

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): November 6, 2015

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.)

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)

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 2.02 Results of Operations and Financial Condition

On November 6, 2015, Biota Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the first quarter ended September 30, 2015. 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 November 6, 2015.



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: November 6, 2015

/s/ Joseph M Patti

Name: Joseph M Patti

Title: Chief Executive Officer and President
(Duly Authorized Officer)

EXHIBIT INDEX

*Exhibit
Number*

Description

99.1

Press release dated November 6, 2015.

PRESS RELEASE

FOR IMMEDIATE RELEASE

**BIOTA PHARMACEUTICALS REPORTS FIRST QUARTER
FISCAL YEAR 2016 FINANCIAL RESULTS**

ATLANTA, GA – November 6, 2015 — Biota Pharmaceuticals, Inc. (NASDAQ: BOTA), 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 three month period ended September 30, 2015, which is the first quarter of the Company's 2016 fiscal year, and also provided an update on recent corporate developments and anticipated upcoming pipeline milestones.

“This quarter was about pipeline momentum and expanding our leadership team at Biota. As for our antiviral portfolio, we continued enrolling patients in our ongoing Phase 2 SPIRITUS trial for vapendavir and are now nearing the completion of a single ascending dose trial for BTA585, our RSV F-protein inhibitor. On the corporate front, we are thrilled with the recent addition of a chief financial officer and two new directors to our Board,” reflected Dr. Joseph Patti, President and Chief Executive Officer of Biota Pharmaceuticals. “Looking ahead, we anticipate initiating a multiple ascending dose trial with BTA585 and a Phase 2 trial with BTA074 5% topical gel in patients with condyloma in the near-term.”

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. Prior to joining Biota, Mr. Colonnese was Chief Financial Officer of Stealth BioTherapeutics, Inc.

Appointed Armando Anido and Michael Dunne, M.D. to Board of Directors on September 21, 2015. The Company announced the appointments of Armando Anido and Michael Dunne, M.D. to its Board of Directors. Mr. Anido is currently Chairman of the Board and Chief Executive Officer of Zynherba Pharmaceuticals and Dr. Dunne is currently Chief Science Officer of Iterum Pharmaceuticals LLC.

Anticipated Upcoming Pipeline Milestones

BTA585. BTA585 is an orally bioavailable compound being developed to treat respiratory syncytial virus (RSV) infections in children, the elderly and immunocompromised patients. The Company is currently conducting 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. The ongoing Phase 1 SAD clinical trial has five dose level cohorts ranging from 50 mg to 500 mg and includes an evaluation of the effect of food on the plasma PK of BTA585. To date, four cohorts have completed the study and top-line PK and safety data is anticipated by year-end. The Company also expects to begin a Phase 1 multiple ascending dose trial this month and anticipates top-line results in the first quarter of calendar year 2016.

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BTA074 5% topical gel. BTA074 is a novel, direct-acting antiviral with activity against human papillomavirus types 6 and 11. BTA074 is currently in development for the treatment of genital warts, or condyloma, as well as recurrent respiratory papillomatosis. The Company anticipates that dosing will commence early next year in a double-blind placebo-controlled, randomized, Phase 2 study to assess the safety, tolerability, pharmacokinetics and efficacy of BTA074 5% gel, dosed topically, twice a day for up to 16 weeks in duration, in approximately 210 adult condyloma patients.

Vapendavir. Vapendavir is an oral treatment for human rhinovirus infections in moderate-to-severe asthmatics. The Company is continuing enrollment in the ongoing Phase 2b SPIRITUS trial. The multi-center, randomized, double-blind, placebo-controlled dose-ranging study 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 (FEV1), daily β_2 -agonist use and the incidence of moderate and severe asthma exacerbations. The Company anticipates top-line data from this trial to be available in the second half of next year.

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

Revenue increased to \$1.7 million for the three month period ended September 30, 2015 from \$0.7 million in the same period in 2014 due to a \$1.7 million increase in royalty revenues related to a Relenza[®] government stockpile order, offset in part by a \$0.7 million decrease in service revenue due to the termination of the Company's contract with BARDA in 2014.

Cost of revenue decreased to zero for the three month period ended September 30, 2015 from \$1.7 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 \$5.5 million for the three month period ended September 30, 2015 from \$4.9 million in the same period in 2014. The \$0.6 million increase was the result of a \$2.0 million increase in preclinical, clinical, manufacturing and chemistry costs related to the ongoing Phase 2b SPIRITUS trial for vapendavir, the Phase 1 SAD trial for BTA585, startup expenses for the planned initiation of the Phase 2 trial for BTA074, and chemistry and preclinical expenses for the Company's RSV non-fusion inhibitor compounds, offset in part by a \$0.6 million decrease in compensation expense and a decrease of \$0.7 million in depreciation and facility related expenses associated with the closure of the Company's Melbourne, Australia research facility in March 2015.

General and administrative expense decreased to \$2.2 million for the three month period ended September 30, 2015 from \$2.4 million in the same period in 2014 due to a \$0.1 million decrease in professional and legal fees and a \$0.1 million decrease in other expenses.

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The Company reported a net loss of \$6.6 million for the three month period ended September 30, 2015, as compared to net loss of \$6.9 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 September 30, 2015, as compared to a basic and diluted net loss per share of \$0.20 in the same period of 2014.

The Company held \$66.3 million in cash, cash equivalents, and short and long-term investments as of September 30, 2015.

Conference Call and Webcast Information

Biota Pharmaceuticals will host a conference call today to review these first 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 55857667. 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 four product candidates in clinical development: These include varendavir, 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; BTA585, an oral fusion (F) protein inhibitor in Phase 1 development for the treatment of respiratory syncytial virus (RSV) infections; and laninamivir octanoate, a one-time, inhaled treatment in Phase 2 development for influenza 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 availability of top-line PK and safety data from the BTA585 Phase 1 single ascending dose trial; the planned initiation of the Phase 1 multiple ascending dose study for BTA585; the planned initiation of a Phase 2 clinical trial for BTA074; and the timing of top-line data from the Phase 2b SPIRITUS trial.

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 varendavir, 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 or 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, 2015, as filed with the U.S. Securities and Exchange Commission, on September 11, 2015.

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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.

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BIOTA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in millions, except per share amounts)
(unaudited)

	<u>September 30,</u> <u>2015</u>	<u>June 30, 2015</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 45.3	\$ 44.7
Short-term investments	11.9	12.9
Accounts receivable, net of allowance	3.2	12.6
Prepaid and other current assets	0.8	0.6
Total current assets	61.2	70.8
Non-current assets:		
Long-term investments	9.1	7.9
Property and equipment, net	0.2	0.2
Deferred tax asset	0.5	0.5
Total non-current assets	9.8	8.6
Total assets	\$ 71.0	\$ 79.4
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Contract payables (BARDA)	\$ -	\$ 1.0
Accounts payable	2.9	1.9
Accrued expenses	3.1	5.3
Accrued severance obligations	-	0.1
Deferred tax liability	0.5	0.5
Short term note payable	0.2	0.2
Total current liabilities	6.7	9.0
Non-current liabilities:		
Long term note payable, net of current portion	0.7	0.8
Other liabilities, net of current portion	0.1	0.1
Total liabilities	7.5	9.9
Stockholders' equity:		
Common stock, \$0.10 par value; 200,000,000 shares authorized 38,636,949 and 38,609,086 shares issued and outstanding at September 30, 2015 and June 30, 2015, respectively	3.9	3.9
Additional paid-in capital	156.2	155.6
Accumulated other comprehensive income	18.9	18.9
Accumulated deficit	(115.5)	(108.9)
Total stockholders' equity	63.5	69.5
Total liabilities and stockholders' equity	\$ 71.0	\$ 79.4

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

	Three Months Ended September 30,	
	2015	2014
Revenue:		
Royalty revenue and milestones	\$ 1.7	\$ -
Revenue from services	-	0.7
Total revenue	1.7	0.7
Operating expense:		
Cost of revenue	-	1.7
Research and development	5.5	4.9
General and administrative	2.2	2.4
Foreign exchange loss (gain)	0.7	(1.3)
Total operating expense	8.4	7.7
Loss from operations	(6.7)	(7.0)
Non-operating income:		
Interest income	0.1	0.1
Total non-operating income	0.1	0.1
Loss before tax	(6.6)	(6.9)
Income tax benefit (expense)	-	-
Net loss	\$ (6.6)	\$ (6.9)
Basic loss per share	\$ (0.17)	\$ (0.20)
Diluted loss per share	\$ (0.17)	\$ (0.20)
Basic weighted-average shares outstanding	38,624,227	35,029,300
Diluted weighted-average shares outstanding	38,624,227	35,029,300

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