
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): **May 10, 2018**

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, 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 May 10, 2018, 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, 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
<u>99.1</u>	<u>Press release issued by Fortress Biotech, Inc., dated May 10, 2018.</u>

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, 2018

Fortress Biotech, Inc.
(Registrant)

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

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Section 2: EX-99.1 (EXHIBIT 99.1)

Exhibit 99.1



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

New York, NY – May 10, 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 first quarter ended March 31, 2018.

Lindsay A. Rosenwald, M.D., Fortress’ Chairman, President and Chief Executive Officer, said, “We have made significant advancements in the four years since we created and implemented our unique and efficient business model to benefit all stakeholders. The centralization of a number of critical corporate and R&D functions at Fortress allows our subsidiaries, or “Fortress Companies,” to leverage internal synergies and minimize costs, so they can focus on getting drugs into the hands of people who need them. Our focus on continuing to build value through our strong business development engine and R&D team has led to the launch of nine development-stage subsidiaries, one specialty dermatology subsidiary and the in-licensing of more than 25 development-stage therapies since January 2014. The long-term success of our subsidiaries benefits Fortress through modest royalties on sales and annual and event-driven equity grants.”

Dr. Rosenwald added, “By offering investment opportunities to finance specific Fortress Companies, we enable investors to select more concentrated exposure in innovative therapeutic areas, like CAR-T therapy and checkpoint inhibitors. We have done just that in the 18 months since we completed a successful tender offer for the majority of shares in National Holdings Corporation. This unique relationship enables us to offer National Holdings’ clients the opportunity to invest in drug candidates across a range of developmental stages and therapeutic areas. We are pleased with our synergistic collaboration with National Holdings and the significant progress National Holdings has made in the past 18 months to transform its firm culture.”

Accomplishments since launch of Fortress business model in January 2014:

Research and development

- Established 9 development-stage Fortress Companies in areas including CAR-T therapy, checkpoint inhibitors, gene therapy, rare diseases and pain management
- Established Journey Medical Corporation, a specialty dermatology company with four marketed products (Targadox®, Ceracade®, Triderm™ and Luxamend®) and a contract sales and marketing operation of more than 30 professionals
- In-licensed more than 25 development-stage programs across multiple therapeutic areas, which are currently in development at Fortress and the Fortress Companies

- Established a 27,000 sq. foot CAR-T processing facility at UMass Medicine Science Park in Worcester, Massachusetts, to manufacture Mustang Bio's CAR-T therapies
-

Corporate

- Established a business development / search and evaluate team, and expanded headcount to approximately 20 employees
- Built a corporate operations team (finance, accounting, legal, investor relations and human resources) of 15 employees and expanded manufacturing, quality, regulatory, clinical and R&D staff to 34 employees

Financial Results:

- As of March 31, 2018, Fortress' consolidated cash, cash equivalents, short-term investments (certificates of deposit), cash deposits with clearing organizations and restricted cash totaled \$179.4 million, compared to \$168.3 million as of December 31, 2017, an increase of \$11.1 million for the quarter.
- Net revenue totaled \$55.4 million for the first quarter of 2018, compared to \$44.7 million for the first quarter of 2017. Total revenue as of March 31, 2018, includes \$5.9 million of Fortress revenue and \$49.5 million of revenue from National Holdings. Total revenue as of March 31, 2017, included \$2.8 million of Fortress revenue and \$41.9 million of revenue from National Holdings.
- Research and development expenses were \$25.0 million for the first quarter of 2018, of which \$22.8 million was related to Fortress Companies. This compares to \$7.1 million for the first quarter of 2017, of which \$5.4 million was related to Fortress Companies. Non-cash, stock-based compensation expenses included in research and development were \$2.3 million for the first quarter of 2018, compared to \$0.8 million for the first quarter of 2017.
- Research and development expenses from license acquisitions totaled \$0.1 million for the first quarter of 2018, compared to \$1.3 million for the first quarter of 2017.
- General and administrative expenses were \$13.5 million for the first quarter of 2018, of which \$8.4 million was related to Fortress Companies. This compares to \$10.3 million for the first quarter of 2017, of which \$6.7 million was related to Fortress Companies. Non-cash, stock-based compensation expenses included in general and administrative expenses were \$2.5 million for the first quarter of 2018, compared to \$2.1 million for the first quarter of 2017.
- National Holdings' operating expenses totaled \$50.8 million for the first quarter of 2018, compared to \$43.1 million for the first quarter of 2017.
- Net loss attributable to common stockholders was \$21.0 million, or \$0.49 per share, for the first quarter of 2018, compared to a net loss attributable to common stockholders of \$12.0 million, or \$0.30 per share, for the first quarter of 2017.

Recent Fortress and Fortress Company Highlights:

Aevitas Therapeutics, Inc.

- In January 2018, Aevitas entered into a sponsored research agreement with the laboratory of Guangping Gao, Ph.D., at the University of Massachusetts Medical School to evaluate construct optimization for Aevitas' AAV gene therapy treatment for complement-mediated diseases.

Avenue Therapeutics, Inc.

- In March 2018, Avenue received Notices of Allowance from the U.S. Patent and Trademark Office ("USPTO") for three patent applications covering methods of administration for IV tramadol. Issuance of these patents is expected in the second quarter of 2018.
- In April 2018, Avenue completed enrollment in its Phase 3, multicenter, randomized, double-blind, three-arm clinical trial evaluating the efficacy and safety of IV tramadol 50 mg and 25 mg versus placebo for the treatment of moderate to moderately severe pain in patients following bunionectomy surgery. Avenue expects to report topline data in the second quarter of 2018.

Caelum Biosciences, Inc.

- In March 2018, a new analysis of data from the Phase 1b trial of Caelum's CAEL-101 (mAb 11-1F4) for the treatment of relapsed or refractory amyloid light chain ("AL") amyloidosis was presented at the 16th International Symposium on Amyloidosis. The data demonstrated a correlation between a sustained decrease in N-terminal pro-brain natriuretic peptide (NT-proBNP) levels and an improvement in global longitudinal strain ("GLS") following CAEL-101 treatment in patients with cardiac AL amyloidosis.
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Checkpoint Therapeutics, Inc.

- In March 2018, Checkpoint completed an underwritten public offering that raised net proceeds of \$20.8 million.
- Also in March 2018, Checkpoint completed the dose escalation portion of the ongoing Phase 1 trial of CK-301, a fully human anti-PD-L1 antibody, in selected recurrent or metastatic cancers, and initiated the first dose expansion cohort, which is evaluating an 800 mg dose of CK-301 administered every two weeks.
- In April 2018, Checkpoint presented preclinical data on BET inhibitor CK-103 at the American Association for Cancer Research 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.

Mustang Bio, Inc.

- In March 2018, Mustang announced that Sadik Kassim, Ph.D., was appointed Chief Scientific Officer, and Knut Niss, Ph.D., was named Chief Technology Officer.

National Holdings Corporation:

- Fortress acquired approximately 57% of National Holdings Corporation (“National Holdings”) in September 2016.
- Accomplishments since closing the tender include:
 - o Established new client-focused leadership team at National Holdings and at its wholly-owned operating companies National Securities Corporation and National Asset Management, Inc.;
 - o Invested in new technology infrastructure geared toward risk management and improved client performance; and
 - o Continued to increase revenues, particularly in investment banking, as described in its Q1 10-Q, filed February 14, 2018.

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.

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

	<u>March 31, 2018</u>	<u>December 31, 2017</u>
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 124,020	\$ 113,915
Accounts receivable	8,314	7,758
Short-term investments (certificates of deposit)	37,002	36,002
Cash deposits with clearing organizations	1,041	1,041
Receivables from broker-dealers and clearing organizations	8,464	7,395
Forgivable loans receivable	1,534	1,616
Securities owned, at fair value	4,278	1,985
Inventory	222	171
Other receivables - related party	944	618
Prepaid expenses and other current assets	14,338	12,680
Total current assets	<u>200,157</u>	<u>183,181</u>
Property and equipment, net	12,278	9,513
Restricted cash	17,387	17,387
Long-term investments, at fair value	1,272	1,390
Intangible assets	14,400	15,223
Goodwill	18,645	18,645
Other assets	936	611
Total assets	<u>\$ 265,075</u>	<u>\$ 245,950</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 44,725	\$ 36,127
Accounts payable and accrued expenses - related party	124	222
Accrued commissions and payroll payable	10,713	10,065
Deferred clearing and marketing credits	733	786
Securities sold, not yet purchased, at fair value	-	151
Warrants issued - National	6,671	5,597
Interest payable	332	315
Interest payable - related party	657	669
Notes payable, short-term (net of debt discount of \$0 and \$973 at March 31, 2018 and December 31, 2017, respectively)	-	8,528
Subsidiary convertible note, short-term, at fair value	12,651	4,700
Deferred revenue	690	-
Derivative warrant liability	78	87
Other current liabilities	1,952	181
Total current liabilities	<u>79,326</u>	<u>67,428</u>
Notes payable, long-term (net of debt discount of \$1,047 and \$62 at March 31, 2018 and December 31, 2017, respectively)	73,444	43,222
Subsidiary convertible note, long-term, at fair value	-	10,059
Other long-term liabilities	4,759	4,739
Total liabilities	<u>157,529</u>	<u>125,448</u>
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, 2018 and December 31, 2017; liquidation value of \$25.00 per share	1	1
Common stock, \$.001 par value, 100,000,000 shares authorized, 52,686,537 and 50,991,285 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively	52	51
Common stock issuable, 104,958 and 158,015 shares as of March 31, 2018 and December 31, 2017, respectively	489	500
Additional paid-in-capital	374,254	364,148
Accumulated deficit	(333,145)	(312,127)
Total stockholders' equity attributed to the Company	<u>41,651</u>	<u>52,573</u>

Non-controlling interests	65,895	67,929
Total stockholders' equity	107,546	120,502
Total liabilities and stockholders' equity	\$ 265,075	\$ 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 March 31,	
	2018	2017
Revenue		
<i>Fortress</i>		
Product revenue, net	\$ 5,509	\$ 2,085
Revenue - from a related party	394	693
Net Fortress revenue	5,903	2,778
<i>National</i>		
Commissions	25,618	24,506
Net dealer inventory gains	2,190	2,511
Investment banking	12,704	7,061
Investment advisory	5,333	3,385
Interest and dividends	631	716
Transfer fees and clearing services	2,297	2,498
Tax preparation and accounting	523	856
Other	226	371
Total National revenue	49,522	41,904
Net revenue	55,425	44,682
Operating expenses		
<i>Fortress</i>		
Cost of goods sold - product revenue	1,472	469
Research and development	24,958	7,110
Research and development – licenses acquired	97	1,294
General and administrative	13,548	10,252
Total Fortress operating expenses	40,075	19,125
<i>National</i>		
Commissions, compensation and fees	43,561	37,258
Clearing fees	743	738
Communications	760	722
Occupancy	955	1,008
Licenses and registration	637	405
Professional fees	1,393	1,263
Interest	2	4
Underwriting costs	145	-
Depreciation and amortization	859	506
Other administrative expenses	1,781	1,230
Total National operating expenses	50,836	43,134
Total operating expenses	90,911	62,259
Loss from operations	(35,486)	(17,577)
Other income (expenses)		
Interest income	284	136
Interest expense and financing fee	(2,083)	(698)
Change in fair value of derivative liabilities	(1,065)	4,342
Change in fair value of subsidiary convertible note	250	(97)
Change in fair value of investments	(118)	(668)
Total other income (expenses)	(2,732)	3,015
Net loss	(38,218)	(14,562)
Less: net loss attributable to non-controlling interests	(17,200)	(2,580)
Net loss attributable to common stockholders	\$ (21,018)	\$ (11,982)
Basic and diluted net loss per common share	\$ (0.49)	\$ (0.30)
Weighted average common shares outstanding—basic and diluted	42,518,403	40,357,711

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