

## **Biota Pharmaceuticals Reports Third Quarter Fiscal Year 2015 Financial Results**

ATLANTA, May 7, 2015 (GLOBE NEWSWIRE) -- Biota Pharmaceuticals, Inc. (Nasdaq:BOTA) (the "Company"), a biopharmaceutical company focused on the discovery and development of products to prevent and treat serious and potentially life-threatening viral respiratory infectious diseases, today announced its financial results for the three month period ended March 31, 2015, which is the third quarter of the Company's 2015 fiscal year, and also provided an update on recent corporate developments.

"We are very encouraged by the recent advancement of our pipeline on several fronts," commented Dr. Joseph Patti, President and Chief Executive Officer of Biota Pharmaceuticals, Inc. "We are actively screening and dosing patients with moderate-to-severe asthma in our Phase 2b SPIRITUS trial of vapendavir at 58 clinical sites in the U.S. and Central Europe, and have successfully completed all of the required GLP studies to support the filing of an IND application this quarter for BTA-C585, which we are developing for the treatment of respiratory syncytial virus infections. Furthermore, we are pleased to report that the French Ministry of Finance and Economics has approved our acquisition of Anaconda Pharma. We believe its lead product, AP611074, is uniquely positioned to significantly improve the treatment paradigm for condyloma, as well as the orphan disease recurrent respiratory papillomatosis. Subject to closing this acquisition, we plan on initiating a randomized, placebo-controlled, double-blind, Phase 2 trial of AP611074 in the second half of 2015."

#### **Recent Corporate Developments**

Acquisition of Anaconda Pharma Nears Completion. The Company reported today that it has received approval from the French Ministry of Finance and Economics for its proposed acquisition of Anaconda Pharma, which was one of the closing conditions for this transaction. Anaconda Pharma is a privately-held biotechnology company based in Paris, France, whose lead candidate, AP611074, is a patented, direct-acting antiviral with activity against human papillomavirus (HPV) types 6 and 11. AP611074 is in development for the treatment of condyloma, or anogenital warts, as well as recurrent respiratory papillomatosis (RRP). Anaconda Pharma has successfully completed a Phase 2a clinical trial of AP611074 (5% gel), which demonstrated a significant reduction in the surface area of condyloma while exhibiting favorable local skin tolerability.

Under the terms of the definitive agreement, which was announced in February 2015, all of Anaconda Pharma's outstanding shares will be acquired for 3.5 million shares of Biota common stock and \$8.0 million in cash, subject to certain closing and post-closing adjustments. The Company intends to fund the cash portion of the purchase price with cash on hand. The transaction also includes additional contingent financial consideration of (i) up to \$30.0 million conditional upon the successful achievement of certain future clinical and regulatory milestones, and (ii) a royalty. The closing of the transaction, which is expected to occur within the quarter, is subject to the finalization of other closing conditions, including approval of the proposed Phase 2 protocol by the Argentine National Administration of Drugs, Foods and Medical Devices (ANMAT).

Vapendavir Phase 2b SPIRITUS Trial Actively Enrolling Patients. The Company reported today that it is screening and dosing patients in its Phase 2b SPIRITUS trial of vapendavir at 58 clinical sites in the U.S. and Central Europe. In March 2015, the Company reported the initiation of this trial, the goal of which is to enroll approximately150 laboratory-confirmed human rhinovirus (HRV) infected patients with moderate-to-severe asthma over the next year and to report top-line data in mid-2016. The primary endpoint of this multi-center, randomized, double-blind, placebo-controlled dose-ranging study is the change from baseline to study day 14 in asthma symptoms and lung function as measured by the asthma control questionnaire (ACQ)-6 total score. Key secondary endpoints include safety and tolerability, lung function assessments such as forced expiratory volume in one second (FEV<sub>1</sub>), incidence of asthma exacerbations, assessments of the severity and duration of cold symptoms as measured by the Wisconsin Upper Respiratory Symptom Survey-21 (WURSS-21) and virological assessments such as changes in viral load.

**BTA-C585 Phase 1 Trial Planned for Q3 2015.** The Company reported today that is has successfully completed all good laboratory practice (GLP) studies required to support the filing of an Investigational New Drug (IND) application for its respiratory syncytial virus (RSV) fusion inhibitor, BTA-C585. The Company intends to file an IND application later this quarter and to initiate a Phase 1 single ascending dose trial in the third quarter of 2015.

**Relenza®** Intellectual Property Status. The Company reported today that it has filed a request for a rehearing with the United States Patent Trial and Appeal Board in relation to the pending patent application No. 08/737,141 related to Relenza®. On March 19, 2015, the Company reported that the United States Patent Trial and Appeal Board had issued a decision denying

the appeal and affirming the Examiner's prima facie case of obviousness rejection under 35 U.S.C. 103(a).

**Restructuring Plan Completed.** The Company announced today it has fully completed its previously announced (June 2014) restructuring plan and all activities related to the closure of its Melbourne, Australia operation and facilities.

Laninamivir Octanoate (LANI). The Company reported that it is planning a Type C meeting with the FDA to discuss clinical development strategy for LANI. The Company is preparing a detailed briefing document to outline the proposed primary endpoints and acceptable patient reported outcome tools for use in prospective registration trials of LANI to treat uncomplicated influenza. The Company anticipates filing the Type C meeting request this later quarter.

#### Financial Results for the Three Month Period Ended March 31, 2015

The Company reported net income of \$1.2 million for the three month period ended March 31, 2015, as compared to net income of \$3.2 million in the same quarter of the prior fiscal year. The \$2.0 million decrease in net income from the prior fiscal year was primarily due to a \$23.6 million decrease in revenue, a \$0.7 million increase in research and development expense, a \$0.7 million increase in general and administrative expense and a \$0.2 million loss on disposal of assets, offset in part by a \$19.0 million decrease in cost of revenue, a \$4.1 million increase in foreign exchange gain and a \$0.1 increase in interest income. Basic and diluted net income per share was \$0.03 for the three month period ended March 31, 2015, as compared to a basic and diluted net income per share of \$0.09 in the same period of 2014.

Revenue decreased to \$5.9 million for the three month period ended March 31, 2015 from \$29.5 million in the same period last year due to a \$21.0 million decrease in revenue from services related to the termination of the Company's contract with the Biomedical Advanced Research and Development Authority (BARDA) in May 2014, and a \$2.6 million decrease in royalty revenues primarily related to a decrease in net sales of both Relenza<sup>®</sup> and Inavir<sup>®</sup>.

Cost of revenue decreased to \$0.3 million for the three month period ended March 31, 2015 from \$19.3 million in the same period last year due to a decrease of \$17.8 million in direct third-party clinical costs and manufacturing activities and a \$1.2 million decrease in salaries, benefits and share-based compensation expense and other expenses incurred to develop laninamivir octanoate under the Company's terminated contract with BARDA.

Research and development expense increased to \$4.8 million for the three month period ended March 31, 2015 from \$4.1 million in the same period last year. The \$0.7 million increase was the result of a \$1.2 million increase in preclinical, clinical and manufacturing costs related to the Company's Phase 2b SPIRITUS trial for vapendavir and conducting IND-enabling studies for BTA-C585 (the Company's leadRSV compound), offset in part by a \$0.3 million reduction in salaries, benefits and share-based compensation expense and a \$0.2 million decrease in other expenses due to reduced research activities.

General and administrative expense increased to \$3.2 million for the three month period ended March 31, 2015 from \$2.5 million in the same period of 2014 due to a \$0.4 million increase in professional and legal fees related to the pending acquisition of Anaconda Pharma, a \$0.2 million increase in salaries, benefits and share-based compensation expense and a \$0.1 million increase in other expenses.

#### **Conference Call and Webcast Information**

Biota Pharmaceuticals will host a conference call today to review these third quarter fiscal year 2015 financial results, as well as provide a general update on the Company via a webcast and conference call at 9:00 a.m. EDT. To access the conference call, please dial (877) 312-5422 (domestic) or (253) 237-1122 (international) and refer to conference ID number 33437959. A live audio webcast of the call and the archived webcast will be available in the Investors section of the Biota website at http://www.biotapharma.com.

### About Biota Pharmaceuticals, Inc.

Biota Pharmaceuticals, Inc. is a biopharmaceutical company focused on the discovery and development of products to treat serious viral respiratory infectious diseases. The Company currently has two late-stage product candidates: (i) vapendavir, a potent, broad spectrum capsid inhibitor of enteroviruses in development for the treatment of human rhinovirus infected patients with underlying respiratory illnesses, such as moderate-to-severe asthma and chronic obstructive pulmonary disease (COPD); and (ii) laninamivir octanoate, which is being developed as a one-time, inhaled treatment for influenza A and B infections. The Company has also completed IND-enabling studies for BTA-C585, an orally bioavailable F-protein inhibitor in development for the treatment of respiratory syncytial virus infections and anticipates initiating clinical trials of BTA-C585 in the third quarter of 2015. For additional information about the Company, please visit www.biotapharma.com.

### **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 time frames in which the Company plans to fully enroll and report top line-data from the Phase 2b SPIRITUS clinical trial; the anticipated time to file an IND and initiate a Phase 1 clinical trial for BTA-C585; and the occurrence and timing of the planned closing of the acquisition of Anaconda Pharma and the initiation of a Phase 2 clinical trial for AP611074.

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 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 vapendavir, laninamivir octanoate, BTA-C585, AP611074 or any of the Company's product candidates 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 secure, manage and retain qualified third-party clinical research, preclinical research, data management and contract manufacturing organizations upon which it relies to assist in the design, development, implementation and execution of the clinical and preclinical development of all its product candidates; the Company's ability to complete and file an IND for BTA-C585 on a timely basis that is acceptable to the U.S. Food and Drug Administration (FDA); ANMAT delaying, imposing additional conditions, requiring additional studies or not approving the Phase 2 protocol for AP611074, 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, 2014, as filed with the U.S. Securities and Exchange Commission, on September 30, 2014 and in the Company's Quarterly Reports on Form 10-Q on November 7, 2014 and February 6, 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. Relenza<sup>®</sup> is a registered trademark of GlaxoSmithKline plc and Inavir<sup>®</sup> is a registered trademark of Daiichi Sankyo.

# BIOTA PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(in millions, except per share amounts)

(unaudited)

(unaudited)		
	March 31, 2015	June 30, 2014
ASSETS		
Current assets		
Cash and cash equivalents	\$61.5	\$81.7
Short-term investments	12.0	
Contract-related accounts receivable	2.9	17.8
Other accounts receivable	10.1	0.9
Prepaid and other current assets	0.9	0.7
Total current assets	87.4	101.1
Non-current assets:		
Long-term investments	0.9	10.0
Property and equipment, net	0.3	2.0
Deferred tax asset	0.2	0.9
Total non-current assets	1.4	12.9
Total assets	\$88.8	\$114.0
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Contract-related accounts payable and accrued expenses	\$1.1	\$18.6
Other accrued expenses	4.5	3.4
Other accounts payable	1.0	2.8

Accrued severance obligations	0.4	1.2
Deferred tax liability	0.2	0.9
Total current liabilities	7.2	26.9
Non-current liabilities:		
Other liabilities, net of current portion	0.1	0.2
Total liabilities	7.3	27.1
Stockholders' equity:		
Common stock, \$0.10 par value; 200,000,000 shares authorized 35,124,728 and 35,100,961 shares issued and outstanding at December 31, 2014 and June 30, 2014, respectively	3.5	3.5
Additional paid-in capital	148.0	146.4
Accumulated other comprehensive income	19.0	26.8
Accumulated deficit	(89.0)	(89.8)
Total stockholders' equity	81.5	86.9
Total liabilities and stockholders' equity	\$88.8	\$114.0

# BIOTA PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in millions, except per share amounts) (unaudited)

	Three Months End	Three Months Ended March 31,		<u>ed March 31,</u>
	2015	2014	2015	2014
Revenue:				
Royalty revenue and milestones	\$5.5	\$8.1	\$12.0	\$14.1
Revenue from services	0.4	21.4	8.5	46.1
Other				0.1
Total revenue	5.9	29.5	20.5	60.3
Operating expense:				
Cost of revenue	0.3	19.3	3.6	41.4
Research and development	4.8	4.1	14.5	11.3
General and administrative	3.2	2.5	8.2	8.0
Foreign exchange loss (gain)	(3.7)	0.4	(6.5)	0.6
Loss on disposal of assets	0.2		0.2	
Total operating expense	4.8	26.3	20.0	61.3
Income (loss) from operations	1.1	3.2	0.5	(1.0)
Non-operating income:				
Interest income	0.1		0.3	0.1
Total non-operating income	0.1		0.3	0.1
Income (loss) before tax	1.2	3.2	0.8	(0.9)
Income tax benefit	<del></del> -			0.1
Net income (loss)	<u>\$1.2</u>	\$3.2	\$0.8	\$(0.8)
Basic income (loss) per share	\$0.03	\$0.09	\$0.02	\$(0.03)
Diluted income (loss) per share	\$0.03 \$0.03	\$0.09	\$0.02 \$0.02	\$(0.03) \$(0.03)
Direction (1055) per strate	φυ.υ3	φυ.υ9	φυ.υ∠	Φ(0.03)

 Basic weighted-average shares outstanding
 35,105,978
 33,890,470
 35,102,609
 30,127,156

 Diluted weighted-average shares outstanding
 35,143,178
 34,260,715
 35,127,013
 30,127,156

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