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): **August 9, 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 August 9, 2019, 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, 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 August 9, 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: August 9, 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 Second Quarter 2019 Financial Results and Recent Corporate Highlights

New York, NY – August 9, 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 second quarter ended June 30, 2019.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "We are pleased to have achieved several important milestones in the second quarter, including positive data for three of our late-stage product candidates in development across our partner companies: IV tramadol for post-surgical pain management; MB-107 gene therapy for the treatment of X-linked severe combined immunodeficiency (XSCID); and cosibelimab, an anti-programmed death ligand-1 (PD-L1) antibody for the treatment of multiple advanced cancers. Looking ahead to the remainder of 2019, we anticipate multiple potentially value-creating catalysts, including a New Drug Application filing for IV tramadol and additional important clinical data readouts for many of our product candidates. Our world-class business development team continues to focus on expanding our diverse pipeline with additional high-quality biotech and specialty pharmaceutical assets, further de-risking our product portfolio."

Financial Results:

- As of June 30, 2019, Fortress' consolidated cash, cash equivalents, short-term investments (certificates of deposit), and restricted cash totaled $170.5 million, compared to $137.5 million as of March 31, 2019, and $99.2 million as of December 31, 2018, an increase of $33.0 million for the quarter and an increase of $71.3 million year-to-date.
- Fortress' net revenue totaled $9.3 million for the second quarter of 2019, compared to $6.8 million for the second quarter of 2018.
- Research and development expenses were $18.5 million for the second quarter of 2019, of which $18.0 million was related to Fortress partner companies. This compares to $17.5 million for the second 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 $0.8 million for both the second quarter of 2019 and 2018.
- Research and development expenses from license acquisitions totaled $0.2 million for the second quarter of 2019, compared to a nominal amount for the second quarter of 2018.
- General and administrative expenses were $13.4 million for the second quarter of 2019, of which $9.3 million was related to Fortress partner companies. This compares to $13.1 million for the second quarter of 2018, of which $7.7 million was related to Fortress partner companies. Non-cash, stock-based compensation expenses included in general and administrative expenses were $2.6 million for the second quarter of 2019, compared to $2.4 million for the second quarter of 2018.
- Net loss attributable to common stockholders was $13.1 million, or $0.24 per share, for the second quarter of 2019, compared to a net loss attributable to common stockholders of $21.6 million, or $0.50 per share, for the second quarter of 2018. For the first six months of 2019, net loss attributable to common stockholders was $11.7 million or $0.23 per share, compared to $42.6 million or $0.99 per share for the first six months of 2018.

Recent Corporate Highlights[1]:

Marketed Dermatology Products

- In the second quarter of 2019, our marketed products generated net revenue of $8.2 million, compared to $6.7 million in the second quarter of 2018.
- We are anticipating the launch of a second prescription oral antibiotic drug for acne during the current quarter, Q3 2019.
- This new asset, coupled with our salesforce expansion to 34 territory managers, will allow us to reach over 5,000 dermatologists across the country. This combination is expected to fuel the growth of our dermatology portfolio in 2019 and beyond.
- Our dermatology products are marketed by our partner company, Journey Medical Corporation.

IV Tramadol

- In June 2019, we announced that our second pivotal Phase 3 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 study also included a standard-of-care IV opioid as an active comparator, IV morphine 4 mg. In this study, IV tramadol also demonstrated similar efficacy and safety to that of IV morphine.
- IV Tramadol is currently in development at our partner company, Avenue Therapeutics, Inc.

MB-102 (CD123 CAR T)

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

MB-108 (Oncolytic Virus C134)

- In May 2019, the FDA granted Orphan Drug Designation to MB-108 (oncolytic virus C134) for the treatment of malignant glioma, a type of brain cancer with a median survival of less than 18 months.
- MB-108 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) 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)

	June 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 149,407	$ 65,508
Accounts receivable (net of allowance of $250 and $0 at June 30, 2019 and December 31, 2018, respectively)	3,104	5,498
Short-term investments (certificates of deposit)	5,000	17,604
Inventory	732	678
Other receivables - related party	1,850	2,095
Prepaid expenses and other current assets	3,418	6,735
Current assets held for sale	-	13,089
Total current assets	163,511	111,207
Property and equipment, net	12,023	12,019
Operating lease right-of-use asset, net	22,255	-
Restricted cash	16,074	16,074
Long-term investment, at fair value	11,193	-
Intangible asset	971	1,417
Other assets	1,237	276
Total assets	**$ 227,264**	**$ 140,993**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 24,260	$ 34,067
Accounts payable and accrued expenses - related party	-	149
Interest payable	1,022	1,232
Interest payable - related party	94	97
Notes payable, short-term - related party (net of debt discount of $104 and $336 at June 30, 2019 and December 31, 2018, respectively)	9,396	9,164
Partner company convertible note, short-term, at fair value	-	9,914
Operating lease liabilities - short-term	1,626	-
Derivative warrant liability	-	991
Total current liabilities	36,398	55,614
Notes payable, long-term (net of debt discount of $6,435 and $4,567 at June 30, 2019 and December 31, 2018, respectively)	74,307	60,425
Operating lease liabilities - long-term	24,510	-
Other long-term liabilities	2,229	5,211
Total liabilities	**137,444**	**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 June 30, 2019 and December 31, 2018; liquidation value of $25.00 per share	1	1
Common stock, $.001 par value, 100,000,000 shares authorized, 68,138,203 and 57,845,447 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	68	58
Common stock issuable, 317,804 and 744,322 shares as of June 30, 2019 and December 31, 2018, respectively	490	659
Additional paid-in-capital	439,295	397,408
Accumulated deficit	(407,980)	(396,274)
Total stockholders' equity attributed to the Company	31,874	1,852
Non-controlling interests	57,946	17,891
Total stockholders' equity	89,820	19,743
Total liabilities and stockholders' equity	**$ 227,264**	**$ 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 June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenue				
Product revenue, net	$ 8,199	$ 6,689	$ 14,324	$ 12,198
Revenue - from a related party	1,051	126	1,403	520
Net revenue	9,250	6,815	15,727	12,718
Operating expenses				
Cost of goods sold - product revenue	2,386	1,668	4,270	3,140
Research and development	18,511	17,488	41,784	42,446
Research and development – licenses acquired	200	1	650	98
General and administrative	13,443	13,056	26,921	26,604
Total operating expenses	34,540	32,213	73,625	72,288
Loss from operations	(25,290)	(25,398)	(57,898)	(59,570)
Other income (expenses)				
Interest income	779	294	1,217	572
Interest expense and financing fee	(3,106)	(2,590)	(5,575)	(4,993)
Change in fair value of derivative liability	-	79	-	102
Change in fair value of subsidiary convertible note	-	(140)	-	110
Change in fair value of investments	-	(707)	-	(825)
Other loss	-	(333)	-	(333)
Gain on deconsolidation of Caelum	137	-	18,521	-
Total other (expenses) income	(2,190)	(3,397)	14,163	(5,367)
Loss from continuing operations	(27,480)	(28,795)	(43,735)	(64,937)
Discontinued operations:				
Loss from discontinued operations, net of tax	-	(6,921)	-	(8,997)
Total loss from discontinued operations	-	(6,921)	-	(8,997)
Net loss	**(27,480)**	**(35,716)**	**(43,735)**	**(73,934)**
Less: net loss attributable to non-controlling interests	14,382	14,105	32,029	31,305
Net loss attributable to common stockholders	**$ (13,098)**	**$ (21,611)**	**$ (11,706)**	**$ (42,629)**
Loss from continuing operations per common share - basic and diluted	$ (0.51)	$ (0.66)	$ (0.86)	$ (1.51)
Loss from discontinued operations per common share - basic and diluted	$ -	$ (0.16)	$ -	$ (0.21)
Net loss per common share attributable to common stockholders - basic and diluted	$ (0.24)	$ (0.50)	$ (0.23)	$ (0.99)
Weighted average common shares outstanding - basic and diluted	53,726,125	43,377,629	51,130,977	42,948,780

[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.