diversified portfolio of seven commercial products and over 25 product candidates in development across our partner companies."

Financial Results:[1]

- As of March 31, 2019, Fortress' consolidated cash, cash equivalents, short-term investments (certificates of deposit), and restricted cash totaled $137.5 million, compared to $99.2 million as of December 31, 2018, an increase of $38.3 million for the quarter.
- Fortress' net revenue totaled $6.5 million for the first quarter of 2019, compared to $5.9 million for the first quarter of 2018.
- Research and development expenses were $23.3 million for the first quarter of 2019, of which $22.6 million was related to Fortress partner companies. This compares to $25.0 million for the first quarter of 2018, of which $22.8 million was related to Fortress partner companies. Non-cash, stock-based compensation expenses included in research and development were $0.6 million for the first quarter of 2019, compared to $2.3 million for the first quarter of 2018.
- Research and development expenses from license acquisitions totaled $0.5 million for the first quarter of 2019, compared to $0.1 million for the first quarter of 2018.
- General and administrative expenses were $13.5 million for the first quarter of 2019, of which $8.9 million was related to Fortress partner companies. This compares to $13.5 million for the first quarter of 2018, of which $8.4 million was related to Fortress partner companies. Non-cash, stock-based compensation expenses included in general and administrative expenses were $2.7 million for the first quarter of 2019, compared to $2.4 million for the first quarter of 2018.
- Net income attributable to common stockholders was $1.4 million, or $0.03 per share, for the first quarter of 2019, compared to a net loss attributable to common stockholders of $21.0 million, or $0.49 per share, for the first quarter of 2018.

Recent Corporate Highlights:[2]

Marketed Dermatology Products

- In the first quarter of 2019, our seven marketed products generated net revenue of $6.1 million, compared to $6.0 million in the fourth quarter of 2018 and $5.5 million in the first quarter of 2018.

IV Tramadol

- The stock purchase stage of the strategic transaction between InvaGen and our partner company 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 is currently running a second pivotal Phase 3 efficacy and safety study of IV tramadol in patients with post-operative pain following abdominoplasty procedure, as well as an open-label, single-arm safety study. Both are expected to complete around mid-2019.

CAEL-101

- In January 2019, Caelum Biosciences, Inc. ("Caelum") signed 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 has 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 for pre-negotiated economics.

Triplex

- The multicenter Phase 2 study of Triplex for cytomegalovirus ("CMV") control in allogeneic stem cell transplant recipients has concluded, and its primary endpoint was met. The full dataset was presented at the 45th Annual Meeting of the European Society for Blood and Marrow Transplantation ("EBMT") in March 2019. We plan to complete an End of Phase 2 Meeting with the FDA for Triplex in the second half of 2019 and plan to initiate a Phase 3 study of Triplex in the first half of 2020.

MB-107 (XSCID gene therapy)

- In April 2019, the *New England Journal of Medicine* published data from St. Jude Children's Research Hospital ("St. Jude"). The data are from a Phase 1/2 clinical trial of a lentiviral gene therapy for the treatment of newly diagnosed infants under two years old with XSCID. Data demonstrate the lentiviral gene therapy 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.
- MB-107 (XSCID gene therapy) is currently in development at our partner company, Mustang Bio, Inc.

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

- In January 2019, we announced that the ongoing multi-center clinical trial of anti-PD-L1 antibody, cosibelimab, was expanded to enroll patients in three endometrial and colorectal cohorts intended to support potential requests for accelerated approval and Biologics License Application ("BLA") submissions to the U.S. Food and Drug Administration ("FDA"). The ongoing trial is also enrolling cohorts of patients with non-small cell lung cancer ("NSCLC") and cutaneous squamous cell carcinoma.
- In May 2019, we announced positive interim results from our ongoing multicenter Phase 1 clinical trial of cosibelimab. There were >40% objective response rates observed in first-line non-small cell lung cancer and cutaneous squamous cell carcinoma and the antibody was well-tolerated.
- Cosibelimab (anti-PD-L1 antibody) is currently in development at our partner company, Checkpoint Therapeutics, Inc.

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 (third-generation EGFR inhibitor) is currently in development at our partner company, Checkpoint Therapeutics, Inc.

MB-108 (Oncolytic Virus C134)

- In February 2019, we partnered and entered into an exclusive worldwide license agreement with Nationwide Children's Hospital to develop an oncolytic virus (C134) for the treatment of glioblastoma multiforme. We intend to combine MB-108 with MB-101 (IL13Rα2-specific CAR) to potentially enhance efficacy in treating glioblastoma multiforme.
- MB-108 (oncolytic virus C134) is currently in development at our partner company, Mustang Bio, Inc.

MB-104 (CS1-specific CAR T)

- In May 2019, we announced that City of Hope began enrolling patients with relapsed or treatment-resistant multiple myeloma in an innovative CS1 chimeric antigen receptor ("CAR") T cell therapy (MB-104) trial. The Phase 1 clinical trial is the first autologous CAR T trial to target the CS1 protein, which is expressed by cancer cells in nearly all multiple myeloma patients.
- MB-104 (CS1-specific CAR T) is currently in development at our partner company, Mustang Bio, Inc.

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 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 UCL Business PLC. 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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[1] Financial results do not include National Holdings Corporation ("National"), as Fortress sold all of its remaining shares in National in February 2019 for an aggregate purchase price totaling approximately $22.9 million. The National segment results have been classified as discontinued operations in the accompanying Consolidated Balance Sheets and Consolidated Statements of Operations.

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

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

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 116,444	$ 65,508
Accounts receivable	8,022	5,498
Short-term investments (certificates of deposit)	5,044	17,604
Inventory	629	678
Other receivables - related party	2,129	2,095
Prepaid expenses and other current assets	4,281	6,735
Current assets held for sale	–	13,089
Total current assets	136,549	111,207
Property and equipment, net	11,833	12,019
Operating lease right-of-use asset, net	22,618	–
Restricted cash	16,074	16,074
Long-term investment, at fair value	11,056	–
Intangible asset	1,183	1,417
Other assets	1,225	276
Total assets	**$ 200,538**	**$ 140,993**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 37,073	$ 34,067
Accounts payable and accrued expenses - related party	16	149
Interest payable	1,013	1,232
Interest payable - related party	97	97
Notes payable, short-term - related party (net of debt discount of $223 and $336 at March 31, 2019 and December 31, 2018, respectively)	9,277	9,164
Partner company convertible note, short-term, at fair value	–	9,914
Operating lease liabilities – short-term	1,481	–
Derivative warrant liability	–	991
Total current liabilities	48,957	55,614
Notes payable, long-term (net of debt discount of $6,385 and $4,567 at March 31, 2019 and December 31, 2018, respectively)	73,607	60,425
Operating lease liabilities – long-term	24,989	–
Other long-term liabilities	2,276	5,211
Total liabilities	**149,829**	**121,250**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 1,000,000 shares issued and outstanding as of March 31, 2019 and December 31, 2018; liquidation value of $25.00 per share	1	1
Common stock, $.001 par value, 100,000,000 shares authorized, 63,126,521 and 57,845,447 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	63	58
Common stock issuable, 475,225 and 744,332 shares as of March 31, 2019 and December 31, 2018, respectively	765	659
Additional paid-in-capital	414,870	397,408
Accumulated deficit	(394,882)	(396,274)
Total stockholders' equity attributed to the Company	20,817	1,852
Non-controlling interests	29,892	17,891
Total stockholders' equity	50,709	19,743
Total liabilities and stockholders' equity	**$ 200,538**	**$ 140,993**

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

	For the Three Months Ended March 31,	
	2019	**2018**
Revenue		
Product revenue, net	$ 6,125	$ 5,509
Revenue - from a related party	352	394
Net revenue	6,477	5,903
Operating expenses		
Cost of goods sold - product revenue	1,884	1,472
Research and development	23,273	24,958
Research and development - licenses acquired	450	97
General and administrative	13,478	13,548
Total operating expenses	39,085	40,075
Loss from operations	(32,608)	(34,172)
Other income (expenses)		
Interest income	438	278
Interest expense and financing fee	(2,469)	(2,403)
Change in fair value of derivative liabilities	–	23
Change in fair value of subsidiary convertible note	–	250
Change in fair value of investments	–	(118)
Gain on deconsolidation of Caelum	18,384	–
Total other income (expense)	16,353	(1,970)
Loss from continuing operations	(16,255)	(36,142)
Discontinued operations		
Loss from discontinued operations, net of tax	–	(2,076)
Total loss from discontinued operations	–	(2,076)
Net loss	**(16,255)**	**(38,218)**
Less: net loss attributable to non-controlling interests	17,647	17,200
Net income (loss) attributable to common stockholders	**$ 1,392**	**$ (21,018)**
Loss from continuing operations per common share - basic and diluted	$ (0.34)	$ (0.85)
Loss from discontinued operations per common share - basic and diluted	$ –	$ (0.05)
Net income (loss) per common share attributable to common stockholders - basic	$ 0.03	$ (0.49)
Net income (loss) per common share attributable to common stockholders - diluted	$ 0.02	$ (0.49)
Weighted average common shares outstanding - basic	48,506,994	42,518,403
Weighted average common shares outstanding - diluted	63,811,136	42,518,403