

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): April 21, 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 8.01. Other Events.

On April 21, 2016, Helocyte, Inc., a Fortress Biotech, Inc. subsidiary, issued a press release announcing several corporate and clinical milestones, including the advancement of lead programs into Phase 2.

A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated April 21, 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: April 21, 2016

/s/ Lindsay A. Rosenwald

Name: Lindsay A. Rosenwald

Title: Chairman, President and Chief Executive
Officer



HELOCYTE ANNOUNCES CORPORATE AND CLINICAL MILESTONES

- *Frank Taffy Appointed President and Chief Executive Officer*
- *Lead Immunotherapies PepVax and Triplex Advanced into Phase 2*
- *Triplex Phase 1 Data Presented at ASH*
- *PepVax Phase 1b Data Published in The Lancet*

New York, New York – April 21, 2016 – Helocyte, Inc. a majority-owned subsidiary of Fortress Biotech, Inc. (NASDAQ: FBIO) focused on the acquisition, development and commercialization of novel immunotherapies for the prevention and treatment of cancer and infectious disease (and in particular, cytomegalovirus or “CMV”), today announced several corporate and clinical milestones.

- In June 2015, Helocyte’s Board of Directors appointed Frank Taffy as President and Chief Executive Officer (and in December 2015, as an additional member of the Board). Mr. Taffy has more than fifteen years of experience in life sciences corporate development and business operations. He identified the Helocyte programs and co-founded the company during his role as Entrepreneur in Residence at Fortress Biotech. Mr. Taffy previously held the positions of Head (Senior Director) of Business Affairs at Forest Laboratories (now Allergan) and Director of Corporate Development at Life Technologies (now Thermo Fisher Scientific), where he also held Board positions on behalf of the company. Mr. Taffy began his career as Counsel for Intellectual Property at Procter & Gamble. He holds a J.D. from Syracuse University College of Law and a B.A. in biochemistry from the University of North Texas.
 - In June 2015, a Phase 2 study of Helocyte’s PepVax opened for enrollment. The randomized, placebo-controlled, multicenter trial will evaluate the potential of PepVax to reduce the frequency of CMV events in 96 recipients of allogeneic hematopoietic stem cell transplant. The study is supported by funding from the National Cancer Institute. For additional information on the Phase 2 study of PepVax, please visit: <https://clinicaltrials.gov/ct2/show/NCT02396134>.
 - In November 2015, a Phase 2 study of Helocyte’s universal Triplex opened for enrollment. The randomized, placebo-controlled, multicenter trial will evaluate the potential of Triplex to reduce the frequency of CMV events in 115 recipients of allogeneic hematopoietic stem cell transplant. The study is also supported by funding from the National Cancer Institute. For additional information on the Phase 2 study of Triplex, please visit: <https://clinicaltrials.gov/ct2/show/NCT02506933>.
 - In November 2015, the results of a Phase 1 study of Triplex were selected for presentation at the 57th Annual Meeting of the American Society of Hematology (ASH). Triplex is the first CMV immunotherapy that uses a recombinant Modified Vaccinia Ankara (MVA) vector incorporating multiple CMV response antigens. The Phase 1 study demonstrated the safety and marked immunogenicity of Triplex. The complete text of the ASH abstract can be accessed at: <https://ash.confex.com/ash/2015/webprogram/Paper81450.html>.
 - In December 2015, the results of a Phase 1b study of PepVax were published in *The Lancet Haematology*. PepVax was observed to be well-tolerated, immunogenic and highly effective in controlling CMV in patients. To our knowledge, PepVax is the first immunotherapy to demonstrate proof of concept for CMV control in the post-transplant setting. PepVax further demonstrated the unexpected clinical outcomes of reduced relapse and increased survival (from underlying cancer). The full text of the *Lancet* publication can be accessed at: [http://www.thelancet.com/journals/lanhae/article/PIIS2352-3026\(15\)00246-X/abstract](http://www.thelancet.com/journals/lanhae/article/PIIS2352-3026(15)00246-X/abstract).
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About Helocyte

Helocyte is a clinical-stage company developing novel immunotherapies for the prevention and treatment of cancer and infectious disease (and in particular, cytomegalovirus or “CMV”). The Centers for Disease Control estimate that 50 to 80 percent of Americans are infected with CMV by the age of 40. While the virus is asymptomatic in healthy individuals, it can cause severe and life-threatening disease in those with weakened or uneducated immune systems. Patients undergoing allogeneic stem cell and solid organ transplantation are at particularly high risk of experiencing complications associated with CMV. Helocyte’s PepVax and Triplex vaccines are engineered to induce a robust and durable virus-specific T cell response to control CMV in transplant recipients. Helocyte’s Pentamer vaccine is designed to induce a neutralizing antibody response to prevent the transmission of CMV from mother to fetus, the most common congenital infection. There is no approved therapy for the prevention or treatment of congenital CMV. While current antiviral therapies have reduced the rate of CMV disease-related mortality in transplant recipients, such treatments have been linked to increased toxicity, delayed immune reconstitution and late onset of CMV. The Helocyte vaccines can educate the body’s innate immune system to fight CMV. For more information, please visit www.helocyte.com.

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, 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 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 are: risks related 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 (including the risk that clinical data will not be reproduced in larger studies); 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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Contact:

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