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

Form 10-K

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

For the fiscal year ended June 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	**59-1212264**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*
2500 Northwinds Parkway, Suite 100, Alpharetta, GA	**30009**
(Address of Principal Executive Offices)	*(Zip Code)*

(678) 221 3343
(Registrant's telephone number, including area code)
Securities registered pursuant to section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value $.10 per share	**The Nasdaq Stock Market LLC** **NASDAQ Global Select Market**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 definition 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 aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price on December 31, 2013 was approximately 117.8 million.

Number of shares of Common Stock outstanding as of September 25, 2014: 35,100,961. The common stock is listed on the NASDAQ Global Select Market (trading symbol "BOTA")

Documents incorporated by reference:

Portions of the definitive Proxy Statement with respect to the 2014 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year are incorporated by reference into Part III of this report.

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ITEM 1. ***BUSINESS***

PART I
SPECIAL NOTE ON FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Securities Exchange Act of 1934, as amended. These forward-looking statements are principally contained in the sections entitled "Item 1-Business", "Item 2-Properties" and "Item 7-Management's Discussion and Analysis of Financial Condition and Results of Operations", but may appear elsewhere. All statements other than those of historical facts contained herein are forward looking statements, which reflect our current expectations and assumptions about the future. Forward looking statements involve known and unknown risks and uncertainties that may cause actual future results, performance, achievements or events to be materially different from any results, performance, achievements or events expressed or implied by the forward-looking statements. In general, you can identify forward-looking statements by terms such as, but not limited to, "may," "will," "should," "could," "would," "expect," "plan," "intend," "anticipate," "believe," "estimate," "project," "predict," "forecast," "potential," "continue," "target," "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, but are not limited to, statements relating to:

- *our plans surrounding the future clinical development of laninamivir octanoate;*
- *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 Stop-Work Order we received April 23, 2014 and 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;*
- *our plan and timing to initiate a Phase 2 trial for vapendavir in patients with moderate to severe asthma and our consideration of developing vapendavir for patients with chronic obstructive pulmonary disease ("COPD");*
- *our plan to complete IND-enabling studies to support the preclinical development of BTA-C585 for the treatment of infections caused by respiratory syncytial virus ("RSV") and our plans and timing to initiate a Phase 1 trial;*
- *our plan to consider licensing, merger and acquisition or other similar strategic transactions in order to bolster our clinical development pipeline;*
- *our plan to closely align our internal overhead costs with our estimated royalty revenue;*
- *our plans to out-license the rights to laninamivir octanoate outside of Japan in concert with* Daiichi Sankyo Company Ltd. ("Daiichi Sankyo")*;*
- *our anticipation that royalty revenue from net sales of Relenza® may decrease in fiscal 2015 due to the expiration of the composition of matter patents for Relenza® in the U.S. and the duration and outcome of the pending patent in the U.S.;*
- *our plan to complete an analysis of the Phase IGLOO data and any discussion of this data with the United States Food and Drug Administration ("FDA");*
- *our plans to advance the chemistry, manufacturing and controls ("CMC") for vapendavir to develop a new commercial grade, free-base tablet formulation;*
- *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 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 capacity to successfully enroll, manage and conduct worldwide clinical trials on a timely basis; 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, or that of our clinical research organizations or clinical investigators, to enroll a sufficient number of patients in our clinical trials on a timely basis; our ability to successfully identify and in-license or enter into co-development or other merger and acquisition agreements with third parties to obtain additional development programs on appropriate terms; 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”) or Daiichi Sankyo continuing to generate net sales from Relenza® and Inavir®, 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 financial 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 Annual Report on Form 10-K and the risk factors described in or referred to in greater detail in the “Risk Factors” section of this 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-K, as well as the documents that we reference herein and that have been filed or incorporated by reference as exhibits, completely and with the understanding that our actual future results may be materially different from our expectations. Our business, financial condition, results of operations, and prospects may change. We undertake no obligation to update these forward-looking statements, unless we are required by law. We qualify all of the information presented in this Form 10-K, and particularly our forward-looking statements, by these cautionary statements.

Biota is a registered trademark of Biota Pharmaceuticals, Inc., Relenza® is a registered trademark of GlaxoSmithKline plc, Inavir® is a registered trademark of Daiichi Sankyo Company, Ltd, and TwinCaps® is a registered trademark of Hovione FarmaCiencia SA.

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

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 are 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 80 mg dose of laninamivir octanoate to placebo. We refer to this trial as IGLOO. 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 have not received the full data set from this trial and anticipate continuing to assess this additional safety and efficacy data when received.

We are also developing BTA-798, also known as vapendavir, which is in Phase 2 for the treatment of human rhinovirus ("HRV") infections in patients with moderate to severe asthma. We have successfully completed two Phase 2 trials of vapendavir to-date and recently completed additional Phase 1bioavailability and drug-drug interaction studies in healthy volunteers that support its continued development.

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 NI that is marketed worldwide by GSK as Relenza®, for the prevention and treatment of influenza A and B. GSK markets Relenza® pursuant to a royalty-bearing research and license agreement we entered into with it 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 NI's, including FLUNET and laninamivir octanoate. In 2009, we entered into a commercialization agreement with Daiichi Sankyo that provided it with an exclusive license to commercialize laninamivir octanoate in Japan and entitled us to a royalty on those net sales. Laninamivir octanoate, which is marketed in Japan by Daiichi Sankyo as Inavir®, 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 Investigational New Drug application ("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. We continue to work with ASPR/BARDA to close out this contract, which involves completing several clinical trials, 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.

Background

We have historically focused our research and drug development capabilities on discovering and developing small molecule compounds that can prevent or treat infectious diseases. Infectious diseases are caused by pathogens that are present in the environment, such as viruses and bacteria, which enter the body through various means and overwhelm its natural defenses and cause an infection. The severity of an infectious disease varies depending on the nature of the infectious pathogen, as well as the degree to which the body's immune system or available therapies can prevent or fight the infection. The market for anti-infective drugs generally can be divided into three general categories: antiviral, antibacterial and antifungal. We are currently focused on developing antiviral compounds.

The use of antiviral drugs has led to a significant reduction in the morbidity and mortality associated with infectious diseases. However, for many infectious diseases, current treatment options, to the extent any such treatment options are currently available, are associated with suboptimal treatment outcomes, significant adverse or toxic side effects, the emergence of drug resistant pathogens, complex dosing schedules, and inconvenient methods of administration. These sub-optimal factors of existing treatments often lead to patients prematurely discontinuing treatment or not fully complying with treatment dosing schedules, resulting in a treatment failure. A patient's failure to comply fully with a recommended dosing schedule can both accelerate and exacerbate the emergence of drug-resistant strains. The ability of both viruses and bacteria to adapt rapidly to existing or new treatments through genetic mutations allows new strains to develop that may be resistant to currently available drugs. In recent years, the increasing prevalence of drug-resistant pathogens has created ongoing treatment challenges with respect to many infectious diseases.

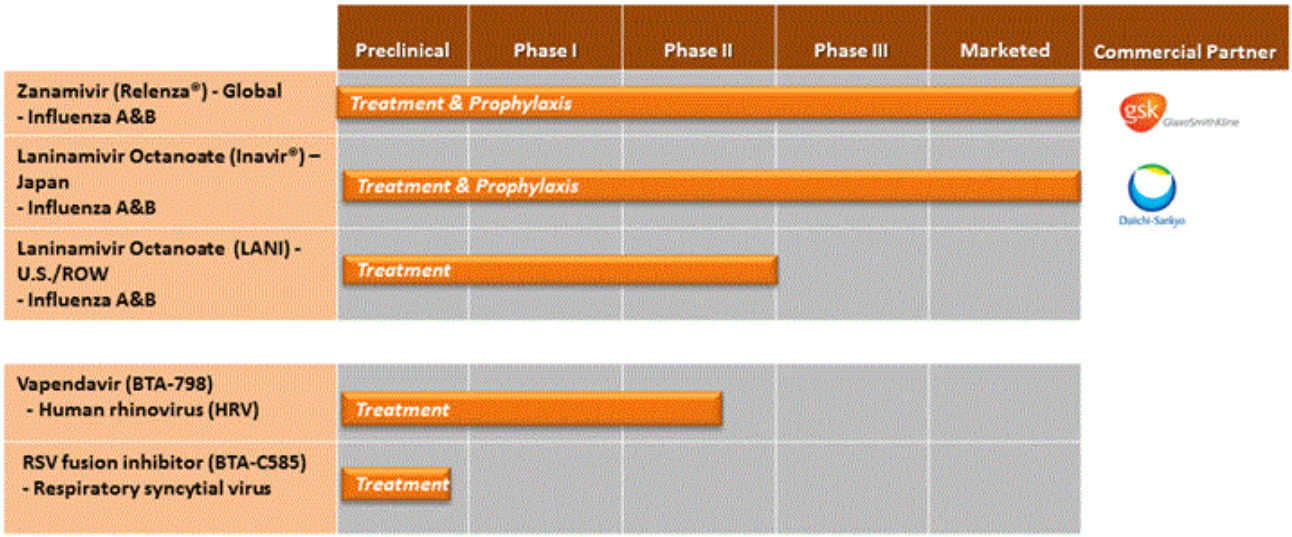
Viruses

Viruses are microscopic infectious agents consisting of an outer layer of protein surrounding a core of genetic material comprised of deoxyribonucleic acid ("DNA") or Ribonucleic acid ("RNA"). Viruses generally must invade healthy, living host cells in order to replicate and spread. In many cases, the body's immune system can effectively combat an infection caused by a virus. However, with certain viral infections, the body's immune system is unable to fully destroy or inhibit the replication of the virus, which results in persistent and ongoing viral replication and the subsequent infection of healthy cells by the virus. This ultimately leads to the deterioration or destruction of the infected cells, resulting in disease.

Viruses that develop resistance to existing antiviral drugs increasingly represent a major public health challenge. The existence of drug-resistant strains, and the ability of viruses to mutate spontaneously during replication, allow drug-resistant strains to emerge when patients do not comply with a dosing regimen, or use drugs that are not potent enough to quickly and completely inhibit viral replication. Drug resistance occurs due to the fact that viruses continually replicate and can make millions of copies of themselves every day, some of which will contain mutations in their genetic material. Mutations that emerge in the presence of a suppressive antiviral drug will give rise to mutant strains that are wholly or partially resistant to that drug. These mutant viruses, while initially low in number, eventually become the predominant strain in an infected patient as the strains that remain susceptible to the drug are inhibited from replicating. Once this occurs, the treatment benefit of that particular antiviral drug often diminishes, resulting in treatment failure and the need for an alternate therapy with different or possibly new drugs, or classes of drugs.

Our Pipeline

The following chart summarizes key information regarding our antiviral product candidates:



Influenza

Seasonal influenza, or the flu, is an acute viral infection caused by an influenza virus. There are three types of seasonal influenza – A, B and C. Type A influenza viruses are further typed into subtypes according to the different kinds and combinations of virus surface proteins. Among the many subtypes of influenza A viruses, currently influenza A(H1N1)pmd09 and influenza A(H3N2) are the most common subtypes circulating among humans. Type C influenza cases occur much less frequently than A and B.

Seasonal influenza is characterized by a sudden onset of high fever, headache, muscle and joint pain, severe malaise (feeling unwell), cough (usually dry), sore throat and a runny nose. Most people recover from fever and most other symptoms within a week without requiring medical attention. However, influenza can cause severe illness, hospitalization or death in people at high risk, which include the very young, the elderly and the chronically ill. The time from infection to illness, known as the incubation period, is generally about two days. Influenza epidemics generally occur annually during the autumn and winter in temperate regions. According to the World Health Organization ("WHO"), annual epidemics result in about three to five million cases of severe illness and about 250,000 to 500,000 deaths worldwide. Most deaths associated with influenza in industrialized countries occur among people ages 65 or older.

Controlling influenza virus infections continues to be a major public health challenge. Despite increasingly widespread vaccination, influenza remains a significant burden that can give rise to a potential crisis, even in communities with advanced health care. In 2010, the Centers For Disease Control and Prevention ("CDC") estimated that from 1976-2007, influenza caused an average of 23,607 deaths per year in the U.S. Immunization is the primary form of preventing influenza infection. However, the efficacy of influenza vaccination varies, decreasing with age, and for seasonal influenza is dependent on how well matched the chosen vaccine is with the emergent circulating virus. In pandemic influenza outbreaks, vaccines can only be developed following identification of the pandemic strain, which results in vaccines not being available immediately. These limitations of vaccination emphasize the importance of and need for antiviral drugs to treat and prevent influenza.

Market Opportunity for the Treatment of Influenza

Data from the CDC suggest that each year 5-20% of the population (16-63 million according to 2012 U.S. population estimates) suffers from seasonal influenza, and approximately 200,000 people in the U.S. are hospitalized each year for respiratory and heart conditions associated with seasonal influenza infections.

The market opportunity for antivirals to prevent or treat influenza, and their utilization in the seasonal influenza market, is often difficult to project given the year-to-year variability in the circulating strain of influenza, the severity of influenza illness, and the length of the influenza season. Further, if there is a year in which a pandemic occurs, the variability in the market potential is magnified. IMS retail prescription data covering the 2007/2008 – 2011/2012 influenza seasons indicated that average annual combined sales of oseltamivir phosphate (Tamiflu®) and zanamivir (Relenza®) in the U.S., Japan, and the European Union (“EU”) over that three year period, were approximately $409 million, $259 million, and $32 million, respectively, which reflects total annual seasonal sales in these three markets of approximately $700 million. In addition to this seasonal influenza market, government stockpiling of antivirals to prevent or treat influenza have historically contributed significantly to the overall market opportunity.

Antiviral Drugs for Influenza

While vaccines play an important role in the prevention of influenza, the benefit of being vaccinated can be significantly reduced in the event there is a sub-optimal match between the seasonal influenza vaccine available in any given year and the circulating influenza virus. Therefore, antivirals play an important role in the prevention and management of influenza. There are two classes of antiviral agents used to prevent and/or treat influenza: neuraminidase inhibitors, or NI’s, and adamantanes.

NI’s are generally effective against all human, avian and animal influenza viruses. NIs inhibit the release of virions by competitively inhibiting viral neuraminidase, which is a key glycoprotein at the surface of the virus. Currently there are two NIs that have been approved worldwide for the prevention and treatment of acute, uncomplicated illness due to influenza A and B: oseltamivir phosphate (Tamiflu®) and zanamivir (Relenza®). In addition to these two drugs, laninamivir octanoate (Inavir®) is approved in Japan for the prevention and treatment of influenza A and B, and intravenously administered peramivir is approved in Japan (Rapiacta®) and Korea (PeramiFlu®) for the treatment of influenza.

Adamantanes (amantadine and rimantadine) are generally not recommended as stand-alone treatment for influenza due to their lack of activity against influenza B, as well as a high level of influenza A resistance.

Limitations of Current Therapies for the Treatment of Influenza

Oseltamivir-resistant influenza viruses are a recognized public health issue. During the 2007-2008 Northern Hemisphere influenza season there was a significant increase in the frequency of seasonal H1N1 influenza viruses carrying the highly oseltamivir-resistant H274Y mutation. This spontaneously occurring oseltamivir-resistant mutation became prevalent worldwide in the 2008-2009 influenza season, and continues to circulate today. Furthermore, although pandemic (H1N1)2009 has remained largely susceptible to oseltamivir phosphate, sporadic cases of resistance have been reported. To the contrary, to date there have been no clinically significant reports of zanamivir or laninamivir octanoate resistance in circulating influenza A (H1N1) viruses, or any other human influenza viruses. The potential for oseltamivir resistance in any given influenza season, together with the recent spread of pandemic (H1N1)2009 (swine origin), highlight the need for the development of new options for the treatment of influenza.

The frequency of dosing and patient compliance with the currently approved drugs for the treatment of uncomplicated influenza is another potential limitation that can be improved upon. For adults, the dosing regimen for oseltamivir phosphate and zanamivir is twice a day for five consecutive days. In contrast, laninamivir octanoate (Inavir®) is a one-time inhaled treatment. We believe this more convenient dosing regimen may result in better patient compliance as compared to both oseltamivir phosphate and zanamivir.

Laninamivir Octanoate

In 2003, we cross-licensed intellectual property related to a new class of inhaled long acting NI's with Daiichi Sankyo. The lead product from this collaboration is LANI, also known as CS-8958, a second-generation octanoyl ester pro-drug of laninamivir. Laninamivir has been shown to have *in vitro* neuraminidase-inhibitory activity against various influenza A and B viruses, including subtypes N1 to N9 and oseltamivir-resistant viruses, and it has also been found to be effective against a swine origin H1N1 strain. Moreover, laninamivir octanoate has long-lasting antiviral activity. Preclinical studies in mice have demonstrated that after intranasal administration, it was rapidly converted to its active metabolite, laninamivir, which was retained in the lungs where it had a long half-life of approximately 40 hours. Further, a single intranasal dose of laninamivir octanoate exhibited efficacy similar to that of repeated doses of zanamivir or oseltamivir phosphate.

LANI was successfully developed by Daiichi Sankyo in Japan and since 2010 has been marketed there as Inavir® for the treatment of influenza A and B infections. In December 2013, Inavir® was approved for use in the post-exposure prevention of influenza. Since 2009, we have been developing LANI under an IND in the U.S. for the treatment of influenza A and B.

Laninamivir Octanoate Clinical Trials

Phase 2. In June 2013, we commenced enrollment in a multi-national, randomized, double blind, placebo controlled, parallel arm Phase 2 clinical trial that compared the safety and efficacy of 40 mg and 80 mg of laninamivir octanoate with placebo, all delivered by a TwinCaps® inhaler in adults with symptomatic influenza A or B infection. The trial, which we refer to as "IGLOO", was designed to enroll 636 subjects, randomized equally across the three treatment arms. The primary endpoint of the IGLOO trial was the reduction in the median time to alleviation (reported to be mild or absent for greater than 24 hours) of seven influenza symptoms (headache, feeling feverish, body aches and pains, fatigue, cough, sore throat and nasal congestion) plus fever (<38^{o}C), compared to placebo. Symptom data were collected through the Flu-iiQ™ patient-recorded outcomes ("PRO") questionnaire. Secondary end points included quantitative changes in virus shedding, evaluating whether the use of laninamivir octanoate reduces the incidence of secondary bacterial infections compared to placebo, the development of resistance by phenotypic and genotypic analyses, and the impact of treatment with laninamivir octanoate on the quality of life.

On August 1, 2014, we announced top-line data from the IGLOO trial. We enrolled a total of 639 patients across 12 countries in the northern and southern hemispheres from June 2013 to April 2014. Of the 639 patients enrolled, 248, or 39%, had PCR confirmed influenza A or B virus and were included in the intent-to-treat efficacy analyses. Approximately 75% and 19% of the influenza-confirmed patients were infected with influenza A H1N1 2009 and H3N2, respectively, while 6% were infected with influenza B. 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 the seven influenza symptoms. The median time to alleviation of the seven influenza symptoms was 102.3 hours for the 40 mg cohort and 103.2 hours for the 80 mg cohort, as compared to 104.1 hours for the placebo cohort.

Although neither the 40 mg nor the 80 mg laninamivir octanoate cohorts achieved a statistically significant difference compared to placebo for the entire seven symptom primary endpoint, notable effects were seen in individual symptoms, the subset of systemic symptoms (headache, feeling feverish, body aches and pains and fatigue) and a number of key secondary endpoints. Subjects in the 40 mg cohort reported alleviation of the subset of systemic symptoms significantly earlier as compared to placebo (median time 58 hours and 72 hours, respectively, p=0.007). Patients in the 40 mg cohort also reported a significant reduction in the number of days in which all seven symptoms were severe (p=0.02) and in secondary bacterial infections as compared to placebo (0% compared to 7.8% of placebo recipients; p=0.013). Patients in the 40 mg (p<0.001) cohort demonstrated a statistically significant reduction in viral shedding on Day 3 of the study compared to placebo as quantified by qRT-PCR. In addition, a statistically significant proportion of patients in both the 40 mg (p=0.002) and 80 mg (p=0.02) cohorts were culture negative on Day 3 of the study as compared to placebo. The nature and extent of adverse events were similar in the three cohorts, with diarrhea (3.1% vs. 0.9%), headache (1.4% vs. 0.5%), gastritis (1.4% vs. 0%), urinary tract infection (1.4% vs. 0%), and sinusitis (1.2% vs. 0.9%) being the most common adverse events that occurred more frequently in the treatment cohorts as compared to placebo. The incidence of serious adverse events was low and balanced across the three cohorts. We anticipate additional safety and pharmacokinetic ("PK") data to be available shortly.

We are in the process of completing an analysis of the full safety, pharmacokinetic, and Flu-iiQ™ data from this trial. We intend to complete these analyses and 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, prospective registration trials of laninamivir octanoate to treat influenza.
In addition to the Phase 2 IGLOO trial, we also initiated a Phase 1/2 clinical trial of laninamivir octanoate in December 2013 in pediatric patients (aged 5-17) that were infected with influenza A or B. We enrolled 15 patients in this trial through April 2014, of which 89% were PCR-positive. As a result of the termination of the BARDA contract, we recently terminated this study and anticipate that the safety and efficacy data analyses from this study and an abbreviated clinical study report will be completed over the next several months.

Phase 1. In May 2014, we completed two Phase 1 clinical trials of laninamivir octanoate; one to evaluate its safety and pharmacokinetics in patients with chronic asthma and the other being a QT/QTc study to evaluate the effect of therapeutic (40 mg) and supra-therapeutic (240 mg) doses of laninamivir octanoate on the QT-interval.

The safety profile of 40 mg and 80 mg doses of laninamivir octanoate by inhalation via the TwinCaps® DPI in adults with mild or moderate chronic asthma demonstrated that inhaled laninamivir octanoate was well tolerated. Treatment with inhaled laninamivir octanoate at therapeutic antiviral doses did not result in significant changes in lung function as measured by spirometry. These results suggest that inhaled laninamivir octanoate can be safely administered to asthma patients. Top-line results of the QT/QTc study indicate laninamivir octanoate was not associated with any clinically significant electrocardiogram ("ECG") changes, no serious adverse events ("SAEs") occurred, no subjects terminated the study or the study treatment due to an adverse event and a low proportion of subjects experienced adverse events during the study treatments. Between these two recent Phase 1safety studies, a total of 211 subjects participated and, of these, 118 received inhaled laninamivir octanoate at doses ranging from 40 mg to 240 mg.

Prior to initiating the Phase 2 IGLOO trial in June 2013, we completed three other Phase 1 trials of inhaled laninamivir octanoate. These trials provided safety and pharmacokinetic data at single doses of laninamivir octanoate ranging from 5 to 40 mg in healthy volunteers aged 18 to 77 years, and at multiple doses up to 40 mg (twice daily for 3 days or twice weekly for 6 weeks) in healthy volunteers aged 20 to 47 years. A total of 94 subjects were enrolled in these studies, with 70 of those receiving laninamivir octanoate. In healthy adult volunteers, laninamivir octanoate was generally well tolerated at single doses up to 120 mg and at multiple doses up to 40 mg administered twice daily for three days or twice weekly for six weeks.

Daiichi Sankyo Clinical Trials. Daiichi-Sankyo has conducted a number of clinical trials that it used to support the 2010 approval of laninamivir octanoate (Inavir®) in Japan. These clinical trials include seven Phase 3 studies, four Phase 2 studies and eight Phase 1 studies of inhaled laninamivir octanoate at single doses up to 120 mg, and multiple doses up to 40 mg. The results of a number of these clinical studies have been published. Data pooled from a total of 21 clinical trials indicate that the most common adverse events ("AE's") in subjects were diarrhea (4.6%), nausea (1.03%) and nasopharyngitis (1.89%). The majority of adverse events ("AEs") across the clinical studies were mild in intensity. As of March 2014, we estimate that approximately 8.1 million patients have been exposed to laninamivir octanoate in post-market use in Japan. Commonly reported adverse drug reactions ("ADRs") in the post-marketing period are abnormal behavior, diarrhea/nausea and dizziness, with most ADRs occurring within three days of dosing.

BARDA Contract for Laninamivir Octanoate

In March 2011, our wholly owned subsidiary, Biota Scientific Management Pty Ltd., was awarded a contract from BARDA for the late-stage development of laninamivir octanoate on a cost-plus-fixed-fee basis, the total of which was not to exceed $231.2 million. BARDA is part of ASPR within HHS. The BARDA contract was designed to fund and provide us with all technical and clinical data, as well as U.S. based manufacturing, to support the filing of a NDA with the FDA for laninamivir octanoate.

On April 23, 2014, we were notified by HHS office of ASPR and BARDA that pending a decision regarding the outcome of a recently completed IPR of our contract for the development of laninamivir octanoate, ASPR/BARDA had issued a Stop-Work Order notifying us to discontinue work on a number of activities under this contract. On May 7, 2014, HHS and ASPR/BARDA notified us of their decision to terminate our contract with BARDA for the convenience of the U.S. Government based upon this IPR. Certain activities ongoing at the time of termination, particularly those associated with the recently-concluded Phase 1 trials of laninamivir octanoate, were excluded from the termination notice and will continue until completed.

We continue to work with ASPR/BARDA to close out this contract, which involves completing several clinical trials, finalizing invoices and billings for those activities undertaken pursuant to the contract, determining the nature and extent of any equitable adjustments and negotiating a final termination settlement. As of June 30, 2014, we recorded $17.8 million in accounts receivable due from BARDA, which does not include $3.7 million of contract service revenue and accounts receivable that we did not recognize related to amounts for which we believe we are entitled to be reimbursed under our terminated contract with BARDA and pursuant to applicable government regulations, but for which we potentially may not be fully reimbursed. The terms and conditions contained in the vast majority of our agreements with our sub-contractors under the BARDA agreement are such that we are obligated to pay these sub-contractors only when and to the extent that we are reimbursed by BARDA. As such, to the extent that BARDA does not reimburse us for allowable costs incurred, we may not be obligated to reimburse our subcontractors. At this time, we cannot determine when certain invoices will be approved and reimbursed by, or when a final termination settlement may be finalized with, BARDA, or what the final financial outcome resulting from the termination of the BARDA contract may be.

Human Rhinovirus (HRV), Asthma and COPD

Market Opportunity for the Treatment of HRV, Asthma and COPD

Human rhinoviruses (“HRV”) are non-enveloped, single-stranded viruses that belong to the *Picornaviridiae* family. Currently more than 100 distinct serotypes of HRV are classified into three species, HRV-A, HRV-B, and HRV-C. HRV infection is not only the most frequent cause of the common cold, but is also associated with more severe lower respiratory tract illnesses including pneumonia and exacerbations among individuals with chronic lung diseases, such as asthma and COPD. A 2008 study in the U.S. indicated that the incidence of colds among those with asthma was 1.4 per subject-year.

Asthma is a common disease with underlying inflammation of the airways that affects an estimated 300 million people worldwide and 25 million people in the United States. In 2011, Datamonitor estimated that 10 million people in the U.S. were classified as having moderate to severe asthma. Acute deterioration of symptoms and lung function, which often results in respiratory failure, is classified as an “exacerbation”. Acute asthma exacerbations are a major healthcare burden, accounting for almost half of the total healthcare costs associated with this disease, and also have a major impact on the quality of life and in some cases can cause death. Recent studies in adults with asthma have documented an association between respiratory tract infection and worsening asthma symptoms, decline in lung function, and exacerbations. Respiratory viruses, and in particular HRV, are an important cause of exacerbations. In a recent study of asthma patients with cold-like symptoms, 63% of the patients had respiratory viruses that were detected by qPCR and the majority of samples (68%) contained HRV.

Exacerbations are important sequelae of HRV infection and their prevention has historically been the focus of asthma drug development. In recent years asthma treatment guidelines have also focused on asthma control as an important goal. Asthma control is defined by a global assessment of symptoms, use of rescue medications, lung function, and patient-reported functioning and activity limitations. The Asthma Control Questionnaire ("ACQ-6") is a patient reported outcome ("PRO") tool often used to measure a drug's therapeutic impact on the worsening of asthma symptoms. In general, a well-controlled asthma patient has an ACQ score of ≤ 0.75 and a patient with uncontrolled asthma has an ACQ score of ≥ 1.50. An improvement in ACQ score of ≥ 0.5 is generally considered indicative of a clinically meaningful change. Although there are several FDA approved drugs for the treatment of asthma, none are directed at respiratory viruses, including HRV.

COPD is the most common chronic respiratory condition in adults whose prevalence is expected to continue to increase in the future. Currently, the WHO estimates that 64 million people have moderate to severe COPD worldwide. In the U.S. there are an estimated 28 million individuals over the age of 40 with COPD, with an annual average growth rate of 1.9%. Further, of the estimated 28 million COPD patients in the U.S., approximately 13 million people are classified as having moderate to severe/very severe COPD.

Similar to asthma, HRV was the most common virus detected during exacerbations of COPD. Colds often precede exacerbation symptoms, and in an experimental HRV challenge study, the HRV load was highest at day 5 post-challenge. In this experimental challenge study, HRV infection showed more severe and prolonged lower respiratory symptoms, airway obstruction, and neutrophilic airway inflammation in COPD patients than in subjects without COPD. In addition, a recent natural exposure study in COPD patients demonstrated that HRV prevalence and viral load at exacerbation presentation were significantly higher than in the stable state. Further, the HRV viral load was elevated in COPD patients that presented to the clinic, consistent with the experimental challenge model, suggesting that viral replication may be ongoing, and antiviral therapy may be an effective treatment modality to prevent or reduce the severity of exacerbations.

There are currently no direct antiviral drugs approved for the treatment of HRV. As such, there remains a significant unmet medical need to identify treatments that can reduce the impact that HRV infection has on the frequency of exacerbations and loss of control, prevent viral transmission, lessen the severity and duration of cold-like HRV symptoms and minimize secondary bacterial infections in asthma and COPD patients.

Vapendavir (BTA798)

HRV accesses respiratory tract cells by attaching to a receptor on the cell surface. Canyon-like clefts on the surface, or capsid, of the virus attach to the receptor which precedes virus infection of the cell. We are developing vapendavir (BTA798), a potent antiviral capsid binder that is designed to bind to a highly conserved pocket in the floor of the canyon and interfere with receptor binding and/or related early steps in the infectious cycle. Vapendavir is a potent inhibitor of picornaviruses and has been shown to inhibit the replication of a wide range of HRV serotypes and the replication of a majority of recent HRV clinical isolates in tissue culture assays. The median EC50 value for vapendavir against the 100 HRV serotypes was 5.8 ng/mL(15.2 nM). Vapendavir has also demonstrated antiviral activity against other clinically relevant enteroviruses (EV) including EV- 71 and poliovirus types 1, 2 and 3.

We currently plan to initiate a randomized, double-blind, placebo-controlled dose-ranging Phase 2 study in moderate and severe asthmatic patients at risk of loss of asthma control and exacerbation due to presumptive HRV infection in the first quarter of 2015. This study will be conducted at approximately 60 sites across six to eight countries in North America and Central Europe with an anticipated enrollment being targeted of approximately 375 randomized subjects. The therapeutic effect of two different doses of vapendavir on asthma control following HRV infection will be assessed, as will the safety and tolerability of vapendavir, the prevention of asthma exacerbations, virology outcomes, lung function tests, and the effect on symptoms of HRV. The planned primary endpoint is the Least Square (LS) mean change from baseline to Study Day 14 in ACQ-6 total score. Planned secondary endpoints include the proportion of subjects with a moderate or severe asthma exacerbation during the interval of Study Days 1-14, the LS mean change from baseline to Study Day 7, 21 and 28 in ACQ-6 total score, and the maximum decrease in clinic-based forced expiratory volume in one second (FEV1) during Study Days 1-14 as a percent of Study Day 1 level. The primary efficacy analysis population will be the ITT-infected population defined as all subjects with confirmed HRV infection (by either RVP or RT-PCR on any of Study Days 1, 3, 5, or 7).

In addition to investigating the therapeutic potential of vapendavir in moderate to severe asthma patients in this planned Phase 2 trial, we are also considering a clinical development plan in COPD patients.

Vapendavir Clinical Trials

Phase 1. In July 2014, we completed enrollment in two Phase 1 trials of vapendavir. One, entitled 'A Randomized, Single-Center, Open-Label, Two-Period, Two-Sequence, Crossover, Comparative Study to Compare the Oral Bioavailability of Single Doses of Two Vapendavir Drug Product Formulations in Healthy Volunteers' was undertaken to establish the systemic exposure profile of a single dose of a vapendavir free-base tablet formulation compared to the exposure profile following a single dose of two vapendavir phosphate salt capsules, which was the formulation used in prior clinical trials. Thirty-six subjects received a single dose of the capsule formulation or the tablet formulation in period 1 and, after a washout, crossed over to receive a single dose of the other formulation in Period 2 of the study, according to their sequence treatment assignment. Of the 36 subjects randomized, 34 completed both periods of the study and were evaluable for the primary pharmacokinetic ("PK") assessment, which was a comparison of the drug exposure between the two formulations. Two subjects prematurely terminated after the completion of study period 1; one due to an adverse event of viral syndrome considered unrelated to study drug treatment and one subject withdrew consent for continued study participation. No serious adverse events (SAEs) occurred during the study. The PK results demonstrated that the free-base tablet formulation achieved approximately 60% of the mean bioavailability as the phosphate salt capsule formulation. The half-life and time to peak concentration (Tmax) were comparable between the two formulations. We intend to use the existing capsule formulation for the planned Phase 2 study in moderate to severe asthma patients. We also plan to conduct additional formulation activities on the free-base formulation to further improve its characteristics and intend to use this formulation in any future development of vapendavir beyond the currently planned Phase 2 trial. We filed a patent application for this free-base formulation in 2014, which, if issued, would expire in 2034, not including extensions.

The second Phase 1 trial we recently completed was a drug-drug interaction study entitled 'A Phase 1b, Randomized, Open-Label Study to Evaluate the Effect of Vapendavir (BTA798) on the Pharmacokinetics of Orally Administered Midazolam, a CYP3A4 Substrate, in Healthy Male and Female Volunteers'. We undertook this study to assess the effect of vapendavir on the PK profile of midazolam, a CYP3A4 substrate. Additionally, the effect of midazolam on the PK profile of vapendavir, the PK profile differences of vapendavir in males and females, and the safety profile of vapendavir were assessed. Twelve male and 12 female subjects aged 18 to 55 years were randomized to receive one of two oral doses of vapendavir and midazolam. Of the 24 subjects randomized, 22 completed all study visits. No SAEs occurred during the study. The results of the study confirmed vapendavir's pharmacokinetic profile as established in prior clinical trials and that vapendavir is a weak to moderate inducer of CYP3A4, which suggests that vapendavir can be used to treat asthma and COPD patients receiving multiple background medications.

Phase 2b. In March 2012, we completed a 300-patient, Phase 2b clinical trial of vapendavir that evaluated the safety and efficacy of 400 mg of vapendavir, dosed twice daily for six days, for the treatment of HRV infections in patients with mild to moderate asthma. The trial successfully met its primary endpoint, which was a reduction of cold symptoms based on the Wisconsin Upper Respiratory Symptom Survey ("WURSS-21") severity score. Vapendavir was generally tolerated and most treatment-related adverse events were of mild intensity, with moderate treatment-related events reported in 2.3% of subjects.

Phase 2a. In 2009, we completed a Phase 2a placebo-controlled, double-blind, randomized, parallel group trial to determine the potential of 25 mg, 100 mg and 400 mg of vapendavir, when dosed twice daily for 10 days, to prevent experimental HRV infection (challenge design) in 41 healthy volunteers. Subjects that received 400 mg of vapendavir achieved a statistically significant reduction compared to placebo in mean viral load on Days 2 to 5 inclusive. Vapendavir was generally well tolerated, and the overall incidence of adverse events was low, not dose dependent, and was similar to placebo. There was one SAE of neutropenic sepsis in a subject in the 100 mg arm of the trial.

Phase 1. In 2006, we completed a Phase 1, placebo-controlled, single and multiple oral dose, safety, tolerability and pharmacokinetic study in 56 healthy volunteers. Single oral doses of 25 mg, 50 mg, 100 mg, 200 mg, 400 mg, 800 mg or 1600 mg of vapendavir were evaluated. Vapendavir was generally well tolerated and there were no dose limiting toxicities or trends in adverse events or laboratory parameters observed, with the incidence and nature of adverse events similar between placebo recipients and all dosing groups of vapendavir. In a subsequent multiple ascending dose trial evaluating 200 and 400 mg of vapendavir, administered either once a day ("QD") or twice a day ("BID") for seven or eight consecutive days, vapendavir was well tolerated. There were no SAE's and there were no dose limiting toxicities or clinically relevant changes in vital signs, ECG or laboratory parameters observed.

Respiratory Syncytial Virus (RSV)

RSV, a member of the *Paramyxoviridae* family of viruses, is a major cause of acute upper and lower respiratory tract infections in infants, young children, and adults. Datamonitor estimates that approximately 18 million people are infected annually with RSV in the seven major markets, including over 9 million children under the age of four, 5.5 million elderly, and 3 million adults with underlying disease. About 900,000 of these individuals are hospitalized for their RSV infection. These infections are particularly problematic in infants, as approximately 91,000 infants are hospitalized with RSV infection in the U.S. in any given year. RSV infections are also responsible for 40 to 50% of hospitalizations for pediatric bronchiolitis and 25% of hospitalizations for pediatric pneumonia. In addition to pediatric patients, elderly patients with cardiac or pulmonary conditions and adults that have received a bone marrow transplant are at an increased risk for severe RSV infection. The overall magnitude of hospitalizations makes RSV a costly disease, although mortality is low.

To date, only three drugs have been approved to either prevent or treat RSV infections. Ribavirin is used to treat serious RSV infections in infants with severe bronchiolitis and in immunocompromised patients. However, its use is restricted due to highly variable efficacy and toxicity risks. In fact, current American Academy of Pediatrics guidelines for the treatment of bronchiolitis in children do not recommend the routine use of ribavirin to treat RSV infection due to lack of clinical evidence supporting its use. Antibody-based products RespiGam® (no longer available) and Synagis® (palivizumab) were designed, developed and approved to prevent, not treat, RSV infections in high risk premature infants. Due to the high cost of treatment with Synagis®, its use is limited in many hospitals. There remains a significant unmet need for a safe and effective treatment for RSV in all at-risk populations.

BTA-C585

Our preclinical RSV antiviral programs are focused on orally bio-available F (fusion) protein and non-F protein inhibitors. Our lead compound, *BTA-C585*, is an F-protein inhibitor whose mechanism of action is believed to be via inhibition of fusion of the viral envelope to the cell membrane of the host cell. Laboratory data has demonstrated that BTA-C585 exhibits potent antiviral activity against RSV A and B clinical isolates. *In vitro* studies in various tissues from multiple species, including humans, indicate that BTA-C585's cellular toxicity (CC_{50}) ≥ 100 μM. Data we presented at 54th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) Meeting in Washington, DC (ICAAC) included the results from a number of *in vivo* studies designed to assess the antiviral activity of BTA-C585 prior to and during experimental RSV infection in a cotton rat model, which demonstrated a dose-dependent decrease in virus titers in lung tissue. Similarly, a highly significant dose-dependent decrease in RSV mRNA in lung tissue was also observed in the cotton rat model. Further, preliminary, non-clinical oral, single and multiple-dose data from several animal toxicology studies indicated that BTA-C585 was highly bioavailable and well tolerated.

We have initiated IND-enabling studies on *BTA-C585*, and subject to the successful completion of these studies, we plan to file an IND and initiate a Phase 1 clinical trial in mid-2015.

Our Strategy

Our goal is to become a leading biopharmaceutical company that develops differentiated products that can prevent and treat serious infections. In order to achieve this goal, in the near-term we intend to employ the following strategy:

- *Focus Our Resources on the Development of our Antiviral Product Candidates*. We plan to focus our resources primarily on further developing vapendavir to treat patients with moderate to severe asthma and possibly COPD, and advancing our preclinical RSV program. More specifically, over the next year we intend to:

  - evaluate the safety and efficacy of vapendavir in a Phase 2 clinical trial in adult patients with moderate to severe asthma that are infected with HRV, which we intend to initiate in the first quarter of 2015;
  - advance our CMC for vapendavir to develop a free-base formulation;
  - evaluate the potential of advancing vapendavir into clinical development plan in patients with COPD; and
  - complete our ongoing IND-enabling studies of BTA-C585 (our RSV fusion inhibitor) with the intent to file an IND and commence Phase 1 clinical studies in mid-2015.

- *Manage Our Internal Research, Development and General and Administrative Expenses at a Level that is Reasonably Similar to Our Anticipated Royalty Revenues*. Upon the anticipated completion of our restructuring plan in mid-2015, we intend to manage our operations such that the costs of supporting our internal research, development and general and administrative activities are generally in line with the revenue we anticipate receiving from royalty revenues from the net sales of Inavir® and Relenza®. By doing so, we intend to conserve the majority of our cash on hand and short and long term investments for use towards (i) the direct external costs of engaging various clinical research, manufacturing or similar third-party organizations, vendors or consultants to assist us in advancing our vapendavir and RSV development programs, or other programs we may discover or obtain in the future.

- *Evaluate and Consider In-licensing, Merger, Acquisition, Co-development or Other Similar Transactions to Bolster our Clinical-Stage Development Pipeline*. We intend to proactively consider a range of corporate development or other strategic transactions that can bolster our pipeline and enhance the creation of shareholder value. While we intend to generally focus our evaluation on development programs targeting infectious, respiratory and inflammatory diseases, we may consider other opportunistic situations.

- *Seek to Out-license laninamivir octanoate*. Subject to our analysis of the full data set from the Phase 2 IGLOO study, we intend to pursue a license agreement, or other similar transaction, with larger third-party pharmaceutical or biopharmaceutical companies that have greater clinical development, manufacturing and commercialization capabilities than we do that we believe could advance the development and/or commercialization of laninamivir octanoate.

Research and Development

Our research and development expense in fiscal 2014, 2013 and 2012 was $17.5 million, $19.2 million and $24.1 million, respectively. In 2015, we plan to focus our research and development resources primarily on (i) the clinical development of vapendavir in patients with moderate to severe asthma and possibly COPD and (ii) completing the ongoing IND-enabling studies of *BTA-C585* with the intent to file an IND and commence Phase 1 clinical studies in mid-2015.

Our basic research and discovery activities, including medicinal chemistry, virology, and cell culture assays have historically been conducted by our research staff in our laboratory facility in Melbourne, Australia. We plan to close this facility by the end of June, 2015. Once this facility is closed and our planned reduction in staff is completed, we will no longer have these internal research, discovery and development resources to support work on discovery stage projects or our current pipeline. We currently do not have any plans to build similar laboratory facilities or hire staff to conduct research, discovery and certain development activities. To the extent we conduct these activities in the near-future, we anticipate that we will outsource them and rely on third-party vendors and consultants.

Sales and Marketing

We currently do not have any commercialization or sales and marketing capabilities, and we have no plans to invest in or build such capabilities internally in the near-term, if ever. At this time, we anticipate partnering, collaborating with or licensing certain rights to our development programs to other larger pharmaceutical or biopharmaceutical companies in the future to support the late stage development and commercialization of our product candidates. However, other than our existing license and commercialization agreements with GSK and Daiichi Sankyo, we may decide not to license any commercialization rights to our product candidates in the future.

Manufacturing

We currently do not own or operate any facilities in which we can formulate, manufacture, fill or package our product candidates. With respect to laninamivir octanoate, we currently rely on a single group of contract manufacturers to produce our drug substance, the TwinCaps® dry powder inhaler device, and to fill and package the materials required to conduct clinical trials under current good manufacturing practices, (“cGMP”). For vapendavir and our RSV preclinical program, we currently use a number of contract manufacturers to produce our drug substance and to fill and package materials for preclinical studies and clinical trials. If an existing contract manufacture fails to deliver on schedule, or at all, or fails to manufacture our material is accordance with their or our specifications and/or FDA regulations, it could significantly delay or interrupt the development or commercialization of our product candidates and affect our operating results and estimated timelines. We have used contract manufacturers to produce all of the clinical trial material used in the preclinical studies and clinical trials we have conducted to-date.

Competition

The pharmaceutical and biotechnology industries are intensely competitive. Many companies, including biotechnology, chemical and pharmaceutical companies, are actively engaged in activities similar to ours, including research and the development of product candidates for the treatment of infectious diseases. Many of these companies have substantially greater financial and other resources, larger research and development staffs, and more extensive marketing and manufacturing capabilities than we do. In addition, some of them have considerably more experience in preclinical testing, conducting clinical trials and other regulatory approval procedures. There are also academic institutions, governmental agencies and other research organizations that are conducting research in areas in which we are working. We expect to encounter significant competition for any of the product candidates we plan to develop. Companies that complete clinical trials obtain required regulatory approvals and commence commercial sales of their products before their competitors may achieve a significant competitive advantage.

The pharmaceutical market for products that prevent or treat influenza is very competitive. Key competitive advantages for laninamivir octanoate may include its single administration treatment regimen, its antiviral resistance profile, and to-date, its reported safety profile. A number of NIs are currently available in the U.S. and/or other counties, including Japan, for the prevention and/or treatment of influenza. These include oseltamivir phosphate from Hoffmann-La Roche Ltd. (“Roche”), which is marketed as Tamiflu®, zanamivir from GSK, which is marketed as Relenza®, laninamivir octanoate from Daiichi Sankyo, which is marketed as Inavir®, and peramivir from Shionogi & Co., Ltd, which is marketed as Rapiacta®. Biocryst, Inc. has filed a NDA in the U.S. for peramivir. Roche’s and GSK’s NIs are approved for both the prevention and treatment of influenza, and both Roche and GSK have intravenous therapy formulations of oseltamivir and zanamivir in clinical development. In addition to NIs, there are other companies working to develop antiviral drugs with other mechanisms of action to be used against various strains of influenza.

We anticipate that laninamivir octanoate, if ever successfully developed and approved, would compete directly or indirectly with drugs that will be “generic” by the time laninamivir octanoate may be approved for sale. Generic drugs are drugs whose patent protection has expired, which generally have an average selling price substantially lower than drugs protected by patents and intellectual property rights. Unless a patented drug can sufficiently differentiate itself from a competing generic drug in a meaningful manner, the existence of generic competition in any indication will generally impose significant pricing pressure on competing patented drugs.

Currently, there are no approved direct-acting antiviral drugs to treat HRV or RSV infections. However, our vapendavir product candidate would indirectly compete with drugs approved to reduce the incidence of exacerbations in patients with asthma and COPD, such as fluticasone propionate (Advair®), tiotoprium bromide (Spiriva®), fluticasone furoate/vilanterol (Breo Ellipta®), and roflumilast (Daliresp®). In addition to these approved drugs, there are compounds at the clinical development stage, such as inhaled ß-interferon, that if successfully developed for the treatment of HRV infections could compete with vapendavir. We also anticipate that our preclinical RSV compound *BTA-C585*, if successfully developed, may compete with GS-5806 and AL-8176, Phase 2 investigational drugs in development for the treatment of RSV infections in the event any of these compounds are ever approved for sale.

Intellectual Property Rights and Patents

Patents and other proprietary intellectual rights are crucial in our business and industry, and establishing and maintaining these rights are essential to justify the cost to develop and commercialize any of our product candidates and products. We have sought, and intend to continue to seek, viable and strategic intellectual property rights, including, but not limited to, patent protection for our inventions, and intend to rely upon patents, trade secrets, confidential information, know-how, trademarks, improvements in our technological innovations and licensing opportunities to develop and maintain a competitive advantage for our products and product candidates. In order to protect our intellectual property rights, we typically require employees, consultants, collaborators, advisors, potential partners, service providers and contractors to enter into confidentiality agreements with us, generally stating that they will not disclose our confidential information to third parties for a certain period of time, and will otherwise not use our confidential information for anyone’s benefit but ours.

The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, the patentability of subject matter we claim in our patent applications, the breadth of the claims ultimately granted, or their enforceability cannot be predicted. For this reason, we may not have or be able to obtain or maintain worldwide patent protection for any or all of our products and product candidates, and our intellectual property rights may not be protected or legally enforceable in all countries throughout the world. In some cases we may rely upon data exclusivity or similar exclusivities, although there is no guarantee that data exclusivity will be available or obtained in any jurisdiction. Further, as the publication of discoveries in the scientific and/or patent literature often lags behind the actual discoveries, we cannot be certain that we or our licensors were the first to make the inventions described in our patent applications or that we or our licensors were the first to file patent applications for such inventions.

Pursuant to the terms of the Uruguay Round Agreements Act, patents filed on or after June 8, 1995 in the U. S. have a term of 20 years from the date of filing, regardless of the period of time it may take for the patent to ultimately issue. This may shorten the period of patent protection afforded to our products as patent applications in the biopharmaceutical sector often take considerable time to issue. Under the Drug Price Competition and Patent Term Restoration Act of 1984, a sponsor may obtain marketing exclusivity for a period of time following FDA approval of certain drug applications, regardless of patent status, if the drug is a new chemical entity or if new clinical studies were used to support the marketing application for the drug.

Zanamivir, a neuraminidase inhibitor approved for the treatment and prevention of influenza A and B, is marketed worldwide as Relenza® by GSK. The Relenza® patent portfolio, which is solely owned by us and exclusively licensed to GSK, is scheduled to expire as follows: December 2014 in the U.S., May 2015 in Australia, 2016 in the major countries of the EU, and July 2019 in Japan. However, GSK has verified that we will continue to receive royalties on the net sales of Relenza® in the U.S. beyond December 2014 to the extent that U.S. Patent Application No. 08/737,141 remains pending. On August 25, 2014, GSK filed an appeal to the United States Patent Trial Appeal Board in relation to this pending patent application. While we cannot determine the duration or the outcome of this appeal process, or how long this patent application will remain pending, if the patent claims are ultimately issued, we expect that we would be eligible to receive royalties from net sales of Relenza® in the U.S. for an additional 17 years from the date of allowance.

Laninamivir octanoate, a long acting NI for the treatment and prevention of influenza A and B, is currently marketed as Inavir® in Japan by Daiichi-Sankyo. The patent relating to the structure of laninamivir octanoate expires in 2017 in the U.S., the EU and Japan. The patent relating to hydrates and the crystalline form of laninamivir octanoate actually used in the product expires in 2021(not including extensions) in the U.S. and EU and in 2024 in Japan. The dry-powder inhaler device patent portfolio, which includes TwinCaps®, is owned by Hovione International Limited (“Hovione”) and is exclusively licensed to us and Daiichi Sankyo worldwide for the prevention and treatment of influenza and other influenza-like viral infections. These patents will expire in 2029 in the U.S., and in 2027 in the EU and Japan.

Vapendavir, is an oral antiviral, is being developed to treat HRV infections. We exclusively own the vapendavir patent portfolio, and issued claims under this portfolio will begin to expire in some countries in December 2021, not including extensions. Claims filed in recent patent applications related to a free-base form of vapendavir, if allowed, would extend coverage until 2034, without extensions, however we cannot make any assurance that these claims will be allowed.

We also own a patent portfolio focused on developing oral antivirals for RSV. Our RSV patent portfolio is comprised of a number of patent filings directed to several compound series, with the earliest projected expiries of such patents ranging from late-2024 to late-2031. Issued patent claims covering BTA-C585 will begin to expire in 2031.

Patent Term Restoration/Extension and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval for the intended use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term, or extension, of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product’s approval date. Subject to certain limitations, the patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a NDA plus the time between the submission date of an NDA and the approval of that application, up to a total of five years. Only one patent applicable to an approved drug is eligible for the extension. The application for such extension must be submitted prior to the expiration of the patent and within 60 days of the drug’s approval. The United States Patent and Trademark Office (“USPTO”), in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, we may apply for restoration of patent term for one or more of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the Federal Drug, Food and Cosmetic Act ("FDCA") can also delay the submission or the approval of certain applications of other companies seeking to reference another company's NDA. The FDCA provides a five-year period of non-patent data exclusivity within the U.S. to the first applicant to obtain approval of a NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an Abbreviated New Drug Application ("ANDA"), or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. We cannot assure you that we will be able to take advantage of either the patent term extension or marketing exclusivity provisions of this law.

Pediatric exclusivity is another type of exclusivity available in the U.S. Pediatric exclusivity, if granted, provides an additional six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or the patent term, may be granted based on the voluntary completion of a pediatric study in accordance with a FDA request for such a study. The current pediatric exclusivity provision was reauthorized in September 2007 as part of the Food and Drug Administration Amendments Act.

Licenses and Agreements

GSK

In 1990, we entered into a royalty-bearing research and license agreement with GSK for the development and commercialization of zanamivir, a NI marketed by GSK as Relenza® to prevent and treat influenza. Under the terms of the agreement, we licensed zanamivir to GSK on an exclusive, worldwide basis and are 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 and 10% in Australia, New Zealand, South Africa and Indonesia to the extent that the underlying patents in those respective countries do not expire. 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 EU, and July 2019 in Japan. GSK has recently verified that we will continue to receive royalties on the net sales of Relenza® in the U.S. beyond December 2014 to the extent that U.S. Patent Application No. 08/737,141 remains pending. On August 25, 2014, GSK filed an appeal to the United States Patent Trial Appeal Board in relation to this patent application. We are unable at this time to determine the duration or the outcome of this appeal process, or how long this patent application will remain pending. If the patent claims are ultimately issued, we would expect to be eligible to receive royalties from net sales of Relenza® in the U.S. for an additional 17 years from the date of allowance.

Daiichi Sankyo

In 2003, we entered into collaboration and license agreement with Daiichi Sankyo related to the development of second generation long acting NIs, including laninamivir octanoate. Under the collaboration and license agreement, we and Daiichi Sankyo cross-licensed the right to develop, make, use, sell or offer for sale, or import products based on our respective intellectual property related to our long acting NIs. A primary focus of the agreement was for the parties to collectively seek third-party licensees that could develop and commercialize the related long-acting NIs on a worldwide basis. In the event that the related intellectual property was out-licensed to a third party, we would share equally with Daiichi Sankyo in any future royalties, license fees, milestones or other payments received from such a licensee. Further, although it was the intention of the parties to seek a third-party licensee or licensees worldwide, the parties retained the right to market or co-market related products in the U.S. and other markets outside of Japan, and any sales made by either party in the U.S. would result in the selling party paying the other party a royalty rate that was half of the royalty rate paid by any other third-party licensee. To date, there have been no third-party licenses granted pursuant to this agreement; therefore a royalty rate on net sales outside of Japan has not been established.

In March 2009, we entered into a commercialization agreement with Daiichi Sankyo, pursuant to which Daiichi Sankyo obtained exclusive marketing rights in Japan for long acting NI's, including laninamivir octanoate, covered by the 2003 collaboration and license agreement between the parties. In consideration for these rights, Daiichi Sankyo agreed to pay us a royalty rate equal to 4% or potentially higher in certain circumstances, on net sales in Japan. In September 2010, laninamivir octanoate (Inavir®) was approved for sale by the Japanese Ministry of Health and Welfare for the treatment of influenza in adults and children. Accordingly, under this agreement, we currently receive a 4% royalty on net sales of Inavir® in Japan and are eligible to earn sales milestone payments.

Hovione

On January 25, 2007, together with Daiichi Sankyo, we entered into an exclusive license agreement with Hovione for the use of its proprietary dry-powder inhaler technology for prevention and treatment of influenza and other influenza-like viral infections with laninamivir octanoate or any other long-acting NI selected by us or Daiichi Sankyo during the term of the agreement. Under the terms of the agreement, in the event we sublicense laninamivir octanoate administered by the dry-powder inhaler to a third-party, we will owe Hovione a sublicense fee and a royalty on net sales. In the event we or Daiichi Sankyo commercialize laninamivir octanoate administered by the dry-powder inhaler outside of Japan, the terms, conditions, and any royalty rate due to Hovione have not yet been determined. The license agreement terminates with expiration of the last patent claim covering the dry-powder inhaler intellectual property used. These claims are currently scheduled to expire in 2029 in the U.S., and in 2027 in the EU and Japan.

BARDA Contract for the Development of Laninamivir Octanoate

In March 2011, our wholly owned subsidiary, Biota Scientific Management Pty Ltd., was awarded a contract from BARDA for the late-stage development of laninamivir octanoate on a cost-plus-fixed-fee basis, the total of which was not to exceed $231.2 million. BARDA is part of ASPR within HHS. The BARDA contract was designed to fund and provide us with all technical and clinical data, as well as U.S. based manufacturing, to support the filing of a NDA with the FDA for laninamivir octanoate.

On April 23, 2014, we were notified by the HHS office of ASPR and BARDA that pending a decision regarding the outcome of a recently completed IPR of our contract for the development of laninamivir octanoate, ASPR/BARDA had issued a Stop-Work Order notifying us to discontinue work on a number of activities under this contract. On May 7, 2014, the HHS office of ASPR and BARDA notified us of their decision to terminate our contract with BARDA for the convenience of the U.S. Government based upon this IPR. Certain activities ongoing at the time of termination, particularly those associated with the recently-concluded Phase 1 trials of laninamivir octanoate, were excluded from the termination notice and will continue until completed.

We continue to work with ASPR/BARDA to close out this contract, which involves completing several clinical trials, finalizing invoices and billings for those activities undertaken pursuant to the contract, determining the nature and extent of any equitable adjustments and negotiating a final termination settlement. As of June 30, 2014, we had $17.8 million in accounts receivable due from BARDA, which does not include $3.7 million of contract service revenue and accounts receivable that we did not recognize related to amounts that we are entitled to be reimbursed for under our terminated contract with BARDA and pursuant to applicable government regulations, but for which we potentially may not be fully reimbursed. The terms and conditions contained in the vast majority of our agreements with our sub-contractors under the BARDA agreement are such that we are obligated to pay these sub-contractors only when and to the extent that we are reimbursed by BARDA. As such, to the extent that BARDA does not reimburse us for allowable costs incurred, we may not be obligated to reimburse our subcontractors. At this time, we cannot determine when certain invoices will be approved and reimbursed by, or when a final termination settlement may be finalized with, BARDA, or what the final financial outcome resulting from the termination of the BARDA contract may be.

Regulatory Matters

Overview

The preclinical and clinical testing, manufacture, labeling, storage, distribution, promotion, sale, export, reporting and record-keeping of drug products and product candidates is subject to extensive regulation by numerous governmental authorities in the U.S., principally the FDA and corresponding state agencies, and similar regulatory authorities in other countries.

Non-compliance with applicable regulatory requirements can result in, among other things, total or partial suspension of the clinical development, manufacturing and marketing of a product or product candidate, the refusal of the FDA or similar regulatory authorities in other countries to grant marketing approval, the withdrawal of marketing approvals, fines, injunctions, seizure of products and criminal prosecution.

U.S. Regulatory Approval

Pursuant to FDA regulations, we are required to successfully undertake a long and rigorous development process before any of our product candidates can be marketed or sold in the U.S. This regulatory process typically includes the following steps:

- the successful completion of satisfactory preclinical studies under the FDA's good laboratory practices ("GLP") regulations;
- the submission and acceptance of an IND that must be reviewed and accepted by the FDA and become effective before human clinical trials may begin;
- the approval of an Institutional Review Board ("IRB") at each site or location where we plan to conduct a clinical trial to protect the welfare and rights of human subjects in clinical trials;
- the successful completion of a series of adequate and well-controlled human clinical trials to establish the safety, potency, efficacy and purity of any product candidate for its intended use, which conform to the FDA's good clinical practice ("GCP") regulations;
- the development and demonstration of manufacturing processes that conform to FDA-mandated current Good Manufacturing Practices ("cGMPs"); and
- the submission to, and review and approval by, the FDA of a New Drug Application ("NDA") prior to any commercial sale or shipment of a product.

Successfully completing this development process requires a substantial amount of time, risk and financial resources. We cannot assure you that this process will result in the granting of an approval for any of our product candidates on a timely basis, if at all, or that we will have sufficient financial resources to see the process for any of our product candidates through to completion.

Preclinical Studies

Preclinical studies generally include laboratory, or *in vitro*, evaluation of a product candidate, its chemistry, formulation, stability and toxicity, as well as certain *in vivo* animal studies to assess its potential safety and biologic activity. We must submit the results of these preclinical studies, together with other information, including manufacturing records, analytical data and proposed clinical trial protocols, to the FDA as part of an IND, which must be reviewed by the FDA and become effective before we may begin any human clinical trials. An IND generally becomes effective approximately 30 days after receipt by the FDA, unless the FDA, within this 30-day time period, raises material concerns or questions about the intended conduct of the proposed trials and imposes what is referred to as a clinical hold or partial clinical hold. If one or more of our product candidates is placed on clinical hold, we may be required to resolve any outstanding issues to the satisfaction of the FDA before we can begin, or continue, clinical trials of such product candidates. Preclinical studies supportive of an IND generally take a year or more to complete, and there is no guarantee that an IND based on those studies will become effective, thus allowing human clinical testing to begin.

Certain preclinical studies must be conducted in compliance with the FDA's GLP regulations and the U.S. Department of Agriculture's Animal Welfare Act. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring such studies to be conducted again.

Clinical Trials

The clinical trial phase of drug development occurs after a successful IND submission, and involves the activities necessary to demonstrate the safety, tolerability, biologic activity, efficacy and dosage of an investigational new drug substance in humans, as well as the ability to produce the drug substance in accordance with the FDA's cGMP requirements. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial and the parameters to be used in assessing the safety and the activity or efficacy of the product candidate. Each clinical trial protocol must be submitted to the FDA under the IND prior to beginning the trial. Each trial, and the related clinical protocol, must be reviewed, approved and conducted under the auspices of an IRB and, with limited exceptions, requires the patient's informed consent to participate in the trial. Sponsors, investigators, and IRBs also must satisfy extensive GCPs, including regulations and guidelines for obtaining informed consent from the study subjects, complying with the protocol and investigational plan, adequately monitoring the clinical trial, and reporting any SAEs on a timely basis.

Clinical trials to support a NDA for marketing approval are typically conducted in three sequential phases: Phase 1, 2 and 3. Data from these activities are compiled in a NDA for submission to the FDA requesting approval to market the drug. These phases may be compressed, may overlap, or may be omitted in some circumstances. The FDA may also require sponsors to conduct Phase 4 clinical trials after market approval to study certain safety issues or other patient populations.

- *Phase 1*: After an IND becomes effective, Phase 1 human clinical trials can begin. A product candidate is typically introduced either into healthy human subjects or in certain cases, patients with the medical condition for which the product candidate is intended to be used. Generally, the purpose of a Phase 1 trial is to assess a product candidate's safety and the ability of the human body to tolerate it at different dose levels. Absorption, metabolism, distribution and pharmacokinetic trials are also generally performed at this stage. Phase 1 trials typically evaluate these aspects of the investigational drug in both single and multiple doses.

- *Phase 2*: During Phase 2 clinical trials, a product candidate is generally studied in an exploratory trial or trials in a limited number of patients with the disease or medical condition for which it is intended to be used in order to (i) further identify any possible adverse side effects and safety risks, (ii) assess the preliminary or potential effectiveness or biologic activity of the product candidate for specific targeted diseases or medical conditions, and (iii) assess dose tolerance and determine the optimal dose for a subsequent Phase 2 or Phase 3 trial. Phase 2 trials generally involve patients who are divided into one or more groups that will get one of several dose levels of the product candidate, and a control group that is not treated with the product candidate but either receives a placebo or a drug already on the market for the same indication. Typically, two or more Phase 2 studies will be conducted for a product candidate prior to advancing to Phase 3.

- *Phase 3*: If and when one or more Phase 2 trials demonstrate that a specific dose or range of doses of a product candidate is potentially effective and has an acceptable safety and tolerability profile, one or more Phase 3 trials may be undertaken to further demonstrate or confirm the clinical efficacy and safety of the investigational drug in an expanded patient population, with the goal of evaluating its overall risk-benefit relationship. Phase 3 trials are generally designed to reach a specific goal or end point, the achievement of which is intended to demonstrate the product candidate's clinical efficacy. The successful demonstration of clinical efficacy and safety in one or more Phase 3 trials is typically a prerequisite to the filing of a NDA for a product candidate.

The sponsor of a clinical-stage development program may request an "end-of-Phase 2 Meeting" with the FDA to assess the safety of the dose regimen to be studied in a Phase 3 clinical trial, to evaluate the planned design of a Phase 3 trial, and to identify any additional information that will be needed to support a NDA. If a Phase 3 clinical trial has been the subject of discussion at an end-of-Phase 2 Meeting, the sponsor may be eligible for a Special Protocol Assessment ("SPA"), a process by which the FDA, at the request of the sponsor, will evaluate the trial protocol and issues relating to the protocol to assess whether it is deemed to be adequate to meet the scientific and regulatory requirements identified by the sponsor. If the FDA and the sponsor reach agreement on the design and size of a Phase 3 clinical trial intended to form the primary basis of an efficacy claim in a NDA, the FDA may reduce the understanding to writing. The SPA, however, is not a guarantee of product approval by the FDA, or approval of any permissible claims about the product.

Throughout the various phases of clinical development, samples of the product candidate made in different batches are tested for stability to establish any shelf life constraints. In addition, large-scale production protocols and written standard operating procedures for each aspect of commercial manufacture and testing must be developed and validated.

Phase 1, 2, and 3 testing may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical development and may, at its discretion, reevaluate, alter, suspend, or terminate further evaluation or trials based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. The FDA, the sponsor, a data safety monitoring board or an IRB may suspend or terminate a clinical trial at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health or safety risk. The FDA can also request additional clinical trials be conducted as a condition to product approval or advancement to the next stage of development. Additionally, new government requirements may be established that could delay or prevent regulatory approval of product candidates under development.

Clinical trials performed outside the U.S. under an IND must meet the same requirements that apply to studies conducted in the U.S. The FDA may also accept a foreign clinical study not conducted under an IND if the study is well-designed, well-conducted, performed by qualified investigators, and conforms to the ethical principles contained in the Declaration of Helsinki, or with the laws and regulations of the country in which the research was conducted, whichever provides greater protection of the human subjects.

Certain information about clinical trials, including a description of the study, participation criteria, location of study sites, and contact information, is required to be sent to the National Institutes of Health, ("NIH") for inclusion in a publicly-accessible database that is available at www.clinicaltrials.gov. Sponsors also are subject to certain state laws imposing requirements to make publicly available certain information on clinical trial results. In addition, the Food and Drug Administration Amendments Act of 2007 directed the FDA to issue regulations that will require sponsors to submit to the NIH the results of all controlled clinical studies, other than Phase 1 studies.

New Drug Applications (NDA)

If and when we believe that all the requisite clinical trials for a product candidate have been completed with satisfactory and supporting clinical, toxicology, safety and manufacturing-related data, we must submit a NDA to the FDA in order to obtain approval for the marketing and sale of a product candidate in the U.S. Among many other items, a NDA typically includes the results of all preclinical and toxicology studies and human clinical trials and a description of the manufacturing process and quality control methods. The FDA must approve the NDA prior to the marketing and sale of the related product. The FDA may deny or reject a NDA if it believes all applicable regulatory criteria are not satisfied, or it may require additional data, including clinical, toxicology, safety or manufacturing data prior to approval. The FDA has 60 days from its receipt of a NDA to review the application to ensure that it is sufficiently complete for a substantive review before accepting it for filing. The FDA may request additional information rather than accept a NDA for filing. In this event, the NDA must be amended with any additional information requested. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee.

A NDA can receive either standard or priority review. A product candidate representing a potentially significant improvement in the treatment, prevention or diagnosis of a life threatening or serious disease may receive a priority review. In addition, product candidates studied for their safety and effectiveness in treating serious or life-threatening illnesses that provide meaningful therapeutic benefit over existing treatments may also receive accelerated approval on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Priority review and accelerated approval do not change the standards for approval, but may expedite the approval process.

If the results of the FDA's evaluation of the NDA and inspection of manufacturing facilities are favorable, the FDA may issue an approval letter. An approval letter authorizes the commercial marketing of the drug with specific prescribing information for a specific indication. As a condition of NDA approval, the FDA may require post-approval testing, including Phase 4 trials, and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling or distribution restrictions which can materially impact the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

If the FDA determines that it cannot approve the NDA in its present form, it generally issues what is referred to as a complete response letter. A complete response letter will describe all of the specific deficiencies that the agency has identified in an application that must be met in order to secure final approval of the NDA. If and when those conditions are met to the FDA's satisfaction, the FDA will typically re-review the application and possibly issue an approval letter. However, even after submitting this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. It can take several years for the FDA to approve a NDA once it is submitted, and the actual time required for any product candidate to be approved may vary substantially, depending upon the nature, complexity and novelty of the product candidate.

We cannot assure you that the FDA, or any other similar regulatory authority in another country, will grant approval for any of our product candidates on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later stage clinical trials. Data obtained from preclinical and clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval.

Post-Approval Regulations

If and when a product candidate receives regulatory approval to be marketed and sold, the approval is typically limited to a specific clinical indication or use. Further, even after regulatory approval is obtained, subsequent discovery of previously unknown safety problems with a product may result in restrictions on its use, or even complete withdrawal of the product from the market. Any FDA-approved products manufactured or distributed by us are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse events or experiences. Further, drug manufacturers and their subcontractors are required to register their establishments with the FDA and state agencies, and are subject to periodic inspections by the FDA and state agencies for compliance with cGMP regulations, which impose rigorous procedural and documentation requirements upon us and our contract manufacturers. We cannot be certain that we, or our present or future contract manufacturers or suppliers, will be able to comply with cGMP regulations and other FDA regulatory requirements. Failure to comply with these requirements may result in, among other things, total or partial suspension of production activities for our current and future product candidates, failure of the FDA to grant approval for the marketing of such product candidates, and withdrawal, suspension, or revocation of marketing approvals.

If the FDA approves one or more of our product candidates, we and our contract manufacturers must provide the FDA with certain updated safety, efficacy and manufacturing information. Product changes, as well as certain changes in the manufacturing process or facilities where the manufacturing occurs or other post-approval changes may necessitate additional FDA review and approval. We rely, and expect to continue to rely, on third parties for the formulation and manufacture of clinical and commercial quantities of our products. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

The labeling, advertising, promotion, marketing and distribution of an approved drug or biologic product must also comply with FDA and Federal Trade Commission, ("FTC") requirements which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing the company to correct deviations from regulatory standards and enforcement actions that can include seizures, fines, injunctions and criminal prosecution.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and in some circumstances the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

From time to time, legislation is drafted and later introduced and passed that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will change or what the impact of such changes, if any, may be. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad, or the impact such changes could have on our business.

Other U.S. Health Care Laws and Compliance Requirements

In the U.S., our activities are subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of HHS (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provisions of the Health Insurance Portability and Accountability Act ("HIPAA") and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the Veterans Health Care Act, ("VHCA"), drug companies are required to offer certain drugs at a reduced price to a number of federal agencies including U.S. Department of Veterans Affairs and U.S. Department of Defense, the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Recent legislative changes purport to require that discounted prices be offered for certain U.S. Department of Defense purchases for its TRICARE program via a rebate system. Participation under VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing a product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities or register their sales representatives, as well as prohibiting pharmacies and other health care entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and prohibiting certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Foreign Regulation

In addition to regulations in the U.S., we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates to the extent we choose to develop these product candidates or sell any products outside of the U.S. Whether or not we obtain FDA approval for a product, we must obtain similar approval by comparable regulatory authorities in foreign countries before we can commence clinical trials or the marketing of a product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

EU member states require both regulatory clearances by the national competent authority and a favorable ethics committee opinion prior to the commencement of a clinical trial. Under the E.U. regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all E.U. member states. The centralized procedure is compulsory for medicines produced by certain biotechnological processes, products with a new active substance indicated for the treatment of certain diseases such as neurodegenerative disorder or diabetes and products designated as orphan medicinal products and optional for those products which are highly innovative or for which a centralized process is in the interest of patients. The decentralized procedure of approval provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state, known as the reference member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials (draft summary of product characteristics, draft labeling and package leaflet) to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all member states.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical products for which we may obtain regulatory approval to market and sell. In the U.S. and other countries, sales of any products for which we receive regulatory approval to sell will depend considerably on the availability of reimbursement from third-party payers. Third-party payers include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payer will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the product. Third-party payers may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, which would be in addition to the costs required to obtain FDA approvals. Our products may not be considered medically necessary or cost-effective. A payer's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in developing a product.

In 2003, the U.S. government enacted legislation providing a prescription drug benefit for Medicare recipients, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval. However, to obtain payments under this program, we would be required to sell products to Medicare recipients through prescription drug plans operating pursuant to this legislation. These plans will likely negotiate discounted prices for our products. In March 2010, the Patient Protection and Affordable Care Act became law in the U.S., which substantially changed the way healthcare is financed by both governmental and private insurers. We anticipate that this legislation will result in additional downward pressure on the price, if any, that we may receive for any approved product. Federal, state and local governments in the U.S. continue to consider legislation to limit the growth of health care costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceutical products, including the product candidates that we are developing.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of our particular drug products to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any products for which we receive regulatory approval to sell may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the U.S. has increased, and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Employees

As of June 30, 2014, we had 66 full-time employees, 51 of whom were that engaged in research and development, and 15 of whom were engaged in corporate, administration, finance, and business development activities. In June 2014, we announced plans to reduce our workforce to approximately 20 employees by the end of March 2015, and close our Melbourne, Australia facility by June 30, 2015.

All of our employees have entered into non-disclosure agreements with us regarding our intellectual property, trade secrets and other confidential information. None of our employees are represented by a labor union or covered by a collective bargaining agreement, nor have we experienced any work stoppages. We believe that we maintain satisfactory relations with our employees.

Available Information

Our website address is www.biotapharma.com. Please note that this website address is provided as an inactive textual reference only. We make available free of charge through our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. The information provided on our website is not part of this report, and is therefore not incorporated by reference unless such information is otherwise specifically referenced elsewhere in this report.

ITEM 1A. RISK FACTORS

You should carefully consider the following discussion of risks, together with the other information contained in this Form 10-K. The occurrence of any of the following risks could materially harm our business, our financial condition, our ability to raise additional capital in the future, or ever become profitable. In that event, the market price per share of our common stock could decline and you could lose a portion or all of your investment in our common stock.

RISKS RELATED TO THE TERMINATION OF OUR CONTRACT WITH BARDA

The termination of our contract with BARDA in May 2014 impaired our ability to further develop or commercialize laninamivir octanoate independently, which could significantly harm our financial condition, prospects and business.

In March 2011, we were awarded a contract from BARDA for the development of laninamivir octanoate. Under this contract, we were entitled to receive up to $231 million in funding to support the development of laninamivir octanoate under an IND in the U.S. On May 7, 2014 HHS/ASPR/BARDA notified us of its decision to terminate this contract for the convenience of the U.S. Government. We currently believe that we do not have sufficient capital resources to continue to independently fund the future development and commercialization of laninamivir octanoate, therefore, in order fund such development and commercialization, we would need to raise additional capital, or agree to sell or license the rights to, or co-develop laninamivir octanoate with a third party. If, however we are able raise additional capital in the future to support the continued development of laninamivir octanoate, our shareholders may suffer significant dilution, or if we and Daiichi Sankyo license the rights to develop and commercialize laninamivir octanoate outside of Japan to a third party, we may be required to give up a significant portion of the commercial value of laninamivir octanoate to this third party licensee. We cannot assure you that we will be able to raise sufficient capital or enter into an acceptable license or similar transaction to further advance the development of laninamivir octanoate.

BARDA may not fully reimburse us for all the costs we have incurred to advance the development of laninamivir octanoate under our contract with BARDA or as a result of its termination, which could harm our financial condition or otherwise result in us incurring significant management time and expense to recover such costs through administrative or legal remedies.

On May 7, 2014 HHS/ASPR/BARDA notified us of its decision to terminate our contract with BARDA to advance the development of laninamivir octanoate for the convenience of the U.S. Government. As outlined in the U.S. Government's Federal Acquisition Regulations (Title 48 of the Code of Federal Regulations) Clause 52.249-6 "Termination (Cost-Reimbursement)", with particular, but not exclusive, reference to subsections (c) and (f)-(h), the termination-for-convenience provisions in these regulations and our contract with BARDA generally entitle us to be reimbursed for (i) the cost incurred for any work or activities that occurred or were contractually committed to prior to the termination date of May 7, 2014, (ii) any work or activities specifically allowed to continue subsequent to the termination date as described in the termination letter or agreed upon by BARDA after the termination, and for certain wind-down and other settlement costs incurred as a result of the termination of the contract. BARDA has not yet reimbursed us for certain costs that were incurred prior to the termination date, as well as most of the costs incurred after the termination date, as we are working with BARDA and our sub-contractors to reconcile and finalize these invoices and a reach agreement on a final termination settlement.

As of June 30, 2014, we had $17.8 million in accounts receivable due from BARDA, which does not include $3.7 million of contract service revenue and accounts receivable relating to amounts that we believe we are entitled to receive reimbursement for under our terminated contract with BARDA and pursuant to applicable government regulations, but for which we potentially may not be fully reimbursed. The terms and conditions contained in the vast majority of our agreements with our sub-contractors under the BARDA agreement are such that we are obligated to pay these sub-contractors only when and to the extent that we are reimbursed by BARDA. As such, to the extent that BARDA does not reimburse us for allowable costs incurred, we may not be obligated to reimburse our subcontractors.

In the event BARDA does not agree to fully reimburse us for costs we believe to be reimbursable or we decide to pay vendors for costs we have not yet been reimbursed for, we intend to pursue all available administrative and legal remedies under the FAR and applicable law, which could cause us to incur significant additional time and expense in an attempt to recover these costs. We cannot assure you that we will be successful in being reimbursed or otherwise recovering all the costs we have incurred and believe we are entitled to be reimbursed for in connection with the development of laninamivir octanoate or the termination of the contract, or how long it may take to recover such costs.

RISKS RELATED TO RECENT STRATEGIC AND OPERATIONAL DECISIONS

We may be unable to successfully restructure and transition our operations and close our Melbourne, Australia facility in a timely and cost-effective manner, if at all, which could increase our cost of doing business, delay the development of our product candidates or harm our operations and business prospects.

On June 2, 2014, we announced that following the completion of an operational review of the Company, our Board of Directors has adopted a plan to restructure our operations. The adoption of the plan was the result of a decision by BARDA to terminate its contract with us for the convenience of the U.S. Government. As a result, we are currently restructuring our operations, which we expect will involve a significant reduction in the number of our employees, the transition of a number of key roles and responsibilities from Australia to the U.S., and the closure of our Melbourne, Australia facility. Specifically, we intend to reduce our work force from 66 employees at June 30, 2014 to approximately 20 as of April 1, 2015 and close our Melbourne operation and facility by June 30, 2015. The transition of operations and all clinical, regulatory, financial and legal records and corporate documents from Australia to the U.S. is ongoing. In order to successfully implement this restructuring and transition in a timely manner, if at all, including the migration of our information systems, financial records, reporting systems, internal controls and legal contracts, we may incur additional costs and these activities may consume a significant amount of management's time. Further, the transition of all research and development and general and administrative responsibilities to a smaller number of employees in the U.S. may result in a delay in the development of our programs or difficulties in managing our business in the event we cannot identify and attract employees with the requisite skills and experience to support the needs of our operation, or otherwise do not satisfactorily implement this transition.

As a result of our decision to close our Melbourne, Australia facility by June 30, 2015, we will no longer have laboratories in which to conduct basic research and discovery activities, which may impair our ability to support our current antiviral pipeline, limit the discovery of future product candidates, and could harm our business prospects.

Our basic research and discovery activities, including medicinal chemistry, virology, and cell culture assays, have historically been conducted by our research staff in our laboratory facility in Melbourne, Australia. Pursuant to our current restructuring plan, we intend to close this facility by the end of June 2015. Once this facility is closed and our planned reduction in staff is completed, we will not have internal research and development capacity to work on discovery stage projects or support our current pipeline. We currently do not have any plans to build similar laboratory facilities elsewhere or hire staff to conduct discovery, research and certain development activities. To the extent we conduct these activities in the near future, we anticipate that we will outsource them and rely on third-party vendors and consultants, which may require us to incur higher costs.

We have adopted a corporate strategy, a component of which reflects our intent to pursue in-licensing, acquisition, co-development, and other possible strategic transactions in order to bolster our pipeline with additional clinical-stage development programs. We may be unable to implement or successfully execute on this component of our strategy on a timely basis, if at all, which could harm our business.

The number of clinical-stage development programs available for in-licensing, acquisition or co-development are limited, and there are numerous other large pharmaceutical and biopharmaceutical companies competing for these same opportunities. Many of these companies have greater capital resources, experience and capabilities than we have. We may not be able to successfully identify or execute a transaction for any suitable in-licensing, acquisition or co-development candidates, or be able to do so on terms acceptable to us. Any transactions we may complete in the future or potential future strategic decisions we make may disappoint investors and depress the price of our common stock and the value of your investment in our common stock. Further, we may need to raise capital to acquire or support the transaction, incur acquisition fees or other non-recurring charges, and face significant integration challenges and/or management and business disruptions, any of which could materially and adversely affect our business and financial results

RISKS RELATED TO THE DEVELOPMENT OF OUR PRODUCT CANDIDATES

Our Phase 2 IGLOO clinical trial of laninamivir octanoate did not achieve its primary efficacy endpoint, which impaired the value of this program and our ability to further develop or commercialize laninamivir octanoate, or license it to a third-party, which could materially harm our financial condition, prospects and business.

On August 1, 2014, we announced top-line data from the Phase 2 IGLOO trial. As compared to placebo, neither the 40 mg or 80 mg cohort achieved a statistically significant reduction in the median time to alleviation of influenza symptoms as measured by the Flu-iiQ patient-recorded outcome questionnaire, which was the primary endpoint of the study. The failure to achieve the primary endpoint of this study impaired the value of the program and our ability to continue the development of laninamivir octanoate or for us and our partner Daiichi Sankyo to find a third-party licensee or collaborator that is willing to further develop laninamivir octanoate and may adversely impact our royalty stream on sales of Inavir®. We cannot assure you that laninamivir octanoate can be developed further or otherwise monetized by us in the future.

Our success depends largely upon our ability to advance our product candidates through the various stages of drug development. If we are unable to successfully advance or develop our product candidates, our business will be materially harmed.

Even though we generate royalty revenue from two of our influenza products, all of our product candidates are in early stages of development and their commercial viability remains subject to the successful outcome of current and future preclinical studies, clinical trials, manufacturing processes, regulatory approvals and the risks generally inherent in the development of pharmaceutical product candidates. Failure to advance the development of one or more of our product candidates may have a material adverse effect on our business. The long-term success of our business ultimately depends upon our ability to advance the development of our product candidates through preclinical studies and clinical trials, appropriately formulate and consistently manufacture them in accordance with strict specifications and regulations, obtain approval of our product candidates for sale by the FDA or similar regulatory authorities in other countries, and ultimately have our product candidates successfully commercialized by us or a strategic partner or licensee. We cannot assure you that the results of our ongoing or future research, preclinical studies or clinical trials will support or justify the continued development of our product candidates, or that we will ultimately receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidates**.**

Our product candidates must satisfy rigorous regulatory standards of safety, efficacy and manufacturing before we can advance or complete their development and before they can be approved for sale by the FDA or similar regulatory authorities in other countries. To satisfy these standards, we must engage in expensive and lengthy studies and clinical trials, develop acceptable and cost effective manufacturing processes, and obtain regulatory approval of our product candidates. Despite these efforts, our product candidates may not:

- demonstrate clinically meaningful therapeutic or other medical benefits as compared to a patient receiving no treatment or over existing drugs or other product candidates in development to treat the same patient population;
- be shown to be safe and effective in current and future preclinical studies or clinical trials;
- have the desired therapeutic or medical effects;
- be free from undesirable or unexpected side effects;
- meet applicable regulatory standards;
- be capable of being appropriately formulated and manufactured in commercially suitable quantities or scale and at an acceptable cost; or
- be successfully commercialized by us or by our licensees or collaborators.

Even if we demonstrate favorable results in preclinical studies and early-stage clinical trials, we cannot assure you that the results of late-stage clinical trials will be sufficient to support the continued development of our product candidates. Many, if not most companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in preclinical testing or early-stage clinical trials. Accordingly, results from completed preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results we may obtain in late-stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving any of our product candidates demonstrate a satisfactory safety and efficacy profile, such results may not be sufficient to obtain regulatory approval from the FDA in the U.S., or other similar regulatory agencies in other jurisdictions, which is required to market and sell the product.

Clinical trials are risky, lengthy and expensive. We incur substantial expense for, and devote significant time to, preclinical testing and clinical trials, yet cannot be certain that these tests and trials will demonstrate that a product candidate is effective and well tolerated, or will ever support the approval and commercial sale of a product. For example, clinical trials require adequate supplies of clinical trial material and sufficient patient enrollment. Delays in patient enrollment can result in increased costs and longer development times. Even if we, or a licensee or collaborator, if applicable, successfully complete clinical trials for our product candidates, we or they might not file the required regulatory submissions in a timely manner and may not receive marketing approval for the product candidate. We cannot assure you that any of our product candidates will successfully progress further through the drug development process, or will result in an approved and commercially viable product.

If the actual or perceived therapeutic benefits, or the safety or tolerability profile of any of our product candidates are not equal to or superior to other competing anti-infective treatments approved for sale or in clinical development, we may terminate the development of any of our product candidates at any time, and our business prospects and potential profitability could be harmed.

We are aware of a number of companies marketing or developing various classes of anti-infective product candidates or products for the treatment of patients infected with influenza, HRV and RSV that are either approved for sale or further advanced in clinical development than ours, such that their time to approval and commercialization may be shorter than that for our product candidates. Accordingly, if at any time we believe that any of our product candidates may not provide meaningful or differentiated therapeutic benefits, perceived or real, equal to or better than our competitor's products or product candidates, or we believe our product candidates may not have as favorable a safety or tolerability profile as potentially competitive compounds, we may delay or terminate the future development of any of our product candidates. We cannot provide any assurance that the future development of any or our product candidates will demonstrate any meaningful therapeutic benefits over potentially competitive compounds currently approved for sale or in development, or an acceptable safety profile sufficient to justify its continued development.

We also anticipate that several drugs, such as oseltamivir phosphate (Tamiflu®) and zanamivir (Relenza®) and peramivir (Rapiacta®) would compete with laninamivir octanoate, if ever approved for sale, for the treatment of influenza. Furthermore, by the time laninamivir octanoate may be approved, these competing products are likely to be generic drugs. Generic drugs are compounds that have no patent protection, and generally have an average selling price substantially lower than drugs that are protected by patents and intellectual property rights. Unless a patented drug can differentiate itself from generic drugs that treat or prevent the same condition or disease in a clinically meaningful manner, the existence of generic competition may impose significant pricing pressure on patented drugs. We may delay or terminate the future development of our product candidates if at any time we believe that they may not provide meaningful therapeutic or safety benefits, over generic drugs. We cannot provide any assurance that late-stage clinical trials of our product candidates that may compete with generic drugs in the future will demonstrate any meaningful therapeutic or safety benefits over these drugs sufficient to justify its continued development. Even if we successfully develop a product candidate and it is approved for sale, we cannot assure you that any real or perceived therapeutic benefits of our drug over generic drugs will result in it being prescribed by physicians or commanding a price higher than the existing generic drugs

Our vapendavir product candidate would indirectly compete with drugs approved to reduce the incidence of exacerbations in patients with asthma and COPD, such as fluticasone propionate (Advair®), tiotoprium bromide (Spiriva®), fluticasone furoate/vilanterol (Breo Ellipta®), and roflumilast (Daliresp®). In addition to approved drugs, there are compounds at the clinical development stage, such as inhaled ß-interferon, that if successfully developed for the treatment of HRV infections could compete with vapendavir. We also anticipate that our preclinical RSV compound *BTA-C585* will compete with GS-5806 and AL-8176, Phase 2 investigational drugs in development for the treatment of RSV infections in the event any of these compounds are ever approved for sale.

Our product candidates may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products, which may delay or preclude their development or regulatory approval, or limit their use if ever approved.

Throughout the drug development process, we must continually demonstrate the activity, safety and tolerability of our product candidates in order to obtain regulatory approval to further advance their clinical development, or to eventually market them. Even if our product candidates demonstrate adequate biologic activity and clear clinical benefit, any unacceptable side effects or adverse events, when administered alone or in the presence of other pharmaceutical products, may outweigh these potential benefits. We may observe adverse or serious adverse events or drug-drug interactions in preclinical studies or clinical trials of our product candidates, which could result in the delay or termination of their development, prevent regulatory approval, or limit their market acceptance if they are ultimately approved.

If the results from preclinical studies or clinical trials of our product candidates, including those that are subject to existing or future license or collaboration agreements, are unfavorable, we could be delayed or precluded from the further development or commercialization of our product candidates, which could materially harm our business.

In order to further advance the development of, and ultimately receive marketing approval to sell our product candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate their safety and efficacy to the satisfaction of the FDA or similar regulatory authorities in other countries, as the case may be. Preclinical studies and clinical trials are expensive, complex, can take many years to complete, and have highly uncertain outcomes. Delays, setbacks, or failures can and do occur at any time, and in any phase of preclinical or clinical testing, and can result from concerns about safety, tolerability, toxicity, a lack of demonstrated biologic activity or improved efficacy over similar products that have been approved for sale or are in more advanced stages of development, poor study or trial design, and issues related to the formulation or manufacturing process of the materials used to conduct the trials. The results of prior preclinical studies or early-stage clinical trials are not predictive of the results we may observe in late-stage clinical trials. In many cases, product candidates in clinical development may fail to show the desired tolerability, safety and efficacy characteristics, despite having favorably demonstrated such characteristics in preclinical studies or early-stage clinical trials.

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process, which could delay or impede our ability to advance the development of, receive marketing approval for, or commercialize our product candidates, including, but not limited to:

- communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials, or placing the development of a product candidate on clinical hold until questions or issues are satisfactorily resolved;
- regulatory authorities or IRB's not authorizing us to commence or conduct a clinical trial at a prospective trial site;
- enrollment in our clinical trials being delayed, or proceeding at a slower pace than we expected, because we have difficulty recruiting participants or because participants drop out of our clinical trials at a higher rate than we anticipated;
- our third-party contractors, upon whom we rely to conduct preclinical studies, clinical trials and the manufacturing of our clinical trial materials, failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- having to suspend or ultimately terminate a clinical trial if participants are being exposed to unacceptable health or safety risks;
- regulatory authorities or IRBs requiring that we hold, suspend or terminate our preclinical studies and clinical trials for various reasons, including non-compliance with regulatory requirements; and
- the supply or quality of material necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate or unavailable.

Even if the data collected from preclinical studies or clinical trials involving our product candidates demonstrate a satisfactory tolerability, safety and efficacy profile, such results may not be sufficient to support the submission of a NDA to obtain regulatory approval from the FDA in the U.S., or other similar regulatory authorities in other foreign jurisdictions, which is required for us to market and sell the product.

Our product candidates are generally being developed to treat seasonal respiratory infections, which could cause their clinical development to be more complex, take longer and cost more to complete than product candidates intended for non-seasonal infections.

Influenza, HRV, and RSV are respiratory infections that generally occur more frequently in certain months of the year in a particular geography. Accordingly, it is more efficient to conduct clinical trials in patients with these respiratory infections during the months in which the infections are more prevalent, and these trials generally cannot be as efficiently conducted year-round in any one region of the world. The seasonality in the incidence of these respiratory infections may require us to conduct clinical trials in both the northern and southern hemispheres in order to fully enroll these trials on a timely basis. Seasonality or variability in the incidence of these infections increases the complexity of our trial designs, exposes us to additional regulatory oversight in more countries, and generally increases the cost and time to conduct these trials.

In the event that the severity, nature and extent of influenza in any given year or season is moderate to mild, we may not be able to recruit a sufficient number of patients or clearly demonstrate the efficacy of laninamivir octanoate in a placebo-controlled clinical trial, which could materially harm our business prospects and financial condition.

To support a NDA filing, we expect that we would need to conduct several additional placebo-controlled clinical trials of laninamivir octanoate with the primary efficacy endpoints designed to demonstrate in a statistically significant manner that laninamivir octanoate has superior clinical benefit in reducing the duration of certain influenza symptoms as compared to placebo. In the event the severity, nature and extent of influenza and its correlate symptoms are mild during the seasons in which we are conducting our clinical trials, we may not be able to enroll a sufficient number of patients in the trial in a timely manner or demonstrate a statistical difference in outcomes between those patients that receive laninamivir octanoate and those that receive placebo due to the milder symptoms. This could result in the clinical trial failing to achieve its primary end point, which may cause us to have to repeat the trial, or BARDA to terminate our contract, either of which would materially harm our business prospects and financial condition.

If third-party contract manufacturers, upon whom we rely to formulate and manufacture our product candidates, do not perform, fail to manufacture according to our specifications, or fail to comply with strict government regulations, our preclinical studies or clinical trials could be adversely affected and the development of our product candidates could be delayed or terminated, or we could incur significant additional expenses.

We do not currently own any manufacturing facilities. We have historically used third-party contract manufacturers and we intend to continue to rely on third-party on these contractors for the foreseeable future, to formulate, manufacture, fill and package our product candidates. Our reliance on these third-party contract manufacturers, which in some cases are sole sourced, exposes us to a number of risks, any of which could delay or prevent the completion of our preclinical studies or clinical trials, or the regulatory approval or commercialization of our product candidates, result in higher costs or deprive us of potential product revenues in the future. Some of these risks include, but are not limited to:

- our contract manufacturers failing to develop an acceptable formulation to support late-stage clinical trials for, or the commercialization of, our product candidates;
- our contract manufacturers failing to manufacture our product candidates according to their own standards, our specifications, cGMPs or regulatory guidelines, or otherwise manufacturing material that we or regulatory authorities deem to be unsuitable for our clinical trials or commercial use;
- our contract manufacturers being unable to increase the scale of or the capacity for, or reformulate the form of our product candidates, which may cause us to experience a shortage in supply, or cause the cost to manufacture our product candidates to increase. We cannot assure you that our contract manufacturers will be able to manufacture our product candidates at a suitable scale, or we will be able to find alternative manufacturers acceptable to us that can do so;
- our contract manufacturers placing a priority on the manufacture of other customers' or their own products, rather than ours;
- our contract manufacturers failing to perform as agreed or exiting from the contract manufacturing business; and
- our contract manufacturers' plants being closed as a result of regulatory sanctions or a natural disaster.

Manufacturers of pharmaceutical drug products are subject to ongoing periodic inspections by the FDA, the U.S. Drug Enforcement Administration ("DEA") and corresponding state and other foreign agencies to ensure strict compliance with FDA-mandated cGMPs, other government regulations and corresponding foreign standards. We do not have control over our third-party contract manufacturers' compliance with these regulations and standards and accordingly, failure by our third-party manufacturers, or us, to comply with applicable regulations could result in sanctions being imposed on us or the manufacturer, which could significantly and adversely affect our business.

In the event that we need to change our third-party contract manufacturers, our preclinical studies, clinical trials or the commercialization of our product candidates could be delayed, adversely affected or terminated, or such a change may result in the need for us to incur significantly higher costs, which could materially harm our business.

Due to various regulatory restrictions in the U.S. and many other countries, as well as potential capacity constraints on manufacturing that occur from time-to-time in our industry, various steps in the manufacture of our product candidates are sole-sourced to certain contract manufacturers. In accordance with cGMPs, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing our current or future contract manufacturers may be difficult, if not impossible for us, and could be extremely costly if we do make such a change, which could result in our inability to manufacture our product candidates for an extended period of time and a delay in the development of our product candidates. Further, in order to maintain our development timelines in the event of a change in a third-party contract manufacturer, we may incur significantly higher costs to manufacture our product candidates.

If third-party vendors, upon whom we rely to conduct our preclinical studies or clinical trials, do not perform or fail to comply with strict regulations, these studies or trials may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.

We have limited resources dedicated to designing, conducting and managing preclinical studies and clinical trials. We have historically relied, and intend to continue to rely, on third parties, including clinical research organizations, consultants and principal investigators, to assist us in designing, managing, conducting, monitoring and analyzing the data from our preclinical studies and clinical trials. We rely on these vendors and individuals to perform many facets of the clinical development process on our behalf, including conducting preclinical studies, the recruitment of sites and patients for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our product candidates may be delayed or prove unsuccessful.

Further, the FDA, or similar regulatory authorities in other countries, may inspect some of the clinical sites participating in our clinical trials or our third-party vendors' sites to determine if our clinical trials are being conducted according to GCP or similar regulations. If we or a regulatory authority determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to applicable regulations, we may be forced to delay, repeat or terminate such clinical trials.

We have limited capacity for managing clinical trials, which could delay or impair our ability to initiate or complete clinical trials of our product candidates on a timely basis and materially harm our business.

We have limited capacity to recruit and manage all of the clinical trials necessary to obtain approval by the FDA or similar regulatory authorities in other countries. By contrast, larger pharmaceutical and biopharmaceutical companies often have substantial staff or departments with extensive experience in conducting clinical trials with multiple product candidates across multiple indications. In addition, these companies may have greater financial resources to compete for the same clinical investigators, sites and patients that we are attempting to recruit for our clinical trials. As a result, we may be at a competitive disadvantage that could delay the initiation, recruitment, timing and completion of our clinical trials and obtaining of marketing approvals, if achieved at all, for our product candidates.

If we are unable to attract or retain key employees, advisors or consultants, we may be unable to successfully develop our product candidates in a timely manner, if at all, or otherwise manage our business effectively.

We have increasingly adopted an operating model that relies on the outsourcing of a number of key responsibilities and activities to third-party consultants and contract research and manufacturing organizations in order to advance the development of our product candidates. Therefore, our success depends in part on our ability to retain highly qualified key management, personnel and directors to develop, implement and execute our business strategy and operations, and oversee the activities of our vendors and consultants, as well as any academic and corporate advisors or consultants that may assist us in this regard. We are currently highly dependent upon the efforts of our management team to accomplish this. In order to advance the development of our product candidates, we need to retain and be able to recruit certain key personnel, consultants or advisors with experience in a number of disciplines, including but not limited to, research and development, product development, clinical trials, medical affairs, government regulation of pharmaceutical products, quality control and assurance, formulation and manufacturing, business development, accounting, finance, human resources and information systems. Although we have not experienced material difficulties in retaining key personnel in the past, we may not be able to continue to do so in the future on acceptable terms, if at all. If we lose any key employees, or are unable to retain qualified key personnel, directors, advisors or consultants, the development of our product candidates could be delayed or terminated and our business may be harmed.

Our industry is highly competitive and subject to rapid technological changes. As a result, we may be unable to compete successfully or develop innovative products, which could harm our business.

Our industry is highly competitive and characterized by rapid technological change. Key competitive factors in our industry include, among others, the ability to successfully advance the development of a product candidate through preclinical and clinical trials; the efficacy, toxicology, safety, resistance or cross-resistance, interaction or dosing profile of a product or product candidate; the timing and scope of marketing approvals, if ever achieved; reimbursement rates for and the average selling price of competing products and pharmaceutical products in general; the availability of raw materials and qualified contract manufacturing and manufacturing capacity to produce our product candidates; relative manufacturing costs; establishing, maintaining and protecting our intellectual property and patent rights; and sales and marketing capabilities.

We face significant competition from large pharmaceutical and biotechnology companies, many of whom have substantially greater resources. In Japan, zanamivir (Relenza®) and laninamivir octanoate (Inavir®) compete with oseltamivir phosphate (Tamiflu®) and peramivir (Rapiacta®). A similar situation would likely exist if laninamivir octanoate is ever approved and marketed in territories outside Japan. We anticipate that vapendavir would indirectly compete with drugs approved to reduce the incidence of exacerbations in patients with asthma and COPD, such as fluticasone propionate (Advair®), tiotoprium bromide (Spiriva®), fluticasone furoate/vilanterol (Breo Ellipta®), and roflumilast (Daliresp®). In addition to approved drugs, there are compounds at the clinical development stage, such as inhaled ß-interferon, that if successfully developed for the treatment of HRV infections could compete with vapendavir. Our preclinical RSV compound *BTA-C585* would compete with GS-5806 (Gilead) and AL-8176 (Alios), both of which are investigational drugs in Phase 2 development for the treatment of RSV infections.

Developing pharmaceutical product candidates is a highly competitive, expensive and risky activity with a long business cycle. Many organizations, including the large pharmaceutical and biopharmaceutical companies that have existing products on the market or in clinical development that may compete with our product candidates, have substantially more resources than we have, as well as much greater capabilities and experience than we have in research and discovery, designing and conducting preclinical studies and clinical trials, operating in a highly regulated environment, formulating and manufacturing drug substances, products and devices, and marketing and sales. Our competitors may be more successful than we are in obtaining regulatory approvals for their product candidates and achieving broad market acceptance once they are approved. Our competitors' products or product candidates may be more effective, have fewer adverse effects, be more convenient to administer, have a more favorable resistance profile, or be more effectively marketed and sold than any product we, or our potential future licensees or collaborators, may develop or commercialize. New drugs or classes of drugs from competitors may render our product candidates obsolete or non-competitive before we are able to successfully develop them or, if approved, before we can recover the expenses of developing and commercializing them. We anticipate that we or our potential future licensees or collaborators will face intense and increasing competition as new drugs and drug classes enter the market and advanced technologies or new drug targets become available. If our product candidates do not demonstrate any meaningful competitive advantages over existing products, or new products or product candidates, we may terminate the development or commercialization of our product candidates at any time.

These competitors, either alone or with their collaborators, may succeed in developing product candidates or products that are more effective, safer, less expensive or easier to administer than ours. Accordingly, our competitors may succeed in obtaining regulatory approvals for their product candidates more rapidly than we can. Companies that can complete clinical trials, obtain required marketing approvals and commercialize their products before their competitors do so may achieve a significant competitive advantage, including certain patent and marketing exclusivity rights that could delay the ability of competitors to market certain products.

We also face, and expect that we will continue to face, intense competition from other companies in a number of other areas, including (i) attracting larger pharmaceutical and biopharmaceutical companies to enter into collaborative arrangements with us to acquire, license or co-develop our product candidates, (ii) identifying and obtaining additional clinical-stage development programs to bolster our pipeline, (iii) attracting investigators and clinical sites capable of conducting our clinical trials, and (iv) recruiting patients to participate in our clinical trials. We cannot assure you that product candidates resulting from our research and development efforts, or from joint efforts with our potential future licensees or collaborators, will be able to compete successfully with our competitors' existing products or product candidates in development.

We may be unable to successfully develop a product candidate that is the subject of an existing or future license agreement or collaboration if our licensee or collaborator does not perform or fulfill its contractual obligations, delays the development of our product candidate, or terminates our agreement.

We expect to continue to enter into and rely on license and collaboration agreements, or other similar business arrangements with third parties, to further develop and/or commercialize some or all of our existing and future product candidates. Such licensees or collaborators may not perform as agreed upon or anticipated, may fail to comply with strict regulations, or may elect to delay or terminate their efforts in developing or commercializing our product candidates even though we have met our obligations under the arrangement.

A majority of the potential revenue from existing and any future licenses and collaborations we may enter into will likely consist of contingent payments, such as payments received for achieving development or regulatory milestones, and royalties payable on the sales of approved products. Milestone and royalty revenues that we may receive under these licenses and collaborations will depend primarily upon our licensee's or collaborator's ability to successfully develop and commercialize our product candidates. In addition, our licensees or collaborators may decide to enter into arrangements with third parties to commercialize products developed under our existing or future collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. In many cases, we will not be directly or closely involved in the development or commercialization of our product candidates that are subject to licenses or collaborations and, accordingly, we will depend largely on our licensees or collaborators to develop or commercialize our product candidates. Our licensees or collaborators may fail to develop or effectively commercialize our product candidates because they:

- do not allocate the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise, limited capital resources, or the belief that other product candidates or internal programs may have a higher likelihood of obtaining regulatory approval, or may potentially generate a greater return on investment;
- do not have sufficient resources necessary to fully support the product candidate through clinical development, regulatory approval and commercialization;
- are unable to obtain the necessary regulatory approvals; or
- prioritize other programs or otherwise diminish their support for developing and/or marketing our product candidate or product due to a change in management, business operations or strategy.

Should any of these events occur, we may not realize the full potential or intended benefit of our license or collaboration arrangements, and our results of operations may be adversely affected. In addition, a licensee or collaborator may decide to pursue the development of a competitive product candidate developed outside of our agreement with them. Conflicts may also arise if there is a dispute about the progress of, or other activities related to, the clinical development or commercialization of a product candidate, the achievement and payment of a milestone amount, the ownership of intellectual property that is developed during the course of the arrangement, or other license agreement terms. If a licensee or collaborator fails to develop or effectively commercialize our product candidates for any of these reasons, we may not be able to replace them with another third-party willing to develop and commercialize our product candidates under similar terms, if at all. Similarly, we may disagree with a licensee or collaborator as to which party owns newly or jointly-developed intellectual property. Should an agreement be revised or terminated as a result of a dispute and before we have realized the anticipated benefits of the arrangement, we may not be able to obtain certain development support or revenues that we anticipated receiving. We may also be unable to obtain, on terms acceptable to us, a license from such collaboration partner to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize the product candidate. We cannot assure you that any product candidates will emerge from any existing or future license or collaboration agreements we may enter into for any of our product candidates.

RISKS RELATED TO COMMERCIAL MATTERS

We have a history of incurring net losses and we may never achieve profitability.

We have a history of incurring net losses, some of which are significant. We expect to incur additional net losses in the near-term, and these losses could increase as our research and development efforts progress. To become profitable, we, or our licensees or collaborators if applicable, must successfully manufacture and develop product candidates, receive regulatory approval, successfully commercialize and/or enter into profitable agreements with other parties and maintain existing and/or obtain additional intellectual property rights. It could be several years, if ever, before we receive significant royalties from any future license agreements or revenues directly from the sale of any of our product candidates.

Royalty revenues from Relenza® and Inavir® are unpredictable and subject to the seasonal incidence and severity of influenza, which could adversely affect our results of operations and financial condition.

We currently earn royalty revenue from the net sales of Relenza® and Inavir®, which are marketed by our licensees. Although the royalty rates paid to us by our licensees are fixed at a proportion of our licensees' net sales of these products, our periodic and annual revenues from these royalties have historically been variable and subject to fluctuation based on the seasonal incidence and severity of influenza. In addition, returns of products to our licensees that were sold in prior years are taken into account in the calculation of net sales for purposes of determining the royalty revenue we receive and the amount of such returns are generally unpredictable. We cannot predict with any certainty what our royalty revenues are likely to be in any given year.

If safety, tolerability, resistance, drug-drug interactions, or efficacy concerns should arise with Relenza® or Inavir®, our future royalty revenue may be reduced, which would adversely affect our financial condition and business.

We currently earn royalty revenue from Relenza® and Inavir®, which are marketed by our licensees. Data supporting the marketing approvals and forming the basis for the safety warnings in the product labels for these products were obtained in controlled clinical trials of limited duration in limited patient populations and, in some cases, from post-approval use. As these marketed products are used over longer periods of time and by more patients, some with underlying health problems or taking other medicines, new issues such as safety, tolerability, resistance or drug-drug interaction issues could arise, which may require our licensees to provide additional warnings or contraindications on their product labels, or otherwise narrow the approved indications. Further, additional information from ongoing research or clinical trials of these products that raise any doubts or concerns about their efficacy may arise. If serious safety, tolerability, resistance, drug-drug interaction, efficacy, or any other concerns or issues arise with respect to these marketed products, sales of these products could be impaired, limited or abandoned by our licensees or by regulatory authorities, in which case our royalty revenue would decrease.

If government and third-party payers fail to provide adequate reimbursement or coverage for our products or those that are developed through licenses or collaborations, our revenues and potential for profitability may be harmed.

In the U.S. and most foreign markets, product revenues or related royalty revenue, and therefore the inherent value of our products, will depend largely upon the reimbursement rates established by third-party payers for such products. Third-party payers include government health administration authorities, managed-care organizations, private health insurers and other similar organizations. Third-party payers are increasingly examining the cost effectiveness of medical products, services and pharmaceutical drugs and challenging the price of these products and services. In addition, significant uncertainty exists as to the reimbursement status, if any, of newly approved pharmaceutical products. Further, the comparative effectiveness of new products over existing therapies and the assessment of other non-clinical outcomes are increasingly being considered in the decision by payers to establish reimbursement rates. We, or our licensees or collaborators if applicable, may also be required to conduct post-marketing clinical trials in order to demonstrate the cost-effectiveness of our products. Such studies may require us to commit a significant amount of management time and financial resources. We cannot assure you that any products we or our licensees or collaborators may successfully develop will be reimbursed in part, or at all, by any third-party payers in any country.

Many governments continue to propose legislation designed to expand the coverage, yet reduce the cost, of healthcare, including pharmaceutical products. In many foreign markets, governmental agencies control the pricing of prescription drugs. In the U.S., significant changes in federal health care policy were approved over the past several years and continue to evolve, and will likely result in reduced reimbursement rates for many pharmaceutical products in the future. We expect that there will continue to be federal and state proposals to implement increased government control over reimbursement rates of pharmaceutical products. In addition, we expect that increasing emphasis on managed care and government intervention in the U.S. healthcare system will continue to put downward pressure on the pricing of pharmaceutical products there. Government cost control initiatives could decrease the price that we or our licensees or collaborators may receive for any of our products that may be approved for sale in the future, which would limit our revenues and profitability. Legislation and regulations affecting the pricing of pharmaceutical products may change before our product candidates are approved for sale, which could further limit or eliminate their reimbursement rates. Further, social and patient activist groups, whose goal it is to reduce the cost of healthcare, and in particular the price of pharmaceutical products, may also place downward pressure on the price of these products, which could result in decreased prices of our products.

If any product candidates that we develop independently, or through licensees or collaborators if applicable, are approved but do not gain meaningful acceptance in their intended markets, we are not likely to generate significant revenues.

Even if our product candidates are successfully developed and we or a licensee or collaborator obtain the requisite regulatory approvals to market them in the future, they may not gain market acceptance or broad utilization among physicians, patients or third-party payers. The degree of market acceptance that any of our products may achieve will depend on a number of factors, including:

- the efficacy or perceived clinical benefit of the product, if any, relative to existing therapies;
- the timing of market approval and the existing market for competitive drugs, including the presence of generic drugs;
- the level of reimbursement provided by third-party payers to cover the cost of the product to patients;
- the net cost of the product to the user or third-party payer;
- the convenience and ease of administration of the product;
- the product's potential advantages over existing or alternative therapies;
- the actual or perceived safety of similar classes of products;
- the actual or perceived existence, incidence and severity of adverse effects;
- the effectiveness of sales, marketing and distribution capabilities; and
- the scope of the product label approved by the FDA or similar regulatory agencies in other jurisdictions.

There can be no assurance that physicians will choose to prescribe or administer our products, if approved, to the intended patient population. If our products do not achieve meaningful market acceptance, or if the market for our products proves to be smaller than anticipated, we may never generate significant revenues.

If we fail to enter into or maintain collaborations or other sales, marketing and distribution arrangements with third parties to commercialize our product candidates, or otherwise fail to establish marketing and sales capabilities in the future, we may not be able to successfully commercialize our products.

We currently have no infrastructure to support the commercialization of any of our product candidates, and have little, if any, experience in the commercialization of pharmaceutical products. Therefore, if we successfully develop any product candidate, and it is ultimately approved for sale, our future profitability will depend largely on our ability to access, arrange or develop suitable marketing and sales capabilities. Other than for laninamivir octanoate, which if approved, could potentially be sold in the U.S. or other federal governments for stock-piling measures, we anticipate that we will need to establish relationships with other companies, through license, collaboration, commercialization or similar marketing and sales agreements, to successfully commercialize and market our product candidates in the U.S. and in other countries around the world. To the extent that we enter into these types of agreements with other companies to sell, promote or market our products in the U.S. or abroad, our product revenues, which may be in the form of indirect revenue, a royalty, or a split of profits, may depend largely on the efforts of the other party, which may not be successful. In the event we decide to develop our own sales force and marketing capabilities, this may result in us incurring significant upfront costs to do so before we may generate any significant product revenues. We may not be able to attract and retain qualified third parties or marketing or sales personnel, or be able to establish marketing capabilities or an effective sales force.

Currency fluctuations and changes in exchange rates could increase our costs or lower our revenues.

We collect and pay a portion of our revenue and expenses in currencies other than the U.S. dollar. Therefore, fluctuations in foreign currency exchange rates can affect our operating results. We retain the majority of our cash and cash equivalents in U.S. dollars and utilize foreign currency accounts, particularly in Australia, for collection and payment of revenues and expenses for our subsidiaries. Any significant foreign exchange rate fluctuations could adversely affect our financial position and results of operations.

Unless we reach an agreement with Daiichi Sankyo and Hovione with respect to commercial rights to laninamivir octanoate outside of Japan, disputes between us and these parties may occur and could adversely affect our financial condition and business prospects.

Pursuant to our 2003 license and collaboration agreement with Daiichi Sankyo, if the parties agree to license the commercial rights to laninamivir octanoate in territories outside Japan to a third-party licensee, we share all licensing revenue equally with Daiichi Sankyo. The agreement does not, however, specifically address the respective rights or obligations of, or any consideration between, the parties in the event that either we or Daiichi Sankyo directly market laninamivir octanoate in territories outside Japan and a license has not been granted to a third-party licensee anywhere in the world. Further, the license agreement that we and Daiichi Sankyo collectively entered into with Hovione for use of the TwinCaps® dry powder inhaler provides us and Daiichi Sankyo with the exclusive right to import, export, make, use, and distribute for sale the drug product comprised of laninamivir octanoate and the TwinCaps® dry powder inhaler ("Drug Product") worldwide in the field of preventing and/or treating influenza infections. The contract specifies what consideration is payable to Hovione in the event Drug Product is marketed by a third-party licensee other than us or Daiichi Sankyo outside of Japan. The agreement does not, however, specifically address the respective rights or obligations of, or any consideration between, the parties in the event that either we or Daiichi Sankyo directly market Drug Product in territories outside Japan.

The consideration potentially payable to Daiichi Sankyo under our license agreement with it, if any, or to Hovione under our license with it, related to direct sales of laninamivir octanoate we may generate in territories outside of Japan is uncertain. If we fail to reach a mutually acceptable commercial agreement in the future with either Daiichi Sankyo, Hovione, or both with respect to the development and marketing of laninamivir octanoate or drug product of Japan, disputes could result, which could further result in arbitration, litigation or other legal proceedings, or delay our ability to generate significant revenue from the sale of such products outside Japan. Such proceedings can be expensive and consume a significant amount of our management's time. We cannot assure you we will reach a satisfactory commercial agreement with Daiichi Sankyo or Hovione in the future.

Under our previous contract with BARDA, our operations, and those of our contractors, continue to be subject to audit by the U.S. government, and a negative outcome of such an audit could adversely affect our financial condition and business.

U.S. Government agencies, such as the Department of Health and Human Services ("HHS") and the Defense Contract Audit Agency ("DCAA"), routinely audit and investigate government contractors and recipients of federal grants. These agencies evaluate a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards. Notwithstanding the fact that our contract with BARDA was terminated by the U.S. Government for its convenience, the U.S. Government has not yet reimbursed us for all of the costs we have incurred or expect to incur to develop laninamivir octanoate under that contract. Accordingly, we remain subject to the audit provisions under the terminated contract.

The HHS and the DCAA also review the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a contract will not be reimbursed, while such costs already reimbursed must generally be repaid. If an audit identifies improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including, but not limited to:

- termination of contracts;
- forfeiture of profits;
- suspension of payments;
- fines; and
- suspension or prohibition from conducting business with the U.S. Government.

Our employees, representatives or agents may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could expose us to financial, reputational or other harm.

Our employees, representatives or agents may engage in any fraud or other improper activities, including but not limited to:

- complying with FDA regulations or similar regulations of similar regulatory authorities in other countries;
- providing accurate information to the FDA or similar regulatory authorities in other countries;
- complying with manufacturing standards we or the FDA have established;
- complying with federal and state healthcare fraud and abuse laws and regulations or similar laws and regulations established and enforced by comparable foreign regulatory authorities; or
- reporting financial information or data accurately.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.

Because we have operations outside of the U.S., we must comply with numerous laws and regulations in each jurisdiction in which we operate. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the company, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the Department of Justice, while the SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical studies and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our operations outside of the U.S. require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. Government until the pending claims are resolved. Conviction for a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we are unable to adequately protect or expand our intellectual property related to our products, or current or future product candidates, our business prospects could be materially harmed.

Our business success depends in part on our ability to:

- obtain, maintain and protect our intellectual property rights;
- protect our trade secrets; and
- prevent others from infringing on our proprietary rights or patents.

We can protect our proprietary intellectual property rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of pharmaceutical and biopharmaceutical companies involves complex legal and factual questions, and, therefore, we cannot predict with certainty whether we will be able to ultimately enforce our patents or proprietary rights, or avoid infringing on the patents or proprietary rights of others. Any issued patents that we own or otherwise have rights to may be challenged, invalidated or circumvented, and may not provide us with the protection against competitors that we anticipate.

The degree of future protection for our proprietary intellectual property rights is uncertain because issued patents and other legal means of establishing proprietary rights afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Our future patent position will be influenced by the following factors:

- we, or our licensors, may not have been the first to discover the inventions covered by each of our or our licensors' pending patent applications and issued patents, and we may have to engage in expensive and protracted interference proceedings to determine priority of invention;
- our, or our licensors', pending patent applications may be denied and may not result in issued patents;
- our, or our licensors', issued patents may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties; and
- third parties may develop intellectual property that circumvents our or our licensors' patent claims or design competitive intellectual property and ultimately product candidates that fall outside the scope of our or our licensors' patents.

Due to the extensive time required for the development, testing and regulatory review and approval of a product candidate, it is possible that before a product candidate of ours may be approved for sale and commercialized, our relevant patent rights may expire, or such patent rights may remain in force for only a short period following marketing approval. We currently rely on certain patents to provide us and our licensees with exclusive rights for certain of our products. When all patents underlying a license expire, our revenue from that license may cease, and there can be no assurance that we will be able to replace it with revenue from new or existing licenses. Our composition of matter patents relating to Relenza® will expire in December 2014 in the U.S., May 2015 in Australia, 2016 in the major countries of the European Union, and July 2019 in Japan; however, as long as a current U.S. patent application (08/737,141) is pending, we will be eligible to receive royalties on the net sales from Relenza® in the U.S. There can be no assurance that the pending patent application will be approved, or when that may occur, if ever.

The composition of matter patent relating to the structure of laninamivir octanoate expires in 2017 in the U.S., the E.U. and Japan. The patent relating to hydrates and the crystalline form of laninamivir octanoate that is used in the product expires in 2021 (without extensions) in the U.S. and EU and in 2024 in Japan. The patent relating to the dry powder inhaler device used for Inavir®, known as TwinCaps®, expires in 2029 in the U.S., and in 2027 in the EU and Japan. Patent claims in the U.S. covering the phosphate salt form of vapendavir will expire in 2022 without extensions, and at the end of 2021 in the EU and Japan in the absence of marketing approval prior to this date. We filed a patent application for a free-base formulation of vapendavir in 2014, and, if issued, this patent would expire in 2034, without extensions. Composition of matter claims relating to our RSV fusion inhibitor BTA-C585 will begin to expire in the U.S., EU, and Japan in 2031. Patent expirations will in all likelihood adversely affect our ability to protect or maintain our direct product or royalty revenue.

Patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with or developing similar technologies or approaches to ours. The laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the U.S., and certain countries may lack adequate rules and procedures for defending our intellectual property rights. For example, we may not be able to prevent a third party from infringing our patents in a country that does not recognize or enforce patent rights, or that imposes compulsory licenses on or restricts the prices of drugs. Changes in either patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. We may need to in-license certain technologies to successfully develop and commercialize our product candidates. We may not develop or obtain rights to products or processes that are patentable. Even if we or our licensors do obtain patents, such patents may not adequately protect the products or technologies licensed, or may otherwise be limited in scope. In addition, we may not have total control over the patent prosecution of subject matter that we license from others. Accordingly, we may be unable to exercise the same degree of control over this intellectual property as we would over our own. Others may challenge, seek to invalidate, infringe or circumvent any pending or issued patents we own or license, and rights we receive under those issued patents may not provide competitive advantages to us. We cannot assure you of the degree of protection that will be afforded by any of our issued or pending patents, or those licensed by us.

We cannot be sure that any patents will be issued from the patent applications we own or have licensed or, should any patents issue, that we will be provided with adequate protection against potentially competitive products. Furthermore, we cannot be sure that patents issued or licensed to us will be of any commercial value, or that private parties or competitors will not successfully challenge these patents or circumvent our patent position in the U.S. or abroad. In the absence of adequate patent protection, our business may be adversely affected by competitors who develop comparable technology or products.

If a third-party claims we are infringing on its intellectual property rights, we could incur significant expenses, or be prevented from further developing or commercializing our product candidates, which could materially harm our business.

Our success will also depend on our ability to operate without infringing the patents and other proprietary intellectual property rights of third parties. This is generally referred to as having the “freedom to operate.” The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property claims, interference proceedings and related legal and administrative proceedings, both in the U.S. and internationally, involve complex legal and factual questions. As a result, such proceedings are lengthy, costly and time-consuming, and their outcome is highly uncertain. We may become involved in protracted and expensive litigation in order to determine the enforceability, scope and validity of the proprietary rights of others, or to determine whether we have the freedom to operate with respect to the intellectual property rights of others.

Patent applications in the U.S. are, in most cases, maintained in secrecy until approximately 18 months after the patent application is filed. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to product candidates similar to ours may have already been filed by others without our knowledge. In the event that a third party has also filed a patent application covering our product candidate or other claims, we may have to participate in an adversarial proceeding, known as an interference proceeding, in the USPTO or similar proceedings in other countries, to determine the priority of invention. In the event an infringement claim is brought against us, we may be required to pay substantial legal fees and other expenses to defend such a claim and, if we are unsuccessful in defending the claim, we may be prevented from pursuing the development and commercialization of a product candidate and may be subject to injunctions and/or damage awards.

In the future, the USPTO or a foreign patent office may grant patent rights to our product candidates or other claims to third parties. Subject to the issuance of these future patents, the claims of which will be unknown until issued, we may need to obtain a license or sublicense to these rights in order to have the appropriate freedom to further develop or commercialize them. Any required licenses may not be available to us on acceptable terms, if at all. If we need to obtain such licenses or sublicenses, but are unable to do so, we could encounter delays in the development of our product candidates, or be prevented from developing, manufacturing and commercializing our product candidates at all. If it is determined that we have infringed an issued patent and do not have the freedom to operate, we could be subject to injunctions, and/or compelled to pay significant damages, including punitive damages. In cases where we have in-licensed intellectual property, our failure to comply with the terms and conditions of such agreements could harm our business.

It is becoming common for third parties to challenge patent claims on any successfully developed product candidate or approved drug. If we or our licensees or collaborators become involved in any patent litigation, interference or other legal proceedings, we could incur substantial expense, and the efforts and attention of our technical and management personnel could be significantly diverted. A negative outcome of such litigation or proceedings may expose us to the loss of our proprietary position or to significant liabilities, or require us to seek licenses that may not be available from third parties on commercially acceptable terms, if at all. We may be restricted or prevented from developing, manufacturing and selling our product candidates in the event of an adverse determination in a judicial or administrative proceeding, or if we fail to obtain necessary licenses.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.

We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is obtainable, or prior to us filing patent applications on any inventions we may make. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate and academic partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information or result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of these agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we may not be able to assert any trade secret rights against such party. Enforcing a claim that a third party illegally obtained and is using our trade secret is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and our failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary fee payments and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies. These employees typically executed proprietary rights, non-disclosure and non-competition agreements in connection with their previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

RISKS RELATED TO OWNING OUR COMMON STOCK

Our revenue, expenses and results of operations may be subject to significant fluctuations, in particular over the next several quarters as we continue to work with BARDA to finalize invoices and a final termination settlement, which will make it difficult to compare our operating results from period to period.

Our revenues have historically been highly variable. Royalty revenues we earn are derived from the net sales of products used for the treatment and/or prevention of influenza. Influenza as a disease is seasonal and highly unpredictable, and sales of these products fluctuate in line with the nature and extent of the incidence and severity of influenza each season. Payments potentially due to us under our existing or any future collaborative arrangements, including any milestone and royalty payments, are generally intermittent in nature and are subject to significant fluctuation in both timing and amount, or may never be earned or paid at all. In addition, the returns of products to our licensees are taken into account in the calculation of net sales for purposes of calculating the royalty revenue we receive and the amount of such returns are in general unpredictable. Further, we anticipate that we will continue to record revenue and costs under our recently-terminated contract with BARDA over the next several quarters. Revenue under this contract in any given period will be based on the reimbursable costs we incur or record during that period, or on changes in estimates we may make with respect to any revenue reserves we have recorded in prior periods, all of which we expect will continue to fluctuate significantly from month to month and quarter-to-quarter. Accordingly, our quarterly and annual revenue may be highly variable, and comparisons to previous periods may be difficult to make. Our historical and current revenues may not be indicative of our ability to achieve additional payment-generating milestones or royalties in the future, or vice versa. We expect that our operating results will also vary significantly from quarter-to-quarter and year-to-year as a result of the initiation and success or failure of preclinical studies or clinical trials we undertake, the timing of the formulation and manufacture of our product candidates, or other development-related factors and activities, as well as the restructuring of our operations that we are currently implementing. Accordingly, our revenues, expenses and results of operations for any period, particularly over the next several quarters, may not be comparable to the revenues, expenses or results of operations for any other period.

The reporting requirements of being a company that is publicly traded on the NASDAQ Global Select Market (NASDAQ) increase our overall operating costs and subject us to increased costs and regulatory risk that may negatively impact our business or our ability to raise capital in the future.

As a company that is publicly-traded on NASDAQ, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”), and the listing requirements of NASDAQ. Further, Section 404 of the Sarbanes-Oxley Act requires that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, management must perform system and process evaluation and testing of our internal control over financial reporting to assess the effectiveness of our internal control over financial reporting and our independent auditor must perform its own assessment on our internal control over financial reporting. This testing is expensive and requires the attention of our limited management resources. The various financial reporting, legal, corporate governance and other obligations associated with being a company that is publicly traded on NASDAQ in the U.S. require us to incur significant expenditures and place additional demands and requirements on our board of directors, executive officers, and other administrative, operational and financial personnel and resources. If we are unable to comply with these requirements in a timely and effective manner, we and/or our executive officers may be subject to sanctions by the SEC. We expect that we will continue to incur additional expenses as a result of being a company that is publicly traded on NASDAQ.

The price of our common stock price has been highly volatile, and your investment in us could suffer a decline in value.

The market price of our common stock has been and is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors and events, including but not limited to:

- our ability to successfully advance our product candidates through preclinical and clinical development;
- disclosure of any favorable or unfavorable data from our preclinical studies or clinical trials, or other regulatory developments concerning our preclinical studies or clinical trials, the formulation and manufacturing of our product candidates, or those of our competitors;
- the approval or commercialization of new products by us or our competitors, and the disclosure thereof;
- not negotiating a favorable final termination settlement associated with the termination of the contract we had with BARDA;
- novel scientific innovations by us or our competitors;
- rumors relating to us or our competitors;
- public concern about the safety or tolerability of our products, product candidates, or similar classes of compounds;
- litigation to which we may become subject;
- actual or anticipated variations in our quarterly or annual revenue or operating results;
- changes in general conditions or trends in the biotechnology and pharmaceutical industries;
- changes in drug reimbursement rates or government policies related to such reimbursement;
- significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- new regulatory legislation adopted in the U.S. or abroad;
- changes in patent legislation in the U.S. or abroad;
- our failure to achieve or meet equity research analysts' expectations or their estimates of our business or prospects, or a change in their recommendations concerning us, the value of our common stock or our industry in general;
- termination or delay in any of our existing or future license or collaboration arrangements;
- future sales of equity or debt securities, or the perception that such future sales may occur;
- the loss of our eligibility to have shares of our common stock traded on the NASDAQ Global Select Market or other listed markets due to our failure to maintain minimum listing standards;
- changes in accounting principles or a restatement of previously reported financial results;
- failure to comply with the periodic reporting requirements of publicly-owned companies under the Exchange Act and the Sarbanes-Oxley Act; and
- conditions in the economy generally and the capital markets in particular.

In addition, the stock market in general, and more specifically the NASDAQ Global Select Market, upon which our common stock is traded, and the market for smaller biotechnology stocks in particular have historically experienced significant price and volume fluctuations. Volatility in the market price for a particular biotechnology company's stock has often been unrelated or disproportionate to the operating performance of that company. Market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Due to this volatility, you may be unable to sell your shares of our common stock at or above the price you paid and you could lose all or part of your investment in us.

In order to develop our product candidates and support our operations beyond 12 months from June 30, 2014, we may need to raise additional capital. Such capital may not be available to us on acceptable terms, if at all, which could materially harm our financial condition, business and business prospects.

We believe that our existing cash, cash equivalents and long-term investments of $91.7 million as of June 30, 2014, along with the anticipated proceeds from our existing royalty-bearing licenses for Relenza® and Inavir® and reimbursements from BARDA related to expenses incurred in the development of laninamivir octanote and a final termination settlement will enable us to operate for a period of at least 12 months from June 30, 2014. This estimate assumes that we implement our restructuring and transition plan as previously disclosed and continue the development of our existing product candidates. This estimate does not include the impact of in-licensing or acquiring other clinical-stage development programs, any other significant transaction or change in our strategy or development plans in the near-future. We currently do not have any commitments for additional future funding, nor do we anticipate that we will generate any significant incremental revenue from the sale of any of our product candidates in the foreseeable future. Therefore, in order to meet our anticipated liquidity needs beyond 12 months to continue the development of our product candidates, or possibly sooner in the event we in-license or acquire another clinical-stage development program, enter into other transactions, change our strategy or accelerate our development plans, we may need to secure additional capital. In the event we need to raise additional capital, we expect to raise it primarily through the sale of our common stock or other equity securities, as well as potentially through forms of debt financing or other financing vehicles we may enter into in the future. 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, plans, financial condition and results of operations. If adequate capital is 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. If additional capital is not available to us on acceptable terms, we may also need to obtain funds through license or collaborative arrangements, pursuant to which we would likely relinquish potentially valuable rights to certain of our 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 restrictive covenants that restrict how we operate our business.

The timing and extent of our future financing needs are uncertain and will depend on many factors, some of which are very difficult to predict or may be beyond our control, including:

- the variability of future royalty revenue we may receive under our existing royalty-bearing license agreements;
- the timing of and extent to which we receive reimbursements and a final termination settlement from BARDA for costs incurred under our terminated contract;
- 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 these 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 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;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish in the future;
- the cost to maintain a corporate infrastructure to support being a company that is publicly traded in the U.S. on NASDAQ; and
- the cost of filing, prosecuting, and enforcing patent and other intellectual property claims.

Future issuances of shares of our common stock may cause our stock price to decline, even if our business is doing well.

The sale and issuance of additional shares of our common stock, or the perception that such future sales could occur, including any sales by our directors, executive officers, and other insiders or their affiliates, could materially and adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities at a price we deem appropriate.

If we raise additional capital in the future, your level of ownership in us could be diluted or we could be required to relinquish certain rights.

Any issuance of securities we may undertake in the future to raise additional capital could cause the price of our common stock to decline, or require us to issue shares at a price that is lower than that paid by holders of our common stock in the past, which would result in those newly issued shares being dilutive. Further, if we obtain funds through a debt financing or through the issuance of debt or preferred securities, these securities would likely have rights senior to your rights as a common stockholder, which could impair the value of our common stock. The terms of any debt financing we enter into may include covenants that limit our flexibility in conducting our business. We also could be required to seek funds through arrangements with collaborators or others, which might require us to relinquish valuable rights to our intellectual property or product candidates that we would have otherwise retained.

We do not anticipate paying cash dividends in the foreseeable future, and accordingly, you must rely on appreciation in the price of our common stock for any return on your investment in us.

We anticipate that we will retain our earnings, if any, for future growth and therefore do not anticipate paying cash dividends in the foreseeable future. As a result, our common stock will likely only provide a return to stockholders in the event there is appreciation in its price.

Our certificate of incorporation, our bylaws, and the laws of Delaware contain provisions that could discourage, delay or prevent a change in our control or in our management.

Certain provisions of our restated certificate of incorporation, our bylaws and the laws of Delaware, the state in which we are incorporated, may discourage, delay or prevent a change in control of us or a change in our directors or management that stockholders may consider favorable. These provisions:

- allow the authorized number of directors to be changed only by resolution of our Board of Directors;
- provide that our stockholders may remove our directors only for cause;
- authorize our Board of Directors to issue without stockholder approval, up to 5,000,000 shares of preferred stock, the rights of which will be determined at the discretion of the Board of Directors that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our Board of Directors;
- establish advance notice requirements for stockholder nominations to our Board of Directors or for stockholder proposals that can be acted on at stockholder meetings;
- limit who may call stockholder meetings; and
- contain a fair price provision.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights of our common stock, from merging or combining with us for a prescribed period of time. These provisions could discourage proxy contests and make it more difficult for you and other stockholders to remove and elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock has been and may continue to be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will continue to cover us or provide favorable ratings. If any analysts who cover us downgrade our stock, change their opinion of our stock or disseminate negative information regarding our business, our share price may decline. If any analysts cease coverage of our company, or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

RISKS RELATED TO OTHER ASPECTS OF OUR BUSINESS

If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently have product liability insurance coverage for our ongoing clinical trials in the amount of $15 million. Further, we also require clinical research and manufacturing organizations that assist us in the conduct of our clinical trials or manufacture materials used in these trials to carry product liability insurance against such claims. This insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event any of our product candidates are approved for sale by the FDA or similar regulatory authorities in other countries and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business.

If our use of hazardous materials results in contamination or injury, we could suffer significant reputational or financial loss.

Our research activities may involve the controlled use of certain hazardous chemical and biological materials from time-to-time. Notwithstanding the various regulations controlling the use and disposal of these materials, as well as the safety procedures we undertake, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental discharge or exposure, we may be held liable for any resulting damages, which may negatively impact our operations, our financial resources or our ability to recruit new staff.

Our ability to use our net operating loss carry forwards to reduce taxable income generated in the future could be substantially limited or eliminated.

Our ability to use our net operating losses in the U.S., Australia and the United Kingdom is subject to limitations and re-assessment due to ownership changes that have occurred, or that could occur in the future. Depending on the actual amount of any limitation on our ability to use our net operating loss carry forwards, a significant portion of our future taxable income could be taxable. Additionally, tax law limitations may result in our net operating losses expiring before we have the ability to use them. In addition, financing and acquisition transactions that we may enter into in the future could significantly limit or eliminate our ability to realize any value from our net operating losses.

ITEM 1B. *UNRESOLVED STAFF COMMENTS*

None.

ITEM 2. *PROPERTIES*

We have entered into an operating lease for an office and laboratory facility located in Melbourne, Australia through September 30, 2015, as well as a corporate office in Alpharetta, Georgia through September 2019. We do not anticipate renewing our lease in Melbourne, Australia. The total annual rent expense under these leases is approximately $0.6 million, of which approximately $0.5 million is associated with our Melbourne lease. We do not own any real property. We believe that our facilities are adequate for our current business as a conducted, as well as our expected business for the foreseeable future.

ITEM 3. *LEGAL PROCEEDINGS*

We may from time to time become subject to various claims and legal actions during the ordinary course of our business. We are not party to any legal proceedings at the date of filing of this Annual Report on Form 10-K.

ITEM 4. *MINE SAFETY DISCLOSURES*

Not Applicable.

PART II

ITEM 5. *MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES*

Our common stock trades on the NASDAQ Global Select Market under the symbol "BOTA." At September 25, 2014 we had 9,692 common stockholders of record. This figure does not represent the actual number of beneficial owners of common stock because shares are generally held in "street name" by securities dealers and others for the benefit of individual owners who may vote the shares.

The following table shows the range of high and low sales prices for our common stock for each completed fiscal quarter since June 30, 2013.

	2013	
	High	**Low**
First Quarter (July 2012 to September 2012)	$ 1.71	$ 1.55
Second Quarter (October 2012 to December 2012)	4.71	1.56
Third Quarter (January 2013 to March 2013)	4.40	3.80
Fourth Quarter (April 2013 to June 2013)	4.39	3.01

	2014	
	High	**Low**
First Quarter (July 2013 to September 2013)	$ 4.44	$ 3.20
Second Quarter (October 2013 to December 2013)	4.30	3.75
Third Quarter (January 2014 to March 2014)	7.07	4.17
Fourth Quarter (April 2014 to June 2014)	6.17	2.36

Securities Authorized for Issuance under Equity Compensation Plans

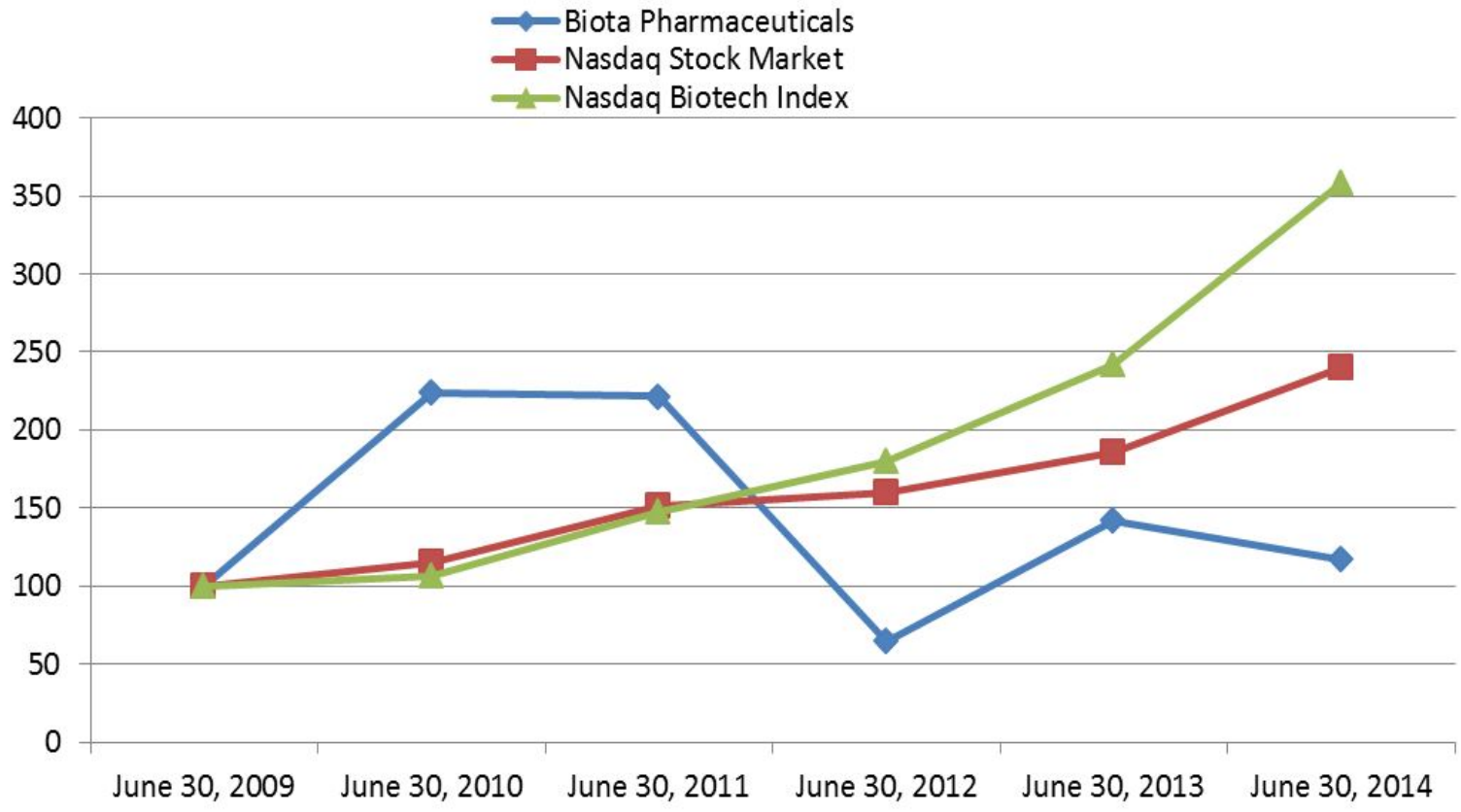
For certain information concerning securities authorized for issuance under our 2007 Omnibus Equity and Incentive Plan, see Item 12 – Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Dividend Policy

We have not paid or declared any dividends on our common stock in either of the two most recent fiscal years, and we do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain any earnings we may generate to fund our product development, operations and future growth. Any future determination to pay a dividend will be at the sole discretion of our Board of Directors, and will depend upon a number of factors, including our results of operations, capital requirements, financial condition, future prospects, contractual arrangements, restrictions imposed by applicable law, any limitations on payments of dividends present in any debt arrangements we may enter into in the future and other factors our Board of Directors may deem relevant.

Comparative Stock Performance

The following graph and related information should not be deemed "soliciting material" or to be "filed" with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933, as amended or the Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.



	6/30/2009	6/30/2010	6/30/2011	6/30/2012	6/30/2013	6/30/2014
Biota Pharmaceuticals (1)	$100	$224	$221	$65	$142	$117
Nasdaq Stock Market	$100	$115	$151	$160	$185	$240
Nasdaq Biotech Index	$100	$107	$148	$180	$242	$358

Assumes $100 invested on June 30, 2009

(1) Nabi Pharmaceuticals, Inc. stock performance from June 30, 2008 to November 7, 2012. On November 8, 2012, Biota Holdings Limited completed a reverse merger with Nabi Pharmaceuticals, Inc. and renamed the resulting company Biota Pharmaceuticals, Inc.

Issuer Purchases of Equity Securities

There were no stock repurchases or other purchases of equity securities by the Company during the fourth quarter ended June 30, 2014.

ITEM 6. ***SELECTED FINANCIAL DATA***

The following selected financial data are derived from our audited consolidated financial statements. This data should be read in conjunction with our audited consolidated financial statements and related notes, which are included elsewhere in this Annual Report on Form 10-K, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 below.

	Years Ended June 30,				
	2014	2013	2012	2011	2010
	(in millions, except share and per share data)				
Statement of Operations Data:					
Revenues	$ 68.7	$ 33.6	$ 20.4	$ 12.5	$ 60.8
Operating expense:					
Cost of revenue	51.1	20.4	9.9	2.5	4.1
Research and development	17.5	19.2	24.1	33.5	35.5
General and administrative	10.2	18.0	9.4	7.0	8.2
Foreign exchange (gain) loss	1.4	(1.9)	(0.1)	-	-
Total operating expense	80.2	55.7	43.3	43.0	47.8
Operating (loss) income	(11.5)	(22.1)	(22.9)	(30.5)	13.0
Total non-operating income, net	0.2	13.3	3.2	4.3	2.2
Income tax benefit (expense)	0.3	(0.1)	0.5	0.8	(3.3)
Net (loss) income	(11.0)	(8.9)	(19.2)	(25.4)	11.9
Net (loss) income per common share:					
Basic and Diluted	$ (0.35)	$ (0.32)	$ (0.85)	$ (1.12)	$ 0.53
Weighted average number of shares used in per common share calculations:					
Basic	31,347,888	28,217,515	22,713,566	22,567,958	22,320,632
Diluted	31,347,888	28,217,515	22,713,566	22,567,958	22,320,632

	As of June 30,				
	2014	2013	2012	2011	2010
			(in millions)		
Balance Sheet Data:					
Cash, cash equivalents and long-term investments	$ 91.7	$ 66.8	$ 53.8	$ 74.2	$ 89.8
Total assets	114.0	85.8	69.3	88.5	102.2
Total liabilities	27.1	17.8	10.0	7.1	14.8
Total stockholders' equity	$ 86.9	$ 68.0	$ 59.3	$ 81.4	$ 87.4

ITEM 7. ***MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS***

You should read this discussion together with the audited financial statements, related notes and other financial information included elsewhere in this Form 10-K. The following discussion contains assumptions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors," "Special Note on Forward-Looking Statements" and elsewhere in this Form 10-K. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.

References to "we," "us," and "our" refer to Biota Pharmaceuticals, Inc. and its consolidated subsidiaries. References to "Notes" refer to the Notes to Consolidated Financial Statements included herein (refer to Item 8).

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 are 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 80 mg dose of laninamivir octanoate to placebo. We refer to this trial as IGLOO. 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 have not received the full data set from this trial and anticipate continuing to assess this additional safety and efficacy data when received.

We are also developing BTA-798, also known as vapendavir, which is in Phase 2 for the treatment of human rhinovirus ("HRV") infections in patients with moderate to severe asthma. We have successfully completed two Phase 2 trials of vapendavir to-date and recently completed additional Phase 1bioavailability and drug-drug interaction studies in healthy volunteers that support its continued development.

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 NI that is marketed worldwide by GSK as Relenza®, for the prevention and treatment of influenza A and B. GSK markets Relenza® pursuant to a royalty-bearing research and license agreement we entered into with it 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 NI's, including FLUNET and laninamivir octanoate. In 2009, we entered into a commercialization agreement with Daiichi Sankyo that provided it with an exclusive license to commercialize laninamivir octanoate in Japan and entitled us to a royalty on those net sales. Laninamivir octanoate, which is marketed in Japan by Daiichi Sankyo as Inavir®, 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, respectively. In 2009, we filed an Investigational New Drug application ("IND") with the United States Food and Drug Administration ("FDA") to develop laninamivir octanoate in the U.S.

In March 2011, we were awarded a contract from 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 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. We continue to work with ASPR/BARDA to close out this contract, which involves completing several clinical trials, 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 short-term and long-term 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 our successful management of our cash resources, our continuing to receive royalty revenue under our existing licenses, our ability to negotiate appropriate reimbursements from BARDA for costs incurred under our prior contract with it and for final termination settlement, our ability to enter into future collaboration, license or commercialization agreements, the successful development of our product candidates, our ability to execute future financings, if needed, and ultimately, upon the approval of our products for sale and achievement of 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 that 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 Board and Management **–** On September 26, 2014, we announced a number of changes to our board of directors and management structure. The board has appointed Joseph M. Patti, PhD to the position of President and Chief Executive Officer, replacing Russell H. Plumb, who has been appointed Executive Chairman of the Board of Directors and will continue to have certain ongoing responsibilities with the Company. James Fox is resigning as Chairman of the Board of Directors, but will remain on the board as its Lead Director. These changes will become effective as of October 1, 2014.

Corporate Strategy – On September 26, 2014 we announced that, based on a strategic review of the Company, our assets and our prospects, our Board of Directors has adopted a near-term strategic and operating plan, summarized as follows: (i) align internal overhead costs with anticipated royalty revenues; (ii) support the development of the our vapendavir and RSV programs (iii) proactively consider a range of corporate development or other strategic transactions that can complement our pipeline and enhance the creation of shareholder value, and (iv) discuss the Phase 2 IGLOO trial results with the FDA and work in concert with Daiichi Sankyo, our partner on LANI, to out-license the rights to the LANI program outside of Japan.

Relenza® – On September 26, 2014, we announced that GSK has verified that we will continue to receive royalties on the net sales of Relenza® in the U.S. beyond December 2014 to the extent that U.S. Patent Application No. 08/737,141 remains pending. On August 25, 2014 GSK filed an appeal to the United States Patent Trial Appeal Board in relation to this patent application. At this time, we cannot determine the duration or the outcome of this appeal process or how long this patent application will remain pending. If patent claims are ultimately issued, we expect that we would be eligible to receive royalties from net sales of Relenza® in the U.S. for an additional 17 years from the date of allowance.

Respiratory Syncytial Virus ("RSV") Program – On September 8, 2014, we presented preclinical data on BTA-C585, an oral small molecule F-protein inhibitor, at the 54th Interscience Conference on Antimicrobial Agents and Chemotherapy ("ICAAC") Meeting in Washington, DC. Data presented at ICAAC included the results from a number of *in vivo* studies designed to assess the antiviral activity of BTA-C585 prior to and during experimental RSV infection in a cotton rat model, which demonstrated a dose-dependent decrease in virus titers in lung tissue. Similarly, a highly significant dose-dependent decrease in RSV mRNA in lung tissue was also observed in the cotton rat model. Further, preliminary, non-clinical oral, single and multiple-dose data from several animal toxicology studies indicated that BTA-C585 was highly bioavailable and well tolerated. We have initiated IND-enabling studies with BTA-C585 and subject to the successful completion of these studies, we believe we can be in position to file an IND and initiate Phase 1 clinical trials in mid-2015.

Vapendavir – On September 26, 2014 we announced that we have completed enrollment in a bioavailability study designed to establish the systemic exposure profile of a single dose of a vapendavir free-base tablet formulation compared to a single dose of an existing capsule phosphate salt formulation, which was the formulation used in previous clinical trials of vapendavir. We plan to conduct additional formulation activities on a free-base formulation to further improve its characteristics. We filed a patent application for this free-base formulation in 2014 and if issued, this patent would expire in 2034, without extensions. We have also recently completed enrollment in a drug-drug interaction study in 24 healthy volunteers to assess the effect of vapendavir on the pharmacokinetic profile of midazolam, a CYP3A4 substrate. The results of the study confirmed both vapendavir's pharmacokinetic profile established in prior studies, and that vapendavir is a weak to moderate inducer of CYP3A4, which suggests that vapendavir can be used to treat asthma and COPD patients receiving multiple background medications. In both of these Phase 1 studies vapendavir was well tolerated and there were no untoward safety trends.

We plan to initiate a randomized, double-blind, placebo-controlled dose-ranging Phase 2 trial of vapendavir in moderate and severe asthmatic patients at risk of loss of asthma control due to presumptive HRV infection in the first quarter of 2015. The planned Phase 2 trial is expected be conducted at approximately 60 sites across six to eight countries in North America and Central Europe, with anticipated enrollment being targeted at approximately 375 randomized patients. The planned primary endpoint is the Least Square ("LS") mean change from baseline to Study Day 14 in ACQ-6 total score. Planned secondary endpoints include the measurement of asthma exacerbations, changes in lung function, virology outcomes and effects on symptoms of HRV infection. ACQ-6 is a validated tool designed to assess asthma control and utilizes both patient reported outcomes and forced expiratory volume in 1 second (FEV1). The primary efficacy analysis population will be the ITT-infected population, defined as all subjects with confirmed HRV infection who receive a study treatment. We are also considering a Phase 2a HRV challenge study with vapendavir in patients with chronic obstructive pulmonary disease ("COPD").

Laninamivir Octanoate – On August 1, 2014, we announced top-line data from a randomized, double-blind, placebo-controlled, parallel-arm Phase 2 clinical trial comparing the safety and efficacy of 40 mg and 80 mg doses of laninamivir octanoate ("LANI") with placebo. We refer to this trial as "IGLOO". The primary endpoint of IGLOO was the difference in the median time to alleviation (reported to be mild or absent for greater than 24 hours) of all seven influenza symptoms (headache, feeling feverish, body aches and pains, fatigue, cough, sore throat and nasal congestion) plus fever. Symptom data were collected through the influenza intensity domain of the influenza intensity and impact Flu-iiQ^{TM} questionnaire. As compared to placebo, neither the 40 mg nor the 80 mg cohort achieved a statistically significant difference in the median time to alleviation of all seven influenza symptoms plus fever. The median time to alleviation of the seven influenza symptoms plus fever was 102.3 hours for the 40 mg cohort and 103.2 hours for the 80 mg cohort, as compared to 104.1 hours for the placebo cohort.

Although the 40 mg or 80 mg LANI cohorts did not achieve a statistically significant difference for the primary endpoint, notable effects were seen in individual symptoms, the sub-set of systemic symptoms (headache, feeling feverish, body aches and pains, and fatigue) and a number of secondary endpoints. Subjects in the 40 mg cohort reported alleviation of all four systemic symptoms significantly earlier than placebo (median time 58 hours and 72 hours, respectively, p=0.007). Patients in the 40 mg cohort also reported a significant reduction in the number of days in which all seven symptoms were severe (p=0.02) and in the number of secondary bacterial infections (p=0.013) as compared to placebo. A statistically significant proportion of patients in both the 40 mg (p=0.002) and 80 mg (p=0.02) cohorts were influenza culture negative on Day 3 of the study as compared to placebo. In addition, patients in the 40 mg (p<0.001) cohort also demonstrated a significant reduction in viral shedding on Day 3 of the study compared to placebo as quantified by qRT-PCR. The nature and extent of adverse events were similar in the three cohorts, with diarrhea (3.1% vs. 0.9%), headache (1.4% vs. 0.5%), gastritis (1.4% vs. 0%), urinary tract infection (1.4% vs. 0%), and sinusitis (1.2% vs. 0.9%) being the most common adverse events that occurred more frequently in the LANI treatment cohorts as compared to placebo. The incidence of serious adverse events was low and balanced across the three cohorts.

We are in the process of completing an analysis of the full safety, pharmacokinetic, and Flu-iiQ^{TM} data from this trial. We intend to complete these analyses and 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, prospective registration trials of laninamivir octanoate to treat uncomplicated influenza.

Restructuring of Operations - On June 2, 2014, we announced that following the termination of our contract with BARDA and the completion of an operational review, our Board of Directors adopted a plan to restructure our operations. Specifically, we plan to reduce our workforce to approximately 20 employees by March 2015 and close our Melbourne, Australia facility by June 30, 2015. We anticipate recording an estimated total charge of approximately $5.0 to $5.5 million related to this restructuring plan, a portion of which was recorded in fiscal 2014. Upon our completion of this plan, we anticipate that our ongoing internal research and development and general and administrative overhead costs, excluding the direct external costs to advance the development of its pipeline, will be approximately $9-$10 million per year.

BARDA- On April 23, 2014, we announced that we were notified by the HHS office of ASPR and BARDA that pending a decision regarding the outcome of an IPR of our contract for the development of LANI, ASPR/BARDA had issued a Stop-Work Order notifying us to discontinue work on a number of activities that would no longer be reimbursed under the contract. On May 7, 2014, and based upon the results of the IPR, HHS/ASPR/BARDA notified us of its decision to terminate the contract for the convenience of the U.S. Government. Certain ongoing activities at the time of termination were excluded from the termination-for-convenience notice.

We have been and continue to work with ASPR/BARDA to close out this contract, which involves completing several clinical trials, 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 June 30, 2014, we had $17.8 million in accounts receivable due from BARDA, which does not include $3.7 million of contract service revenue and accounts receivable related to amounts that we believe we are entitled to be reimbursed for under our terminated contract with BARDA and pursuant to applicable government regulations, but for which we potentially may not be fully reimbursed. At this time we cannot determine when and to what extent our invoices will be approved and reimbursed by, or when a final termination settlement may be finalized with, BARDA, or what the final financial outcome may be.

Financial Operations Overview

Revenue. We have historically generated revenue primarily from royalty payments, license fees, milestone payments, payments for services performed pursuant to contracts, such as the recently terminated BARDA contract, and certain early-stage research and development activities pursuant to collaborations with other entities. Revenues are earned when the underlying service is rendered and all contingencies have been satisfied. Revenue for royalties is recognized when the net sales of the underlying product by the relevant third party, including actual or estimated returns within the royalty period based on agreement, are determinable. In 2015, we anticipate revenue from services to decrease substantially due to the termination of our contract with BARDA for the clinical advancement of laninamivir octanoate, and we expect our royalty revenues will be lower than in 2014, excluding any potential stockpiling orders. Further, the Relenza® patents are scheduled to expire in the U.S. in December 2014 and in Australia in May 2015. However, GSK has recently verified that we will continue to be eligible to receive royalties on the net sales of Relenza® in the U.S. beyond December 2014 to the extent that U.S. Patent Application No. 08/737,141 remains pending. On August 25, 2014, GSK filed an appeal to the United States Patent Trial Appeal Board in relation to this patent application. We are unable at this time to determine the duration or the outcome of this appeal process, or how long this patent application will remain pending, but anticipate that there is a reasonable likelihood that we will continue to receive royalty revenue from net sales of Relenza® in the U.S. during our 2015 fiscal year.

Cost of Revenue. Cost of revenue represents expenses incurred by us in performing services and activities pursuant to government contracts or grants for which we record related revenue and expense on the gross basis of accounting. Cost of revenue expense, the vast majority of which relates to the BARDA contract, includes, but is not limited to, the cost of third-party service providers incurred in connection with conducting external preclinical studies and treating patients enrolled in clinical trials and monitoring, accumulating and evaluating the related clinical data; salaries and personnel-related expenses for our internal staff allocated to a contract or grant, including benefits; and, the cost to develop, formulate and manufacture product candidates directly allocated to the specific contract. cost of Revenue expenses are expensed as incurred. In 2015, we expect our cost of revenue to decrease from 2014 levels due to the termination of our contract with BARDA for the clinical advancement of laninamivir octanoate.

Research and Development Expense. Research and development expense generally includes the cost of activities associated with the discovery, preclinical development, and clinical development of our product candidates other than those captured under Cost of revenue. These costs include, but are not limited to, fees paid to third-party service providers in connection with conducting external preclinical studies and treating patients enrolled in clinical trials and monitoring, accumulating and evaluating the related clinical data; salaries and personnel-related expenses for our internal staff, including benefits and share-based compensation; the cost to develop, formulate and manufacture product candidates; legal fees associated with patents and intellectual property related to our product candidates; research consulting fees; license expenses and sponsored research fees paid to third parties; and specialized information systems, depreciation and laboratory facility costs. Research and development expenses are expensed as incurred.

We anticipate that our research and development expense will increase in 2015, as compared to 2014, based on our plans to advance the clinical development of vapendavir into a Phase 2 clinical trial in patients with moderate and severe asthma with a presumptive HRV infection, and the advancement of our RSV compound, *BTA-C585* into IND-enabling preclinical studies. Due to the early stage nature of our programs, our future research and development expense may be highly variable in future periods depending on the results of these activities. From time-to-time, we will make determinations as to how much funding or resources to direct to these programs in response to their scientific, clinical and regulatory status, anticipated market opportunity and the availability of capital to fund our programs.

A discussion of the risks and uncertainties associated with the development of our existing or future product candidates, is set forth in the “Risk Factors” section of this Form 10-K.

General and Administrative Expense. General and administrative expense reflects the costs incurred to manage and support our research and development activities, operations, contracts and grants, and status as a publicly-traded company. General and administrative expense consists primarily of salaries and personnel-related expenses, including share-based compensation for personnel in executive, finance, accounting, information technology, business development and human resources functions. Other significant costs include professional fees for legal, auditing, tax, and consulting services, insurance premiums, other expenses incurred as a result of being a company that is publicly traded, and depreciation and facility expenses. In 2015, we expect our general and administrative expense to decrease from our 2014 levels as result of our restructuring plan, which includes a significant reduction in personnel, the consolidation of all corporate functions into our U.S. head office, and the closure of our Melbourne, Australia facility.

Foreign Exchange (Gain) or Loss. Foreign exchange (gain) or loss primarily relates to remeasurement of transactions denominated in a currency other than the functional currency that the financial records are maintained per ASC 830, *Foreign Currency Matters*.

Other Income (Expense). Other income (expense) has historically consisted of the proceeds from the gain or loss on the disposal of equipment, research and development tax grants and interest income. Interest income consists of interest earned on our cash, cash equivalents, and short-term and long-term investments.

Critical Accounting Policies and Estimates

This discussion and analysis of our current financial condition and historical results of operations are based on our audited financial statements, which have been prepared in accordance with generally accepted accounting principles in the U.S. (“GAAP”). The preparation of our financial statements requires us to make estimates and judgments with respect to the selection and application of accounting policies that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosures of contingent assets and liabilities. We believe the following critical accounting policies are important in understanding our financial statements and operating results.

Use of Estimates. The preparation of our financial statements in conformance with GAAP requires us to make estimates and judgments with respect to the selection and application of accounting policies that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosures of contingent assets and liabilities. We base our estimates on historical experience, current economic and industry conditions, and various other factors that we believe to be reasonable at the time, the results of which form the basis for making judgments about the carrying values of certain assets and liabilities. Actual future results may differ from these estimates under different assumptions or conditions.

Revenue Recognition. We recognize revenue as we perform services or fulfill contractual obligations under licensing and other collaborative research and development agreements. Revenue from royalties is recognized when the net sales of the underlying product by the relevant third-party licensee, including actual or estimated returns within the royalty period based on agreement, are determinable. Revenue from services performed pursuant to a contract or grant is generally recognized as revenue when earned, typically when the underlying services or activities are rendered. Revenue from collaborative research and development activities typically consists of fees for services, or payments when specific milestones are met and match underlying activities occurring during the term of the arrangement. When circumstances arise where collection of the underlying services is uncertain, recognition of the revenue is delayed until such time as collection is reasonably assured.

Accrued Expenses. The preparation of our financial statements requires us to estimate expenses that we believe have been incurred but for which we have not yet received invoices from our vendors, and for employee services that we have not yet made payment. This process primarily involves identifying services and activities that have been performed by third-party vendors on our behalf and estimating the level to which they have been performed and the associated cost incurred for such service as of each balance sheet date. Examples of expenses for which we generally accrue based on estimates include fees for services, such as those provided by clinical research and data management organizations and investigators in conjunction with the conduct of our clinical trials, research organizations that perform preclinical studies, and fees owed to contract manufacturers in connection with the formulation or manufacture of materials for our preclinical studies and clinical trials. In order to estimate costs incurred to-date and evaluate the adequacy of a related accrued liability, we monitor and analyze the progress and related activities, the terms of the underlying contract or agreement, any invoices received and the budgeted costs. We make these estimates based upon the facts and circumstances known to us at the time and in accordance with GAAP.

Share-Based Compensation We use the Black-Scholes method to estimate the value of stock options granted to employees and directors. Our forfeiture rate is based on historical experience as well as anticipated turnover and other qualitative and quantitative factors, which may change over time. There may be adjustments to future periods if actual forfeitures differ from current estimates. Our time-based awards are issued with graded vesting. The compensation cost of these graded vesting awards is recognized using the straight-line method.

Recent Accounting Pronouncements

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 July 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.

Results of Operations

Fiscal Years Ended June 30, 2014 and 2013

Summary. For the year ended June 30, 2014, we reported a net loss of $11.0 million, as compared to $8.9 million in 2013. The $2.1 million increase in net loss in 2014 was the result of a $31.4 million increase in cost of revenue, a $3.3 change from a foreign exchange gain to a loss, non-recurring other income of $12.0 million that we recorded in 2013 as a result of a gain on merger and a research and development tax credit, and a $1.1 million decrease in interest income, offset largely by a $29.6 million increase in revenue from services and other revenue, a $5.5 million increase in revenue from royalties and milestones, a $7.8 million decrease in general and administrative expense, a $2.4 million decrease in research and development expense and a $0.4 million increase in income tax benefit. Basic and diluted net loss per share were $0.35 for the year ended June 30, 2014, as compared to a basic and diluted net loss per share of $0.32 in 2013.

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.

Revenue. Revenue increased to $68.7 million for the year ended June 30, 2014 from $33.6 million in 2013. The following table summarizes the key components of our revenue for the years ended June 30, 2014 and 2013:

	(in millions) Twelve Months Ended June 30,	
	2014	**2013**
Royalty revenue – Relenza®	$ 10.6	$ 2.6
– Inavir®	4.5	4.2
Commercial milestone – Inavir®	-	2.8
Revenue from contract services, grants and collaborations	53.6	24.0
Total revenue	$ 68.7	$ 33.6

Royalty revenue from net sales of Relenza® increased in 2014 primarily due to a stockpiling order in Japan, and higher net commercial sales of Relenza®. Royalty revenue from Inavir® increased due to higher commercial sales. A non-recurring commercial milestone was earned in 2013 due to the net sales of Inavir® reaching a certain threshold. Revenue from contract services, grants and collaborations increased primarily due to the increased reimbursements received from BARDA as a result of the clinical and manufacturing advancements of the laninamivir octanoate program under our recently terminated BARDA contract, offset by a slight decrease in other grant revenue. For the three month period ended June 30, 2014, we did not recognize $3.7 million of contract service revenue relating to amounts we believe we are entitled to be reimbursed for under our terminated contract with BARDA and pursuant to applicable government regulations, but for which we potentially may not be fully reimbursed

Cost of Revenue. Cost of revenue increased to $51.1 million in 2014 from $19.7 million in 2013, representing an increase of $31.4 million. The following table summarizes the components of our cost of revenue in 2014 and 2013.

	June 30,	
	2014	2013
	(in millions)	
Direct preclinical, clinical and product development expense	$ 44.6	$ 14.5
Salaries, benefits and share-based compensation expense	5.9	4.5
Other expense	0.6	0.7
Total cost of revenue expense	$ 51.1	$ 19.7

Direct preclinical, clinical and product development expense increased in 2014 primarily due to the Phase 2 IGLOO trial and three other Phase 1 and Phase 2 trials of laninamivir octanoate conducted during 2014, as well as related manufacturing activities under the recently terminated BARDA contract. Salaries, benefits and share-based compensation expense increased in 2014 principally due to severance benefits of $1.6 million being recorded as a result of the termination of the BARDA contract in May 2014. Other expenses decreased due to lower administrative expenses as a result of the termination of the BARDA contract in May 2014.

Research and Development Expense. Research and development expense decreased to $17.5 million in 2014 from $19.9 million in 2013, representing a decrease of $2.4 million. The following table summarizes the components of our research and development expense for 2014 and 2013.

	June 30,	
	2014	2013
	(in millions)	
Direct preclinical, clinical and product development expense	$ 5.1	$ 3.7
Salaries, benefits and share-based compensation expense	7.1	9.3
Other expense	2.0	3.3
Depreciation and facility related expense	3.3	3.6
Total research and development expense	$ 17.5	$ 19.9

Direct preclinical, clinical and product development expense increased in 2014 due largely to a $3.1 million increase in direct clinical expenses associated with the advancement of our vapendavir and RSV programs in 2014, offset in part by $1.7 million decrease in other research and development activities. Salaries, benefits and share-based compensation expense decreased in 2014 due to a reduction of $4.6 million in ongoing compensation expenses, offset in part by $2.4 million of severance benefits recorded in relation to several restructurings that occurred during 2014. Other expenses decreased due to fewer research programs in 2014 than 2013. Depreciation and facility expense decreased to a reduction in research facilities.

General and Administrative Expense. General and administrative expense decreased to $10.2 million in 2014 from $18.0 million in 2013, representing a decrease of $7.8 million. The following table summarizes the components of our general and administrative expense in 2014 and 2013.

	June 30,	
	2014	2013
	(in millions)	
Salaries, benefits and share-based compensation expense	$ 5.3	$ 9.8
Professional and legal fees expense	1.6	3.8
Other expense	3.3	4.4
Total general and administrative expense	$ 10.2	$ 18.0

Salaries, benefits and share-based compensation expense decreased in 2014 largely due to a $1.5 million reduction in ongoing compensation expenses as result of integration of the Company’s administrative functions, as well as a charge for severance benefits and merger expenses of $3.0 million that occurred in 2013. Professional and legal fees expense decreased in 2014 primarily due to non-recurring merger-related expenses of $1.4 million that were incurred in 2013, as well as lower ongoing professional fees as result of integration of the Company’s administrative functions. Other expenses decreased in 2014 due to lower administrative expenses as a result of the Company’s integration efforts.

Foreign Exchange Loss, (Gain). Foreign exchange change from a gain to a loss for $3.3 million in 2014 due to an increase in the volatility of the exchange rate of the U.S. dollar to the Australian dollar during the year, which resulted in a decrease in the value of the U.S. dollar as compared to the Australian dollar 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 also translate all of our 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.

Other Income (Expense). Other income decreased by $13.1 million in 2014 primarily due to non-recurring gains recorded in 2013 of $7.6 million related to a gain on a merger and the receipt of $4.4 million with respect to an Australian research and development tax credit in 2013, as well as a $1.1 million decrease in interest income in 2014 due to lower available interest rates, and higher amount of U.S. dollar cash balances as compared to 2013.

Fiscal Years Ended June 30, 2013 and 2012

Summary. For the year ended June 30, 2013, we reported a net loss of $8.9 million, as compared to $19.2 million in 2012. The $10.3 million decrease in net loss in 2013 was the result of a $13.2 million increase in revenue, a $7.6 million gain recorded in November 2012 pursuant to the merger, and an increase of $4.4 million in research and development tax credits received in 2013, offset in part by a $12.4 million increase in operating expenses that included a $1.8 million reduction from a foreign exchange gain, a $1.9 million decrease in interest and other income, and $0.6 million decrease in income tax benefit. Basic and diluted net loss per share were $0.32 for the year ended June 30, 2013, as compared to a basic and diluted net loss per share of $0.85 in 2012.

Revenue. Revenue increased to $33.6 million for the year ended June 30, 2013 from $20.4 million in 2012. The following table summarizes the key components of our revenue for the years ended June 30, 2013 and 2012:

	(in millions) Twelve Months Ended June 30,	
	2013	**2012**
Royalty revenue – Relenza®	$ 2.6	$ 4.4
– Inavir®	4.2	4.5
Commercial milestone – Inavir®	2.8	-
Revenue from services, grants and collaborations	24.0	11.5
Total revenue	$ 33.6	$ 20.4

Royalty revenue from net sales of Relenza® decreased in 2013 due to lower gross sales and an increase in the amount of returns of Relenza® to GSK. Royalty revenue from Inavir® decreased due to a decrease in the value of the Japanese yen relative to the U.S. dollar in 2013. A commercial milestone was earned in 2013 due to the net sales of Inavir® reaching a certain threshold. Revenue from services increased by $12.8 million primarily due to the increased reimbursements received as a result of the clinical advancement of the laninamivir octanoate program into the Phase 2 IGLOO clinical trial under the BARDA contract, offset by a $0.3 million decrease in other grant revenue.

Cost of Revenue. Cost of revenue increased to $19.7 million in 2013 from $9.9 million in 2012, representing an increase of $9.8 million. The following table summarizes the components of our cost of revenue in 2013 and 2012.

	June 30,	
	2013	**2012**
	(in millions)	
Direct preclinical, clinical and product development expense	$ 14.5	$ 6.5
Salaries, benefits and share-based compensation expense	4.5	3.2
Other expense	0.7	0.2
Total cost of revenue expense	$ 19.7	$ 9.9

Direct preclinical, clinical and product development expense increased in 2013 due largely to the advancement of our laninamivir octanoate program into the Phase 2 IGLOO clinical trial under the BARDA contract. Salaries, benefits and share-based compensation expense increased in 2013 principally due to more research and development resources being deployed on the laninamivir octanoate program under the BARDA contract in 2013 than in 2012. Other expenses increased due to the more activities occurring under the BARDA contract.

Research and Development Expense. Research and development expense decreased to $19.9 million in 2013 from $24.1 million in 2012, representing a decrease of $4.2 million. The following table summarizes the components of our research and development expense for 2013 and 2012.

	June 30,	
	2013	2012
	(in millions)	
Direct preclinical, clinical and product development expense	$ 3.7	$ 7.3
Salaries, benefits and share-based compensation expense	9.3	10.0
Other expense	3.3	3.3
Depreciation and facility related expense	3.6	3.5
Total research and development expense	$ 19.9	$ 24.1

Direct preclinical, clinical and product development expense decreased in 2013 due largely to a $3.1 million decrease in clinical expenses associated with the completion of the Phase 2 clinical trial of vapendavir in 2012 and lower preclinical and chemistry expenses of $0.5 million associated with a decrease in the number of preclinical programs. Salaries, benefits and share-based compensation decreased in 2013 due to a $1.8 million decrease in personnel costs as a result of more resources being deployed on the laninamivir octanoate program under the BARDA contract, offset in part by a charge for severance benefits of $1.1 million that was recorded in 2013.

General and Administrative Expense. General and administrative expense increased to $18.0 million in 2013 from $9.4 million in 2012, representing an increase of $8.6 million. The following table summarizes the components of our general and administrative expense in 2013 and 2012.

	June 30,	
	2013	2012
	(in millions)	
Salaries, benefits and share-based compensation expense	$ 9.8	$ 4.5
Professional and legal fees expense	3.8	1.8
Other expense	4.4	3.1
Total general and administrative expense	$ 18.0	$ 9.4

Salaries, benefits and share-based compensation expense increased in 2013 largely due to an increase in non-cash share-based compensation of $2.2 million as a result of the accelerated vesting of prior years' grants pursuant to the completion of the merger in 2013, a $1.6 million charge recorded for severance benefits in 2013 due to a reduction in our workforce, and a $1.5 million increase in personnel costs associated with adding corporate personnel in the U.S. Professional and legal fees expense increased in 2013 primarily due to non-recurring merger-related expenses of $1.4 million as well as other ongoing transition costs. Other expenses increased in 2013 due to an increase in corporate governance expenses of $1.1 million associated with our move to the NASDAQ exchange in the U.S. and increased depreciation and facility related expenses due to the inclusion of a U.S. headquarters.

Foreign Exchange Gain, net. Foreign exchange gain increased by $ 1.8 million in 2013 due to increased volatility related to the U.S. dollar as compared to the Australian dollar during the last fiscal quarter of 2013, which resulted in an increase in the value of the U.S. dollar as compared to the Australian dollar 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 also 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.

Other Income (Expense). Other income increased by $10.1 million in 2013 primarily due to a non-recurring $7.6 million gain on merger and the receipt of $4.4 million with respect to an Australian research and development tax credit in 2013. Interest income decreased by $1.9 million in 2013 due to lower available interest rates in 2013 as compared to 2012, as well as lower average cash balances held in 2013 compared to 2012.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 1965 through June 30, 2014, we have funded our operations primarily with public offerings of equity securities and license fees, royalties, research agreements and grants. In March 2011, we were 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. On May 7, 2014 the HHS office of the ASPR and BARDA notified us of its decision to terminate the contract for the development of laninamivir octanoate for the convenience of the U.S. Government.

At June 30, 2014, our cash, cash equivalents and long-term investments were $91.7 million. Our cash and cash equivalents are generally held in a variety of interest-bearing short-term deposits with large U.S. and Australian banks, and our long-term investments have an average maturity of less than 2 years.

Cash Flows

For the year ended June 30, 2014, cash and cash equivalents increased by $14.9 million, from $66.8 million to $81.7 million. This increase was primarily the result of $26.8 million in net cash proceeds we received upon the issuance of common stock, offset in part by cash used for operating activities and other investing activities during the period.

Net cash used in operating activities was $3.3 million in 2014, which reflected our net loss for the period of $11.0 million and an increase in net operating assets of $5.7 million, offset in part by non-cash charges for share-based compensation and depreciation and amortization of $4.1 million and by an increase in net operating liabilities of $9.3 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 activities, offset in part by revenue from services, royalties and other revenue from grants and collaborations. The net change in operating assets and liabilities reflects a $7.6 million increase in accounts receivable due largely to higher contract revenue billed or accrued under our recently terminated contract with BARDA, a decrease of $1.8 million in accrued severance obligations and a decrease of $0.3 million in deferred revenue, offset in part by a $1.5 million decrease in prepaid expenses, and a $12.0 million increase in accounts payable and other accrued expenses, excluding foreign currency translations of the underlying balances.

Net cash used in investing activities during 2014 was $10.1 million, which reflects us investments of $10.0 million in long-term investments and $0.1 million for the purchase of property and equipment.

Funding Requirements

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;
- the reimbursements we ultimately receive 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 these 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 the general and administrative function we 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 preclinical and clinical development of our product candidates, we believe that our existing cash, cash equivalents and long-term investments of approximately $92 million as of June 30, 2014, along with the anticipated proceeds from existing royalty-bearing licenses and expected reimbursements under the BARDA contract to finalize closeout activities, will enable us to operate for a period of at least 12 months from June 30, 2014.

We currently do not have any commitments for future funding, nor do we anticipate that we will generate significant revenue, aside from revenue from existing royalty-bearing arrangements. 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. If we do, 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 arrangement. 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, if not all, of our research and development programs, or delay or curtail 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 restrictive covenants that restrict how we operate our business.

Off-Balance Sheet Arrangements

At June 30, 2014, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. We are, therefore, not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

Contractual Obligations and Commitments

We have entered into an operating lease for an office and laboratory facility located in Melbourne, Australia through September 2015, as well as corporate offices in Alpharetta, Georgia through September, 2019. The total annual rent expense under these leases is approximately $0.6 million. As result of the termination of the BARDA contract in May, we have no open reimbursable purchase orders with third party vendors for goods and services as of June 30, 2014. As of June 30, 2014, future payments under these non-cancellable operating leases and purchase obligations are as follows (in millions):

	Payments Due By Period				
	Total	Less than 1 year	1-3 Years	4-5 Years	After 5 Years
Operating leases	$ 1.2	$ 0.6	$ 0.5	$ 0.1	$ —
Total contractual obligations	$ 1.2	$ 0.6	$ 0.5	$ 0.1	$ —

The above contractual obligations table does not include any amounts or payments related to development, regulatory, or commercialization milestones, as the payments are contingent on the achievement of these milestones, which has not occurred. As of June 30, 2014 there are no off balance sheet obligations.

ITEM 7A. ***QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK***

Interest Rate Risk

Our exposure to interest rate risk is currently confined to interest earnings, as our cash, cash equivalents and short and long term investments are invested in highly liquid money market funds, short-term bank deposits and AA/ Aa grade bond securities. The primary objective of our investment activities is to preserve our capital to fund operations. We do not use derivative financial instruments to manage interest rate risk. If a 10% change in interest rates were to have occurred on June 30, 2014, this change would not have had a material effect on future earnings or cash flows.

Credit Risk

Our exposure to credit risk is managed through our investment policy that specifies credit quality standards for our cash, cash equivalents and investments, which limits the amount of credit exposure to any single party or industry. We place any excess cash not needed to fund operations with high credit quality financial institutions and AA/ Aa grade bond securities in order to limit the amount of credit exposure.

Foreign Currency Exchange Rate Risk

We report our financial results in U.S. dollars; however we conduct business in foreign countries. For U.S. reporting purposes, we translate all assets and liabilities of our non-U.S. entities at the period-end exchange rate and revenue and expenses at the average exchange rates in effect during the periods. The net effect of these translation adjustments is shown in the accompanying condensed consolidated financial statements as a component of stockholders' equity.

We generate a significant portion of our revenue and collect receivables in foreign currencies. Similarly, we incur costs in foreign currencies and are subject to fluctuations in the exchange rate of the U.S. dollar against major foreign currencies, including the Euro, British Pound, Japanese Yen and Australian dollar, which can result in foreign currency exchange gains and losses that may significantly impact our financial results. Continued currency exposure to fluctuation in these exchange rates could result in financial results that are not comparable from quarter-to-quarter, or year-to-year. Where appropriate, we hold cash reserves in currencies in which those reserves are anticipated to be expended.

ITEM 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

The information required by this Item is included in our Financial Statements and Supplementary Data listed in Item 15 of Part IV of this Annual Report on Form 10-K.

ITEM 9. ***CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE***

None.

ITEM 9A. ***CONTROLS AND PROCEDURES***

Evaluation of Disclosure Controls and Procedures

Our management, including our Principal Executive Officer and Principal Financial Officer, have 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 (the "Exchange Act")) of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, management and our Chief Executive Officer have concluded that our disclosure controls and procedures are effective as of the end of the period covered by this report.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f)) under the Exchange Act as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel, 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 and includes those policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the Company's assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit the preparation of financial statements in accordance with generally accepted accounting principles, and that the receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and,
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Our management, including our Chief Executive Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived, operated, tested and monitored, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

Our management, including our Chief Executive Officer, assessed the effectiveness of our internal control over financial reporting as of the end of the fiscal year covered by this Annual Report on Form 10-K. In making this assessment, management used the criteria set forth in Internal Control-Integrated Framework issued in 1992 by the Committee of Sponsoring Organizations of the Treadway Commission, ("COSO"). Based on their assessment, management has concluded that, as of June 30, 2014, our internal control over financial reporting is effective based on the COSO criteria.

The effectiveness of our internal control over financial reporting as of June 30, 2014 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fourth quarter of 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. ***OTHER INFORMATION***

None.

PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

Incorporated by reference to the sections labeled “Proposal 1 Election of Directors,” “Executive Officers,” and “Corporate Governance” in our definitive proxy statement to be filed in connection with our 2014 annual meeting of stockholders.

Code of Ethics

We have adopted a code of ethics for our directors, officers and employees, which is available on our website at www.biotapharma.com in the Investor section under “Corporate Governance.” If we make any substantive amendments to the code of ethics or grant any waiver from a provision of the code of ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website. The information on, or that can be accessed from, our website is not incorporated by reference into this Annual Report.

ITEM 11. *EXECUTIVE COMPENSATION*

Incorporated by reference to the sections labeled “Executive Compensation,” “Compensation of Directors” and “Compensation Committee Report” in our definitive proxy statement to be filed in connection with our 2014 annual meeting of stockholders.

ITEM 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT, AND RELATED STOCKHOLDER MATTERS*

Incorporated by reference to the sections labeled “Principal Stockholders,” and “Executive Compensation” in our definitive proxy statement to be filed in connection with our 2014 annual meeting of stockholders.

ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE*

Incorporated by reference to the sections labeled “Certain Relationships and Related Transactions” and “Corporate Governance” in our definitive proxy statement to be filed in connection with our 2014 annual meeting of stockholders.

ITEM 14. *PRINCIPAL ACCOUNTING FEES AND SERVICES*

Incorporated by reference to the section labeled “Independent Registered Public Accountants” in our definitive proxy statement to be filed in connection with our 2014 annual meeting of stockholders.

PART IV

ITEM 15. ***EXHIBITS AND FINANCIAL STATEMENT SCHEDULES***

(a)(1) Financial Statements

The following documents are included on pages F-1 through F-29 attached hereto and are filed as part of this annual report on Form 10-K.

(a)(2) Financial Statement Schedules

Not applicable

(a)(3) List of Exhibits Required by Item 601 of Regulation S-K

See Item 15(b) below.

(b) Exhibits

The exhibits which are filed or furnished with this report or which are incorporated herein by reference are set forth in the Exhibit Index hereto.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) 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, in the City of Alpharetta, Georgia on this 30th day of September 2014.

Biota Pharmaceuticals, Inc.

By: /s/ Russell H. Plumb
Russell H. Plumb
President and Chief Executive Officer

Pursuant to the requirements the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Russell H. Plumb Russell H. Plumb	President, Chief Executive Officer and Director (Principal Executive Officer and Principal Financial Officer)	September 30, 2014
/s/ Peter Azzarello Peter Azzarello	Vice President of Finance and Chief Accounting Officer (Principal Accounting Officer)	September 30, 2014
/s/ Dr. James Fox James Fox	Chairman of the Board of Directors	September 30, 2014
/s/ Geoffrey Cox Geoffrey Cox	Director	September 30, 2014
/s/ John Richard John Richard	Director	September 30, 2014
/s/ Richard Hill Richard Hill	Director	September 30, 2014
/s/ Anne VanLent Anne VanLent	Director	September 30, 2014
/s/ Michael Dougherty Michael Dougherty	Director	September 30, 2014

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Biota Pharmaceuticals, Inc.

In our opinion, the accompanying consolidated balance sheet and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Biota Pharmaceuticals, Inc. and its subsidiaries at June 30, 2014, and the results of their operations and their cash flows for the year ended June 30, 2014 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2014, based on criteria established in Internal Control - Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting under Item 9A. Our responsibility is to express an opinion on these financial statements and on the Company's internal control over financial reporting based on our integrated audit. We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audit of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP
Atlanta, Georgia
September 30, 2014

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Biota Holdings Limited

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, of equity and of cash flows present fairly, in all material respects, the financial position of Biota Pharmaceuticals, Inc. and its subsidiaries at June 30, 2013 and June 30, 2012 and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2013 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2013 based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the Management's Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our audits which was an integrated audit in 2013.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As described in Note 3 to the consolidated financial statements, the Company completed the acquisition of Nabi Biopharmaceuticals, Inc. which has been accounted for as a reverse merger.

A company’s internal control over financial reporting is a process designed 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. A company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PricewaterhouseCoopers
Melbourne, Australia
27 September 2013

Biota Pharmaceuticals, Inc.
Consolidated Balance Sheets
(in millions), except share data

	As of June 30,	
	2014	**2013**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 81.7	$ 66.8
Contract receivable (BARDA)	17.8	10.9
Other accounts receivable	0.9	0.1
Prepaid expenses and other assets	0.7	2.2
Total current assets	101.1	80.0
Non-current assets:		
Long-term investments	10.0	—
Deferred tax asset	0.9	1.5
Property and equipment, net	2.0	4.3
Total non-current assets	12.9	5.8
Total assets	$ 114.0	$ 85.8
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Contract payables and accrued expenses (BARDA)	$ 18.6	$ 6.5
Accrued expenses and other current liabilities	3.4	3.9
Accounts payable	2.8	2.4
Accrued severance obligations	1.2	3.0
Deferred tax liability	0.9	1.5
Deferred revenue	—	0.3
Total current liabilities	26.9	17.6
Other liabilities, net of current portion	0.2	0.2
Total liabilities	$ 27.1	$ 17.8
Commitments and contingencies	—	—
Stockholders' equity:		
Common stock, $0.10 par value; 200,000,000 shares authorized 35,100,961 shares and 28,352,326 shares issued and outstanding at June 30, 2014 and June 30, 2013, respectively	3.5	2.8
Additional paid-in capital	146.4	118.7
Accumulated other comprehensive income	26.8	25.3
Accumulated deficit	(89.8)	(78.8)
Total stockholders' equity	86.9	68.0
Total liabilities and stockholders' equity	$ 114.0	$ 85.8

See accompanying notes to the financial statements

Biota Pharmaceuticals, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in millions), except share data

	Years Ended June 30,		
	2014	**2013**	**2012**
Revenue:			
Royalty revenue and milestones	$ 15.1	$ 9.6	$ 8.8
Revenue from services	53.5	23.2	11.0
Other	0.1	0.8	0.6
Total revenue	68.7	33.6	20.4
Operating expense (income):			
Cost of revenue	51.1	19.7	9.9
Research and development	17.5	19.9	24.1
General and administrative	10.2	18.0	9.4
Foreign exchange loss (gain)	1.4	(1.9)	(0.1)
Total operating expense	80.2	55.7	43.3
Loss from operations	(11.5)	(22.1)	(22.9)
Other income:			
Gain recorded on merger	—	7.6	—
Research and development credit	—	4.4	—
Interest income	0.2	1.3	3.2
Total other income	0.2	13.3	3.2
Loss before tax	(11.3)	(8.8)	(19.7)
Income tax benefit (expense)	0.3	(0.1)	0.5
Net loss	$ (11.0)	$ (8.9)	$ (19.2)
Basic and diluted loss per share	(0.35)	(0.32)	(0.85)
Basic and diluted weighted average shares outstanding	31,347,888	28,217,515	22,713,566
Comprehensive loss:			
Net loss	(11.0)	(8.9)	(19.2)
Exchange differences on translation of foreign operations	1.5	(4.2)	(3.0)
Total comprehensive loss	$ (9.5)	$ (13.1)	$ (22.2)

See accompanying notes to the financial statements

Biota Pharmaceuticals, Inc.
Consolidated Statements of Stockholders Equity
(in millions), except share data

	Common Stock		Additional Paid-in Capital	Treasury Shares		Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount		Shares	Amount			
Balances at June 30, 2011	181,417,556	99.8	0.8	(1,311,034)	(1.0)	$ (50.7)	32.5	$ 81.4
Comprehensive loss								
Exchange differences on translation of foreign operations	-	-	-	-	-	-	(3.0)	(3.0)
Net loss	-	-	-	-	-	(19.2)	-	(19.2)
Total Comprehensive loss								(22.2)
New shares issued on exercise of options	932,760	0.6	(0.6)	-	-	-	-	-
Purchase of treasury shares	-	-	-	(505,144)	(0.4)	-	-	(0.4)
Share-based compensation	-	-	0.5	-	-	-	-	0.5
Balances at June 30, 2012	182,350,316	100.4	0.7	(1,816,178)	(1.4)	(69.9)	29.5	59.3
Comprehensive loss								
Exchange differences on translation of foreign operations	-	-	-	-	-	-	(4.2)	(4.2)
Net loss	-	-	-	-	-	(8.9)	-	(8.9)
Total Comprehensive loss								(13.1)
New shares issued on exercise of options	413,335	0.4	(0.4)	-	-	-	-	-
New shares issued on vesting of options on merger	4,639,104	1.1	(1.1)	-	-	-	-	-
Acquisition of Nabi Biopharmaceuticals	(153,398,048)	(98.5)	233.4	(4,051,183)	(115.7)	-	-	19.2
Retirement of treasury shares	(5,867,361)	(0.6)	(116.5)	5,867,361	117.1	-	-	-
Restricted stock units issued, net	214,983	-	-	-	-	-	-	-
Retirement of common stock	(3)	-	-	-	-	-	-	-
Share-based compensation	-	-	2.6	-	-	-	-	2.6
Balances at June 30, 2013	28,352,326	$ 2.8	$ 118.7	-	-	$ (78.8)	$ 25.3	$ 68.0
Comprehensive loss								
Exchange differences on translation of foreign operations	-	-	-	-	-	-	1.5	1.5
Net loss	-	-	-	-	-	(11.0)	-	(11.0)
Total Comprehensive loss								(9.5)
Common stock issued	6,685,985	0.7	26.1	-	-	-	-	26.8
Restricted stock units issued, net	62,650	-	0.2	-	-	-	-	0.2
Share-based compensation	-	-	1.4	-	-	-	-	1.4
Balances at June 30, 2014	35,100,961	$ 3.5	$ 146.4	-	-	$ (89.8)	$ 26.8	$ 86.9

See accompanying notes to the financial statements

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

	Years Ended June 30,		
	2014	**2013**	**2012**
Cash flows from operating activities provided by/(used in):			
Net loss	$ (11.0)	$ (8.9)	$ (19.2)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2.4	3.0	3.1
Share based compensation	1.7	2.6	0.5
Gain recorded on merger		(7.6)	—
Deferred income taxes	—	1.5	(0.2)
Change in operating assets and liabilities (net of liabilities acquired):			
Accounts receivable	(7.1)	(4.2)	(3.4)
Prepaid expenses and other assets	1.4	(0.6)	0.2
Deferred revenue	(0.3)	(0.1)	0.2
Accounts payable and accrued expenses and other liabilities	10.6	2.8	2.9
Accrued severance obligations	(1.0)	(2.4)	—
Net cash used in operating activities	(3.3)	(13.9)	(15.9)
Cash flows from investing activities:			
Cash acquired on merger	—	32.7	—
Purchases of long-term investments	(10.0)	—	—
Purchases of property and equipment	(0.1)	(1.0)	(1.3)
Net cash (used in) provided by investing activities	(10.1)	31.7	(1.3)
Cash flows from financing activities:			
Payment for treasury shares	—	—	(0.4)
Issuance of common stock	26.8	—	—
Net cash provided by (used in) financing activities	26.8	—	(0.4)
Net increase (decrease) in cash and cash equivalents	13.4	17.8	(17.6)
Cash and cash equivalents at beginning of period	66.8	53.8	74.2
Effects of exchange rate movements on cash and cash equivalents	1.5	(4.8)	(2.8)
Cash and cash equivalents at end of period	$ 81.7	$ 66.8	$ 53.8
Supplemental cash flow disclosure:			
Proceeds from issuance of common stock on merger	$ —	$ 27.0	$ —
Proceeds to settle accrued severance obligations and other accrued liabilities on merger	—	5.7	—
Cash acquired on merger	$ —	$ 32.7	$ —

See accompanying notes to the financial statements

(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 is 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 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 has not received the full data set from this trial and plans to assess this additional safety and efficacy data from this trial when received.

The Company is also developing BTA-798, also known as vapendavir, which is in Phase 2 for the treatment of human rhinovirus ("HRV") infections in patients with moderate to severe asthma. 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.

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 ("RSV") infections in children, the elderly and immune-compromised patients. The Company is currently conducting IND-enabling studies with *BTA-C585*, the lead compound from our F-protein inhibitor program.

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 U.S. 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, and based upon the results of the IPR, HHS/ASPR/BARDA notified the Company of its decision to terminate the contract for the convenience of the U.S. Government. The Company continues to work with ASPR/BARDA to close out this contract, which involves completing several clinical trials, 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 with the Company, Biota 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 recent 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 levels.

The Company plans to continue to finance its operations with (i) existing cash, cash equivalents and long-term 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 it receives from BARDA related to the close-out of its recently terminated contract, continuing to receive royalty revenue under existing licenses, entering into future collaboration, license or commercialization agreements, the successful development of its product candidates, executing future financings and ultimately, upon the 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, 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) Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements of Biota Pharmaceuticals, Inc. and its wholly owned subsidiaries have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). All intercompany balances and transactions have been eliminated in consolidation. The Company's fiscal year ends on June 30. The Company operates as one operating segment.

Use of Estimates

The preparation of the consolidated financial statements requires management of the Company to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Significant items subject to such estimates and assumptions include accruals and obligations, tangible and intangible assets and deferred income taxes. Actual results could differ from those estimates.

Fair Value of Financial Instruments

Financial instruments include cash and cash equivalents, investments, accounts receivable, accounts payable and accrued liabilities. The carrying amounts of those financial instruments are considered to be representative of their respective fair values because of the short-term nature of those investments.

Cash Equivalents and Investments

Cash equivalents consist of short-term, highly liquid investments with original maturities of 90 or fewer days when purchased. Investments with original maturities between 90 and 365 days when purchased are considered to be short-term investments. Investments with original maturities over 365 days when purchased are considered to be long-term investments The Company has classified its entire investment portfolio as available-for-sale. These securities are recorded as either cash equivalents, short term or long term investments. Short-term and long-term investments are carried at the fair value based upon observable inputs based on quoted market prices. The amortized cost of securities is adjusted for amortization of premiums and accretion of discounts to maturity. Amortization and accretion are included in interest income, net, and realized gains and losses are also included in interest income, net. All unrealized gains and losses are reported in other comprehensive loss. The cost basis of all securities sold is based on the specific identification method. Available-for-sale securities as of June 30, 2014 consisted primarily of U.S. treasury securities and U.S. government agency securities.

Concentration of Credit Risk and Other Risks and Uncertainties

Cash, cash equivalents and short and long term investments consist of financial instruments that potentially subject the Company to concentrations of credit risk to the extent recorded on the balance sheets. The Company believes that it has established guidelines for investment of its excess cash that maintain principal and liquidity through its policies on concentration, diversification, investment maturity, and investment grade.

Receivables

Accounts receivable are recorded at the invoiced amount. An allowance for doubtful accounts is estimated based on probable credit losses in the existing accounts receivable. The allowance is determined based on a review of individual accounts for collectability, generally focusing on those that are past due. The current year expense to adjust the allowance for doubtful accounts, if any, is recorded in the consolidated statement of operations. An allowance for uncollectible accounts receivable is estimated based on a combination of default history, aging analysis and any specific, known troubled accounts. When a receivable is finally established as uncollectible, it is written off against the allowance account for accounts receivables. The allowance for doubtful accounts balance is $0 as of June 30, 2014 and 2013, respectively.

Property and Equipment

Property and equipment are recorded at acquisition cost, net of accumulated depreciation and impairment. Depreciation on property and equipment is calculated using the straight-line method over the estimated useful lives of the assets. The estimated useful life of machinery and equipment is three to 10 years. Leasehold improvements are amortized using the straight-line method over the shorter of the remaining lease term or estimated useful life of the asset. Maintenance and repairs are charged to operations as incurred.

Intangible Assets

Intangible assets generally consist of two elements:

Royalty prepayments. Royalty prepayments represent expenditures made to research institutions where the parties agreed to exchange future variable royalty payments in relation to intellectual property for a fixed payment. These prepayments have a finite useful life, usually being the expiration of the underlying patent or contract, and are carried at the present value of costs at acquisition date, less accumulated amortization. Amortization is based on the anticipated usage of the asset, determined with reference to expected sales of the related product over the contract or patent life.

Computer software. Costs incurred in acquiring software and licenses that are expected to provide future period financial benefits are capitalized to computer software. Amortization is calculated on a straight-line basis over periods ranging from one to three years.

Leased Assets

The Company accounts for its leases at their inception as either an operating or capital lease, depending on certain defined criteria. All of the Company's leases in effect at June 30, 2014 and June 30, 2013 are considered operating leases. The costs of operating leases are charged to the consolidated statement of operations on a straight-line basis over the lease term. The difference between cash rent payments and straight line rent expense is recorded as deferred rent liability. The balance of deferred rent liabilities is classified in the balance sheet as other liabilities. Additionally, any incentives the Company receives are treated as a reduction of expenses over the term of the agreement. Leasehold improvements by the Company or landlord are capitalized at cost and amortized over the lesser of their expected useful life or the life of the lease, without assuming renewal features, if any, are exercised.

Impairment of Long-lived Assets

The Company reviews its tangible and intangible assets, including patents and licenses, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. In performing an impairment review, the Company estimates undiscounted cash flows from products that are covered by these patents and licenses. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than the carrying amount of the asset. If the evaluation indicates that the carrying value of an asset is not recoverable from its undiscounted cash flows, an impairment loss is measured by comparing the carrying value of the asset to its fair value.

Foreign Currency

Functional and reporting currency. Items included in the Company's consolidated financial statements are measured using the currency of the primary economic environment in which the entity operates, referred to as the functional currency. The Company operates in several jurisdictions with functional currencies of the U.S. dollar, the Australian dollar, and British Pound. The consolidated financial statements are presented in U.S. dollars.

Transactions and balances. Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the related transactions. Foreign exchange gains and losses resulting from the settlement of such transactions, as well as from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies, are recognized in the consolidated statements of operations.

The results and financial position of any operations that have a functional currency different from the U.S. dollar are translated into U.S. dollar amounts. Assets and liabilities are translated into U.S. dollars at exchange rates in effect at the balance sheet date. Income and expense items are translated at average rates for the period. All resulting exchange differences are recognized as accumulated other comprehensive income, a separate component of stockholders' equity. On consolidation, exchange differences arising from the translation of any net investment in foreign entities are recorded in stockholders' equity as part of accumulated other comprehensive income, net of related taxes.

Patent and License Expense

Legal fees incurred for patents relating to commercialized products are capitalized and amortized over the life of the patents and reported in research and development expense. Legal fees incurred for patent application costs have been charged to expense and reported in research and development expense.

Share-Based Compensation Expense

Share-based compensation expense relates to stock options, restricted stock units or other equity-based grants. The fair market value of stock options is determined at the grant date using an option pricing model based on the closing price of the Company's common stock on that date. The fair market value of restricted stock units or other equity-based grants are also determined at the grant date, based on the closing price of the Company's common stock on that date. The value of the awards that are ultimately expected to vest is recognized, net of forfeitures, as an expense on a straight-line basis over the employee's requisite service period.

Income Taxes

The Company applies ASC 740 – *Income Taxes*, which established financial accounting and reporting requirements for the effects of income taxes that result from the Company's activities during the current and preceding years. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Where the Company determines that it is more likely than not that some portion or all of the deferred tax assets will not be realized in the future, the deferred tax assets are reduced by a valuation allowance. The valuation allowance is sufficient to reduce the deferred tax assets to the amount that the Company determines is more likely than not to be realized.

Revenue Recognition

Revenue consists primarily of royalty payments, license fees, milestone payments, payments for services performed pursuant to contracts and certain research and development activities pursuant to collaborations with other corporate entities.

Revenue from royalties is recognized when the net sales of the underlying product by the relevant third party, including actual or estimated returns within the royalty period based on agreement, are determinable. The Company receives estimates of the amount of royalty revenue from its licensees on a quarterly basis, based on the license agreement.

Revenue from services performed pursuant to contracts or grants is recognized when earned, typically when the underlying services or activities are rendered. When circumstances arise where collection of the underlying services is uncertain, recognition of the revenue is delayed until such time as collection is reasonably assured. The Company analyzes cost reimbursable grants and contracts to determine whether it should report such reimbursements as revenue, or as an offset to the related research and development expenses incurred. For costs incurred and revenues generated from third parties where the Company is deemed to be the principal participant, such as the BARDA contract, it recognizes revenue and costs using the gross basis of accounting.

Revenue for collaborative research and development activities typically consists of fees for services, or payments when specific milestones are met and match underlying activities occurring during the term of the arrangement.

For milestones that are deemed substantive, the Company recognizes the contingent revenue when: (i) the milestones have been achieved; (ii) no further performance obligations with respect to the milestones exist; and (iii) collection is reasonably assured. A milestone is considered substantive if all of the following conditions are met: (i) the milestone is non-refundable; (ii) achievement of the milestone was not reasonably assured at the inception of the arrangement; (iii) substantive effort is involved to achieve the milestone; and (iv) the amount of the milestone appears reasonable in relation to the effort expended with the other milestones in the arrangement and the related risk associated with achievement of the milestone. If a milestone is deemed not to be substantive, the Company recognizes the portion of the milestone payment as revenue that correlates to activities already performed; the remaining portion of the milestone payment is deferred and recognized as revenue as the Company completes its performance obligations.

Cost of Revenue

Cost of revenue expense includes, but is not limited to, reimbursement for the cost of third-party service providers incurred in connection with conducting external preclinical studies and treating patients enrolled in clinical trials and monitoring, accumulating and evaluating the related clinical data; salaries and personnel-related expenses for internal staff allocated to a contract, including benefits; and the cost to develop, formulate and manufacture product candidates directly allocated to a specific contract. Cost of Revenue expenses are expensed as incurred.

Research and Development Expense

Research and development expense includes, but is not limited to, the costs of activities associated with: drug discovery, such as medicinal chemistry, virology, microbiology, and biochemistry; drug target discovery, molecular biology and structural biology; fees paid to third-party service providers in connection with conducting external preclinical studies and treating patients enrolled in clinical trials and monitoring, accumulating and evaluating the related clinical data; salaries and personnel-related expenses for our internal staff, including benefits and share-based compensation; the cost to develop, formulate and manufacture product candidates; legal fees associated with patents and intellectual property related to our product candidates; research consulting fees; license expenses and sponsored research fees paid to third parties; and specialized information systems, depreciation and laboratory facility costs. Research and development expenses are expensed as incurred.

General and Administrative Expense

General and administrative expense reflects the costs incurred to support our operations and research and development activities. General and administrative expense consists primarily of salaries and personnel-related expenses, including share-based compensation for personnel in executive, finance, accounting, information technology, business development and human resources functions. Other significant costs include professional fees for legal and auditing services, as well as premiums for insurance, other expenses as a result of being a publicly traded company, and depreciation and facility expenses.

Total Comprehensive Income (loss)

Comprehensive income is defined as the total change in stockholders' equity during the period other than from transactions with stockholders, and for the Company, includes net income (loss) and cumulative translation foreign currency adjustments.

Limited Suppliers

The Company may rely on single-source third-party suppliers and contract manufacturers to formulate or manufacture its product candidates pursuant to FDA current good manufacturing practices ("cGMP") requirements. The failure of single-source suppliers or single-source contract manufacturers to produce and deliver specific candidates on a timely basis, or at all, could delay or interrupt the development process and affect the Company's operating results.

Reclassifications

Certain reclassifications have been made to prior period amounts to conform to the current year presentation.

Revision

In connection with the analysis of deferred tax balances in 2014, the Company identified an error that required correction to the 2013 financial statements and related footnote disclosure to properly reflect the deferred tax assets and liabilities as of June 30, 2013. Accordingly, certain deferred tax assets and liabilities in the 2013 Balance sheet have been revised. The revision increased non-current deferred tax assets by $1.5 million and increased current deferred tax liabilities by $1.5 million as of June 30, 2013. The revision had no impact on the previously reported net deferred taxes, income tax expense, net loss, Stockholders' equity, or cash flow."

Recent Accounting Standards

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 July 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.

(3) Short-Term Financial Instruments

Financial Assets (in millions)

	As of June 30,	
	2014	**2013**
Financial assets:		
Cash and cash equivalents	$ 81.7	$ 66.8
Accounts receivable	18.7	11.0
Total financial assets	100.4	77.8
Financial liabilities:		
Accounts payable and current accrued liabilities	26.0	15.8
Total current financial liabilities	26.0	15.8
Net financial assets	$ 74.4	$ 62.0

The carrying value of the cash and cash equivalents, accounts receivable and accounts payable approximates fair value because of their short-term nature. The Company regularly reviews all financial assets for impairment. There were no impairments recognized in 2014 and 2013.

(4) 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:

Level 1 Quoted prices in active markets for identical assets or liabilities.
Level 2 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.
Level 3 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 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 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.

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

Cash equivalents consist primarily of money market funds. Long-term investments consist of U.S. agency securities and U.S. Treasury 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 June 30, 2014. The following table shows the unrealized gains and losses and fair values for those investments as of June 30, 2014 and June 30, 2013 aggregated by major security type:

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

June 30, 2013	At Cost	Unrealized Gains	Unrealized (Losses)	At Fair Value
Money market funds	$ —	$ —	$ —	$ —
Debt securities of U.S. government agencies	—	—	—	—
US Treasury securities	—	—	—	—
Total	$ —	—	—	—

As of June 30, 2014, the Company had investments in an unrealized loss position. The Company has determined that the unrealized losses below $0.1 milllion on these investments at June 30, 2014 are temporary in nature and expects the security to mature at its stated maturity principal. All available-for-sale securities held at June 30, 2014 will mature in over one year.

(5) Property and Equipment

Property and equipment consist of the following (in millions):

	As of June 30,	
	2014	2013
Property and equipment	$ 20.8	$ 20.6
Leasehold improvements	6.9	6.8
Total Property and equipment	27.7	27.4
Accumulated depreciation	(25.7)	(23.1)
Property and equipment, net	$ 2.0	$ 4.3

Depreciation and amortization expense was $2.4 million, $3.0 million and $3.1 million for the fiscal years ended June 30, 2014, 2013 and 2012, respectively.

(6) Accrued and Other Current Liabilities

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

	As of June 30,	
	2014	2013
Professional Fees	$ 1.0	$ 0.4
Salary and related costs	0.4	2.1
Research and development materials and services	0.8	1.1
Other accrued expenses	1.2	0.3
Total accrued expenses and other liabilities	$ 3.4	$ 3.9

(7) Public Offering

Public Offering. In January 2014, the Company closed a public offering in which it sold approximately 6.7 million shares of its common stock at a purchase price of $4.30 per share. The net proceeds to the Company from the sale of these shares after underwriting discounts, commissions and other offering expenses were approximately $26.8 million.

(8) Commitments and Contingent Liabilities

Operating Leases

The Company has two main operating leases. The lease at 2500 Northwinds Parkway is for the Company's corporate headquarters in Alpharetta, Georgia. The lease commenced in April, 2013 and expires in September, 2018. The lease includes an escalating base rent schedule as well as a seven month rent holiday and a tenant incentive towards leasehold improvements of approximately $0.1 million which are being recognized as a reduction in rent expense on a straight line basis over the term of the lease. The lease at 585 Blackburn Road, Notting Hill, Victoria, Australia was renewed on September 1, 2014 for one year and expires on September 1, 2015.

Future minimum lease payments, in millions, under non-cancellable operating leases (with initial or remaining lease terms in excess of one year) as of June 30, 2014 are:

2015	$ 0.6
2016	0.2
2017	0.2
2018	0.1
2019	0.1
Thereafter	0.0
Total minimum lease payments	$ 1.2

Rent expense was $0.7 million, $1.1 million and $0.8 million for the fiscal years ended June 30, 2014, 2013 and 2012, respectively. The Company also has operating lease agreements for office copier equipment under standard terms which are included in the minimum lease payment schedule above.

(9) Income Taxes

For financial reporting purposes, income before taxes includes the following components:

	Years Ended June 30,		
	2014	2013	2012
United States	$ (8.3)	$ 6.5	$ -
Foreign	(3.0)	(15.3)	(19.7)
Total	$ (11.3)	$ (8.8)	$ (19.7)

The expense (benefit) for income taxes is comprised of:

	Years Ended June 30,		
	2014	2013	2012
Current:			
Federal	$ -	$ -	$ -
State	-	-	-
Foreign	(0.3)	0.1	(0.3)
	(0.3)	0.1	(0.3)
Deferred:			
Federal	-	-	-
State	-	-	-
Foreign	-	-	(0.2)
	-	-	(0.2)
Total Tax Expense	$ (0.3)	$ 0.1	$ (0.5)

The reconciliation between the company's effective tax rate and the statutory rate is as follows:

	Years Ended June 30,		
	2014	**2013**	**2012**
Income tax expense (benefit) at federal statutory rate	$ (4.0)	$ (3.3)	$ (6.9)
State and local income taxes, net of federal benefit	(0.3)	0.3	-
Foreign tax rate differential	0..4	1.3	0.9
Change in valuation allowance	4.1	4.2	2.8
Gain on merger	0.1	(3.0)	-
Research and development expenses	(0.1)	1.1	2.9
Research and development tax credits	(0.3)	(1.1)	(0.3)
Employee stock options	-	0.5	0.2
Other	(0.2)	0.1	(0.1)
Income tax expense (benefit)	$ (0.3)	$ 0.1	$ (0.5)

The following table includes deferred tax assets and liabilities as of June 30, 2014 and 2013:

	As of June 30,	
	2014	**2013**
Deferred tax assets:		
Foreign net operating loss carryforwards	$ 18.2	$ 18.2
US federal and state loss carryforwards	2.8	-
Amortization	0.8	0.8
Depreciation	0.6	0.2
Accrued compensated-related costs	0.8	0.4
Other	4.3	3.7
Subtotal	27.5	23.3
Less Valuation Allowance	(26.4)	(21.4)
Total Net DTA	1.1	1.9)
Unearned Income	(1.1)	(1.9)
Net deferred tax assets	$ -	$ -
Current net DTL	(0.9)	(1.5)
Noncurrent net DTA	0.9	1.5
Net deferred taxes	$ -	$ -

Significant components of deferred income taxes reflect the net tax effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting and tax purposes. As of June 30, 2014 a full valuation allowance has been established, as the Company has determined that the realization of its deferred tax assets is not more likely than not. The Company recorded $26.4 million and $21.4 million of valuation allowance as of June 30, 2014 and 2013, respectively.

As of June 30, 2014, the Company has had $7.3 million of gross U.S. federal net operating loss carryforwards that expire at various dates through 2034. Under IRC section 382, certain significant changes in ownership may restrict the future utilization of our U.S. tax loss carryforwards. As of June 30, 2014, the Company also has accumulated Australian tax losses of $42.7 million and accumulated United Kingdom tax losses of $26.7 million available for carry forward against future earnings, which under relevant tax laws do not expire but may not be available under certain circumstances.

As of June 30, 2014, the Company's foreign subsidiaries have no positive accumulated earnings. As such, no federal or state income taxes have been provided on the losses of its foreign subsidiaries under ASC 740. If in the future there are positive earnings generated from the Company's foreign subsidiaries, the Company will evaluate whether to record any applicable federal and state income taxes on such earnings.

Uncertain Tax Positions

The Company files income tax returns in the U.S, Australia, and the United Kingdom, as well as with various U.S. states. The Company is subject to tax audits in all jurisdictions for which we file income tax returns. Tax audits by their very nature are often complex and can require several years to complete. There are currently no tax audits that have commenced with respect to income tax returns in any jurisdiction.

Under the tax statute of limitations applicable to the Internal Revenue Code, we are no longer subject to U.S. federal income tax examinations by the Internal Revenue Service for years before 2011. Under the statute of limitations applicable to most state income tax laws, the Company is no longer subject to state income tax examinations by tax authorities for years before 2010 in states in which we have filed income tax returns. Certain states may take the position that the Company is subject to income tax in such states even though the Company has not filed income tax returns in such states and, depending on the varying state income tax statutes and administrative practices, the statute of limitations in such states may extend to years before 2009. The Company began foreign operations in 1985. The Company is subject to foreign tax examinations by tax authorities for all years of operations.

The Company does not have any unrecognized tax benefits as of June 30, 2014.

(10) Share-Based Compensation

For the twelve months ended June 30, 2014 and 2013, the Company recorded share-based compensation expense related to grants from equity incentive plans of $1.7 million and $2.6 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 twelve months ended June 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:

	Twelve Months Ended	
	2014	**2013**
Weighted-average risk-free interest rate	1.5%	1.50%
Dividend yield	—	—
Expected weighted-average volatility	.79	.79
Expected weighted-average term of options (years)	5.92	6.0
Weighted-average fair value of options granted	$ 2.47	$ 2.39

The risk-free rate interest rate is based on the expected life of the option and the corresponding United States ("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 ($0000)
Balance at June 30, 2013	1,658,529	$ 13.57		
Granted (1)	912,975	3.95		
Exercised	—	—		
Forfeited or expired	(108,135)	34.36		
Balance at June 30, 2014	2,463,369	$ 9.09	6.34	$ -

(1) Includes performance-based options of 432,975, subject to specific performance conditions.

The Company granted performance-based stock options to purchase 432,975 during the year ending June 30, 2014 with an average exercise price of $4.15, resulting in total unrecognized share-based compensation expense of $1.0 million. Vesting is contingent upon meeting specific performance goals related to the development of laninamivir octanoate. As of June 30, 2014, no share-based compensation expense related to these performance-based options has been recognized as it is not probable that the performance condition will be achieved. The Company will evaluate the probability of achieving these performance goals quarterly, and if the Company determines that it is probable that a performance goal will occur, the effect of the change in estimate will be accounted in the period of change by recording a cumulative catch-up adjustment to retroactively apply the new estimate. As of June 30, 2014, all performance-based options are unvested and will expire six-years from the grant date, or will be forfeited if the performance goals are not achieved.

The total intrinsic value of stock options exercised during the twelve month period ended June 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.

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

	June 30, 2014				
	Outstanding			Exercisable	
Exercise Prices	Number of Shares	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$2.56 — $4.05	490,000	9.22	$ 3.38	86,250	$ 3.96
$4.07	931,590	8.37	4.07	310,531	4.07
$4.13 — $6.65	628,675	3.49	4.38	—	—
$11.22 — $93.36	413,104	2.69	34.37	413,104	34.37
	2,463,369	6.34	$ 9.09	809,885	19.51

Restricted Stock Awards. A summary of the Company's outstanding restricted stock activity for the twelve months ended June 30, 2014 is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at June 30, 2013	—	$ —
Granted	54,000	4.10
Released	(45,250)	4.13
Forfeited	—	—
Outstanding at June 30, 2014	8,750	$ 3.93

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

	Shares	Weighted Average Grant Date Fair Value
Outstanding at June 30, 2013	170,139	$ 4.07
Awarded	123,183	$ 3.86
Released	(17,400)	$ 4.05
Forfeited	(13,850)	$ 4.02
Unvested at June 30, 2014	262,072	$ 3.98

In December 2013, the Company awarded 108,183 MSUs to employees that vest on January 1, 2017. The vesting of these awards is subject to the respective employee's continued employment through this settlement period. 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 our stock price. The number of MSUs actually earned 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.

The Company values grants of MSUs using a lattice model with a Monte Carlo simulation. This valuation methodology utilizes several key assumptions, including the 20-day average closing stock price on the grant date, expected volatility of the Company's stock price, risk-free rates of return and expected dividend yield. The assumptions used in the Company's valuation of the MSU's are summarized as follows:

	For the Twelve Month Period Ended June 30,	
	2014	2013
Expected dividend yield	0.00%	—
Expected stock price volatility	0.86	—
Risk-free interest rate	0.64%	—
20-day trading average stock price on grant date	$3.98	—
Weighted-average per share grant date fair value	$7.69	—

As of June 30, 2014 there was $3.5 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.

In August 2014, the Company's Board made a determination that the specific milestone was not and would not be achieved on 432,975 of performance-based stock options, therefore the options will not vest and are cancelled.

(11) Retirement Benefits

The Company contributed $0.8 million, $1.1 million and $1.1 million for the fiscal years ended June 30, 2014, 2013 and 2012, respectively, toward standard defined contribution plans for employees. Contributions by the Company for non-U.S. employees can be up to nine per cent of employee salary during fiscal year ending June 30, 2014 and up to four per cent of employee salary for U.S. employees.

(12) 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 warrants) are excluded from the calculation of diluted net loss per share as their inclusion would be anti-dilutive. The Company has excluded all options to purchase common stock in periods indicating a loss, as their effect is anti-dilutive.

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

	Year Ended June 30,		
	2014	**2013**	**2012**
Net loss (in millions)	$ (11.0)	$ (8.9)	$ (19.2)
Weighted average shares outstanding	31,347,888	28,217,515	181,775,444
Weighted average shares outstanding adjusted using exchange ratio used to compute basic earnings per share	-	-	22,713,566
Shares used to compute diluted earnings per share	31,347,888	28,217,515	22,713,566
Basic loss per share	$ (0.35)	$ (0.32)	$ (0.85)
Diluted loss per share	$ (0.35)	$ (0.32)	$ (0.85)
Number of antidilutive stock options excluded from computation	2,725,441	1,828,668	-

(13) Research and Development Credit

In 2013, an application for a claim of $4.4 million was made by the Company's subsidiary, Biota Holdings Limited, under the Australian Government's Research and Development tax incentive when Biota Holdings Limited submitted its tax return for its fiscal year ended June 30, 2012. This amount was recorded as a contingent asset as of June 30, 2012. On November 7, 2012, Biota Holdings Limited received cash for this claim. Although the credit is administered by the Australian government, it is not linked to the level of taxable income and is effectively a government grant. As such, the Company obtained an immediate benefit and therefore, the entire amount has been recognized within non-operating income in the consolidated statement of operations for the year ending June 30, 2013. For 2014, the Company will not receive a research and development credit as its revenue has exceeded the qualifying revenue threshold.

(14) Licenses, Royalty Collaborative and Contractual Arrangements

Royalty agreements

The Company entered into a royalty-bearing research and license agreement with 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. GlaxoSmithKline (GSK) has recently verified that the Company will continue to receive royalties on the net sales of Relenza® in the U.S. beyond December 2014 to the extent that U.S. Patent Application No. 08/737,141 remains pending. On August 25, 2014, GSK filed an appeal to the United States Patent Trial Appeal Board in relation to this patent application.

The Company also generates royalty revenue from the sale of 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, which Daiichi Sankyo markets as Inavir®. 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 Assistant Secretary for Preparedness and Response ("ASPR") within the U.S. Department of Health and Human Services ("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 In-Process Review ("IPR"). The Company has been and continues to work with ASPR/BARDA to close out this contract, which involves completing several clinical trials, 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 June 30, 2014, the Company had $17.8 million in accounts receivable due from BARDA, which does not include $3.7 million of contract service revenue and accounts receivable that the Company did not recognize for certain expenses that it has incurred in association with the development of LANI and for other equitable adjustments that the Company believes it is entitled to receive under 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.

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

	Years Ended June 30,		
	2014	**2013**	**2012**
Royalty revenue – Relenza®	$ 10.6	$ 2.6	$ 4.4
– Inavir®	4.5	4.2	4.5
Commercial milestone – Inavir®	-	2.8	-
Revenue from services	53.6	24.0	11.5
Total revenue	$ 68.7	$ 33.6	$ 20.4

(15) Restructuring Charges

We recognize restructuring charges when a plan that materially changes the scope of our 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, we announced restructuring actions as a result of the termination for convenience of the BARDA contract. These restructuring activities are expected to be completed in fiscal 2015. We recorded $2.1 million in restructuring charges during fiscal 2014, which comprised of severance and other employee related benefits. $0.9 million was recorded in cost of revenue, $1.0 million in research and development and $0.2 million in general and administrative. As of June 30, 2014, we had a remaining liability of approximately $2.0 million.

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

Fiscal 2014 Restructuring Plans:	Balance at June 30, 2013	Provision	Payments	Balance at June 30, 2014
Severance and employment costs	—	2.1	(0.1)	$ 2.0
Total restructuring costs	$ —	$ 2.1	$ (0.1)	$ 2.0

The remaining severance and other employment costs of approximately $2.0 million will be paid in fiscal 2015. Also, included in accrued severance are balances of $1.2 million and $1.0 million as of June 30, 2014 and 2013, respectively. These balances relate to acquired severance balances as part of the Nabi merger. This remaining balance is to be paid in fiscal 2015.

(16) Quarterly Financial Information (Unaudited)

The table below sets forth summary unaudited consolidated quarterly financial information for the years ended June 30, 2014 and 2013 (in millions):

	Quarter Ended			
	6/30/2014	**3/31/2014**	**12/31/2013**	**9/30/2013**
Revenues	$ 8.5	$ 29.5	$ 18.5	$ 12.3
Operating expenses	19.0	19.3	11.4	10.7
Net (loss) income	(10.2)	3.2	(0.1)	(3.9)
Net (loss) income per share (1):				
Basic	$ (.29)	$ 0.09	$ 0.00	$ (0.14)
Diluted	$ (.29)	$ 0.09	$ 0.00	$ (0.14)

	Quarter Ended			
	6/30/2013	**3/31/2013**	**12/31/2012**	**9/30/2012**
Revenues	$ 9.3	$ 12.5	$ 10.4	$ 1.4
Operating expenses	7.7	4.1	7.1	1.5
Net loss	(6.5)	0.2	4.6	(7.2)
Net loss per share (1):				
Basic	$ (0.23)	$ 0.01	$ 0.16	$ (0.32)
Diluted	$ (0.23)	$ 0.01	$ 0.16	$ (0.32)

(1) Due to the use of the weighted average shares outstanding for each quarter for computing earnings per share, the sum of the quarterly per share amounts may not equal the per share amount for the year.

EXHIBIT INDEX

Exhibit Number	Exhibit Title	Filed with this Form 10-K	Incorporation by Reference		
			Form	File No.	Date Filed
2.1	Merger Implementation Agreement, dated April 22, 2012, between Nabi Biopharmaceuticals and Biota Holdings Limited		8-K	001-35285-12773718	04/23/12
2.2	Amendment Deed, dated August 6, 2012, to the Merger Implementation Agreement, dated April 22, 2012, between Nabi Biopharmaceuticals and Biota Holdings Limited		8-K	001-35285-121016660	08/08/12
2.3	Amendment Deed, dated September 17, 2012, to the Merger Implementation Agreement, dated April 22, 2012, as amended by the Merger Implementation Agreement Amendment dated August 6, 2012, between Nabi Biopharmaceuticals and Biota Holdings Limited		8-K	001-35285-121096040	09/18/12
3.1	Composite Certificate of Incorporation of Biota Pharmaceuticals, Inc.		10-Q	001-35285-13592912	02/11/13
3.2	By-Laws of Biota Pharmaceuticals, Inc.		10-Q	001-35285-13592912	02/11/13
4.1	Form of Common Stock Certificate		10-K	000-04829-08651814	03/15/07
10.1†	Collaboration and License Agreement, dated September 29, 2003, between Biota Holdings Limited and Sankyo Co., Ltd.		10-Q	001-35285-13834721	05/10/13
10.2†	Amendment #1 to Collaboration and License Agreement, dated June 30, 2005, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd. and Sankyo Company, Ltd.		10-Q	001-35285-13834721	05/10/13
10.3	Amendment #2 to Collaboration and License Agreement, dated March 27, 2009, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd. and Daiichi Sankyo Company, Limited.		10-Q	001-35285-13834721	05/10/13
10.4†	Commercialization Agreement, dated March 27, 2009, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd and Daiichi Sankyo Company, Ltd.		10-Q	001-35285-13834721	05/10/13

10.5†	Contract, dated March 31, 2011, between Biota Scientific Management Pty. Ltd. and Office of Biomedical Advanced Research and Development Authority within the Office of the Assistant Secretary for preparedness and Response at the U.S. Department of Health and Human Services.		10-Q	001-35285-13834721	05/10/13
10.6	Research and License Agreement, dated February 21, 1990, by and among Biota Scientific Management Pty. Ltd., Biota Holdings Limited, Glaxo Australia Pty. Ltd. and Glaxo Group Limited.		10-Q	001-35285-1384721	05/10/13
10.7	Form of Indemnification Agreement for Directors and Executive Officers		8-K	001-35285-13817036	05-06-13
10.9+	Executive Employment Agreement, dated as of November 12, 2012, between Biota Pharmaceuticals, Inc., and Russell H. Plumb		8-K	001-35285-121206005	11/14/12
10.10+	Executive Employment Agreement, dated as of November 12, 2012, between Biota Pharmaceuticals, Inc., and Joseph M. Patti		8-K	001-35285-121206005	11/14/12
10.11+	Form Non-Plan Stock Units Agreement		8-K	001-35285-121206005	11/14/12
10.12+	Form of Letter Agreement for Stock Option Grant		8-K	001-35285-121206005	11/14/12
10.13+	2007 Omnibus Equity and Incentive Plan		DEF 14A	000-04829-07763351	04-12-07
10.14+	Executive Employment Agreement, dated as of November 26, 2013, between Biota Pharmaceuticals, Inc., and Peter Azzarello		8-K	001-35285-131247987	11/27/13
10.15+	Form of Employee Stock Option Agreement under the 2007 Omnibus Equity and Incentive Plan		8-K	001-35285-131266832	12/10/13
10.16+	Form of Market-Based Stock Unit Award Agreement under the 2007 Omnibus Equity and Incentive Plan		8-K	001-35285-131266832	12/10/13
16.1	Letter from Ernst & Young dated December 10, 2012.		8-K	001-35285-121257087	12-11-12
16.2	Letter from PricewaterhouseCoopers dated April 29, 2014		8-K	001-35285-14795541	4/30/14
21.1	List of Subsidiaries	X			

23.1	Consent of PricewaterhouseCoopers LLP.	X
23.1a	Consent of PricewaterhouseCoopers.	X
31.1*	Certification of Principal Executive Officer and 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**	XBRL Instance Document	X
101**	XBRL Taxonomy Extension Schema Document	X
101**	XBRL Taxonomy Calculation Document	X
101**	XBRL Taxonomy Definition Linkbase Document	X
101**	XBRL Taxonomy Label Linkbase Document	X
101**	XBRL Taxonomy Presentation Linkbase Document	X

+ Indicates a management contract or compensatory plan or arrangement in which any director or named executive officer participates.
† Confidential treatment has been granted with respect to certain portions of this exhibit.
* This certification is being furnished solely to accompany this annual 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.
** Furnished, not filed.

Exhibit 21.1

List of Subsidiaries

Biomune Corporation

Biota Holdings LTD

Biota Scientific Management PTY LTD

Biota Respiratory Research PTY LTD

Biota Investments PTY LTD

Biota Europe Limited

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (No. 333-190594) and Form S-8 (No. 333-188111, No. 333-115691, No. 333-115688, No. 333-109017, No. 333-38864, No. 333-38868, No. 333-95269, No. 333-56037, No. 333-56071, No. 033-65069, No. 033-60795, No. 333-134954, No. 333-143238 and No. 333-143239) of Biota Pharmaceuticals, Inc. of our reports dated September 30, 2014 relating to the financial statements and the effectiveness of internal control over financial reporting, which appear in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Atlanta, GA
September 30, 2014

Exhibit 23.1a

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (No. 333-190594) and Form S-8 (No. 333-188111, No. 333-115691, No. 333-115688, No. 333-109017, No. 333-38864, No. 333-38868, No. 333-95269, No. 333-56037, No. 333-56071, No. 033-65069, No. 033-60795, No. 333-134954, No. 333-143238 and No. 333-143239) of Biota Pharmaceuticals, Inc. of our report dated 27 September 2013 relating to the financial statements and the effectiveness of internal control over financial reporting, which appear in this Form 10-K.

/s/ PricewaterhouseCoopers
Melbourne, Australia
30 September 2014

Exhibit 31.1

Certification of Chief Executive Officer and Chief Financial Officer
Pursuant to Rule 13a-14(a) or Rule 15d-14(a)
Under the Securities Exchange Act of 1934

I, Russell H. Plumb, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended June 30, 2014 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(s) 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(s) 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.

Date: September 30, 2014

/s/ Russell H. Plumb

President, Chief Executive Officer, Chief Financial Officer

Exhibit 32.1

Certification Pursuant To Section 906 of the
Sarbanes-Oxley Act 2002

In connection with the Annual Report on Form 10-K of Biota Pharmaceuticals, Inc. (the "Company") for the year ended June 30, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certifies, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

1. The report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Russell H. Plumb

President, Chief Executive Officer, Chief Financial Officer, (Principal Executive Officer and Principal Financial Officer)

September 30, 2014