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, 2013

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 June 30, 2013 was approximately $86,220,523.

Number of shares of Common Stock outstanding as of September 20, 2013: 28,423,987. 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 2013 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 "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 plan to continue to advance the clinical development of laninamivir octanoate, including the anticipated time to complete the ongoing Phase 2 IGLOO clinical trial;*
- *our plan to shift our resources and focus from preclinical research to clinical-stage development programs and the anticipated therapeutic focus of our preclinical programs;*
- *our plan to pursue in-licensing, acquisition, co-development or other similar collaboration opportunities to better balance our pipeline with additional clinical-stage development programs;*
- *our plan to support the preclinical development of compounds intended to treat infections caused by respiratory syncytial virus ("RSV") and gram negative bacterial pathogens;*
- *our plan to seek to out-license our preclinical gram-positive antibiotic program;*
- *our plan to seek collaboration, co-development or license arrangements with third parties to advance the clinical development of vapendavir;*
- *our estimated cash on hand at June 30, 2014;*
- *our anticipation that revenue and the related cost of providing services under our U.S. Office of Biomedical Advanced Research and Development Authority ("BARDA") contract will continue to increase in the near-future, assuming the program continues to advance further into clinical development;*
- *our belief that royalty revenue from net sales of Relenza may decrease in fiscal 2014;*
- *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, our contract with BARDA, 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: BARDA, or we, not terminating or significantly amending our existing contract with BARDA to develop laninamivir octanoate in the U.S.; we, BARDA, the U.S. Food and Drug Administration ("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 laninamivir octanoate at any time for a lack of safety, tolerability, biologic activity, commercial viability, regulatory or manufacturing issues, or any other reason whatsoever; the results of research activities and studies related to our product candidates being unfavorable, delayed or terminated; the safety or efficacy data from ongoing or future preclinical studies of any of our product candidates not supporting further 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 that we are conducting, and expect to conduct, clinical trials; our ability to satisfactorily manage the integration of the recent merger and our operations in the future; our ability to successfully identify and in-license, acquire, or enter into co-development or other similar collaboration opportunities 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, implementation and conduct of the clinical 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; 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 failure to obtain regulatory approval to advance the clinical development of or to ultimately market our product candidates; GlaxoSmithKline ("GSK") or Daiichi Sankyo Company Ltd. ("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 expectation; 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 industry or product candidates; and other statements contained elsewhere in this Annual Report on Form 10-K and 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 and the documents that we reference herein and have been filed or incorporated by reference as exhibits, completely and with the understanding that our actual future results may be materially different from what we expect. Our business, financial condition, results of operations, and prospects may change. We 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 Holdings Limited, 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

On November 8, 2012, Nabi Pharmaceuticals, Inc. (“Nabi”) and Biota Holdings Limited, a biopharmaceutical company based in Melbourne, Australia that had been listed on the Australian Stock Exchange since 1985, completed a merger, and renamed the resulting company Biota Pharmaceuticals, Inc. (“Biota”, the “Company”, “us” or “we”). Former Biota Holdings Limited shareholders retained approximately 83% of our shares of common stock, while former Nabi shareholders retained approximately 17% as consideration for Nabi’s net assets, which consisted primarily of $27 million in net cash on hand on the date of the merger. Upon completion of the merger, each outstanding share of Biota Holdings Limited converted into 0.1249539870 shares of Nabi common stock as determined by the exchange ratio, including the impact of a reverse stock split of Nabi’s common stock at a ratio of 1:6. As Nabi had minimal ongoing activity with respect to its development programs or related operations at the time of the merger, our historical and current operations primarily reflect the operations of Biota Holdings Limited. Due to the fact that former Biota Holdings Limited shareholders held a significant majority of the voting interest in us upon the completion of the merger, the merger was accounted for as a “reverse merger”, such that, notwithstanding the fact that Nabi was the legal acquirer, Biota Holdings Limited was considered the accounting acquirer for financial reporting purposes. Accordingly, the financial statements of Biota Holdings Limited are treated as our historical financial statements, with the operating results of Nabi being included therein beginning November 8, 2012. As a result of the reverse merger, the Company adopted a June 30 fiscal year end.

We are a biopharmaceutical company focused on the discovery and development of innovative anti-infective products to prevent and treat serious and potentially life-threatening infectious diseases. We were incorporated in the state of Delaware since 1969 and our corporate headquarters are located in Alpharetta, Georgia.

We are currently focused on developing oral, small molecule compounds to treat a number of viral and bacterial infections. Our most advanced clinical-stage program is laninamivir octanoate, a long-acting neuraminidase inhibitor we are developing for the treatment of influenza A and B that is currently enrolling patients in a multi-national Phase 2 trial, which we refer to as (“IGLOO”). In addition to laninamivir octanoate, we are developing an orally bioavailable therapeutic for the treatment of RSV infections in children, the elderly, and immune compromised patients. We also have a Phase 2 compound, vapendavir (“BTA798”), which has been in clinical development for the treatment of human rhinovirus (“HRV”) infections in patients with mild to moderate asthma. Finally, we have a discovery stage program focused on novel antibiotics designed to treat gram-positive and gram-negative bacterial infections.

We previously developed zanamivir, a neuraminidase inhibitor (“NI”), which is marketed worldwide by GSK as Relenza® for the prevention and treatment of influenza A and B. GSK developed and 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 their intellectual property related to second-generation long acting neuraminidase inhibitors ("LANI"), including FLUNET and laninamivir octanoate. In 2009, we entered into a separate commercialization agreement with Daiichi Sankyo, which provided it an exclusive license to laninamivir octanoate in Japan and entitled us to a royalty on net sales of laninamivir octanoate in Japan. In September 2010, laninamivir octanoate was approved for sale by the Japanese Ministry of Health and Welfare for the treatment of influenza A and B in adults and children. Laninamivir octanoate is marketed in Japan by Daiichi Sankyo as Inavir®. In 2009, we filed an Investigational New Drug application (“IND”) with the FDA to develop laninamivir octanoate in the U.S, and in 2011 we were awarded a contract from the U.S. Office of Biomedical Advanced Research and Development Authority (“BARDA”) designed to provide up to $231 million in support of the development of and submission for a new drug application (“NDA”) of laninamivir octanoate for the treatment of influenza A and B infections in the United States. In June 2013, we initiated a Phase 2 clinical trial of laninamivir octanoate under this IND.

Although several of our influenza product candidates have been successfully developed and commercialized by other larger pharmaceutical companies under collaboration, license 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 of our existing or future development-stage influenza or other product candidates that we are developing now, or may develop in the future.

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.

The use of anti-infective drugs has led to a significant reduction in the morbidity and mortality associated with infectious diseases. However, for many infectious diseases, current treatment options 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 factors often lead to patients prematurely discontinuing treatment or not fully complying with treatment dosing schedules, resulting in a treatment failure. Moreover, 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 respective 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 antiviral drugs increasingly represent a major challenge public health challenge. The existence of drug-resistant strains, as well as 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 because 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 those 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.

Bacteria

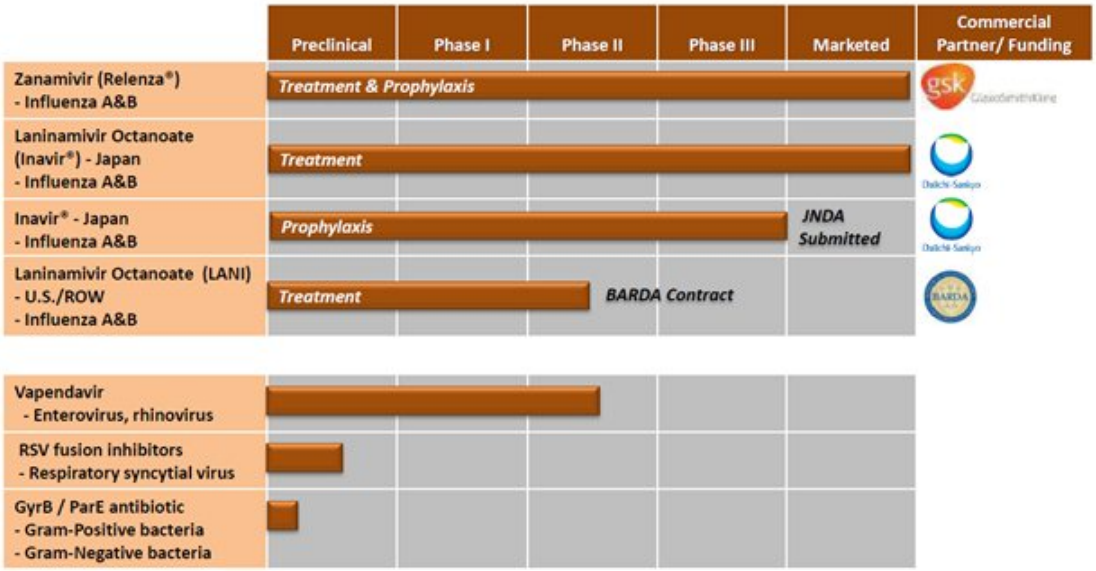
Unlike viruses, bacteria do not generally invade a living host cell in order to grow and replicate. Bacteria are unicellular, self-propagating microorganisms that multiply through growth in bacterial cell size and the subsequent division of the cell. Bacteria can be broadly classified into two categories based upon the composition of their cell walls: gram-positive or gram-negative. Many antibacterial drugs that are effective against gram-positive bacteria are less effective or totally ineffective against gram-negative bacteria, and vice versa. Antibacterial drugs that are active against a large number of both classes of bacteria are often referred to as "broad-spectrum" antibiotics.

Antibiotics, which are small molecule chemical compounds, comprise the vast majority of currently marketed antibacterial drugs. Antibiotics have historically proved to be highly successful in controlling the morbidity and mortality that accompany many bacterial infections. However, the widespread use, and in some cases the overuse of antibiotics has led to the emergence of bacteria-resistant strains, which limit the effectiveness of existing drugs. This led the World Health Organization ("WHO") to state in 2010 that antibiotic resistance is one of the three greatest threats to human health. The Centers for Disease Control and Prevention ("CDC") estimates that more than 70% of U.S. hospital-based infections are resistant to at least one of the antibiotics most commonly used to treat them.

Antibiotic resistance is primarily caused by genetic mutations in bacteria selected by exposure to antibiotics where the drug does not kill all of the bacteria. In addition to mutated bacteria being resistant to the drug used for treatment, many bacterial strains can also be cross-resistant, meaning that the use of a particular treatment to address one kind of bacteria can result in resistance to other kinds of bacteria as well as to other antibiotics. As a result, the effectiveness of many antibiotics has declined, limiting physicians' options to treat serious infections. Antibiotic resistance has a significant impact on mortality and contributes heavily to health care system costs worldwide.

Our Pipeline

The following chart summarizes key information regarding our anti-infective product candidates:



In addition to the product candidates listed in the table above, we conduct research with other compounds that may address different therapeutic areas, or have other mechanisms of action. We continue to identify, evaluate and test early-stage compounds to determine if any should be advanced further into development.

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 different kinds and combinations of virus surface proteins. Among many subtypes of influenza A viruses, currently influenza A(H1N1)pmd09 and influenza A(H3N2) subtypes are circulating among humans. Influenza viruses circulate in every part of the world. Type C influenza cases occur much less frequently than A and B. Seasonal influenza is characterized by a sudden onset of high fever, cough (usually dry), headache, muscle and joint pain, severe malaise (feeling unwell), sore throat and runny nose. Most people recover from fever and other symptoms within a week without requiring medical attention. However, influenza can cause severe illness or death in people at high risk, which include the very young, elderly or 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. Illness can result in hospitalization and death, mainly among high-risk groups. According to the WHO, these 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 age 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 “CDC estimated that in the U.S. from 1976-2007, influenza caused an average of 23,607 deaths per year. Immunization is the primary form of preventing influenza infection. However, the efficacy of influenza vaccination varies, decreasing with age, and in the prevention of seasonal influenza, is dependent on how well matched the chosen vaccine is to 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

Viral respiratory tract infections are among the most common reasons for visits to the emergency department and the hospitalization of children in the U.S. 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. However, over a five year period, the seasonal influenza market opportunity can be more accurately assessed. 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 EU, were approximately $409M, $259M, and $32M, respectively, which reflects total annual sales in the three markets of approximately $700 million. In addition to seasonal influenza, government stockpiling of antivirals to prevent or treat influenza have historically contributed significantly to the overall market opportunity.

Influenza Antiviral Drugs

Vaccines play an important role in the prevention of influenza. Nevertheless, the benefit of this intervention can be significantly reduced in the event there is a mismatch between the seasonal influenza vaccine and the circulating influenza virus, and the inability of an individual to mount a proper immune response. Therefore, antivirals also play an important role in the prevention and management of influenza. There are two classes of antiviral agents used for influenza: adamantanes and neuraminidase inhibitors, or NI’s. 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. NI’s are generally effective against all human, avian and animal influenza viruses. NIs inhibits 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: oseltamivir phosphate (Tamiflu®) and zanamivir (Relenza®). Both drugs are approved for the treatment of acute, uncomplicated illness due to influenza A and B, and are also approved for preventive use. Further, laninamivir octanoate (Inavir®) is approved in Japan, and intravenously administered peramivir is approved in Japan (Rapiacta®) and Korea (PeramiFlu®) for the treatment of influenza.

Limitations of Current Therapies for the Treatment of Influenza

An increase in the frequency of oseltamivir-resistant influenza viruses is a growing problem. When oseltamivir was first introduced, the proportion of oseltamivir-resistant viruses among circulating viruses was low, generally less than 1%. However, 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 mutant 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 has been no clinically significant reports of zanamivir or laninamivir octanoate resistance, in circulating influenza A (H1N1) viruses, or any other human influenza viruses. The increasing levels of oseltamivir-resistance, 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 of, and therefore 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 will result in better patient compliance as compared to both oseltamivir phosphate and zanamivir.

Laninamivir Octanoate

In collaboration with Daiichi-Sankyo, we have identified a new class of inhaled long acting neuraminidase inhibitors (“LANI”). Laninamivir octanoate, also known as CS-8958, is a second-generation octanoyl ester prodrug 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.

In 2003, we cross-licensed intellectual property related to LANI with Daiichi Sankyo, of which the lead product, laninamivir octanoate, was successfully developed and, since 2010, is being marketed by Daiichi Sankyo as Inavir® in Japan for the treatment of influenza A and B infections. In November 2012, Daiichi Sankyo submitted a Japanese New Drug Application (“JNDA”) to the Japanese Ministry of Health and Welfare for approval of Inavir® for use in post-exposure prophylaxis. We are currently developing laninamivir octanoate 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 of laninamivir octanoate. The trial, which we refer to as “IGLOO”, will compare 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 is designed to enroll 636 subjects, randomized equally across the three treatment arms, with the primary end point being the time to alleviation of influenza symptoms (cough, sore throat, nasal congestion, headache, body aches and pains, feeling feverish, and fatigue) and fever for ≥24 hours. Secondary end points include evaluating whether the use of laninamivir octanoate reduces the incidence of secondary bacterial infections compared to placebo, quantitative changes in virus shedding, the development of resistance by phenotypic and genotypic analyses, and the impact of treatment with laninamivir octanoate on the quality of life. Our goal is to complete enrollment in this trial by the end of the upcoming influenza season in the Northern Hemisphere and have top-line data available in mid-2014.

Phase 1. We have completed three Phase 1 trials of inhaled laninamivir octanoate. These trials provide safety and pharmacokinetic data at single doses of laninamivir octanoate ranging from 5 to 40 mg in healthy volunteers aged 18 to 77 years of age, 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 of age. 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 conducted a number of clinical trials that supported 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 were diarrhea (4.6% of subjects), nausea (1.03% of subjects) and nasopharyngitis (1.89% of subjects). The majority of AEs across the clinical studies were mild in intensity. As of September 2012, we estimate that approximately 4.8 million patients had 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 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 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 is designed to fund and provide us with all technical and clinical data and U.S. based manufacturing to support the filing of a NDA with the FDA for laninamivir octanoate. The performance period of the BARDA contract commenced on March 31, 2011, and continues for five years. To-date, we have recognized revenue totaling $34.1 million pursuant to this contract.

Human Rhinovirus (HRV)

HRV belongs to a diverse family of plus-strand RNA viruses referred to as picornaviridiae. This family also includes the human enteroviruses and hepatoviruses (human hepatitis A), as well as certain animal viruses. While more than 200 different viruses are known to cause symptoms of the common cold, it is estimated that HRV causes 30%-50% of all cases. However, HRV infection is also associated with more serious conditions, including acute otitis media, sinusitis and lower respiratory tract diseases such as pneumonia, bronchitis and bronchiolitis and exacerbation of chronic respiratory illnesses. Individuals with chronic lung diseases, such as asthma and chronic obstructive pulmonary disease ("COPD"), are especially vulnerable to HRV infections, which may cause acute exacerbations of asthma, emphysema or chronic bronchitis in these more susceptible individuals. HRV is believed to be the primary cause of asthma exacerbations.

Epidemiological studies have demonstrated that a significant number of pulmonary exacerbations of cystic fibrosis ("CF") are preceded by HRV infections. Each episode of infection appears to cause the progression of the underlying disease and, each exacerbation may shorten the life of the patient. Accordingly, HRV infection in this population is potentially life-threatening.

There remains a significant unmet medical need to identify treatments which can shorten the duration of HRV-induced illness, lessen the severity of symptoms, minimize secondary infections and exacerbations of underlying respiratory disease and, reduce virus transmission. There are also potentially important health economic and quality of life benefits arising from reducing the number of upper respiratory tract infections.

Vapendavir (BTA798)

Rhinoviruses access 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 have developed the antiviral compound vapendavir (BTA798) which is designed to bind to a highly conserved pocket in the floor of the canyon. Vapendavir, a capsid binder, effectively stops infection by interfering with receptor binding and/or related early steps in the infectious cycle. Vapendavir is a broad spectrum inhibitor of the large group of culturable HRVs with strong potency against a variety of diverse enteroviruses (such as poliovirus). Vapendavir is dosed orally and is in development for the treatment of HRV infections in patients with asthma.

Vapendavir Clinical Trials

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 the 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 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 incidence to placebo. There was one serious adverse event 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 multiple ascending dose trial evaluating 200 and 400 mg of vapendavir, administered either QD or bid for seven or eight consecutive days, vapendavir was well tolerated. There were no serious or severe adverse events and there were no dose limiting toxicities, 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. The virus is typically spread via respiratory secretions through close contact with contaminated surfaces and objects. The peak incidence of infections occurs in the winter months, usually coinciding with the influenza epidemic. Datamonitor estimates that annually, approximately 18 million people are infected 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 928,000 of these individuals become hospitalized for this infection. RSV infections are particularly problematic in infants. In a given year, around 91,000 infants are hospitalized with RSV infection in the U.S. These infections are responsible for 40 to 50% of hospitalizations for pediatric bronchiolitis and 25% of hospitalizations for pediatric pneumonia. The overall magnitude of hospitalizations makes RSV a very 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 limited due to highly variable efficacy and toxicity risks. In fact, current American Academy of Pediatrics guidelines for the treatment of bronchiolitis in children does not recommend the routine use ribavirin 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, and are very expensive. As such, their use is limited in many hospitals. In 2011, Astra Zeneca reported global sales of Synagis® of $975.0 million, with U.S. sales of $570.0 million and European sales of $404.0 million. Based upon an estimated pool of 2.3 million pediatric RSV patients (ages 0-59 months), we estimate that Synagis® is used in approximately 3% of the estimated pediatric RSV patients in the U.S. These data suggest that there remains a significant unmet need for safe and effective RSV antiviral treatments in all RSV populations.

Our preclinical RSV antiviral program is focused on orally bio-available F (fusion) protein inhibitors. The mechanism of action of these compounds is believed to be via inhibition of fusion of the viral envelope to the cell membrane of the host cell. The antiviral activity of our compounds has been demonstrated *in vitro*. Potent antiviral activity has been demonstrated *in vitro* against RSV A2, Long and B/Washington strains and the potency is not materially reduced in presence of serum proteins. The antiviral activity of our compounds in a cytopathic effect inhibition assay using the laboratory isolate RSV A2 has produced EC50's that range from of 13-31 nM with a corresponding CC50 of >20 µm. Several of our fusion inhibitors have been dosed orally in preclinical studies and have demonstrated a pharmacokinetic profile that suggests the potential for once daily dosing in humans.

Gram-Negative and Gram-Positive Bacterial Infections

We believe there is a significant need for new antibiotics to treat serious gram-negative and gram-positive and bacterial infections, due primarily to the growing incidence of drug resistance to currently marketed antibiotics. The CDC estimates that more than 70% of U.S. hospital infections are resistant to at least one of the antibiotics most commonly used to treat them. Antibiotic resistance has limited the effectiveness of many existing drugs, and the discovery of new antibiotics to address resistance has not kept pace with the increasing incidence of difficult-to-treat microorganisms. According to the Infectious Diseases Society of America, the estimated cost to the U.S. healthcare system of antibiotic-resistant infections is approximately $21.0 - $34.0 billion annually, a substantial portion of which is due to increased length of stay. Despite the significant need for new antibiotics with the above attributes, linezolid and daptomycin are the only examples of novel antibiotics that have been developed in the last few decades. Further, many of the existing antibiotics used to treat serious infections are difficult or inconvenient to administer. Many antibiotics are given twice daily for seven to 14 days or more and patients can be hospitalized for much or all of this period, or require in-home IV therapy. We believe that there is a need for new antibiotics that have improved potency and pharmacokinetics, effectiveness against resistant bacterial strains, improved side effect profiles and more flexible administration formulations.

We believe the bacterial type II topoisomerases, such as DNA gyrase and topoisomerase IV, are attractive targets for new antibacterial drug discovery. Our preclinical compounds are novel dual-targeting inhibitors of the ATPase activity of DNA gyrase (GyrB) and topoisomerase IV (ParE) that exhibit potent bactericidal activity against drug-resistant bacterial pathogens and a low frequency of spontaneous resistance. Our dual-targeted antibiotics are active against the most relevant Gram-positive bacteria, including *Staphylococcus aureus*, *Enterococcus faecium*, *Enterococcus faecalis*, *Streptococcus pneumonia*, and *Streptococcus pyogenes*. Additionally, we have compounds in development that target medically important Gram-negative bacteria, such as *Pseudomonas aeruginosa*, *Acinetobacter baumannii*, *Klebsiella pneumonia*, *Hemophilus influenza* and *Escherichia coli*. We have tested our preclinical compounds in antibacterial assays against a variety of bacteria, including representative panels of current clinical isolates. In general, our dual-targeting GyrB/ParE antibiotics have similar potency versus both wild type and antibiotic-resistant bacterial strains. Further, we have demonstrated that our compounds targeting Gram-positive bacteria have anti-bacterial activity in multiple animal models of infection.

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 strategic goal, in the near-term we intend to employ the following strategy:

- *Focus Our Resources on the Development of Antiviral Product Candidates*. In the near-term, we plan to focus our resources primarily on further developing laninamivir octanoate under our contract with BARDA and advancing our preclinical RSV program. More specifically, we intend to:

- Complete our ongoing Phase 2 IGLOO clinical trial of laninamivir octanoate and, subject to the results of this trial, develop and complete plans with BARDA to support a Phase 3 clinical trial program;
- advance our chemistry, manufacturing and controls ("CMC") for laninamivir octanoate with respect to both the active pharmaceutical ingredient (API) and the TwinCaps® powder inhaler necessary to make Phase 3 and commercial grade drug product;
- continue to support and maintain the contract we have with BARDA for the late-stage development of laninamivir octanoate; and
- nominate a RSV fusion inhibitor for advancement into IND-enabling GLP preclinical studies in 2014.

- *Seek Strategic Collaborations to Accelerate the Development of Certain of Our Product Candidates to Optimize Economic Returns while Managing Risk*. We intend to pursue collaboration, co-development or license agreements, or enter into other transactions in the future with third-party pharmaceutical or biopharmaceutical companies with greater clinical development, manufacturing and commercialization capabilities, which we believe can accelerate the development and/or commercialization of vapendavir, our preclinical-stage GyrB/ParE antibiotic compounds, and our preclinical hepatitis C polymerase inhibitors.

- *Evaluate and consider in-licensing, acquisition, co-development, and other similar collaborative clinical-stage development opportunities to better balance our pipeline.* We intend to identify, evaluate and consider adding additional clinical-stage development programs to our pipeline if we believe doing so can create incremental shareholder value in the near-term. We intend to focus our evaluation on development programs targeting infectious, respiratory and inflammatory diseases.

- *Manage our preclinical research and general and administrative expenses at a level that is reasonably similar to our anticipated revenues*. We intend to manage our operations such that the costs of our preclinical research and our general and administrative activities are generally in line with revenue we anticipate receiving from royalties, milestones, and amounts permitted under our contract with BARDA. By doing so, we intend to conserve a significant portion of our existing capital resources for use towards obtaining and advancing clinical-stage development programs, other than laninamivir octanoate, in the future.

Research and Development

Our research and development expense in fiscal 2013, 2012 and 2011 was $19.2 million, $24.1 million and $33.5 million, respectively. In 2014, we plan to focus our resources primarily on (i) the development of laninamivir octanoate, of which a majority of the related costs are fully reimbursable under the BARDA contract, (ii) nominating a preclinical candidate from our RSV fusion inhibitor program for advancement into IND-enabling GLP preclinical studies, and (iii) continuing research and preclinical activities with respect to our gram negative antibiotic compounds.

Sales and Marketing

We currently do not have any commercialization or sales and marketing capabilities, and have no plans to invest in or build such capabilities internally in the near-term, if ever. At this time, other than potentially with respect to future sales of laninamivir octanoate, if approved, to government agencies for stockpiling purposes, we anticipate partnering or collaborating with, or licensing certain rights to other larger pharmaceutical or biopharmaceutical companies to support the 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 API, the TwinCaps® dry powder inhaler device, and to fill and package the materials required to conduct clinical trials under current good manufacturing practices, ("cGMP"). If an existing contract manufacture fails to deliver on schedule, or at all, or fails to manufacture our material is accordance with 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 time lines. We have used contract manufacturers to produce all the clinical trial material for use in the preclinical studies we have conducted to-date, as well as for all clinical trials of vapendavir and laninamivir octanoate.

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 organizations than we do. In addition, some of them have considerable experience in preclinical testing, 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. They may also market commercial products, either on their own or through collaborative efforts. We expect to encounter significant competition for any of the pharmaceutical products 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 is 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 recently announced its intention to file a NDA in the U.S. for peramivir. Roche's and GSK's NI's 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 NI's, there are other companies working to develop additional antiviral drugs to be used against various strains of influenza. Further, several pharmaceutical and biotechnology firms, including major pharmaceutical companies, have announced efforts in the field of structure-based drug design and in the therapeutic areas of cancer, infectious disease, autoimmune, and inflammatory disorders, as well as other therapeutic areas where we are focusing our drug discovery efforts.

We anticipate that our product candidates, and in particular laninamivir octanoate, if successfully developed and approved, will compete directly or indirectly with or drugs that will be generic by the time our product candidates may be approved for sale. Generic drugs are drugs whose patent protection has expired, and 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 directly-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.

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 development, advancement and commercialization 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 further, 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. The Drug Price Competition and Patent Term Restoration Act of 1984 also allows a patent owner to obtain an extension of applicable patent terms for a period equal to one-half the period of time elapsed between the filing of an IND and the filing of the corresponding NDA plus the period of time between the filing of the NDA and FDA approval, with a five year maximum patent extension. 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.

Zanamivir, a first-in-class 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, will begin to expire in 2014. Our 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.

Laninamivir octanoate, a long acting neuraminidase inhibitor 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., EU and Japan. The patent relating to hydrates and the crystalline form of laninamivir octanoate used in the product expires in 2021(without extensions) in the U.S. and EU and in 2024 in Japan.

The dry-powder inhaler device patent portfolio, which known as TwinCaps® and is owned by Hovione International Limited ("Hovione") and exclusively licensed to Biota and Daiichi Sankyo for the prevention and treatment of influenza and other influenza-like viral infections, expires in 2029 in the U.S., and in 2027 in the EU and Japan.

Vapendavir, an oral antiviral, has been in clinical development for the reduction of cold symptoms caused by HRV in patients with mild to moderate asthma. The vapendavir patent portfolio is exclusively owned by us and will begin expire in some countries in December 2021, without extensions.

We own a patent portfolio focused on developing an oral antiviral for RSV. Our RSV patent portfolio is comprised of a number of patent filings directed to several compound series, with the earliest projected expiries ranging from late-2024 to late-2031.

We are the exclusive owner of a patent portfolio focused on developing oral/IV antibiotics targeting GyrB/ParE with activity against gram-negative and multi-drug resistant bacterial pathogens. The GYR patent portfolio comprises a number of patent filings directed to several compound series, with the earliest projected expiries ranging from mid-2027 to early-2033.

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, or 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.

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.

Daiichi Sankyo

In 2003, we entered into a collaboration and license agreement with Daiichi Sankyo related to the development of second generation long acting NI's, 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 NI's. A primary focus of the agreement was for the parties to collectively seek third-party licensees that would develop and commercialize the related long-acting NI's on a worldwide basis. In the event that the related intellectual property was out-licensed to a third party, we and Daiichi Sankyo agreed to share equally 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 have not been established.

In March 2009, we entered into a commercialization agreement with Daiichi Sankyo, pursuant to which it 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.

BARDA Contract for the Development of Laninamivir Octanoate

On March 31, 2011, we were awarded a contract from 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"). Pursuant to this contract, reimbursable costs include, but are not limited to, those incurred by the Company for the clinical development, scale-up, formulation and the design of a manufacturing facility needed to support the filing of a NDA with, and the potential licensure of laninamivir octanoate by, the FDA. The performance period of the BARDA contract commenced on March 31, 2011, and continues for five years. As of June 30, 2013, we have recognized revenue totaling $34.1 million pursuant to this contract.

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 regulatory agencies in foreign 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 failure of the FDA or similar regulatory agency 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") regulation;
- 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 NDA prior to any commercial sale or shipment of a product.

Successfully completing this development process requires a substantial amount of time 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, 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

This 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 as part of 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 serious adverse events 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 agency 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 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, 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 the U.S. Department of Health and Human Services (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 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 will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop 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.

European Union ("E.U.") 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, 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 product development.

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, 2013, we had 89 full-time employees. 71 that were that engaged in research and development, and 18 of whom were engaged in corporate, administration, finance, and business development activities. 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 these website addresses are provided as inactive textual references 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 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 DEVELOPMENT OF OUR PRODUCT CANDIDATES

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 success of our business ultimately depends upon our ability to advance the development of our product candidates through preclinical studies and clinical trials, be able to consistently manufacture them in accordance with strict specifications and regulations, get these product candidates approved 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 research, preclinical studies or clinical trials will support or justify the continued development of our product candidates, or that we will 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 or they can be approved for sale. 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:

- offer therapeutic or other medical benefits over existing drugs or other product candidates in development to treat the same patient population;
- be proven to be safe and effective in current and future preclinical studies or clinical trials;
- have the desired effects;
- be free from undesirable or unexpected effects;
- meet applicable regulatory standards;
- be capable of being formulated and manufactured in commercially suitable quantities and at an acceptable cost; or
- be successfully commercialized by us or by our 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 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 ever result in the 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 our collaborators 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 a commercially viable product.

The continuation of our BARDA contract depends on our ability to meet development milestones previously agreed to with BARDA and on our compliance with certain operating procedures and protocols. The termination, suspension or reduction of our contract with BARDA could adversely affect our business and impair our ability to further develop or commercialize laninamivir octanoate.

In 2011, we were awarded a contract from BARDA for the late-stage development of laninamivir octanoate. Under this contract, we are entitled to receive up to $231 million in funding and we are relying on this funding to support the advanced development of laninamivir octanoate in the U.S. BARDA may suspend or terminate this contract should we fail to achieve key objectives or milestones, or fail to comply with the operating procedures and processes approved by BARDA and its audit agency, the Defense Contract Audit Agency. There can be no assurance that we will be able to achieve these milestones or continue to comply with these procedures and protocols, or that we will be able to successfully develop laninamivir octanoate under this contract. If our contract with BARDA contract is terminated, suspended or significantly reduced, we will likely not have access to sufficient resources to continue to fund the development and commercialization of laninamivir octanoate, and our business could be adversely affected.

BARDA may not fully reimburse all the development costs required to support the approval of laninamivir octanoate in the U.S. and we may need to expend additional financial resources to achieve a NDA filing, which could harm our financial condition.

Costs that can be reimbursed under our contract with BARDA are currently capped at $231.2 million. If we surpass this amount or otherwise materially alter the development plans for laninamivir octanoate, and BARDA does not agree to modify the scope of the contract plan, we may incur additional costs to complete the development of laninamivir octanoate and file a NDA.

If the actual or perceived therapeutic benefits or the safety or tolerability profile of any of our product candidates, including laninamivir octanoate, 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 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 influenza, RSV, HRV and bacterial infections. Many of these product candidates are either approved for sale or further advanced in clinical development than ours such that their time to approval and commercialization may be sooner than that for our product candidates. Accordingly, if at any time we believe that any of our product candidates may not provide meaningful therapeutic benefits, perceived or real, equal to or better than our competitor's products or product candidate's, or we believe such 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 at any time. 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®), will compete with laninamivir octanoate for the treatment of influenza, if approved for sale. We also believe a number of antibiotics, such as: vancomycin, which is marketed by a number of manufacturers including Abbott Laboratories; Cubicin® marketed by Cubist Pharmaceuticals, Inc.; Zyvox® marketed by Pfizer Inc. and Avelox® marketed by Bayer for the treatment of bacterial infections, will compete with certain of our antibiotic product candidates if they are successfully developed and approved for sale. Furthermore, at the time our products may be approved, several of 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 in any indication may impose significant pricing pressure on patented drugs. Accordingly, if at any time we believe that any of our product candidates may not provide meaningful therapeutic or safety benefits, perceived or real, over these generic drugs, we may delay or terminate its future development at any time. 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. Further, 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 product candidates may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products, which may delay or preclude their further development or regulatory approval, or limit their use if approved.

Throughout the drug development process, we must continually demonstrate the activity, safety and tolerability of our product candidates to obtain regulatory approval to further advance their clinical development, or to 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 their potential benefit. We may observe adverse or serious adverse events or drug-drug interactions in future 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 of preclinical studies or clinical trials for 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, or 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 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 institutional review boards 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 patients 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, may fail 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 foreign regulatory authorities in foreign jurisdictions, which is required for us to market and sell the product.

Several of our product candidates are 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 much more frequently in the fall and winter months in any given region, as opposed to the spring and summer months. Accordingly, clinical trials being conducted in patients with these seasonal respiratory infections need to be conducted during the season in which the infections occur, and generally cannot be conducted year-round in any one region of the world. The seasonality of these respiratory infections generally requires us to plan to conduct clinical trials in both the northern and southern hemisphere in order to enroll these trials on a timely basis. In the event we cannot enroll a sufficient number of patients during a season in any one region of the world, such as the Northern Hemisphere, we may need to also conduct the trial in countries in the Southern Hemisphere in order to meet our enrollment targets, which increases the complexity of these 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 would could materially harm our business prospects and financial condition.

To support a NDA filing with the FDA, we anticipate conducting several placebo-controlled clinical trials of laninamivir octanoate with the primary efficacy endpoints designed to show in a statistically significant manner that laninamivir octanoate has superior clinical benefit 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. 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 contractors at least 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. Some of these risks include, but are not limited to:

- our third-party contractors 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;
- our contract manufacturers being unable to increase the scale of, increase the capacity for, or reformulate the form of our product candidates. We may experience a shortage in supply, or the cost to manufacture our product candidates may increase to the point where it adversely affects their cost. 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 regulatory restrictions inherent 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 various 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, which could result in our inability to manufacture our product candidates for an extended period of time and therefore a delay in the development of our product candidates. Further, in order to maintain our development time lines in the event of a change in our 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, monitoring and conducting 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 certain 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 bodies 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 recruiting and managing clinical trials, which could delay or impair our timing to initiate or complete clinical trials of our product candidates and materially harm our business.

We have limited capacity to recruit and manage 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, they 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 marketing approvals, if at all, for our product candidates.

If we are unable to retain or attract 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 adopted an operating model that relies on the outsourcing of a number of responsibilities and key 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 consultants and vendors, as well as academic and corporate advisors or consultants that 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 research and development, product development, clinical trials, medical affairs, government regulation of pharmaceutical products, 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, and 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; manufacturing costs; establishing and maintaining intellectual property and patent rights and their protection; 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®). A similar situation would likely exist if laninamivir octanoate is approved and marketed in territories outside Japan. In addition, a number of companies are pursuing the development of technologies and product candidates that will compete with our other product candidates and research programs. These companies include specialized pharmaceutical firms and large pharmaceutical companies acting either independently or together with other pharmaceutical companies.

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 could compete with our product candidates, have substantially more resources than we have, and 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, 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 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 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, new products or product candidates, we may terminate the development or commercialization of our product candidates at any time.

We also face, and expect we will continue to face, intense competition from other companies for collaborative arrangements with pharmaceutical and biopharmaceutical companies for attracting investigators and clinical sites capable of conducting our preclinical studies and clinical trials, and for patients to participate in our clinical trials. 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 cannot assure you that product candidates resulting from our research and development efforts, or from joint efforts with our 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 collaboration if our 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 of our existing and future product candidates. Such 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 future collaborations 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 collaborations will depend primarily upon our collaborator's ability to successfully develop and commercialize our product candidates. In addition, our 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 and, accordingly, will depend entirely on our collaborators. Our 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
- de-prioritize the importance of or otherwise diminish their support for developing and/or marketing our product candidate or product due to a change in management, business operations or financial strategy.

Should any of these events occur, we may not realize the full potential or intended benefit of our collaboration arrangements, and our results of operations may be adversely affected. In addition, a collaborator may decide to pursue the development of a competitive product candidate developed outside of our collaboration 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 collaborative arrangement, or other licensing agreement terms. If a 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 collaborator willing to develop and commercialize our product candidates under similar terms, if at all. Similarly, we may disagree with a 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 collaboration, 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 collaboration agreements we may enter into for any of our product candidates.

Our early-stage research and development efforts may not result in additional product candidates being discovered, which could limit our ability to generate revenues in the future.

Our early-stage research and discovery efforts may not lead to the development of any additional product candidates that may be suitable for further preclinical or clinical development to treat viral or bacterial infections. The discovery of additional product candidates requires significant research and preclinical studies, as well as a substantial commitment of internal and/or external resources. Many candidate or lead compounds that appear to be promising in early stages of discovery or research, fail to progress to become product candidates in preclinical studies or clinical trials. There is a great deal of uncertainty inherent in the research and development process and, as a consequence, in our ability to advance the development of lead compounds to potentially promising product candidates. We cannot assure you that our early research activities and efforts will yield any additional preclinical or clinical product candidates.

RISKS RELATED TO COMMERCIAL MATTERS

We have a history of incurring net losses and we may never achieve or maintain 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 consistently profitable, we, or our collaborators, 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 products.

Royalty revenues from our marketed products are unpredictable and subject to the seasonal incidence and severity of influenza, which could harm our results of operations and financial condition.

We currently earn royalty revenue from net sales of Relenza® and Inavir®, which are marketed by 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 revenue from these royalties has historically been variable and subject to fluctuation based on the seasonal incidence of influenza. In addition, the return of products to our licensees is taken into account in the calculation of net sales for purposes of calculating the royalty revenue we receive and are in general unpredictable. We cannot predict with any certainty what our royalty revenues are likely to be in any given year.

If significant safety, tolerability, resistance or drug interaction issues should arise with Relenza® and 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 interaction issues may arise, which may require our licensees to provide additional warnings or contraindications on their product labels, or otherwise narrow the approved indications. If serious safety, tolerability, resistance, drug interaction or any other significant issues arise with respect to these marketed products, sales of these products could be 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 we develop through collaborations, our revenues and potential for profitability will 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 may also need 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 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 drugs. In many foreign markets, governmental agencies control the pricing of prescription drugs. In the U.S., significant changes in federal health care policy were recently approved and will mostly likely result in reduced reimbursement rates 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 receive for any of our products that may be approved for sale in the future, which would limit our revenues and profitability. Accordingly, 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 collaborations 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 collaborator obtain the requisite regulatory approvals to market them in the future, they may not gain market acceptance or 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 potentially the sale of laninamivir octanoate, if approved, to 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 their efforts, 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 costs before the time that 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 and may cause our profitability to decline.

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 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 our 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 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 and Daiichi Sankyo share all licensing revenue equally. 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 provide we and Daiichi Sankyo with the exclusive right to import, export, make, use, distribute for sale, 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 we 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 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 outside 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 managements' time. We cannot assure you we will reach a satisfactory commercial agreement with Daiichi Sankyo or Hovione in the future.

RISKS RELATED TO OUR CONTRACTS WITH THE U.S. GOVERNMENT

If BARDA suspends, cancels, or otherwise terminates our contract with them, our financial condition and business could be materially harmed.

BARDA is a U.S. government agency and has certain contracting requirements that allow it to unilaterally control its contracts. Contracts with U.S. government agencies typically contain termination provisions unfavorable to the other party, and are subject to audit and modification by the U.S. government at its sole discretion, which can subject us to additional risks. , These risks include the ability of the U.S. government to unilaterally:

- audit or object to our contract-related costs and fees, and require us to reimburse all such costs and fees;
- suspend or prevent us from receiving new contracts or extending our existing contracts for a set period of time based on violations or suspected violations of laws or regulations;
- cancel, terminate or suspend our contracts based on violations or suspected violations of laws or regulations;
- terminate our contracts if doing so is in the government's best interest, including if funds become unavailable to the applicable governmental agency;
- reduce the scope and value of our contracts; and
- change certain terms and conditions in our contracts.

BARDA is able to terminate its contracts with us, either for its best interests or if we default by failing to perform in accordance with, or to achieve the milestones set forth in the contract schedules and terms. Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed and settlement expenses on the work completed prior to termination.

The U.S. government's determination to award any contracts may be challenged by an interested party, such as another competitor or bidder. If such a challenge is successful, our contract or any future contract we may be awarded may be reduced, suspended or terminated, which would harm our financial condition and prospects.

The laws and regulations governing the procurement of goods and services by the U.S. government provide procedures by which other bidders and interested parties may challenge the award of a government contract. Such challenges or protests could be filed even if there are not any valid legal grounds on which to base the protest. If any such protests are filed, the government agency may decide to suspend our performance under the contract while such protests are being considered by the GAO or the applicable federal court, thus potentially delaying delivery of payment. In addition, we could be forced to expend considerable funds to defend any potential award. If a protest is successful, the government may be ordered to limit or terminate any one or more of our contracts and reselect bids. The government agencies with which we have contracts could also be directed to award a potential contract to one of the other bidders.

Under our contract with BARDA, our operations, and those of our contractors, are subject to audit by the U.S. government, a negative outcome to which could adversely affect 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.

The DHHS 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 United States government.

Any contracts we have with U.S. government agencies may lead to claims against us under the Federal False Claims Act, and these claims could result in substantial fines and other penalties, which could harm our financial condition, reputation and prospects.

Our U.S. government contracts are subject to substantial financial penalties under the Federal Civil Monetary Penalties Act and the Federal Civil False Claims Act. Under the False Claims Act's "whistle blower" provisions, private enforcement of fraud claims against businesses on behalf of the U.S. government has increased due in part to amendments to the False Claims Act that encourage private individuals to sue on behalf of the government. These whistle blower suits may be filed by individuals, including present and former employees. The False Claims Act statute provides for treble damages and up to $11,000 per false claim. If our operations are found to be in violation of any of these laws, or any other U.S. governmental regulation that applies to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs, and the curtailment or restructuring of our operations.

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 harmed.

Our business success depends in part on our ability to:

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

We will be able to 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. Therefore, 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 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 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 around our or our licensors' patent claims to 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 can 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 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. The patent relating to the structure of laninamivir octanoate expires in 2017 in the U.S., EU and Japan. The patent relating to hydrates and the crystalline form of laninamivir octanoate 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 expirations will in all likelihood adversely affect our ability to protect or maintain our direct product or royalty revenue.

Also, patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies. The laws of certain foreign countries do not protect our 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 life-saving 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 collaborators become involved in any patent litigation, interference or other legal proceedings, we could incur substantial expense, and the efforts 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 inventions we may make from time-to time. 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 nor 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 the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a third-party illegally obtained and is using our trade secrets 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 failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

RISKS RELATED TO OWNING OUR COMMON STOCK

Our revenue, expenses and results of operations may be subject to significant fluctuations, 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. In addition, the return of products to our licensees is taken into account in the calculation of net sales for purposes of calculating the royalty revenue we receive and are in general unpredictable. Further, revenue we record under our contract with BARDA in any given period is based on the reimbursable costs we incur during that period, which have and will continue to fluctuate from quarter-to-quarter and year-to-year. 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. 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, the timing of the formulation and manufacture of our product candidates, or other development related factors. Accordingly, our revenues, expenses and results of operations for any period may not be comparable to the revenues, expenses or results of operations for any other period.

The reporting requirements of being a company 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 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 their 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 publicly-traded company on NASDAQ in the U.S. require us to incur significant expenditures and place additional demands and requirements on our board of directors and executive officers, as well as 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;
- Variation, suspension or termination of the contract we have with BARDA, or its funding ability;
- 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 collaborative 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 due to our failure to maintain minimum listing standards or other listed markets;
- 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
- general economic conditions and capital markets.

In addition, the stock market in general, and more specifically the NASDAQ Global Select Market, upon which our common stock trades, 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, which could generate losses.

In order to develop our product candidates and support our operations beyond 12 months from June 30, 2013 and continue as a going concern, 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 and cash equivalents of $66.8 million as of June 30, 2013, along with the anticipated proceeds from existing royalty-bearing licenses for Relenza® and Inavir® and our contract with BARDA, will enable us to operate for a period of at least 12 months from June 30, 2013. This estimate assumes that we continue current operations and development plans with our existing product candidates, but 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 agreements, or collaborative or partner arrangements, pursuant to which we will likely relinquish rights 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 and others that may be beyond our control, including:

- the variability of future royalty revenue we may receive under our existing royalty-bearing license agreements;
- continuing to receive sufficient revenue under our contract with BARDA to advance the development of laninamivir octanoate in the U.S.;
- 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 publicly-traded company 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 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 require us to relinquish 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. 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, 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 certain 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 on 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.

RISKS RELATED TO OTHER ASPECTS OF OUR BUSINESS

We may be unable to successfully integrate the operations of Nabi Biopharmaceuticals and Biota Holdings in a timely manner, if at all, which could increase our cost of doing business or harm our operations and business prospects.

On November 8, 2012 we were formed as a result of the merger of Nabi and Biota Holdings Limited, with the resulting organization being called Biota Pharmaceuticals, Inc. The relocation of the corporate headquarters and integrating the operations and financial and legal records between the organizations is still ongoing. In addition, we appointed a new CEO and Executive Vice President in the U.S. subsequent to the merger. We may incur additional costs and consume a significant amount of management's time to integrate our U.S., Australian and United Kingdom operations, including information systems, financial records, reporting systems, internal controls and legal contracts, in a timely manner, if at all.

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. Such 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 is subject to limitations and re-assessment due to ownership changes that have occurred or that could occur in the future, in the U.S., Australia and the United Kingdom. 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.

We have adopted a corporate strategy, a component of which reflects our intent to pursue in-licensing, acquisition, co-development, and other similar collaborative clinical-stage development opportunities to better balance our pipeline. 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.

ITEM 2. *PROPERTIES*

We have entered into an operating lease for an office and laboratory facility located in Melbourne, Australia through July, 2016, as well as corporate offices in Alpharetta, Georgia through September, 2019 and office and laboratory facility in Oxford, United Kingdom through 2018. The total annual rent expense under these leases is approximately $0.5 million. 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 13, 2013, we had 6,855 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.

	2012	
	High	**Low**
First Quarter (July 2011 to September 2011)	$ 5.82	$ 1.62
Second Quarter (October 2011 to December 2011)	2.07	1.50
Third Quarter (January 2012 to March 2012)	2.03	1.74
Fourth Quarter (April 2012 to June 2012)	1.95	1.53

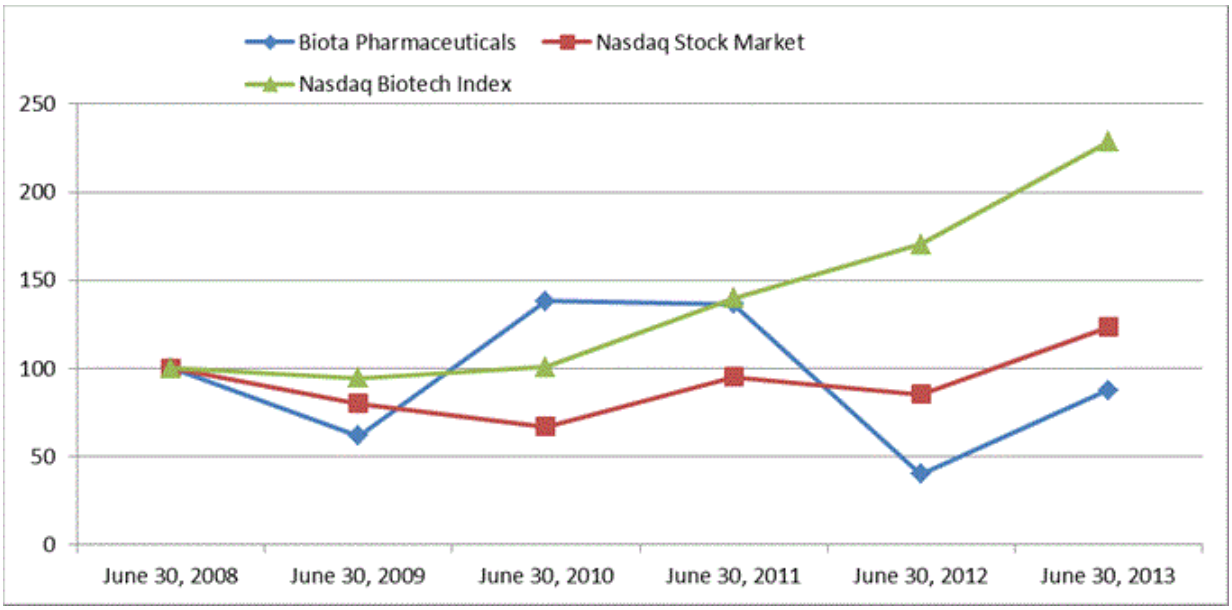
	2013	
	High	**Low**
First Quarter (July 2012 to September 2012)	$ 1.71	$ 1.55
Second Quarter (October 2012 to December 2012)	4.71	1.56
Third Quarter (January 2013 to March 2013)	4.40	3.80
Fourth Quarter (April 2013 to June 2013)	4.39	3.01

Dividend Policy

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 future growth, product development and operations. 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 our current and future debt arrangements 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 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.



	6/30/2008	6/30/2009	6/30/2010	6/30/2011	6/30/2012	6/30/2013
Biota Pharmaceuticals (1)	$100	$62	$138	$137	$40	$88
Nasdaq Stock Market	$100	$80	$67	$95	$85	$124
Nasdaq Biotech Index	$100	$94	$101	$140	$170	$229

Assumes $100 invested on June 30, 2008

(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.

ITEM 6. ***SELECT 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,				
	2013	2012	2011	2010	2009
	(in millions, except share and per share data)				
Statement of Operations Data:					
Revenues	$ 33.6	$ 20.4	$ 12.5	$ 60.8	$ 60.1
Operating expense:					
Cost of revenue	20.4	9.9	2.5	4.1	9.6
Research and development	19.2	24.1	33.5	35.5	8.9
General and administrative	18.0	9.4	7.0	8.2	12.6
Foreign exchange (gain) loss	(1.9)	(0.1)	-	-	0.1
Total operating expense	55.7	43.3	43.0	47.8	31.2
Operating (loss) income	(22.1)	(22.9)	(30.5)	13.0	28.9
Total non-operating income, net	13.5	3.2	4.3	2.2	2.2
Income tax benefit (expense)	(0.1)	0.5	0.8	(3.3)	(2.7)
Net (loss) income	(8.7)	(19.2)	(25.4)	11.9	28.4
Net (loss) income per common share:					
Basic and Diluted	$ (0.31)	$ (0.85)	$ (1.12)	$ 0.53	$ 1.29
Weighted average number of shares used in per common share calculations:					
Basic	28,217,515	22,713,566	22,567,958	22,320,632	22,048,912
Diluted	28,217,515	22,713,566	22,567,958	22,320,632	22,048,912

	As of June 30,				
	2013	2012	2011	2010	2009
			(in millions)		
Balance Sheet Data:					
Cash and cash equivalents	$ 66.8	$ 53.8	$ 74.2	$ 89.8	$ 69.8
Total assets	84.3	69.3	88.5	102.2	89.9
Total liabilities	16.1	10.0	7.1	14.8	11.9
Total stockholders' equity	$ 68.2	$ 59.3	$ 81.4	$ 87.4	$ 78.1

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 a biopharmaceutical company focused on the discovery and development of innovative anti-infective products to prevent and treat serious and potentially life-threatening infectious diseases. We were incorporated in the state of Delaware since 1969 and our corporate headquarters are located in Alpharetta, Georgia.

On November 8, 2012, Nabi Pharmaceuticals, Inc. ("Nabi") and Biota Holdings Limited, a biopharmaceutical company based in Melbourne, Australia that had been listed on the Australian Stock Exchange since 1985, completed a merger, and renamed the resulting company Biota Pharmaceuticals, Inc. ("Biota", the "Company", "us" or "we"). Former Biota Holdings Limited shareholders retained approximately 83% of our shares of common stock, while former Nabi shareholders retained approximately 17% as consideration for Nabi's net assets, which consisted primarily of $27 million in net cash on hand on the date of the merger. As Nabi had minimal ongoing activity with respect to its development programs or related operations at the time of the merger, our historical and current operations primarily reflect the operations of Biota Holdings Limited. Due to the fact that former Biota Holdings Limited shareholders held a significant majority of the voting interest in us upon the completion of the merger, the merger was accounted for as a "reverse merger", such that, notwithstanding the fact that Nabi was the legal acquirer, Biota Holdings Limited was considered the accounting acquirer for financial reporting purposes. Accordingly, the financial statements of Biota Holdings Limited are treated as our historical financial statements, with the operating results of Nabi being included therein beginning November 8, 2012. As a result of the reverse merger, the Company adopted a June 30 fiscal year end.

We are currently focused on developing oral, small molecule compounds to treat a number of viral infections. Our most advanced clinical-stage program is laninamivir octanoate, a long-acting neuraminidase inhibitor we are developing for the treatment of influenza A and B that is currently enrolling patients in a multi-national Phase 2 clinical trial, which we refer to as IGLOO. In addition to laninamivir octanoate, we are developing an orally bioavailable, preclinical compound for the treatment of RSV infections in children, the elderly and immunocompromised patients. We also have a Phase 2 compound, vapendavir ("BTA798"), which has been in clinical development for the treatment of human rhinovirus ("HRV") infections in patients with mild to moderate asthma. Finally, we have a discovery stage program focused on novel antibiotics designed to treat gram-positive and gram-negative bacterial infections.

We previously developed zanamivir, a neuraminidase inhibitor ("NI"), which is marketed worldwide by GSK as Relenza® for the prevention and treatment of influenza A and B. GSK developed and 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 neuraminidase inhibitors ("LANI"), including FLUNET and laninamivir octanoate. In 2009, we entered into a separate commercialization agreement with Daiichi Sankyo, which provided it an exclusive license to laninamivir octanoate in Japan and entitled us a royalty on net sales of laninamivir octanoate in Japan. In September 2010, laninamivir octanoate was approved for sale by the Japanese Ministry of Health and Welfare for the treatment of influenza A and B in adults and children. Laninamivir octanoate is marketed in Japan by Daiichi Sankyo as Inavir®. In 2009, we have filed an Investigational New Drug application ("IND") with the FDA to develop laninamivir octanoate in the U.S, and in 2011 we were awarded a contract from the U.S. Office of Biomedical Advanced Research and Development Authority ("BARDA") designed to provide up to $231.2 million in support of the development of and submission for a new drug application ("NDA") of laninamivir octanoate for the treatment of influenza A and B infections in the United States. In June 2013, we initiated Phase 2 IGLOO clinical trial of laninamivir octanoate under this IND.

Although several of our influenza product candidates have been successfully developed and commercialized by other larger pharmaceutical companies under collaboration, license 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 of our existing or future development-stage influenza or other product candidates that we are developing now, or may develop in the future.

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

Recent Corporate Developments

Laninamivir Octanoate – On June 11, 2013 we announced that we had commenced dosing in a multi-national, randomized, double blind, placebo-controlled, parallel arm Phase 2 clinical trial of laninamivir octanoate, a long-acting neuraminidase inhibitor the Company is developing for the treatment of influenza A and B. The trial, referred to as IGLOO, is designed to enroll 636 subjects to evaluate the safety and efficacy of 40 mg and 80 mg of laninamivir octanoate as compared with placebo, all delivered by a TwinCaps® inhaler in adults with symptomatic influenza A or B infection. We initiated IGLOO in several countries in the southern hemisphere, with a goal of completing enrollment in the trial by the end of the upcoming flu season in the northern hemisphere and having top-line data available from the trial in mid-2014.

Changes to the Board of Directors – On May 6, August 19, 2013 and September 10, we announced various changes to our Board of Directors, namely the resignations of Dr. Raafat Fahim, Mr. Paul Bell, Dr. Jeffrey Errington and Mr. Peter Cook as well the appointments of Ms. Anne M. VanLent, Mr. Michael R. Dougherty and Mr. John Richard to fill those vacancies.

Vapendavir (BTA798) – On September 18, 2013 we reported that we no longer plan to independently continue the clinical development of vapendavir in patients with asthma or chronic obstructive pulmonary disease ("COPD"), but rather intend to seek collaboration, co-development or license arrangements with third parties to advance its clinical development. In March 2012, we completed a 300-patient, Phase 2b clinical trial that evaluated the safety and clinical benefit of vapendavir for the treatment of human rhinovirus ("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") severity score.

Relenza® Royalty Revenue – On September 18, 2013, we reported that due to a recent increase in the amount of returns of Relenza® from distributors to GlaxoSmithKline, we recorded no royalty revenue in the quarter ended June 30, 2013, and anticipate earning an equal or lesser amount of royalty revenue from net sales of Relenza® in fiscal 2014 than in 2013.

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 BARDA contract, as well as 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 becomes determinable for the royalty period defined in each agreement. In 2014, we anticipate revenue from services to increase due to the clinical advancement of laninamivir octanoate, and for royalty revenue to remain the same or decrease from 2013 levels. In 2015, we expect our royalty revenues will decrease from 2013 levels as royalties from net sales of Relenza® will likely decrease due to the fact that the underlying patents will expire in the U.S. near the end of calendar 2014.

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 2014, we expect our cost of revenue to increase from 2013 due to 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 decrease in 2014, as compared to 2013, due to a reduction in the number of preclinical programs we expect to focus on in 2014, which are our preclinical RSV and GyrB/ParE antibiotic programs, and our decision not to independently advance the clinical development of vapendavir. Due to the early stage nature of our preclinical 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, if at all, and some of the possible consequences of failing to do so, 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 publicly-traded, and depreciation and facility expenses. In 2014, we expect our general and administrative expense to decrease from our 2013 expense levels as 2013 included a number of non-recurring expenses associated with the merger.

Foreign Exchange (Gain) or Loss. Foreign exchange (gain) or loss primarily relates to translation of foreign currency balances in our subsidiaries that have a different functional currency than the reporting currency of the parent per ASC 830, *Foreign Currency Matters*.

Other Income (Expense). Other income and (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 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 becomes determinable for the royalty period defined in each agreement. Revenue for services performed pursuant to contracts or grants is recognized as revenue when earned, typically when the underlying services or activities are rendered.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.

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, or for employee services that have not been paid. 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 on the straight-line method.

Recent Accounting Pronouncements

In December 2011, the FASB issued ASU 2011-11, which amended the disclosure requirements regarding offsetting assets and liabilities of derivatives, sale and repurchase agreements, reverse sale and repurchase agreements, and securities borrowing and securities lending arrangements. The enhanced disclosures will require entities to provide both net and gross information for these assets and liabilities. The amendment is effective for fiscal years beginning on or after January 1, 2013. We do not anticipate that this amendment will have a material impact on our consolidated financial statements.

In February 2013, the FASB issued ASU No. 2013-02, *Comprehensive Income (Topic 220)—Reporting Amounts Reclassified Out of Accumulated Other Comprehensive Income (ASU 2013-02).* The ASU adds new disclosure requirements for items reclassified out of accumulated other comprehensive income ("AOCI") and is intended to help entities improve the transparency of changes in other comprehensive income and items reclassified out of AOCI in their financial statements. The new disclosure requirements became effective for us for all interim and annual financial statement reporting periods beginning after December 15, 2012. The adoption of ASU 2013-02 did not change the recognition or measurement of net income or accumulated other comprehensive income.

Results of Operations

Fiscal Years Ended June 30, 2013 and 2012

Summary. For the year ended June 30, 2013, we reported a net loss of $8.7 million, as compared to $19.2 million in 2012. The $10.5 million decrease in net loss in 2013 was the result of a $13.2 million increase in revenue, a $7.8 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 $0.31 for the year ended June 30, 2013, as compared to a basic and diluted net loss per share of $0.85 in 2012.

We expect to generally incur losses for the foreseeable future as we intend to continue to support the clinical development of laninamivir octanoate, and several of our preclinical programs.

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 to 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 $20.4 million in 2013 from $9.9 million in 2012, representing an increase of $10.5 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 expenses	$ 15.4	$ 6.5
Salaries, benefits and share-based compensation expenses	4.7	3.2
Other expenses	0.3	0.2
Total cost of revenue expense	$ 20.4	$ 9.9

Direct preclinical, clinical and product development expense increased in 2013 due largely due 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 to the laninamivir octanoate in 2013 than in 2012 program under the BARDA contract.

Research and Development Expense. Research and development expense decreased to $19.2 million in 2013 from $24.1 million in 2012, representing a decrease of $4.9 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 expenses	$ 3.5	$ 7.3
Salaries, benefits and share-based compensation expenses	8.9	10.0
Other expenses	3.3	3.3
Depreciation and facility related expenses	3.5	3.5
Total research and development expense	$ 19.2	$ 24.1

Direct preclinical, clinical and product development expense decreased in 2013 due largely to a due to a $3.1 million decrease in direct clinical expenses associated with the completion of the Phase 2 clinical trial of vapendavir in 2012 and lower preclinical and chemistry expenses of $1.5 million associated with a decrease in the number of preclinical programs, offset in part by an increase of $0.8 million in manufacturing expenses related to our preclinical studies. Salaries, benefits and share-based compensation decreased in 2013 due to a $1.7 million decrease in salaries and benefits as a result of more resources being deployed on the laninamivir octanoate program under the BARDA contract, and lower consulting fees of $0.5 million, offset in part by a charge for termination 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 expenses	$ 9.8	$ 4.5
Professional and legal fees expenses	3.8	1.8
Other expenses	4.4	3.1
Total general and administrative expense	$ 18.0	$ 9.4

Salaries, benefits and share-based compensation 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 year's grants pursuant to the completion of the merger in 2013 and hiring additional of executives in the U.S., a $1.6 million charge recorded for termination benefits in 2013 due to a reduction in our workforce, and a $1.5 million increase in net salaries and benefits associated with adding personnel in the U.S. Professional and legal fees expenses increased in 2013 primarily due to non-recurring merger 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 the U.S. headquarters.

Foreign Exchange Gain, net. Foreign exchange gain increased in 2013 due to the significant increase in value of the U.S. dollar as compared to the Australian dollar during the last fiscal quarter of 2013 related to translation of foreign currency balances in our subsidiaries that have a different functional currency than the reporting currency of the parent

Other Income (Expense). Other income increased in 2013 primarily due to a $7.8 million gain we recorded related to the merger, as well as the receipt of $4.4 million with respect to an Australian research and development credit. Interest income decreased 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.

Fiscal Years Ended June 30, 2012 and 2011

Summary. For the year ended June 30, 2012, we reported a net loss of $19.2 million, as compared to $25.4 million for 2011. The $6.2 million decrease in net loss in 2012 was primarily the result of $7.9 million increase in revenue, offset in part by a $1.2 million decrease in interest and other income, an increase in operating expenses of $0.3 million and a $0.2 million decrease in income tax expense. Basic and diluted net loss per share were $0.85 for the year ended June 30, 2012, as compared to a basic and diluted net loss per share of $1.12 in 2011.

Revenue. Revenue increased to $20.4 million for the year ended June 30, 2012 from $12.5 million in 2011. The following table summarizes the key components of our revenue for the years ended June 30, 2012 and 2011:

	(in millions) Twelve Months Ended June 30,	
	2012	2011
Royalty revenue– Relenza® and Inavir®	$ 8.9	$ 9.5
Revenue from services, grants and collaborations	11.5	3.0
Total revenue	$ 20.4	$ 12.5

Royalty revenue from net sales of Relenza® and Inavir® decreased in 2012 due to lower net sales or of Relenza® during the period. Revenue from services increased primarily as a result of increased service revenue of $10.4 million in 2012 due to the preparations for the advancement of the Company's laninamivir octanoate program into a Phase 2 clinical trial under the BARDA contract, offset in part by $1.8 decrease in other grant revenue.

Cost of Revenue. Research and development expense increased to $9.9 million in 2012 from $2.5 million in 2011, representing an increase of $7.4 million. The following table summarizes the components of our cost of revenue expense for 2012 and 2011.

	June 30,	
	2012	2011
	(in millions)	
Direct preclinical, clinical and product development expenses	$ 6.5	$ 1.6
Salaries, benefits and share-based compensation expenses	3.2	0.7
Other expenses	0.2	0.2
Total cost of revenue expense	$ 9.9	$ 2.5

Direct preclinical, clinical and product development expense increased in 2012 due largely to preparations for the initiation of our Phase 2 clinical trial for laninamivir octanoate in 2013 under the BARDA contract. Salaries, benefits and share-based compensation expense increased in 2012 due largely due to more research and development resources being deployed on to the laninamivir octanoate program under the BARDA contract than in 2011.

Research and Development Expense. Research and development expense decreased to $24.1 million in 2012 from $33.5 million in 2011, representing a decrease of $9.4 million. The following table summarizes the components of our research and development expense for 2012 and 2011.

	June 30,	
	2012	2011
	(in millions)	
Direct preclinical, clinical and product development expenses	$ 7.3	$ 13.3
Salaries, benefits and share-based compensation expenses	10.0	12.6
Other expenses	3.3	4.0
Depreciation and facility related expenses	3.5	3.6
Total research and development expense	$ 24.1	$ 33.5

Direct preclinical, clinical and product development expense decreased in 2012 due to a $4.9 million decrease in clinical expenses related to the completion of a Phase 2 vapendavir trial in 2012 and a decrease in preclinical manufacturing expenses of $1.8 million, offset in part by higher preclinical development expenses of $0.7 million. Salaries, benefits and share-based compensation decreased in 2012 due primarily to more staff being deployed on to the laninamivir octanoate program in 2012 under the BARDA contract, as well as lower consulting and professional fees. Other expenses decreased in 2012 primarily due to lower intellectual property related expenses.

General and Administrative Expense. General and administrative expense increased to $9.4 million in 2012 from $7.0 million in 2011, representing an increase of $2.4 million. The following table summarizes the components of our general and administrative expense for 2012 and 2011.

	June 30,	
	2012	2011
	(in millions)	
Salaries, benefits and share-based compensation expenses	$ 4.5	$ 3.9
Professional and legal fees expenses	1.8	0.5
Other expenses	3.1	2.6
Total general and administrative expense	$ 9.4	$ 7.0

Salaries, benefits and share-based compensation increased due to additional personnel. Professional and legal fees expenses increased in 2012 due primarily to merger related expenses incurred in 2012. Other expenses increased in 2012 primarily due to higher other expenses associated with the merger.

Other Income (Expense). Other income decreased in 2012 due to lower interest income as result of lower available interest rates in 2012 as compared to 2011, as well as lower average cash balances held in 2012 compared to 2011.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 1965 through June 30, 2013, we have funded our operations primarily with public offerings and license fees, royalties, research agreements and grants. In 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. The performance period of the BARDA contract commenced on March 31, 2011, and continues for five years. To date revenue totaling $34.1 million has been recognized to-date pursuant to this contract.

At June 30, 2013, our cash and cash equivalents were $66.8 million and we held no investments with a maturity greater than 12 months. Our cash and cash equivalents are generally held in a variety of interest-bearing short-term deposits with large U.S. and Australian banks.

Cash Flows

For the year ended June 30, 2013, cash and cash equivalents increased by $13.0 million, from $53.8 million to $66.8 million. This increase was primarily the result of $32.7 million of cash received as a result of the merger, offset in part by cash used for operating activities and other investing activities during the period.

Net cash used in operating activities was $13.9 million in 2013, which reflected our net loss for the period of $8.7 million that included a gain of $7.8 million we recorded as a result of the merger, an increase in net operating assets of $3.4 million, offset in part by non-cash charges for share-based compensation and depreciation and amortization of $5.6 million and an increase in operating liabilities of $0.3 million.

Our net loss resulted largely from our funding of research and development activities including basic research: conducting preclinical studies; manufacturing and formulation expenses; incurring ongoing general and administrative expenses; as well as expenses associated with the merger, offset in part by revenue from services, royalty and other revenue from grants and collaborations, a $7.8 million gain we recorded pursuant to the merger, the receipt of a $4.4 million research and development credit, and interest income. The net change in operating assets and liabilities reflects a $4.2 million increase in accounts receivable due to higher contract revenue billed or accrued, a $0.6 million increase in prepaid expenses, and a $2.8 million decrease in accounts payable and accrued expenses, offset in part by an increase of $2.4 million in accrued severance obligations related to the merger and a $1.4 million decrease in deferred tax assets.

Net cash provided from investing activities during 2013 was $31.7 million, which was due to $32.7 million in cash we received pursuant to the merger, offset in part by $1.0 million for the purchase of laboratory and computer 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;
- whether we continue to receive sufficient revenue under our contract with BARDA to advance the development of laninamivir octanoate in the U.S.;
- 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 enrolment 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 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 of $66.8 million as of June 30, 2013, along with the anticipated proceeds from existing royalty-bearing licenses and revenue from our contract with BARDA will enable us to operate for a period of at least 12 months from June 30, 2013.

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, and our BARDA contract. 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.

Contractual Obligations and Commitments

We have entered into an operating lease for an office and laboratory facility located in Melbourne, Australia through July, 2016, as well as corporate offices in Alpharetta, Georgia through September, 2019 and office and laboratory facility in Oxford, United Kingdom through 2018. The total annual rent expense under these leases is approximately $0.5 million. In connection with the development of laninamivir octanoate we have open reimbursable purchase orders with third party vendors for goods and services of $40.2 million as of June 30, 2013. As of June 30, 2013, 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	$ 1.5	$ 0.5	$ 0.6	$ 0.3	$ 0.1
Purchase obligations	40.2	35.1	5.1	—	—
Total contractual obligations	$ 41.7	$ 35.6	$ 5.7	$ 0.3	$ 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.

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 and cash equivalents are invested in liquid money market funds and short-term deposits. 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, 2013, this change would not have had a material effect on future earnings or cash flows.

Our exposure to credit risk is managed through our policy that specifies credit quality standards for our cash deposits and limits the amount of credit exposure to any single party. We place any excess cash not needed to fund operations with high credit quality financial institutions 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 expenditure in foreign currencies and 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.

With respect to work performed under the BARDA contract, we give priority to service providers who bill in U.S. dollars to match our contract, which is settled in U.S. dollars. 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 Chief Executive 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 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 Securities Exchange Act of 1934 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 and operated, 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 by the Committee of Sponsoring Organizations of the Treadway Commission, ("COSO"). Based on their assessment, management has concluded that, as of June 30, 2013, our Company's 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, 2013 has been audited by PricewaterhouseCoopers, 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 2013 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 definite proxy statement to be filed in connection with our 2013 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 definite proxy statement to be filed in connection with our 2013 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 definite proxy statement to be filed in connection with our 2013 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 definite proxy statement to be filed in connection with our 2013 annual meeting of stockholders.

ITEM 14. *PRINCIPAL ACCOUNTING FEES AND SERVICES*

Incorporated by reference to the section labeled “Independent Registered Public Accountants” in our definite proxy statement to be filed in connection with our 2013 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 27th day of September 2013.

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 and Accounting Officer)	September 27, 2013
/s/ Dr. James Fox James Fox	Chairman of the Board of Directors	September 27, 2013
/s/ Geoffrey Cox Geoffrey Cox	Director	September 27, 2013
/s/ John Richard John Richard	Director	September 27, 2013
/s/ Richard Hill Richard Hill	Director	September 27, 2013
/s/ Anne VanLent Anne VanLent	Director	September 27, 2013
/s/ Michael Dougherty Michael Dougherty	Director	September 27, 2013

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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)

	As of June 30,	
	2013	**2012**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 66.8	$ 53.8
Accounts receivable	11.0	6.0
Prepaid expenses and other assets	2.2	1.4
Total current assets	80.0	61.2
Non-current assets:		
Property and equipment, net	3.7	4.9
Intangible assets, net	0.6	1.8
Deferred tax assets	—	1.4
Total assets	$ 84.3	$ 69.3
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4.4	$ 2.9
Accrued expenses and other current liabilities	8.2	6.1
Accrued severance obligations	3.0	—
Deferred revenue	0.3	0.4
Deferred tax liabilities	—	0.1
Total current liabilities	15.9	9.5
Other liabilities	0.2	0.5
Total liabilities	$ 16.1	$ 10.0
Commitments and contingencies (Note 8)	—	—
Stockholders' equity:		
Common stock, $0.10 par value; 200,000,000 shares authorized 28,352,326 shares issued and 22,713,566 shares outstanding at June 30, 2013 and June 30, 2012, respectively	2.8	100.4
Common stock treasury	—	(1.4)
Additional paid-in capital	118.7	0.7
Accumulated other comprehensive income	25.3	29.5
Accumulated deficit	(78.6)	(69.9)
Total stockholders' equity	68.2	59.3
Total liabilities and stockholders' equity	$ 84.3	$ 69.3

See accompanying notes to the financial statements

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

	Years Ended June 30,		
	2013	**2012**	**2011**
Revenue:			
Royalty revenue and milestones	$ 9.6	$ 8.8	$ 9.5
Revenue from services	23.8	11.0	0.6
Other	0.2	0.6	2.4
Total revenue	33.6	20.4	12.5
Operating expense (income):			
Cost of revenue	20.4	9.9	2.5
Research and development	19.2	24.1	33.5
General and administrative	18.0	9.4	7.0
Foreign exchange gain	(1.9)	(0.1)	—
Total operating expense	55.7	43.3	43.0
Loss from operations	(22.1)	(22.9)	(30.5)
Other income:			
Gain recorded on merger	7.8	—	—
Research and development credit	4.4	—	—
Interest income	1.3	3.2	4.3
Total other income	13.5	3.2	4.3
Loss before tax	(8.6)	(19.7)	(26.2)
Income tax benefit	(0.1)	0.5	0.8
Net loss	$ (8.7)	$ (19.2)	$ (25.4)
Basic loss per share	(0.31)	(0.85)	(1.12)
Diluted loss per share	(0.31)	(0.85)	(1.12)
Basic weighted average shares outstanding	28,217,515	22,713,566	22,567,958
Diluted weighted average shares outstanding	28,217,515	22,713,566	22,567,958
Comprehensive loss:			
Net loss	(8.7)	(19.2)	(25.4)
Exchange differences on translation of foreign operations	(4.2)	(3.0)	18.8
Total comprehensive loss	$ (12.9)	$ (22.2)	$ (6.6)

See accompanying notes to the financial statements

Biota Pharmaceuticals, Inc.
Consolidated Statements of Equity
(in millions, except for share amounts)

	Common Stock		Additional Paid-in Capital	Treasury Shares		Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount		Shares	Amount			
Balances at July 1, 2010	179,209,987	$ 97.8	$ 1.4	(479,779)	$ (0.2)	$ (25.3)	$ 13.7	87.4
Comprehensive income	-	-	-	-	-	-	-	-
Exchange differences on translation of foreign operations	-	-	-	-	-	-	18.8	18.8
Net loss	-	-	-	-	-	(25.4)	-	(25.4)
Total Comprehensive income								(6.6)
New shares issued on exercise of options	1,394,548	1.2	(1.2)	-	-	-	-	-
Shares issued to Welcome Trust	813,021	0.8	-	-	-	-	-	0.8
Purchase of treasury shares	-	-	-	(831,255)	(0.8)	-	-	(0.8)
Share-based compensation	-	-	0.6	-	-	-	-	0.6
Balances at June 30, 2011	181,417,556	99.8	0.8	(1,311,034)	(1.0)	$ (50.7)	32.5	$ 81.4
Comprehensive income								
Exchange differences on translation of foreign operations	-	-	-	-	-	-	(3.0)	(3.0)
Net loss	-	-	-	-	-	(19.2)	-	(19.2)
Total Comprehensive income								(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 income								
Exchange differences on translation of foreign operations	-	-	-	-	-	-	(4.2)	(4.2)
Net loss	-	-	-	-	-	(8.7)	-	(8.7)
Total Comprehensive income								(12.9)
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, 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	-	-	$ (78.6)	$ 25.3	$ 68.2

See accompanying notes to the financial statements

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

	Years Ended June 30,		
	2013	**2012**	**2011**
Cash flows from operating activities provided by/(used in):			
Net loss	$ (8.7)	$ (19.2)	$ (25.4)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3.0	3.1	3.0
Share based compensation	2.6	0.5	0.6
Gain recorded on merger	(7.8)	—	—
Loss on fixed assets disposal	—	—	0.1
Change in operating assets and liabilities (net of liabilities acquired):			
Accounts receivable	(4.2)	(3.4)	(1.6)
Prepaid expenses and other assets	(0.6)	0.2	(0.4)
Deferred income taxes	1.5	(0.2)	0.4
Deferred revenue	(0.1)	0.2	(2.4)
Accounts payable and accrued expenses and other liabilities	2.8	2.9	(8.0)
Accrued severance obligations	(2.4)	—	—
Net cash used in operating activities	(13.9)	(15.9)	(33.7)
Cash flows from investing activities:			
Cash acquired from merger	32.7	—	—
Purchases of property and equipment	(1.0)	(1.3)	(0.7)
Net cash provided by (used in) investing activities	31.7	(1.3)	(0.7)
Cash flows from financing activities:			
Payment for Treasury shares	—	(0.4)	(0.7)
Proceeds from issues of shares	—	—	0.7
Net cash used in financing activities	—	(0.4)	—
Net (decrease) increase in cash and cash equivalents	17.8	(17.6)	(34.4)
Cash and cash equivalents at beginning of period	53.8	74.2	89.8
Effects of exchange rate movements on cash and cash equivalents	(4.8)	(2.8)	18.8
Cash and cash equivalents at end of period	$ 66.8	$ 53.8	$ 74.2
Supplemental cash flow disclosure:			
Proceeds from issuance of common stock on merger	$ 27.0	$ —	$ —
Net cash used in financing activities	—	—	—
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

Notes to Consolidated 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 the corporate headquarters are located in Alpharetta, Georgia. On November 8, 2012, Nabi Biopharmaceuticals (“Nabi”) merged with Biota Holdings Limited, which was previously listed on the Australian Stock Exchange (ASX:BTA), and the resulting company was renamed to Biota Pharmaceuticals, Inc.

The Company currently has two Phase 2 clinical-stage product candidates; laninamivir octanoate, which it is developing under an existing contract with the U.S. Office of Biomedical Advanced Research and Development Authority ("BARDA") to provide up to $231.2 million in financial support to complete the clinical development of laninamivir octanoate for the treatment of influenza A and B infections in the U.S. market; and vapendavir, a potent, oral broad-spectrum capsid inhibitor of enteroviruses including human rhinovirus ("HRV"). In addition, the Company has preclinical programs focused on developing treatments for respiratory syncytial virus ("RSV") as well as for gram-negative and multi-drug resistant bacterial infections.

The Company has developed a neuraminidase inhibitor, zanamivir, which is marketed worldwide by GlaxoSmithKline (“GSK”) as Relenza® for the prevention and treatment of influenza under a research and license agreement entered into with the Company in 1990. In addition, the Company and Daiichi Sankyo Inc. have cross-licensed the world-wide rights to develop and commercialize long-acting neuraminidase inhibitors (“LANI’s”), including laninamivir octanoate, which is marketed by Daiichi Sankyo Inc. as (“Inavir®) in Japan for the treatment of influenza A & B infections in adults and children. In November 2012, Daiichi Sankyo submitted an application for a label change in Japan to manufacture and market the influenza antiviral product Inavir ® for the prevention of influenza infection. The Company has filed an Investigational New Drug application (“IND”) with the United States Food and Drug Administration (“FDA”) to develop laninamivir octanoate, and in 2011 entered into a contract with BARDA designed to provide up to $231.2 million for the completion of the clinical development and U.S. based manufacturing of laninamivir octanoate for the treatment of influenza A and B infections.

Although several of the Company’s influenza products have been successfully developed and commercialized by other larger pharmaceutical companies under license agreements, the Company has not received regulatory approval for any product candidates it has developed independently, and does not have any sales, marketing or commercial capabilities. Therefore, it is possible that the Company may not successfully derive any significant product revenues from any of its existing or future development-stage product candidates.

Merger between Nabi Biopharmaceuticals and Biota Holdings Limited

On November 8, 2012, Nabi and Biota Holdings Limited completed a merger (the “Merger”), and renamed the resulting company Biota Pharmaceuticals, Inc. Former Biota Holdings Limited shareholders retained approximately 83% of the Company’s shares of common stock, while former Nabi shareholders retained approximately 17% as consideration for Nabi’s net assets, the vast majority of which was $27.0 million in net cash on hand on the date of the transaction. As Nabi had minimal ongoing activity with respect to its development programs and related operations at the time of the merger, the Company’s future operations will be largely represented by the operations of Biota Holdings Limited. Further, due to the fact that former Biota Holdings Limited shareholders held a significant majority of the voting interest in the Company upon the completion of the merger, the merger has been accounted for as a “reverse merger”, such that, notwithstanding the fact that Nabi was the legal acquirer, Biota Holdings Limited is considered the accounting acquirer for financial reporting purposes. Accordingly, the financial statements of Biota Holdings Limited are treated as the historical financial statements of the Company, with the operating results of Nabi being included from November 8, 2012. As a result of the reverse merger, the accompanying financial statements share and per share information has been retroactively adjusted to reflect the exchange ratio in the Merger. See Note 3 for additional discussion of the merger.

(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.

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, short-term 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 Short-Term Investments

The Company considers all highly liquid investments with maturities from the date of purchase of three months or less to be cash equivalents. Short-term investments constitute all highly liquid investments with term to maturity from three months to 12 months. The carrying amount of short-term investments is equivalent to its fair value. The Company did not have any short-term investments at June 30, 2013 and June 30, 2012.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that are exposed to credit risk consist of cash equivalents and accounts receivable. The Company's cash is deposited with several large commercial banks located in the U.S. and Australia that are federally insured or guaranteed. While balances deposited in these institutions often exceed insured or guaranteed limits, we have not experienced any losses on related accounts to date. If any of these financial institutions or customers fails to perform their obligations under the terms of these financial instruments, the maximum exposure to potential losses would equal amounts reported on the accompanying consolidated balance sheets.

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.

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 on 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, 2013 and June 30, 2012 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 U.K. Sterling. 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 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 patent application costs have been charged to expense and reported in research and development 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.

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 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.

Severance Obligations and Employee Benefits

As a result of the purchase consideration and net assets acquired pursuant to the merger (Note 3) the Company has a $3.0 million liability for severance obligations and employee benefits related to certain key officers and employees. This accrual is classified as a current liability on the consolidated balance sheet.

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 as well as certain research and development activities pursuant to collaborations with other corporate entities.

Revenue for royalties is recognized when the net sales of the underlying product by the relevant third party becomes determinable for the royalty period defined in each agreement. The Company receives communications of the amount of net sales from its licensees' on a quarterly basis that indicate the amount of royalty revenue for the relevant royalty period. The royalty periods for current license agreements range between one quarter and one year.

Revenue from services performed pursuant to contracts or grants is recognized as revenue when earned, typically when the underlying services or activities are rendered. 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 the 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, such as 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 manage and support our 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, and services, as well as premiums for insurance, other expenses as a result of being publicly-traded, and depreciation and facility expenses.

Total Comprehensive Income

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 and cumulative translation foreign currency adjustments.

Reclassifications

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

Recent Accounting Standards

In December 2011, the FASB issued ASU 2011-11, which amended the disclosure requirements regarding offsetting assets and liabilities of derivatives, sale and repurchase agreements, reverse sale and repurchase agreements, and securities borrowing and securities lending arrangements. The enhanced disclosures will require entities to provide both net and gross information for these assets and liabilities. The amendment is effective for fiscal years beginning on or after January 1, 2013. The Company does not anticipate that this amendment will have a material impact on its consolidated financial statements.

In February 2013, the FASB issued ASU No. 2013-02, *Comprehensive Income (Topic 220)—Reporting Amounts Reclassified Out of Accumulated Other Comprehensive Income (ASU 2013-02).* The ASU adds new disclosure requirements for items reclassified out of accumulated other comprehensive income ("AOCI") and is intended to help entities improve the transparency of changes in other comprehensive income and items reclassified out of AOCI in their financial statements. The new disclosure requirements became effective for the Company for all interim and annual financial statement reporting periods beginning after December 15, 2012. The adoption of ASU 2013-02 did not change the recognition or measurement of net income or accumulated other comprehensive income.

(3) Merger

Summary

On April 22, 2012, Nabi and Biota Holdings Limited entered into a merger implementation agreement (the "Agreement"), which was subsequently amended on August 6, 2012 and further amended on September 17, 2012. On November 8, 2012, Nabi and Biota Holdings Limited completed the merger and pursuant to the terms and subject to the conditions set forth in the Agreement, Biota Holdings Limited became a wholly owned subsidiary of Nabi. As outlined in Note 1, Nabi then changed its name to Biota Pharmaceuticals, Inc.

Reverse Stock Split

On November 8, 2012, as contemplated by the merger and as approved by Nabi's stockholders and board of directors, Nabi filed a Certificate of Amendment to its Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to affect a reverse stock split of Nabi's common stock at a ratio of 1:6. As a result of the reverse stock split, each six shares of Nabi common stock issued and outstanding immediately prior to the reverse stock split were automatically combined into and became one share of Nabi common stock. Also, as a result of the reverse stock split, the per share exercise price of, and the number of shares of common stock underlying, the Company outstanding stock options immediately prior to the reverse stock split were automatically proportionally adjusted based on the one-for-six split ratio in accordance with the terms of such options. The reverse stock split did not alter the par value or modify any voting rights or other terms of the common stock.

Merger between Nabi Biopharmaceuticals and Biota Holdings Limited

Upon complication of the merger the resulting company was renamed Biota Pharmaceuticals, Inc. Former Biota Holdings Limited shareholders retained approximately 83% of the Company's shares of common stock, while former Nabi shareholders retained approximately 17% as consideration for Nabi's net assets, the vast majority of which was $27.0 million in net cash on hand on the date of the transaction. As Nabi had minimal ongoing activity with respect to its development programs and related operations at the time of the merger, the Company's future operations will be largely represented by the operations of Biota Holdings Limited. Further, due to the fact that former Biota Holdings Limited shareholders held a significant majority of the voting interest in the Company upon the completion of the merger, the merger has been accounted for as a "reverse merger", such that, notwithstanding the fact that Nabi was the legal acquirer, Biota Holdings Limited is considered the accounting acquirer for financial reporting purposes. Accordingly, the financial statements of Biota Holdings Limited are treated as the historical financial statements of the Company, with the operating results of Nabi being included from November 8, 2012. As a result of the reverse merger, historical common stock amounts and additional paid-in capital have been adjusted.

Exchange Ratio

Upon completion of the merger, each outstanding share of Biota Holdings Limited common stock converted into the right to receive 0.1249539870 shares of Nabi common stock as determined by the exchange ratio - as calculated pursuant to the terms of the Transaction Agreement, as amended. Pursuant to the various agreements, Biota Holdings Limited stockholders received shares of Nabi common stock representing approximately 83% of the outstanding combined shares of the resulting combined company. Nabi stockholders continued to own their shares of existing Nabi common stock, which represented approximately 17% of the outstanding combined shares of the resulting combined company. The issued share capital upon completion of the merger was comprised of the following:

	No. of Shares
Ex-Nabi stockholders	4,720,999
Ex-Biota Holdings Limited stockholders	23,416,347
Total	28,137,346

Purchase Consideration and Net Assets Acquired

The purchase consideration in a reverse merger is determined with reference to the value of equity that the accounting acquirer (in this case Biota Holdings Limited,) issues to the stockholders of the accounting acquiree (Nabi, in this case) to give them their interest in the combined entity. Further, as a result of the merger, stock options to purchase an aggregate of 0.5 million shares of Nabi common stock that were held by officers and directors of Nabi immediately vested. The fair values of Nabi's outstanding stock options were determined using the Black-Scholes option pricing model with the following assumptions: a strike price range of $11.34 – $99.91; a volatility range between 78.79% – 99.62%; a risk-free interest rate range of 0.12% – 0.87%; and an expected life range of 0.3 – 6.1 years.

The purchase price, based on the price per share of the Company's common stock as of the date of the merger is as follows:

Number of shares issued to Nabi stockholders		4,720,999
Fair value per share, using the volume weighted share price on November 9, 2012	$	4.0168
Implied purchase consideration (in millions)	$	19.0
Number of stock options outstanding to former Nabi employees		508,918
Fair value per option	$	0.456
Implied purchase consideration (in millions)	$	0.2
Total implied purchase consideration (in millions)	$	19.2

The net assets acquired as a result of the merger consist of (in millions):

Cash	$	32.7
Accrual for severance obligations and employee benefits		(5.0)
Accounts payable		(0.7)
Net cash received	$	27.0
Excess of net assets acquired over total fair value purchase consideration/gain recorded on merger	$	7.8

Due to the significant uncertainty associated with future cash flows from these assets, no purchase consideration has been allocated to the residual value of any of Nabi's drug development programs, or the potential royalty of Phoslyra that was sold to a third party in 2006.

Pursuant to the Agreement, Biota Holdings Limited received net cash of $27.0 million from Nabi, while Nabi stockholders received a proportion of the combined entity based on the Biota Holdings Limited share price upon completion of the merger. Movements in the Biota Holdings Limited share price and the U.S. and Australian dollar exchange rates between the date of the determination of the exchange ratio and the date of the completion of the merger, coupled with changes in the fair value of certain assets and liabilities, resulted in the net assets acquired exceeding the calculated purchase consideration. The resulting gain of $7.8 million recorded on the completion of the merger is recognized as other income in the consolidated statements of operations.

Acquisition-related Costs

Acquisition-related costs related to the merger, including adviser, investment banking, legal, accounting and various other costs of $4.6 million and $1.9 million have been included as a general and administrative expense for the years ended June 30, 2013 and June 30, 2012, respectively. Total acquisition-related costs were approximately $6.5 million.

Pro forma Financial Information

The following table presents selected unaudited financial information, as if the merger with Nabi had occurred on July 1, 2011 (in millions, except per share data).

	As of June 30,	
	2013	**2012**
Pro forma net revenue	$ 34.9	$ 23.6
Pro forma net loss	(15.2)	(24.3)
Pro forma basic loss per share	(0.54)	(1.07)

(4) Financial Instruments

Financial Assets (in millions)

	As of June 30,	
	2013	**2012**
Financial assets:		
Cash and cash equivalents	$ 66.8	$ 53.8
Accounts receivable	11.0	6.0
Total financial assets	77.8	59.8
Financial liabilities:		
Accounts payable	4.4	2.9
Total financial liabilities	4.4	2.9
Net financial assets	$ 73.4	$ 56.9

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 2013, 2012 and 2011.

(5) Property and Equipment

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

	As of June 30,	
	2013	**2012**
Property and equipment	$ 6.3	$ 7.0
Leasehold improvements	6.8	7.0
Total Property and equipment	13.1	14.0
Accumulated depreciation	(9.4)	(9.1)
Property and equipment, net	$ 3.7	$ 4.9

Depreciation expense was $1.8 million, $1.8 million and $1.7 million for the fiscal years ended June 30, 2013, 2012 and 2011, respectively.

(6) Intangible Assets

Intangible assets consist of the following (in millions):

	As of June 30,	
	2013	**2012**
Royalty prepayment	$ 12.8	$ 14.0
Computer software	1.6	1.6
Total intangible assets	14.4	15.6
Accumulated depreciation	(13.8)	(13.8)
Intangible assets, net	$ 0.6	$ 1.8

Amortization expense was $1.2 million, $1.3 million and $1.3 million for the fiscal years ended June 30, 2013, 2012 and 2011, respectively. As of June 30, 2012, estimated future aggregate amortization expense is $0.5 million and $0.1 million for the years ending June 30, 2014 and 2015, respectively. All future amortization amounts in foreign currencies have been translated at exchange rates as of June 30, 2013 and the remaining amortization period for royalty prepayment is one year.

(7) Accrued and Other Current Liabilities

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

	As of June 30,	
	2013	**2012**
Legal, tax and accounting fees	$ 0.4	$ 0.9
Salary and related costs	2.1	2.7
Research and development materials and services	5.4	2.5
Other accrued expenses	0.3	-
Total accrued expenses	$ 8.2	$ 6.1

(8) Commitments and Contingent Liabilities

Operating Leases

The Company has three main operating leases.

The lease at 2500 Northwinds Parkway is for the Company's headquarters in Alpharetta, Georgia. The lease commenced in April, 2013 and expires in September, 2018. The lease includes an escalating base rent schedule; a seven month rent holiday and a tenant incentive towards leasehold improvements of approximately $0.1 million, which were 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 relates to the main Biota laboratories. The lease commenced in September 2004 and was last amended in December 2007. The lease term expires on September 1, 2014 and the Company has the option at that time to extend this lease for a further term of five years at an agreed market rate.

The lease at 597 Blackburn Road, Notting Hill, Victoria, Australia commenced on November 2007 and expired on July 30, 2013. Under the term of the lease, a security deposit of $0.1 million has been paid and has been recorded under “Other Assets” in the Consolidated Balance sheets. In accordance with the terms of the lease, the lessee has to restore the building to its original condition and the lessor can deduct costs from the security cost.

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, 2013 are:

2014	$	0.5
2015		0.3
2016		0.3
2017		0.2
2018		0.1
Thereafter		0.1
Total minimum lease payments	$	1.5

Rent expense was $1.1 million, $0.8 million and $0.8 million for the fiscal years ended June 30, 2013, 2012 and 2011, respectively. The Company also has operating lease agreements for the Oxford, UK offices and office copier equipment under standard terms which are included in the minimum lease payment schedule above.

Government Research Grants

Grant funding is initially recognized as deferred income and released to revenue to match the costs that they are intended to compensate for. Revenue recognized in relation to these grants was $0.6 million, $0.6 million and $2.4 million for the fiscal years ended June 30, 2013, 2012 and 2011, respectively.

In 2006, Biota was awarded a grant of $8.5 million by the National Institute of Allergy and Infectious Diseases, an institute of National Institutes of Health (“NIH”). The award was to develop a class of long-acting neuraminidase inhibitors. This grant was completed in 2011.

In 2011, Biota was awarded a grant of $2.9 million by the NIH. This grant is to fund the Preclinical development of a lead candidate for the treatment of Clostridium Difficile (C diff).

All payments under NIH grants are subject to satisfactory progress and the availability of funding.

(9) Income Taxes

On November 8, 2012, Nabi and Biota Holdings Limited completed a merger, and renamed the resulting company Biota Pharmaceuticals, Inc. For U.S. federal income tax purposes, the merger was treated as a tax-free transaction with Nabi being treated as the tax acquirer. The merger caused a "change in ownership" of Nabi's stock under the provisions of Internal Revenue Code ("IRC") section 382. As a result of the "change in ownership" certain Nabi tax attributes, including net operating losses and tax credits, are subject to limitation pursuant to IRC sections 382 and 383 as discussed below.

The following table includes deferred tax assets and liabilities as of June 30, 2013 and 2012:

	As of June 30,	
	2013	2012
Deferred tax assets:		
Foreign net operating loss carryforwards	$ 18.2	$ 21.1
Amortization	0.8	0.9
Depreciation	0.2	0.1
Accrued compensated-related costs	0.4	1.8
Other	3.7	0.4
	23.3	24.3
Deferred tax liabilities:		
Royalties	(1.9)	(1.9)
	(1.9)	(1.9)
Total deferred tax assets	21.4	22.4
Valuation allowance	(21.4)	(21.1)
Net deferred tax assets	$ -	$ 1.3

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, 2013 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 $21.4 million and $21.1 million of valuation allowance as of June 30, 2013 and 2012, respectively. As of June 30, 2013, the Company has had less than $0.1 million of gross U.S. federal net operating loss carryforwards that expire at various dates through 2033. Under IRC section 382, certain significant changes in ownership may restrict the future utilization of our tax loss carryforwards and tax credit carryforwards. Nabi's pre-"change in ownership" net operating losses and tax credits are unable to be utilized and are therefore not recorded.

As of June 30, 2013, the Company also has accumulated Australian tax losses of $44.6 million and accumulated United Kingdom tax losses of $23.9 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, 2013, 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.

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

	Years Ended June 30,		
	2013	2012	2011
United States	$ 6.7	$ -	$ -
Foreign	(15.3)	(19.7)	(26.1)
Total	$ (8.6)	$ (19.7)	$ (26.1)

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

	Years Ended June 30,		
	2013	2012	2011
Current:			
Federal	$ -	$ -	$ -
State	-	-	-
Foreign	0.1	(0.3)	(1.2)
	0.1	(0.3)	(1.2)
Deferred:			
Federal	-	-	-
State	-	-	-
Foreign	-	(0.2)	0.4
	-	(0.2)	0.4
Total Tax Expense	$ 0.1	$ (0.5)	$ (0.8)

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

	Years Ended June 30,		
	2013	2012	2011
Income tax expense (benefit) at federal statutory rate	$ (3.3)	$ (6.9)	$ (9.2)
State and local income taxes, net of federal benefit	0.3	-	-
Foreign tax rate differential	1.3	0.9	0.5
Change in valuation allowance (Net of Nabi merger)	4.2	2.8	9.8
Gain on merger	(3.0)	-	-
Research and development expenses	1.1	2.9	(1.3)
Research and development tax credits	(1.1)	(0.3)	(1.1)
Employee stock options	0.5	0.2	0.1
Other	0.1	(0.1)	0.4
Income tax expense (benefit)	$ 0.1	$ (0.5)	$ (0.8)

Uncertain Tax Positions

The Company is subject to income taxes in the U.S., various states, Australia, and the United Kingdom. Significant judgment is required in evaluating the Company’s tax positions and determining the provision for income taxes. The Company has established reserves for tax-related uncertainties based on estimates of whether, and to the extent to which, additional taxes may be due. These reserves are established when the Company believes that certain positions might be challenged despite its belief that its tax return positions are fully supportable. The Company adjusts these reserves in light of changing facts and circumstances, such as the outcome of a tax audit.

The Company is subject to tax audits in all jurisdictions for which it files tax returns. Tax audits by their very nature are often complex and can require several years to complete. Under the tax statute of limitations application to the IRC, the Company is no longer subject to U.S. federal income tax examinations by the Internal Revenue Services (“IRS”) for years before 2010. 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 2009 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, 2013.

(10) Share-Based Compensation

A summary of stock options outstanding as of June 30, 2013, and the related activity during the year ended June 30, 2013, is presented below.

	Number of Options		
Options	**Biota Holdings Limited**	**Nabi**	**Biota Pharmaceuticals, Inc.**
Outstanding at June 30, 2012	6,182,853	3,665,201	-
Granted	686,365	-	-
Exercised	(413,335)	-	-
Forfeited	-	(20,000)	-
Expired	(601)	(591,485)	-
	6,455,282	3,053,716	-
Adjustment for Consolidation of shares		(2,544,798)	-
Vested and exercised upon merger	(6,455,282)	-	-
Balance on November 8, 2012 (date of merger)	-	508,918	-
Post-merger transactions:			
Granted	-	-	1,166,590
Expired	-	(16,979)	-
Outstanding at June 30, 2013	-	491,939	1,166,590
Exercisable at June 30, 2013	-	491,939	-

On November 8, 2012, and in connection with the merger and based upon stockholder approval, Nabi's board of directors approved a 1:6 reverse stock split of existing Nabi shares, which reduced the number of shares of common stock reserved for outstanding stock options to 508,918. The exercise price of all outstanding stock options as of that date have been adjusted to reflect the reverse stock split and are now between $11.22 and $99.94 per share, with terms expiring from March, 2014 to January, 2019.

Biota Holdings Limited had outstanding stock options to purchase 6,455,282 shares of its common stock at September 30, 2012. Upon approval of the merger with Nabi by the Supreme Court of Victoria on October 26, 2012, all of these outstanding stock options vested, resulting in the issuance of 4,639,104 shares of common stock and the vesting of 1,816,178 shares held by Biota Holdings Limited for this purpose. The related expense of $1.1 million associated with the issuance of shares of common stock has been recognized as a general and administrative expense in the consolidated statement of operations of Biota Holdings Limited.

During the year ended June 30, 2013, the Company granted, and the Board of Directors approved, stock options to purchase a total of 1,166,590 shares of common stock. Of this total, 1,076,590 stock options were granted to employees at exercise prices between $3.14 and $4.07. The employee grants are exercisable from one to four years from the date of the grant and have a 10 year term. The Company granted 30,000 stock options to existing Board of Directors members at an exercise price of $4.05, exercisable one year from the date of grant with a six year term and 60,000 stock options to new Board of Directors members at an exercise price of $4.05, exercisable from one to three years from the date of grant with a 10 year term.

The weighted average fair value of awards granted during the year ended June 30, 2013 was estimated to be $2.39. The Company estimated the fair value of each stock option on the date of grant, using the Black-Scholes option-pricing formula, using the following key assumptions:

Expected Term: The expected term represents the period over which the share-based awards are expected to be outstanding, giving consideration to the expectations of future employee behavior, the contractual terms of the share-based awards and vesting conditions, option price and stock price. The Company estimates an expected term of six years for employee option grants, four years for existing director grants and five years for new director grants.

Risk-Free Interest Rate: The Company used risk-free rates between 0.30% and 0.60%, based upon the risk-free interest rate used in the assumptions on the implied yield currently available on the U.S. Treasury zero-coupon issues with a remaining term equivalent to the expected term of the stock option award.

Expected volatility: The Company used an expected volatility factor of 79.12%, based on the historical price of its common stock over the most recent period commensurate with the expected term of the stock option award.

Expected Dividend Yield: The Company does not intend to pay any cash dividends on common stock for the foreseeable future. Accordingly, it assumed a dividend yield of zero.

Expected Forfeitures: The total number of stock option awards expected to vest is adjusted by estimated forfeiture rates. The Company estimated the expected forfeiture rate to be 5.0% based on actual and anticipated forfeitures.

The Company amortizes share-based compensation expense over the option's vesting period using the straight-line attribution approach. For the year ended June 30, 2013, the Company recognized approximately $0.5 million of share-based compensation expense related to the issuance of stock option grants.

A summary of outstanding restricted stock awards as of June 30, 2013, and the related activity during the year ending June 30, 2013 is presented below:

	Number of Awards	
Awards	**Nabi**	**Biota Pharmaceuticals, Inc.**
Unvested at June 30, 2012	196,254	-
Vested and shares issued	(196,254)	-
Balance on November 8, 2012 (date of merger)	-	-
Post-merger transactions:		
Granted	-	241,083
Vested	-	(71,661)
Outstanding at June 30, 2013	Nil	169,422

On November 12, 2012, the Company granted 214,983 units of restricted stock awards with an average fair value of $4.07. The restricted shares vest over three equal installments: upon 90 days, and on the first and second anniversaries of the grant date. On May 1, 2013, the Company granted 26,100 of restricted stock units with an average fair value of $4.05 and vest one year from the date of grant. For the year ended June 30, 2013, the Company recognized approximately $0.5 million of share-based compensation expense related to the issuance of restricted stock units.

At June 30, 2013, there was $2.3 million of unrecognized compensation expense related to unvested share-based compensation arrangements. The weighted-average period over which this expense is expected to be recognized is 2.6 years.

(11) Retirement Benefits

The Company contributed $1.1 million, $1.1 million and $1.0 million for the fiscal years ended June 30, 2013, 2012 and 2011, 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, 2013 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 stock 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,		
	2013	2012	2011
Net loss (in millions)	$ (8.7)	$ (19.2)	$ (25.4)
Weighted-average shares outstanding	28,217,515	181,775,444	180,610,151
Weighted- average shares outstanding adjusted using exchange ratio used to compute basic earnings per share	-	22,713,566	22,567,958
Shares used to compute diluted earnings per share	28,217,515	22,713,566	22,567,958
Basic loss per share	$ (0.31)	$ (0.85)	$ (1.12)
Diluted loss per share	$ (0.31)	$ (0.85)	$ (1.12)
Number of antidilutive stock options excluded from computation	-	-	1,658,529

(13) Research and Development Credit

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 the current fiscal year, the Company does not expect to receive a research and development credit as its revenue is expected to exceed 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. Beginning in 2014, the patents on Relenza® are scheduled to expire in certain countries and are scheduled to fully expire in 2019.

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

On March 31, 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 is 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 continues for five years.

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. Revenue totaling $34.1 million has been recognized to-date pursuant to this contract.

Changes in government policies, priorities or funding levels through agency or program budget reductions by the U.S. Congress or executive agencies could materially adversely affect the Company's financial condition or results of operations if such changes negatively impacted our contract with BARDA. Furthermore, contracts with the U.S. government may be terminated or suspended by the U.S. government at any time, with or without cause. Such contract suspensions or terminations could result in expenses or charges not being reimbursed, or otherwise adversely affect the Company's financial condition and/or results of operations.

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

	Years Ended June 30,		
	2013	**2012**	**2011**
Royalty revenue – Relenza®	$ 2.6	$ 4.4	$ 6.6
– Inavir®	4.2	4.5	2.9
Commercial milestone – Inavir®	2.8	-	-
Revenue from services	24.0	11.5	3.0
Total revenue	$ 33.6	$ 20.4	$ 12.5

(15) Quarterly Financial Information (Unaudited)

The table below sets forth summary unaudited consolidated quarterly financial information for the years ended June 30, 2013 and 2012 (in millions):

	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) income	(6.5)	0.2	4.8	(7.2)
Net (loss) income per share (1):				
Basic	$ (0.23)	$ 0.01	$ 0.17	$ (0.32)
Diluted	$ (0.23)	$ 0.01	$ 0.17	$ (0.32)

	Quarter Ended			
	6/30/2012	**3/31/2012**	**12/31/2011**	**9/30/2011**
Revenues	$ 7.1	$ 7.1	$ 2.1	$ 4.1
Operating expenses	3.8	1.8	2.9	1.4
Net loss	(5.9)	(2.0)	(7.1)	(4.2)
Net loss per share (1):				
Basic	$ (0.26)	$ (0.09)	$ (0.31)	$ (0.18)
Diluted	$ (0.26)	$ (0.09)	$ (0.31)	$ (0.18)

(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.	X			
10.7	Form of Indemnification Agreement for Directors and Executive Officers		8-K	001-35285-13817036	05-06-13
10.8+	Amended and Restated Employment Agreement dated as of March 16, 2011, by and between Nabi Biopharmaceuticals and Raafat E.F. Fahim, Ph.D		8-K	000-04829-11704690	03/22/11
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
16.1	Letter from Ernst & Young dated December 10, 2012.		8-K	001-35285-121257087	12-11-12
21.1	List of Subsidiaries	X			
23.1	Consent of PricewaterhouseCoopers LLP.	X			
24.1	Power of Attorney (included on the signature page hereto).	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.INS**	XBRL Instance Document	X
101.SCH**	XBRL Taxonomy Extension Schema Document	X
101.CAL**	XBRL Taxonomy Calculation Document	X
101.DEF**	XBRL Taxonomy Definition Linkbase Document	X
101.LAB**	XBRL Taxonomy Label Linkbase Document	X
101.PRE**	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 quarterly report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of Biota Pharmaceuticals, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.
** Furnished, not filed.

COPY As executed 21/2/90. 383

DATED 1990

BIOTA SCIENTIFIC MANAGEMENT PTY. LTD.
("BSM")

BIOTA HOLDINGS LIMITED
("Biota")

GLAXO AUSTRALIA PTY. LTD.
("Glaxo Australia")

AND

GLAXO GROUP LIMITED
("GGL")

- RESEARCH AND LICENCE AGREEMENT -

MALLESONS STEPHEN JAQUES
Solicitors and Notaries
Rialto
525 Collins Street
MELBOURNE VIC 3000

Tel: 619 0619
Telex: AA30931
Fax: (03) 614 1329
Ref: WCB : AHD
WCB8847A

Entered DB 7/6/99.

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RESEARCH AND LICENCE AGREEMENT

THIS AGREEMENT is made on 1990.

BETWEEN :

BIOTA SCIENTIFIC MANAGEMENT PTY LTD a company incorporated in the State of Victoria and having its registered office at 525 Collins Street, Melbourne, Victoria, Australia ("**BSM**")

BIOTA HOLDINGS LIMITED a company incorporated in the State of Victoria and having its registered office at 525 Collins Street, Melbourne, Victoria, Australia ("**Biota**")

GLAXO AUSTRALIA PTY LTD a company incorporated in the State of Victoria and having its registered office at 1061 Mountain Highway, Boronia, Victoria, Australia ("**Glaxo Australia**")

AND **GLAXO GROUP LIMITED** a company incorporated in the United Kingdom and having its registered office at Clarges House, 6-12 Clarges Street, London, United Kingdom ("**GGL**")

RECITALS :

A. BSM has been endeavouring to develop a number of agents capable of inhibiting viral neuraminidase with the potential to be used in the control of human or animal viral disease states, specifically, as anti-influenza agents.

B. In March 1988 BSM disclosed information to GGRL pursuant to a confidentiality agreement for the purpose of enabling GGRL to assess the neuraminidase inhibitors and potential anti-viral agents being developed by BSM.

C. By a letter agreement dated 5 August 1988, BSM and GGRL agreed that BSM would co-operate with GGRL and that a research programme would be undertaken by GGRL to establish whether a blockade of influenza virus neuraminidase produces an observable anti-influenza effect in vivo.

D. The Heads of Agreement outlined proposed research collaboration between BSM and Glaxo Australia on the discovery, and ultimate exploitation, of Compounds.

E. After signature of the Heads of Agreement a patent specification was provided to Glaxo Australia, as a result of which a number of discussions took place which have ultimately lead to BSM continuing with a BSM Patent in the United States of America, filing a new BSM Patent in Australia and adopting an alternative Patent strategy.

F. This agreement is the formal written contract between BSM and Glaxo Australia which is to supercede and cancel the Heads of Agreement although it may not entirely reflect the Heads of Agreement having regard to the discussions which have subsequently taken place between BSM and Glaxo Australia.

G. In broad terms Glaxo Australia is to take over funding responsibility for the funding of research into Compounds and will have the ultimate responsiblity for the commercialisation of appropriate Compounds, which will give rise to a royalty stream in favour of BSM. In addition Glaxo Australia has agreed to pay to BSM a certain sum in respect of gaining access and rights to the existing Intellectual Property Rights and other information including in particular the Patent Specifications (collectively "the Core Technology"). Payment for such Core Technology however is to be made in staggered payments upon achievement of certain bench marks during the research development and clinical trial phases covered by this agreement.

H. Biota and GGL are parties to this agreement to give certain assurances that this agreement will be given effect.

OPERATIVE PROVISIONS :

1. PURPOSE AND INTERPRETATION

1.1. This agreement sets out the objectives of this agreement and the terms and conditions on which BSM and Glaxo Australia will collaborate on the design of the Compounds and the exploitation of Products arising from the Project.

1.2. The following words have these meanings in this agreement unless the contrary intention appears.

"A$" means Australian dollars or other lawful currency of Australia.

"Agreement Field" means the field of the identification, synthesis, evaluation and testing of Compounds prior to submission of Compounds for Exploratory Development Approval.

"approval" means formal approval without conditions or, if BSM and Glaxo Australia agree, formal approval upon conditions.

"Associated Research Expenditure" means the reasonable overseas expenses of BSM representatives and key researchers to visit and consult as required by Glaxo Australia with Glaxo Group advisers.

"Australia" means the Commonwealth of Australia, the States and Territories of Australia and any dependant territory from time to time.

"BSM Patents" means any Patents or Patent Applications now or hereafter granted to or made by BSM in respect of Compounds or Intellectual Property or their method of manufacture or use, or intermediates therefor, or formulations thereof, and any continuations, continuations in part, divisions, registrations, confirmations, re-issues, renewals or extensions of term thereof, details of which are set out in Parts A and B of schedule 1 or included or referred to in the BSM Patent Agenda.

"BSM Patent Agenda" means the patent agenda BSM proposes to adopt, details of which are set out in schedule 4.

"**Biota Group**" means Biota Holdings, BSM and their Related Corporations from time to time.

"**Budget**" means the budget for the Project determined by the Management Committee pursuant to clause 10.10.

"**cease**" in the context of Effective Patent Protection means insurmountable opposition, non-curtailed infringement, absolute revocation, invalidity, abandonment, irrevocable lapse or expiration. "Ceases and "ceased" shall have a corresponding meaning.

"**challenge**" means legal or other proceedings instituted to oppose or contest a Patent Application or revoke a Patent.

"**Commencement Date**" means the later of the date of this agreement and the date on which the conditions precedent set out in clause 2.1 are satisfied.

"**Commercialise**" means the exploitation or attempted exploitation with a view to financial gain or other commercial advantage.

"**Compounds**" means chemical compounds which act as or have the potential to act as inhibitors to block the active sites of influenza virus A and/or B neuraminidase being all chemical compounds which are:

(a) synthesised or produced in the course of the Project; or

(b) brought to the Project by BSM or Glaxo Australia either at the start of or during the course of the Project;

being chemical compounds having generally a molecular weight of less than 10,000 but does not include antibodies or antibody-like molecules, and includes any chemical compounds which may be the result of modifications or changes made to Compounds by any person during the Exploratory Development Phase or later and includes Start Compounds.

"**Confidential Information**" means all Intellectual Property and includes -

(a) any other information disclosed or communicated to any member of the Glaxo Group by or on behalf of BSM, including any disclosure by Dr P Colman, Dr M von Itzstein or Dr J Varghese or their associates or other employees of CSIRO, VCP or any other third party researcher, and

(b) any other information disclosed or communicated by or on behalf of any member of the Glaxo Group to BSM, CSIRO, VCP or any other third party researcher or the associates or employees of those entities,

either orally or in recorded form but does not include information which:

(i) at the time of first disclosure to a party is in the public domain;

(ii) after disclosure to a party becomes part of the public domain otherwise than as a result of the wrongful act of a party or one of that party's disclosees;

(iii) a party can show was in its possession at the time of first disclosure and was not acquired directly or indirectly from the other party; or

(iv) is received from a third party provided that it was not acquired directly or indirectly by that third party from a party to this agreement;

PROVIDED THAT the onus shall be on the party alleging the same to prove that one of the above exceptions has application.

"covered by" when used in the context that a Product, Compound, Process or Intellectual Property is covered by a Patent Claim means the said Product, Compound, Process or Intellectual Property or the method of manufacture or operation or use of such Product, Compound, Process or Intellectual Property would, when and where such Product, Compound, Process or Intellectual Property is sold or otherwise exploited by Glaxo Australia or its permitted sub-licensees, constitute (but for any licence which may be granted pursuant to this agreement) an infringement of a Subsisting Claim or a Pending Claim (where such Pending Claim is treated as if it were a Subsisting Claim).

"CSIRO" means the Commonwealth Scientific and Industrial Research Organisation.

"CSIRO Agreement" means an agreement to be negotiated between BSM and CSIRO.

"Diagnostic Application" means use in or in connection with diagnosing an ailment in humans or animals.

"Direct Research Expenditure" means Glaxo Australia's financial commitments to the Project as they arise during the Research Period and shall include :-

(a) any and all payments to VCP pursuant to the VCP Agreement save and except royalties;

(b) any and all payments to CSIRO pursuant to the CSIRO Agreement save and except royalties and any Agreement Fee (as that term is defined in the CSIRO Agreement) payable by BSM;

(c) all other outgoings in relation to the Project included in the Budget.

"**Effective Patent Protection**" means, in respect of a particular country, being covered by a Patent Claim or Patent Claims.

"**Exploitation Phase**" means, in relation to any Compound or Product, the period after completion of the Research Phase.

"**Exploratory Development**" means that programme of chemistry, toxicology formulation, pre-clinical trialling and general investigation leading to submission of an IND/CTX Application as a prelude to commencement of clinical trials in humans, to be carried out by Glaxo Australia or by a member of the Glaxo Group on behalf of Glaxo Australia, the structure of which and the criteria applied during which are set out in schedule 3.

"**Exploratory Development Approval**" means approval by the exploratory development committee of GGRL given after submission of a formal proposal by the Management Committee or Glaxo Australia in relation to a Compound.

"**Full Development Phase**" means, in relation to a Compound, the period after Exploratory Development Approval is given and ending at the time a Product Licence Application is made and includes the submission and approval of an IND/CTX Application at which stage clinical trials in humans can commence.

"**Future BSM Patents**" means any Patent Application made or Patent granted after the date of this agreement in addition to the BSM Patents in respect of Compounds, Processes or Intellectual Property or their method of manufacture or use, or intermediates therefor, or formulations thereof and any continuations, continuations in part, divisions, registrations, confirmations, re-issues, renewals or extensions of time thereof.

"**GGRL**" means Glaxo Group Research Limited of Greenford Road, Greenford, Middlesex, UB6 OHE, United Kingdom or such other address from time to time.

"**Glaxo Group**" means GGL, Glaxo Australia, GGRL and their Related Corporations from time to time.

"**Heads of Agreement**" means the heads of agreement dated 8 June 1989 entered into between BSM and Glaxo Australia.

"**Health Regulatory Body**" means any governmental body empowered by law to investigate and licence or grant marketing or clinical trials approval for any potential human therapeutic agent.

"**IND/CTX Application**" means an application to a Health Regulatory Body to commence human clinical trial studies on a Compound where "IND" means investigational new drug and "CTX" means clinical trial exemption.

"**IR & D Board**" means the Industry Research and Development Board established by the Industry Research and Development Act 1986 (Cth.).

"**Intellectual Property**" means information, know-how, trade secrets, ideas, concepts, inventions, processes, technology, knowledge, techniques, methods of use or application or other material of commercial value or potential commercial value arising from the Project related to or associated with Compounds, Processes or Serendipitous Discoveries but does not include any information, know-how, trade secrets, ideas, concepts, inventions, processes, technology, knowledge, techniques, methods of use or application or other material of commercial value and, in particular, Product Registration Data in relation to a Product, generated by Glaxo Australia or any member of the Glaxo Group independently of the Project during the Exploitation Phase.

"**Intellectual Property Rights**" means any rights arising or obtainable under laws relating to patents, trade marks, copyrights, confidential information, trade secrets or unfair competition whether known in any country or place under those names or other names and includes rights under the BSM Patents and Future BSM Patents.

"**Licence**" means the exclusive licence granted by BSM to Glaxo Australia to exploit pursuant to clause 6.1 and which may become non-exclusive pursuant to clause 6.2.

"**Major Market**" means any one of Canada, France, Germany, Italy, Japan, United Kingdom and the United States of America provided that a country shall cease to be a Major Market for the purposes of this definition if such country ceases to have a Product Licence Application system similar to the Product Licence Application system it presently has, being a system substantially similar to or generally based upon the Product Licence Application system of the Food and Drug Administration of the United States of America as at the date hereof.

"**Management Committee**" means the management committee established pursuant to clause 10.1.

"**Material Cost**" means the into store cost of a complete delivery system or the aggregate into store cost of its component parts as sourced from a third party or manufactured by Glaxo Australia or its permitted sub-licensee, but excluding any labour or overhead cost of Glaxo Australia or its permitted sub-licensee, respectively.

"**Net Proceeds of Exploitation**" means in the case of any lump sum, royalty or combined lump sum and royalty received or receivable by Glaxo Australia from the sub-licencing of any Intellectual Property or Intellectual Property Rights associated therewith to a third party, being a person who is not a member of the Glaxo Group, the net amount received from such third party after deducting all actual reasonable external expenses (as opposed to internal in house expenses of Glaxo Australia).

"**Net Sales Revenue**" means in respect of Products the gross price of Sales of Products invoiced to customers of a member of the Glaxo Group or any permitted sub-licensee, less -

(a) returned goods and any amount shown separately on invoices for transportation costs, trade and quantity discounts, sales, use or turnover tax or other government fees, taxes, import, export and excise duties and charges or impost; and

(b) where Products are sold in a Targeted Delivery System, the amount (if any) by which the Material Cost of such Targeted Delivery System is greater than US$1.00 indexed in accordance with clause 18 **PROVIDED THAT** where the Material Cost of the standard Targeted Delivery System or Targeted Delivery System used in the largest selling version of the Product in the United States market varies from US$1.00 indexed in accordance with clause 18 by more than 20%, the amount shall not exceed a sum agreed between the parties as properly reflecting the Material Cost of a then-current standard Targeted Delivery System,

PROVIDED THAT in respect of any Sale that is not at arm's length and for proper commercial consideration the gross price shall be deemed to be the price which would reasonably have been obtained in relation to the Sale if the Sale had been at arms-length and for proper commercial consideration.

"**New Zealand**" includes dependent territories of New Zealand.

"**Non-Therapeutic Application**" means any human application of a Compound which is not a Therapeutic Application and does not include a Veterinary Application.

"**Patent**" means a patent as defined in the Patents Act 1952 (Cth) and any national or regional patent within the terms of the Patent Co-operation Treaty and includes any re-issue, renewal or extension of a patent (whether in whole or in part) and any patent of addition or any substantially similar form of protection for inventions granted by any other country, the essence of which is a right in the holder of such form of protection to an exclusive right to make use and sell products or processes, the subject matter of the said invention.

"**Patent Agenda**" means the agendas for the BSM Patents set out in schedule 4.

"**Patent Application**" means any patent application as defined in the Patents Act 1952 (Cth) and any national, regional or international application within the terms of the Patent Co-operation Treaty and includes any continuation, continuation in part, division, re-issue or substitution of a patent application or application for any substantially similar form of protection for inventions granted by any other country, the essence of which is a right in the holder of such form of protection to an exclusive right to make use and sell products or processes, the subject matter of the said invention..

"**Patent Claim**" means and is limited to a Subsisting Claim or a Pending Claim.

"**Patent Specifications**" means the specifications for the BSM Patents or Future BSM Patents as the case may be.

"**Pending Claim**" means any claim asserted in an application forming part of a BSM Patent or Future BSM Patent or in the Patent Specifications.

"**Pharmaceutical Competitor**" means any entity or authority either currently holding or making application for a product licence to sell prescription or over the counter pharmaceuticals.

"**Process**" means any process disclosed in the Confidential Information and any process or method of application or use arising from, or invented, discovered, developed or acquired in the course of, the Project.

"**Product**" means:

(a) a pharmaceutical product having as one of or as its sole active ingredient a Compound; or

(b) a substance being or comprising a Compound to be used in a pharmaceutical product.

"**Product Licence Application**" means an application to a Health Regulatory Body to commence general marketing of any Product.

"**Product Registration Data**" means any data or information submitted to a Health Regulatory Body in support of a Product Licence Application including any information which relates to research, development, pre-clinical studies or clinical studies of Products (including any analysis interpretation or summaries thereof).

"**Project**" means the research project within the Agreement Field to be carried out being generally a project directed at the Rational Design, rational (as opposed to random) identification and/or synthesis of compounds designed to be complementary to the catalytic sites of influenza virus A and/or B neuraminidase and which will act or have the potential to act as inhibitors of influenza virus A and/or B neuraminidase (examples of such compounds being set out in the Patent Specifications for the BSM Patents) involving amongst other things the design formulation and testing for effectiveness of various compounds in the light of knowledge of the crystalline structure of neuraminidase and the effectiveness or ineffectiveness of inhibitors already generated in the course of the Project or produced prior to its commencement pursuant to the CSIRO Agreement, the VCP Agreement or any third party research agreement or brought to the Project by or on behalf of BSM or by or on behalf of Glaxo Australia as a Start Compound.

"**Rational Design**" means the creation, identification and/or structural modification of a chemical compound based on the co-ordinates of the active site of influenza virus A and/or B neuraminidase and from relevant structure-activity relationships.

"**Related Corporation**" has the same meaning given to it in section 7(5) of the Companies (Victoria) Code.

"Research Period" means the period of the Project referred to in clause 4.8 and any extension thereof pursuant to clause 4.9.

"Research Phase" in relation to any Compound means the period between the Commencement Date and the date when Exploratory Development Approval is given.

"Sale" means the last sale by Glaxo Australia or a permitted sub-licensee of Glaxo Australia.

"Serendipitous Discovery" means a potentially commercially valuable discovery, invention or development arising from, or made or invented in the course of, the Project or such a discovery in respect of a Compound made by a member of the Glaxo Group at any time before Exploratory Development is completed in respect of that Compound not -

(a) having a use or potential use to act as an inhibitor of influenza virus A and/or B neruaminidase,

(b) being a Therapeutic Application, Non- Therapeutic Application or Veterinary Application of a Compound,

(c) being a Process used in the manufacture or production of a Compound in so far as that Process is used in the manufacture or production of a Compound, and/or

(d) within the ambit of the Project or general objectives of this agreement.

"Start Compound" means a chemical compound having generally a molecular weight of less than 10,000 but does not include anti-bodies or antibody like molecules, which compound has or is identified as having the potential to have an inhibitory effect to block the active sites of influenza virus A and/or B neuraminidase.

"Subsisting Claim" means any claim of a validly issued Patent being a BSM Patent or Future BSM Patent which has not ceased.

"Targeted Delivery System" means a metered dose delivery system targeted on a particular organ or organs or targeted on a particular form of treatment or method of application.

"Territories" means Australia, New Zealand, Indonesia and such countries in Africa as may be agreed by Glaxo Australia and BSM in writing from time to time.

"Therapeutic Application" means use in or in connection with -

(a) the identifying, preventing, curing or alleviating of an ailment in humans, or

(b) the influencing, inhibiting or modifying of a physiological process in humans.

and includes a Diagnostic Application but not a Veterinary Application.

"**VCP**" means the Victorian College of Pharmacy.

"**VCP Agreement**" means the agreement dated 10 October 1989 between BSM and VCP.

"**Veterinary Application**" means use in or in connection with animals other than humans.

"**writing**" includes typewriting, printing, lithography, photography and other modes of representing or reproducing words in a visible form and "written" has a corresponding meaning.

1.3. Words importing the singular include the plural and vice versa and words importing the masculine include the feminine and neuter.

1.4. A reference to any Act of Parliament or section thereof or schedule thereto shall be read as if the words "or any statutory modification or re-enactment thereof or substitution therefor" were added to the reference.

1.5. Where a word or phrase is given a particular meaning, other parts of speech and grammatical forms that word or phrase have corresponding meanings.

1.6. Person and words importing persons include bodies corporate.

1.7. Each party includes its successors and permitted assigns.

1.8. Any marginal notes or headings are included for convenience and do not affect the interpretation of this agreement.

1.9. An agreement, representation or covenant on the part of or in favour of two or more persons in this agreement binds or is for the benefit of them jointly and severally.

1.10. If any day appointed or specified by this agreement for the payment of any money falls on a Saturday, Sunday or a day appointed under the Bank Holidays Act 1958 as a holiday for the whole day the day so appointed or specified shall be deemed to be the day after the day so appointed or specified which is not in turn a Saturday, Sunday or day so appointed as a holiday for the whole day.

1.11. A reference to any agreement, document or instrument includes that agreement, document or instrument as amended, varied, supplemented or novated from time to time.

2. CONDITIONS PRECEDENT

2.1. Clauses 3 (other than clause 3.1), 4 (other than clauses 4.4(a) and 4.6), 5, 6, 7, 8, 9, 10, 11.6-11.9 (inclusive), 12 (other than clause 12.14) 13, 14, 15, 16, 17, 18 and 20 of this agreement shall be conditional upon and shall not come into operation until the satisfaction of all of the following conditions precedent:

(a) BSM procures that the CSIRO Agreement covers any safeguards identified, acceptable and formally agreed to by BSM, CSIRO and Glaxo Australia; and

(b) BSM procures the amendment of the VCP Agreement to cover any additional safeguards identified, acceptable and formally agreed to by BSM, VCP and Glaxo Australia.

2.2. If the conditions precedent referred to in clause 2.1 are not satisfied by 30 March 1990 or such later date as the parties mutually agree then, subject to clauses 2.3, 2.4 and 11.10, this agreement shall forthwith cease and determine.

2.3. If this agreement ceases and determines in accordance with clause 2.2, the parties shall have no claim against each other with respect to any matter or thing arising out of, done or omitted to be done or performed under this agreement.

2.4. If this agreement ceases and determines in accordance with clause 2.2, BSM shall withdraw its application for the BSM Patent set out in Part B of schedule 1.

2.5. The parties agree to use their best endeavours to do and cause to be done all acts, matters and things reasonably required and within their respective powers to cause the conditions precedent to be satisfied in accordance with this clause.

2.6. Each condition precedent referred to in clause 2.1 may be waived in whole or in part by mutual agreement between the parties or, where only one party is concerned, by that party.

2.7. BSM or Glaxo Australia, as appropriate, shall give written notice to the other on the satisfaction of the conditions precedent set out in clause 2.1.

3. OBJECTIVES AND BEST ENDEAVOURS

3.1. The objective of this agreement is to develop influenza inhibitors by the use of Rational Design for the creation, identification and/or synthesis of Compounds which are designed to be complementary to the catalytic sites of influenza virus A and/or B neuraminidase, which Compounds are to be protected by at least a specific Patent or Patents. To this end the parties have agreed to:

(a) establish a collaborative research programme for the development of Compounds;

(b) ensure that sufficient funds and other resources are available to properly carry out the Project and to fully exercise the Licence;

(c) ensure that the Biota Group and the Glaxo Group bring all their accumulated knowledge and expertise relevant to or associated with the Project to the Project to the full extent they are able to do so;

(d) set the framework for world-wide exploitation of Compounds and Products to the mutual benefit of BSM and Glaxo Australia; and

(e) ensure that the results of the Project are protected by way of Patent or other legal protection in all parts of the world where such protection is available or commercially prudent and to ensure that information not otherwise legally protected is kept confidential to the fullest extent possible.

3.2. The general objectives of the Research Phase are to:

(a) ensure sufficient funds and other resources are provided to permit appropriately resourced research to be undertaken into the identification and development of Compounds;

(b) obtain appropriately qualified research personnel and appropriately resourced research facilities through sub-contracted researchers or otherwise as BSM and Glaxo Australia determine to be most appropriate from time to time;

(c) develop future generations of Compounds for as long as is commercially feasible and prudent; and

(d) create the widest possible patent coverage for Compounds.

3.3. The general objective of the Full Development Phase is to ensure that Exploratory Development is undertaken in a timely and efficient manner to test and evaluate any Compound to a stage where an IND/CTX Application can be made and approved.

3.4. The general objective of the Exploitation Phase is to generate profitable sales of Products through advertising and promotion in all economically practicable markets.

3.5. BSM and Glaxo Australia will each use their best endeavours to implement, carry out and undertake the Project, the Research Phase, the Exploratory Development Phase and the Exploitation Phase insofar as is reasonably within their respective capabilities and otherwise in accordance with this agreement.

3.6. Without limiting the generality of clause 3.5, BSM shall use its best endeavours to:

(a) ensure that the CSIRO and the VCP carry out, perform and observe their obligations and liabilities pursuant to the CSIRO Agreement and the VCP Agreement, respectively, and that any other third party research organisation or person carries out performs and observes its obligations and liabilities pursuant to any agreement between BSM and that third party;

(b) bring to the Project all its accumulated knowledge and expertise in relation to or connected with existing Compounds and the Agreement Field generally to the full extent BSM is able to do so;

(c) subject to any necessary disclosures for the purposes of Patents or Patent Applications, ensure that Confidential Information remains confidential to the fullest extent possible and to procure that all its sub-contractors do the same;

(d) prosecute and maintain the BSM Patents in accordance with the Patent Agenda in the commercial interests of the parties;

(e) at all times provide suitable and adequately qualified representatives to sit on the Management Committee; and

(f) disclose to Glaxo Australia all the Intellectual Property necessary or desirable for the purposes of the Project.

3.7. Without limiting the generality of clause 3.5, Glaxo Australia shall use its best endeavours to:

(a) bring, and to procure that the other members of the Glaxo Group provide, to the Project all its and their accumulated knowledge and expertise in relation to or connected with the Project to the full extent it and they are able to do so;

(b) disclose, and to procure that the other members of the Glaxo Group disclose, to BSM for the purposes of the Project all information and research data and results in relation to or connected with the Project to the full extent it and they are able to do so;

(c) procure that no other member of the Glaxo Group undertakes research in relation to or connected with the inhibition of influenza virus A and/or B neuraminidase using an approach the same as or similar to the Project during the Research Period;

(d) bring, and to procure that the other members of the Glaxo Group bring, to the Exploratory Development Phase and the Exploitation Phase all its and their accumulated knowledge and expertise in relation to or connected with Exploratory Development, IND/CTX Applications, Product Licence Applications, obtaining Health Regulatory body approvals, formulating packaging distributing and promoting pharmaceutical products and within the Agreement Field generally to the full extent it and they are able to do so;

(e) subject to any necessary disclosures for the purposes of Patents or Patent Applications ensure that Confidential Information remains confidential to the fullest extent possible and to procure that all other members of the Glaxo Group, permitted sub-licencees and sub-contractors do the same;

(f) prosecute and maintain Future BSM Patents in accordance with the commercial interests of the parties;

(g) at all times provide suitable and adequately qualified representatives to sit on the Management Committee;

(h) ensure that the Full Development Phase in relation to a Compound is carried out in a timely and diligent manner;

(i) apply for and prosecute all appropriate IND/CTX Applications, Product Licence Applications and Health Regulatory Body approvals in a timely and diligent manner;

(j) where appropriate undertake a clinical trials programme in a timely and diligent manner in respect of a relevant Compound or Product so that a Product Licence Application can be made and obtained in respect of the relevant Product;

(k) advertise and promote Products pursuant to the Licence on a proper commercial basis;

(l) give due consideration to the objectives of this agreement and the interests of BSM in determining whether or not to take proceedings to defend any challenge or curtail any infringement of BSM Patents, Future BSM Patents, Intellectual Property Rights or any part thereof pursuant to clause 12.13;

(m) keep BSM reasonably informed of the results of Exploratory Development, the course of a Compound through the Full Development Phase, IND/CTX Applications, Product Licence Applications and Health Regulatory Body approvals; and

(n) keep BSM reasonably informed at a general as opposed to a detailed scientific level of all research or development activities carried out by any member of the Glaxo Group in relation to neuraminidase generally but which research falls outside the Project including, but not limited to, research in relation to or connected with the inhibition of influenza virus A and/or B neuraminidase using an approach which is not the same as or similar to the approach of the Project.

3.8. **Commercial exploitation of results of the Project**

3.8.1. Glaxo Australia undertakes to exploit the results of the Project on normal commercial terms and in a manner that will be for the benefit of the Australian economy, such exploitation to be carried out within a reasonable period of the completion of the Project giving due consideration to the guidelines of the IR & D Board.

3.8.2. Provided it is scientifically and economically reasonable to do so, Glaxo Australia undertakes to carry out Product development work using Australian resources, including where appropriate, product formulation, design of production synthesizing routes, establishment of a pilot plant and clinical trials and with the continued support of BSM, CSIRO and VCP such additional compound design and synthesis as may be required to support a continuing compound development and back up programme.

3.8.3. Provided it is scientifically and economically reasonable to do so, Glaxo Australia will undertake in Australia manufacture of the active ingredient for its Australian serviced markets and for those markets in which BSM exercises its entitlement to distribute and sell a Product.

Glaxo Australia will undertake formulation of finished product in Australia for its Australian serviced markets and for those markets in which BSM exercises its entitlement to distribute and sell a Product.

Glaxo Australia undertakes to liaise with the IR & D Board, CSIRO and the Department of Industry, Technology and Commerce on final production arrangements consistent with Glaxo Australia's present commitments to the Australian Government in terms of the Pharmaceutical Industry Development Programme.

3.8.4. Glaxo Australia and BSM undertake to keep the IR & D Board and the CSIRO promptly informed of achievements of milestone objectives.

3.8.5. The rights and obligations contained in this clause shall survive the completion of the Project or termination of any IR & D Board grants or tax concessions.

3.9. **Start Compounds**

If during the Research Phase Glaxo Australia either directly or through one of the members of the Glaxo Group discovers or gains access to a Start Compound and desires to bring that Start Compound to the Project then Glaxo Australia shall bring that Start Compound to the Project whereupon it shall be treated as a Compound for all purposes provided that:

(a) where the Start Compound is offered to be made available by a third party (other than another member of the Glaxo Group) then Glaxo Australia shall not be obliged to licence in such Start Compound but shall make the availability of that Start Compound known to BSM, and BSM and Glaxo Australia shall negotiate in good faith as to what should be done with the Start Compound being offered;

(b) the obligation to bring a Start Compound to the Project shall not apply where the Start Compound is independently developed or discovered by Glaxo Australia or another member of the Glaxo Group and such Start Compound has an inhibitory effect sufficient to justify its submission for Exploratory Development Approval then such Start Compound shall not be property of the Project and the whole of the right title and interest therein shall belong to Glaxo **PROVIDED THAT** such Start Compound is not developed or discovered using, or in any way based on or arising from access to, Intellectual Property or Confidential Information; and

(c) where any Start Compound brought to the Project by Glaxo Australia is the subject of a Patent or Intellectual Property Rights owned by or licensed to a member of the Glaxo Group, the submission of that Start Compound shall not preclude or curtail the right of the Glaxo Group to exploit such Start Compound for uses other than influenza virus A and/or B neuraminidase inhibitors and to the extent that BSM can have rights in relation to that Start Compound and Compounds derived from that Start Compound by virtue of or in the course of the Project which are the same as per normal Compounds under this agreement, BSM shall have such rights, provided such rights do not otherwise derogate from the rights reserved to the relevant member of the Glaxo Group pursuant to this clause.

4. RESEARCH PHASE

Research Expenditure

4.1. Glaxo Australia shall assume and pay the Associated Research Expenditure and the Direct Research Expenditure during the course of Project.

To the extent that Biota or BSM has paid funds in the nature of Associated Research Expenditure prior to the Commencement Date, Glaxo Australia shall within 7 days after the Commencement Date reimburse Biota or BSM (as the case may be) for the funds so paid after 5 September 1989.

To the extent that Biota or BSM has paid funds in the nature of Direct Research Expenditure prior to Commencement Date, Glaxo Australia shall within 7 days after the Commencement Date reimburse Biota or BSM (as the case may be) for the funds so paid after 8 June 1989.

On or prior to the Commencement Date, BSM shall provide to Glaxo Australia a full accounting in respect of funds paid prior to the Commencement Date reconciled to the budget, it being acknowledged that Glaxo Australia's obligation to make payment pursuant to this clause shall only extend to amounts properly paid in respect of budgeted items.

4.2. Glaxo Australia acknowledges that the budgetted Direct Research Expenditure will not be less than A$750,000 annually and that research will be stepped up so that Direct Research Expenditure will not be less than A$1,000,000 annually **PROVIDED THAT** nothing in this clause will oblige Glaxo Australia to pay A$750,000, or A$1,000,000 annually unless Direct Research Expenditure at least equals those sums in any year.

4.3. Unless otherwise agreed in writing by BSM and Glaxo Australia, Glaxo Australia shall pay direct to BSM or as BSM reasonably directs in writing any amounts required to be paid in respect of Associated Research Expenditure provided that Glaxo Australia shall not be obliged to make payment in any foreign currency. In respect of Direct Research Expenditure Glaxo Australia will assume direct funding responsibility in respect of payments required to be made pursuant to the CSIRO Agreement, the VCP Agreement or any other third party research agreement and shall pay such liabilities in accordance with the terms of those agreements.

BSM fee

4.4. In addition to the Direct Research Expenditure and Associated Research Expenditure Glaxo Australia shall pay to BSM an annual fee in respect of research and development activities carried on by officers or staff of BSM and in respect of scientific facilities and staff provided to Glaxo Australia for the purpose of conduct of research and development activities as contemplated herein. The amount of the annual fee shall be:

(a) A$300,000 for the first year of the Research Period ("first fee");

(b) A$300,000 indexed in accordance with clause 18 for the second year of the Research Period;

(c) **A$**300,000 indexed in accordance with clause 18 for the third year (if any) of the Research Period; and

(d) **A$**200,000 indexed in accordance with clause 18 for the fourth year (if any) of the Research Period; and

(e) for any year of the Research Period subsequent to the fourth year, such fee as is agreed by the parties to reflect the ongoing importance and worth of scientific consultation and the status of scientific personnel provided by BSM and engaged in the Project.

4.5. The first fee shall be paid at the times set out in clause 4.6 and shall be non-refundable. Subsequent fees shall be paid in advance on the anniversary of the Commencement Date during the Research Period and shall be non-refundable.

4.6. The first fee shall be paid by Glaxo Australia to BSM as follows:

(a) A$30,000 on the signing of the Heads of Agreement (receipt of which is acknowledged by BSM); and

(b) the balance of the first fee on the Commencement Date.

4.7. In addition to the first fee, Glaxo Australia shall on the Commencement Date pay to BSM an amount being a pro rata fee from 11 September 1989 to the Commencement Date calculated at the rate of A$300,000 per annum.

Research Period

4.8. The term of the Project shall be 2 years commencing on the Commencement Date ("initial term").

4.9. The Research Period will be extended indefinitely for further terms of 1 year each ("subsequent terms") unless Glaxo Australia gives 6 months notice in writing to BSM of its intention to terminate the Research Period.

4.10. Glaxo Australia shall not give notice in accordance with clause 4.9 until 18 months have elapsed since the Commencement Date.

5. EXPLORATORY DEVELOPMENT PHASE

5.1. Upon the first giving of Exploratory Development Approval for a Compound, Glaxo Australia shall pay to BSM A$1,000,000, indexed in accordance with clause 18, within 14 days after the giving of that approval.

5.2. Subject to payment of the sum referred to in clause 5.1, Glaxo Australia shall undertake or shall cause Exploratory Development to be undertaken in respect of the relevant Compound. It is acknowledged by BSM and Glaxo Australia that it is highly likely that additional Compounds will be discovered in the course of the Project after Exploratory Development Approval is given for a Compound, and that it is intended that such additional Compounds may also be subject to submission for Exploratory Development Approval and may be so approved. No sum will be payable by Glaxo Australia to BSM in respect of the giving of

Exploratory Development Approvals other than in respect of the first Exploratory Development Approval for a Compound.

5.3. Exploratory Development shall be carried out by Glaxo Australia or on behalf of Glaxo Australia in accordance with schedule 3.

IND/CTX Application

5.4. Upon first approval by the Health Regulatory Body in the United States of America of an IND/CTX Application made by a member of the Glaxo Group or any permitted sub-licensee in respect of a Compound, Glaxo Australia shall pay to BSM **A$**2,000,000, indexed in accordance with clause 18, within 14 days after the giving of that approval.

5.5. Upon each first approval by the Health Regulatory Body in the United States of America of an IND/CTX Application made by a member of the Glaxo Group or any permitted sub-licensee in respect of subsequent Compounds, Glaxo Australia shall pay to BSM **A$**3,000,000, indexed in accordance with clause 18, within 14 days after the giving of that approval.

Product Licence Application

5.6. Upon approval by the Health Regulatory Body in the United States of America of a Product Licence Application made by a member of the Glaxo Group or any permitted sub-licensee in respect of any Product, Glaxo Australia shall pay to BSM **A$**3,000,000, indexed in accordance with clause 18, within 14 days after the giving of that approval.

5.7. Notwithstanding that a Compound proceeds to the Exploitation Phase, the parties acknowledge that the Project will continue in order to achieve the objectives hereunder in accordance with this agreement.

5.8. Notwithstanding clauses 5.4, 5.5 and 5.6, if Glaxo Australia, the Glaxo Group or permitted sub-licensees together -

(a) obtain first approval of an IND/CTX Application by a Health Regulatory Body in 4 Major Markets (including Japan but not the United States of America) for a Compound,

(b) obtain first approval of an IND/CTX Application by a Health Regulatory Body in 4 Major Markets (including Japan but not the United States of America) for a subsequent Compound, or

(c) obtain approval of a Product Licence Application by a Health Regulatory Body in 4 Major Markets (including Japan but not the United States of America) for a Product,

and the same approvals are not obtained from the Health Regulatory Body in the United States of America within 12 months from the last date of approval in the 4 relevant Major Markets (including Japan but not the United States of America), the amounts payable to BSM under clauses 5.4, 5.5 and 5.6 shall be paid to BSM on the expiration of the 12 month period referred to in this clause.

5.9. The payments to be made by Glaxo Australia under this clause 5 shall only be payable once in respect of a particular Compound that has received Exploratory Development Approval.

6. EXPLOITATION PHASE

6.1. Subject to this agreement and to Glaxo Australia complying with its obligations under this agreement and for the purposes of obtaining and furthering the general objectives as set out in clause 3 and as otherwise contemplated by this agreement, Glaxo Australia shall, on and from the Commencement Date, have an exclusive right and licence (including the right to sub-licence in accordance with the terms of clause 9) in each country of the world to -

(a) make use, exercise or sell Compounds, and

(b) exploit and exercise the Intellectual Property and Intellectual Property Rights associated therewith arising from or discovered, developed, invented or acquired during the course of the Project,

but not otherwise subject to the rights granted to BSM pursuant to clause 8.

6.2. The Licence and any relevant permitted sub-licence shall become non-exclusive in any country and in relation to any Intellectual Property or Intellectual Property Right associated therewith when royalties cease to be payable in respect of that Intellectual Property or Intellectual Property Right pursuant to this agreement.

Term of Licence

6.3. Unless terminated pursuant to clause 13 the Licence, whether exclusive in accordance with clause 6.1 or non-exclusive pursuant to clause 6.2 or limited pursuant to clause 13.1A, shall continue indefinitely.

7. ROYALTIES

7.1. Subject to clause 7.3, Glaxo Australia shall pay to BSM a royalty equal to:

(a) 7 per cent of total Net Sales Revenue earned on Sales of Products for Therapeutic Applications;

(b) 7 per cent or such other percentage rate as BSM and Glaxo Australia in good faith agree to be reasonable in respect of total Net Sales Revenue earned on Sales of Products for Non-Therapeutic Applications;

(c) such percentage rate as BSM and Glaxo Australia in good faith agree to be reasonable in respect of total Net Sales Revenue earned on Sales of Products for Veterinary Applications;

(d) in the case of Commercialisation of any Intellectual Property (other than Serendipitous Discoveries) or Intellectual Property Rights associated therewith and not being Sales of Products for Therapeutic Applications, Non-Therapeutic Applications or Veterinary Applications -

(i) 7 per cent or such other percentage rate as BSM and Glaxo Australia in good faith agree to be reasonable in respect of Net Sales Revenue earned on Sales of products treating those products as Products within the definition of Net Sales Revenue, or

(ii) where the Commercialisation is by way of sub-licence to a third party other than a member of the Glaxo Group, 50% of the Net Proceeds of Exploitation received by Glaxo Australia from such third party.

(e) in the case of Commercialisation of a Serendipitous Discovery -

(i) 7 percent or such other rate as BSM and Glaxo Australia in good faith agree to be reasonable in respect of the Net Sales Revenue earned on Sales of products treating those products as Products within the definition of Net Sales Revenue, or

(ii) where the Commercialisation is by way of sub-licence to a third party other than a member of the Glaxo Group, 50% of the Net Proceeds of Exploitation received by Glaxo Australia from such third party.

7.2. If Effective Patent Protection for a Product or Compound is never obtained in a country for the reason that such country does not recognise patent rights or the patent regime or system which does exist is not, in the opinion of BSM and Glaxo Australia, commercially acceptable, no royalty shall be payable in respect of Products sold in such country when -

(a) 15 years has elapsed since the priority date of the Patent Application in relation to that Product or Compound (as the case may be) in the United States of America, or

(b) Effective Patent Protection for the Product or Compound (as the case may be) in the United States of America ceases,

whichever is the earlier.

7.3. Subject to clause 7.3A, if Effective Patent Protection for a Product or Compound ceases in a country then thereafter no royalty shall be payable in respect of that Product or Compound (as the case may be) PROVIDED THAT:

(a) this clause shall only apply to extinguish the royalty payable in respect of the Product or Compound (as the case may be) in the country or countries in which Effective Patent Protection for that Product or Compound (as the case may be) has ceased; and

(b) this clause shall not apply to royalties payable pursuant to clause 7.1(e), which royalties are payable whether or not Effective Patent Protection is ever obtained or ceases in relation to the Serendipitous Discovery referred to in clause 7.1(e).

7.3A. Where -

(a) a Process is the subject of a Future BSM Patent and that Process is used in the manufacture of a Compound in a Product that has received a Product Licence Application approval, and

(b) save for such Process, Effective Patent Protection for that Compound would have ceased,

a 7 per cent royalty shall continue to be payable in respect of that approved Product in accordance with clause 7.1 until the earlier of:

(c) the Process not being covered by a Patent Claim or Patent Claims; or

(d) a product which is directly competitive with the approved Product and is manufactured by a process different to the Process becomes available;

PROVIDED THAT:

(i) the 7 per cent royalty will only cease to be payable in respect of the approved Product in the country or countries in which that Process is not covered by a Patent Claim or Patent Claims or in which a competitive product becomes available (whichever first occurs);

(ii) if the 7 per cent royalty ceases to be payable because of the circumstances set out in clause 7.3A(d), Glaxo Australia shall continue to pay a royalty to BSM at such percentage rate as BSM and Glaxo Australia agree in good faith to be reasonable so long as that Process is covered by a Patent Claim or Patent Claims;

(iii) if BSM and Glaxo Australia cannot agree on a royalty rate pursuant to the preceding paragraph, Glaxo Australia's licence in respect of that Process shall cease and BSM shall be entitled to use and exploit or licence third parties to use and exploit that Process subject to that Process not being offered to a third party on terms more favourable then those BSM offers to Glaxo Australia;

(iv) so long as royalties are payable to BSM in respect of the Process, Glaxo Australia's licence in respect of that Process shall remain exclusive; and

(v) nothing in this agreement is to be construed as obliging Glaxo Australia to use any Process in the manufacture or production of Products.

7.4. The royalties set out in clauses 7.1 and 7.3A shall, subject to clause 7.5, be paid 6 monthly in arrears such 6 month periods to end on 30 June and 31 December respectively in any year. Glaxo Australia shall within 60 days of the end of each 6 month period make written reports to BSM setting out:

(a) the total Net Sales Revenue earned from all Products which have been sold by Glaxo Australia or its permitted sub-licensees during the preceding 6 months;

(b) the total Net Proceeds of Exploitation received by Glaxo Australia or its permitted sub-licensees during the preceding 6 months;

(c) the basis for calculation of royalties; and

(d) the royalty payable;

together with payment of the royalty for that period.

7.5. On the date being 6 months after the date of first Sale of a Product in the United States of America, Glaxo Australia shall pay to BSM A$4,000,000 indexed in accordance with clause 18 on account of cumulative and prospective royalties payable on all Sales of the Product ("advance royalty"). The advance royalty shall not be refundable. Once the accrued royalties equal the advance royalty, Glaxo Australia shall make payments in accordance with this clause 7.

The advance royalty shall only be payable once in respect of a particular Compound that has received Exploratory Development Approval.

7.6. All royalty payments contemplated by this agreement must be free from any deductions and must be made in Australian dollars. Where calculation of royalty requires the conversion of foreign currency to Australian dollars, conversion shall be at the exchange rate of the relevant country's currency to Australian dollars published by National Australia Bank Limited in Melbourne on the last day of the period to which the royalty payment relates.

The parties may agree from time to time to vary the mode and manner of payment of royalties.

7.7. All royalty payments must be paid to BSM at such place or places in Australia as BSM directs in writing.

7.8. It is hereby acknowledged and agreed that notwithstanding that a Product may be covered by one or more Patents or Patent Applications only one royalty shall be paid on a Sale of that Product.

8. BSM MARKETING

8.1. Notwithstanding the Licence, BSM or a Related Corporation of BSM nominated by BSM shall be entitled at any time to distribute and sell a Product under its own trade mark or brand name in any one or more countries in the Territories upon giving written notice to Glaxo Australia. The notice shall specify the country or countries in which BSM decides to distribute and sell and specify the particular Product.

BSM shall use, and shall procure that its nominated Related Corporation uses, best endeavours to:

(a) use the Product supplied under this clause 8 by Glaxo Australia for its intended purposes; and

(b) ensure that sales of Product supplied by Glaxo Australia under this clause 8 are to customers within the specified country or countries and shall not be exported from that country or those countries.

8.2. BSM shall when giving notice under clause 8.1 inform Glaxo Australia of the ex factory price necessary to enable it to obtain a 50% gross profit margin based on Australian selling price to wholesalers and recognising that Product supplied by Glaxo Australia to BSM pursuant to this clause will be supplied FOB Glaxo Australia's premises at Boronia.

8.3. Glaxo Australia shall thereafter supply such Product to BSM or its nominated Related Corporation at the greater of:

(a) the price specified in clause 8.2; and

(b) 115% of the actual cost to Glaxo Australia of supplying the specified Product as required by BSM or its nominated Related Corporation, including the cost of labour, materials and chemicals used in that Product and a reasonable allowance for overheads.

8.4. In the event of co-marketing under this clause 8, BSM shall be responsible for bearing the costs of obtaining any and all relevant marketing approvals or licences, the costs incurred in respect of BSM's artwork and packaging materials required for the packaging of the Product under BSM's own trademark or brand name and any additional costs incurred on an ongoing basis in respect of the marketing or packaging of BSM product. An appropriate allowance shall be made for such additional costs in the ex-factory price to BSM.

Glaxo Australia shall provide, or shall procure, the provision of reasonable information (including Product Registration Data) and assistance to BSM or its nominated Related Corporation to obtain or procure all statutory, regulatory, administrative or government approvals, consents or registrations (including any Health Regulatory Body approvals or registrations and Product Licence Application approvals) required by law to be obtained in connection with the use and sale of the specified Products in the nominated country or countries and otherwise to enable BSM or its nominated Related Corporation to exercise the co-marketing rights granted under this clause 8.

8.5. Any Product supplied by Glaxo Australia to BSM or its nominated Related Corporation pursuant to clause 8.2 shall not be included in the calculation of royalties payable by Glaxo Australia pursuant to clause 7.

8.6. If the Licence becomes non-exclusive in respect of Intellectual Property or Intellectual Property Rights associated therewith pursuant to clause 6.2, BSM may itself or through a third party licensee exploit that Intellectual Property and the Intellectual Property Rights associated therewith including, but not limited to -

(a) manufacturing, distributing and selling Products, or

(b) granting a non-exclusive right and licence to manufacture, distribute and sell Products,

under BSM's or its licensee's trade mark or brand name in the country or countries in respect of which the Licence has become non-exclusive.

8.6A If the Licence becomes limited pursuant to clause 13.1A, BSM may itself or through a third party licensee exploit Intellectual Property and the Intellectual Property Rights associated therewith not covered by the limited Licence.

8.7. BSM may, to the extent reasonably necessary, disclose Confidential Information to any licensee to enable BSM and that licensee to exercise the rights and licences granted under clauses 8.6 and 8.6A **PROVIDED THAT** the licensee first undertakes in writing to keep disclosed Confidential Information confidential in a similar manner to that imposed on Glaxo Australia under clause 11 of this agreement.

Pharmaceutical Competitor

8.8. If BSM becomes a Related Corporation to a Pharmaceutical Competitor, Glaxo Australia may give to BSM a notice under this clause 8.8 ("election notice"). The election notice shall provide that Glaxo Australia desires to terminate the rights given to BSM or its nominated Related Corporation under this clause 8 ("rights").

BSM shall, within 60 days of becoming aware that it has become a Related Corporation to a Pharmaceutical Competitor, give notice of that fact to Glaxo Australia.

Upon receipt of the election notice, BSM and Glaxo Australia shall meet and discuss in good faith the terms and conditions (including compensation to BSM for the loss of rights) upon which the rights will terminate. If BSM and Glaxo Australia cannot agree on the terms and conditions within 60 days after service of the election notice, the rights shall continue in full force and effect.

If Glaxo Australia does not give the election notice within 60 days after becoming aware that BSM has become a Related Corporation of a Pharmaceutical Competitor, Glaxo Australia's right to give the election notice shall lapse and the rights shall continue.

9. SUB-LICENCES

9.1. BSM recognises that Glaxo Australia will find it desirable to sub-license the Licence to a Related Corporation or Related Corporations in a particular country or group of countries in respect of one or more Products. Glaxo Australia recognises that any such sub-licence would of necessity require similar obligations to be imposed on any sub-licensee as those imposed on Glaxo Australia under this agreement to preserve and protect BSM's rights.

9.2. Glaxo Australia shall have the right to grant sub-licences to a Related Corporation in respect of a particular country or group of countries in respect of one or more Products provided such sub-licence contains the terms and conditions as generally set out below:

(a) the sub-licence is granted to a Related Corporation of Glaxo Australia with the commercial capacity to promote and exploit the relevant Product with due diligence and probity;

(b) the sub-licence recognises that the sub-licence may become non-exclusive pursuant to clause 6.2 hereof or limited pursuant to clause 13.1A hereof;

(c) the sub-licensee acknowledges that BSM owns the Intellectual Property and Intellectual Property Rights associated therewith;

(d) the sub-licence prohibits the sub-licensee from taking any action or allowing any action to be taken which detracts from the ownership of the Intellectual Property Rights by BSM;

(e) the sub-licence is in the English language, executed by the sub-licensee and giving its place of business;

(f) the sub-licence requires the sub-licensee to maintain all books, records and accounts necessary to enable verification of the amount of Sales and total Net Sales Revenue and royalties and other income required to be paid by Glaxo Australia to BSM;

(g) the sub-licence limits the duration of the sub-licence in respect of any Product to the term of this agreement and further provides for the sub-licence to terminate automatically upon the termination of this agreement or upon an Insolvency Event (as that term is defined in clause 13) occurring in relation to the sub-licensee;

(h) the sub-licence prohibits the sub-licensee, without the consent of BSM, from assigning, transferring, mortgaging or parting with any of its rights under the sub-licence;

(i) the sub-licence provides that the sub-licence will terminate in the event that the relevant company ceases to be a Related Corporation of Glaxo Australia and prevents the sub-licensee from assigning transferring mortgaging or parting with any of its rights under the sub-licence save and except to a Related Corporation of Glaxo Australia.

(j) the sub-licence obliges the sub-licensee to maintain the insurances referred to in clause 16 of this Agreement and to obtain and maintain the registrations and approvals referred to in clause 15 of this Agreement as apply to that sub-licensee.

9.3. If a sub-licence to be granted by Glaxo Australia in favour of its Related Corporation complies in all material respects with the above requirements it will not be necessary for Glaxo Australia to seek the consent of BSM to the granting of such sub-licence. Glaxo Australia shall however within 1 month of the entering into of such sub-licence notify BSM of the granting of the licence by Glaxo Australia and shall provide BSM with general details of the sub-licensee and a copy of the executed sub-licence.

9.4. In the event that Glaxo Australia desires to sub-licence its right and licence hereunder on terms and conditions not in accordance with the clauses 9.1-9.3, then no such sub-licence shall be entered into except with the prior consent in writing of BSM which consent will not be unreasonably withheld where that sub-licence includes terms and conditions similar to those referred to in clause 9.2, imposes upon the sub-licensee the material obligations with which Glaxo Australia would be obliged to comply if it was to do what it is intended the sub-licensee is to do under the sub-licence and the proposed sub-licensee has the capacity to promote and exploit the relevant products with due diligence and probity.

10. MANAGEMENT

Management Committee

10.1. BSM and Glaxo Australia shall form a management committee consisting of 4 persons, 2 of which will be representatives of BSM and 2 of which will be representatives of Glaxo Australia. Either party may replace one or more of its representatives at any time.

The Management Committee shall appoint 1 of its members as chairman. The first chairman shall be a BSM representative, who will hold office for the first 2 meetings of the Management Committee. The second chairman shall be appointed by Glaxo Australia for the ensuing 2 meetings of the Management Committee. Thereafter, the chairman shall rotate between a BSM representative and a Glaxo Australia representative for each ensuing 2 meetings. The chairman shall not have a second or casting vote on decisions of the Management Committee.

10.2. The Management Committee will be established, representatives will be nominated by the parties and its first meeting shall be held at such place and at a time that BSM and Glaxo Australia may mutually agree.

10.3. The Management Committee shall meet and regulate its own proceedings as decided from time to time by it **PROVIDED THAT** a quorum for any meeting shall be 1 BSM representative and 1 Glaxo Australia representative and **PROVIDED FURTHER THAT** the Management Committee will meet at least 3 times in each 12 month period during the term of this agreement.

10.4. The Management Committee may invite representatives of CSIRO, VCP and GGRL to attend and speak at meetings but those persons shall not be entitled to participate or vote on Management Committee decisions.

10.5. Minutes of all Management Committee meetings shall be kept.

Decisions

10.6. Only if Glaxo Australia and BSM representatives agree to a decision of the Management Committee will that decision be implemented or caused to be implemented.

Duties

10.7. **The general** duty of the Management Committee shall be to manage and direct the Project.

10.8. Specific duties of the Management Committee shall include determining and agreeing upon -

(a) a detailed network plan for the conduct of the Project including a series of short and middle term objectives designed to give effect to the objectives, plans, activities, experiments, milestones and all other specific activities of the Project ("Network Plan");

(b) a work schedule for the conduct of the Network Plan setting out the anticipated date of the completion of the various tasks comprising the Network Schedule and projections as to performance of the various research tasks comprising the Network Plan ("Work Schedule");

(c) a detailed specific cost analysis of the specific costs of each item comprising the Network Plan and the Work Schedule;

(d) the Budget;

(e) formal proposals to obtain Exploratory Development Approval in relation to Compounds **PROVIDED THAT** Glaxo Australia shall be entitled to submit any Compound to GGRL for Exploratory Development Approval;

(f) the terms, subject matter and content of disclosure of Confidential Information pursuant to clause 11;

(g) investigation of the patentability of Intellectual Property pursuant to clause 12; and

(h) publication of research pursuant to clause 11.

Reports

10.9. The Management Committee shall for each of its meetings during the Research Period cause to be prepared the following written reports -

(a) **Status Summary Report** - this report shall summarise the current status of the Project including -

(i) all current activities;

(ii) all activities which have been completed since the last report;

(iii) all activities which are to be begun;

(iv) any changes in technical, personnel or financial plans; and

(v) the identification of the problems solved since the last report.

(b) **Problem Analysis Report** - this report shall specify the problems which have been solved or which are to be resolved which substantially affect the progress of the Project;

(c) **Updated Network Plan** - this shall indicate which specific Network Plan milestones have been achieved, any approved changes to the Network Plan since the last report, any approved revised schedule completion dates, durations, actual completion dates, any re-estimated critical or near critical paths and all other such matters relating to the Network Plan;

(d) **Technical Report** - this report shall include a detailed technical report covering each milestone in the Work Plan specifying in detail the work undertaken and the results obtained including a statement of the activity, its aim, and the variables being investigated, detailed descriptions (including chemical analysis where appropriate) and detailed description of all test results and evaluations of all test results; and

(e) **Personnel Report** - this report shall include the names of professional personnel engaged on the project, the number of hours each professional person has worked and any explanatory notes for any significant changes to the personnel plan.

Budget

10.10. The Management Committee shall prepare a budget for the Project. The first budget will cover the period up to the next 30 June occurring after the Commencement Date and thereafter for the 12 month periods during the Research Period.

10.11. The Budget will be updated by the Management Committee on a half yearly basis so that the Budget continuously covers a period of 12 months in advance of each half year.

10.12. The Budget shall include estimates of Direct Research Expenditure and Associated Research Expenditure for the period covered by it.

Access

10.13. Each of BSM and Glaxo Australia shall have full and free access to any minutes, reports, plans, budgets or other documents produced held by or tabled before the Management Committee.

Reporting

10.14. BSM and the Glaxo Group shall provide full and complete information and reports to the Management Committee of each of their individual activities during the Project at such times and in the manner required by the Management Committee.

11. CONFIDENTIALITY AND PUBLICATIONS

Confidentiality

11.1. All Confidential Information disclosed by any member of the Biota Group or any member of the Glaxo Group to each other or to any of their employees, officers, agents or contractors under or in connection with this agreement shall be and be deemed to be so disclosed on terms of strict confidence, permanently prohibiting further disclosure or use which is not authorised under this agreement.

11.2. The parties shall and shall procure that each member of the Biota Group and the Glaxo Group will each use their best endeavours at all times to protect and preserve the confidential nature and continued secrecy of all Confidential Information and shall not directly or indirectly -

(a) publish, disclose or release Confidential Information to third parties or the public, or

(b) use, permit or suffer third parties or the public to use the Confidential Information,

except for the purposes of exercising its rights and performing its obligations under this agreement.

11.3. Further to safeguard the confidentiality of Confidential Information, the parties shall and shall procure that each member of the Biota Group and the Glaxo Group will each take all practicable steps to procure that the same is not disclosed to, or obtained from it or its employees, officers, agents or contractors by, any persons other than those laboratory and other technical or sales personnel employed by it or acting on its behalf who are required to have access to it in order to enable this agreement to be carried into effect and ensure that each and every employee, officer, agent, contractor or person who does or may have access to Confidential Information will execute a confidentiality agreement in the form of the document set out in Part A of schedule 2.

11.4. The parties shall and shall procure that each member of the Biota Group and the Glaxo Group shall each use their best endeavours to procure that each of its employees, officers, agents or contractors to whom Confidential Information is or has been disclosed ("disclosee") shall not disclose or use any of that Confidential Information contrary to the requirements of this clause 11, either during or after the termination of the employment, office, agency or contract of the disclosee. Any disclosure to a disclosee shall only be made on a needs to know basis and subject to the disclosee entering into a written undertaking to keep Confidential Information confidential in the form of the confidentiality agreement set out in Part A of schedule 2 prior to disclosure. In the event of any breach or threatened breach of the undertaking given by a disclosee, the relevant disclosor shall use best endeavours to enforce or procure the enforcement of that undertaking or obligation. Glaxo Australia and GGL shall be deemed to have complied with their obligations under clauses 11.3 and 11.4 in respect of obtaining written undertakings of confidentiality in respect of employees if confidentiality undertakings are given by those employees in their contract of employment with a member of the Glaxo Group.

11.5. The parties shall and shall procure that each member of the Biota Group and the Glaxo Group shall not at any time make or assist any other person whatsoever to make any unauthorised disclosure or use of any Confidential Information and shall take all practicable steps to procure and ensure that every person who, as its employee, officer, agent, contractor or otherwise through or from it, acquires or becomes possessed or apprised of any Confidential Information at any time shall not make or assist any other person whatsoever to make any unauthorised disclosure or use of that Confidential Information.

Disclosure

11.6. If it is necessary or desirable to disclose Confidential Information to third persons other than employees, officers, agents, sub-contractors, sub-licensees, licensees or Related Corporations of BSM or Glaxo Australia in order to explore the Commercialisation of Products -

(a) the party wishing to make the disclosure will inform the Management Committee of the identity of the person to whom the party wishes to make the disclosure and the proposed subject matter and content of the disclosure;

(b) subject to clause 11.6(c), the Management Committee may, after consultation, permit the party to make the disclosure on such terms as to subject matter and content as the Management Committee may prescribe; and

(c) a party may not make a disclosure pursuant to this clause unless, before the disclosure is made, the party obtains agreement in writing from the disclosee that the disclosee will not, directly or indirectly, publish disclose release use or assist any third person to publish disclose release or use the Confidential Information except for the limited purpose approved by the Management Committee.

It shall not be necessary for Glaxo Australia to obtain the prior approval of the Management Committee under this clause 11.6 where it is necessary to disclose such information to a prospective sub-licensee (being a Related Corporation of Glaxo Australia) for the purposes of evaluation by that prospective sub-licensee, so long as such a prospective sub-licensee and all persons to whom the information is to be disclosed executes prior to receipt of any such information a confidentiality agreement in the form set out in Part B of schedule 2.

If a party discloses Confidential Information to a person pursuant to this clause 11.6, the party will -

(a) use its best endeavours to procure that the disclosee abides by the agreement of confidentiality given by the disclosee; and

(b) take all practicable steps to enforce or procure the enforcement of the agreement of confidentiality given by the disclosee.

Publications

11.7. A party or any Related Corporation ("the publishing party") may publish research arising from or related to the Project after first obtaining the consent in writing of the other parties ("the non-publishing parties") as provided in this clause -

(a) not less than 3 months before the date on which it is proposed to publish the research or submit it for publication, as the case may be, the publishing party must submit the proposed publication ("the proposal") to the Management Committee for consideration;

(b) the non-publishing parties must inform the Management Committee whether they consent to publication of the proposal in the form submitted to the Management Committee within 1 month of the date of such submission;

(c) if any non-publishing party does not consent to publication in the form submitted, the parties, through the Management Committee, will consider publication with such amendments (including deletions) as may be agreed and the publishing party may only publish research in the form consented to by the non-publishing party;

(d) if any non-publishing party does not consent to a proposal (whether as originally submitted or with any proposed amendments, including deletions), the publishing party may, after the end of the 6th month from the date the proposal was finally refused, re-submit the proposal to the Management Committee for consideration and the provisions of this clause will apply to that re-submission as if it were a new proposal;

(e) in deciding whether to consent to a proposal pursuant to this sub-clause, the parties will have regard to the necessity of preserving the confidentiality of the Disclosed Information, any prejudice which may result to the grant, or the possible grant, of a patent for any invention made in or arising from the conduct of the Project and the consequences and implications for the commercial exploitation of the Products.

PROVIDED THAT nothing in this clause shall affect the operation of the CSIRO Agreement and the reservation by CSIRO of rights to publish (if any) contained therein.

11.8. A party may not disclose or otherwise release to any person the terms or substance of this agreement (or any part thereof) without first obtaining the prior written consent of the other parties.

11.9. Nothing in this agreement prevents disclosure by a party of information about the Project or this agreement -

(a) to the extent required by law, pursuant to the rules or regulations of a recognised stock exchange applicable to the party or a Related Corporation or to any agency authority instrumentality or Minister of any state or government, or

(b) to the party's legal advisors (including patent attorneys) for the purposes of obtaining legal advice (including advice in connection with the patenting, or patentability, of any invention), or

(c) to potential investors in the Project or the Products if notice of withdrawal is given by Glaxo Australia or BSM pursuant to clause 4.11,

PROVIDED THAT, before making a disclosure under clause 11.9(a), the party consults with the other party and obtains that party's consent to the terms and content of disclosure such consent not to be unreasonably withheld having regard to the disclosure requirements placed upon the party.

11.10. The rights and obligations of the parties with respect to confidentiality and restrictions herein as to use shall survive termination of this agreement **PROVIDED THAT** nothing in this clause 11 will restrict or inhibit a party from exercising its rights in relation to Intellectual Property or Intellectual Property Rights associated therewith after termination of this agreement or after the Licence is limited pursuant to clause 13.1A.

12. PATENTS AND OTHER INTELLECTUAL PROPERTY

12.1. BSM shall be responsible for drawing the specifications for, prosecuting, obtaining or maintaining the BSM Patents including the payment of all costs and expenses associated therewith. If BSM does not comply with its obligations hereunder, Glaxo Australia may, at its cost, prosecute, obtain or maintain the BSM Patents on behalf of BSM.

12.2. Glaxo Australia shall be responsible for drawing the specifications for, prosecuting, obtaining or maintaining the Future BSM Patents in the name of BSM, including the payment of all costs and expenses associated therewith in addition to its obligations in respect of Direct Research Expenditure and Associated Research Expenditure.

12.3. If either Glaxo Australia or BSM considers that the Intellectual Property (or part thereof) is, or may be, patentable in any country or countries, it must forthwith in writing notify the Management Committee.

12.4. Upon receiving notification pursuant to clause 12.3, the Management Committee will take such steps as it considers necessary or desirable to investigate whether the Intellectual Property (or part thereof) is patentable in any country and the utility of patenting the Intellectual Property (or part thereof) in any country and will report to the parties.

12.5. Upon receiving a report pursuant to clause 12.4, or upon expiration of a period of 21 days after notification pursuant to clause 12.3, whichever is the earlier, BSM and Glaxo Australia may agree to -

(a) file and prosecute a Patent Application for a Future BSM Patent for the Intellectual Property (or part thereof);

(b) take further steps to promote or secure the grant of a Future BSM Patent for the Intellectual Property (or part thereof); or

(c) treat the Intellectual Property (or part thereof) as a trade secret.

Notwithstanding that BSM and Glaxo Australia do not agree to file and prosecute a Patent Application under this clause, Glaxo Australia may nonetheless file and prosecute a Patent Application in accordance with this agreement.

12.6. If a decision is made pursuant to clause 12.5 to proceed to a Future BSM Patent of the Intellectual Property (or part thereof) or Glaxo Australia unilaterally decides to do so pursuant to clause 12.5, Glaxo Australia -

(a) agrees that any Future BSM Patent will be in BSM's name;

(b) agrees that it will draw specifications for, file and prosecute all applications for such Future BSM Patent and will promptly and fully inform BSM about the progress of Patent Applications; and

(c) will pay the cost of obtaining and maintaining any Future BSM Patent including the costs of any patent attorney retained by Glaxo Australia for the purpose of obtaining the Future BSM Patent but excluding any Future BSM Patent applied for by BSM pursuant to clause 12.7.

12.7. If, pursuant to clause 12.5, a decision is made not to apply for or proceed with Patent Application for a Future BSM Patent for the Intellectual Property (or part thereof) and subject to any agreement reached under clause 12.5, BSM may apply for that Future BSM Patent on its own behalf (and will bear the cost and expense of obtaining and maintaining such Future BSM Patent) **PROVIDED THAT** Glaxo Australia may, after meeting and discussing the reasons for and against with BSM, veto BSM's decision to do so in which case Glaxo Australia shall take into account any possible adverse effect that veto may have on BSM's position in respect of Intellectual Property Rights and BSM's entitlement to royalties under this agreement.

12.8. Each party will render and shall procure that where necessary its employees or consultants will render all reasonable assistance which the other party may reasonably require to file prosecute obtain or maintain any Patent Application made pursuant to this agreement or any Patent granted as a result thereof.

12.9. The parties shall procure that any third party research organisation (including CSIRO and VCP) and any individual research scientist involved in the Project shall assign, set over or better assure to BSM all and any rights or interests (if any) held or purportedly held by that organisation or that person related to the Intellectual Property or Intellectual Property Rights associated therewith.

Infringement or challenge

12.10. Each party will promptly and fully inform the other in writing of -

(a) any infringement or threatened infringement of BSM's or Glaxo Australia's rights in and to the BSM Patents, Future BSM Patents, Intellectual Property Rights associated with the Intellectual Property or any part thereof,

(b) any unauthorised use of the BSM Patents, Future BSM Patents, Intellectual Property Rights associated with the Intellectual Property or any part thereof, or

(c) any challenge or threatened challenge to the grant or validity of any BSM Patent or Future BSM Patent or any part thereof or a party's rights to use the Intellectual Property Rights associated with the Intellectual Property or any part thereof as contemplated by this agreement,

which may come to that party's attention.

12.11. Upon receiving a notice under clause 12.10, BSM and Glaxo Australia will confer in good faith to determine what reasonable steps should be taken and the best course of action to adopt in relation to the threatened infringement, unauthorised use or challenge.

12.12. Except where the, or the threatened, infringement, unauthorised use or challenge relates to Intellectual Property (or part thereof) for which BSM has applied for a Future BSM Patent pursuant to clause 12.7, Glaxo Australia shall have the exclusive first right but not the obligation to initiate infringement proceedings, oppose or defend any challenge, initiate proceedings to curtail any unauthorised use or take such other steps, as the case requires, in relation to any BSM Patent, Future BSM Patent or the Intellectual Property Rights. If Glaxo Australia decides to take action in accordance with this clause, it shall notify BSM in writing of that decision and shall pay all costs or expenses associated with that action (including costs and expenses of legal proceedings) with a right to recoupment as set out in clause 12.13 and will indemnify BSM from and against all costs and expenses incurred in or about the same.

12.13.1 If Glaxo Australia either in its own name or through its sub-licensee, decides to take action (including the taking of legal proceedings) to defend any challenge or curtail any infringement (in this clause 12.13 referred to as "Proceedings") the following provisions shall apply.

(a) The Proceedings will be instituted in the country where the challenge or infringement occurs or, where the challenge or infringement arises in a member country of the European Economic Community, in such country within the European Economic Community deemed most appropriate (in this clause 12.13 referred to as the "Relevant Country").

(b) Glaxo Australia shall bear 100% of the costs of the Proceedings.

(c) From the commencement of the Proceedings, Glaxo Australia shall be entitled to retain and accrue 50% of the actual reasonable external legal costs (as opposed to internal in house legal costs of Glaxo Australia including staff lawyers experienced in patent law) of the Proceedings incurred by Glaxo Australia during each 6 month royalty period (as determined by clause 7.4) from the royalties otherwise payable by Glaxo to BSM for Sales of Product **PROVIDED THAT** in no event will the amount retained and accrued each 6 month period exceed 50% of the royalties otherwise payable to BSM for Sales. At the end of each 6 month period, Glaxo Australia will provide a statement to BSM setting out the actual reasonable costs of the Proceedings incurred during that period. Glaxo Australia's right to retain and accrue royalties hereunder shall continue until either successful conclusion of the Proceedings or cessation of the infringement or challenge occurs.

(d) If there are insufficient accrued royalties to meet 50% of the external legal costs incurred during the course of the Proceedings, Glaxo Australia shall be entitled to recoup the outstanding amount from future royalties payable to BSM by withholding a sum not exceeding one third of the royalties payable to BSM.

(e) Glaxo Australia or its permitted sub-licensee shall not compromise or settle the Proceedings without the prior written consent of BSM. If Glaxo Australia considers that the Proceedings should be compromised or settled prior to Final Judgement, Glaxo Australia and BSM shall meet and discuss in good faith the appropriate course of action recognising that BSM's rights to royalty may be adversely effected if the infringement is permitted to continue or the challenge is not successfully defended as a result of a compromise or settlement of the Proceedings. It is acknowledged by Glaxo Australia and BSM that the compromise of such proceedings may involve the licensing or cross licensing of the Intellectual Property Rights, BSM Patents or Future BSM Patents and/or the payment of a royalty to a third party in order to enable continued manufacture of Glaxo's Products, in which case it may be appropriate that the royalty payable to BSM be reduced by an appropriate amount to take account of such additional external royalties.

(f) If Glaxo Australia or its permitted sub-licensee recovers any damages or accounts of profit in any successful Proceedings, the amounts of any judgment for past infringement or challenge actually paid to Glaxo Australia or its relevant sub-licensee shall be first applied to reimburse Glaxo Australia or its permitted sub-licensee for its reasonable internal costs and expenses (as opposed to external legal costs) in prosecuting such proceedings and to reimburse BSM for expenses incurred by it in accordance with clause 12.13(g). The balance, if any, shall be apportioned and paid as follows:

(i) to BSM - that percentage equal to the royalty rate then payable to BSM on Sales in the Relevant Country; and

(ii) to Glaxo Australia - the balance.

(g) If Glaxo Australia or its permitted sub-licensee recovers legal costs from the other party or parties to the Proceedings, 50% of those recovered costs shall be payable to BSM but shall, prior to payment to BSM, be applied in paying any legal costs not recouped from royalties pursuant to clause 12.13.1(d). Any remaining balance shall be paid to BSM.

(h) BSM shall furnish Glaxo Australia, upon the request of Glaxo Australia, with all evidence and information in its possession and control pertaining to the Proceedings and BSM shall join therein on a non controlling basis to the extent requested by Glaxo Australia including if required the lending of its name to any such action either as a direct party or as a third party. If the furnishing of evidence and information or joining as a party as aforesaid is likely to involve BSM in any material expense those expenses shall be reimbursed to BSM pursuant to clause 12.13.1(f).

(i) If a Final Judgement is received in the Relevant Country resulting in the Proceedings being unsuccessful, all royalties payable in respect of Sales of Product in the Relevant Country shall cease to be payable from the date of the Final Judgement and clause 6.2 shall operate in respect of the Licence in the Relevant Country.

(j) For the purposes of this clause 12.13.1, "Final Judgment" means a judgment or decree which is entered and which becomes not further reviewable through the exhaustion of permissible applications for re-hearing or review by any superior Court or tribunal, or through the expiration of the time permitted for such application in the Relevant Country.

12.13.2 Where there is an alleged infringement or challenge and Glaxo Australia decides not to take Proceedings, BSM shall have the right to take legal proceedings to defend the challenge or curtail the infringement and in such case it shall do so at its own expense and will be entitled to any damages or accounts of profits awarded in its favour as a result of such proceedings. Glaxo Australia will at BSM's expense provide all reasonable evidence information and assistance to BSM in its possession or control pertaining to such proceedings and Glaxo Australia or its relevant sub-licensee shall join therein on a non controlling basis to the extent requested by BSM including if required the lending of its name to any such action either as a direct party or a third party. If BSM's proceedings are successful, the Licence in the Relevant Country shall not revert to an exclusive licence.

12.13.3 If an infringement or challenge occurs in any further country ("Second Country") similar to that which has occurred in the Relevant Country, the following provisions shall apply.

(a) BSM and Glaxo Australia shall confer in good faith to determine what reasonable steps should be taken and the best course of action to adopt in relation to that infringement or challenge in the Second Country.

(b) If BSM and Glaxo Australia agree to take Proceedings in the Second Country, clause 12.13.1 shall apply mutatis mutandis and references therein to Relevant Country will be read as references to Second Country.

(c) If BSM and Glaxo Australia agree not to take Proceedings, all royalties payable in respect of Sales of Products in the Second Country shall cease to be payable from the date of the decision and clause 6.2 shall operate in respect of the Licence in the Second Country.

(d) Notwithstanding clause 12.13.3(c), BSM may itself decide to take Proceedings whereupon royalties shall still cease in accordance with that clause, but if BSM's Proceedings are successful the Licence in the Second Country shall not revert to an exclusive licence.

Ownership

12.14 Other than the rights given to it pursuant to this agreement and in particular clause 3.9, Glaxo Australia shall have no right title or interest in the Intellectual Property or the Intellectual Property Rights associated therewith.

12.15 Subject to clause 3.9(c), if Glaxo Australia or any member of the Glaxo Group brings to the Project any Compound or develops or generates any Compound during the course of the Project, Glaxo Australia acknowledges and agrees and shall procure that any member of the Glaxo Group acknowledges and agrees that BSM shall have all right title and interest in the Intellectual Property relevant to that Compound and shall execute and deliver any document or other instrument necessary or desirable to fully assure and vest in BSM all Intellectual Property Rights in that Compound.

12.16 Subject to any applicable laws, Glaxo Australia will not and shall procure that no member of the Glaxo Group or any permitted sub-licensee will, infringe or challenge any, or any application for any, BSM Patent or Future BSM Patent anywhere in the world. The obligations of Glaxo Australia under this clause shall survive termination of this agreement.

12.17 BSM will in determining whether to proceed with publication of the Patent Specifications for the BSM Patents take into account any possible adverse effect that publication may have on Glaxo Australia's position in respect of ultimately obtaining patent protection by a specific patent on a Compound used or to be used in a Product or the achievement of the general objectives of this agreement. Glaxo Australia and BSM will meet and discuss the reasons for and against publication prior to publication at a mutually convenient time upon the written request of Glaxo Australia.

13. TERMINATION

13.1. BSM or Glaxo Australia may terminate this agreement if:

(a) the other or any Related Corporation of the other is in material breach or default of its obligations under this agreement; or

(b) any of the following events ("Insolvency Event") occurs in relation to the other:

(i) a petition is presented or an order is made for provisional liquidation, dissolution or winding up;

(ii) any proposal to or the making of a compromise or arrangement with creditors or commission of an act of bankruptcy occurs;

(iii) a receiver or receiver and manager is appointed over the whole or any part of its undertaking, property or assets and the appointment is not revoked or overturned within 30 days after the date of the appointment;

(iv) an agent in possession is appointed by any third party over or in respect of any of its undertaking, property or assets; or

(v) any distress, execution, attachment or other process is made or levied against any asset for an amount in excess of $100,000 (indexed in accordance with clause 18) and remains outstanding or unsatisfied for a period of 60 days.

13.1A BSM may terminate this agreement if any member of the Glaxo Group whether pursuant to clause 3.9 or otherwise -

(a) makes an IND/CTX Application for, or

(b) Commercialises,

a chemical compound which falls within the description of a Start Compound and is to be incorporated in a product which is to inhibit influenza virus A and/or B neuraminidase **PROVIDED THAT** if a Compound has received IND/CTX Application approval, BSM's right to terminate this agreement shall not be absolute and this agreement shall continue in respect of that Compound, it being the intention of the parties that the Licence, in respect of that Compound and associated Intellectual Property Rights, continue in accordance with this agreement and that the terms and conditions of this agreement apply mutatis mutandis to that limited Licence.

13.2. BSM and Glaxo Australia may mutually agree to terminate this agreement.

13.3. This agreement terminates on and from -

(a) in the case of termination pursuant to clauses 13.1(a) or 13.1A, the date the party serves on the other party ("defaulting party") a notice terminating this agreement for that breach or default **PROVIDED THAT** a party may not serve such a notice until the expiry of 60 days from the service on the defaulting party of a notice specifying the breach or default and allowing the defaulting party 60 days to remedy that breach or default,

(b) in the case of termination pursuant to paragraphs 13.1(b)(i), (ii) or (iv), on and from the date of the Insolvency Event;

(c) in the case of termination pursuant to paragraphs 13.1(b)(iii) or (v), on and from the expiration of the time period referred to in the relevant paragraph; or

(d) in the case of termination pursuant to clause 13.2, on and from the date mutually agreed by BSM and Glaxo Australia.

13.4. If an Insolvency Event occurs in respect of any permitted sub-licensee of Glaxo Australia, the relevant sub-licence shall terminate on and from the date of the Insolvency Event.

13.5. In this clause 13, a winding up or liquidation for the purpose of a reconstruction or amalgamation by any party or by either the Biota Group or the Glaxo Group shall not be an event permitting or giving rise to termination if after that reconstruction or amalgamation the resulting corporation becomes bound by the terms of this agreement by way of assignment or novation.

14. CONSEQUENCES OF TERMINATION

14.1. Subject to clauses 11 and 13.1A and the succeeding provisions of this clause 14, upon termination of this agreement pursuant to clause 13, this agreement, the Licence and all other rights and obligations are at an end.

14.2. Any termination of this agreement is without prejudice to any party's rights against the other party which have accrued prior to the time at which termination occurred.

14.3. Subject to clause 14.5, Glaxo Australia shall immediately upon termination return to BSM all samples and information in documentary form relating to Compounds together with any information in documentary form relating to the Confidential Information, the Intellectual Property or the Intellectual Property Rights and any copies of information in documentary form relating to the Compounds the Confidential Information obtained or received by Glaxo Australia from persons other than BSM during the term of this agreement.

14.4. BSM recognises that Glaxo Australia may have stocks of Product at the time of termination and in that event may -

(a) require Glaxo Australia to deliver those stocks to BSM at manufactured cost plus 15% and FOB Glaxo Australia's or its sub-licensee's premises **PROVIDED THAT** Glaxo Australia or its permitted sub-licensee shall be entitled to remove from such Product all labelling identifying the Product as that of Glaxo Australia or its permitted sub-licensee, or

(b) permit Glaxo Australia to sell those stocks of Product within 3 months of termination whereupon Glaxo Australia will continue to comply with the obligations imposed by clauses 9, 11, 12, 15, 16 and 17 of this agreement for sales made by it pursuant to this clause 14.4(b),

PROVIDED THAT this clause shall not operate if clause 14.5 operates.

Breach by BSM

14.5. In the event that Glaxo Australia terminates this agreement pursuant to clauses 13.1(a) or 13.1(b) the following provisions shall apply.

(a) The Licence shall continue in effect in accordance with this agreement and Glaxo Australia's right to sub-licence shall become unconstrained by clause 9 hereof.

(b) Royalties shall cease to be payable in respect of any Product incorporating a Compound that has not, at the effective date of termination, been given Exploratory Development Approval.

(c) Royalties shall continue to be paid in accordance with this agreement in respect of Sales of Products incorporating Compounds that have, prior to the effective date of termination, been given Exploratory Development Approval.

(d) No further amounts shall be payable pursuant to clauses 4.4, 5.1, 5.4, 5.5, 5.6 or 7.5 other than:

(i) payments that have accrued and remain unpaid as at the effective date of termination; and

(ii) payments pursuant to clauses 5.4, 5.5 and 5.6 in respect of Compounds which have received Exploratory Development Approval as at the date of effective termination.

(e) BSM shall, subject to the consent of CSIRO and the VCP, assign to Glaxo Australia its right title and interest in and to the CSIRO Agreement and the VCP Agreement, respectively, and Glaxo Australia shall assume all BSM's liabilities and obligations under those agreements (including the obligation to pay royalty) **PROVIDED THAT** nothing in this clause shall vest in Glaxo Australia or require BSM to assign to Glaxo Australia Intellectual Property, Intellectual Property Rights associated therewith or any other intellectual property or intellectual property rights vested in or owned by BSM pursuant to the CSIRO Agreement or the VCP Agreement.

(f) Any Intellectual Property generated after the effective date of termination shall be or become the property of Glaxo Australia.

(g) BSM shall refund to Glaxo Australia the pro rata proportion of the BSM fee which has been paid in advance calculated from the effective date of termination such amount to be paid to Glaxo Australia within 30 days of the effective date of termination **PROVIDED THAT** if that amount is not paid Glaxo Australia shall be entitled to set off the amount against any royalty payments then due and owing to BSM.

(h) BSM's rights under clause 8 shall cease from the effective date of termination.

(i) Other than as set out in this clause and subject to clause 11, on the effective date of termination this agreement and all other rights and obligations shall be at an end.

15. REGISTRATIONS AND APPROVALS

Glaxo Australia or any sub-licensee of Glaxo Australia shall at its expense undertake and be responsible for applying for, obtaining and maintaining all statutory, regulatory, administrative or government approvals, consents or registrations (including any Health Regulatory Body approvals or registrations and Product Licence Applications) required by law to be obtained in connection with the manufacture, use, exercise or sale of Products in any country in which Glaxo Australia or any sub-licensee proposes to make, use, exercise or sell Products **PROVIDED THAT** nothing in this clause shall require Glaxo Australia or any sub-licensee of Glaxo Australia to obtain any approvals or registrations in any Territory where BSM exercises its rights pursuant to clause 8 if Glaxo Australia has not marketed the relevant Products.

16. INSURANCE AND INDEMNITY

16.1. Glaxo Australia agrees to, and shall procure that any sub-licensee agrees to, maintain adequate product liability and third party liability insurance in respect of any Product, information or advice arising from the Project used by Glaxo Australia or the sub-licensee and will make, use, exercise and sell Products at Glaxo Australia's or the sub-licensee's own risk and will release and indemnify BSM and its officers, employees, agents and contractors from and against all actions, claims, proceedings or demands which may be brought against it or them for any loss, expense, injury or damage (whether personal or property) including consequential financial loss and, subject to clause 12, any infringement of copyright, patents, trademarks, designs or other intellectual property rights howsoever arising out of the exercise by Glaxo Australia, any sub-licensee or both Glaxo Australia and any sub-licensee of its or their rights under this agreement or under any sub-licence, respectively, and from and against all damages, costs and expenses incurred in defending or settling any such action, claim, proceeding or demands.

16.2. Glaxo Australia will, upon the request of BSM, produce evidence of currency of the insurance policies referred to in clause 16.1. If Glaxo Australia fails to produce such evidence of currency within 60 days from the date it receives notice of such request, Glaxo Australia will be deemed to be in breach of this clause and the provisions of clause 13 will apply.

16.3. Except as expressly provided in this agreement, BSM makes no representations or warranties of any kind, either express or implied to Glaxo Australia or any sub-licensee of Glaxo Australia including express or implied conditions as to merchantable quality or fitness for a particular purpose of the Products.

17. ACCOUNTS AND INSPECTION

17.1. Glaxo Australia shall keep at its principal office in Australia and, in addition, each country in which Products are sold (so far as is relevant to Sales in that country) full, true and accurate books of account and records which disclose -

(a) the total number and value of Sales made by Glaxo Australia under the Licence, and

(b) details of all sub-licences granted by Glaxo Australia and the total number and value of Sales made by sub-licencees.

17.2. If BSM disputes any written report provided to it pursuant to clause 7.4 or the calculation of royalty payable on the basis of any report, BSM shall be entitled to retain an independent expert to investigate the report. The expert shall be from one of the major firms of chartered accountants practising in Australia. If the expert reports that the royalty payable is understated, Glaxo Australia shall immediately pay the additional royalty to BSM. The expert shall act as an expert and not as an arbitrator and the expert's decision shall be final and binding on Glaxo Australia and BSM. The costs of the expert shall be paid by Glaxo Australia if the expert reports that Glaxo Australia's written report understates royalties payable to BSM by more than 5%. Otherwise, BSM shall pay the costs of the expert.

17.3. BSM or its duly authorised representatives (including the expert referred to in clause 17.2) shall have access during normal business hours and upon prior appointment to inspect the accounts and records of Glaxo Australia which it is required to maintain under this clause and to take exerts therefrom or make copies thereof solely for the purpose of verifying the accuracy of royalty payments and reports required under this agreement.

18. INDEXATION

18.1. Where there is a reference in clauses 4, 5 and 13 to "indexed in accordance with clause 18", the following provisions shall apply.

18.2. The amount to be indexed shall be multiplied by a factor equal to the number (calculated to 3 decimal places) ascertained by dividing the index number in respect of the completed quarter prior to the quarter in which the amount is to be paid falls, by the index number in respect of the quarter ending 30 June 1989.

18.3. In this clause "index number" in relation to a quarter means the All Groups Consumer Price Index number, being the weighted average of the 8 capital cities of Australia, published by the Australian Bureau of Statistics ("Bureau") in respect of that quarter.

18.4. Subject to clause 18.5, if at any time whether before or after the date hereof, the Bureau has published or publishes an index number in respect of a quarter in substitution for an index number previously published by the Bureau in respect of that quarter, the publication of the later index number shall be disregarded for the purposes of this clause 18.

18.5. If at any time whether before or after the date hereof, the Bureau has changed or changes the reference base for the Consumer Price Index then, for the purposes of this clause, after the change took place or takes place regard shall be had only to index numbers published in terms of the new reference base.

18.6. The parties agree that the index number for the quarter ending 30 June 1989 is 192.6.

19. ASSURANCES AND EXCHANGE OF INFORMATION

19.1. Biota and GGL shall each use their best endeavours to ensure that BSM and Glaxo Australia, respectively, and any other member of the Biota Group and the Glaxo Group, respectively, perform and observe all agreements, covenants, conditions, acknowledgements or obligations under this agreement and any agreement or transaction contemplated by this agreement.

19.2. Each party shall, and shall procure each of their Related Corporations to keep and maintain full and accurate data and information concerning their respective research under, work on and involvement in the Project and will make that data and information freely available to each other as and when necessary or as and when reasonably requested by any party.

19.3. Each party will, and will procure each of their Related Corporations and any third party researchers (including the CSIRO and the VCP) will, give to the other parties at all convenient times and upon reasonable notice full and free access to its premises and facilities used for the purpose of activities related to the Project or Exploratory Development for the purpose of inspecting activities or data and information kept pursuant to clause 19.2 **PROVIDED THAT** access to the premises of Glaxo Australia, GGL and their Related Corporations pursuant to this clause for the purpose of inspecting activities shall be limited to those premises and facilities which are dedicated to the Project, and then subject to the same conditions and controls as visitors to those premises and facilities are ordinarily subject.

20. RESERVATIONS

Veterinary Applications

20.1. This agreement and the Project are not intended to encompass research and development of Veterinary Applications of Compounds.

20.2. BSM shall be entitled to carry out independent research and development into Veterinary Applications of a Compound or Compounds and to Commercialise Veterinary Applications of a Compound with the prior written consent of Glaxo Australia which consent will not be unreasonably withheld where:

(a) the potential for Therapeutic Application of the Compound has been substantially eliminated;

(b) Glaxo Australia is reasonably satisfied that Patent protection is secure in relation to the Compound; and

(c) Glaxo Australia's commercial interests in relation to the exploitation of a Product for Therapeutic Applications are safeguarded and will not be prejudiced or jeopardised by the Veterinary Application of the Compound.

Diagnostic Applications

20.3. The parties acknowledge and agree that BSM may carry out research and development into Diagnostic Applications of a Compound or Compounds with the prior written consent of Glaxo Australia which consent will not be unreasonably withheld where:

(a) the potential for Therapeutic Application of the Compound or Compounds will not be jeopardised;

(b) Glaxo Australia is reasonably satisfied that Patent protection is secure in relation to the Compound or Compounds; and

(c) Glaxo Australia is reasonably satisfied that its commercial interests in relation to the exploitation of a Product for Therapeutic Application are safeguarded.

Serendipitous Discoveries

20.4. BSM hereby grants to Glaxo Australia a first right to exclusively carry out or conduct further research and development with a view to the Commercialisation of a Serendipitous Discovery upon terms and conditions to be agreed between BSM and Glaxo Australia **PROVIDED THAT** BSM will not, in the event that Glaxo Australia does not exercise its first right hereunder, enter into such further research and development with a third party on terms and conditions more favourable than those allowed to Glaxo Australia.

Glaxo Australia shall, and shall procure other members of the Glaxo Group to, disclose and provide reasonable information and details to BSM of the results of any testing, screening or other research work Glaxo Australia or any other member of the Glaxo Group carries out in relation to Compounds or other Intellectual Property which results constitute or may constitute a Serendipitous Discovery.

Third party collaboration

20.5. The parties acknowledge that circumstances may arise where research collaboration with third parties in the Agreement Field or in relation to applications of Compounds is beneficial. BSM and Glaxo Australia shall, if such circumstances arise, meet and discuss in good faith the terms and conditions upon which third party collaboration might take place. The general guidelines for any third party collaboration are as follows.

(a) The collaboration may only be conducted with the written consent of BSM and Glaxo Australia.

(b) If funding or costs are involved, these are to be covered by the party that enters into the collaboration unless Glaxo Australia and BSM otherwise agree.

(c) Any disclosure of Confidential Information to a third party collaborator should only be made to the extent to which such information is required to be disclosed for the purposes of carrying out collaboration.

(d) Information arising from collaboration should be retained as confidential on the same terms and conditions as set out in this agreement.

(e) The party entering into the collaboration agreement should use its best efforts to ensure that any inventions or other intellectual property made by or arising from the third party collaborator in the course of the collaboration are the property of BSM or Glaxo Australia as appropriate and that such intellectual property is treated as far as possible as intellectual property created by one of their employees. In essence the obligations must be such as to place all intellectual property in the same category as Intellectual Property derived from the course of the Project.

(f) If as a result of a collaboration by BSM a royalty becomes payable to a third party as a result of manufacture use or sale of a Product in

accordance with the terms of this agreement then any such payments so made are to be debited against royalties payable to Biota on sales of such Products.

21. GENERAL

Notices

21.1. A notice, approval, consent or other communication in connection with this agreement:

(a) must be in writing;

(b) must be marked for the attention of the Managing Director; and

(c) must be left at the address of the addressee, or sent by prepaid ordinary post (airmail if posted to or from a place outside Australia) to the address of the addressee or sent by facsimile to the facsimile number of the addressee which is specified in this clause or if the addressee notifies another address or facsimile number then to that address or facsimile number.

The address and facsimile number of each party is:

BSM and Biota
Address: Level 28, Rialto, 525 Collins Street, Melbourne, Australia, 3000
Facsimile: (059) 443 170

Glaxo Australia
Address: 1061 Mountain Highway, Boronia, Australia, 3155
Facsimile: (03) 729 5319

GGL
Address: 6-12 Clarges Street, London W1Y8DH United Kingdom
Facsimile: 0011 44 1 493 4809

21.2. A notice, approval, consent or other communication takes effect from the time it is received unless a later time is specified in it.

21.3. A letter or facsimile is taken to be received:

(a) in the case of a posted letter, on the third (seventh, if posted to or from a place outside Australia) day after posting: and

(b) in the case of facsimile, on production of a transmission report by the machine from which the facsimile was sent which indicates that the facsimile was sent in its entirety to the facsimile number of the recipient **PROVIDED THAT** where transmission is completed after 5pm on a Business Day or is sent on a day that is not a Business Day, the message will not be deemed to have been received until the next Business Day.

Assignment

21.4. BSM or Glaxo Australia may not sell, assign, pledge or otherwise dispose of its rights or interests under this agreement or interest in the Project or the Intellectual Property Rights associated with Intellectual Property without the consent of Glaxo Australia or BSM, as the case may be, who may exercise a first right of refusal for any right or interest proposed to be sold or otherwise disposed of ("the first right"). The first right shall be exercisable within 60 days ("exercise period") after the party wishing to sell or otherwise dispose of its rights or interests ("the selling party") gives notice to BSM or Glaxo Australia, as the case may be ("the exercising party") of the terms and conditions, including the price, upon which the selling party proposes to sell or otherwise dispose of its rights and interests. If the exercising party exercises the first right within the exercise period, it shall pay a deposit equal to 10% of the price to the selling party upon exercise of the first right. The balance of the price shall, subject to the obtaining of all necessary government approvals, be paid to the selling party within 90 days after the date of exercise of the first right. If the exercising party does not exercise the first right during the exercise period, the first right shall lapse and the selling party may sell or otherwise dispose of the rights or interests the subject of the first right to any third party **PROVIDED THAT** the sale or other disposal is not on terms or conditions more favourable than that allowed to the exercising party **AND PROVIDED THAT** any sub-licence by Glaxo Australia pursuant to clause 9 shall not be treated as a sale, assignment, pledge or disposal of any of its rights or interests in the Intellectual Property.

Waiver and variation

21.5. A provision of or a right created under this agreement may not be:

(a) waived except in writing signed by the party granting the waiver; or

(b) varied except in writing signed by the parties.

Remedies cumulative

21.6. The rights, powers and remedies provided in this agreement are cumulative with and not exclusive of the rights, powers or remedies provided by law independently of this agreement.

Survival of indemnities

21.7. Each indemnity in this agreement is a continuing obligation, separate and independent from other obligations and survives termination of this agreement.

Further assurances

21.8. Each party agrees, at its own expense, on the request of another party, to:

(a) do everything reasonably necessary to give effect to this agreement and the transactions contemplated by it, including without limitation the execution of documents; and

(b) use its best endeavours to cause relevant third parties to do likewise.

Supervening legislation

21.9. Any present or future legislation which operates to vary an obligation or right, power or remedy of a person in connection with this agreement is excluded except to the extent that its exclusion is prohibited or rendered ineffective by law.

Time of the essence

21.10. Time is of the essence of this agreement in respect of an obligation of Glaxo Australia to pay money.

Severability

21.11. If the whole or any part of a provision of this agreement is void, unenforceable or illegal in a jurisdiction it is severed for that jurisdiction. The remainder of this agreement has full force and effect and the validity or enforceability of that provision in any other jurisdiction is not affected. This clause has no effect if the severance alters the basic nature of this agreement or is contrary to public policy.

Entire Agreement

21.12. This agreement constitutes the entire agreement of the parties about its subject matter and all previous agreements, undertakings and negotiations on that subject matter cease to have any effect.

Governing law, jurisdiction and service of process

21.13. (a) This agreement and the transactions contemplated by this agreement are governed by the law in force in the State of Victoria.

(b) Each party irrevocably and unconditionally submits to the non-exclusive jurisdiction of the courts of the State of Victoria and courts of appeal from them for determining any dispute concerning this agreement or the transactions contemplated by this agreement. Each party waives any right it has to object to an action being brought in those courts, to claim that the action has been brought in an inconvenient forum, or to claim that those courts do not have jurisdiction.

(c) Without preventing any other mode of service, any document in an action (including, without limitation, any writ of summons or other originating process or any third or other party notice) may be served on any party by being delivered to or left for that party at its address for service of notices under clause 21.1.

EXECUTED as an agreement.

SCHEDULE 1

(BSM Patents)

Part A:

Patent designated P1 8111 or PCT/AU89/00197 lodged under rule 1.41 at the United States of America patent office on 19 October 1989.

Part B:

A patent in preparation at the date hereof entitled "Antiviral compounds" with designated inventors being P Colman, M von Itzstein, J Varghese and others. The Patent specifications for this patent have been agreed between the parties.

This patent is based on the patent set out in Part A of this Schedule, and is designed to replace it.

The parties acknowledge that this patent will be filed prior to 28 February 1990. At the time of filing the parties will acknowledge the application number, to identify this patent.

SCHEDULE 2

(Confidentiality agreements)

Part A: Disclosure to employees, etc. (clause 11.3 and 11.4)

SCHEDULE 2
PART A

IF BIOTA IS THE PRINCIPAL, SELECT THE FIRST OPTION IN EACH SET OF SQUARE BRACKETS.

IF GLAXO IS THE PRINCIPAL, SELECT THE SECOND OPTION IN EACH SET OF SQUARE BRACKETS.

THIS AGREEMENT is made the day of 19

BETWEEN: [BIOTA SCIENTIFIC MANAGEMENT PTY LTD of 121 William Street, Melbourne in the State of Victoria ("the Principal" or "Biota")/GLAXO AUSTRALIA PTY LTD of 1061 Mountain Highway, Boronia in the State of Victoria ("the Principal" or "Glaxo")]

of the first part

AND:

of
("the Third Party")

of the second part

WHEREAS:

A. Biota and Glaxo and other persons are parties to the Principal Agreement under which Biota, Glaxo and other persons have conducted and are conducting research and development in the Agreement Field.

B. The Third Party desires to collaborate with the Principal, to be employed by the Principal or to continue to be employed by the Principal in a programme of research and development which is in whole or in part within the Agreement Field.

C. The Third Party acknowledges that in the course of or as a result of the collaboration or employment the Third Party may have access to or may become acquainted with

Technical Information. The Third Party acknowledges the desire and right of Biota and Glaxo to preserve the secrecy of the Technical Information and agrees to deal with the Information in accordance with the terms set out herein.

D. The Third Party acknowledges that in the course of or as a result of the collaboration or employment the Third Party may either alone or with the Principal make an invention or discovery, improve on an existing invention, technique or process, or author an original work. The Third Party acknowledges the desire and right of Biota and Glaxo to preserve the secrecy of Results and to secure to Biota the entire right, title and interest in Results including the right to apply for and have granted in Biota's name any patents, registered designs, copyright or other rights of a like nature throughout the world, so that such rights may be dealt with in accordance with the Principal Agreement.

NOW THIS DEED WITNESSES as follows:-

1. **Definitions**

1.1 In this Agreement, unless there is something inconsistent with the context, the following terms and expressions shall have the following meanings:-

(a) **"Agreement Field"** means the identification, synthesis and evaluation of potential Inhibitors.

(b) ["**Glaxo**" means Glaxo Australia Pty Ltd of 1061 Mountain Highway, Boronia/"**Biota**" means Biota

Scientific Management Pty Ltd of 121 William Street, Melbourne];

(c) "Inhibitor" means a compound to inhibit influenza virus A and B neuraminidase.

(d) "Principal Agreement" means an agreement dated the day of , 1990 (as amended) between Glaxo, Biota and other persons in relation to a programme of research in the Agreement Field.

(e) "Results" means any and all substances, products, processes, techniques, procedures, methods, formulas, designs, literary works, artistic works and other intellectual property and any and all improvements on substances, products, processes, techniques, procedures, methods, formulas, designs, literary works, artistic works and other intellectual property, whether or not same are registrable as patents or designs or protected by copyright, which have arisen or arise out of or which have resulted or result in whole or in part from the Third Party's access to or acquaintance with the Technical Information.

(f) "Technical Information" means any and all technical information written or oral whether in the form of unpatented inventions, formulas, procedures or methods, or current and accumulated knowhow skills and experience contributed to the conduct of research and development pursuant to the Principal Agreement or discovered, invented or developed as a result of or in the course of the conduct of

research and development pursuant to the Principal Agreement and any and all substances and products contributed to the conduct of research and development pursuant to the Principal Agreement or discovered, invented or developed as a result of in the course of the conduct of research and development pursuant to the Principal Agreement.

1.2 In this Agreement, unless inconsistent with the context, references to the singular shall include references to the plural and vice versa and a reference to any gender shall include a reference to all genders. A reference to persons shall include a reference to corporations and other forms of legal entity and vice versa.

1.3 In this Agreement clause headings are for convenience only and shall not form part of this Agreement nor shall they affect its construction.

2. **Confidentiality**

2.1 The Third Party agrees to keep any and all details of Technical Information and Results strictly secret and confidential and agrees that details of Technical Information and Results will not be disclosed or permitted to be disclosed to any third party.

2.2 It is hereby acknowledged and agreed that the details of Technical Information and Results to be kept secret and confidential shall not include any information which becomes part of the public knowledge or public literature

(otherwise than by reason of a breach by the Third Party of its obligation of confidentiality). The onus of proof shall be on the Third Party to establish that this exception has application.

3. Use of Technical Information and Results

3.1 Irrespective of whether Technical Information or Results are to be kept strictly secret and confidential the Third Party agrees not to use Technical Information or Results or allow any part of same to be used for the benefit of the Third Party or any third party other than Biota, Glaxo or any other person bound by the Principal Agreement.

3.2 The Third Party shall not, for whatever reason, either for itself or any third party, appropriate, copy, memorise or in any manner reproduce or reverse engineer any of the Technical Information or Results.

3.3 The Third Party shall not remove the Technical Information or Results or any details relating thereto from premises without the written consent of the Principal.

3.4 Upon the cessation of the Third Party's collaboration or employment with the Principal or when otherwise directed by [the Principal/the Principal and Biota] the Third Party shall forthwith return to the Principal all documents, records, drawings, production drawings and designs, note books and other similar repositories

containing details of Technical Information or Results, including all copies thereof in the possession of the Third Party.

4. Assignment of Rights

4.1 The Third Party hereby absolutely and irrevocably assigns to Biota all legal and beneficial right title and interest which it has, may have acquired or may acquire to or in Results.

4.2 The Third Party agrees to do all such acts and things and sign all documents as Biota or its legal representatives may reasonably request to secure to Biota ownership or rights in the matters referred to in clause 4.1.

4.3 The Third Party agrees to fully co-operate with Biota and its advisors and to lend its name and assistance to any applications, proceedings, filings, registrations or renewals Biota wishes to make or affect in relation to any Results.

4.4 The Third Party agrees to disclose to [the Principal/the Principal and Biota] all details of Results of which the Third Party is aware.

5. Third Party's Warranties

The Third Party warrants and represents to [the Principal/the Principal and Biota]:-

(a) that it has full right, power, authority and liberty to enter into this Agreement and to perform its duties and obligations hereunder; and

(b) that it has not entered into and will not enter into any agreements, arrangement, understanding or obligation with any third party which is contrary to or inconsistent with its duties and obligations hereunder.

6. Continuation of Covenants

The Third Party's covenants and undertakings in this Agreement shall not cease upon the cessation of the Third Party's collaboration or employment with the Principal and shall continue in full force and effect thereafter for so long as any Technical Information or Results are being or are to be commercially exploited.

7. Assignment by Biota [to be inserted only where Biota is Principal]

Biota may assign all or any part of its rights, benefits, obligations and responsibilities contained in this Agreement by notice in writing to the Third Party.

IN WITNESS WHEREOF the parties hereto have executed this Agreement the day and year first hereinbefore mentioned.

THE COMMON SEAL of [BIOTA SCIENTIFIC MANAGEMENT PTY LTD/GLAXO AUSTRALIA PTY LTD] was hereunto affixed in accordance with its Articles of Association in the presence of:)

..... Director

..... Secretary

SIGNED SEALED AND DELIVERED by the said in the presence of:)

..... Witness

SCHEDULE 2

(Confidentiality agreements)

Part B: Disclosure to 3rd parties (clause 11.6)

SCHEDULE 2
PART B

IF BIOTA IS THE PRINCIPAL, SELECT THE FIRST OPTION IN EACH SET OF SQUARE BRACKETS.

IF GLAXO IS THE PRINCIPAL, SELECT THE SECOND OPTION IN EACH SET OF SQUARE BRACKETS.

IF CSIRO IS THE RESEARCHER, SELECT THE FIRST OPTION IN EACH SET OF BRACES.

IF VCP IS THE RESEARCHER, SELECT THE SECOND OPTION IN EACH SET OF BRACES.

THIS AGREEMENT is made the day of 19

BETWEEN: [**BIOTA SCIENTIFIC MANAGEMENT PTY. LTD.** of 121 William Street, Melbourne in the State of Victoria ("the Principal" or "Biota")/**GLAXO AUSTRALIA PTY LTD** of 1061 Mountain Highway, Boronia in the State of Victoria ("the Principal" or "Glaxo")]

of the first part

{**THE COMMONWEALTH SCIENTIFIC & INDUSTRIAL RESEARCH ORGANISATION** of Limestone Avenue, Campbell, ACT ("the Researcher")/**VICTORIAN COLLEGE OF PHARMACY LTD** of 381 Royal Parade, Parkville in the said State ("the Researcher")}

of the second part

AND:

of
("the Third Party")

of the third part

WHEREAS:

A. The Researcher and the Principal are parties to the Research Agreement under which the Researcher and the Principal have conducted and are conducting research and development in the Agreement Field.

B. The Third Party desires to collaborate with, to be engaged by, to be employed by or to continue to be employed by the Researcher in a programme of research and development which is in whole or in part within the Agreement Field.

C. The Researcher acknowledges that in the course of or as a result of the said collaboration engagement or employment it may have access to or become acquainted with Information. The Researcher acknowledges the desire and right of the Third Party to preserve the secrecy of the Information and agrees to deal with the Information in accordance with the terms set out herein.

D. The Third Party acknowledges that in the course of or as a result of the said collaboration, engagement or employment and/or as a result of access to the Information any or all of the Researcher or the Participants may either alone, in combination or with the Third Party make an invention or discovery, improve on an existing invention, technique or process, or author an original work. The Third Party acknowledges the desire and right of the Researcher and the Participants to preserve the secrecy of Results and to secure to Biota the entire right, title and interest in Results including the right to apply for and have granted in Biota's name any patents, registered designs, copyright or other rights of a like nature throughout the world, so that such rights may be dealt with in accordance with the Research Agreement and the Principal Agreement.

NOW THIS DEED WITNESSES as follows:-

1. **Definitions**

1.1 In this Agreement, unless there is something inconsistent with the context, the following terms and expressions shall have the following meanings:-

(a) **"Agreement Field"** means the identification, synthesis and evaluation of potential Inhibitors.

(b) [**"Glaxo"** means Glaxo Australia Pty Ltd of 1061 Mountain Highway, Boronia/**"Biota"** means Biota Scientific Management Pty Ltd of 121 William Street, Melbourne]

(c) **"Information"** means any and all substances, products, processes, techniques, procedures, methods, formulas, designs, literary works, artistic works and other intellectual property whether or not registrable as patents or designs or protected by copyright to which the Third Party allows the Researcher or the Participants access or with which the Third Party allows the Researcher or the Participants to become acquainted.

(d) **"Inhibitor"** means a compound to inhibit influenza virus and A and B neuraminidase.

(e) **"Participants"** means and any and all persons who are parties to the Principal Agreement together with their holding and subsidiary companies, employees and contractors but only to the extent such persons are engaged in a programme of research and development in the Agreement Field.

(f) **"Principal Agreement"** means an agreement dated the [ ] day of [ ], 19 (as amended) between Biota, Glaxo and other persons in relation to a programme of research in the Agreement Field.

(g) **"Research Agreement"** means the agreement dated the [ ] day of [ ], 19 (as amended) between Biota and the Researcher in relation to a programme of research in the Agreement Field;

(h) **"Results"** means any and all substances, products, processes, techniques, procedures, methods, formulas, designs, literary works, artistic works and other intellectual property and any and all improvements on substances, products, processes, techniques, procedures, methods, formulas, designs, literary works, artistic works and other intellectual property, whether or not same are registrable as patents or designs or protected by copyright which have arisen or arise out of or which have resulted or result in whole or in part from the Researcher's or the Participants' access to or acquaintance with the Information.

1.2 In this Agreement, unless inconsistent with the context, references to the singular shall include references to the plural and vice versa and a reference to any gender shall include a reference to all genders. A reference to persons shall include a reference to corporations and other forms of legal entity and vice versa.

1.3 In this Agreement clause headings are for convenience only and shall not form part of this Agreement nor shall they effect its construction.

2. **Confidentiality**

2.1 The Researcher agrees to keep any and all details of Information strictly secret and confidential and agrees that details of Information will not be disclosed or

permitted to be disclosed to any third party other than in confidence and on a "needs to know" basis only to a Participant who has agreed in writing as follows (and who shall then be known as a "Signed Participant"):

(a) to keep any and all details of Information strictly secret and confidential;

(b) not to disclose Information or permit Information to be disclosed to any third party other than a Signed Participant; and

(c) not to allow the Information to be used for the benefit of any person other than a Signed Participant.

2.2 It is hereby acknowledged and agreed that the details of Information to be kept secret and confidential by the Researcher and Signed Participants shall not include any Information which becomes part of the public knowledge or public literature (otherwise than by reason of a breach by the Researcher or a Signed Participant of its obligations of confidentiality). The onus of proof shall be on the Researcher or the Signed Participants to establish that the exception has application.

2.3 The Third Party agrees to keep any and all details of Results strictly secret and confidential and agrees that details of Results will not be disclosed or permitted to be disclosed to any third party.

2.4 It is hereby acknowledged and agreed that the details of Results to be kept secret and confidential shall not

include any Results which becomes part of the public knowledge or public literature (otherwise than by reason of a breach by the Third Party of its obligations hereunder). The onus of proof shall be on the Third Party to establish that the exception has application.

3. Use of Information and Results

3.1 Irrespective of whether Information is to be kept strictly secret and confidential the Researcher agrees not to allow the Information to be used for the benefit of any third party other than a Signed Participant.

3.2 Upon the cessation of the Third Party's collaboration, engagement or employment with the Researcher or when otherwise directed by the Third Party the Researcher shall forthwith return to the Third Party all documents, records, drawings, production drawings and designs, note books and other similar repositories containing Information, including all copies thereof in the possession of Participants.

3.3 Irrespective of whether Results are to be kept strictly secret and confidential the Third Party agrees not to allow the Results to be used for the benefit of any person other than the Researcher, the Principal or any other person bound by the Principal Agreement.

3.4 Upon the cessation of the Researcher's collaboration with or engagement or employment of the Third Party or when otherwise directed by the Researcher the Third Party

shall forthwith return to the Researcher all documents, records, drawings, production drawings and designs, note books and other similar repositories containing Results, including all copies thereof in the possession of the Third Party.

3.5 The Third Party will not remove Results or any details relating thereto from the premises of the Researcher without the written consent of the Researcher.

3.6 Upon the cessation of the Third Party's collaboration or employment with or engagement of the Researcher or when otherwise directed by the Researcher or Biota the Third Party shall forthwith return to the Researcher all documents, records, drawings, production drawings and designs, note books and other similar repositories containing details of Results, including all copies thereof in the possession of the Third Party.

4. Assignment of Rights

4.1 The Third Party hereby absolutely and irrevocably assigns to ~~the Principal~~ Biota all legal and beneficial right title and interest which it has, may have acquired or may acquire to or in Results. Nothing in this Agreement shall prevent the disclosure of any Information to or use of Information by ~~the Principal's~~ Biota's patent attorneys for purposes related to the patenting of Results.

4.2 The Third Party agrees to do all such acts and things and sign all such documents as ~~the Principal~~ Biota or its legal

representatives may reasonably request to secure to Biota ~~the Principal~~ ownership or rights in the matters referred to in clause 4.1.

4.3 The Third Party agrees to fully co-operate with Biota ~~the Principal~~ and its advisors and to lend its name and assistance to any applications, proceedings, filings, registrations or renewals Biota ~~the Principal~~ wishes to make or effect in relation to any Results.

5. **Third Party's Warranties**

The Third Party warrants and represents to the Researcher and the Principal:-

(a) that it has full right, power, authority and liberty to enter into this Agreement and to perform its duties and obligations hereunder; and

(b) that it has not entered into and will not enter into any Agreement, arrangement, understanding or obligation with any third party which is contrary to or inconsistent with its duties and obligations hereunder.

(c) to the extent any Information has arisen out of or resulted in whole or in part from the Third Party's collaboration or employment with or engagement of any third party, that third party has, in writing, consented to the Third Party disclosing Information pursuant to this Agreement and has given the Third Party the full right, power, authority and liberty to enter into this Agreement and to perform its duties and obligations hereunder.

6. Continuation of Covenants

The Third Party's covenants and undertakings in this Agreement shall not cease upon the cessation of the Third Party's collaboration or employment or engagement with the Researcher and shall continue in full force and effect thereafter for so long as any Information or Results are being or are to be commercially exploited.

7. Assignment by BIOTA

Biota may assign all or any part of its rights, benefits, obligations and responsibilities contained in this Agreement by notice in writing to the Third Party.

IN WITNESS WHEREOF the parties hereto have executed this Agreement the day and year first hereinbefore mentioned.

THE COMMON SEAL of [BIOTA SCIENTIFIC MANAGEMENT PTY LTD/GLAXO AUSTRALIA PTY LTD] was hereunto affixed in accordance with its Articles of Association in the presence of:)

..... Director

..... Secretary

THE COMMON SEAL of {THE COMMONWEALTH SCIENTIFIC & INDUSTRIAL RESEARCH ORGANISATION/ VICTORIAN COLLEGE OF PHARMACY LIMITED} was hereto affixed by the authority of the Executive of the said Organisation in the presence of:)

..... Director

..... Secretary

SIGNED SEALED and DELIVERED by)
in the presence of:)

..... Witness

SCHEDULE 3

(Exploratory Development)

The following is an outline of various areas which are investigated in the course of exploratory development. It is to be understood that there may be other areas which are also the subject of activity, that there may be activities undertaken which are not listed, and that some of the following activities may be undertaken sequentially or in parallel.

1. There will be a pre-clinical programme of animal testing in order to provide a detailed profile of the efficacy and safety of the Compound.

   (a) **Acute Toxicity**

   - single doses at various dosage levels.
   - Several routes (oral, intravenous and others).
   - At least two species (rodent and non-rodent).

   (b) **Pharmacodynamic Activity**

   (c) **Pharmacokinetics**

   - Absorption.
   - Distribution.
   - Metabolism.
   - Excretion.

   (d) **Sub-acute Toxicity**

   - Repeated administration.
   - One month in two species.

   (e) **Reproduction**

   - Fertility.

   (f) **Toxicology**

   - Teratogenicity - ability to cause foetal abnormalities.
   - peri - and post-natal toxicity.

   (g) **Mutagenicity Tests**

   - Ability to cause mutation in bacterial, yeast or mammalian cells.

   (h) **Long-Term Toxicity Studies**

   - Started when active drug identified.
   - Lasts two years or more, very expensive.
   - Carcinogenicity and oncogenicity (ability to cause benign and malignant tumours).

Animal testing lasts up to five years; some testing will overlap initial clinical trials.

2. Production and Formulation

(a) Laboratory synthesis of substances for screening has to be scaled up when extensive animal testing is started. The resulting pilot plant production may use different synthetic routes, different reagents and introduce new contaminants or by-products.

(b) Formulation pharmacists study the physico-chemical properties of the drug in depth then develop and analytically evaluate potential dosage forms:

- Tablets or capsules.
- Granules or powder.
- Cream or ointment.
- Other forms.

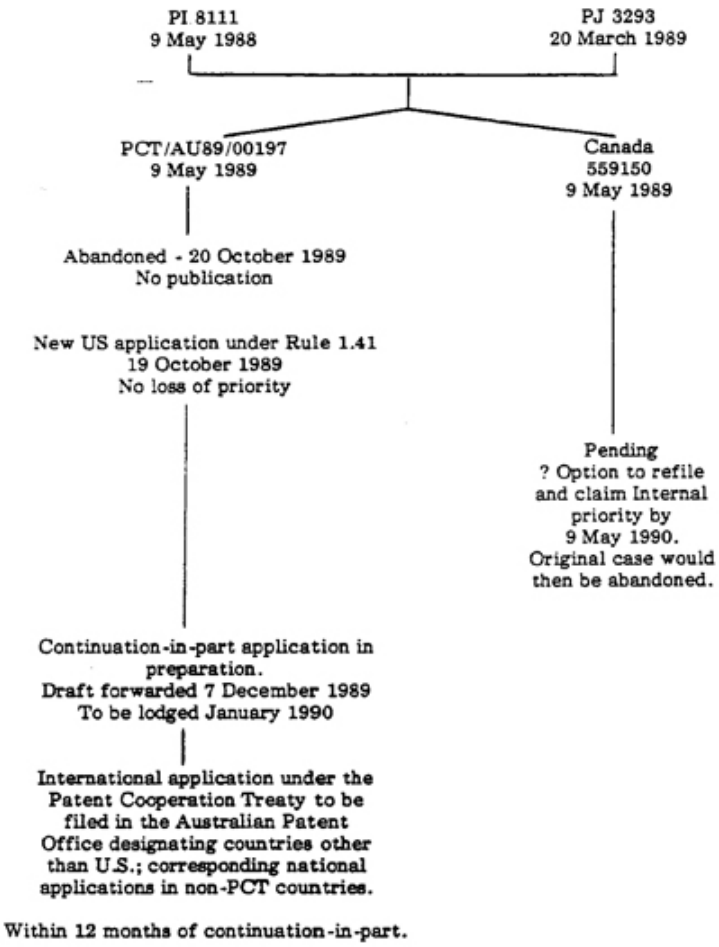
The potential drug is then minutely characterised in terms of:

- Molecular structure and weight.
- Colour.
- Solubility.
- pH.

SCHEDULE 4

(BSM Patent Agenda)

Part A:



Part B:

The Patent Application described in Part B of Schedule 1 will initially be filed as a provisional patent in Australia.

Within 12 months of that filing the Patent Application will be entered as a Patent Co-operation Treaty ("PCT") patent application in all major PCT countries as well as any other country mutually agreed between BSM and Glaxo Australia.

Filings will be made in the following countries/states, unless otherwise agreed:

- European Patent (according to the European Patent Convention)
- Denmark
- Norway
- Australia
- Finland
- Japan
- United States of America
- Soviet Union
- Eire
- New Zealand
- South Africa
- Taiwan
- Greece
- Israel
- Phillipines
- Portugal

BIOTA SCIENTIFIC MANAGEMENT PTY. LTD. THE COMMON SEAL OF *

THE COMMON SEAL of **BIOTA SCIENTIFIC MANAGEMENT PTY LTD** is affixed in accordance with its articles of association in the presence of:

Signature of authorised person	Signature of authorised person
Chairman of Directors	Director
Office held	Office held
COLIN CAMPBELL TRUMBLE	WILLIAM JOHN KERFERD
Name of authorised person	Name of authorised person

BIOTA HOLDINGS LIMITED THE COMMON SEAL OF *

THE COMMON SEAL of **BIOTA HOLDINGS LIMITED** is affixed in accordance with its articles of association in the presence of:

Signature of authorised person	Signature of authorised person
Chairman of Directors	Director
Office held	Office held
COLIN CAMPBELL TRUMBLE	WILLIAM JOHN KERFERD
Name of authorised person	Name of authorised person

THE COMMON SEAL of **GLAXO AUSTRALIA PTY LTD** is affixed in accordance with its articles of association in the presence of:

.....
Signature of authorised person

MANAGING DIRECTOR
Office held

HENRY KENNETH WINDLE
Name of authorised person

.....
Signature of authorised person

DIRECTOR
Office held

ROBERT FOX
Name of authorised person

SIGNED by **TERRY EAVES**, director, for and on behalf of **GLAXO GROUP LIMITED** who hereby certifies that he is authorised so to do in the presence of:

.....
Signature of witness

G. POULTEN
Full name of witness

47 Orchard Grove
Address of witness
Croydon St Peter
Bucks SL9 9ET.

.....
T Eaves

PLL Agts.

GlaxoSmithKline

Our Ref: SCH/hg/~~EX3062/US~~

FILE	~~EX3062/US~~
HDN	
PAR	
RAW	
SPT	
JR	
BCL	
BMBL	
BVL	

SmithKline Beecham plc
980 Great West Road
Brentford
Middlesex
TW8 9GS
Tel. +44 (0)20 8047 5000
www.gsk.com

15 February 2002

By fax and airmail: 00 613 9529 2261

Biota Holdings Limited
Level 4
616 St Kilda Road
Melborne VIC 3004
Australia

For the attention of Simon Tucker

Dear Simon,

Re: Biota – GSK Amendment to 21 February 1990 Agreement

Further to my letter of 16 January 2002, which as we have not received an acknowledgement, I enclose a copy, I look forward to receiving your confirmation that the list attached is complete and that you will inform Griffith Hack that we do not wish to be copied on correspondence in these cases, nor will be responsible for the payment of invoices.

We will be marking these cases as lapsed on our records system and contacting CPA to inform them that Griffith Hack should be billed for renewals.

We have received a copy of Vivien's of 13 February 2002 on US Patent application 09/823766 (Ref: EX3062/US) I will write to Vivien to request that we do not receive any correspondence on this case and that further instructions will follow from you.

I believe that examination is due in at least Canada and Korea on the EX3062 family of cases on **26 February 2002**.

Yours sincerely

pp Siân Hockley

Encl.

Our Ref: SCH/hg

FILE	FLJ
HDN	
PAR	
RAW	
SPT	
JR	
BCL	
SMBL	
BVL	

New Horizons Court
Great West Road
Brentford
Middlesex
TW8 9EP
Tel. +44 (0)20 8975 2000
www.gsk.com

Reg 1 of 3.

16 January 2002

By fax and airmail: 00 613 9529 2261

Biota Holdings Limited
Level 4
616 St Kilda Road
Melbourne VIC 3004
Australia

For the attention of Simon Tucker

Dear Simon,

Re: Biota - GSK Amendment to 21 February 1990 Agreement

Firstly, congratulations on your appointment as Head of Research. Please also pass on my congratulations to Phil Reece although I am sure the loss of Hugh Niall will be felt through out your company.

Turning now to the consolidated final amendment to the 21 February 1990 Agreement, which was signed before Christmas. As the Licence Agreement has now been limited to zanamivir, Glaxo Group Limited's licence under some of Biota's patents/applications i.e. those not listed in Appendix C is terminated. We will therefore no longer be responsible for any costs incurred on these patents/applications or take any role in the prosecution thereof. We will, as agreed, pay the costs incurred in filing the latest selection cases. A list of cases under which we are no longer licenced is as attached, I would appreciate your confirmation that this list is complete.

I trust you will instruct Griffith Hack that correspondence on these cases should no longer be copied to us. We will instruct CPA that Griffith Hack should pay any renewal fees on these cases due after 1 January 2002.

gsk 0082

I note that under the new clause 6.6, Glaxo will deliver up to Biota all such data, samples and information with 180 days commencement at the date of this agreement. Please confirm that you would like all the files relating to the cases listed in the attachment to be sent over to you.

I look forward to continuing working with you on the remaining cases, if you have any questions, please do not hesitate to contact me. I am out of the office the week of 21 January 2002.

Yours sincerely

Siân Hockley

Encl.

Our Ref	Title	Base Application No	Date of base application
AV143	Antiviral Dana Analogues	PK9051	23/10/1991
EX2190	Carboxamide Neuraminidase Inhibitors	GB9510141.6	19/05/1995
GR2122	Carbamate Derivatives of GG167	GB9516276.4	08/08/1995
PX3062	Methods of detection of Influenza Virus and Compounds for Use therein (diagnostic)	PN8397	01/03/1996
PX3159	Method and novel Compounds for Use therein (macromolecules)	PO3632	14/11/1996
PX4189	Novel Chemical Compounds and their Use (dimer)	PP9139	12/03/1999
PX4245	Multimeric neuraminidase inhibitors long lasting multimers of Zanamivir.	PQ4824	22/12/1999
PX4176 (PX4495)	Compositions for the Prevention and Treatment of Influenza (multimer) and PX4495 - our reference for the foreign filing	PR0010	08/09/2000
PG4490	Process for the preparation of intermediates for the preparation of zanamivir dimers/multimers.	PR7574	07/09/2001
PG4527	Selection application - Zanamivir Dimers - Aryl Linker Compounds	PR8797	09/11/2001
PG4525	Selection application - Zanamivir Dimers - Alkyl Linker Compounds	PR8795	09/11/2001
PG4526	Selection application - Zanamivir Dimers - Bis Aryl Linkers.	PR8798	09/11/2001
PX4672	Selection application - Zanamivir Dimers - non-aromatic bis amides	PR8794	09/11/2001

AV6000

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 Statements on Form S-3 (No. 333-190594) and S-8 (No. 333-188111) of Biota Pharmaceuticals, Inc. of our report dated September 26, 2013 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

PricewaterhouseCoopers
Melbourne, Australia
September 27, 2013

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, 2013 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 15(d)-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 27, 2013

/s/ Russell H. Plumb

President, Chief Executive Officer, Chief Financial Officer, Secretary and Treasurer

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, 2013, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of 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, Secretary and Treasurer

September 27, 2013