

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM 8-K

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CURRENT REPORT

Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 1, 2014

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

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**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)

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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 August 1, 2014, Biota Pharmaceuticals, Inc. (the “Company”) issued a press release announcing top-line data from its Phase 2 Igloo trial of laninamivir octanoate. 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 August 1, 2014.

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**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: August 1, 2014

/s/ Russell H Plumb

Name: Russell H Plumb  
Title: Chief Executive Officer and President  
(Duly Authorized Officer)

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**EXHIBIT INDEX**

<b><i>Exhibit Number</i></b>	<b><i>Description</i></b>
99.1	Press release dated August 1, 2014.

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PRESS RELEASE



FOR IMMEDIATE RELEASE

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**BIOTA REPORTS TOP-LINE DATA FROM ITS PHASE 2 “IGLOO” TRIAL  
OF LANINAMIVIR OCTANOATE**

**ATLANTA, GA – August 1, 2014** — Biota Pharmaceuticals, Inc. (NASDAQ: BOTA, the “Company”) today announced top-line data from a randomized, double-blind, placebo-controlled, parallel-arm Phase 2 clinical trial comparing the safety and efficacy of a 40 mg and 80 mg dose of laninamivir octanoate (“LANI”) to placebo. The trial, referred to as IGLOO, enrolled 639 patients across 12 countries in the Northern and Southern Hemisphere from June 2013 to April 2014. Of the 639 patients enrolled, 248, or 39%, had PCR confirmed influenza A or B virus and were included in the intent-to-treat efficacy analyses. Approximately 75% and 19% of the influenza-confirmed patients were infected with influenza A H1N1 2009 and H3N2, respectively, with 6% being infected with influenza B.

As compared to placebo, neither the 40 mg or 80 mg cohort achieved a statistically significant reduction in the median time to alleviation of influenza symptoms as measured by the Flu-iiQ patient-recorded outcome questionnaire ( $p=0.248$  and  $p=0.776$ , respectively), which was the primary endpoint of the study. The median time to alleviation of influenza symptoms was 102.3 hours for the 40 mg cohort and 103.2 hours for the 80 mg cohort, as compared to 104.1 hours for the placebo cohort.

Patients in both the 40 mg ( $p<0.001$ ) and 80 mg ( $p=0.070$ ) cohorts demonstrated a statistically significant reduction in viral shedding on Day 3 of the study compared to placebo as quantified by qRT-PCR. In addition, a statistically significant proportion of patients in both the 40 mg ( $p=0.002$ ) and 80 mg ( $p=0.020$ ) cohorts were culture negative on Day 3 of the study as compared to placebo. Influenza-infected patients in the 40 mg cohort also demonstrated a statistically significant reduction in the incidence of secondary bacterial infections as compared to placebo ( $p=0.013$ ). The nature and extent of adverse events were similar in the three cohorts, with diarrhea (3.1% vs. 0.9%), headache (1.4% vs. 0.5%), gastritis (1.4% vs. 0%), urinary tract infection (1.4% vs. 0%), and sinusitis (1.2% vs. 0.9%) being the most common adverse events that occurred more frequently in the treatment cohorts as compared to placebo. The incidence of serious adverse events was low and balanced across the three cohorts.

“It is disappointing that the rapid and significant onset of antiviral activity against the influenza virus that the two treatment arms demonstrated with LANI did not translate into a meaningful reduction in the time to alleviate patient-reported influenza symptoms,” stated Russell H. Plumb, the Company’s President and CEO. “We expect to complete a full analysis of additional clinical, safety, and pharmacokinetic data forthcoming from this trial over the next several months; however, at this time we do not have any plans to independently advance the development of LANI for the treatment of influenza and intend to evaluate next steps for the LANI program outside of Japan with our partner, Daiichi Sankyo”.

The Company plans to provide a detailed update on the full efficacy and safety results of the Phase 2 IGLOO trial, the status of the LANI program and its corporate strategy during its fourth quarter and fiscal year-end earnings call in early September.

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

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## About Laninamivir Octanoate (LANI)

Laninamivir octanoate is a second-generation octanoyl ester prodrug of laninamivir that has demonstrated *in vitro* neuraminidase-inhibitory activity against influenza A and B viruses, including subtypes N1 to N9, swine origin H1N1 strains and oseltamivir-resistant viruses. Laninamivir octanoate has long-lasting antiviral activity and exhibits a calculated half-life of approximately 58 hours in the respiratory tract. In a previous Phase 3 clinical trial, a single 40 mg inhaled dose of laninamivir octanoate exhibited efficacy similar to that of daily repeated doses of oseltamivir phosphate.

In 2003, the Company and Daiichi Sankyo cross-licensed intellectual property related to long-acting neuraminidase inhibitors, of which the lead product, laninamivir octanoate, has been successfully developed and subsequently marketed in Japan by Daiichi Sankyo as Inavir<sup>®</sup> for the treatment and prevention of influenza A and B infections. The Company has been developing laninamivir octanoate outside of Japan for the treatment of influenza A and B infections.

## 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 viral respiratory infectious diseases. The Company currently has two Phase 2 clinical-stage product candidates: laninamivir octanoate, which the Company is developing for the treatment of influenza A and B infections; and vapendavir, a potent, oral broad spectrum capsid inhibitor of enteroviruses, including human rhinovirus and EV-71, which is being developed to treat patients with underlying respiratory illnesses, such as asthma and chronic obstructive pulmonary disease (COPD). In addition to these clinical development programs, the Company also has late-stage preclinical programs focused on developing oral antivirals for the treatment of respiratory syncytial virus infections. For additional information about the Company, please visit [www.biotapharma.com](http://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. Any statements that are not historical facts may be deemed to be forward-looking statements, including statements related to the timing of additional clinical, safety and pharmacokinetic data from the IGLOO Phase 2 trial, the Company's current plan to not independently advance the development of LANI for the treatment of influenza, the Company's intent to evaluate next steps for the LANI program outside of Japan with its partner, Daiichi Sankyo, and the Company's plan to provide a more detailed update on the full results of the Phase 2 IGLOO trial, the status of the LANI program and its corporate strategy during its fourth quarter and fiscal year-end earnings call in early September. 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's ability to receive and analyze additional data from the IGLOO trial on a timely basis; future changes in the Company's strategy and the implementation of those changes; 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, 2013, as filed with the U.S. Securities and Exchange Commission, or SEC, on September 27, 2013 and its Form 10-Q's as filed with the SEC on November 12, 2013, February 10, 2014 and May 12, 2014.

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. Inavir<sup>®</sup> is a registered trademark of Daiichi Sankyo Company, Ltd.

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