# 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, 2018**

# Fortress Biotech, Inc.
(Exact Name of Registrant as Specified in Charter)

| **Delaware** | **001-35366** | **20-5157386** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (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, 2018, 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, 2018. 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 |
|---|---|
| 99.1 | Press release issued by Fortress Biotech, Inc., dated November 9, 2018. |

**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, 2018

**Fortress Biotech, Inc.**
(Registrant)

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

**Exhibit 99.1**


## Fortress Biotech Reports Third Quarter 2018 Financial Results and Recent Corporate Highlights

**New York, NY – November 9, 2018** – 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, 2018.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "Fortress and our subsidiaries continued to achieve important corporate and clinical milestones in the third quarter of 2018. Mustang Bio expanded its pipeline into gene therapy by securing an exclusive worldwide license for the development of a potentially first-in-class *ex vivo* lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency ("X-SCID") from St. Jude Children's Research Hospital ("St. Jude"). Additionally, Checkpoint Therapeutics announced positive interim safety and efficacy data from its Phase 1/2 clinical trial of CK-101, a third-generation epidermal growth factor receptor ("EGFR") inhibitor being evaluated in advanced non-small cell lung cancer ("NSCLC"). Finally, Cyprium Therapeutics' product candidate for patients diagnosed with classic Menkes disease, CUTX-101, was granted Fast Track Designation by the U.S. Food and Drug Administration ("FDA"). We plan to continue to acquire and develop compelling and, in some instances, potentially life-saving product candidates, which could lead to maximizing shareholder value."

**Financial Results:**

- As of September 30, 2018, Fortress' consolidated cash, cash equivalents, short-term investments (certificates of deposit), cash deposits with clearing organizations and restricted cash totaled $136.1 million, compared to $168.3 million as of December 31, 2017, a decrease of $32.2 million year-to-date.
- Net revenue totaled $63.7 million for the third quarter of 2018, compared to $46.9 million for the third quarter of 2017. Total revenue as of September 30, 2018 includes $5.2 million of Fortress revenue, primarily from the sale of Journey Medical Corporation products, and $58.5 million of revenue from National Holdings Corporation[1] ("National Holdings"). Total revenue as of September 30, 2017 included $2.5 million of Fortress revenue and $44.4 million of revenue from National Holdings.
- Research and development expenses were $16.1 million for the third quarter of 2018, of which $15.1 million was related to Fortress Companies. This compares to $15.9 million for the third quarter of 2017, of which $14.2 million was related to Fortress Companies. Non-cash, stock-based compensation expenses included in research and development were $1.8 million for the third quarter of 2018, compared to $1.6 million for the third quarter of 2017.
- Research and development expenses from license acquisitions were $3.7 million for the third quarter of 2018, compared to $0.3 million for the third quarter of 2017.
- General and administrative expenses were $12.2 million for the third quarter of 2018, of which $7.4 million was related to Fortress Companies. This compares to $15.1 million for the third quarter of 2017, of which $10.5 million was related to Fortress Companies. Non-cash, stock-based compensation expenses included in general and administrative expenses were $2.3 million for the third quarter of 2018, compared to $2.6 million for the third quarter of 2017.
- National Holdings' operating expenses totaled $55.2 million for the third quarter of 2018, compared to $47.7 million for the third quarter of 2017.
- Net loss attributable to common stockholders was $16.6 million, or $0.37 per share, for the third quarter of 2018, compared to a net loss attributable to common stockholders of $27.1 million, or $0.67 per share, for the third quarter of 2017. For the first nine months of 2018, net loss attributable to common stockholders was $59.3 million or $1.36 per share, compared to $56.5 million or $1.39 per share in the first nine months of 2017.

**Recent Fortress and Fortress Company Highlights:**

**Aevitas Therapeutics, Inc.**

- In August 2018, Aevitas announced that it entered into a sponsored research agreement with the laboratory of Wenchao Song, Ph.D., at the University of Pennsylvania to evaluate Aevitas' adeno-associated virus ("AAV") gene therapy technology in the university's proprietary animal models of complement-mediated diseases.

**Caelum Biosciences, Inc.**

- In November 2018, Caelum announced that global longitudinal strain ("GLS") data from the Phase 1b study of CAEL-101 (a light chain fibril-reactive monoclonal antibody 11-1F4) in patients with amyloid light chain ("AL") amyloidosis and imaging data from a pre-clinical study have been selected for two oral presentations at the 60th American Society of Hematology ("ASH") Annual Meeting, to be held December 1-4, 2018, in San Diego.

**Checkpoint Therapeutics, Inc.**

- In September 2018, Checkpoint announced positive interim safety and efficacy data from its Phase 1/2 clinical trial of CK-101, a third-generation EGFR tyrosine kinase inhibitor ("TKI") being evaluated in advanced NSCLC. The data were presented in an oral presentation at the International Association for the Study of Lung Cancer ("IASLC") 19th World Conference on Lung Cancer in Toronto. CK-101 was well tolerated across multiple dose groups and safe. Durable anti-tumor activity was observed, particularly in treatment-naïve EGFR mutation-positive NSCLC patients.
- In October 2018, Checkpoint appointed Christian Béchon to its Board of Directors.

**Cyprium Therapeutics, Inc.**

- In July 2018, Cyprium announced that the FDA granted Fast Track Designation to CUTX-101, a product candidate for patients diagnosed with classic Menkes disease who have not demonstrated significant clinical progression.
- In September 2018, Cyprium announced the publication of preclinical data on AAV-based gene therapy combined with subcutaneous CUTX-101 ("Copper Histidinate") for Menkes disease in *Molecular Therapy: Methods & Clinical Development.*

**Mustang Bio, Inc.**

- In July 2018, Mustang completed a pre-Investigational New Drug ("pre-IND") meeting with the FDA for MB-102 ("CD123 CAR T"). Based on the meeting, Mustang expects to file an IND in the fourth quarter of 2018 to support a Phase 1/2 trial of MB-102 in acute myeloid leukemia, blastic plasmacytoid dendritic cell neoplasm and high-risk myelodysplastic syndrome.
- In August 2018, Mustang announced that it entered into an exclusive worldwide license agreement with St. Jude for the development of a potentially first-in-class *ex vivo* lentiviral gene therapy for the treatment of X-SCID, also known as bubble boy disease. The therapy is currently being evaluated in a Phase 1/2 multicenter trial in infants under the age of two. This study is the world's first lentiviral gene therapy trial for infants with X-SCID. The therapy is also being investigated in patients over the age of two in a second Phase 1/2 trial at the National Institutes of Health ("NIH").
- In October 2018, Mustang appointed Martina A. Sersch, M.D., Ph.D., as Chief Medical Officer.
- Also in October 2018, Mustang announced that a first-of-its-kind Phase 1 clinical trial evaluating the safety and effectiveness of intraventricular delivery of CAR T cells to the brains of patients with HER2-positive breast cancer with brain metastases has been initiated at City of Hope. In addition, Mustang announced that City of Hope has dosed the first patient in a Phase 1 clinical trial of HER2-specific CAR T cells in treating recurrent or refractory grade III-IV glioma. The trial will evaluate the side effects and best dose of HER2-specific CAR T cells in treating patients with grade III-IV glioma that has come back or does not respond to treatment.

**About Fortress Biotech**
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 may be required by law.

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[1] Fortress acquired approximately 56 percent of National Holdings in September 2016.

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

| | September 30, 2018 (Unaudited) | December 31, 2017 |
|---|---|---|
| **ASSETS** | | |
| Current assets | | |
| Cash and cash equivalents | $ 95,867 | $ 113,915 |
| Accounts receivable | 5,431 | 7,758 |
| Short-term investments (certificates of deposit) | 22,538 | 36,002 |
| Cash deposits with clearing organizations | 336 | 1,041 |
| Receivables from broker-dealers and clearing organizations | 11,884 | 7,395 |
| Forgivable loans receivable | 1,610 | 1,616 |
| Securities owned, at fair value | 6,675 | 1,985 |
| Inventory | 674 | 171 |
| Other receivables - related party | 414 | 618 |
| Prepaid expenses and other current assets | 14,089 | 12,680 |
| Total current assets | 159,518 | 183,181 |
| | | |
| Property and equipment, net | 14,642 | 9,513 |
| Restricted cash | 17,358 | 17,387 |
| Long-term investments, at fair value | – | 1,390 |
| Intangible assets | 13,935 | 15,223 |
| Goodwill | 18,645 | 18,645 |
| Other assets | 821 | 611 |
| **Total assets** | **$ 224,919** | **$ 245,950** |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities | | |
| Accounts payable and accrued expenses | $ 37,345 | $ 36,127 |
| Accounts payable and accrued expenses - related party | 153 | 222 |
| Accrued commissions and payroll payable | 11,974 | 10,065 |
| Deferred clearing and marketing credits | 629 | 786 |
| Securities sold, not yet purchased, at fair value | 24 | 151 |
| Warrants issued - National | – | 5,597 |
| Interest payable | 613 | 887 |
| Interest payable - related party | 94 | 97 |
| Notes payable, short-term (net of debt discount of $447 and $973 at September 30, 2018 and December 31, 2017, respectively) | 9,054 | 8,528 |
| Subsidiary convertible note, short-term, at fair value | 10,657 | 4,700 |
| Deferred revenue | 155 | – |
| Derivative warrant liability | – | 87 |
| Other current liabilities | 77 | 181 |
| Total current liabilities | 70,775 | 67,428 |
| | | |
| Notes payable, long-term (net of debt discount of $445 and $62 at September 30, 2018 and December 31, 2017, respectively) | 64,546 | 43,222 |
| Subsidiary convertible note, long-term, at fair value | – | 10,059 |
| Other long-term liabilities | 4,961 | 4,739 |
| **Total liabilities** | **140,282** | **125,448** |
| | | |
| **Stockholders' equity** | | |
| Preferred stock, $0.001 par value, 15,000,000 authorized, 5,000,000 designated Series A shares, 1,000,000 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively; liquidation value of $25.00 per share | 1 | 1 |
| Common stock, $0.001 par value, 100,000,000 shares authorized, 56,183,480 and 50,991,285 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively | 56 | 51 |
| Common stock issuable, 347,684 and 158,015 shares as of September 30, 2018 and December 31, 2017, respectively | 495 | 500 |
| Additional paid-in-capital | 408,615 | 364,148 |
| Accumulated deficit | (371,394) | (312,127) |
| Total stockholders' equity attributed to the Company | 37,773 | 52,573 |
| | | |
| Non-controlling interests | 46,864 | 67,929 |
| Total stockholders' equity | 84,637 | 120,502 |
| **Total liabilities and stockholders' equity** | | |

| | | |
|---|---|---|
| | $ 224,919 | $ 245,950 |

**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 September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| **Revenue** | | | | |
| ***Fortress*** | | | | |
| Product revenue, net | $ 5,168 | $ 2,170 | $ 17,366 | $ 8,309 |
| Revenue - from a related party | 5 | 350 | 525 | 1,393 |
| Net Fortress revenue | 5,173 | 2,520 | 17,891 | 9,702 |
| | | | | |
| ***National*** | | | | |
| Commissions | 28,397 | 24,881 | 85,422 | 73,380 |
| Net dealer inventory gains | 482 | 1,789 | 5,601 | 6,666 |
| Investment banking | 19,271 | 8,942 | 43,012 | 26,595 |
| Investment advisory | 5,281 | 3,605 | 15,811 | 10,480 |
| Interest and dividends | 771 | 674 | 2,003 | 2,065 |
| Transfer fees and clearing services | 1,606 | 1,649 | 5,680 | 5,834 |
| Tax preparation and accounting | 2,444 | 2,527 | 6,835 | 6,527 |
| Other | 268 | 299 | 697 | 1,016 |
| Total National revenue | 58,520 | 44,366 | 165,061 | 132,563 |
| Net revenue | 63,693 | 46,886 | 182,952 | 142,265 |
| | | | | |
| **Operating expenses** | | | | |
| ***Fortress*** | | | | |
| Cost of goods sold - product revenue | 1,406 | 505 | 4,546 | 1,852 |
| Research and development | 16,082 | 15,890 | 58,528 | 34,683 |
| Research and development - licenses acquired | 3,706 | 300 | 3,804 | 3,394 |
| General and administrative | 12,184 | 15,104 | 38,788 | 36,490 |
| Total Fortress operating expenses | 33,378 | 31,799 | 105,666 | 76,419 |
| | | | | |
| ***National*** | | | | |
| Commissions, compensation and fees | 48,556 | 39,963 | 141,462 | 118,983 |
| Clearing fees | 451 | 470 | 1,772 | 1,826 |
| Communications | 856 | 690 | 2,429 | 2,094 |
| Occupancy | 738 | 972 | 2,834 | 2,916 |
| Licenses and registration | 861 | 391 | 2,028 | 1,223 |
| Professional fees | 1,076 | 1,082 | 3,047 | 3,336 |
| Interest | 26 | 5 | 30 | 13 |
| Underwriting costs | 43 | – | 230 | – |
| Depreciation and amortization | 871 | 507 | 2,587 | 1,513 |
| Other administrative expenses | 1,726 | 3,610 | 5,839 | 7,315 |
| Total National operating expenses | 55,204 | 47,690 | 162,258 | 139,219 |
| Total operating expenses | 88,582 | 79,489 | 267,924 | 215,638 |
| Loss from operations | (24,889) | (32,603) | (84,972) | (73,373) |
| | | | | |
| Other income (expenses) | | | | |
| Interest income | 269 | 204 | 841 | 530 |
| Interest expense and financing fee | (2,228) | (3,220) | (6,455) | (5,298) |
| Change in fair value of derivative liabilities | - | (639) | (7,931) | 5,155 |
| Change in fair value of subsidiary convertible note | (84) | (74) | 26 | (359) |
| Change in fair value of investments | (565) | 270 | (1,390) | (241) |
| Other expenses | (146) | (245) | (258) | (232) |
| Total other expenses | (2,754) | (3,704) | (15,167) | (445) |
| **Loss before income taxes** | **(27,643)** | **(36,307)** | **(100,139)** | **(73,818)** |
| Income tax expense | 944 | – | 2,382 | – |
| **Net loss** | **(28,587)** | **(36,307)** | **(102,521)** | **(73,818)** |
| **Less: net loss attributable to non-controlling interests** | (11,949) | (9,191) | (43,254) | (17,355) |
| **Net loss attributable to common stockholders** | **$ (16,638)** | **$ (27,116)** | **$ (59,267)** | **$ (56,463)** |
| | | | | |
| **Basic and diluted net loss per common share** | **$ (0.37)** | **$ (0.67)** | **$ (1.36)** | **$ (1.39)** |
| | | | | |
| **Weighted average common shares outstanding-basic and diluted** | **44,818,186** | **40,724,115** | **43,578,763** | **40,547,364** |