Section 1: 8-K (FORM 8-K)

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, 2018**

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. ☐

Item 2.02. Results of Operations and Financial Condition.

On August 9, 2018, 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, 2018. 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, 2018.

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: August 9, 2018

Fortress Biotech, Inc.
(Registrant)

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

(Back To Top)

Section 2: EX-99.1 (EXHIBIT 99.1)

Exhibit 99.1

Fortress Biotech Reports Second Quarter 2018 Financial Results and Recent Corporate Highlights

New York, NY – August 9, 2018 – Fortress Biotech, Inc. (NASDAQ: FBIO) ("Fortress"), a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products, today announced financial results and recent corporate highlights for the second quarter ended June 30, 2018.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "During the second quarter, our Fortress Company subsidiaries reported significant value-driving milestones, including positive Phase 3 data from Avenue Therapeutics' IV tramadol, which, if approved, would be the only Schedule IV intravenous opioid in the U.S. and could replace highly addictive Schedule II narcotics in many patients with moderate to moderately severe postoperative pain. Additionally, Cyprium Therapeutics was granted FDA Fast Track Designation for its CUTX-101 Copper Histidinate injection in patients with Menkes disease, a rare pediatric disease with no FDA-approved treatments. Also during the quarter, Mustang Bio expanded its infrastructure with the launch of a proprietary 27,000 sq. ft. CAR T cell manufacturing facility that will enable us to oversee product safety from needle-to-needle and help improve supply chain efficiencies from clinical development into commercialization."

Dr. Rosenwald continued, "We believe in the value proposition represented by our company and strive to protect the best interests of our shareholders and those of our subsidiaries. As we continue to build long-term value, our novel and efficient business model provides benefits for all stakeholders and offers unique synergies not typical of traditional biopharma companies."

Financial Results:

- As of June 30, 2018, Fortress' consolidated cash, cash equivalents, short-term investments (certificates of deposit), cash deposits with clearing organizations and restricted cash totaled $151.8 million, compared to $168.3 million as of December 31, 2017, a decrease of $16.5 million year-to-date.
- Net revenue totaled $63.8 million for the second quarter of 2018, compared to $50.7 million for the second quarter of 2017. Total revenue as of June 30, 2018, includes $6.8 million of Fortress revenue, primarily from the sale of Journey Medical Corporation products, and $57.0 million of revenue from National Holdings Corporation[1] ("National Holdings"). Total revenue as of June 30, 2017, included $4.4 million of Fortress revenue and $46.3 million of revenue from National Holdings.
- Research and development expenses were $17.5 million for the second quarter of 2018, of which $15.1 million was related to Fortress Companies. This compares to $11.7 million for the second quarter of 2017, of which $9.5 million was related to Fortress Companies. Non-

cash, stock-based compensation expenses included in research and development were $0.8 million for the second quarter of 2018, compared to $2.4 million for the second quarter of 2017.

- Research and development expenses from license acquisitions were nominal for the second quarter of 2018, compared to $1.8 million for the second quarter of 2017.
- General and administrative expenses were $13.1 million for the second quarter of 2018, of which $7.7 million was related to Fortress Companies. This compares to $11.1 million for the second quarter of 2017, of which $6.6 million was related to Fortress Companies. Non-cash, stock-based compensation expenses included in general and administrative expenses were $2.4 million for the second quarter of 2018, compared to $2.2 million for the second quarter of 2017.
- National Holdings' operating expenses totaled $56.2 million for the second quarter of 2018, compared to $48.4 million for the second quarter of 2017.
- Net loss attributable to common stockholders was $21.6 million, or $0.50 per share, for the second quarter of 2018, compared to a net loss attributable to common stockholders of $17.4 million, or $0.43 per share, for the second quarter of 2017. For the first six months of 2018, net loss was $42.6 million or $0.99 per share, compared to $29.3 million or $0.73 per share in the first six months of 2017.

---

1 Fortress acquired approximately 56 percent of National Holdings in September 2016.

Recent Fortress and Fortress Company Highlights:

Fortress Biotech, Inc.

- In June 2018, data from a Phase 1 trial evaluating Fortress' CNDO-109-activated allogeneic natural killer (NK) cells in acute myeloid leukemia (AML) patients were published in the journal *Biology of Blood and Marrow Transplantation*. The data demonstrated that CNDO-109-activated NK cells are safe, well tolerated and may be capable of extending complete remissions in high-risk AML patients.

Aevitas Therapeutics, Inc.

- In August 2018, Aevitas announced that it entered a sponsored research agreement with the laboratory of Wenchao Song, Ph.D., at the University of Pennsylvania to evaluate Aevitas' adeno-associated virus ("AAV") gene therapy technology in Penn's proprietary animal models of complement-mediated diseases.

Avenue Therapeutics, Inc.

- In May 2018, Avenue announced that its first pivotal Phase 3 trial of IV tramadol achieved the primary endpoint of a statistically significant improvement in Sum of Pain Intensity Difference over 48 hours (SPID48) compared to placebo in patients with moderate to moderately severe postoperative pain following bunionectomy surgery. In addition, the trial met its key secondary endpoints and demonstrated a clear dose response. Avenue plans to initiate a second pivotal Phase 3 trial of IV tramadol in patients following abdominoplasty surgery in the second half of 2018.

Caelum Biosciences, Inc.

- In June 2018, Caelum announced a complete analysis of cardiac data from a Phase 1b trial of CAEL-101 (mAb 11-1F4) for the treatment of relapsed or refractory amyloid light chain ("AL") amyloidosis demonstrating CAEL-101's potential to improve myocardial function as assessed by global longitudinal strain and generate a sustained decrease in N-terminal pro-brain natriuretic peptide levels in AL amyloidosis patients experiencing cardiac involvement. The data were presented by Columbia University at the American Society of Echocardiography 29th Annual Scientific Sessions.

Checkpoint Therapeutics, Inc.

- In April 2018, preclinical data was presented on Checkpoint's BET inhibitor, CK-103, at the American Association for Cancer Research (AACR) Annual Meeting. CK-103 demonstrated combinatorial effects in an *in vivo* model with anti-PD-1 antibodies, which may support the development of CK-103 as an anti-cancer agent alone and in combination with Checkpoint's anti-PD-L1 antibody CK-301.

Cyprium Therapeutics, Inc.

- In July 2018, Cyprium announced that the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to CUTX-101, a product candidate for patients diagnosed with classic Menkes disease who have not demonstrated significant clinical progression.

Mustang Bio, Inc.

- In May 2018, Mustang announced the publication of preclinical data in *JCI Insight* demonstrating that glioblastoma-targeted CD4+ CAR T cells mediate superior antitumor activity over CD8+ CAR T cells. The data, published by research partner City of Hope, will be applied in the ongoing Phase 1 trial of Mustang's IL13Rα2-specific CAR T MB-101 in glioblastoma.
- In June 2018, Mustang opened a proprietary CAR T cell therapy manufacturing facility at UMass Medicine Science Park in Worcester, Mass. The facility will support the clinical development and commercialization of Mustang's CAR T product candidates and enable proprietary cell therapy research.
- Also in June 2018, Mustang was added to the Russell 2000®, 3000® and Microcap® Indexes.
- In July 2018, Mustang completed a pre-Investigational New Drug (pre-IND) meeting with the FDA for MB-102 (CD123 CAR T). Based on the meeting, Mustang expects to file an IND in the fourth quarter of 2018 to support a Phase 1/2 trial of MB-102 in AML, blastic plasmacytoid dendritic cell neoplasm and high-risk myelodysplastic syndrome.

About Fortress Biotech

Fortress is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress develops and commercializes products both within Fortress and through certain subsidiary companies, also known as Fortress Companies. In addition to its internal development programs, Fortress leverages its biopharmaceutical business expertise and drug development capabilities and provides funding and management services to help the Fortress Companies achieve their goals. Fortress and the Fortress Companies may seek licensing arrangements, acquisitions, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support their research and development programs. 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. 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.

Company Contact:
Jaclyn Jaffe
Fortress Biotech, Inc.
(781) 652-4500
ir@fortressbiotech.com

Investor Relations Contact:
Jeremy Feffer
Managing Director, LifeSci Advisors, LLC
(212) 915-2568
jeremy@lifesciadvisors.com

Media Relations Contact:
Laura Bagby
6 Degrees
(312) 448-8098
lbagby@6degreespr.com

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

	June 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current assets		
Cash and cash equivalents	$ 98,591	$ 113,915
Accounts receivable	5,321	7,758
Short-term investments (certificates of deposit)	35,000	36,002
Cash deposits with clearing organizations	836	1,041
Receivables from broker-dealers and clearing organizations	11,412	7,395
Forgivable loans receivable	1,598	1,616
Securities owned, at fair value	3,812	1,985
Inventory	299	171
Other receivables - related party	775	618
Prepaid expenses and other current assets	13,880	12,680
Total current assets	171,524	183,181
Property and equipment, net	14,163	9,513
Restricted cash	17,389	17,387
Long-term investments, at fair value	565	1,390
Intangible assets	13,614	15,223
Goodwill	18,645	18,645
Other assets	966	611
Total assets	**$ 236,866**	**$ 245,950**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 38,126	$ 36,127
Accounts payable and accrued expenses - related party	73	222
Accrued commissions and payroll payable	10,652	10,065
Deferred clearing and marketing credits	681	786
Securities sold, not yet purchased, at fair value	8	151
Warrants issued - National	-	5,597
Interest payable	1,143	887
Interest payable - related party	94	97
Notes payable, short-term (net of debt discount of $0 and $973 at June 30, 2018 and December 31, 2017, respectively)	-	8,528
Subsidiary convertible note, short-term, at fair value	10,573	4,700
Deferred revenue	650	-
Derivative warrant liability	-	87
Other current liabilities	158	181
Total current liabilities	62,158	67,428
Notes payable, long-term (net of debt discount of $1,035 and $62 at June 30, 2018 and December 31, 2017, respectively)	73,456	43,222
Subsidiary convertible note, long-term, at fair value	-	10,059
Other long-term liabilities	4,987	4,739
Total liabilities	**140,601**	**125,448**
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, 2018 and December 31, 2017; liquidation value of $25.00 per share	1	1
Common stock, $.001 par value, 100,000,000 shares authorized, 53,987,074 and 50,991,285 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	54	51
Common stock issuable, 259,813 and 158,015 shares as of June 30, 2018 and December 31, 2017, respectively	776	500
Additional paid-in-capital	397,858	364,148
Accumulated deficit	(354,756)	(312,127)
Total stockholders' equity attributed to the Company	43,933	52,573

Non-controlling interests	52,332	67,929
Total stockholders' equity	96,265	120,502
Total liabilities and stockholders' equity	**$ 236,866**	**$ 245,950**

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,	
	2018	**2017**	**2018**	**2017**
Revenue				
Fortress				
Product revenue, net	$ 6,689	$ 4,054	$ 12,198	$ 6,139
Revenue - from a related party	126	350	520	1,043
Net Fortress revenue	6,815	4,404	12,718	7,182
National				
Commissions	31,407	23,993	57,025	48,499
Net dealer inventory gains	2,929	2,366	5,119	4,877
Investment banking	11,037	10,592	23,741	17,653
Investment advisory	5,197	3,490	10,530	6,875
Interest and dividends	601	675	1,232	1,391
Transfer fees and clearing services	1,777	1,687	4,074	4,185
Tax preparation and accounting	3,868	3,144	4,391	4,000
Other	203	346	429	717
Total National revenue	57,019	46,293	106,541	88,197
Net revenue	63,834	50,697	119,259	95,379
Operating expenses				
Fortress				
Cost of goods sold - product revenue	1,668	878	3,140	1,347
Research and development	17,488	11,683	42,446	18,793
Research and development – licenses acquired	1	1,800	98	3,094
General and administrative	13,056	11,134	26,604	21,386
Total Fortress operating expenses	32,213	25,495	72,288	44,620
National				
Commissions, compensation and fees	49,345	41,762	92,906	79,020
Clearing fees	578	618	1,321	1,356
Communications	813	682	1,573	1,404
Occupancy	1,141	936	2,096	1,944
Licenses and registration	530	427	1,167	832
Professional fees	578	991	1,971	2,254
Interest	2	4	4	8
Underwriting costs	42	-	187	-
Depreciation and amortization	857	500	1,716	1,006
Other administrative expenses	2,332	2,475	4,113	3,705
Total National operating expenses	56,218	48,395	107,054	91,529
Total operating expenses	88,431	73,890	179,342	136,149
Loss from operations	(24,597)	(23,193)	(60,083)	(40,770)
Other income (expenses)				
Interest income	294	190	572	326
Interest expense and financing fee	(2,144)	(1,380)	(4,227)	(2,078)
Change in fair value of derivative liabilities	(6,866)	1,452	(7,931)	5,794
Change in fair value of subsidiary convertible note	(140)	(188)	110	(285)
Change in fair value of investments	(707)	157	(825)	(511)
Other loss	(118)	13	(112)	13
Total other (expenses) income	(9,681)	244	(12,413)	3,259
Loss before income taxes	(34,278)	(22,949)	(72,496)	(37,511)
Income tax expense	1,438	-	1,438	-
Net loss	**(35,716)**	**(22,949)**	**(73,934)**	**(37,511)**
Less: net loss attributable to non-controlling interests	(14,105)	(5,584)	(31,305)	(8,164)
Net loss attributable to common stockholders	**$ (21,611)**	**$ (17,365)**	**$ (42,629)**	**$ (29,347)**

Basic and diluted net loss per common share	$ (0.50)	$ (0.43)	$ (0.99)	$ (0.73)
Weighted average common shares outstanding—basic and diluted	43,377,629	40,551,844	42,948,780	40,457,524

(Back To Top)