#### 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): June 11, 2013

#### 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) 762-3240

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 June 11, 2013, Biota Pharmaceuticals, Inc. (the "Company") issued a press release announcing that it has initiated the Phase 2 clinical trial of laninamivir octanoate for the treatment of influenza in adults. A copy of the Company's press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

# Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated June 11, 2013.

## 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: June 12, 2013

<u>/s/ Russell H Plumb</u> Name: Russell H Plumb Title: Chief Executive Officer and President (Duly Authorized Officer) Exhibit Number 99.1

Description Press release dated June 11, 2013.



## FOR IMMEDIATE RELEASE

# BIOTA INITATES PHASE 2 TRIAL OF LANINAMIVIR OCTANOATE FOR THE TREATMENT OF INFLUENZA IN ADULTS

ATLANTA, GA – June 11, 2013 — Biota Pharmaceuticals, Inc. (NASDAQ: BOTA, the "Company") today announced that it has commenced dosing in a multi-national, randomized, double blind, placebo controlled, parallel arm Phase 2 clinical trial of laninamivir octanoate, a long-acting neuraminidase inhibitor. The trial, referred to as "IGLOO", will compare the safety and efficacy of 40 mg and 80 mg of laninamivir octanoate with placebo, all delivered by a TwinCaps<sup>®</sup> inhaler in adults with symptomatic influenza A or B infection. The trial is designed to enroll 636 subjects, randomized equally across the three treatment arms, with the primary end point being the time to alleviation of influenza symptoms. Secondary end points include whether the use of laninamivir octanoate reduces the incidence of secondary bacterial infections compared to placebo. The Company's goal is to have top-line data from this trial available in mid-2014.

IGLOO is being conducted under the Company's contract with the U.S. Office of Biomedical Advanced Research and Development Authority ("BARDA"). Further details regarding the design of IGLOO are available at <u>www.clinicaltrials.gov</u>.

"The initiation of this robust, multi-center Phase 2 trial for the treatment of influenza is an important milestone in the clinical development of laninamivir octanoate," stated Dr. John Lambert, the Company's Vice President of Product Development. "We believe that the potential for once-only inhaled dosing of laninamivir octanoate could represent a significant advantage over the five-day, twice-daily dosing associated with the currently marketed neuraminidase inhibitors to treat influenza."

## **About Biota**

Biota Pharmaceuticals, Inc. is a biopharmaceutical company focused on the discovery and development of products to prevent and treat serious and potentially life-threatening infectious diseases. The Company currently has two Phase 2 clinical-stage product candidates in development: laninamivir octanoate, which it is developing under an existing contract with BARDA that is intended to provide up to \$231 million in financial support for the Company to complete the clinical development of laninamivir octanoate for the treatment of influenza A and B infections in the U.S.; and vapendavir, a potent, oral broad-spectrum capsid inhibitor of human rhinovirus. In addition to these clinical-stage programs, the Company has preclinical programs focused on developing treatments for respiratory syncytial virus and gram-negative and multi-drug resistant bacterial infections. The Company has a world-wide license from Daiichi Sankyo Company, Ltd to develop and commercialize a number of long-acting neuraminidase inhibitors, including laninamivir octanoate, which is marketed by Daiichi Sankyo in Japan as Inavir<sup>®</sup>. The Company receives a royalty on net sales of Inavir<sup>®</sup> in Japan, as well as on global net sales of Relenza<sup>®</sup>, a first-generation neuraminidase inhibitor marketed by GlaxoSmithKline. For additional information about the Company, please visit www.biotapharma.com.

#### Safe Harbor Statement

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. All statements, other than historical facts, including statements regarding the Company's goal to have top-line data from the IGLOO trial available in mid-2014, the potential for once-only dosing of laninamivir octanoate and the amount of financial support the BARDA contract may provide, are forward looking statements. Various important factors could cause actual results, performance, events or achievements to materially differ from those expressed or implied by the forward-looking statements, including the Company, BARDA, the FDA, a data safety monitoring board, or an institutional review board, delaying, limiting, suspending or terminating the clinical development of laninamivir octanoate at any time for a lack of safety, tolerability, anti-viral activity, commercial viability, regulatory or manufacturing issues, or any other reason whatsoever; the Company's ability to comply with extensive government regulations in various countries and regions in which it expects to conduct its clinical trials; the Company's inability to secure, manage and retain qualified third-party clinical research, preclinical research, data management and contract manufacturing organizations which it relies on to assist in the design, development and implementation of the clinical development of laninamivir octanoate; the Company's inability to recruit and enroll a sufficient number of qualified influenza patients in its IGLOO trial during the upcoming influenza seasons in the Northern and Southern Hemispheres; BARDA not terminating or significantly amending the Company's existing contract to develop laninamivir octanoate; and other cautionary statements contained in the Company's Quarterly Reports on Form 10-Q for the quarters ended December 31, 2012 and March 31, 2013, as filed with the U.S. Securities and Exchange Commission, or SEC, on February 11, 2013 and May 10, 2013, respectively. 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 Holdings Limited. Relenza<sup>®</sup> is a trademark of GlaxoSmithKline, Inavir<sup>®</sup> is a registered trademark of Daiichi Sankyo Company, Ltd and TwinCaps<sup>®</sup> is a registered trademark of Hovione FarmaCiencia SA.

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