
**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): **November 9, 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, 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 November 9, 2017, Fortress Biotech, Inc. issued a press release to provide a corporate update and to announce its financial results for the third quarter ended September 30, 2017. 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 November 9, 2017.</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: November 9, 2017

Fortress Biotech, Inc.
(Registrant)

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



Fortress Biotech Reports Third Quarter 2017 Financial Results and Recent Corporate Highlights

New York, NY – November 9, 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 third quarter ended September 30, 2017.

Dr. Lindsay A. Rosenwald, Fortress’ Chairman, President and Chief Executive Officer, said, “Fortress enjoyed strong third quarter performance, beginning with the formation of a new gene therapy subsidiary company, Aevitas Therapeutics. Fortress’ other subsidiaries also continued to achieve important corporate and clinical milestones during the quarter. Avenue dosed the first patient in its pivotal Phase 3 study of IV tramadol for the management of moderate to moderately severe pain in patients following bunionectomy surgery. Additionally, Checkpoint dosed the first patient in its Phase 1 clinical study evaluating the safety and tolerability of its anti-PD-L1 antibody, CK-301, in selected recurrent or metastatic cancers. The FDA also granted Orphan Drug Designation to Checkpoint’s third-generation EGFR inhibitor, CK-101, for the treatment of EGFR mutation-positive NSCLC. Mustang Bio has continued to make meaningful progress throughout the quarter, with its common stock commencing trading on the NASDAQ Global Market, and the licensing of a CD20 CAR T cell therapy from the Fred Hutchinson Cancer Research Center, expanding its pipeline to six novel CAR T candidates.”

Dr. Rosenwald continued, “We look forward to oral data presentations on both Mustang Bio’s and Caelum Biosciences’ clinical programs at the 59th American Society of Hematology Annual Meeting in December, and plan to continue delivering on meaningful milestones for the remainder of the year.”

Financial Results:

- As of September 30, 2017, Fortress’ consolidated cash, cash equivalents and short-term investments totaled \$154.6 million, compared to \$88.3 million at December 31, 2016, an increase of \$66.3 million year-to-date. The September 30, 2017 consolidated cash, cash equivalents and short-term investments total excludes restricted cash of \$16.9 million and cash deposits with clearing organizations of \$1.0 million.
 - Net revenue totaled \$46.9 million for the third quarter of 2017 and \$142.3 million for the first nine months of 2017, compared to \$1.0 million for the third quarter of 2016 and \$3.9 million for the first nine months of 2016. Net total revenue for the third quarter ending September 30, 2017 includes \$2.5 million of Fortress revenue and \$44.4 million of revenue from National Holdings Corporation (“National”), which Fortress acquired in September 2016, with no revenue attributable to National prior to the acquisition.
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- Research and development expenses were \$15.9 million for the third quarter of 2017, of which \$14.2 million was related to Fortress Companies, and \$34.7 million for the first nine months of 2017, of which \$29.1 million was related to Fortress Companies. This compares to \$7.3 million for the third quarter of 2016, of which \$5.5 million was related to Fortress Companies, and \$21.4 million for the first nine months of 2016, of which \$15.8 million was related to Fortress Companies. Non-cash stock-based compensation expense included in research and development for the third quarter of 2017 was \$1.6 million, compared to \$0.9 million for the third quarter of 2016, and \$4.8 million for the first nine months of 2017, compared to \$3.4 million for the first nine months of 2016.
- Research and development expenses from license acquisitions totaled \$0.3 million for the third quarter of 2017 and \$3.4 million for the first nine months of 2017, compared to \$1.0 million for the third quarter of 2016 and \$3.1 million for the first nine months of 2016.
- General and administrative expenses were \$15.1 million for the third quarter of 2017, of which \$10.9 million was related to Fortress Companies, and \$36.5 million for the first nine months of 2017, of which \$23.8 million was related to Fortress Companies. This compares to \$8.9 million for the third quarter of 2016, of which \$3.8 million was related to Fortress Companies, and \$25.4 million for the first nine months of 2016, of which \$11.5 million was related to Fortress Companies. Non-cash stock-based compensation expenses included in general and administrative expenses were \$2.6 million for the third quarter of 2017, compared to \$2.0 million for the third quarter of 2016, and \$6.9 million for the first nine months of 2017, compared to \$5.4 million for the first nine months of 2016.
- National's operating expenses totaled \$47.7 million for the third quarter of 2017 and \$139.2 million for the first nine months of 2017, with no expenses attributable to National prior to Fortress' acquisition of the company in September 2016.
- Net loss attributable to common stockholders was \$27.1 million, or \$0.67 per share, for the third quarter of 2017, compared to a net loss attributable to common stockholders of \$13.0 million, or \$0.32 per share, for the third quarter of 2016. For the first nine months of 2017, net loss attributable to common stockholders was \$56.5 million or \$1.39 per share, compared to a net loss attributable to common stockholders of \$37.7 million or \$0.94 per share in the first nine months of 2016.

Recent Fortress Biotech and Fortress Company Highlights:

Fortress Biotech, Inc.

- In November 2017, Fortress announced that it priced an underwritten public offering of one million shares of its 9.375% Series A Cumulative Redeemable Perpetual Preferred Stock at a price of \$25.00 per share, with expected gross proceeds to Fortress of \$25 million. In addition, Fortress granted the underwriters a 30-day option to purchase up to 150,000 additional shares at the public offering price, less underwriting discounts and commissions. The offering is expected to close on November 14, 2017, subject to customary closing conditions.
- In July 2017, Fortress formed a new subsidiary company, Aevitas Therapeutics, Inc. ("Aevitas"), to develop novel gene therapy approaches for complement-mediated diseases. The proprietary technology, licensed from a leading university, uses adeno-associated virus (AAV)-based gene therapy to restore lasting production of functional complement regulatory proteins, providing a potentially curative treatment.

Avenue Therapeutics, Inc.

- In September 2017, Avenue announced that the first patient had been dosed in the pivotal Phase 3 clinical trial of intravenous (IV) tramadol for the management of moderate to moderately severe pain in patients following bunionectomy surgery.
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Caelum Biosciences, Inc.

- In November 2017, Caelum announced that Columbia University will present the final analysis of CAEL-101 (11-1F4) Phase 1a/1b data for the treatment of relapsed or refractory amyloid light chain “AL” amyloidosis during an oral session at the 59th American Society of Hematology (ASH) Annual Meeting in December 2017. Caelum licensed the rights to CAEL-101 in January 2017.
- During the third quarter of 2017, Caelum completed a third-party Convertible Note financing. In connection with this financing, Caelum raised \$9.9 million.

Cellvation, Inc.

- In November 2017, Cellvation announced that the U.S. Food and Drug Administration (FDA) granted CEVA101 (autologous bone marrow-derived stem cells) Regenerative Medicine Advanced Therapy (“RMAT”) designation for the treatment of traumatic brain injury (“TBI”). Under terms of the RMAT designation, the FDA will help facilitate the program’s expedited development and review, and will provide guidance on generating the evidence needed to support approval of CEVA101 for TBI.

Checkpoint Therapeutics, Inc.

- In October 2017, Checkpoint announced that the first patient had been dosed in a Phase 1 clinical study evaluating the safety and tolerability of its anti-PD-L1 antibody, CK-301, in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers.
- In September 2017, Checkpoint announced that the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation to CK-101 (also known as RX518), the Company’s third-generation epidermal growth-factor receptor (EGFR) inhibitor, for the treatment of EGFR mutation-positive non-small cell lung cancer (NSCLC).

Mustang Bio, Inc.

- In November 2017, Mustang announced that its research and development partner, City of Hope (“COH”), will present initial Phase 1 data for MB-102 (CD123 CAR) in acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN) during an oral session at the ASH Annual Meeting.
 - In October 2017, Mustang announced that preclinical data for MB-103, its second-generation HER2 CAR T cell therapy, were published online in *Clinical Cancer Research*, a journal of the American Association for Cancer Research. These preclinical data from a study conducted by COH demonstrate effective targeting of breast cancer brain metastases with intraventricular delivery of HER2-BBζ CAR T cells, and support the clinical development of this therapy.
 - In October 2017, Mustang entered into a lease agreement with the UMass Medicine Science Park in Worcester, Massachusetts, for a manufacturing facility to support the clinical development and commercialization of the Company’s CAR T product candidates. The facility is expected to be operational for the production of personalized CAR T therapies in 2018.
 - In October 2017, Mustang announced that COH received a \$12.8 million grant from the California Institute for Regenerative Medicine (CIRM) to fund an ongoing Phase 1 study of Mustang’s MB-101 (IL13Rα2-specific CAR T cells) for the treatment of patients with recurrent and refractory malignant glioma, including glioblastoma.
 - In September 2017, Mustang announced an exclusive, worldwide licensing agreement with Fred Hutchinson Cancer Research Center (“Fred Hutch”) for the use of a CAR T therapy related to autologous T cells engineered to express a CD20-specific chimeric antigen receptor (“CD20 Technology”). The CAR T was developed in the laboratory of Oliver Press, M.D., Ph.D., and Brian Till, M.D., in Fred Hutch’s Clinical Research Division. As part of the transaction, Mustang entered into an investigator-initiated clinical trial agreement to provide partial funding for a Phase 1/2 clinical trial at Fred Hutch evaluating the safety and efficacy of the CD20 Technology in patients with relapsed or refractory B-cell non-Hodgkin lymphomas. The trial began recruiting participants in the fourth quarter of 2017, and is led by principal investigator Mazyar Shadman, M.D., Assistant Member of Fred Hutch’s Clinical Research Division.
 - In August 2017, Mustang’s common stock commenced trading on the NASDAQ Global Market under the symbol “MBIO.”
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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 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 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)

	September 30, 2017 <u>(Unaudited)</u>	December 31, 2016
ASSETS		
Current assets		
Cash and cash equivalents	\$ 110,536	\$ 88,294
Accounts receivable	5,582	1,830
Short-term investment (certificate of deposit)	44,088	-
Cash deposits with clearing organizations	1,040	1,030
Receivables from broker-dealers and clearing organizations	8,282	3,357
Forgivable loans receivable	1,269	1,712
Securities owned, at fair value	1,595	2,357
Inventory	318	203
Other receivables - related party	638	1,790
Prepaid expenses and other current assets	10,739	9,061
Total current assets	<u>184,087</u>	<u>109,634</u>
Property and equipment, net	8,221	7,376
Restricted cash	16,886	15,860
Long-term investments, at fair value	923	1,414
Intangible asset - license	15,983	17,408
Goodwill	18,645	18,645
Other assets	346	394
Total assets	<u>\$ 245,091</u>	<u>\$ 170,731</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 31,978	\$ 23,871
Accrued expense - related party	88	-
Accrued commissions and payroll payable	11,255	11,940
Deferred clearing and marketing credits	838	995
Deferred product revenue	680	-
Securities sold, not yet purchased, at fair value	-	298
Interest payable	161	88
Interest payable - related party	497	77
Notes payable, short-term (net of debt discount of \$1,277 and \$0 at September 30, 2017 and December 31, 2016, respectively)	8,223	1,000
Subsidiary convertible note, short-term, at fair value	4,733	1,031
Contingent consideration payable	637	424
Warrants issued in 2017 and issuable in 2016 - National	8,832	14,359
Contingently issuable liabilities	-	1,682
Derivative warrant liability	313	481
Other current liabilities	193	319
Total current liabilities	<u>68,428</u>	<u>56,565</u>
Notes payable, long-term (net of debt discount of \$2,550 and \$2,009 at September 30, 2017 and December 31, 2016, respectively)	40,734	22,528
Subsidiary convertible note, long-term, at fair value	9,928	3,656
Other long-term liabilities	4,736	5,014
Total liabilities	<u>123,826</u>	<u>87,763</u>

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

Commitments and contingencies		
Stockholders' equity		
Convertible preferred stock, \$.001 par value, 129,767 Series C shares authorized, 0 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively	-	-
Common stock, \$.001 par value, 100,000,000 shares authorized, 50,584,937 and 48,932,023 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively	51	49
Common stock issuable, 86,272 and 0 shares as of September 30, 2017 and December 31, 2016, respectively	353	-
Additional paid-in-capital	338,254	283,697
Accumulated deficit	<u>(301,714)</u>	<u>(245,251)</u>
Total stockholders' equity attributed to the Company	36,944	38,495
Non-controlling interests	<u>84,321</u>	<u>44,473</u>
	121,265	82,968
Total stockholders' equity		
Total liabilities and stockholders' equity	<u>\$ 245,091</u>	<u>\$ 170,731</u>

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue				
<i>Fortress</i>				
Product revenue, net	\$ 2,170	\$ 429	\$ 8,309	\$ 1,793
Revenue - from a related party	350	546	1,393	2,072
Net Fortress revenue	2,520	975	9,702	3,865
<i>National</i>				
Commissions	24,881	-	73,380	-
Net dealer inventory gains	1,789	-	6,666	-
Investment banking	8,942	-	26,595	-
Investment advisory	3,605	-	10,480	-
Interest and dividends	674	-	2,065	-
Transfer fees and clearing services	1,649	-	5,834	-
Tax preparation and accounting	2,527	-	6,527	-
Other	299	-	1,016	-
Total National revenue	44,366	-	132,563	-
Net revenue	46,886	975	142,265	3,865
Operating expenses				
<i>Fortress</i>				
Cost of goods sold - product revenue	505	41	1,852	365
Research and development	15,890	7,316	34,683	21,416
Research and development – licenses acquired	300	1,000	3,394	3,143
General and administrative	15,104	8,864	36,490	25,414
Total Fortress operating expenses	31,799	17,221	76,419	50,338
<i>National</i>				
Commissions, compensation and fees	39,963	-	118,983	-
Clearing fees	470	-	1,826	-
Communications	690	-	2,094	-
Occupancy	972	-	2,916	-
Licenses and registration	391	-	1,223	-
Professional fees	1,082	-	3,336	-
Interest	5	-	13	-
Depreciation and amortization	507	-	1,513	-
Other administrative expenses	3,610	-	7,315	-
Total National operating expenses	47,690	-	139,219	-
Total operating expenses	79,489	17,221	215,638	50,338
Loss from operations	(32,603)	(16,246)	(73,373)	(46,473)
Other income (expenses)				
Interest income	204	89	530	241
Interest expense and financing fee	(3,220)	(689)	(5,298)	(1,838)
Change in fair value of derivative liabilities	(639)	(16)	5,155	(105)
Change in fair value of subsidiary convertible note	(74)	(13)	(359)	(13)
Change in fair value of investments	270	(81)	(241)	(1,800)
Other expenses	(245)	-	(232)	-
Total other income (expenses)	(3,704)	(710)	(445)	(3,515)
Net loss	(36,307)	(16,956)	(73,818)	(49,988)

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

Less: net loss attributable to non-controlling interests	9,191	3,975	17,355	12,324
Net loss attributable to common stockholders	<u>\$ (27,116)</u>	<u>\$ (12,981)</u>	<u>\$ (56,463)</u>	<u>\$ (37,664)</u>
Basic and diluted net loss per common share	<u>\$ (0.67)</u>	<u>\$ (0.32)</u>	<u>\$ (1.39)</u>	<u>\$ (0.94)</u>
Weighted average common shares outstanding—basic and diluted	<u>40,724,115</u>	<u>40,128,475</u>	<u>40,547,364</u>	<u>39,885,685</u>
