

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 11, 2016

Biota Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-35285
(Commission
File Number)

59-1212264
(IRS Employer
Identification No.)

2500 Northwinds Parkway, Suite 100
Alpharetta, GA
(Address of principal executive offices)

30009
(Zip Code)

Registrant's telephone number, including area code: (678) 221-3350

Not Applicable
(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 (see General Instruction A.2. below):

- 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 8.01 Other Events

On April 11, 2016, Biota Pharmaceuticals, Inc. (the “Company”) issued a press release announcing the initiation of a Phase 2a challenge study of BTA585, an oral fusion inhibitor in development for the treatment and prevention of respiratory syncytial virus (“RSV”) infections. A copy of the press release is attached as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated April 11, 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.

Biota Pharmaceuticals, Inc.

Date: April 11, 2016

/s/ Joseph M Patti

Name: Joseph M Patti

Title: Chief Executive Officer and President
(Duly Authorized Officer)

EXHIBIT INDEX

***Exhibit
Number***

Description

99.1

Press release dated April 11, 2016.

**PRESS RELEASE****FOR IMMEDIATE RELEASE**

BIOTA INITIATES PHASE 2A EFFICACY STUDY OF BTA585 FOR THE TREATMENT OF RSV INFECTIONS

ATLANTA, GA – April 11, 2016 - Biota Pharmaceuticals, Inc. (NASDAQ: BOTA), a biopharmaceutical company focused on the discovery and development of direct-acting antivirals that address infections that have limited therapeutic options, today announced the initiation of its Phase 2a challenge study of BTA585, an oral fusion inhibitor in development for the treatment and prevention of respiratory syncytial virus (RSV) infections. BTA585 has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for RSV infections in infants, young children and adults.

“We are pleased to initiate this Phase 2a challenge study just seven months after initiating our first-in-man Phase 1 study with BTA585. The rapid progress of the program has been encouraging and reinforces our commitment to developing a safe and efficacious treatment for the millions of children that suffer annually from serious RSV infections,” commented Joseph Patti, PhD, president and chief executive officer of Biota. “We expect data readout from this challenge study later this year, which will help inform our plans for a Phase 2b natural exposure trial in this important indication.”

The double-blind, placebo-controlled, Phase 2a trial is designed to evaluate the safety, pharmacokinetics, and antiviral activity of orally dosed BTA585 in healthy volunteers challenged intranasally with RSV. Following a positive test for RSV or five days after challenge, approximately 60 healthy adults will be randomized to receive either BTA585 or placebo, dosed twice daily for seven days and monitored for 28 days. The primary endpoint of the study is area under the curve for the viral load in nasal wash among subjects who test positive for RSV prior to dosing. Secondary efficacy endpoints include measures of RSV clinical symptoms and other viral load endpoints such as peak viral load and time to cessation of virus detection. The study includes assessment of PK levels in both plasma and nasal wash.

About Respiratory Syncytial Virus (RSV)

RSV is a major cause of acute upper (colds) and lower (pneumonia and bronchiolitis) respiratory tract infections in infants, young children, and adults. Each year in the United States, RSV accounts for an estimated 2.1 million medical visits in children under the age of five, with many of the children afflicted requiring hospitalization. At the present time there is no effective vaccine to prevent or recommended therapy to treat RSV infections.

About Biota Pharmaceuticals, Inc.

Biota Pharmaceuticals is focused on the discovery and development of direct-acting antivirals to treat infections that have limited therapeutic options and affect a significant number of patients globally. The Company has three product candidates in active clinical development: These include vapendavir, an oral treatment for human rhinovirus infections in moderate-to-severe asthmatics currently being evaluated in the Company’s ongoing Phase 2b SPIRITUS trial; BTA585, an oral fusion protein inhibitor that has received Fast Track designation by the U.S. FDA, in Phase 2 development for the treatment and prevention of respiratory syncytial virus (RSV) infections; and BTA074, a topical antiviral treatment in Phase 2 development for condyloma caused by human papillomavirus types 6 & 11. For additional information about the Company, please visit www.biotapharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve known and unknown risks and uncertainties concerning Biota's business, operations and financial performance. Any statements that are not of historical facts may be deemed to be forward-looking statements, including the timing of the Phase 2a RSV challenge study and of the expected timing of data from this study. Various important factors could cause actual results, performance, events or achievements to materially differ from those expressed or implied by forward-looking statements, including: the Company, the U.S. Food and Drug Administration (FDA) or a similar regulatory body in another country, a data safety monitoring board, or an institutional review board delaying, limiting, suspending or terminating the clinical development of any of the Company's product candidates at any time for a lack of safety, tolerability, regulatory or manufacturing issues, or any other reason whatsoever; the Company's ability to secure, manage and retain qualified third-party clinical research data management and contract manufacturing organizations upon which it relies to assist in the design, development, implementation and execution of the clinical development of all its product candidates and those organizations ability to successfully execute their contracted responsibilities; the Company's ability to comply with applicable government regulations in various countries and regions in which we are conducting, or expect to conduct, clinical trials; and other cautionary statements contained elsewhere in this press release and in our Annual Report on Form 10-K, Quarterly Report on Form 10-Q and our other reports filed with the Securities and Exchange Commission. There may be events in the future that the Company is unable to predict, or over which it has no control, and the Company's business, financial condition, results of operations and prospects may change in the future. The Company may not update these forward-looking statements more frequently than quarterly unless it has an obligation under U.S. Federal securities laws to do so.

Biota is a registered trademark of Biota Pharmaceuticals, Inc.

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