

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): August 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, 9<sup>th</sup> 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))
-

**Item 2.02. Results of Operations and Financial Condition.**

On August 9, 2016, Fortress Biotech, Inc. issued a press release announcing its financial results for the second quarter ended June 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>                  |
|--------------------|-------------------------------------|
| 99.1               | Press release dated August 9, 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: August 9, 2016

/s/ Lindsay A. Rosenwald

Name: Lindsay A. Rosenwald

Title: Chairman, President and Chief Executive  
Officer

---

**Fortress Biotech Reports Second Quarter 2016 Financial Results and Recent Corporate Highlights**  
***-Quarter Milestones Include Commercialization of First Two Products-***

**New York, NY – August 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 June 30, 2016.

Dr. Lindsay A. Rosenwald, Chairman, President and CEO of Fortress, said, “During the second quarter of 2016, we attained several milestones, including the commercialization of our first two products from Journey Medical Corporation’s (“Journey”) dermatology franchise: Luxamend™ Wound Cream and Ceracade™ Skin Barrier Emulsion.

Our subsidiary Checkpoint Therapeutics, Inc. (“Checkpoint Therapeutics”) also acquired an exclusive, worldwide license to BRD4-inhibiting (from the Bromodomain and Extra-Terminal motif (“BET”) inhibitor class of anti-cancer proteins) compounds for solid tumors from Jubilant Biosys Limited (“Jubilant”). In addition, Checkpoint Therapeutics entered a sublicense agreement with TG Therapeutics, Inc., a related party (“TG Therapeutics”), to develop and commercialize the BRD4-inhibiting compounds for hematological malignancies, while Checkpoint Therapeutics retains the right to develop and commercialize these compounds for solid tumors. We believe clinical and corporate developments such as these will help position us to diversify our pipeline during the second half of 2016.”

**Financial Results:**

- At June 30, 2016, Fortress’ consolidated cash and cash equivalents totaled \$71.3 million compared to \$81.4 million at March 31, 2016 and \$98.2 million as of December 31, 2015, a decrease of \$10.1 million for the quarter, of which \$6.6 million relates to our subsidiaries, and \$26.9 million year-to-date, of which \$16.1 million relates to our subsidiaries. These totals exclude restricted cash of \$14.6 million.
  - Total revenue for the second quarter of 2016 was \$2.2 million consisting of \$1.0 million of net product revenue from our subsidiary Journey and \$1.2 million of collaboration revenue from a related party, compared with no revenue reported during last year’s second quarter. \$2.9 million in total revenue was reported for the first six months of 2016 consisting of \$1.4 million of net product sales from Journey and \$1.5 million of collaboration revenue from a related party, compared with \$0.5 million of collaboration revenue from a related party reported for the first six months of 2015.
  - Research and development expenses were \$6.3 million, of which \$4.0 million relates to our subsidiaries for the second quarter of 2016 and \$14.1 million, of which \$9.0 million relates to our subsidiaries for the first six months of 2016. This compares with \$2.4 million, of which \$1.1 million relates to our subsidiaries for the second quarter of 2015 and \$4.1 million, of which \$1.2 million relates to our subsidiaries for the first six months of 2015. Noncash stock-based compensation expense included in research and development for the second quarter of 2016 was \$1.1 million, compared to \$0.6 million for the second quarter of 2015, and \$2.4 million for the first six months of 2016, compared with \$0.9 million for the first six months of 2015.
-

- Research and development licenses acquired expenses were \$2.0 million for the second quarter of 2016 and \$2.1 million for the first six months of 2016, compared to \$1.5 million for the second quarter 2015 and \$9.0 million for the first six months of 2015.
- General and administrative expenses were \$8.6 million, of which \$3.7 million relates to our subsidiaries for the second quarter of 2016 and \$16.6 million, of which \$6.6 million relates to our subsidiaries for the first six months of 2016, compared to \$3.8 million, of which \$0.3 million relates to our subsidiaries for the second quarter of 2015 and \$7.3 million, of which \$1.6 million relates to our subsidiaries for the first six months of 2015. Noncash stock-based compensation expense included in general and administrative for the second quarter of 2016 was \$1.9 million, compared to \$1.3 million for the second quarter of 2015, and \$3.5 million for the first six months of 2016, compared with \$2.5 million for the first six months of 2015.
- Net loss was \$12.5 million, or \$0.31 per share, for the second quarter of 2016, compared to a net loss of \$6.2 million, or \$0.16 per share, for the second quarter of 2015. For the first six months of 2016, net loss was \$24.7 million or \$0.62 per share, compared with \$18.2 million or \$0.47 per share in the first six months of 2015.

### **Recent Corporate Highlights:**

#### **Avenue Therapeutics**

- Avenue completed an End-of-Phase 2 (“EOP2”) meeting with the FDA and, based on the outcome of the EOP2 meeting, Avenue anticipates that its Phase 3 program will consist of three studies: 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.

#### **Checkpoint Therapeutics**

- In May 2016, Jubilant and Checkpoint Therapeutics announced the signing of an exclusive, worldwide license agreement under which Jubilant out-licensed to Checkpoint Therapeutics a family of patents covering compounds that inhibit BRD4, a member of the BET domain for cancer treatment. In connection with the license agreement with Jubilant, Checkpoint Therapeutics entered into a sublicense agreement with TG Therapeutics to develop and commercialize the licensed compounds for hematological malignancies, while Checkpoint Therapeutics retains the right to develop and commercialize these compounds for solid tumors.

#### **Journey Medical Corporation**

- In June 2016, sales began for Luxamend™ Wound Cream and Ceracade™ Skin Barrier Emulsion, the first two products in Journey’s dermatology franchise. Both products were showcased at the 2016 American Academy of Dermatology (AAD) Summer Meeting in July 2016.
  - In July 2016, Journey received FDA approval for the manufacturing of a product for the treatment of acne, for which it had entered into a license and supply agreement in 2015. Journey expects sales of this product to begin in the fourth quarter of 2016.
-

### **Mustang Bio, Inc.**

- In April 2016, Mustang announced that two abstracts pertaining to MB-101 (IL13R $\alpha$ 2-specific CAR-T cells) for the treatment of glioblastoma were selected for presentation at the American Society of Gene and Cell Therapy's 19th Annual Meeting ("ASGCT"). Pre-clinical and preliminary Phase I data were presented at ASGCT.
- In May 2016, an oral presentation related to MB-101 (IL13R $\alpha$ 2-specific CAR-T cells) was presented by City of Hope investigators at the ASGCT at the Marriott Wardman Park Hotel in Washington, DC.

### **Fortress Biotech**

- On June 10, 2016, CB Pharma Acquisition Corp ("CB Pharma") held an extraordinary general meeting of its shareholders. At such meeting, the shareholders approved each of the following items: (i) an amendment to the CB Pharma's Amended and Restated Memorandum and Articles of Association (the "Charter") to extend the date by which CB Pharma has to consummate a business combination from June 12, 2016 to December 12, 2016 (the "Extension"), (ii) an amendment to the Charter to allow the holders of the CB Pharma's ordinary shares issued in their initial public offering to elect to convert their shares into their pro rata portion of the funds held in trust, if the Extension is approved, and (iii) the change of CB Pharma's name from "CB Pharma Acquisition Corp." to "Origo Acquisition Corporation" ("Origo"). In connection with the meeting, Fortress transferred 1,050,000 of its CB Pharma ordinary shares to Origo, retaining a holding of 265,000 Origo shares.
- In May 2016, positive data from the Phase 1/2 study of CNDO-109-Activated Allogeneic Natural Killer (NK) Cells in patients with acute myeloid leukemia were presented in an oral session at the Innate Killer Summit 2016 in San Diego, CA.
- In July 2016 Fortress' stock was added to the Russell 2000® Index.

### **About Fortress Biotech**

Fortress Biotech, Inc. ("Fortress") 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. Fortress intends to leverage its biopharmaceutical business expertise and drug development capabilities to help the Fortress Companies achieve their goals. Additionally, Fortress intends to provide funding and management services to each of the Fortress Companies and, from time to time, Fortress 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](http://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 are: 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.

### **Contact:**

Lucy Lu, MD, Executive Vice President & Chief Financial Officer  
Fortress Biotech, Inc.  
781-652-4525; [ir@fortressbiotech.com](mailto:ir@fortressbiotech.com)

---

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

|  | <u>June 30,</u><br><u>2016</u> | <u>December 31,</u><br><u>2015</u> |
|--|--------------------------------|------------------------------------|
|  | <u>(Unaudited)</u>             |                                    |
| <b>ASSETS</b>  |                                |                                    |
| Current assets   |                                |                                    |
| Cash and cash equivalents  | \$ 71,336                      | \$ 98,182                          |
| Accounts receivable  | 967                            | -                                  |
| Inventory  | 100                            | -                                  |
| Other receivables - related party  | 2,570                          | 156                                |
| Prepaid expenses and other current assets  | 1,579                          | 1,599                              |
| Total current assets   | <u>76,552</u>                  | <u>99,937</u>                      |
| Property and equipment, net  | 4,535                          | 309                                |
| Restricted cash  | 14,586                         | 14,586                             |
| Long-term investments, at fair value   | 766                            | 2,485                              |
| Intangible asset - license   | 1,579                          | 1,250                              |
| Other assets   | 44                             | 43                                 |
| <b>Total assets</b>  | <b><u>\$ 98,062</u></b>        | <b><u>\$ 118,610</u></b>           |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |                                |                                    |
| Current liabilities  |                                |                                    |
| Accounts payable   | \$ 5,126                       | \$ 1,868                           |
| Accrued expenses   | 8,883                          | 8,570                              |
| Interest payable   | 26                             | 27                                 |
| Derivative liabilities   | 302                            | 114                                |
| Total current liabilities  | <u>14,337</u>                  | <u>10,579</u>                      |
| Notes payable, long-term (net of debt discount of \$412 and \$835 at June 30, 2016 and December 31, 2015, respectively)  | 20,805                         | 23,174                             |
| Convertible note, at fair value  | 1,000                          | -                                  |
| Other long-term liabilities  | 3,706                          | 584                                |
| <b>Total liabilities</b>   | <b><u>39,848</u></b>           | <b><u>34,337</u></b>               |
| <b>Commitments and contingencies</b>   |                                |                                    |
| <b>Stockholders' equity</b>  |                                |                                    |
| Convertible Preferred stock, \$.001 par value, 129,767 Series C shares authorized, 0 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively     | -                              | -                                  |
| Common Stock, \$.001 par value, 100,000,000 shares authorized, 48,668,630 and 47,147,032 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively | 49                             | 47                                 |
| Additional paid-in-capital   | 250,127                        | 246,955                            |
| Accumulated deficit  | (214,839)                      | (190,156)                          |
| Total stockholders' equity attributed to the Company   | <u>35,337</u>                  | <u>56,846</u>                      |
| Non-controlling interests  | <u>22,877</u>                  | <u>27,427</u>                      |
| Total stockholders' equity   | <u>58,214</u>                  | <u>84,273</u>                      |
| <b>Total liabilities and stockholders' equity</b>  | <b><u>\$ 98,062</u></b>        | <b><u>\$ 118,610</u></b>           |



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

|  | For the Three Months Ended June<br>30, |                   | For the Six Months Ended June<br>30, |                    |
|--|--|-------------------|--------------------------------------|--------------------|
|  | 2016                                   | 2015              | 2016                                 | 2015               |
| Product revenue, net   | \$ 981                                 | \$ -              | \$ 1,364                             | \$ -               |
| Revenue - from a related party                               | 1,249                                  | -                 | 1,526                                | 500                |
| <b>Total revenue</b>   | <b>2,230</b>                           | <b>-</b>          | <b>2,890</b>                         | <b>500</b>         |
| Cost of goods sold - product revenue                         | 324                                    | -                 | 324                                  | -                  |
| <b>Gross margin</b>  | <b>1,906</b>                           | <b>-</b>          | <b>2,566</b>                         | <b>500</b>         |
| <b>Operating expenses</b>                                    |  |                   |                                      |                    |
| Research and development                                     | 6,347                                  | 2,411             | 14,100                               | 4,066              |
| Research and development – licenses acquired                 | 2,060                                  | 1,548             | 2,143                                | 8,987              |
| General and administrative                                   | 8,635                                  | 3,803             | 16,550                               | 7,280              |
| <b>Total operating expenses</b>                              | <b>17,042</b>                          | <b>7,762</b>      | <b>32,793</b>                        | <b>20,333</b>      |
| <b>Loss from operations</b>                                  | <b>(15,136)</b>                        | <b>(7,762)</b>    | <b>(30,227)</b>                      | <b>(19,833)</b>    |
| <b>Other income (expenses)</b>                               |  |                   |                                      |                    |
| Interest income  | 77                                     | 74                | 152                                  | 156                |
| Interest expense and financing fee                           | (529)                                  | (352)             | (1,149)                              | (683)              |
| Change in fair value of derivative liabilities               | -                                      | -                 | (89)                                 | -                  |
| Change in fair value of investments                          | (801)                                  | 1,622             | (1,719)                              | 1,407              |
| <b>Total other income (expenses)</b>                         | <b>(1,253)</b>                         | <b>1,344</b>      | <b>(2,805)</b>                       | <b>880</b>         |
| <b>Net loss</b>  | <b>(16,389)</b>                        | <b>(6,418)</b>    | <b>(33,032)</b>                      | <b>(18,953)</b>    |
| Less: net loss attributable to non-controlling interests     | 3,911                                  | 243               | 8,349                                | 722                |
| <b>Net loss attributable to common stockholders</b>          | <b>\$ (12,478)</b>                     | <b>\$ (6,175)</b> | <b>\$ (24,683)</b>                   | <b>\$ (18,231)</b> |
| Basic and diluted net loss per common share                  | \$ (0.31)                              | \$ (0.16)         | \$ (0.62)                            | \$ (0.47)          |
| Weighted average common shares outstanding—basic and diluted | 39,867,724                             | 39,119,606        | 39,762,956                           | 38,848,660         |