

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): February 16, 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 February 16, 2016, Biota Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) granted Fast Track designation to its antiviral compound, 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 February 16, 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.

Date: February 17, 2016

Biota Pharmaceuticals, Inc.

/s/ Joseph M Patti

Name: Joseph M Patti

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

EXHIBIT INDEX

***Exhibit
Number***

99.1

Description

Press release dated February 16, 2016.



PRESS RELEASE

www.biotapharma.com

FOR IMMEDIATE RELEASE

**BIOTA RECEIVES FDA FAST TRACK DESIGNATION FOR ITS ANTIVIRAL BTA585
FOR THE TREATMENT OF RESPIRATORY SYNCYTIAL VIRUS INFECTIONS**

ATLANTA, GA – February 16, 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, announced today that the U.S. Food and Drug Administration (FDA) granted Fast Track designation to its antiviral compound, BTA585, for the treatment of respiratory syncytial virus (RSV) infections in infants, young children and adults. The FDA Fast Track process is designed to expedite the development and review of drugs used in the treatment of serious or life-threatening conditions and which demonstrate potential to address unmet medical needs.

“There are no direct antiviral products approved to treat the millions of RSV infections that occur each year in the U.S. and we are pleased that the FDA has recognized BTA585 and its potential to address this significant unmet medical need” remarked Joseph Patti, PhD, president and chief executive officer at Biota. “Fast Track designation is another positive step for BTA585 and its development for the treatment of respiratory infections in children and adults.”

BTA585 is an oral RSV fusion inhibitor in development for the treatment and prevention of RSV infections. BTA585 has successfully completed a Phase 1 single ascending dose trial and has recently completed dosing in a multiple ascending dose trial with results expected to be reported this quarter. A Phase 2 RSV challenge trial is expected to begin in the second quarter of 2016.

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.

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 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 potential efficacy of the Company's three programs in the clinic. 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.

Contacts:

Mark Colonnese

Executive Vice President and Chief Financial Officer

Biota Pharmaceuticals, Inc.

(678) 221-3352

m.colonnese@biotapharma.com

Beth DelGiacco

Stern Investor Relations, Inc.

(212) 362-1200

beth@sternir.com