

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, 2016

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 November 9, 2016, Fortress Biotech, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 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>
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99.1	Press release dated November 9, 2016.
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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: November 9, 2016

/s/ Lindsay A. Rosenwald

Name: Lindsay A. Rosenwald

Title: Chairman, President and Chief Executive
Officer



Fortress Biotech Reports Third Quarter 2016 Financial Results and Recent Corporate Highlights

New York, NY – November 9, 2016 – Fortress Biotech, Inc. (NASDAQ: FBIO) (“Fortress”), a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products, today announced its financial results and recent corporate highlights for the quarter ended September 30, 2016.

Dr. Lindsay A. Rosenwald, Chairman, President and CEO of Fortress, said, “We recently launched our seventh Fortress Company, Cellvation, based on compelling science from The University of Texas Health Science Center at Houston in traumatic brain injury, an area of great unmet need, including two Phase 2 cell therapy programs. In addition, the clinical oncology pipeline of our Fortress Companies continues to grow, with the initiation of Checkpoint’s Phase 1/2 study of its EGFR inhibitor CK-101. In September, Fortress, through its subsidiary FBIO Acquisition, Inc., closed its tender offer for shares of National Holdings Corporation. We believe that as Fortress and National leverage their synergies, growth opportunities will be created for both companies.”

Financial Results:

- As of September 30, 2016, Fortress’ consolidated cash and cash equivalents totaled \$82.5 million, compared to \$71.3 million as of June 30, 2016, and \$98.2 million as of December 31, 2015, an increase of \$11.2 million for the third quarter and a decrease of \$15.7 million year-to-date. These totals exclude restricted cash of \$15.9 million as of September 30, 2016.
 - Total revenue for the third quarter of 2016 was \$1.0 million, consisting of \$0.43 million of net product revenue from Journey Medical Corporation (“JMC”), a Fortress Company, and \$0.55 million of collaboration revenue from a related party, compared to \$0.03 million in total revenue reported during the third quarter of 2015. Total revenue for the first nine months of 2016 was \$3.9 million, consisting of \$1.8 million in net product sales from JMC and \$2.1 million in collaboration revenue from a related party, compared to \$0.5 million in collaboration revenue from a related party reported for the first nine months of 2015.
 - Research and development expenses were \$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. This compares to \$9.1 million for the third quarter of 2015, of which \$4.9 million was related to Fortress Companies, and \$13.2 million for the first nine months of 2015, of which \$3.8 million was related to Fortress Companies. Noncash stock-based compensation expense included in research and development for the third quarter of 2016 was \$0.9 million, compared to \$4.3 million for the third quarter of 2015, and \$3.4 million for the first nine months of 2016, compared to \$5.2 million for the first nine months of 2015.
 - Research and development expenses from licenses acquired were \$1.0 million for the third quarter of 2016 and \$3.1 million for the first nine months of 2016, compared to \$1.9 million for the third quarter of 2015 and \$10.9 million for the first nine months of 2015.
 - General and administrative expenses were \$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, compared to \$7.1 million for the third quarter of 2015, of which \$1.7 million was related to Fortress Companies, and \$14.4 million for the first nine months of 2015, of which \$3.3 million was related to Fortress Companies. Noncash stock-based compensation expense included in general and administrative expenses was \$2.0 million for the third quarter of 2016 and \$5.4 million for the first nine months of 2016, compared to \$4.2 million for the third quarter of 2015 and \$6.7 million for the first nine months of 2015.
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- Net loss was \$13.0 million, or \$0.32 per share, for the third quarter of 2016, compared to a net loss of \$18.2 million, or \$0.46 per share, for the third quarter of 2015. For the first nine months of 2016, net loss was \$37.7 million, or \$0.94 per share, compared to \$36.4 million, or \$0.93 per share, for the first nine months of 2015.

Recent Fortress and Fortress Company Highlights:

Fortress Biotech, Inc.

- In September 2016, Fortress, through its subsidiary FBIO Acquisition, Inc., purchased approximately 56% of National Holdings Corporation (NASDAQ: NHLD) common stock, par value \$0.02 per share, at a purchase price of \$3.25 per share in cash, for an aggregate purchase price of approximately \$22.9 million.

Cellvation, Inc.

- In October 2016, Cellvation entered into an agreement with The University of Texas Health Science Center at Houston to secure exclusive worldwide rights to three programs for TBI, including two Phase 2 cell therapies and a next-generation bioreactor that enhances the anti-inflammatory potency of bone marrow-derived cells without genetic manipulation.

Checkpoint Therapeutics, Inc.

- In August 2016, the U.S. Food and Drug Administration (“FDA”) accepted an Investigational New Drug Application (“IND”) for a Phase 1/2 clinical trial of Checkpoint’s epidermal growth-factor receptor inhibitor (“EGFR”) CK-101, and in September 2016, the first patient was dosed. The Phase 1 dose escalation portion of the study will evaluate the safety and tolerability of ascending doses of CK-101 in patients with advanced solid tumors to determine the maximum tolerated dose and/or recommended Phase 2 dose of CK-101. The Phase 2 portion of the study is planned to evaluate the safety and efficacy of the recommended Phase 2 dose of CK-101 in patients with EGFR T790M mutation-positive non-small cell lung cancer.

Helocyte, Inc.

- On June 30, September 30 and October 31, 2016, Helocyte closed on additional sales of convertible promissory notes raising an aggregate of approximately \$4.0 million to date.
- In October 2016, Helocyte announced the online publication of data in *Blood* from the Phase 1 trial of Triplex vaccine for control of cytomegalovirus (CMV) in allogeneic hematopoietic stem cell transplant (HSCT) and solid organ transplant (SOT) recipients. In the Phase 1 study, Triplex was found to be safe, well-tolerated and highly immunogenic when administered to healthy volunteers at multiple dose levels. These data supported the initiation of an ongoing Phase 2 trial evaluating Triplex in patients undergoing allogeneic HSCT.

Journey Medical Corporation (JMC)

- In July 2016, JMC received FDA approval to manufacture Targadox™ for the treatment of severe acne. Sales commenced in October 2016.
- Also in July 2016, JMC products Luxamend[®] Wound Cream and Ceracade™ Skin Emulsion were showcased at the 2016 American Academy of Dermatology (AAD) Summer Meeting in Boston.

Mustang Bio, Inc.

- On September 30 and October 25, 2016, Mustang Bio closed on private placements of Units, comprised of shares of its common stock and warrants, raising an aggregate of approximately \$19.5 million, less offering expenses. Units were sold at \$65,000 each. National Securities Corporation acted as sole placement agent in the private placements.

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. Such statements include, but are not limited to, any statements relating to our growth strategy, potential acquisitions, 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 related to our growth strategy; our ability to continue to commercialize products; our ability to identify, acquire, close and integrate product candidates and companies successfully and on a timely basis; our need for substantial additional funds; 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; our dependence on third-party suppliers; our ability to attract, integrate, and retain key personnel; the early stage of products under development; government regulation; patent and intellectual property matters; competition; and 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)

	<u>September 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
	<u>(Unaudited)</u>	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 82,537	\$ 98,182
Accounts receivable	5,007	-
Cash deposits with clearing organizations	1,030	-
Receivables from broker-dealers and clearing organizations	1,607	-
Securities owned, at fair value	2,178	-
Inventory	123	-
Other receivables - related party	1,545	156
Prepaid expenses and other current assets	4,556	1,599
Total current assets	<u>98,583</u>	<u>99,937</u>
Property and equipment, net	6,957	309
Restricted cash	15,859	14,586
Long-term investments, at fair value	685	2,485
Intangible assets, net	1,550	1,250
Goodwill	21,739	-
Other assets	48	43
Total assets	<u>\$ 145,421</u>	<u>\$ 118,610</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 21,831	\$ 10,438
Accrued commissions and payroll payable	14,029	-
Deferred clearing and marketing credits	1,007	-
Interest payable	68	27
Derivative warrant liability	951	114
Other current liabilities	707	-
Total current liabilities	<u>38,593</u>	<u>10,579</u>
Notes payable, long-term (net of debt discount of \$2,764 and \$835 at September 30, 2016 and December 31, 2015, respectively)	24,373	23,174
Subsidiary convertible note, at fair value	3,031	-
Other long-term liabilities	4,583	584
Total liabilities	<u>70,580</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 September 30, 2016 and December 31, 2015, respectively	-	-
Common Stock, \$.001 par value, 100,000,000 shares authorized, 48,875,087 and 47,147,032 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	49	47
Additional paid-in-capital	264,397	246,955
Accumulated deficit	(227,820)	(190,156)
Total stockholders' equity attributed to the Company	<u>36,626</u>	<u>56,846</u>
Non-controlling interests	38,215	27,427
Total stockholders' equity	<u>74,841</u>	<u>84,273</u>
Total liabilities and stockholders' equity	<u>\$ 145,421</u>	<u>\$ 118,610</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,	
	2016	2015	2016	2015
Revenue				
Product revenue, net	\$ 429	\$ -	\$ 1,793	\$ -
Revenue - from a related party	546	25	2,072	525
Total revenue	<u>975</u>	<u>25</u>	<u>3,865</u>	<u>525</u>
Cost of goods sold - product revenue	41	-	365	-
Gross margin	<u>934</u>	<u>25</u>	<u>3,500</u>	<u>525</u>
Operating expenses				
Research and development	7,316	9,073	21,416	13,172
Research and development - licenses acquired	1,000	1,895	3,143	10,882
General and administrative	8,864	7,129	25,414	14,376
Total operating expenses	<u>17,180</u>	<u>18,097</u>	<u>49,973</u>	<u>38,430</u>
Loss from operations	(16,246)	(18,072)	(46,473)	(37,905)
Other income (expenses)				
Interest income	89	39	241	195
Interest expense and financing fees	(689)	(350)	(1,838)	(1,033)
Change in fair value of derivative liabilities	(16)	-	(105)	-
Change in fair value of subsidiary convertible note	(13)	-	(13)	-
Change in fair value of investments	(81)	(1,472)	(1,800)	(65)
Total other expenses	<u>(710)</u>	<u>(1,783)</u>	<u>(3,515)</u>	<u>(903)</u>
Net loss	(16,956)	(19,855)	(49,988)	(38,808)
Less: net loss attributable to non-controlling interests	3,975	1,694	12,324	2,416
Net loss attributable to common stockholders	\$ (12,981)	\$ (18,161)	\$ (37,664)	\$ (36,392)
Basic and diluted net loss per common share	<u>\$ (0.32)</u>	<u>\$ (0.46)</u>	<u>\$ (0.94)</u>	<u>\$ (0.93)</u>
Weighted average common shares outstanding-basic and diluted	<u>40,128,475</u>	<u>39,412,056</u>	<u>39,885,685</u>	<u>39,038,522</u>