

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): December 18, 2015

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))
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Item 8.01 Other Events

On December 18, 2015, Biota Pharmaceuticals, Inc. (the “Company”) issued a press release announcing the initiation of a Phase 1 multiple ascending dose trial to evaluate the safety and pharmacokinetics of BTA585. 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 December 18, 2015.

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: December 18, 2015

/s/ Joseph M Patti

Name: Joseph M Patti
Title: Chief Executive Officer and President
(Duly Authorized Officer)

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated December 18, 2015.

PRESS RELEASE

www.biotapharma.com

FOR IMMEDIATE RELEASE

BIOTA ANNOUNCES POSITIVE PHASE 1 DATA FOR DIRECT-ACTING RSV ANTIVIRAL BTA585**- Commences Dosing in Phase 1 Multiple Ascending Dose Study with Top-Line Data Expected in 1H 2016 -**

ATLANTA, GA – December 18, 2015 - 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, announced today that it completed an initial Phase 1 single ascending dose (SAD) trial of BTA585, an oral respiratory syncytial virus (RSV) fusion inhibitor in development for the treatment and prevention of RSV infections. Top-line data demonstrated that BTA585 was generally well tolerated at all dose levels; there were no serious adverse events (AEs), and no drug-related clinically-significant changes in ECGs or clinical laboratory values were observed. The Company plans to present the full data from this trial at an upcoming scientific meeting in 2016.

“We are encouraged by the data from this first-in-man study and, based on these favorable results, we have commenced dosing in a Phase 1 multiple ascending dose (MAD) study of BTA585 in healthy volunteers. We anticipate top-line data from the MAD trial in the first half of 2016,” stated Joseph Patti, PhD, president and chief executive officer of Biota. “Given the significant demand for a new modality to treat potentially life-threatening RSV infections in the pediatric, elderly, and immunocompromised patient populations, we are pleased with the progress we’ve made with BTA585 and look forward to building upon the momentum by initiating a Phase 2 trial in the first half of 2016.”

The blinded, placebo-controlled SAD study, which was conducted in the United States under an Investigational New Drug Application (IND), evaluated the safety and pharmacokinetics (PK) of five oral doses of BTA585 (50, 100, 200, 400, and 500 mg) in healthy volunteers. In addition, the 100 mg cohort included an evaluation of the effect of food on the PK profile of BTA585. Each of the dose cohorts consisted of seven subjects that received BTA585 and three that received placebo. Overall, there was low incidence of AEs with BTA585 treatment. AEs occurring in more than two BTA585-treated subjects included headache, nausea, and chromaturia. In the fasted subjects, pharmacokinetic data demonstrated that doses \geq 100 mg achieved BTA585 plasma levels that exceeded the mean EC50 of RSV clinical isolates for 24 hours. The EC50 represents the concentration of drug that is required for 50% inhibition of viral replication *in vitro*. The BTA585 plasma C_{max} was rapidly achieved at approximately one hour following oral dosing and the half-life (T_{1/2}) was approximately five to six hours. Additionally, dosing of BTA585 with a high fat meal did not adversely affect the PK.

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 in Phase 1 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.

Biota Pharmaceuticals, Inc. ♦ 2500 Northwinds Parkway, Suite 100 ♦ Alpharetta, GA 30009 ♦ Tel: (678) 221-3343

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 top-line data from the Phase 1 multiple ascending dose study for BTA585; plans to present the full data from the SAD trial at an upcoming scientific meeting in 2016; the timing of initiating a Phase 2 trial for BTA585; and other cautionary statements contained elsewhere in this press release and in the Company's Annual Report on Form 10-K for the year ended June 30, 2015, as filed with the U.S. Securities and Exchange Commission, on September 11, 2015. 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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