

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2014

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from            to            .

Commission File Number: 001-35285

**Biota Pharmaceuticals, Inc.**  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

59-1212264  
(I.R.S. Employer  
Identification No.)

2500 Northwinds Parkway, Suite 100, Alpharetta, GA 30009  
(Address of principal executive offices, including zip code)

(678) 221 3343  
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The number of shares outstanding of the registrant's common stock, par value \$0.10 per share at November 8, 2014 was 35,100,961 shares.

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**PART I. FINANCIAL INFORMATION**  
**ITEM 1. Financial Statements**

**Biota Pharmaceuticals, Inc.**  
**Condensed Consolidated Balance Sheets**  
**(Unaudited)**  
(in millions, except per share amounts)

	<u>September 30,</u> <u>2014</u>	<u>June 30, 2014</u>
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 57.7	\$ 81.7
Contract receivable	16.3	17.8
Short-term investments	1.1	-
Other accounts receivable	0.5	0.9
Prepaid and other current assets	0.5	0.7
Total current assets	76.1	101.1
Non-current assets:		
Long-term investments	18.8	10.0
Deferred tax asset	0.8	0.9
Property and equipment, net	1.6	2.0
Total non-current assets	21.2	12.9
Total assets	\$ 97.3	\$ 114.0
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Contract payables and accrued expenses	\$ 13.3	\$ 18.6
Accounts payable	1.4	2.8
Accrued expenses	3.2	3.4
Accrued severance obligations	0.6	1.2
Deferred tax liability	0.8	0.9
Total current liabilities	19.3	26.9
Non-current liabilities:		
Other liabilities, net of current portion	0.1	0.2
Total liabilities	19.4	27.1
Stockholders' equity:		
Common stock, \$0.10 par value: 200,000,000 shares authorized; 35,100,961 and 35,100,961 shares issued and outstanding at September 30, 2014 and June 30, 2014, respectively	3.5	3.5
Additional paid-in capital	146.8	146.4
Accumulated other comprehensive income	24.3	26.8
Accumulated deficit	(96.7)	(89.8)
Total stockholders' equity	77.9	86.9
Total liabilities and stockholders' equity	\$ 97.3	\$ 114.0

See accompanying notes to these financial statements.

**Biota Pharmaceuticals, Inc.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
**(unaudited)**  
(in millions, except per share amounts)

	<b>Three Months Ended</b>	
	<b>September 30,</b>	
	<b>2014</b>	<b>2013</b>
<b>Revenue:</b>		
Royalty revenue and milestones	\$ -	\$ -
Revenue from services	0.7	12.2
Other	-	0.1
<b>Total revenue</b>	<b>0.7</b>	<b>12.3</b>
<b>Operating expense:</b>		
Cost of revenue	1.7	10.7
Research and development	4.9	3.0
General and administrative	2.4	2.4
Foreign exchange (gain) loss	(1.3)	0.3
<b>Total operating expense</b>	<b>7.7</b>	<b>16.4</b>
<b>Loss from operations</b>	<b>(7.0)</b>	<b>(4.1)</b>
<b>Non-operating income:</b>		
Interest income	0.1	0.1
<b>Loss before tax</b>	<b>(6.9)</b>	<b>(4.0)</b>
Income tax benefit	-	0.1
<b>Net loss</b>	<b>\$ (6.9)</b>	<b>\$ (3.9)</b>
<b>Basic loss per share</b>	<b>\$ (0.20)</b>	<b>\$ (0.14)</b>
<b>Diluted loss per share</b>	<b>\$ (0.20)</b>	<b>\$ (0.14)</b>
Basic weighted-average shares outstanding	35,029,300	28,291,665
Diluted weighted-average shares outstanding	35,029,300	28,291,665
<b>Comprehensive loss:</b>		
Net loss	\$ (6.9)	\$ (3.9)
Exchange differences on translation of foreign operations	(2.5)	0.3
<b>Total comprehensive loss</b>	<b>\$ (9.4)</b>	<b>\$ (3.6)</b>

See accompanying notes to these financial statements.

Biota Pharmaceuticals, Inc.

Condensed Consolidated Statements of Stockholders' Equity  
(unaudited)

(in millions, except for share amounts)

	Common Stock		Additional Paid-in Capital	Treasury Shares		Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount		Shares	Amount			
<b>Balances at July 1, 2014</b>	35,100,961	\$ 3.5	\$ 146.4	-	\$ -	\$ (89.8)	\$ 26.8	\$ 86.9
Exchange differences on translation of foreign operations	-	-	-	-	-	-	(2.5)	(2.5)
Net loss	-	-	-	-	-	(6.9)	-	(6.9)
Share-based compensation	-	-	0.4	-	-	-	-	0.4
<b>Balances at September 30, 2014</b>	<u>35,100,961</u>	<u>\$ 3.5</u>	<u>\$ 146.8</u>	<u>-</u>	<u>\$ -</u>	<u>\$ (96.7)</u>	<u>\$ 24.3</u>	<u>\$ 77.9</u>

See accompanying notes to the financial statements.

**Biota Pharmaceuticals, Inc.**  
**Condensed Consolidated Statements of Cash Flows**  
**(unaudited)**  
(in millions)

	<b>Three Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (6.9)	\$ (3.9)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	0.4	0.5
Share-based compensation	0.4	0.3
Change in operating assets and liabilities (net of liabilities acquired):		
Accounts receivables	0.6	(2.0)
Prepaid expenses and other current assets	0.2	0.9
Deferred revenue	-	(0.2)
Accounts payable and accrued expenses	(5.7)	(1.0)
Accrued severance obligations	(0.6)	(0.8)
Net cash used in operating activities	(11.6)	(6.2)
<b>Cash flows from investing activities:</b>		
Purchases of short and long-term investments	(9.9)	-
Purchases of property and equipment	-	(0.1)
Net cash used in investing activities	(9.9)	(0.1)
Decrease in cash and cash equivalents	(21.5)	(6.3)
Cash and cash equivalents at beginning of period	81.7	66.8
Effects of exchange rate movements on cash and cash equivalents	(2.5)	0.3
<b>Cash and cash equivalents at end of period</b>	<b>\$ 57.7</b>	<b>\$ 60.8</b>

See accompanying notes to these financial statements.

**Biota Pharmaceuticals, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements  
(for the quarterly period ended September 30, 2014)**

**(1) Company Overview**

Biota Pharmaceuticals, Inc., together with its wholly owned subsidiaries (“Biota”, or the “Company”) 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 has been incorporated in the state of Delaware since 1969 and its corporate headquarters are located in Alpharetta, Georgia.

The Company is currently focused on developing oral, small molecule antiviral compounds to treat a number of respiratory-related infections. The most advanced clinical-stage program is laninamivir octanoate, a long-acting neuraminidase inhibitor (“NI”) that the Company has been developing for the treatment of influenza A and B. On August 1, 2014, the Company reported top-line safety and efficacy results from a randomized, double-blind, placebo-controlled, parallel-arm Phase 2 clinical trial comparing the safety and efficacy of a 40 mg and an 80 mg dose of laninamivir octanoate to placebo. As compared to placebo, neither the 40 mg nor the 80 mg cohort achieved a statistically significant reduction in the median time to alleviation of influenza symptoms, the primary endpoint, as measured by the Flu-iiQ patient-recorded outcome questionnaire. Certain important secondary endpoints, including quantitative viral shedding, and secondary bacterial infections, as well as the time to alleviation of influenza symptoms for a number of subcomponents, did achieve statistically significant results for laninamivir octanoate treated cohorts compared to placebo. The Company intends to complete its analyses of the data from this trial and plans to discuss the results of this trial with the U.S. Food and Drug Administration (“FDA”) to determine the appropriate primary endpoint for, and which patient reported outcome tools would be acceptable for use in, any prospective registration trials of laninamivir octanoate to treat uncomplicated influenza.

The Company is also developing BTA-798, also known as vapendavir. Biota has successfully completed two Phase 2 trials of vapendavir to date and recently completed additional Phase 1 bioavailability and drug-drug interaction studies of vapendavir in healthy volunteers. The Company plans to initiate a randomized, double-blind, placebo-controlled dose-ranging Phase 2 trial in moderate and severe asthmatic patients at risk of loss of asthma control due to presumptive human rhinovirus (“HRV”) infection in the first quarter of 2015.

In addition to these Phase 2 clinical-stage development programs, the Company is also developing orally bioavailable F and non-F protein compounds for the treatment of respiratory syncytial virus (“RSV”) infections in children, the elderly and immune-compromised patients. The Company is currently conducting Investigational New Drug application (“IND”) enabling studies with BTA-C585, the lead compound from its F-protein inhibitor program for the treatment of RSV.

In March 2011, the Company was awarded a contract from the U.S. Office of Biomedical Advanced Research and Development Authority (“BARDA”) designed to provide up to \$231 million in support of the development of and submission for a New Drug Application (“NDA”) of laninamivir octanoate for the treatment of influenza A and B infections in the United States. On April 23, 2014, the Company was notified by the U.S. Department of Health and Human Services (“HHS”) office of the Assistant Secretary for Preparedness and Response (“ASPR”) and BARDA that pending a decision regarding the outcome of an In-Process Review (“IPR”) of the Company’s contract for the development of laninamivir octanoate, ASPR/BARDA had issued a Stop-Work Order notifying the Company to discontinue work on a number of activities that would no longer be reimbursed under the contract. On May 7, 2014, HHS/ASPR/BARDA notified the Company of its decision to terminate the contract for the convenience of the U.S. Government based upon the results of the IPR. The Company continues to work with ASPR/BARDA to close out this contract, which involves finalizing invoices and billings, determining the nature and extent of any equitable adjustments, and negotiating a final termination settlement.

Although several of the Company’s influenza product candidates have been successfully developed and commercialized to date by other larger pharmaceutical companies under collaboration, license or commercialization agreements, the Company has not independently developed or received regulatory approval for any product candidate, and the Company does not currently have any sales, marketing or commercial capabilities. Therefore, it is possible that the Company may not successfully derive any significant product revenues from any product candidates that it is developing now, or may develop in the future. The Company expects to incur losses for the foreseeable future as it intends to support the clinical and preclinical development of its product candidates. Also, due to the termination of its contract with BARDA, the Company anticipates that its revenue from service and cost of revenue will decline substantially in the future as compared to recent historical levels.

**Notes to Unaudited Condensed Consolidated Financial Statements  
(for the quarterly period ended September 30, 2014)**

The Company plans to continue to finance its operations with (i) its existing cash, cash equivalents and investments, (ii) proceeds from existing or potential future royalty-bearing licenses or collaborative research and development arrangements, (iii) future equity and/or debt financings, or (iv) other financing arrangements. The Company's ability to continue to support its operations is dependent, in the near-term, upon managing its cash resources, receiving reimbursements from BARDA related to the close-out of its terminated contract, continuing to receive royalty revenue under existing licenses, entering into future collaboration, license or commercialization agreements, successfully developing its product candidates, executing future financings and ultimately, upon obtaining approval of its products for sale and achieving positive cash flows from operations on a consistent basis. There can be no assurance that additional capital or funds will be available on terms acceptable to the Company, if at all, or that the Company will be able to enter into collaboration, license or commercialization agreements in the future, or that the Company will ever generate significant product revenue and become operationally profitable on a consistent basis.

**(2) Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. All material adjustments considered necessary for a fair presentation have been included. Certain information and footnotes disclosure normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to instructions, rules and regulations prescribed by the U.S. Securities and Exchange Commission ("SEC"). Except as disclosed herein, there has been no material change in the information disclosed in the notes to the consolidated financial statements included in the Company's Annual Report on Form 10-K that was filed with the SEC on September 30, 2014.

The unaudited interim consolidated financial statements include the accounts of the Company and all of its wholly owned subsidiaries. All inter-company transactions and balances are eliminated in consolidation.

Operating results for the three months ended September 30, 2014 are not necessarily indicative of the annual results that may be expected for the Company's fiscal year ending June 30, 2015. For a more complete discussion of the Company's significant accounting policies and other information, this report should be read in conjunction with the consolidated financial statements for the fiscal year ended June 30, 2014 included in the Company's Annual Report on Form 10-K that was filed with the SEC on September 30, 2014.

The Company's significant accounting policies have not changed since June 30, 2014, except as outlined below:

***Recent Accounting Standards***

In August 2014, the Financial Accounting Standards Board issued authoritative accounting guidance related to management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. In doing so, the amendments should reduce diversity in the timing and content of footnote disclosures. This guidance is effective for public and nonpublic entities for annual periods ending after December 15, 2016, and interim periods thereafter. Early adoption is permitted. The Company is currently assessing the expected impact, if any, that this ASU will have on its consolidated financial statements.

In May 2014, the Financial Accounting Standards Board issued authoritative accounting guidance related to revenue from contracts with customers. This guidance is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. This guidance is effective for annual reporting periods beginning after December 15, 2016 and early adoption is not permitted. The Company will adopt this guidance on January 1, 2017. Companies may use either a full retrospective or a modified retrospective approach to adopt this guidance. The Company is evaluating which transition approach to use and its impact, if any, on its consolidated financial statements.



**Biota Pharmaceuticals, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements  
(for the quarterly period ended September 30, 2014)**

**(3) Fair Value Measurements**

A fair value hierarchy has been established which requires the Company to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The fair value hierarchy describes three levels of inputs that may be used to measure fair value:

<b>Level 1</b>	Quoted prices in active markets for identical assets or liabilities.
<b>Level 2</b>	Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
<b>Level 3</b>	Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table sets forth the financial assets and liabilities that were measured at fair value on a recurring basis at September 30, 2014 and June 30, 2014, by level within the fair value hierarchy. The assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The Company's long-term and short-term investments have been classified as Level 2, which have been initially valued at the transaction price and subsequently revalued, at the end of each reporting period, utilizing a third party pricing service. The pricing service utilizes industry standard valuation models and observable market inputs to determine value that include surveying the bond dealer community, obtaining benchmark quotes, incorporating relevant trade data, and updating spreads daily. There have been no transfers of assets or liabilities between the fair value measurement classifications during the periods presented.

	<b>Total</b>	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
<b>September 30, 2014</b>				
Cash equivalents	\$ 23.4	\$ 23.4	\$ —	\$ —
Short-term investments available-for-sale	1.1	—	1.1	—
Long-term investments available-for-sale	18.8	—	18.8	—
<b>Total</b>	<b>\$ 43.3</b>	<b>\$ 23.4</b>	<b>\$ 19.9</b>	<b>\$ —</b>

	<b>Total</b>	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
<b>June 30, 2014</b>				
Cash equivalents	\$ 36.9	\$ 36.9	\$ —	\$ —
Long-term investments available-for-sale	10.0	—	10.0	—
<b>Total</b>	<b>\$ 46.9</b>	<b>\$ 36.9</b>	<b>\$ 10.0</b>	<b>\$ —</b>

**Biota Pharmaceuticals, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements  
(for the quarterly period ended September 30, 2014)**

Cash equivalents consist primarily of money market funds. Short-term investments consist of corporate securities and have a maturity less than 365 days from the date of acquisition. Long-term investments consist of U.S. agency securities, U.S. Treasury securities, and corporate securities classified as available-for-sale and have maturities greater than 365 days from the date of acquisition.

The Company has had no realized gains or losses from the sale of investments for the twelve months ended September 30, 2014. The following table shows the unrealized gains and losses and fair values for those investments as of September 30, 2014 and June 30, 2014 aggregated by major security type:

	<u>At Cost</u>	<u>Unrealized Gains</u>	<u>Unrealized (Losses)</u>	<u>At Fair Value</u>
<b>September 30, 2014</b>				
Money market funds	\$ 23.4	\$ —	\$ —	\$ 23.4
Debt securities of U.S. government agencies	9.4	—	—	9.4
U.S. Treasury securities	7.6	—	—	7.6
Corporate Securities	2.9	—	—	2.9
<b>Total</b>	<b>\$ 43.3</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 43.3</b>

	<u>At Cost</u>	<u>Unrealized Gains</u>	<u>Unrealized (Losses)</u>	<u>At Fair Value</u>
<b>June 30, 2014</b>				
Money market funds	\$ 36.9	\$ —	\$ —	\$ 36.9
Debt securities of U.S. government agencies	4.9	—	—	4.9
U.S. Treasury securities	5.1	—	—	5.1
<b>Total</b>	<b>\$ 46.9</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 46.9</b>

As of September 30, 2014 and June 30, 2014, the Company had investments in an unrealized loss position. The Company has determined that the unrealized losses of less than \$0.1 million on these investments at September 30, 2014 and June 30, 2014 are temporary in nature and expects the securities to mature at their stated maturity principal.

**(4) Accrued and Other Current Liabilities**

Accrued and other current liabilities consist of the following (in millions):

	<u>September 30, 2014</u>	<u>June 30, 2014</u>
Professional Fees	\$ 1.1	\$ 1.0
Salary and related costs	1.2	0.4
Research and development materials and services	0.8	0.8
Other accrued expenses	0.1	1.2
<b>Total accrued expenses and other liabilities</b>	<b>\$ 3.2</b>	<b>\$ 3.4</b>

**(5) Net Loss per share**

Basic and diluted loss per share has been computed based on net loss and the weighted-average number of common shares outstanding during the applicable period. For diluted net loss per share, common stock equivalents (shares of common stock issuable upon the exercise of stock options and unvested restricted stock units) are excluded from the calculation of diluted net loss per share as their inclusion would be anti-dilutive. The Company has excluded all anti-dilutive share-based awards to purchase common stock in periods indicating a loss, as their effect is anti-dilutive.

**Biota Pharmaceuticals, Inc.**

**Notes to Unaudited Condensed Consolidated Financial Statements  
(for the quarterly period ended September 30, 2014)**

The following table sets forth the computation of historical basic and diluted net loss per share.

	<b>Three Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
Net loss (in millions)	\$ (6.9)	\$ (3.9)
Weighted-average shares outstanding	35,029,300	28,291,665
Weighted- average shares outstanding adjusted using exchange ratio used to compute basic earnings per share	-	-
Dilutive effect of restricted stock and stock options	-	-
Shares used to compute diluted earnings per share	35,029,300	28,291,665
Basic loss per share	\$ (0.20)	\$ (0.14)
Diluted loss per share	\$ (0.20)	\$ (0.14)
Number of anti-dilutive share-based awards excluded from computation	2,517,636	1,688,529

Notes to Unaudited Condensed Consolidated Financial Statements  
(for the quarterly period ended September 30, 2014)

**(6) Licenses, Royalty Collaborative and Contractual Arrangements**

*Royalty agreements*

The Company entered into a royalty-bearing research and license agreement with GlaxoSmithKline (“GSK”) in 1990 for the development and commercialization of zanamivir, a neuraminidase inhibitor (“NI”) marketed by GSK as Relenza® to treat influenza. Under the terms of the agreement, the Company licensed zanamivir to GSK on an exclusive, worldwide basis and is entitled to receive royalty payments of 7% of GSK’s annual net sales of Relenza® in the U.S., Europe, Japan and certain other countries as well as 10% of GSK’s annual net sales of Relenza® in Australia, New Zealand, South Africa and Indonesia. The Relenza® patent portfolio is scheduled to expire as follows: December 2014 in the U.S., May 2015 in Australia, 2016 in the major countries of the European Union (EU), and July 2019 in Japan. On August 25, 2014, GSK filed an appeal to the United States Patent Trial Appeal Board in relation to U.S. Patent Application No. 08/737,141. GSK has verified that the Company will continue to receive royalties on the net sales of Relenza® in the United States beyond December 2014 to the extent that this patent application remains pending or is ultimately issued. The Company is unable at this time to determine the duration or the outcome of this appeal process, or how long this patent application will remain pending.

The Company also generates royalty revenue from the sale of laninamivir octanoate, which Daiichi Sankyo markets as Inavir® in Japan, pursuant to a collaboration and license agreement that the Company entered into with Daiichi Sankyo in 2009. In September 2010, laninamivir octanoate was approved for sale by the Japanese Ministry of Health and Welfare for the treatment of influenza in adults and children. Under the agreement, the Company currently receives a 4% royalty on net sales of Inavir® in Japan and is eligible to earn sales milestone payments. Under the collaboration and license agreement, the Company and Daiichi Sankyo have cross-licensed the world-wide rights to develop and commercialize the related intellectual property, and have agreed to share equally in any royalties, license fees, or milestone or other payments received from any third party licenses outside of Japan. Patents on laninamivir octanoate in Japan generally expire in 2024.

*Collaborative and contract arrangements*

In March 2011, the Company’s wholly owned subsidiary, Biota Scientific Management Pty Ltd., was awarded a contract by BARDA for the late-stage development of laninamivir octanoate on a cost-plus-fixed-fee basis, the total of which is not to exceed \$231.2 million. BARDA is part of the U.S. Office of the ASPR within the HHS. The BARDA contract was designed to fund and provide the Company with all technical and clinical data and U.S. based manufacturing to support the filing of a U.S. new drug application (“NDA”) with the FDA for laninamivir octanoate. The performance period of the BARDA contract commenced on March 31, 2011, and was intended to continue for five years. On May 7, 2014 HHS/ASPR/BARDA notified the Company of its decision to terminate the contract for the development of laninamivir octanoate for the convenience of the U.S. Government. The decision to terminate for convenience was the result of a recently concluded IPR. The Company has been and continues to work with ASPR/BARDA to close out this contract, which involves finalizing separate invoices and billings for those activities undertaken prior to and after the termination date, determining the nature and extent of any equitable adjustments for costs incurred after the termination date, and negotiating a final termination settlement. As of September 30, 2014, the Company had \$16.3 million in accounts receivable due from BARDA, which does not include \$4.9 million of revenue from services and the related accounts receivable that the Company has not recognized for costs that it believes it is entitled to be reimbursed for its terminated contract with BARDA and pursuant to applicable government regulations, but for which it potentially may not be fully reimbursed.

The Company is considered an active participant in the BARDA contract, with exposure to significant risks and rewards of commercialization relating to the development of laninamivir octanoate. Therefore, revenues from and costs associated with the contract are recorded and recognized on a gross basis in the consolidated statement of operations.

Biota Pharmaceuticals, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements  
(for the quarterly period ended September 30, 2014)

The following tables summarize the key components of the Company's revenues (in millions):

	Three Months Ended September 30,	
	2014	2013
	(in millions)	
Royalty revenue— Relenza®	\$ -	\$ -
— Inavir®	-	-
Service revenue under BARDA contract	0.7	12.2
Revenue under other contracts, grants and collaborations	-	0.1
Total revenue	\$ 0.7	\$ 12.3

(7) Share-based Compensation

For the three months ended September 30, 2014 and 2013, the Company recorded share-based compensation expense related to grants from equity incentive plans of \$0.4 million and \$0.3 million, respectively. No income tax benefit was recognized in the statements of operations and no share-based compensation expense was capitalized as part of any assets for the three months ended September 30, 2014 and 2013.

Stock Options

The fair value of each stock option award was estimated at its respective date of grant using the Black-Scholes method with the following assumptions:

	Three Months Ended September 30,	
	2014	2013
Weighted-average risk-free interest rate	1.70	—%
Dividend yield	—	—
Expected weighted-average volatility	0.82	—
Expected weighted-average life of options (years)	6.0	—
Weighted-average fair value of options granted	\$ 1.64	\$ —

The risk-free interest rate is based on the expected life of the option and the corresponding U.S. Treasury bond, which in most cases is the U.S. five year Treasury bond. The expected term of stock options granted is derived from actual and expected option behavior and represents the period of time that options granted are expected to be outstanding. The Company uses historical data to estimate option exercise patterns and future employee terminations to determine expected life and forfeitures. Expected volatility is based on the historical volatility of the Company's publicly-traded common stock.

	Number of Stock Options	Weighted Average Exercise Price Per Option	Weighted- Average Remaining Contractual Term	Aggregate Intrinsic Value (\$000)
Balance at June 30, 2014	2,463,369	\$ 9.09		
Granted	225,000	2.39		
Exercised	—	—		
Forfeited or expired	(417,904)	4.38		
Balance at September 30, 2014	<u>2,270,465</u>	<u>\$ 9.30</u>	<u>7.61</u>	<u>\$ -</u>

In August 2014, the Company's Board of Directors made a determination that a performance-based milestone was not achieved and as a result, performance-based stock options previously issued during fiscal 2014 will not vest and were cancelled.

The total intrinsic value of stock options exercised during the three month period ended September 30, 2014 was zero, and no cash proceeds were received by the Company. Further, no actual tax benefits were realized, as the Company currently records a full valuation allowance for all tax benefits due to uncertainties with respect to its ability to generate sufficient taxable income in the future.

Biota Pharmaceuticals, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements  
(for the quarterly period ended September 30, 2014)

The following tables summarize information relating to outstanding and exercisable options as of September 30, 2014:

Exercise Prices	September 30, 2014				
	Outstanding Weighted Average			Exercisable	
	Number of Shares	Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
\$ 2.30 — \$3.98	615,000	9.53	\$ 2.91	36,250	\$ 3.84
\$ 4.05	90,000	8.58	4.05	50,000	4.05
\$ 4.07	931,590	8.12	4.07	310,531	4.07
\$ 4.15 — \$93.36	633,875	4.86	23.91	418,875	33.71
	<u>2,270,465</u>	<u>7.61</u>	<u>\$ 9.30</u>	<u>815,656</u>	<u>19.28</u>

*Restricted and Market Stock Units (MSUs).* A summary of the Company's outstanding restricted stock and market stock unit (MSU) activity for the three months ended September 30, 2014 is as follows:

	Shares	Weighted Average Grant Date Fair Value
Outstanding at June 30, 2014	262,072	\$ 3.98
Awarded	—	—
Released	—	—
Forfeited	(14,901)	4.06
Unvested at September 30, 2014	<u>247,171</u>	<u>\$ 3.97</u>

In December 2013, the Company awarded 108,183 MSUs to employees that may vest on January 1, 2017. The vesting of these awards is subject to the respective employee's continued employment through this settlement period. Further, the number of MSUs granted represents the target number of units that are eligible to be earned based on the attainment of certain market-based criteria involving the Company's stock price. The number of MSUs actually earned, if any, is calculated upon the vesting of the award. Participants may ultimately earn between 0% and 250% of the target number of units granted based on actual stock performance. Accordingly, additional MSUs may be issued or currently outstanding MSUs may be cancelled upon final determination of the number of awards earned. Compensation expense, including the effect of forfeitures, is recognized over the applicable service period.

As of September 30, 2014 there was \$3.0 million of unrecognized share-based compensation expense related to all unvested share-based awards, not discounted for future forfeitures. This balance is expected to be recognized over a weighted-average period of two years.

Biota Pharmaceuticals, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements  
(for the quarterly period ended September 30, 2014)

**(8) Restructuring Charges**

The Company recognizes restructuring charges when a plan that materially changes the scope of its business or the manner in which that business is conducted is adopted and communicated to the impacted parties, and the expenses have been incurred or are reasonably estimable.

*Fiscal 2014 Restructuring Activity*

In the fourth quarter of fiscal 2014, the Company announced restructuring actions as a result of the termination of the BARDA contract for the convenience of the U.S. Government. These restructuring activities are expected to be completed in fiscal 2015.

The following is a reconciliation of the beginning and ending balances of the restructuring liability:

	Balance at June 30, 2014	Provision	Payments	Balance at September 30, 2014
Fiscal 2014 Restructuring Plans:				
Severance and employment costs	2.0	-	(0.6)	\$ 1.4
Total restructuring costs	\$ 2.0	\$ -	\$ (0.6)	\$ 1.4

The remaining severance and other employment costs of approximately \$1.4 million are scheduled to be paid in the second and third quarters of fiscal 2015.

**(9) Subsequent Event**

On November 5, 2014, the Company reached a partial settlement agreement with ASPR and BARDA pursuant to which ASPR/BARDA agreed to reimburse the Company an amount of \$4.7 million for all costs associated with the completion of the Phase 2 IGLOO clinical trial of laninamivir octanoate in adults that were incurred after the termination date of the Company's contract with BARDA.

## ITEM 2: Management's Discussion and Analysis of Financial Condition and Results of Operations

### FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In most cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plan," "intend," "anticipate," "believe," "estimate," "project," "predict," "forecast," "potential," "likely" or "possible", as well as the negative of such expressions, and similar expressions intended to identify forward-looking statements. These forward-looking statements include, without limitation, statements relating to:

- expenses we have incurred or may incur associated with the development of laninamivir octanoate that may not be reimbursed by U.S. Office of Biomedical Advanced Research and Development Authority ("BARDA") as a result of the termination of our contract with BARDA for the convenience of the U.S. Government on May 7, 2014;
- the amount and the timing of reimbursements we may receive from BARDA for costs incurred to develop laninamivir octanoate prior to May 7, 2014 or as a final termination settlement from BARDA as result of the termination of our contract with BARDA;
- the timing of the final close-out of the BARDA contract and what the final termination settlement may be;
- the timeframe in which we anticipate recognizing the vast majority, if not all, of the revenue from the recent partial settlement agreement reached with ASPR/BARDA;
- the plan to progress BTA-C585 into clinical development in 2015;
- the timing of completing the assessment of the data from the Phase 2 IGLOO study and subsequent interactions with the FDA;
- the timing of the initiation of a Phase2 trial with vapendavir for the treatment of HRV infections in patients with moderate to severe asthma;
- our anticipation that we will generally incur net losses from operations in the future due to our intention to continue to support the preclinical and clinical development of our product candidates;
- our future financing requirements, the factors that may influence the timing and amount of those requirements and our ability to fund them;
- the number of months that our current cash, cash equivalents and anticipated future proceeds from existing royalty-bearing licenses and other existing license and collaboration agreements will allow us to operate; and
- our plan to continue to finance our operations with our existing cash, cash equivalents and proceeds from existing or potential future royalty-bearing licenses, government contracts, or collaborative research and development arrangements, or through future equity and/or debt financings or other financing vehicles.



*These forward looking statements are subject to key risks and uncertainties including, without limitation: our ability to successfully negotiate a satisfactory final termination settlement with BARDA that appropriately reimburses us for costs incurred under our contract with BARDA associated with the development of laninamivir octanoate; we, the FDA or a similar foreign regulatory agency, a data safety monitoring board, or an institutional review board delaying, limiting, suspending or terminating the clinical development of any of our clinical development programs at any time for a lack of safety, tolerability, biologic activity, commercial viability, regulatory or manufacturing issues, or any other reason whatsoever; the safety or efficacy data from ongoing or future preclinical studies of any of our product candidates not supporting the clinical development of that product candidate; our ability to comply with applicable government regulations in various countries and regions in which we are conducting, or expect to conduct, clinical trials; our ability to manufacture and maintain sufficient quantities of preclinical and clinical trial material on hand to support and complete our preclinical studies or clinical trials on a timely basis; our ability to retain and recruit sufficient staff, including key executive management and employees, to manage our business; our ability to secure, manage and retain qualified third-party clinical research, preclinical research, data management, contract manufacturing and other similar vendors who we outsource many of our activities to and rely on to assist us in the design, development and implementation of the development of our product candidates; our third-party contract research, data management and manufacturing organizations fulfilling their contractual obligations on a timely basis or otherwise performing satisfactorily in the future; GlaxoSmithKline (“GSK”) and Daiichi Sankyo continuing to generate net sales from Relenza<sup>®</sup> and Inavir<sup>®</sup>, respectively, and otherwise continuing to fulfill their obligations under our royalty-bearing license agreements with them in the future; our ability to maintain, protect or defend our proprietary intellectual property rights from unauthorized use by others, or not infringe on the intellectual property rights of others; our ability to successfully manage our expenses, operating results and financial position in line with our plans and expectations; the condition of the equity and debt markets and our ability to raise sufficient funding in such markets; changes in general economic business or competitive conditions related to our industry or product candidates; and other statements contained elsewhere in this in this Quarterly Report on Form 10-Q and our 2014 Annual Report on Form 10-K.*

*There may be events in the future that we are unable to predict accurately, or over which we have no control. You should read this Form 10-Q and the documents that we reference herein and which been filed or incorporated by reference as exhibits completely and with the understanding that our actual future results may be materially different from what we expect. Our business, financial condition, results of operations, and prospects may change. We may not update these forward-looking statements, even though our situation may change in the future, unless we have an obligation under the federal securities laws to update and disclose material developments related to previously disclosed information. We qualify all of the information presented in this Form 10-Q, and particularly our forward-looking statements, by these cautionary statements.*

*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 Company, Ltd.*

*References to “we,” “us,” and “our” refer to Biota Pharmaceuticals, Inc. and its subsidiaries.*

*The following is a discussion and analysis of the major factors contributing to our results of operations for the three months ended September 30, 2014, and our financial condition at that date, and should be read in conjunction with the financial statements and the notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q.*

## **Company Overview**

We are currently focused on developing oral, small molecule compounds to treat a number of respiratory-related viral infections. Our most advanced clinical-stage program is laninamivir octanoate, a long-acting neuraminidase inhibitor (“NI”) that we have been developing for the treatment of influenza A and B. On August 1, 2014 we reported top-line safety and efficacy results from a randomized, double-blind, placebo-controlled, parallel-arm Phase 2 clinical trial comparing the safety and efficacy of a 40 mg and an 80 mg dose of laninamivir octanoate to placebo. We refer to this trial as IGL00. As compared to placebo, neither the 40 mg nor the 80 mg cohort achieved a statistically significant reduction in the median time to alleviation of influenza symptoms, the primary endpoint, as measured by the Flu-iiQ patient-recorded outcome questionnaire. Certain important secondary endpoints, including quantitative viral shedding, and secondary bacterial infections, as well as the time to alleviation of influenza symptoms for a number of subcomponents, did achieve statistically significant results for laninamivir octanoate treated cohorts compared to placebo. We intend to complete our analyses of the data from this trial and to discuss the results of this trial with the FDA to determine the appropriate primary endpoint for, and which patient reported outcome tools would be acceptable for use in, any prospective registration trials of laninamivir octanoate to treat uncomplicated influenza.

We are also developing BTA-798, also known as vapendavir. We have successfully completed two Phase 2 trials of vapendavir to date and recently completed additional Phase 1 bioavailability and drug-drug interaction studies of vapendavir in healthy volunteers. We plan to initiate a randomized, double-blind, placebo-controlled dose-ranging Phase 2 trial in moderate and severe asthmatic patients at risk of loss of asthma control due to presumptive human rhinovirus (“HRV”) infection in the first quarter of 2015.

In addition to these Phase 2 clinical-stage development programs, we are also developing orally bioavailable F and non-F protein compounds for the treatment of RSV infections in children, the elderly and immune-compromised patients. We are currently conducting IND-enabling studies with *BTA-C585*, the lead compound from our F-protein inhibitor program.

We previously developed zanamivir, a neuraminidase inhibitor that is marketed worldwide by GSK as Relenza<sup>®</sup>, for the prevention and treatment of influenza A and B. GSK markets Relenza<sup>®</sup> pursuant to a royalty-bearing research and license agreement we entered into with GSK in 1990. In 2003, we entered into a collaboration and license agreement with Daiichi Sankyo, under which each party cross-licensed its intellectual property related to second-generation, long-acting neuraminidase inhibitors, including FLUNET and laninamivir octanoate. In 2009, we entered into a commercialization agreement with Daiichi Sankyo that provided Daiichi Sankyo with an exclusive license to commercialize laninamivir octanoate in Japan and entitled us to a royalty on net sales of laninamivir octanoate in Japan. Laninamivir octanoate, which is marketed in Japan by Daiichi Sankyo as Inavir<sup>®</sup>, was approved for sale by the Japanese Ministry of Health and Welfare for the treatment of influenza A and B in adults and children in September 2010 and for the prevention of influenza A and B in December 2013. In 2009, we filed an IND with the FDA to develop laninamivir octanoate in the U.S.

In March 2011, we were awarded a contract from BARDA designed to provide up to \$231 million in support of the development of and submission for a New Drug Application (“NDA”) of laninamivir octanoate for the treatment of influenza A and B infections in the U.S. On April 23, 2014 the U.S. Department of Health and Human Services (“HHS”) office of the Assistant Secretary for Preparedness and Response (“ASPR”) and BARDA issued us a Stop Work Order, indicating that we should discontinue work on a number of activities under the contract pending a decision regarding the outcome of an In-Process Review (“IPR”) of the contract. On May 7, 2014 ASPR/BARDA further notified us of its decision to terminate this contract for the convenience of the U.S. Government based upon the results of the IPR. We continue to work with ASPR/BARDA to close out this contract, which involves finalizing invoices and billings, determining the nature and extent of any equitable adjustments, and negotiating a final termination settlement.

Although several of our influenza product candidates have been successfully developed and commercialized to date by other larger pharmaceutical companies under license, collaboration or commercialization agreements with us, we have not independently developed or received regulatory approval for any product candidate, and we do not currently have any sales, marketing or commercial capabilities. Therefore, it is possible that we may not successfully derive any significant product revenues from any product candidates that we are developing now, or may develop in the future. We expect to incur losses for the foreseeable future as we intend to support the clinical and preclinical development of our product candidates. Also, due to the recent termination of our contract with BARDA, we anticipate that our revenue from service and cost of revenue will decline substantially in the future as compared to recent historical levels.

We plan to continue to finance our operations with (i) our existing cash, cash equivalents and investments, (ii) proceeds from existing or potential future royalty-bearing licenses, government contracts, or collaborative research and development arrangements, (iii) future equity and/or debt financings, or (iv) other financing arrangements. Our ability to continue to support our operations is dependent, in the near-term, upon us managing our cash resources, our receipt of reimbursements and settlement proceeds from BARDA, receipt of royalty revenue under our existing licensees, entering into future collaboration, license or commercialization agreements, successfully developing our product candidates, executing future financings and ultimately, upon obtaining of our products for sale and achieving positive cash flows from operations on a consistent basis. There can be no assurance that additional capital or funds will be available on terms acceptable to us, if at all, or we will be able to enter into collaboration, license or commercialization agreements in the future, or that we will ever generate significant product revenue and become operationally profitable on a consistent basis.

## **Recent Corporate Developments**

*Changes to the Company’s Management and Board of Directors* - On September 26, 2014, we announced that the Board of Directors appointed Joseph M. Patti, PhD to the position of President and Chief Executive Officer, replacing Russell H. Plumb, who was appointed Executive Chairman of the Board of Directors. James Fox, PhD resigned as Chairman of the Board of Directors, but remains on the Board as its Lead Director. These changes became effective on October 1, 2014.

*BARDA Contract Termination* - As of September 30, 2014, we had \$16.3 million in accounts receivable due from BARDA, which did not include a total of \$4.9 million of cumulative contract service revenue and accounts receivable that we had not recognized as of that date for costs that we believe we are entitled to be reimbursed under our terminated contract with BARDA and pursuant to applicable government regulations, but for which it potentially may not be fully reimbursed. All of the costs associated with the \$4.9 million in unrecognized revenue have been expensed in our financial statements as of September 30, 2014.

On November 4, 2014, we reached a partial settlement agreement with the U.S. Department of Health and Human Services office of Assistant Secretary for Preparedness and Response (“ASPR”) and BARDA pursuant to which ASPR/BARDA agreed to reimburse us an amount of \$4.7 million for all costs associated with the completion of the Phase 2 IGLOO clinical trial of laninamivir octanoate in adults that were incurred after the termination date of our contract with BARDA. Based on this agreement with ASPR/BARDA, we now expect to recognize this amount as revenue in the quarter ending December 31, 2014. Further, as of September 30, 2014, approximately \$3.4 million of this \$4.7 million settlement amount was included as a component of the total \$4.9 million of contract service revenue and accounts receivable that we had not recognized as of that date.

Other discussions between us and ASPR/BARDA with respect to finalizing invoices for activities undertaken prior to the termination date as well as those activities undertaken after the termination date other than in association with the Phase 2 IGLOO trial, determining the nature and extent of any other equitable adjustments, and negotiating a final termination settlement remain ongoing. At this time, we cannot determine when and to what extent our other outstanding invoices will be approved and reimbursed by, or when a final termination settlement on all costs may be finalized with, ASPR/BARDA.

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

Management’s Discussion and Analysis of Results of Operations discusses our financial results, which (except to the extent described in the Notes thereto) have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

We base our estimates and judgments on historical experience, current economic and industry conditions, and various other factors that we believe to be reasonable under the circumstances. This forms the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies require significant judgment and estimates:

- Use of Estimates
- Revenue Recognition
- Accrued Expenses
- Share-Based Compensation

In August 2014, the Financial Accounting Standards Board issued authoritative accounting guidance related to management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. Management’s evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued. In doing so, the amendments should reduce diversity in the timing and content of footnote disclosures. This guidance is effective for public and nonpublic entities for annual periods ending after December 15, 2016, and interim periods thereafter. Early adoption is permitted. The Company is currently assessing the expected impact, if any, that this ASU will have on our consolidated financial statements.

In May 2014, the Financial Accounting Standards Board issued authoritative accounting guidance related to revenue from contracts with customers. This guidance is a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. This guidance is effective for annual reporting periods beginning after December 15, 2016 and early adoption is not permitted. We will adopt this guidance on January 1, 2017. We may use either a full retrospective or a modified retrospective approach to adopt this guidance. We are evaluating which transition approach to use and its impact, if any, on our consolidated financial statements.

## **Results of Operations**

### ***Three Months Ended September 30, 2014 and September 30, 2013***

*Summary.* For the three months ended September 30, 2014, we reported a net loss of \$6.9 million, as compared to a net loss of \$3.9 million in the same period of 2013. The \$3.0 million increase in net loss in 2014 was primarily due to a \$11.6 million decrease in revenue, a \$1.9 million increase in research and development expense and \$0.1 million reduction in income tax benefit, offset in part by a \$9.0 million decrease in cost of revenue and a \$1.6 million change from a foreign exchange loss in 2013 to a foreign exchange gain in 2014. Basic and diluted net loss per share was \$0.20 for the three month period ended September 30, 2014, as compared to a basic and diluted net loss per share of \$0.14 in the same period of 2013.

*Revenue.* Revenue decreased to \$0.7 million for the three months ended September 30, 2014 from \$12.3 million for the same period in 2013. The following table summarizes the key components of our revenue for the three months ended September 30, 2014 and 2013:

	<b>Three Months Ended September 30</b>	
	<b>(in millions)</b>	
	<b>2014</b>	<b>2013</b>
Royalty revenue— Relenza®	\$ -	\$ -
— Inavir®	-	-
Revenue from services	0.7	12.2
Revenue grants and other	-	0.1
<b>Total revenue</b>	<b>\$ 0.7</b>	<b>\$ 12.3</b>

Revenue from services decreased due to a decrease in contract service revenue related to the cancellation of our contract with BARDA in May 2014. Revenue from grants and other decreased due to a decrease in grant-related research activities.

*Cost of Revenue.* Cost of revenue decreased to \$1.7 million for the three months ended September 30, 2014 from \$10.7 million for the same period in 2013. The following table summarizes the components of our cost of revenue for the three months ended September 30, 2014 and 2013.

	<b>Three Months Ended September 30</b>	
	<b>(in millions)</b>	
	<b>2014</b>	<b>2013</b>
Direct preclinical, clinical and product development expenses	\$ 1.4	\$ 9.4
Salaries, benefits and share-based compensation expenses	0.2	1.2
Other expenses	0.1	0.1
<b>Total cost of revenue expense</b>	<b>\$ 1.7</b>	<b>\$ 10.7</b>

Direct preclinical, clinical and product development expense decreased due to the lower direct third-party clinical costs incurred associated with Phase 1 and 2 clinical trials and manufacturing activities for the laninamivir octanoate program under the recently terminated BARDA contract. Salaries, benefits and share-based compensation expense decreased primarily as a result of fewer personnel being allocated to work under the BARDA contract.

*Research and Development Expense.* Research and development expense increased to \$4.9 million for the three months ended September 30, 2014 from \$3.0 million for the same period in 2013. The following table summarizes the components of our research and development expense for the three months ended September 30, 2014 and 2013.

	<b>Three Months Ended September 30</b>	
	<b>(in millions)</b>	
	<b>2014</b>	<b>2013</b>
Direct preclinical, clinical and product development expenses	\$ 2.3	\$ 0.4
Salaries, benefits and share-based compensation expenses	1.6	1.5
Other expenses	0.3	0.4
Depreciation and facility related expenses	0.7	0.7
<b>Total research and development expense</b>	<b>\$ 4.9</b>	<b>\$ 3.0</b>

Direct preclinical, clinical and product development expense increased in the three months ended September 30, 2014 compared to the same period in 2013 due largely to an increase in direct clinical expenses associated with the startup of the pending Phase 2 clinical trial of vapendavir and preclinical expenses related to the ongoing IND-enabling studies associated with BTA-C585, our RSV fusion inhibitor. Salaries, benefits and share-based compensation slightly increased in the three months ended September 30, 2014 compared to the same period in 2013 due to a reallocation of personnel resources to the vapendavir and RSV programs from the BARDA program, offset in part by reductions in personnel.

*General and Administrative Expense.* General and administrative expense was \$2.4 million for each of the three month periods ended September 30, 2013 and 2014. The following table summarizes the components of our general and administrative expense for the three months ended September 30, 2014 and 2013.

	<b>Three Months Ended September 30</b>	
	<b>(in millions)</b>	
	<b>2014</b>	<b>2013</b>
Salaries, benefits and share-based compensation expenses	\$ 1.4	\$ 1.3
Professional and legal fees expenses	0.3	0.4
Other expenses	0.7	0.7
<b>Total general and administrative expense</b>	<b>\$ 2.4</b>	<b>\$ 2.4</b>

Salaries, benefits and share-based compensation expense increased in the three months ended September 30, 2014 compared to the same period in 2013 largely due to a slight increase in non-cash share-based compensation expense. Professional and legal fees expense decreased in the three months ended September 30, 2014 compared to the same period in 2013 primarily due to lower professional and legal expenses related to corporate matters.

*Foreign Exchange Gain, (Loss) net.* Foreign exchange gain increased by \$1.6 million to \$1.3 million for the three months ended September 30, 2014 from a foreign exchange loss of \$0.3 million for the same period in 2013 due to the increase in the value of the U.S. dollar as compared to the Australian dollar during the three month period ended September 30, 2014 and the related translation of foreign currency transactions in our subsidiaries that have a different functional currency than the reporting currency on our statement of operations. We translate all of the assets and liabilities of our non-U.S. subsidiaries at the period-end exchange rate and the net effect of these translation adjustments is shown on our condensed consolidated balance sheet as a component of stockholders' equity.

*Interest Income.* Interest income increased in the three months ended September 30, 2014 compared to the same period in 2013 due to the Company having a greater amount of investments in 2014 as compared to 2013.

## **LIQUIDITY AND CAPITAL RESOURCES**

For the three months ended September 30, 2014, cash and cash equivalents decreased by \$24.0 million, from \$81.7 million to \$57.7 million. This decrease was primarily the result of cash being used to purchase additional liquid short-term and long-term investments and operating activities during the period.

Net cash used in operating activities was \$11.6 million for the three months ended September 30, 2014, which reflected our net loss for the period of \$6.9 million and a net decrease in operating liabilities of \$6.3 million, offset in part by a decrease in net operating assets of \$0.8 million and non-cash charges for share-based compensation and depreciation of \$0.8 million.

Our net loss resulted largely from our funding of research and development activities including basic research, conducting preclinical studies, manufacturing and formulation of our product candidates, and ongoing general and administrative expenses, partially offset by contract service revenue and interest income. The net change in operating assets and liabilities reflects a \$5.7 million decrease in accounts payable and accrued expenses and a decrease of \$0.6 million in accrued severance obligations, offset in part by a \$0.6 million decrease in accounts receivable due to contract revenue received and a \$0.2 million decrease in prepaid expenses.

Net cash used in investing activities during the three months ended September 30, 2014 consisted of \$9.9 million for purchase of short-term and long-term investments.

At September 30, 2014, our cash and cash equivalents totaled \$57.7 million. Our cash and cash equivalents are currently held in the form of short-term deposits with large U.S. and Australian banks. Our investments totaling \$19.9 million consist primarily of U.S. treasury securities and U.S. government agency securities.

Our future funding requirements are difficult to determine and will depend on a number of factors, including:

- the variability of future royalty revenue we may receive from existing royalty-bearing license agreements;
- whether or not we continue to receive reimbursements and can negotiate an appropriate final termination settlements in the future, and the timing of those payments, under our recently-terminated contract with BARDA;
- the development timelines and plans for our product candidates, including any changes to those timelines, plans or our strategy;
- the variability, timing and costs associated with conducting clinical trials for our product candidates, the rate of enrollment in such clinical trials, and the results of these clinical trials;
- the variability, timing and costs associated with conducting preclinical studies, and the results of those studies;
- the cost of scaling up, formulating and manufacturing preclinical and clinical trial materials to evaluate our product candidates;
- whether we receive regulatory approval to advance or begin the clinical development of our product candidates in a timely manner, if at all;
- the cost and time to obtain regulatory approvals required to advance the development of our product candidates;
- the scope and size of our research and development efforts;
- our pursuit, timing and the terms of any in-licensing, acquisition, co-development, and other similar collaborative clinical-stage development opportunities we may pursue in the future to better balance our pipeline;
- the size and cost of our general and administrative function we may need to manage our operations, including the infrastructure to support being a publicly-traded company; and
- the cost of filing, prosecuting, and enforcing patent and other intellectual property claims.

Based on our current strategy and operating plan, and considering the potential costs associated with advancing the clinical development and preclinical development of our product candidates, we believe that our existing cash, cash equivalents of \$57.7 million and our liquid investments of \$19.9 million as of September 30, 2014, along with the anticipated proceeds from existing royalty-bearing licenses and proceeds from the close-out of our contract with BARDA, will enable us to operate for a period of at least 12 months from September 30, 2014.

We currently do not have any commitments for future funding, nor do we anticipate that we will generate significant revenue, aside from existing revenue from royalty-bearing arrangements, and contract services. Therefore, in order to meet our anticipated liquidity needs beyond 12 months to support the development of our product candidates, or possibly sooner in the event we enter into other transactions or revise our strategy or development plans, we may need to raise or secure additional capital. We would expect to do so primarily through the sale of additional common stock or other equity securities, as well as through proceeds from future licensing agreements, strategic collaborations, forms of debt financing, or any other financing vehicle. Funds from these sources may not be available to us on acceptable terms, if at all, and our failure to raise such funds could have a material adverse impact on our future business strategy and plans, financial condition and results of operations. If adequate funds are not available to us on acceptable terms in the future, we may be required to delay, reduce the scope of, or eliminate one or more of our research and development programs, or delay or curtail our preclinical studies and clinical trials, or reduce our internal cost structure. If additional capital is not available to us on acceptable terms, we may need to obtain funds through license agreements, or collaborative or partner arrangements pursuant to which we will likely relinquish rights to certain product candidates that we might otherwise choose to develop or commercialize independently, or be forced to enter into such arrangements earlier than we would prefer, which would likely result in less favorable transaction terms. Additional equity financings may be dilutive to holders of our common stock, and debt financing, if available, may involve significant payment obligations and covenants that restrict how we operate our business.

## **Contractual and Commercial Commitments**

There have been no material changes from the information included in our Annual Report on Form 10-K for the fiscal year ended June 30, 2014.

## **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements, as defined in Item 303(a)(4) (ii) of Regulation S-K under the Securities Exchange Act of 1934, as amended.

## **ITEM 3: Quantitative and Qualitative Disclosures about Market Risk**

There has been no material change in the Company's assessment of its sensitivity to market risk since its presentation set forth in Item 7A "Quantitative and Qualitative Disclosures about Market Risk" in the Company's Annual Report filed on Form 10-K for the fiscal year ended June 30, 2014.

## **ITEM 4: Controls and Procedures**

### ***Evaluation of Disclosure Controls and Procedures***

Our management, including our Chief Executive Officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report.

### ***Changes in Internal Controls over Financial Reporting***

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II – OTHER INFORMATION**

**ITEM 1A. RISK FACTORS**

There have been no material changes from the risk factors disclosed in the “Risk Factors” section of the Company’s Annual Report on Form 10-K for the fiscal year ended June 30, 2014.

**ITEM 6. EXHIBITS**

The exhibits to this report are listed in the Exhibit Index, which is incorporated into this Item 6 by reference.



## 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 thereunto duly authorized.

### **Biota Pharmaceuticals, Inc.**

Date: November 7, 2014

By: /s/ Joseph M. Patti  
Joseph M. Patti  
Chief Executive Officer  
(Principal Executive Officer)

By: /s/ Russell H. Plumb  
Russell H. Plumb  
Executive Chairman  
(Principal Financial Officer)

By: /s/ Peter Azzarello  
Peter Azzarello  
Vice President of Finance  
(Chief Accounting Officer)

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Title</b>	<b>Filed with this Form 10-Q</b>	<b>Incorporation by Reference</b>		
			<b>Form</b>	<b>File No.</b>	<b>Date Filed</b>
3.1	Composite Certificate of Incorporation of Biota Pharmaceuticals, Inc.		10-Q	001-35285	02/11/13
3.2	By-Laws of Biota Pharmaceuticals, Inc.		10-Q	001-35285	02/11/13
31.1*	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended	X			
31.2*	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended	X			
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350	X			
101	The following materials from the Biota Pharmaceuticals, Inc. Quarterly Report on Form 10-Q for the period ended September 30, 2014 formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets as of September 30, 2014 and June 30, 2014, (ii) the Condensed Consolidated Statements of Operations for the Three Months Ended September 30, 2014, and September 30, 2013, (iii) the Condensed Statements of Stockholders' Equity for the Three Months Ended September 30, 2014, (iv) Condensed Consolidated Statements of Cash Flows for the Three Months Ended September 30, 2014, and September 30, 2013, and (v) Notes to Condensed Consolidated Financial Statements	X			

\* This certification is being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of Biota Pharmaceuticals, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)  
AS ADOPTED PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, Joseph M. Patti, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Biota Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 7, 2014

By: /s/ Joseph M. Patti

Joseph M. Patti

Chief Executive Officer

(Principal Executive Officer)

**CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)  
AS ADOPTED PURSUANT TO SECTION 302 OF  
THE SARBANES-OXLEY ACT OF 2002**

I, Russell H Plumb, certify that:

6. I have reviewed this quarterly report on Form 10-Q of Biota Pharmaceuticals, Inc.;
7. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
8. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
9. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
10. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 7, 2014

By: /s/ Russell H Plumb

Russell H Plumb  
Executive Chairman  
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Biota Pharmaceuticals, Inc. (“the Company”) for the quarterly period ended September 30, 2014 (the “Report”), I, Joseph M. Patti, Chief Executive Officer of the Company, and Russell H. Plumb, Executive Chairman of the Company each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- To my knowledge, the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 7, 2014

By: /s/ Joseph M. Patti

Joseph M. Patti

Chief Executive Officer

(Principal Executive Officer)

By: /s/ Russell H Plumb

Russell H Plumb

Executive Chairman

(Principal Financial Officer)