

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): March 16, 2017

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, New York

(Address of Principal Executive Offices)

10014

(Zip Code)

Registrant's Telephone Number, Including Area Code: **(781) 652-4500**

(Former name or former address, if changed since last report.)

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 (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition.

On March 16, 2017, Fortress Biotech, Inc. issued a press release announcing its financial results for the year ended December 31, 2016. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

The information in this Item 2.02 (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated March 16, 2017.

SIGNATURES

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.

FORTRESS BIOTECH, INC.

Date: March 16, 2017

/s/ Lindsay A. Rosenwald

Name: Lindsay A. Rosenwald

Title: Chairman, President and Chief
Executive Officer



Fortress Biotech Reports Financial Results for the Fourth Quarter and Full Year Ended December 31, 2016

New York, NY – March 16, 2017 – 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 fourth quarter and full year ended December 31, 2016.

Dr. Lindsay A. Rosenwald, Fortress’ Chairman, President and Chief Executive Officer, said, “Fortress had another productive year in 2016 and early 2017, with the launch of three additional Fortress Company subsidiaries, Cellvation, Caelum Biosciences, and Cyprium Therapeutics, which broaden our pipeline in cellular therapeutics and rare disease. In addition, we completed a tender offer purchasing a majority of National Holdings Corporation, a full service investment banking and advisory firm, which has a significant presence in biotechnology and the life sciences. National presents multiple opportunities for synergies with our core biotech drug development business. At the same time, our established Fortress Companies have continued to achieve significant milestones, including the publication of a case study in *The New England Journal of Medicine* in which Mustang Bio’s MB-101 CAR T therapy achieved an unprecedented complete response in a glioblastoma patient. In 2017, we plan to continue to work with our Fortress Companies to advance their pipelines in and toward clinical development, and explore opportunities to strengthen our subsidiary company portfolio.”

Financial Results:

- As of December 31, 2016, Fortress’ consolidated cash and cash equivalents totaled \$88.3 million, compared to \$82.5 million as of September 30, 2016, and \$98.2 million as of December 31, 2015, an increase of \$5.8 million for the fourth quarter and a decrease of \$9.9 million year-to-date. These totals exclude restricted cash of \$15.9 million as of December 31, 2016 and September 30, 2016, and restricted cash of \$14.6 million as of December 31, 2015.
 - Revenue totaled \$16.5 million as of December 31, 2016, compared to \$0.9 million as of December 31, 2015. Total revenue as of December 31, 2016 includes \$6.2 million of Fortress revenue and \$10.3 million of revenue from National Holdings Corporation (includes revenue from the date of the close of the acquisition, September 9, 2016 through September 30, 2016).
 - Research and development expenses were \$29.6 million for the year ended December 31, 2016, of which \$22.6 million was related to Fortress Companies. This compares to \$18.4 million for 2015, of which \$8.4 million was related to Fortress Companies. Noncash stock-based compensation expenses included in research and development were \$4.7 million for the year ended December 31, 2016, and \$5.8 million for 2015.
 - Research and development expenses from license acquisitions totaled \$5.5 million for the year ended December 31, 2016, compared to \$11.4 million for the year ended December 31, 2015.
 - General and administrative expenses were \$34.0 million for the year ended December 31, 2016, of which \$15.4 million was related to Fortress Companies. This compares to \$21.6 million for 2015, of which \$6.7 million was related to Fortress Companies. Noncash stock-based compensation expenses included in general and administrative expenses were \$7.4 million for the year ended December 31, 2016, and \$8.5 million for 2015.
 - Net loss attributable to common stockholders was \$55.1 million, or \$1.38 per share, for the year ended December 31, 2016, compared to a net loss attributable to common stockholders of \$48.4 million, or \$1.24 per share, for 2015.
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Recent Fortress Biotech and Fortress Company Highlights:

Fortress Biotech, Inc.

- Phase 1/2 data demonstrating CNDO-109-activated allogeneic natural-killer cells are safe and well-tolerated, and potentially capable of extending complete remissions in high-risk acute myeloid leukemia patients were presented in May at the Innate Killer Summit 2016.
- In September 2016, Fortress, through its subsidiary FBIO Acquisition, Inc., purchased approximately 56 percent of National Holdings Corporation (NASDAQ: NHLD) common stock at a purchase price of \$3.25 per share in cash, for an aggregate purchase price of approximately \$22.9 million.
- Fortress recently launched three new Fortress Companies: Cellvation, to develop cellular therapeutics for the treatment of traumatic brain injury, Caelum Biosciences, to develop therapies for amyloid light chain (“AL”) amyloidosis and Cyprium Therapeutics, to develop novel therapies for the treatment of Menkes disease and related copper metabolism disorders.

Avenue Therapeutics, Inc.

- In 2016, Avenue completed an end of Phase 2 meeting with the U.S. Food and Drug Administration regarding its lead candidate, intravenous (IV) tramadol, for the management of post-operative pain. Based on the outcome, Avenue anticipates its Phase 3 study will consist of three trials: an efficacy and safety study in an orthopedic model, an efficacy and safety study in a soft tissue model and an open-label safety study. Initiation of the Phase 3 study is planned for 2017.
- In December 2016, Avenue received Notices of Allowance from the U.S. Patent and Trademark Office for two continuation patent applications covering methods of administration for IV Tramadol; issuance of both patents occurred in February 2017.

Caelum Biosciences, Inc.

- In January 2017, Caelum entered into an agreement with Columbia University (“Columbia”) to secure exclusive worldwide license rights to CAEL-101, a chimeric fibril-reactive monoclonal antibody.
- Interim data from the ongoing Phase 1a/1b study of CAEL-101 were presented by Columbia in December 2016 at the American Society of Hematology’s 58th Annual Meeting. These data demonstrate CAEL-101 is safe and well-tolerated, and 67 percent of patients with measurable disease burden showed organ response. Full Phase 1a/1b data are expected mid-2017.

Cellvation, Inc.

- On October 31, 2016, Cellvation secured exclusive worldwide rights to three programs for traumatic brain injury (TBI) from The University of Texas Health Science Center at Houston: two Phase 2 programs evaluating CEVA101 cell therapy in adult and pediatric TBI patients, and CEVA-D, a next-generation bioreactor that enhances the anti-inflammatory potency of bone marrow-derived cells without genetic manipulation. Data from the Phase 2 CEVA101 studies are expected in 2019.
- Phase 1 data demonstrating CEVA101 is safe and effective in modulating the neuroinflammatory response and reducing secondary injury in adults with TBI were published online in November 2016 in *STEM CELLS*.

Checkpoint Therapeutics, Inc.

- In January 2016, Checkpoint announced it signed a license agreement with Teva Pharmaceutical Industries Ltd. for the exclusive worldwide rights to develop and commercialize CK-102, an oral poly (ADP-ribose) polymerase (PARP) inhibitor in early clinical development for solid tumors. A Phase 1b study is planned to commence in the next 12 months.
 - In May 2016, Checkpoint entered into an exclusive worldwide license agreement with Jubilant Biosys Ltd. to develop and commercialize novel compounds that inhibit the BET protein BRD4. In connection therewith, Checkpoint sublicensed development and commercialization rights to the compounds in hematological malignancies to TG Therapeutics, Inc. Checkpoint retains development and commercialization rights in solid tumors. Checkpoint plans to submit an Investigational New Drug (“IND”) application for a Phase 1 study in the second half of 2017.
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- In September 2016, following approval of the IND, the first patient was dosed in the Phase 1 dose-escalation portion of a Phase 1/2 study of epidermal growth-factor receptor (“EGFR”) inhibitor CK-101. Checkpoint expects to initiate the Phase 2 safety and efficacy portion of the study in patients with EGFR T790M mutation-positive non-small cell lung cancer in the second half of 2017.

Cyprium Therapeutics, Inc.

- In March 2017, Cyprium entered into a Cooperative Research and Development Agreement (CRADA) with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), part of the NIH, to advance the clinical development of Phase 3 candidate CUTX-101, a Copper Histidinate injection, for the treatment of Menkes disease. Also effective in March 2017, Cyprium and the NICHD entered into a worldwide, exclusive license agreement to develop and commercialize adeno-associated virus (AAV)-based gene therapy, called AAV-ATP7A, to deliver working copies of the copper transporter that is defective in Menkes patients and to be used in combination with CUTX-101.

Helocyte, Inc.

- In February and March 2016, respectively, Helocyte entered into investigator-initiated clinical research support agreements with City of Hope National Medical Center to support two Phase 2 studies of Helocyte’s immunotherapies Triplex and PepVax for cytomegalovirus control in allogeneic hematopoietic stem-cell transplant recipients (“HSCT”). The ongoing Phase 2 studies are also supported by grants from the National Cancer Institute.
- From June to November 2016, Helocyte closed on sales of convertible promissory notes raising aggregate gross proceeds of approximately \$4.4 million.
- Phase 1 data demonstrating Triplex is safe, well-tolerated and highly immunogenic at multiple dose levels in healthy volunteers were published in December 2016 online in *Blood*. These data supported the initiation of the Phase 2 study of Triplex in HSCT patients, which is expected to be fully enrolled by the second half of 2017.

Journey Medical Corporation (JMC)

- In January 2016, JMC entered into two licensing agreements with third parties for the distribution of the first two products in the company’s dermatology franchise: Luxamend®, a prescription wound cream, and Ceracade®, an emollient for the treatment of various types of dermatitis. Sales commenced for Luxamend® and Ceracade® in April 2016 and June 2016, respectively.
- U.S. sales commenced in October 2016 for JMC’s Targadox® brand of oral antibiotic, indicated for the treatment of severe acne.

Mustang Bio, Inc.

- A case study demonstrating Mustang’s MB-101 (IL13R α 2-specific CAR T cells) achieved a complete response in a glioblastoma patient enrolled in the Phase 1 study was published in the December 29 edition of *The New England Journal of Medicine*. Additional preclinical and Phase 1 data on MB-101 were presented at the American Society of Gene and Cell Therapy 19th Annual Meeting in May 2016, and the 21st Annual Meeting and Education Day of the Society for Neuro-Oncology in November 2016.
- From October 2016 to January 2017, Mustang closed on a total of approximately \$94.5 million in a private placement financing, prior to fees and expenses.

About Fortress Biotech

Fortress Biotech, Inc. (“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 of its subsidiary companies, also known as Fortress Companies. Additionally, Fortress recently acquired a controlling interest in National Holdings Corporation (NASDAQ: NHLD), a diversified independent brokerage company (together with its subsidiaries, “NHLD”). 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 licensings, 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 required by law.

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

	December 31,	
	2016	2015
ASSETS		
Current assets		
Cash and cash equivalents	\$ 88,294	\$ 98,182
Accounts receivable	1,830	-
Cash deposits with clearing organizations	1,030	-
Receivables from broker-dealers and clearing organizations	3,357	-
Forgivable loans receivable	1,712	-
Securities owned, at fair value	2,357	-
Inventory	203	-
Other receivables - related party	1,790	156
Prepaid expenses and other current assets	9,061	1,599
Total current assets	<u>109,634</u>	<u>99,937</u>
Property and equipment, net	7,376	309
Restricted cash	15,860	14,586
Long-term investments, at fair value	1,414	2,485
Intangible asset - license	17,408	1,250
Goodwill	18,645	-
Other assets	394	43
Total assets	<u>\$ 170,731</u>	<u>\$ 118,610</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 24,295	\$ 10,438
Accrued commissions and payroll payable	11,940	-
Deferred clearing and marketing credits	995	-
Securities sold, not yet purchased, at fair value	298	-
Warrants issuable - National	14,359	-
Interest payable	88	27
Interest payable - related party	77	-
Notes payable, short-term	1,000	-
Subsidiary convertible note, short-term, at fair value	1,031	-
Contingently issuable liabilities	1,682	-
Derivative warrant liability	481	114
Other current liabilities	319	-
Total current liabilities	<u>56,565</u>	<u>10,579</u>
Notes payable, long-term (net of debt discount of \$2,009 and \$835 at December 31, 2016 and December 31, 2015, respectively)	22,528	23,174
Subsidiary convertible note, long-term, at fair value	3,656	-
Other long-term liabilities	5,014	584
Total liabilities	<u>87,763</u>	<u>34,337</u>
Commitments and contingencies		
Stockholders' equity		
Convertible Preferred stock, \$.001 par value, 129,767 Series C shares authorized, 0 shares issued and outstanding as of December 31, 2016 and December 31, 2015, respectively	-	-
Common Stock, \$.001 par value, 100,000,000 shares authorized, 48,932,023 and 47,147,032 shares issued and outstanding as of December 31, 2016 and December 31, 2015, respectively	49	47
Additional paid-in-capital	283,697	246,955
Accumulated deficit	(245,251)	(190,156)
Total stockholders' equity attributed to the Company	<u>38,495</u>	<u>56,846</u>
Non-controlling interests	44,473	27,427
Total stockholders' equity	<u>82,968</u>	<u>84,273</u>
Total liabilities and stockholders' equity	<u>\$ 170,731</u>	<u>\$ 118,610</u>

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

	For the Years Ended December 31,		
	2016	2015	2014
Revenue			
<i>Fortress</i>			
Product revenue, net	\$ 3,587	\$ 273	\$ -
Revenue - from a related party	2,570	590	-
Total Fortress revenue	<u>6,157</u>	<u>863</u>	<u>-</u>
<i>National</i>			
Commissions	5,388	-	-
Net dealer inventory gains	253	-	-
Investment banking	2,829	-	-
Investment advisory	904	-	-
Interest and dividends	155	-	-
Transfer fees and clearing services	386	-	-
Tax preparation and accounting	338	-	-
Other	70	-	-
Total National revenue	<u>10,323</u>	<u>-</u>	<u>-</u>
Total revenue	<u>16,480</u>	<u>863</u>	<u>-</u>
Operating expenses			
<i>Fortress</i>			
Cost of goods sold – product revenue	790	-	-
Research and development	29,602	18,402	10,239
Research and development – licenses acquired	5,532	11,408	-
General and administrative	34,003	21,584	10,413
Total Fortress operating expenses	<u>69,927</u>	<u>51,394</u>	<u>20,652</u>
<i>National</i>			
Commissions, compensation and fees	10,414	-	-
Clearing fees	144	-	-
Communications	177	-	-
Occupancy	193	-	-
Licenses and registration	147	-	-
Professional fees	327	-	-
Interest	1	-	-
Depreciation and amortization	545	-	-
Other administrative expenses	315	-	-
Total National operating expenses	<u>12,263</u>	<u>-</u>	<u>-</u>
Total operating expenses	<u>82,190</u>	<u>51,394</u>	<u>20,652</u>
Loss from operations	<u>(65,710)</u>	<u>(50,531)</u>	<u>(20,652)</u>
Other income (expenses)			
Interest income	298	245	662
Interest expense and financing fee	(3,690)	(1,484)	(1,338)
Change in fair value of derivative liabilities	(1,039)	(438)	-
Change in fair value of subsidiary convertible note	(78)	-	-
Change in fair value of investments	(1,071)	(1,675)	942
Total other expenses	<u>(5,580)</u>	<u>(3,352)</u>	<u>266</u>
Net loss	<u>(71,290)</u>	<u>(53,883)</u>	<u>(20,386)</u>
Less: net loss attributable to non-controlling interests	16,195	5,455	-
Net loss attributable to common stockholders	<u>\$ (55,095)</u>	<u>\$ (48,428)</u>	<u>\$ (20,386)</u>
Basic and diluted net loss per common share	<u>\$ (1.38)</u>	<u>\$ (1.24)</u>	<u>\$ (0.56)</u>
Weighted average common shares outstanding—basic and diluted	<u>39,962,657</u>	<u>39,146,589</u>	<u>36,323,596</u>