February 5, 2016

# Biota Pharmaceuticals Reports Second Quarter Fiscal Year 2016 Financial Results

## Conference Call to be Held Today at 9:00 A.M. EST

ATLANTA, Feb. 05, 2016 (GLOBE NEWSWIRE) -- Biota Pharmaceuticals, Inc. (NASDAQ:BOTA) today announced its financial results for the three month period ended December 31, 2015, which is the second quarter of the Company's 2016 fiscal year, and also provided an update on recent corporate developments.

"I am very pleased today to report that significant progress is being made with our antiviral pipeline for respiratory indications and we remain on track to have Phase 2 data readouts in the second half of the year from both the HRV and RSV programs. Our oral RSV fusion inhibitor, BTA585, successfully completed a robust Phase 1 single ascending dose study showing a favorable safety and pharmacokinetic profile. We are nearing completion of the Phase 1 multiple ascending dose study and plan to initiate the Phase 2 RSV challenge study next quarter. Additionally we are progressing with enrollment in the Phase 2b SPIRITUS trial of vapendavir and anticipate top-line data in the second half of this year. Not only is this our lead program but it is the most advanced direct-acting antiviral in the field targeting HRV and has the potential to treat problematic upper respiratory infections in the almost 11 million moderate-to-severe asthmatics in the U.S.," stated Joseph M. Patti, PhD, president and chief executive officer at Biota Pharmaceuticals.

"I am glad to report that we have begun screening patients for the Phase 2 study of BTA074, our first-in-class direct-acting antiviral for the treatment of condyloma caused by HPV types 6 & 11, which is the most common manifestation of HPV infection and also the most common sexually-transmitted viral disease worldwide. Current topical treatments do not act on the virus directly so there is a need for a therapy with improved efficacy and reduced local skin reactions to address this contagious infection."

### Recent Highlights

***Announced positive Phase 1 data for BTA585.*** The top-line results were from a blinded, placebo-controlled single ascending dose study, which tested doses of up to 800 mg of BTA585, an oral fusion inhibitor in development for the treatment and prevention of respiratory syncytial virus (RSV) infections. Findings included:

- No serious or severe adverse events
- Low incidence of adverse events
- Pharmacokinetic (PK) data demonstrated that all doses of 100 mg or greater achieved BTA585 plasma levels that exceeded the mean $EC_{50}$ of RSV clinical isolates for 24 hours. The $EC_{50}$ represents the concentration of drug that is required for 50% inhibition of viral replication *in vitro*
- BTA585 plasma $C_{max}$ was rapidly achieved at approximately one hour following oral dosing and the half-life ($T_{1/2}$) was approximately five to six hours across the dose range
- Dosing of BTA585 with a high fat meal did not adversely affect the PK

***Commenced dosing in Phase 1 multiple ascending dose (MAD) study of BTA585***. This study will evaluate the safety and PK of BTA585 in healthy volunteers following seven days of oral dosing. Top-line data is anticipated to be available in the first quarter of 2016.

***Enrollment on track for Phase 2b SPIRITUS trial for vapendavir.*** Top-line data are expected in the second half of 2016 from the multi-center, randomized, double-blind, placebo-controlled dose-ranging study in moderate-to-severe adult asthmatics with symptomatic human rhinovirus (HRV) and a history of asthma exacerbation from colds.

### Corporate Updates

***Appointed Mark P. Colonnese as Executive Vice President and Chief Financial Officer on November 2, 2015.*** The Company announced the appointment of Mark Colonnese as Executive Vice President and Chief Financial Officer. Mr. Colonnese has held a number of senior executive positions in the pharmaceutical industry and, most recently, was Chief Financial Officer of Stealth BioTherapeutics, Inc.

**Financial Results for the Three Month Period Ended December 31, 2015**

The Company reported a net loss of $6.5 million for the three month period ended December 31, 2015, as compared to net income of $6.5 million in the same quarter of the prior fiscal year. Basic and diluted net loss per share was $0.17 for the three month period ended December 31, 2015, as compared to a basic and diluted net income per share of $0.19 in the same period of 2014.

Revenue decreased to $1.7 million for the three month period ended December 31, 2015 from $13.9 million in the same period in 2014 due to a $4.8 million decrease in royalty revenues, related to a larger Relenza® government stockpile order received in the prior year, as well as lower seasonal sales of Relenza® and Inavir® reflecting an earlier than normal flu season in 2014, and $7.4 million decrease in revenue from services as a result of the termination of the Company's contract with BARDA in 2014.

Cost of revenue decreased to zero for the three month period ended December 31, 2015 from $1.6 million in the same period last year due to the termination of the Company's contract with BARDA in 2014.

Research and development expense increased to $6.3 million for the three month period ended December 31, 2015 from $4.8 million in the same period in 2014. The $1.5 million increase was the result of a $2.8 million increase in clinical costs related to the ongoing Phase 2b SPIRITUS trial for vapendavir; the Phase 1 SAD and MAD trials for BTA585; and startup expenses for the Phase 2 trial for BTA074. These costs were offset in part by a $0.8 million decrease in compensation expenses and a decrease of $0.5 million in depreciation and facility related expenses associated with the closure of the Company's early-stage research facility in March 2015.

General and administrative expense decreased to $2.1 million for the three month period ended December 31, 2015 from $2.6 million in the same period in 2014, due largely to lower compensation expenses as a result of administrative staff reductions related to the facility closure in March 2015.

The Company held $57.2 million in cash, cash equivalents, and short and long-term investments as of December 31, 2015.

**Conference Call and Webcast Information**

Biota Pharmaceuticals will host a conference call today to review these second quarter fiscal year 2016 financial results, as well as provide a general update on the Company, via a webcast and conference call at 9:00 a.m. ET. To access the conference call, please dial (877) 312-5422 (domestic) or (253) 237-1122 (international) and refer to conference ID number 31712361. A live audio webcast of the call and the archived webcast will be available in the Investors section of the Company's 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 three 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 topical antiviral treatment in Phase 2 development for condyloma caused by human papillomavirus types 6 & 11; and BTA585, an oral fusion (F) protein inhibitor in Phase 1 development for the treatment of respiratory syncytial virus (RSV) infections. The Company also has a preclinical stage RSV non-fusion inhibitor program. 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 timing of data readouts on our Phase 2 HRV and RSV programs, the availability of top-line PK and safety data from the BTA585 Phase 1 multiple ascending dose trial; and the planned initiation of the Phase 2a challenge study for 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 U.S. Food and Drug Administration (FDA) or a similar regulatory body in another country, a data safety monitoring board, or an institutional review board delaying, limiting, suspending or terminating any of the Company's clinical development programs 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; and these third-party organizations fulfilling their contractual obligations on a timely and satisfactory basis; the safety or efficacy data from planned or ongoing future preclinical and clinical studies of any of its product candidates not supporting the clinical development of that product candidate; the successful enrollment of the requisite number of study participants 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 retain and recruit sufficient staff, including key executive management and employees, to manage our business; the Company's ability to maintain, protect or defend its proprietary rights from unauthorized use by others, or not infringe on the intellectual property rights of others; changes in the general economic business or competitive conditions in the industry or with respect to our product candidates; 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, 2015, as filed with the U.S. Securities and Exchange Commission on September 11, 2015 and in the Company's Quarterly Report on Form 10-Q, as filed on November 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 PHARMACEUTICALS, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
(in millions, except per share amounts)

| | December 31, 2015 (unaudited) | June 30, 2015 (audited) |
|---|---|---|
| **ASSETS** | | |
| Current assets | | |
| Cash and cash equivalents | $ 39.0 | $ 44.7 |
| Short-term investments | 13.0 | 12.9 |
| Accounts receivable, net of allowance | 5.1 | 12.6 |
| Prepaid and other current assets | 1.5 | 0.6 |
| Total current assets | 58.6 | 70.8 |
| Non-current assets: | | |
| Long-term investments | 5.2 | 7.9 |
| Property and equipment, net | 0.4 | 0.2 |
| Deferred tax asset | - | 0.5 |
| Total non-current assets | 5.6 | 8.6 |
| Total assets | $ 64.2 | $ 79.4 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 1.3 | $ 1.9 |
| Accrued expenses | 4.3 | 5.4 |
| Short term note payable | 0.4 | 0.2 |
| Contract payables (BARDA) | - | 1.0 |
| Deferred tax liability | - | 0.5 |
| Total current liabilities | 6.0 | 9.0 |
| Non-current liabilities: | | |
| Long term note payable, net of current portion | 0.5 | 0.8 |
| Other liabilities, net of current portion | 0.2 | 0.1 |
| Total liabilities | 6.7 | 9.9 |

| | | |
|---|---|---|
| Stockholders' equity: | | |
| Common stock, $0.10 par value; 200,000,000 shares authorized 38,636,946 and 38,609,086 shares issued and outstanding at December 31, 2015 and June 30, 2015, respectively | 3.9 | 3.9 |
| Additional paid-in capital | 156.8 | 155.6 |
| Accumulated other comprehensive income | 18.9 | 18.9 |
| Accumulated deficit | (122.1) | (108.9) |
| Total stockholders' equity | 57.5 | 69.5 |
| Total liabilities and stockholders' equity | $ 64.2 | $ 79.4 |

**BIOTA PHARMACEUTICALS, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
(in millions, except per share amounts)
(unaudited)

| | Three Months Ended December 31, | | Six Months Ended December 31, | |
|---|---|---|---|---|
| | **2015** | **2014** | **2015** | **2014** |
| Revenue: | | | | |
| Royalty revenue and milestones | $ 1.7 | $ 6.5 | $ 3.4 | $ 6.5 |
| Revenue from services | - | 7.4 | - | 8.1 |
| Total revenue | 1.7 | 13.9 | 3.4 | 14.6 |
| Operating expense: | | | | |
| Cost of revenue | - | 1.6 | - | 3.3 |
| Research and development | 6.3 | 4.8 | 11.8 | 9.7 |
| General and administrative | 2.1 | 2.6 | 4.4 | 5.0 |
| Foreign exchange loss (gain) | (0.2) | (1.5) | 0.5 | (2.8) |
| Total operating expense | 8.2 | 7.5 | 16.7 | 15.2 |
| Income (loss) from operations | (6.5) | 6.4 | (13.3) | (0.6) |
| Non-operating income: | | | | |
| Interest income | - | 0.1 | 0.1 | 0.2 |
| Total non-operating income | - | 0.1 | 0.1 | 0.2 |
| Income (loss) before tax | (6.5) | 6.5 | (13.2) | (0.4) |
| Income tax benefit | - | - | - | - |
| Net income (loss) | $ (6.5) | $ 6.5 | $ (13.2) | $ (0.4) |
| Basic income (loss) per share | $ (0.17) | $ 0.19 | $ (0.34) | $ (0.01) |
| Diluted income (loss) per share | $ (0.17) | $ 0.19 | $ (0.34) | $ (0.01) |
| Basic weighted-average shares outstanding | 38,636,946 | 35,100,961 | 38,630,587 | 35,100,961 |
| Diluted weighted-average shares outstanding | 38,636,946 | 35,103,086 | 38,630,587 | 35,100,961 |

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