



September 11, 2015

Biota Pharmaceuticals Reports Fourth Quarter and Fiscal Year 2015 Financial Results

ATLANTA, Sept. 11, 2015 (GLOBE NEWSWIRE) -- Biota Pharmaceuticals, Inc. (NASDAQ:BOTA) (the "Company"), a biopharmaceutical company focused on the discovery and development of direct-acting antivirals to treat infections that have limited therapeutic options, today announced its financial results for the fourth quarter and 2015 fiscal year ended June 30, 2015 and also provided an update on recent corporate developments.

"This has been a tremendous year of progress for our Company, and today our pipeline includes multiple clinical-stage direct-acting antiviral programs. We advanced our vapendavir and RSV programs on schedule and acquired Anaconda Pharma for its first-in-class antiviral for human papilloma virus infections, while still maintaining our strong financial position due to increased royalty revenues, a favorable termination settlement with BARDA, and the successful completion of our corporate restructuring plan," commented Dr. Joseph Patti, President and Chief Executive Officer of Biota Pharmaceuticals. "Looking ahead, we anticipate completing enrollment in robust Phase 2 trials for vapendavir, BTA074, and BTA585 and announcing data from each of these important programs in 2016."

Pipeline and Corporate Highlights

BTA585 Phase 1 Trial Ongoing. In August 2015, the Company commenced dosing in a 50-subject, randomized, placebo-controlled, Phase 1 single ascending dose (SAD) clinical trial to evaluate the safety and pharmacokinetics (PK) of BTA585 in healthy volunteers. BTA585, a potent inhibitor of viral entry into cells, is an orally bioavailable compound in clinical development for the treatment of acute respiratory syncytial virus (RSV) infections in children, the elderly and immunocompromised patients. The ongoing Phase 1 SAD clinical trial has five dose level cohorts ranging from 50 mg to 500 mg and will include an evaluation of the effect of food on the plasma PK of BTA585. Following a safety assessment of the initial dose level cohorts of the SAD trial, the Company plans to begin dosing in a Phase 1 multiple ascending dose (MAD) clinical trial in the fourth quarter of calendar year 2015. The Company expects to report Phase 1 SAD data in fourth quarter of calendar year 2015 and MAD data in the first quarter of calendar year 2016.

Initiation of Phase 2 Trial with BTA074 Planned for Q4, 2015. In June 2015, the Company reported closing the acquisition of Anaconda Pharma. Anaconda Pharma was a privately-held Paris-based biotechnology company, whose lead candidate, BTA074 (AP611074), is a novel, direct-acting antiviral with activity against human papillomavirus types 6 and 11. BTA074 is in development for the treatment of genital warts or condyloma, as well as recurrent respiratory papillomatosis. Prior to the acquisition, Anaconda Pharma had completed a Phase 2a clinical trial, which demonstrated a 38% reduction in the total condyloma area after six weeks of treatment with BTA074 5% gel while exhibiting a favorable local skin tolerability profile. The Company plans on initiating a double-blind placebo-controlled, randomized, Phase 2 study to assess the safety, tolerability, pharmacokinetics and efficacy of twice daily up to 16 week topical applications of BTA074 (5% gel) in approximately 210 adult condyloma patients in the fourth quarter of calendar year 2015.

Vapendavir Phase 2b SPIRITUS Trial Ongoing. The multi-center, randomized, double-blind, placebo-controlled dose-ranging study trial is designed and powered to equally randomize approximately 190 laboratory-confirmed human rhinovirus infected patients across three treatment arms. The primary endpoint of the trial is the change from baseline to study day 14 in asthma symptoms and lung function as measured by the asthma control questionnaire-6 total score. Key secondary endpoints include safety and tolerability, specific lung function assessments such as forced expiratory volume in one second, forced vital capacity, peak expiratory flow, daily b2-agonist use and the incidence of moderate and severe asthma exacerbations. Based upon the number of patients screened to date, the Company anticipates top-line data from this trial to be available in mid-2016.

Relenza® Related Intellectual Property Status. The Company reported today that on August 21, 2015 it filed an appeal in relation to the pending patent application No. 08/737,141 related to Relenza® to the United States Court of Appeals for the Federal Circuit. On March 19, 2015, the Company reported that the United States Patent Trial and Appeal Board (USPTAB) had issued a decision rejecting the previous appeal affirming the Examiner's prima facie case of obviousness rejection under 35 U.S.C. 103(a). On May 12, 2015 the Company filed a request for rehearing under 37 C.F.R. § 41.50 (b)(2) with the USPTAB. On June 23, 2015 the USPTAB denied the Company's request for rehearing.

BARDA Contract Termination. The Company reported today that it has resolved all outstanding claims and has collected all payments due from the Biomedical Advanced Research and Development Authority (BARDA) associated with the termination of its contract in May 2014.

Financial Results for the Three Month Period Ended June 30, 2015

The Company held \$65.5 million in cash, cash equivalents, and short and long-term investments as of June 30, 2015 and further collected an additional \$10.9 million of its outstanding accounts receivable related to fiscal year 2015 Relenza[®] royalty revenue in early July 2015.

The Company reported a net loss of \$19.9 million for the three month period ended June 30, 2015, as compared to net loss of \$10.2 million in the same quarter of the prior fiscal year. The \$9.7 million increase in net loss from the prior period was primarily due to a \$17.6 million non-recurring, in-process research and development (IPR&D) expense recorded in connection with the acquisition of Anaconda Pharma in June 2015. Further contributing to the increase in net loss was a \$7.5 million decrease in revenue from services related to the termination of the Company's BARDA contract in May 2014 and a \$0.2 million reduction in income tax benefit, offset in part by a \$9.7 million decrease in cost of revenue, a \$3.1 million increase in royalty revenues, a \$1.1 million decrease in research and development expense, a \$0.9 million decrease in general and administrative expense, and a \$0.8 million decrease in foreign exchange loss. Basic and diluted net loss per share was \$0.55 for the three month period ended June 30, 2015, as compared to a basic and diluted net loss per share of \$0.29 in the same period of 2014.

Revenue decreased to \$4.1 million for the three month period ended June 30, 2015 from \$8.5 million in the same period last year due to a \$7.5 million decrease in revenue from services related to the termination of the Company's contract with BARDA in May 2014, offset in part by a \$3.1 million increase in royalty revenues in 2015 primarily related to a Relenza[®] government stockpile order.

Cost of revenue decreased to zero for the three month period ended June 30, 2015 from \$9.7 million in the same period last year due to the termination of the Company's contract with BARDA in May 2014.

Research and development expense decreased to \$5.2 million for the three month period ended June 30, 2015 from \$6.3 million in the same period last year. The \$1.1 million decrease was the result of a \$1.3 million decrease in depreciation and facility related expenses associated with the closure of the Company's Melbourne, Australia research facility in March 2015, a \$0.5 million decrease in salaries, benefits and share-based compensation expense as a result of non-recurring severance expenses in 2014 related to the closure of the Melbourne, Australia research facility and a \$0.1 million decrease in other expenses due to reduced research, offset in part by a \$0.8 million increase in preclinical, clinical and manufacturing costs related to the ongoing Phase 2b SPIRITUS trial for vapendavir and the completion of Investigational New Drug (IND)-enabling studies for BTA585, the Company's RSV compound.

As noted above, the Company recorded an IPR&D expense of \$17.6 million during the three month period ended June 30, 2015 related to the acquisition of Anaconda Pharma. Due to the development stage of Anaconda, the acquisition of Anaconda did not constitute a business, according to United States generally accepted accounting principles (U.S. GAAP). The Company therefore accounted for the total consideration paid at closing as an IPR&D with no alternative future use resulting in no goodwill being recognized and the amount being charged to expense at the acquisition date. As part of the IPR&D expense the Company also recorded \$1.0 million of transaction costs directly related to the acquisition, which included expenditures for advisory, legal, accounting and other similar services. No such expenses were incurred in same period of the prior year.

General and administrative expense decreased to \$1.3 million for the three month period ended June 30, 2015 from \$2.2 million in the same period last year due to a \$1.0 million decrease in professional and legal fees, primarily as a result of \$0.8 million of expenses related to the acquisition of Anaconda Pharma being reclassified to IPR&D expense upon the closing of the transaction in June 2015 and a \$0.3 million decrease in other expenses, offset in part by \$0.4 million increase in salaries, benefits and share-based compensation expenses.

Financial Results for the Fiscal Year Ended June 30, 2015

The Company reported a net loss of \$19.1 million for its fiscal year ended June 30, 2015, as compared to a net loss of \$11.0 million in the prior year. The \$8.1 million increase in net loss from the prior year was primarily due to the non-recurring \$17.6 million IPR&D expense recorded during the three month period ended June 30, 2015 related to the acquisition of Anaconda Pharma, a \$44.1 million decrease in revenues due to the cancellation of the BARDA contract, a \$2.3 million increase in research and development expense related to an increase in preclinical, clinical and manufacturing costs related to the Company's vapendavir clinical development program and IND-enabling studies for BTA585, a \$0.2 million reduction in income tax benefits and a \$0.2 million loss on disposal of assets, offset in part by a \$47.5 million decrease in cost of revenue related to the cancellation of the BARDA contract, a \$7.9 million change in foreign exchange from a loss to a gain, a \$0.8 million decrease in general and administrative expense and \$0.1 million increase in other income. Basic and diluted net loss per share was \$0.54 for the fiscal year ended June 30, 2015, as compared to a basic and diluted net loss per share of \$0.35 in the prior year.

Conference Call and Webcast Information

Biota Pharmaceuticals will host a conference call today to review these fourth quarter and fiscal year ended 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 16443675. 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 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 four product candidates in 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; BTA074, a Phase 2 topical antiviral treatment for genital warts caused by human papillomavirus types 6 & 11; BTA585, an oral fusion (F) protein inhibitor in Phase 1 development for the treatment of respiratory syncytial virus A & B infections; and laninamivir octanoate, a one-time, inhaled treatment in Phase 2 development for influenza A and B infections. The Company also has a preclinical stage RSV non-fusion inhibitor program that it believes can complement its fusion-protein inhibitor BTA585. 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 planned initiation of dosing in the Phase 1 multiple ascending dose for BTA585; the planned initiation of a Phase 2 clinical trial for BTA074; the time frame in which the Company plans to report Phase 1 SAD and MAD data for BTA585; the time frames in which the Company plans to fully enroll and report top line-data from its Phase 2b SPIRITUS clinical trial; and the time frame in which the Company anticipates reporting top-line data from its Phase 2 trials of BTA074 and BTA585.

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), Argentina National Administration of Drugs, Foods and Medical Devices (ANMAT), European Medicines Agency (EMA) 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, BTA585, BTA074 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 safety or efficacy data from planned and ongoing future preclinical and clinical studies of any of its product candidates not supporting the clinical development of that product candidate; the Company's capacity to successfully enroll, manage and conduct worldwide clinical trials on a timely basis; 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; the Company's ability to manufacture and maintain sufficient quantities of preclinical and clinical trial material on hand to support and complete its preclinical studies or clinical trials on a timely basis; the Company's ability, or that of its clinical research organizations or clinical investigators, to enroll a sufficient number of patients in its clinical trials on a timely basis; the Company's third-party contract research, data management and manufacturing organizations fulfilling their contractual obligations on a timely basis or otherwise performing satisfactorily in the future; 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 the Company's Quarterly Reports on Form 10-Q for the quarter ended September 30, 2014 and December 31, 2014, and March 31, 2015 as filed with the U.S. Securities and Exchange Commission on November 7, 2014 and February 6, 2015, and May 8, 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[®] is a registered trademark of GlaxoSmithKline plc and Inavir[®] is a registered trademark of Daiichi Sankyo.

(unaudited)

	<u>June 30, 2015</u>	<u>June 30, 2014</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$44.7	\$81.7
Contract receivable (BARDA)	--	17.8
Accounts receivable, net of allowance	12.6	0.9
Short-term investments	12.9	--
Prepaid and other current assets	0.6	0.7
Total current assets	<u>70.8</u>	<u>101.1</u>
Non-current assets:		
Long-term investments	7.9	10.0
Property and equipment, net	0.2	2.0
Deferred tax asset	0.5	0.9
Total non-current assets	<u>8.6</u>	<u>12.9</u>
Total assets	<u><u>\$79.4</u></u>	<u><u>\$114.0</u></u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Contract payables (BARDA)	\$1.0	\$18.6
Accounts payable	1.9	2.8
Accrued expenses	5.3	3.4
Accrued severance obligations	0.1	1.2
Deferred tax liability	0.5	0.9
Short term note payable	0.2	--
Total current liabilities	<u>9.0</u>	<u>26.9</u>
Non-current liabilities:		
Long term note payable, net of current portion	0.8	--
Other liabilities, net of current portion	0.1	0.2
Total liabilities	<u>9.9</u>	<u>27.1</u>
Stockholders' equity:		
Common stock, \$0.10 par value; 200,000,000 shares authorized 38,609,086 and 35,100,961 shares issued and outstanding at June 30, 2015 and June 30, 2014, respectively	3.9	3.5
Additional paid-in capital	155.6	146.4
Accumulated other comprehensive income	18.9	26.8
Accumulated deficit	(108.9)	(89.8)
Total stockholders' equity	<u>69.5</u>	<u>86.9</u>
Total liabilities and stockholders' equity	<u><u>\$79.4</u></u>	<u><u>\$114.0</u></u>

BIOTA PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in millions, except per share amounts)

(unaudited)

<u>Three Months Ended June 30,</u>		<u>Twelve Months Ended June 30,</u>	
<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>

Revenue:				
Royalty revenue and milestones	\$4.1	\$1.0	\$16.1	\$15.1
Revenue from services (BARDA)	--	7.5	8.4	53.5
Other	--	--	0.1	0.1
Total revenue	4.1	8.5	24.6	68.7
Operating expense:				
Cost of revenue	--	9.7	3.6	51.1
Research and development	5.2	6.3	19.8	17.5
In-process research and development (IPR&D)	17.6	--	17.6	--
General and administrative	1.3	2.2	9.4	10.2
Foreign exchange loss (gain)	--	0.8	(6.5)	1.4
Loss on disposal of assets	--	--	0.2	--
Total operating expense	24.1	19.0	44.1	80.2
Income (loss) from operations	(20.0)	(10.5)	(19.5)	(11.5)
Non-operating income:				
Other income	0.1	0.1	0.3	0.2
Total non-operating income	0.1	0.1	0.3	0.2
Loss before tax	(19.9)	(10.4)	(19.2)	(11.3)
Income tax benefit	--	0.2	0.1	0.3
Net loss	<u>(\$19.9)</u>	<u>(\$10.2)</u>	<u>(\$19.1)</u>	<u>(\$11.0)</u>
Basic loss per share	(\$0.55)	(\$0.29)	(\$0.54)	(\$0.35)
Diluted loss per share	(\$0.55)	(\$0.29)	(\$0.54)	(\$0.35)
Basic weighted-average shares outstanding	36,143,337	35,023,500	35,360,841	31,347,888
Diluted weighted-average shares outstanding	36,143,337	35,023,500	35,360,841	31,347,888

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