

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, 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 May 10, 2016, Fortress Biotech, Inc. issued a press release announcing its financial results for the first quarter ended March 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 May 10, 2016.

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: May 10, 2016

/s/ Lindsay A. Rosenwald

Name: Lindsay A. Rosenwald

Title: Chairman, President and Chief Executive Officer



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

New York, NY – May 10, 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 March 31, 2016.

Dr. Lindsay A. Rosenwald, Chairman, President and CEO of Fortress, said, “This year, we have continued to build our portfolio of products under development and Journey Medical Corporation’s roster of marketed products. We have also made significant progress advancing the pipeline of many of our other Fortress Companies, including Mustang Bio, which presented positive initial Phase I data on its CAR-T therapy MB-101 for the treatment of glioblastoma at the American Society of Gene and Cell Therapy 19th Annual Meeting. In addition, we are excited to possibly bring National Holdings Corporation under the Fortress umbrella with the goal of building a world-class biotech and life sciences investment banking operations franchise. In 2016, we plan to continue to seek business development opportunities for Fortress and our Fortress Companies, as we expand our therapeutic focus and advance multiple milestones in our robust pipeline. We look forward to another transformative year in support of our mission of rapidly advancing meaningful treatments to people in need.”

Financial Results:

- At March 31, 2016, Fortress’ consolidated cash and cash equivalents totaled \$81.4 million compared to \$98.2 million at December 31, 2015, a decrease of \$16.8 million for the quarter. These totals exclude restricted cash of \$14.6 million. The majority of the cash payments were related to Fortress and Fortress Companies previously accrued liabilities and upfront fees.
- Revenue totaled \$0.7 million for the first quarter of 2016.
- Research and development expenses were \$7.7 million for the first quarter of 2016, compared to \$1.6 million for the first quarter of 2015.
- General and administrative expenses were \$7.9 million for the first quarter of 2016, compared to \$3.5 million for the first quarter of 2015.
- Net loss was \$12.2 million, or \$0.31 per share, for the first quarter of 2016, compared to a net loss of \$12.1 million, or \$0.31 per share, for the first quarter of 2015.
- Noncash stock-based compensation expense included in net loss for the first quarter of 2016 was \$2.9 million, compared to \$1.5 million for the first quarter of 2015.

Recent Corporate Highlights:

Avenue Therapeutics, Inc.

- During the three months ended March 31, 2016, Avenue completed a pharmacokinetics (PK) study for intravenous (IV) Tramadol.

Checkpoint Therapeutics, Inc.

- In February 2016, Checkpoint repaid its National Securities Corporation (NSC) Debt of \$2.8 million.

FBIO Acquisition, Inc.

- In April 2016, Fortress, FBIO Acquisition, Inc. and National Holdings Corporation (“NHLD”) entered into an agreement and plan of merger for the acquisition of NHLD by FBIO Acquisition, Inc.
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Helocyte, Inc.

- In February 2016, Helocyte entered into an Investigator-Initiated Clinical Research Support Agreement with the City of Hope National Medical Center, to support a Phase 2 clinical study of its Triplex immunotherapy for CMV control in allogeneic stem cell transplant recipients. The Phase 2 study is additionally supported by grants from the National Cancer Institute.
- In February 2016, Helocyte entered into an option agreement with The University of Texas Health Science Center at Houston, for the exclusive rights to license certain intellectual property and clinical data relating to the use of bone marrow derived mononuclear cells for the treatment of severe Traumatic Brain Injury.
- In March 2016, Helocyte entered into an Investigator-Initiated Clinical Research Support Agreement with the City of Hope National Medical Center, to support a Phase 2 clinical study of its PepVax immunotherapy for CMV control in allogeneic stem cell transplant recipients. The Phase 2 study is additionally supported by grants from the National Cancer Institute.

Journey Medical Corporation (JMC)

- In January 2016, JMC entered into a licensing agreement with a third party to distribute a prescription wound cream. JMC intends to commercialize this product in the second quarter of 2016.
- In January 2016, JMC entered into a licensing agreement with a third party to distribute an emollient for the treatment of various types of dermatitis. JMC intends to commercialize this product in the second quarter of 2016.
- Both products will be marketed under the JMC brand.

Mustang Bio, Inc.

- In April 2016, Mustang announced that two abstracts pertaining to MB-101 (IL13R α 2-specific CAR T cells) for the treatment of glioblastoma were selected for presentation at the American Society of Gene and Cell Therapy 19th Annual Meeting (ASGCT). Pre-clinical and preliminary Phase I data were presented at ASGCT on Thursday, May 5.

About Fortress Biotech

Fortress Biotech, Inc. (“Fortress” or “the Company”) is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress plans to develop and commercialize products both within Fortress and through subsidiary companies, also known as Fortress Companies. In addition to its internal development programs, the Company will leverage its biopharmaceutical business expertise and drug development capabilities to help the Fortress Companies achieve their goals. Additionally, the Company will provide funding and management services to each of the Fortress Companies and, from time to time, the Company and the Fortress Companies will seek licensing, 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.

Important Additional Information

The tender offer by FBIO Acquisition, Inc. for shares of NHLD described in this press release has not yet commenced, and this press release is neither an offer to purchase nor a solicitation of an offer to sell securities. At the time the offer is commenced, Fortress will file a tender offer statement on Schedule TO, including an offer to purchase, a letter of transmittal and related documents with the Securities and Exchange Commission (the “Commission”), and NHLD will file a solicitation/recommendation statement on Schedule 14D-9 with respect to the offer with the Commission. The offer to purchase the NHLD shares will only be made pursuant to the offer to purchase, the letter of transmittal and related documents filed as a part of the Schedule TO. SECURITY HOLDERS AND OTHER INVESTORS ARE URGED TO READ THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND CERTAIN OTHER OFFER DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION WHICH SHOULD BE READ CAREFULLY BEFORE ANY DECISION IS MADE WITH RESPECT TO THE TENDER OFFER. The offer to purchase, the related letter of transmittal and certain other offer documents, as well as the solicitation/recommendation statement, will be made available to investors and security holders at no expense to them. The tender offer statement and the solicitation/recommendation statement will be made available for free at the Commission’s web site at www.sec.gov. Free copies of these materials and certain other offering documents will be made available by the information agent for the offer.

In addition to the tender offer statement, Fortress files annual, quarterly and special reports, proxy statements and other information with the Commission. You may read and copy any reports, statements or other information filed by Fortress at the SEC Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference room. Fortress' filings with the Commission are also available to the public from commercial document-retrieval services and at the website maintained by the Commission at www.sec.gov.

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 are: risks related to our growth strategy; 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; risks associated with the proposed transaction with NHLD, including (i) the occurrence of any event, change or other circumstance that could give rise to the termination of the agreement and plan of merger; (ii) successful completion of the proposed transaction on a timely basis; (iii) uncertainties as to how many of the holders of NHLD shares will tender their shares into the tender offer; (iv) the impact of regulatory reviews on the proposed transaction; (v) the outcome of any legal proceedings that may be instituted against one or both of Fortress and NHLD and others following the announcement of the agreement and plan of merger; and (vi) risks that the proposed transaction disrupts current plans and operations and the potential difficulties in employee retention as a result of the transaction; as well as other risks described in our filings with the Commission. 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.

Contact:

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Fortress Biotech, Inc.
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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,</u> <u>2016</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2015</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 81,415	\$ 98,182
Other receivables - related party	1,314	156
Prepaid expenses and other current assets	1,607	1,441
Total current assets	<u>84,336</u>	<u>99,779</u>
Property and equipment, net	2,598	309
Restricted cash	14,586	14,586
Long-term investments, at fair value	1,567	2,485
Intangible asset - license	1,450	1,250
Other assets	376	201
Total assets	<u>\$ 104,913</u>	<u>\$ 118,610</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 2,348	\$ 1,868
Accrued expenses	8,259	8,570
Interest payable	27	27
Derivative warrant liability	203	114
Total current liabilities	<u>10,837</u>	<u>10,579</u>
Notes payable, long-term (net of debt discount of \$466 and \$835 at March 31, 2016 and December 31, 2015, respectively)	20,751	23,174
Other long-term liabilities	2,416	584
Total liabilities	<u>34,004</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 March 31, 2016 and December 31, 2015, respectively	-	-
Common Stock, \$.001 par value, 100,000,000 shares authorized, 48,517,449 and 47,147,032 shares issued and outstanding as of March 31, 2016 and December 31, 2015, respectively	49	47
Additional paid-in-capital	246,877	246,955
Accumulated deficit	(202,361)	(190,156)
Total stockholders' equity attributed to the Company	<u>44,565</u>	<u>56,846</u>
Non-controlling interests	26,344	27,427
Total stockholders' equity	<u>70,909</u>	<u>84,273</u>
Total liabilities and stockholders' equity	<u>\$ 104,913</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 March	
	31,	
	2016	2015
Revenue	\$ 383	\$ -
Revenue - from a related party	277	500
Total revenue	660	500
Operating expenses		
Research and development	7,736	1,642
Research and development – licenses acquired	83	7,439
General and administrative	7,932	3,490
Total operating expenses	15,751	12,571
Loss from operations	(15,091)	(12,071)
Other income (expenses)		
Interest income	75	82
Interest expense	(620)	(331)
Change in fair value of subsidiary's warrant liabilities	(89)	-
Change in fair value of investments	(918)	(215)
Total other income (expenses)	(1,552)	(464)
Net loss	(16,643)	(12,535)
Less: net loss attributable to non-controlling interests	4,438	479
Net loss attributable to common stockholders	\$ (12,205)	\$ (12,056)
Basic and diluted net loss per common share	\$ (0.31)	\$ (0.31)
Weighted average common shares outstanding—basic and diluted	39,658,188	38,574,702

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