#### 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): January 9, 2014

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.)

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))

2500 Northwinds Parkway, Suite 100

Alpharetta, GA (Address of principal executive offices)

□ 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 January 9, 2014, Biota Pharmaceuticals, Inc. (the "Company") issued a press release announcing a proposed public offering. A copy of the press release is furnished as Exhibit 99.1 to this report. The Company is also furnishing its corporate presentation slides. These slides are furnished as Exhibit 99.2 to this report. The slides are also available in the "Investor Relations—Events & Presentations" section of the Company's website, located at www.biotapharma.com. Materials on the Company's website are not part of or incorporated by reference into this report.

#### Item 9.01 Financial Statements and Exhibits

(d) Exhibits

- 99.1 Press release dated January 9, 2014.
- 99.2 Corporate presentation slides dated January 2014

#### 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: January 9, 2014

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

Exhibit		
Number	Description	
99.1	Press release dated January 9, 2014.	
99.2	Corporate presentation slides dated January 2014	

99.2



#### FOR IMMEDIATE RELEASE

#### **BIOTA ANNOUNCES PROPOSED PUBLIC OFFERING**

ATLANTA, GA – January 9, 2014 — Biota Pharmaceuticals, Inc. (NASDAQ: BOTA, "Biota" or the "Company") today announced its intention, subject to market and other conditions, to commence a public offering of its common stock. The Company intends to use the net proceeds from the offering for working capital and general corporate purposes.

Guggenheim Securities, LLC is acting as sole book-running manager of the offering. The offering is being made pursuant to a shelf registration statement previously filed with the Securities and Exchange Commission ("SEC") and declared effective on October 17, 2013. A preliminary prospectus supplement relating to the offering has been filed with the SEC. The offering will be made only by means of a prospectus supplement and the accompanying base prospectus. When available, copies of the prospectus supplement and the accompanying prospectus relating to these securities may be obtained from Guggenheim Securities, LLC, 330 Madison Avenue, 8<sup>th</sup> Floor, New York, NY 10017, Attention: Equity Syndicate Department, by telephone at (212) 518-9349 or by email to GSEquityProspectusDelivery@guggenheimpartners.com. Electronic copies of the prospectus supplement and the accompanying prospectus will also be available on the website of the SEC at http://www.sec.gov.

This press release does not constitute an offer to sell or the solicitation of an offer to buy shares of common stock of Biota, nor shall there be any sale of these securities in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

#### 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, a long-acting neuraminidase inhibitor that the Company is developing for the treatment of influenza A and B infections under an investigational new drug application (IND) in the United States through a contract with the U.S. Office of Biomedical Advanced Research and Development Authority (BARDA) that is designed to provide up to \$231 million in financial support to complete its clinical development; and vapendavir, a potent, oral broad spectrum capsid inhibitor of enteroviruses, including human rhinovirus (HRV). In addition to these clinical-stage programs, the Company has a preclinical program focused on developing treatments for respiratory syncytial virus (RSV). 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

#### 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 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 risks relating to the completion of the public offering, including the satisfaction of customary closing conditions and the use of anticipated proceeds, 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 SEC on September 27, 2013, and in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2013, as filed with the SEC on November 12, 2013.

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<sup>®</sup> is a registered trademark of Biota Holdings Limited.

Contacts: Russell H. Plumb Chief Executive Officer (678) 221-3351 r.plumb@biotapharma.com

Lee M. Stern The Trout Group (646) 378-2922 lstern@troutgroup.com

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January 2014

# Safe Harbor

This presentation contains forward-looking statements about Biota Pharmaceuticals, Inc. and its business, business prospects, strategy and plans, including but not limited to statements regarding anticipated preclinical and clinical drug development activities and timelines and market opportunities. All statements other than statements of historical facts included in this presentation are forward looking statements. The words "anticipates," "may," "can," "plans," "believes," "estimates," "expects," "projects," "intends," "likely," "will," "should," "to be," and any similar expressions or other words of similar meaning are intended to identify those assertions as forward-looking statements. These forward-looking statements involve substantial risks and uncertainties that could cause actual results to differ materially from those anticipated. Factors that may cause actual results to differ materially from such forward-looking statements include those identified under the caption "Risk Factors" in the documents filed by Biota Pharmaceuticals with the Securities and Exchange Commission from time to time, including its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this presentation. Except to the extent required by applicable law or regulation, Biota Pharmaceuticals undertakes no obligation to update the forward-looking statements included in this presentation to reflect subsequent events or circumstances.

# Biota Pharmaceuticals (Nasdaq:BOTA)

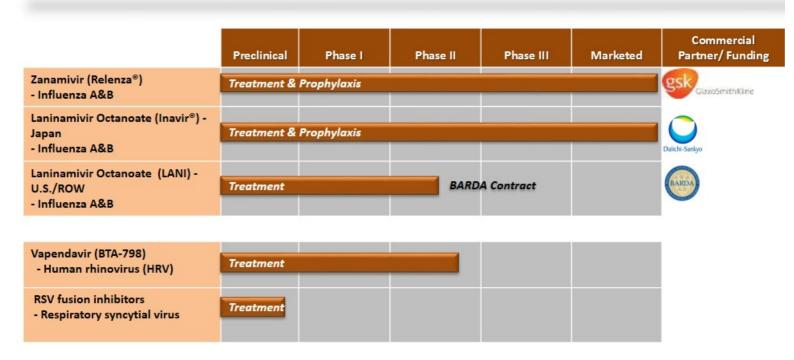
#### Focused on treating and preventing respiratory viral infections

#### Influenza

- Zanamivir First approved neuraminidase inhibitor (NI) for the prevention and treatment of uncomplicated influenza
  - Marketed globally as Relenza<sup>®</sup> by GSK
- Laninamivir octanoate (LANI) 2<sup>nd</sup> generation long-acting NI for the prevention and treatment of uncomplicated influenza
  - Marketed in Japan as Inavir® by Daiichi Sankyo
- Human Rhinovirus (HRV)
  - Vapendavir Phase 2 oral antiviral to treat human rhinovirus infections in patients with moderate to severe asthma and to maintain asthma control
- Respiratory Syncytial Virus (RSV)
  - RSV2 & RSV3 Preclinical stage, oral small molecules for the treatment of RSV in pediatric and immunocompromised patients
- Well capitalized to execute clinical development strategy
  - \$60.8 M cash-on-hand as of 9/30/2013
  - Relenza<sup>®</sup> and Inavir<sup>®</sup> royalty revenues
  - Low net burn rate

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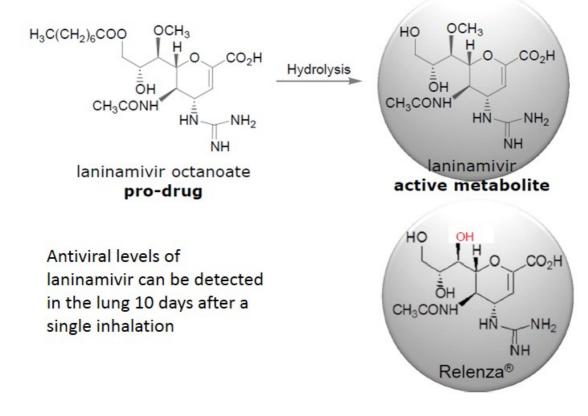
## **Current Pipeline**



# Laninamivir Octanoate A Long-Acting Neuraminidase Inhibitor (LANI)

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# Laninamivir Octanoate (LANI)



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# Laninamivir Octanoate (LANI)

- "One and done" treatment paradigm significantly differentiates LANI from the currently approved influenza therapies
- Marketed as Inavir<sup>®</sup> in Japan by Daiichi Sankyo
  - > Treatment 40 mg single treatment
  - Prophylaxis 20 mg single treatment for two consecutive days
- Favorable resistance profile
  - Active against oseltamivir and peramivir resistant viruses (H1N1; H275Y)
- Captured >40% market share after two seasons on market in Japan
  - Approved in 2010
  - > >7M doses administered to-date with good safety profile
  - Japanese patent expiry 2024





#### Laninamivir (Inavir<sup>®</sup>) vs. Oseltamivir (Tamiflu<sup>®</sup>) Adult Phase 3 Efficacy Data from Japan

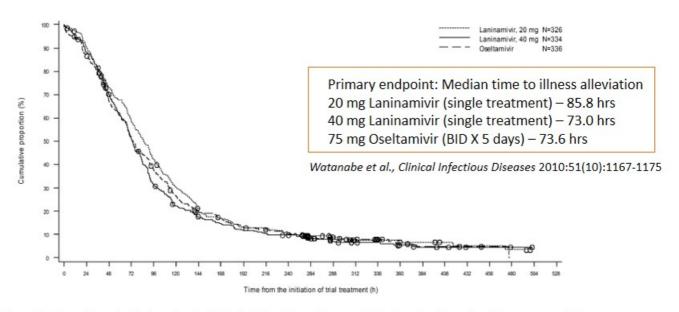


Figure 2. Time to illness alleviation in patients included in the full analysis set. The open circles indicate the patients whose influenza symptoms had not yet been alleviated by the time of their withdrawal from the study or the end of the observation period.

- Phase 3 data demonstrated that a single treatment with Inavir<sup>®</sup> was non-inferior to 5 days of treatment with Oseltamivir (Tamiflu<sup>®</sup>)
- The proportion of patients shedding virus at day 3 was significantly lower (p=0.006) in the 40 mg laninamivir treated cohort (27.6%) compared to the 75 mg oseltamivir treated patients (37.7%)



#### Inavir<sup>®</sup> vs. Oseltamivir (Tamiflu<sup>®</sup>) Phase 3 Safety and Tolerability Data in Japanese Trial

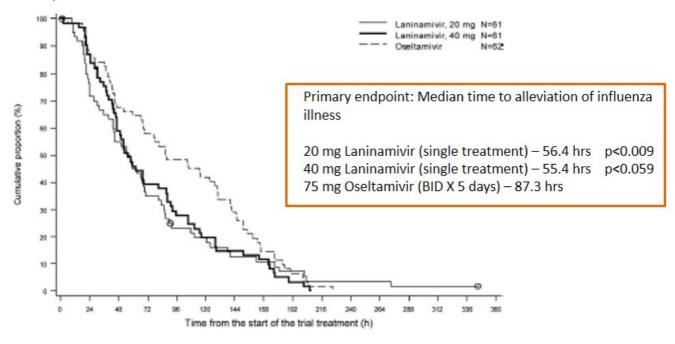
	20 mg Laninamivir (n=326)	40 mg Laninamivir (n=337)	75 mg Oseltamivir (n=336)
Diarrhea (%)	5.5	7.7	7.7
Nausea (%)	2.1	1.2	1.8
Vomiting (%)	0.3	0.3	2.4
Dizziness	1.8	0.9	0

All drugs were well tolerated, the most common adverse events were gastrointestinal events.

Watanabe et al., Clinical Infectious Diseases 2010:51(10):1167-1175

#### Laninamivir (Inavir<sup>®</sup>) vs. Oseltamivir (Tamiflu<sup>®</sup>) Pediatric Phase 3 Efficacy Data from Japan





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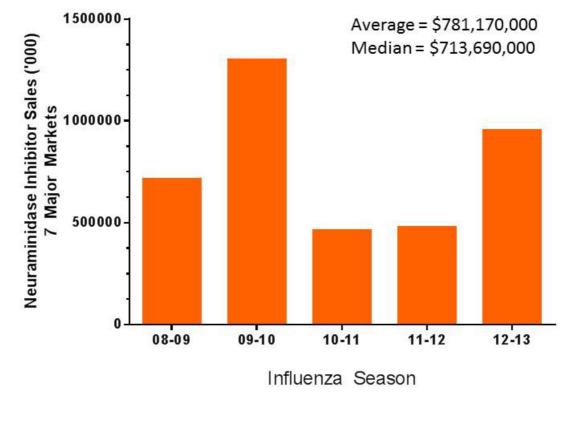
Sugaya and Ohashi, Antimicrobial Agents and Chemotherapy, June 2010:54 (6), 2575-2582

## **Comparison of Approved Neuraminidase Inhibitors**

Effective against Tamiflu-resistant viruses	$\checkmark$	✓	×
"Once and done"	×	✓	×
Direct to the site of infection	✓	✓	×
Simple device	×	✓	✓
Safe & Effective*	$\checkmark$	1	✓

\*Approved in Japan and sold as Inavir® by Daiichi Sankyo

## Seasonal Neuraminidase Inhibitor Market



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Source: IMS

# **Influenza Market Opportunities**

#### Seasonal Market

- Occurs annually during fall and winter seasons in temperate regions
- Circulates between Southern and Northern hemispheres with two peaks in tropical countries
- Approximately 3.5 million cases of severe illness worldwide annually
- □ ≈300,000 to 500,000 deaths mostly in the very young and in those over 65

#### **Stockpile Market**

- WHO recommends governments stockpile to cover
   25%+ of the population
- The majority of the U.S. stockpile of Tamiflu<sup>®</sup> and Relenza<sup>®</sup> scheduled to expire by end of 2014
- Traditional Relenza (15%)/Tamiflu (85%) mix potentially shifting toward 50/50 mix
- Direct-to-government sales
- Estimated to be similar in size to seasonal market over the long run

# LANI Development in the U.S.

- Biota is developing LANI outside of Japan for treatment of influenza A&B
- The Biomedical Advanced Research and Development Authority (BARDA), awarded Biota a 5-year contract for up to \$231M for the development of LANI in the United States
- Phase 2 Randomized, Double Blind, Placebo Controlled, Parallel Arm Study to Investigate the Efficacy and Safety of Inhaled Laninamivir Octanoate TwinCaps<sup>o</sup> Dry Powder Inhaler in Adults with Symptomatic Influenza A or B Infection (IGLOO)
  - Regulatory filings in 16 countries
  - > Enrollment began in the Southern Hemisphere in mid-June 2013
  - > Dosing in the Northern Hemisphere commenced in December 2013
- Additional ongoing clinical trials
  - Phase 1 QT/QTc study (dosing initiated in December)
  - Phase 1 trial in adults with asthma (dosing initiated in December)
  - Phase 1/2 trial in children infected with influenza

# Phase 2 "IGLOO" Trial

- Placebo controlled study of 40 or 80 mg of laninamivir octanoate delivered by the dry powder inhaler TwinCaps<sup>®</sup>
  - > N  $\ge$  636 adult subjects presumed to have influenza
    - Targeting 444 PCR confirmed influenza patients
  - Primary endpoint is time to alleviation of influenza symptoms and (cough, sore throat, nasal congestion, headache, body aches and pains, feeling feverish and fatigue) and fever for ≥ 24 hours
- Goal is to fully enroll trial by March/April 2014 and have top-line data available by mid-year 2014
  - > Approximately 30% enrolled to date



# Vapendavir

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# Vapendavir (BTA-798)

- Oral small molecule VP-1 capsid binding inhibitor of human rhinovirus (HRV)
  - Potent, broad spectrum HRV antiviral
    - EC<sub>50</sub> < 100 nM for ≈ 90% of HRV serotypes</li>
- Target markets
  - Patients with moderate to severe asthma, COPD, and those that are immunocompromised
- Phase 2a challenge study successfully demonstrated prophylactic proof-of-concept in healthy adults
  - 400 mg vapendavir BID demonstrated lower peak viral level (p=0.031) and lower total virus (p=0.017) compared to placebo

## Clinical Experience with Vapendavir in Asthma Patients

- Phase 2b trial of Vapendavir (400 mg BID) treatment of naturally acquired HRV infections in chronic mild-moderate asthma patients (N=300)
  - Successfully met the Wisconsin Upper Respiratory Symptom Survey (WURSS-21) severity score primary endpoint with statistically significant difference in the mean daily change in WURSS-21 severity score over Days 2-4 (anticipated peak of infection) in the ITT-I population (p=0.02)
  - Mean reduction in Asthma Control Questionnaire (ACQ-5) score was greater in the vapendavir group compared to the placebo treated cohort at study days 14 and 28
  - > Vapendavir treatment was associated with decreased viral shedding
- Safety profile generated to-date among 263 unique subjects is favorable
  - > No serious adverse events (SAE) in Vapendavir arm, 1 SAE in placebo
- The most common adverse events (<5%) occurring to vapendavir-treated patients were headache, URI, sinusitis, bronchitis, nausea, diarrhea, and biota</p>
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# **Rationale for Clinical Development**

- Rhinovirus infection is a leading cause of asthma exacerbations and the subsequent loss of asthma control
  - > Upper respiratory viral infections involved in ≈50% of asthma exacerbations
- Attractive commercial opportunity
  - > >10M\* cases of moderate and severe persistent asthma in the U.S.
- Potential study population: Partially controlled and uncontrolled asthma patients who have symptoms of HRV infection
  - > Primary endpoint improvement in asthma control of ≥0.5 (ACQ-5)
- Multiple opportunities exist for label and line extensions
  - > Pediatrics, COPD, and transplant patients
- Vapendavir has demonstrated a favorable safety and tolerability profile
- Proof of principle established in asthma patients

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\*Datamonitor Asthma Epidemiology, July 2012

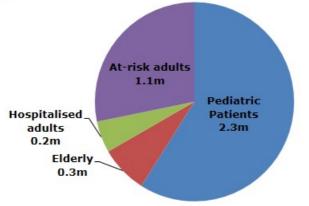
# Respiratory Syncytial Virus (RSV) Fusion Inhibitors

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### Significant Market Opportunity for a RSV Antiviral

#### U.S. Market Analysis

- More than 2.3 million children <5 years present to a doctor with RSV infection each year</p>
- > 75% of children present within 72 hours of symptom onset
- During the RSV season, clinical diagnosis is >80% predictive of infection



Source: Primary market research conducted for Biota by RAL Strategies in August 2012

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# **Target Product Profile**

- Small molecule RSV fusion inhibitor
  - > Acts at early stage of viral replication
  - > Active against both RSV A & B
- Oral and intravenous (IV) dose forms
  - PK supports likelihood of QD dosing
- Primary indication
  - Treatment of clinical manifestations of RSV infections in pediatric patients based on clinical and/or definitive diagnosis
- Secondary indications for immunocompromised patients and the elderly

# **Competitive RSV Antiviral Profile**

- Low nanomolar (nM) potency versus both RSV A & B strains
- Favorable cytotoxicity profile
- No shift in potency in the presence of human serum proteins

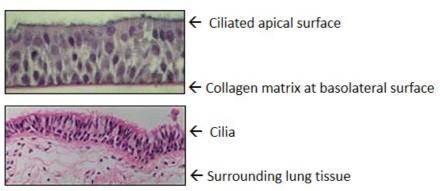
	RSV A2 (EC <sub>50</sub> , nM)	RSV A2 + α-1 Acid Glycoprotein (EC <sub>50</sub> , nM)	RSV B/Washington (EC <sub>50</sub> , nM)	Cytotoxicity (CC <sub>50</sub> , nM)
BTA-RSV2	23	7	208	> 20,000
BTA-RSV3	13	12	167	> 20,000
MDT-637	0.1	0.1	0.3	> 3,000
TMC353121	0.4	22	0.3	11,000

## Potent Antiviral Activity in a Human Lung Model

• MatTek EpiAirway<sup>™</sup>: Human-derived tracheal/bronchial epithelial cells (TBE) that have been cultured to form a multilayered, highly differentiated model which closely resembles the epithelial tissue of the respiratory tract.

Stained cross-section EpiAirway tissue (40X objective)

Stained cross-section of normal human bronchiole (10X objective) showing pseudo-stratified differentiated mucociliary phenotype.



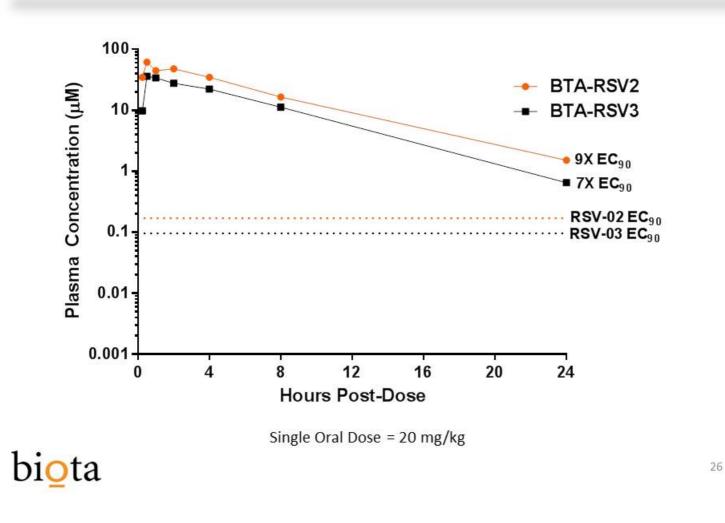
Compound	MatTek tissue EC <sub>50</sub> (nM)	MatTek tissue $CC_{50}$ ( $\mu$ M)
RSV604 (Novartis)	167.2	ND
BTA-RSV2	8.4	>40
BTA-RSV3	7.8	>40

# **Favorable Cell Cytotoxicity Profile**

Cell Line	Onisin	BTA-RSV2	BTA-RSV3
Cell Line	Origin	СС <sub>50</sub> (µМ)	СС <sub>50</sub> (µМ)
H9C2	Rat heart myoblast	>100	>100
NRK	Rat kidney	>100	>100
Clone 9	Rat liver	>100	>100
MDCK	Canine kidney	>100	>100
Vero	Monkey kidney	>100	>100
HeLa Ohio	Human epithelial	>100	>100
HEK293	Human kidney	>100	>100
HepG2 galactose	Human liver	>100	>100
HepG2 glucose	Human liver	>100	>100
Cardiomyocytes	Human heart	>100	>100

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## **Excellent Oral Bioavailability in Dogs**



# **RSV Program Timelines**

- Scaling up sufficient material to test both BTA-RSV2 and BTA-RSV3 in 28-day non-GLP rat toxicology studies
- Subject to these studies, goal is to select one of the compounds for IND-enabling GLP studies mid 2014
- Successful outcomes of IND-enabling studies could support filing of IND in approximately 12 months

# **Balancing the Pipeline**

- Current business strategy includes licensing, acquiring or obtaining additional clinical-stage development programs to better balance our clinical-stage pipeline
- Focused on development programs addressing respiratory, pulmonology or viral infections
  - > Biota's historical areas of focus
  - > Phase 1 or Phase 2 ready
  - > Potential to deliver Phase 2 POC in 2 years or less
  - > Orphan indications
- Considering opportunities that are incremental, not transformational programs
  - Not intended to materially alter the current investment thesis or strategic focus

## Financials (9/30/2013)

Nasdaq Symbol	BOTA
Commons Shares Outstanding (primary)	28.4M
Cash and short-term investments	\$60.8M

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## Summary

- Leveraging our antiviral respiratory expertise and franchise
  - Two partnered neuraminidase inhibitors (Relenza<sup>®</sup> and Inavir<sup>®</sup>) provide on-going royalty revenue
  - LANI program in Phase 2
  - Promising asthma and RSV programs
- Fully-appropriated \$231 million BARDA contract to complete development of LANI in U.S. for the treatment of influenza A & B
  - > LANI exhibits several competitive advantages as a "one and done" treatment option
  - > Initiated a robust multi-national Phase 2 trial (IGLOO) in mid-June
- Financially well positioned to execute our business plan and achieve value inflection milestones over next several years
  - > \$60.8M cash-on-hand at 9/30/2013
  - Low net burn rate
- Pursuing additional acquisition, in-licensing and partnering activities to better balance pipeline with clinical-stage assets

## **Contact Info**

#### www.biotapharma.com

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