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

FORM 10-Q

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

For the quarterly period ended March 31, 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 No.)**

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	x
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 x

The number of shares outstanding of the registrant's common stock, par value $0.10 per share, at May 5, 2013, was 28,423,990 shares.

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PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

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

	March 31, 2013	June 30, 2012
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 70,265	$ 53,790
Accounts receivable	15,173	5,966
Prepaid and other current assets	1,847	1,374
Total current assets	87,285	61,130
Non-current assets:		
Property and equipment, net	4,173	4,944
Intangible assets, net	818	1,804
Deferred tax assets	2,563	1,419
Total non-current assets	7,554	8,167
Total assets	$ 94,839	$ 69,297
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,282	$ 2,851
Accrued expenses	5,935	6,133
Accrued severance obligations	3,858	-
Deferred revenue	650	398
Deferred tax liabilities	1,714	130
Total current liabilities	14,439	9,512
Non-current liabilities:		
Other liabilities, net of current portion	296	504
Total non-current liabilities	296	504
Total liabilities	14,735	10,016
Stockholders' equity:		
Common stock, $0.10 par value; 200,000,000 shares authorized 34,219,690 shares issued and 182,350,316 shares outstanding at March 31, 2013 and June 30, 2012, respectively	3,422	100,394
Additional paid-in capital	234,775	668
Treasury stock, 5,867,361 and 1,816,178 at cost, at March 31, 2013 and June 30, 2012, respectively	(117,048)	(1,397)
Accumulated other comprehensive income	31,053	29,516
Accumulated deficit	(72,098)	(69,900)
Total stockholders' equity	80,104	59,281
Total liabilities and stockholders' equity	$ 94,839	$ 69,297

See accompanying notes to these financial statements.

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2013	**2012**	**2013**	**2012**
Revenue:				
Royalty revenue and milestones	$ 7,709	$ 5,189	$ 9,636	$ 6,649
Revenue from services	4,787	1,879	14,468	6,611
Other	-	22	242	69
Total revenue	12,496	7,090	24,346	13,329
Operating expense:				
Cost of revenue	4,094	1,787	12,731	6,047
Research and development	4,936	5,713	13,583	17,769
General and administrative	3,436	2,220	13,704	5,871
Total operating expense	12,466	9,720	40,018	29,687
Income/(loss) from operations	30	(2,630)	(15,672)	(16,358)
Non-operating income:				
Gain recorded on merger	-	-	7,805	-
Research and development credit	-	-	4,428	-
Interest income	173	739	1,125	2,565
Total non-operating income	173	739	12,358	2,565
Income (loss) before tax	203	(1,891)	(2,314)	(13,793)
Income tax benefit/(expense)	12	(146)	116	504
Net income (loss)	$ 215	$ (2,037)	$ (2,198)	$ (13,289)
Basic income (loss) per share	$ 0.01	$ (0.09)	$ (0.08)	$ (0.59)
Diluted income (loss) per share	$ 0.01	$ (0.09)	$ (0.08)	$ (0.59)
Basic weighted-average shares outstanding	28,162,295	22,709,008	28,145,541	22,709,008
Diluted weighted-average shares outstanding	28,182,697	22,709,008	28,145,541	22,709,008
Comprehensive income (loss):				
Net income (loss)	$ 215	$ (2,037)	$ (2,198)	$ (13,289)
Exchange differences on translation of foreign operations, net of tax	536	1,610	1,537	(1,456)
Total comprehensive income (loss)	$ 751	$ (427)	$ (661)	$ (14,745)

See accompanying notes to these financial statements.

Biota Pharmaceuticals, Inc.

Condensed Consolidated Statements of Stockholders' Equity
(unaudited)
(in thousands, 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, 2012	182,350,316	$ 100,394	$ 668	(1,816,178)	$ (1,397)	$ (69,900)	$ 29,516	$ 59,281
Comprehensive income								
Exchange differences on translation of foreign operations							1,537	1,537
Net loss						(2,198)		(2,198)
Total Comprehensive income								(661)
New shares issued on exercise of options	413,335	410	(410)					-
New shares issued on vesting of options on merger	4,639,104	1,118	(1,118)					-
Acquisition of Nabi Biopharmaceuticals	(153,398,048)	(98,521)	233,367	(4,051,183)	(115,651)			19,195
Restricted stock units, net	214,983	21	(21)					-
Share-based compensation			2,289					2,289
Balances at March 31, 2013	34,219,690	$ 3,422	$ 234,775	(5,867,361)	$ (117,048)	$ (72,098)	$ 31,053	$ 80,104

See accompanying notes to the financial statements.

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

	Nine Months Ended March 31,	
	2013	**2012**
Cash flows from operating activities:		
Net loss	$ (2,198)	$ (13,289)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,447	2,463
Share-based compensation	2,289	424
Gain recorded on merger	(7,805)	-
Change in operating assets and liabilities (net of liabilities acquired):		
Accounts receivables	(8,667)	(5,462)
Prepaid expenses and other current assets	(445)	(360)
Deferred tax assets	414	(504)
Deferred revenue	237	255
Accounts payable and accrued expenses	(1,607)	(1,993)
Accrued severance obligations	(1,032)	-
Net cash used in operating activities	(16,367)	(18,466)
Cash flows from investing activities:		
Cash acquired from merger	32,687	-
Purchases of property and equipment	(490)	(1,062)
Proceeds from sale of property and equipment	-	8
Net cash provided by (used in) investing activities	32,197	(1,054)
Increase (decrease) in cash and cash equivalents	15,830	(19,520)
Cash and cash equivalent at beginning of period	53,790	74,177
Effects of exchange rate movements on cash and cash equivalents	645	(1,319)
Cash and cash equivalents at end of period	$ 70,265	$ 53,338
Supplemental cash flow disclosure:		
Proceeds from the issuance of common stock on merger	$ 27,000	$ -
Proceeds to settle accrued severance obligations and other accrued liabilities on merger	5,687	-
Cash acquired on merger	$ 32,687	$ -

See accompanying notes to these 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 innovative anti-infective 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 and the resulting company was renamed Biota Pharmaceuticals, Inc.

The Company is currently focused on developing oral, small molecule compounds to treat a number of infections, with its clinical-stage programs being directed toward respiratory diseases, including those caused by influenza A and B, and human rhinovirus ("HRV"). In addition, it has preclinical research programs directed toward developing products to treat respiratory syncytial virus ("RSV") as well as a broad spectrum of gram negative 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 pursuant to a research and license agreement entered into with the Company in 1990. In addition, the Company has cross-licensed intellectual property related to second-generation long-acting neuraminidase inhibitors ("LANI") with Daiichi Sankyo Company Ltd ("Daiichi Sankyo"), of which the lead product, laninamivir octanoate, was developed and is being marketed by Daiichi Sankyo as lnavir® Dry Powder Inhaler ("Inavir®") in Japan for the treatment of influenza A & B infections. 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 the U.S. Office of Biomedical Advanced Research and Development Authority ("BARDA") designed to provide up to $231 million for the completion of clinical development and United States ("U.S.") based manufacturing of laninamivir octanoate for the treatment of influenza A and B infections.

Although the Company's influenza products have been successfully 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 commercial capabilities. Therefore, it is possible that the Company may not successfully derive any significant product revenues from any of its existing or future product candidates.

(2) Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. In the opinion of the Company's management, all material adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Certain information and footnotes disclosure normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to instructions, rules and regulations prescribed by the U.S. Securities and Exchange Commission ("SEC"). Except as disclosed herein, there has been no material change in the information disclosed in the notes to the consolidated financial statements included in our Form 8-K/A filed on January 23, 2013.

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

Operating results for the nine months ended March 31, 2013 are not necessarily indicative of the results that may be expected for the year ending June 30, 2013.

For a more complete discussion of the Company's significant accounting policies and other information, this report should be read in conjunction with the consolidated financial statements for the year ended June 30, 2012 included in the Company's Current Report filed on Form 8-K/A that was filed with the SEC on January 23, 2013.

The Company's significant accounting policies have not changed since December 31, 2012, except as outlined below:

Recent Accounting Standards

In February 2013, the Financial Accounting Standards Board ("FASB") issued ASU 2013-02, Comprehensive Income (Topic 220): Reporting of Amounts Reclassified out of Accumulated Other Comprehensive Income. Adoption of the new guidance did not have an impact on the Company's consolidated financial statements.

In March 2013, FASB issued ASU 2013-05, Foreign Currency Matters (Topic 830): Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity (a consensus of the FASB Emerging Issues Task Force), effective prospectively for fiscal years (and interim reporting periods within those years) beginning after December 15, 2013. The Company does not expect adoption will have a material impact on its consolidated financial statements.

(3) Merger

Reverse Stock Split

On November 8, 2012, in connection with the merger - described below 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

On November 8, 2012, Nabi and Biota Holdings Limited completed a merger (the "Merger"), and 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 million in net cash on hand on the date of the merger. 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 merger, 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 thousands)	$18,963
Number of stock options outstanding to former Nabi employees and directors	508,918
Fair value per option	$0.456
Implied purchase consideration (in thousands)	$232
Total implied purchase consideration (in thousands)	$19,195

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

Cash	$32,687
Accrual for severance obligations and employee benefits	(4,977)
Accounts payable	(694)
Other liabilities	(16)
Net cash received	$27,000
Excess of net assets acquired over total fair value purchase consideration/gain recorded on merger	$7,805

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, including NicVAX® or any next-generation nicotine vaccine, or the potential royalty of Phoslyra that was sold to a third party in 2006.

Pursuant to the merger, Biota Holdings Limited received net cash of $27 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 non-operating income in the condensed consolidated statements of operations.

Acquisition-related Costs

Acquisition-related costs associated with the merger, including advisory, investment banking, legal, accounting and various other costs of Nil and $4.6 million have been included as a general and administrative expense for the three and nine month periods ended March 31, 2013, 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 thousands, expect per share data).

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2013	**2012**	**2013**	**2012**
Pro forma net revenue	$13,128	$7,722	$25,610	$8,792
Pro forma net loss	$(3,986)	$(2,473)	$(8,931)	$(13,600)
Pro forma basic loss per share	$(0.14)	$(0.11)	$(0.32)	$(0.60)
Pro forma diluted loss per share	$(0.14)	$(0.11)	$(0.32)	$(0.60)

(4) Net Income (Loss) per Share

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

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2013	**2012**	**2013**	**2012**
Net income (loss) (in thousands)	$215	$(2,037)	$(2,198)	$(13,289)
Weighted-average shares outstanding	28,165,295	181,664,389	28,145,541	181,664,389
Weighted- average shares outstanding adjusted using exchange ratio used to compute basic earnings per share	-	22,709,008	-	22,709,008
Dilutive effect of restricted stock and stock options	20,402	-	-	-
Shares used to compute diluted earnings per share	28,182,697	22,709,008	28,145,541	22,709,008
Basic income (loss) per share	$0.01	$(0.09)	$(0.08)	$(0.59)
Diluted income (loss) per share	$0.01	$(0.09)	$(0.08)	$(0.59)

(5) Share-Based Compensation

A summary of stock option grants outstanding as of March 31, 2013, and the related activity during the nine months ended March 31, 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 (reverse stock split)		(2,544,716)	
Vested and exercised upon merger	(6,455,282)	-	
Balance on November 8, 2012 (date of merger)	-	508,918	
Post-merger transactions:			
Granted	-	-	931,590
Expired	-	(16,979)	-
Outstanding at March 31, 2013	-	491,939	931,590
Exercisable at March 31, 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.

On November 12, 2012, the Company granted options to purchase 931,590 shares of common stock at an exercise price of $4.07. The grant becomes exercisable in three equal installments on the first, second and third anniversary of the grant date. The options have a 10 year term. The Company estimated the fair value of each stock option on the date of grant, using the Black-Scholes option-pricing formula, to be $2.72 using the following key assumptions:

Expected Term: The expected term represents the period over which the share-based awards are expected to be outstanding based on the Company's historical experience. The Company estimated an expected term of 5 years.

Risk-Free Interest Rate: The Company used a risk-free rate of 0.65%, 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 83.84%, 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.

The Company amortizes share-based compensation expense over the option's vesting period using the straight-line attribution approach. For the three and nine month periods ended March 31, 2013, the Company recognized approximately $0.1 million and $0.3 million respectively of share-based compensation expense related to the issuance of stock option grants.

A summary of outstanding restricted stock awards as of March 31, 2013, and the related activity during the nine month period ending March 31, 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	-	214,983
Vested	-	(71,661)
Outstanding at March 31, 2013	Nil	143,322

On November 12, 2012, the Company granted 214,983 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. For the three month and nine month periods ended March 31, 2013, the Company recognized approximately $0.2 million and $0.3 million of share-based compensation expense related to the issuance of restricted stock units.

As of March 31, 2013, there was $2.7 million of unrecognized compensation expense related to unvested share-based compensation arrangements. This expense is expected to be recognized over the next two years as the shares vest.

(6) 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 nine month period ending March 31, 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.

(7) 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 net sales of Inavir® in Japan, pursuant to a collaboration and license agreement that the Company entered into with Daiichi Sankyo in 2009 related to the development and commercialization of second generation, LANI, including laninamivir octanoate. In September 2010, laninamivir octanoate was approved for sale by the Japanese Ministry of Health and Welfare for the treatment of influenza, 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 commercial milestone payments. Under the collaboration and license agreement, the Company and Daiichi Sankyo have cross-licensed 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 to establish U.S. based manufacturing, to support the filing of a U.S. new drug application ("NDA") with the FDA for laninamivr 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 $22.5 million has been recognized to-date pursuant to this contract.

The following tables summarize the key components of the Company's revenues for the three month and nine month periods ended March 31, 2013 and 2012:

	Three Months Ended March 31,	
	2013	2012
	(in millions)	
Royalty revenue – Relenza™	$1.7	$1.7
– Inavir®	3.2	3.6
Commercial milestone – Inavir®	2.9	-
Service revenue under BARDA contract	4.5	1.7
Revenue under other contracts, grants and collaborations	0.2	0.1
Total revenue	$12.5	$7.1

	Nine Months Ended March 31,	
	2013	**2012**
	(in millions)	
Royalty revenue – Relenza™	$2.7	$2.4
– Inavir®	4.1	4.3
Commercial milestone – Inavir®	2.9	-
Service revenue under BARDA contract	13.7	6.2
Revenue under other contracts, grants and collaborations	1.0	0.4
Total revenue	$24.4	$13.3

(8) Subsequent Event

On April 15, 2013, the Company announced that its Board of Directors has adopted a revised corporate strategy following the recent completion of management's strategic and operational review of the organization and its various development programs. The implementation of this strategy will shift the Company's primary strategic and operational focus from early-stage research to clinical-stage development programs. As a result of adopting this strategy, the Company has rationalized its preclinical programs, realigned its resources, and reduced its workforce by approximately 30%.

Accordingly, the Company anticipates recording a charge of approximately $2.0 million in the fourth quarter of its 2013 fiscal year (the Company's fiscal year-end is June 30) related to the cost of one-time termination benefits.

On May 1, 2013 the Board of Directors retired 5,867,361 shares of the Company's treasury stock.

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

FORWARD LOOKING STATEMENTS

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

- *Our plans to continue to advance the clinical development of laninamivir octanoate, including the anticipated initiation of a Phase 2 clinical trial, including the design and size;*
- *the timing and our plans to shift our focus from early-stage research to clinical-stage development programs, rationalize the number of preclinical programs we plan to support and the anticipated therapeutic focus of those remaining programs;*
- *our plans to pursue in-licensing, acquisition, co-development or other similar collaboration opportunities to better balance our pipeline with additional clinical-stage development programs;*
- *the timing and our plans to complete clinical and regulatory evaluations and make a determination as to whether we will independently advance the clinical development of vapendavir;*
- *our plans to conclude our ongoing activities related to our preclinical gram-positive antibiotic and hepatitis C non-nucleoside polymerase inhibitor programs and continue to seek to out-license these programs;*
- *our ability to conserve capital by reducing our current cost structure, the estimated amount of these savings, and our plan to deploy capital resources toward new clinical-stage development opportunities;*
- *our estimated base cash burn from operations, the receipt of a commercial milestone and expected cash on hand;*
- *our anticipation that revenue and the related cost of providing services under our BARDA contract will continue to increase in the near-future, assuming the program continues to advance further into clinical development;*
- *our anticipation that we will generally incur future net losses from operations due to our intention to continue to support the preclinical and clinical development of our product candidates;*
- *our anticipation that we will not qualify for the research and development credit for the current fiscal year;*
- *our future financing requirements, the factors that may influence the timing and amount of these 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 statements reflect our current views with respect to future events and are based on assumptions and subject to key risks and uncertainties including, without limitation: BARDA, or we, not terminating or significantly amending our existing contract to develop laninamivir octanoate in the U.S.; GSK or Daiichi Sankyo continuing to generate net sales from Relenza™ and Inavir®, respectively, and otherwise continuing to fulfill their obligations under our royalty-bearing license agreements with them in the future; we, BARDA, the FDA or similar foreign regulatory agency, a data safety monitoring board, or an institutional review board, delaying, limiting, suspending or terminating the clinical development of laninamivir octanoate at any time for a lack of safety, tolerability, anti-viral activity, commercial viability, regulatory or manufacturing issues, or any other reason whatsoever; the results of research activities 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 for successfully enrolling and managing clinical trials on a timely basis; our ability to comply with extensive government regulations in various countries and regions that we expect to conduct clinical trials in that are applicable to our business; our ability to satisfactorily manage the integration of the recent merger and our operations in the future; our ability to successfully in-license, acquire, or enter into co-development or other similar collaboration opportunities to better balance our pipeline at appropriate terms:our ability to maintain and or recruit sufficient human resources, including executive management and key employees; our ability to secure manage and retain qualified third-party clinical research, preclinical research, data management and contract manufacturing organizations who we rely on to assist us in the design, development and implementation of the clinical development of our product candidates, third-party contract research, data management and manufacturing organizations not fulfilling their contractual obligations or otherwise performing satisfactorily in the future; our ability to maintain sufficient quantities of preclinical and clinical trial material on hand to 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 market our product candidates; our ability to protect and maintain our proprietary intellectual property rights from unauthorized use by others or not infringe on the intellectual property rights of others; the condition of the financial equity and debt markets and our ability to raise sufficient funding in such markets; our ability to manage our current cash reserves as planned; changes in general economic business or competitive conditions related to industry or product candidates; and other statements contained elsewhere in this Quarterly Report on Form 10-Q (including the "Risk Factors" in Part II, Item 1A of this Quarterly Report).

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

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

The following is a discussion and analysis of the major factors contributing to results of operations for the three and nine months ended March 31, 2013, and our financial condition at that date, and should be read in conjunction with the unaudited financial statements and the notes thereto included in Item 1 of this Quarterly Report on Form 10-Q.

Company Overview

Biota Pharmaceuticals, Inc. together with its wholly owned subsidiaries ("Biota", the "Company", "us" or "we") is 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 have been incorporated in the state of Delaware since 1969 and our corporate headquarters are located in Alpharetta, Georgia. On November 8, 2012, Nabi Biopharmaceuticals ("Nabi") merged with Biota Holdings Limited and the resulting company was renamed Biota Pharmaceuticals, Inc.

We are currently focused on developing oral, small molecule compounds to treat a number of viral infections, with our most advanced clinical-stage programs being directed toward respiratory diseases, including those caused by influenza A and B, and human rhinovirus (“HRV”). In addition, we have several preclinical stage programs focused on developing respiratory syncytial virus (“RSV”) as well as novel antibiotics designed to treat a broad spectrum gram negative bacterial infections.

We have developed a neuraminidase inhibitor, zanamivir, which is marketed worldwide by GlaxoSmithKline (“GSK”) as Relenza™ for the prevention and treatment of influenza pursuant to a royalty-bearing research and license agreement we entered into with GSK in 1990. In addition, we have cross-licensed intellectual property related to second-generation long acting neuraminidase inhibitors ("LANI"), including laninamivir octanoate and generate royalty revenue pursuant to a collaboration and license agreement that we 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 A and B in adults and children. Laninamivir octanoate is marketed in Japan by Daiichi Sankyo as Inavir®. We have filed an Investigational New Drug application (“IND”) with the United States Food and Drug Administration (“FDA”) to develop laninamivir octanoate, and in 2012 we entered into a contract with the U.S. Office of Biomedical Advanced Research and Development Authority (“BARDA”) designed to provide up to $231 million in support of the clinical development and U.S. based manufacturing for laninamivir octanoate for the treatment of influenza A and B infections.

Although our influenza products have been successfully commercialized by other larger pharmaceutical companies under license agreements, we have not received regulatory approval for any product candidates we have developed independently, and we do not have any 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 product candidates.

We plan to continue to finance our operations with our existing cash and cash equivalents; proceeds from existing or potential future royalty-bearing licenses, government contracts, or collaborative research and development arrangements; future equity and/or debt financings; and, other financing vehicles. Our ability to continue our operations is dependent, in the near-term, upon managing our cash resources, our continued receipt of royalty revenues and service revenue from the BARDA contract, entering into future collaboration or partnership agreements, the successful development of our product candidates, executing future financings and ultimately, upon the approval of our products for sale and achieving positive cash flows from operations. There can be no assurance that additional capital will be available on terms acceptable to us in the future, or that we will ever generate significant product revenue and become operationally profitable on a consistent basis.

Recent Corporate Developments

Board appointments. On May 6, 2013, we announced a number of changes to our Board of Directors, including the resignations of Dr. Raafat Fahim and Mr. Paul Bell, as well as the appointment of Ms. Anne VanLent and Mr. Michael Dougherty as directors.

Laninamivir Octanoate. We have been notified by Daiichi Sankyo Company Ltd., our partner in Japan, that in the three month period ended March 31, 2013, net sales of Inavir® (laninamivir octanoate) surpassed a key threshold that resulted in us earning a $2.9 million commercial milestone payment from Daiichi Sankyo. We recognized the amount as revenue in the three-month period ended March 31, 2013, and anticipate receiving the milestone payment by June 30, 2013.

Adoption of Revised Corporate Strategy. On April 15, 2013, we announced that our Board of Directors had adopted a corporate strategy following the recent completion of management’s strategic and operational review of the organization and its various development programs. The implementation of this strategy will shift our primary strategic and operational focus from early-stage research to clinical-stage development programs. As a result of us adopting this strategy, we rationalized our preclinical programs, re-aligned resources and reduced our work force by approximately 30%. We anticipate recording a charge of approximately $2.0 million in the fourth quarter of 2013 related to the cost of one-time termination benefits.

Key components of our adopted strategy include, but are not limited to:

- Continuing to fully support and advance the development of laninamivir octanoate for the treatment of influenza A and B infections in the U.S. market under our existing contract with BARDA;
- Reducing the number of our existing preclinical programs by focusing preclinical activities on developing an oral antiviral for RSV and an oral/IV antibiotic targeting GyrB/ParE with activity against gram-negative and multi-drug resistant bacterial pathogens;
- Concluding preclinical activities related to our hepatitis C non-nucleoside polymerase inhibitors and antibiotics for gram-positive bacterial infections, while continuing to pursue out-licensing opportunities for these programs;
- Completing, over the next several quarters, our evaluation of various clinical and regulatory pathways for vapendavir to determine whether to independently continue its late-stage clinical development for the reduction of exacerbations caused by HRV in patients with moderate to severe asthma or chronic obstructive pulmonary disease ("COPD");
- Pursuing in-licensing, acquisition, co-development, and other similar collaborative clinical-stage development opportunities to better balance our pipeline; and
- Reduce our cost structure to provide flexibility to deploy additional resources toward clinical-stage development programs.

In connection with the adoption of this strategy we have reduced our workforce by approximately 30%. As a result, we anticipate recording a charge of approximately $2.0 million in the fourth quarter of our 2013 fiscal year (our fiscal year-end is June 30) related to the cost of one-time termination benefits.

Merger between Nabi Biopharmaceuticals and Biota Holdings Limited. On November 8, 2012, we announced that Nabi and Biota Holdings Limited had completed a merger, resulting in Biota Holdings Limited becoming a wholly-owned subsidiary of Nabi, and the Company being 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, which consisted primarily of $27 million in net cash on the date of the merger.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

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

- Use of Estimates
- Revenue Recognition
- Research and Development Expense
- Share-Based Compensation

In February and March 2013, the FASB issued ASU No. issued ASU 2013-02 and 2013-05, we adopted ASU 2013-02 and we do not anticipate the future adoption of ASU 2013-05 will have a material impact on our consolidated financial statements.

Results of Operations

Three Months Ended March 31, 2013 and March 31, 2012

Summary. We reported net income of $0.2 million for the three months ended March 31, 2013 as compared to net loss of $2.0 million for the same period in 2012. The $2.2 million improvement from a net loss in 2012 to net income in 2013 was primarily the result of a $5.4 million increase in revenue and a $0.1 million decrease in income tax expense offset, in part by a $2.8 million increase in total operating expenses, a $0.5 million decrease in interest income.

Although we reported net income in the two most recent quarters, we generally expect to incur net losses in the near-term as we intend to continue to support the preclinical and clinical development of our product candidates.

Revenue. Revenue increased to $12.5 million for the three months ended March 31, 2013 from $7.1 million in the same period of 2012, primarily as a result of earning a commercial milestone and increased service revenue in 2013. The following table summarizes the key components of our revenue for the three months ended March 31, 2013 and 2012:

	Three Months Ended March 31,	
	2013	2012
	(in millions)	
Royalty revenue – Relenza™	$1.7	$1.7
– Inavir®	3.2	3.6
Commercial milestone – Inavir®	2.9	-
Service revenue under BARDA contract	4.5	1.7
Revenue under other contracts, grants and collaborations	0.2	0.1
Total revenue	$12.5	$7.1

The net sales of Inavir® (laninamivir octanoate) in Japan surpassed a key threshold in the three month period ended March 31, 2013, resulting in us earning a $2.9 million commercial milestone payment from Daiichi Sankyo. Service revenue under the BARDA contract increased due to the advancement of the laninamivir octanoate program toward Phase 2 clinical development and the expansion of the underlying activities covered under the contract. We anticipate that our revenue under the BARDA contract will continue to increase, assuming the program continues to advance further into clinical development.

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 increased to $4.1 million for the three months ended March 31, 2013 from $1.8 million in the same period in 2012, due principally to the advancement of the laninamivir octanoate program under the BARDA contract and the expansion of the underlying activities covered under that contract. We anticipate that our cost of revenue under the BARDA contract will continue to increase assuming the program continues to advance further into clinical development.

Research and development expense. Research and development expense decreased to $4.9 million in the three months ended March 31, 2013 from $5.7 million in the same period in 2012. The following table summarizes the key components of our research and development expense for the three months ended March 31, 2013 and 2012:

	Three Months Ended March 31,	
	2013	2012
	(in millions)	
Direct preclinical, clinical and product development expense	$1.7	$2.3
Salaries, benefits and share-based compensation expense	1.5	2.0
Depreciation and facility-related expense	0.9	0.9
Other expenses	0.8	0.5
Total research and development expense	$4.9	$5.7

Direct preclinical, clinical and product development expense decreased by $0.6 million largely due to the completion of the vapendavir Phase 2 clinical trial during the quarter ended June 30, 2012. Salaries, benefits and share-based compensation expense decreased by $0.5 million due to more staff being deployed on the laninamivir octanoate program under the BARDA contract, which resulted in their related costs being reflected in Cost of Revenue.

General and administrative expense. General and administrative expense increased to $3.4 million for the three months ended March 31, 2013 from $2.2 million for the same period in 2012. The following table summarizes the components of our general and administrative expense for the three months ended March 31, 2013 and 2012:

	Three Months Ended March 31,	
	2013	2012
	(in millions)	
Salaries, benefits and share-based compensation expense	1.4	0.7
Professional and legal expense	0.7	0.2
Other expenses	1.3	1.3
Total general and administrative expense	$3.4	$2.2

Salaries, benefits and share-based compensation expense increased by $0.7 million primarily related to the addition of executive and administrative staff in the U.S. Professional and legal expense increased by $0.5 million due to the integration and transition of our operations subsequent to the merger in November 2012.

Non-operating income. Non-operating income decreased by $0.6 million for the three months ended March 31, 2013 as compared to the same period in 2012, as a result of a decrease in interest income due to lower available interest rates in 2013 as compared to 2012, as well as lower average cash balances held in 2013 as compared to 2012.

Nine Months Ended March 31, 2013 and March 31, 2012

Summary. We reported a net loss of $2.2 million for the nine months ended March 31, 2013, as compared to net loss of $13.3 million for the same period in 2012. This $11.1 million improvement in our net loss in 2013 was primarily the result of a $11.1 million increase in revenue, a $7.8 million gain we recorded pursuant to the merger, and the receipt of a $4.4 million in research and development credits, offset in part by a $10.2 million increase in operating expenses, a $1.4 million decrease in interest income and a $0.4 million decrease in income tax benefits.

We expect to generally incur net losses in the near-term as we intend to continue to support the research and the preclinical and clinical development of our product candidates.

Revenue. Revenue increased to $24.4 million for the nine months ended March 31, 2013 from $13.3 million in the same period of 2012, primarily as a result of a commercial milestone we earned and an increase in service revenue in 2013. The following table summarizes the key components of our revenue for the nine months ended March 31, 2013 and 2012:

	Nine Months Ended March 31,	
	2013	**2012**
	(in millions)	
Royalty revenue – Relenza™	$2.7	$2.4
– Inavir®	4.1	4.3
Commercial milestone – Inavir®	2.9	-
Service revenue under BARDA contract	13.7	6.2
Revenue under other contracts, grants and collaborations	1.0	0.4
Total revenue	$24.4	$13.3

The net sales of Inavir® (laninamivir octanoate) in Japan surpassed a key threshold in the nine month period ended March 31, 2013, resulting in us earning a $2.9 million commercial milestone payment from Daiichi Sankyo. Service revenue under the BARDA contract increased due to the advancement of the laninamivir octanoate program and the expansion of the underlying activities covered under the contract. We anticipate that our revenue under the BARDA contract will continue to increase assuming the program continues to advance further into clinical development. Revenue under other contracts, grants and collaborations increased in 2013 due to a new government grant of $0.2 million and an increase in other research collaborations for $0.3 million.

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 increased to $12.7 million for the nine months ended March 31, 2013 from $6.0 million in the same period in 2012, due principally to the advancement of the laninamivir octanoate program under the BARDA contract, and the expansion of the underlying activities covered under the contract. We anticipate that our costs of providing services under the BARDA contract will continue to increase, assuming the program continues to advance further into clinical development.

Research and development expense. Research and development expense decreased to $13.6 million in the nine months ended March 31, 2013 from $17.8 million in the same period in 2012. The following table summarizes the components of our research and development expense for the nine months ended March 31, 2013 and 2012:

	Nine Months Ended March 31,	
	2013	**2012**
	(in millions)	
Direct preclinical, clinical and product development expense	$4.2	$7.6
Salaries, benefits and share-based compensation expense	5.8	6.6
Depreciation and facility-related expense	2.7	2.7
Other expenses	0.9	0.9
Total research and development expense	$13.6	$17.8

Direct preclinical, clinical and product development expense decreased by $3.4 million in 2013 due largely to the completion of the vapendavir Phase 2 clinical trial during the quarter ended June 30, 2012 representing a $2.8 million reduction, as well as a reduction of $1.4 million in preclinical costs associated with our antibacterial and hepatitis C programs. Salaries, benefits and share-based compensation expense decreased by $0.8 million due to more staff being deployed on to the laninamivir octanoate program under the BARDA contract, which resulted in their related costs being reflected in Cost of Revenue.

General and administrative expense. General and administrative expense increased to $13.7 million for the nine months ended March 31, 2013 from $5.9 million for the same period in 2012. The following table summarizes the components of our general and administrative expense for the nine months ended March 31, 2013 and 2012:

	Nine Months Ended March 31,	
	2013	2012
	(in millions)	
Merger-related expense	$4.6	$-
Salaries, benefits and share-based compensation expense	5.0	3.0
Professional and legal expense	1.4	0.7
Other expenses	2.7	2.2
Total general and administrative expense	$13.7	$5.9

Salaries, benefits and share-based compensation expense increased due to a $1.6 million increase related to the addition of executive and administrative staff in the U.S., and an increase in other personnel-related expenses. Professional and legal expense increased by $0.7 million due to the integration and transition of our operations subsequent to the merger in November Other expenses increased due to generally higher insurance, rent and maintenance costs.

Non-operating income. Non-operating income increased by $10.8 million for the nine months ended March 31, 2013 as compared to the same period in 2012, due to primarily to a $7.8 million gain we recorded related to the merger (see Note 3 to the consolidated financial statements), as well as the receipt of $4.4 million with respect to an Australian research and development credit (see Note 6 to the consolidated financial statements). Interest income decreased by $1.4 million 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. We do not expect to receive additional research and development credits in 2013 fiscal year as we anticipate our revenue will exceed the qualifying revenue threshold.

LIQUIDITY AND CAPITAL RESOURCES

For the nine months ended March 31, 2013, cash and cash equivalents increased by $16.5 million, from $53.8 million to $70.3 million. This increase was primarily the result of $32.7 million of cash received as a result of the merger as described in Note 3 to the consolidated financial statements, offset in part by cash used for operating activities and other investing activities during the period.

Net cash used in operating activities was $16.4 million for the nine months ended March 31, 2013, which reflected (i) our net loss for the period of $2.2 million that included a gain of $7.8 million we recorded as a result of the merger, (ii) an increase in net operating assets of $8.7 million, (iii) a net decrease in operating liabilities of $2.4 million, offset in part by non-cash charges for share-based compensation and derpreciation an amortization of $4.7 million. Our net loss resulted largely from our funding of contract services; 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 to a large degree by contract service, 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 $8.6 million increase in accounts receivable due to a sales milestone earned and contract revenue billed, a $0.4 million increase in prepaid expenses, a $1.6 million decrease in accounts payable and accrued expenses and a decrease of $1.0 million in accrued severance obligations related to the merger, offset in part by a $0.2 million increase in deferred revenue.

Net cash provided from investing activities during the nine months ended March 31, 2013 was $32.2 million, which was largely due to the cash of $32.7 million we received as pursuant to the merger, offset in part by $0.5 million for the purchase of laboratory and computer equipment.

At March 31, 2013, our cash and cash equivalents totaled $70.3 million. Our cash and cash equivalents are currently held in the form of short-term deposits with large U.S. and Australian banks. 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 $70.3 million as of March 31, 2013, along with the anticipated proceeds from existing royalty-bearing licenses, from our contract with BARDA, and from other existing license and collaboration agreements will enable us to operate for a period of at least 12 months from March 31, 2013.

Our future funding requirements beyond 12 months 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;
- 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 to better balance our pipeline;
- the size and cost of general and administrative function 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.

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

ITEM 3: Quantitative and Qualitative Disclosures about Market Risk

There has been no material change in the Company’s assessment of its sensitivity to market risk since its presentation set forth in Item 7A "Quantitive and Qualitative Disclosures about Market Risks" in it's Annual Report on Form 10-K for the years ended December 31, 2011, except as updated and supplemented in its Quarterly Report on Form 10-Q for the quarter ended December 31, 2012.

ITEM 4: Controls and Procedures

Our Chief Executive Officer currently acts as our Principal Financial Officer.

Evaluation of Disclosure Controls and Procedures

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer concluded that these disclosure controls and procedures were effective.

Changes in Internal Controls over Financial Reporting

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1A. RISK FACTORS

An investment in our securities involves a risk of loss. You should carefully consider the risks factors included in our Quarterly Report on Form 10-Q for the quarter ended December 31, 2012, as well as the risk below, together with other information in this Quarterly Report, in evaluating our business, financial condition and our prospects. The risks and uncertainties described therein and herein are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently consider immaterial may also impact our business and prospects.

We have adopted a strategy whereby we plan 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 this 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, it may require us to raise capital to acquire or support the transaction, incur acquisition fees or other non-recurring charges, and may pose significant integration challenges and/or management and business disruptions, any of which could materially and adversely affect our business and financial results. Further we may not be able to successfully integrate a transaction in a suitable time frame or at all.

ITEM 2: UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On April 1, 2013, the Company entered into a letter agreement for a stock option grant to Peter Azzarello, in conjunction with his employment with the Company. The Company granted to Mr. Azzarello, as an inducement grant, an option to purchase 85,000 shares of the Company's common stock at an exercise price of $3.98 with a ten year term. The option will vest in four equal installments on the first, second, third and fourth anniversary of the grant. These securities were granted outside the Company's 2007 Omnibus Equity and Incentive Plan in a transaction exempt from the registration requirements of the Securities Act in reliance on Section 4(2) of the Securities Act of 1933, as amended.

ITEM 6. EXHIBITS

The exhibits to this report are listed in the Exhibit Index beginning on Page 30 hereof.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Biota Pharmaceuticals, Inc.

Date: May 10, 2013

By: /s/ Russell H Plumb

Russell H Plumb
President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer)

EXHIBIT INDEX

Exhibit Number	Exhibit Title	Filed with this Form 10-Q	Incorporation by Reference		
			Form	File No.	Date Filed
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
10.5†	Collaboration and License Agreement, dated September 29, 2003, between Biota Holdings Limited and Sankyo Co., Ltd.	X			
10.6†	Amendment #1 to Collaboration and License Agreement, dated June 30, 2005, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd. and Sankyo Company, Ltd.	X			
10.7	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.	X			
10.8†	Commercialization Agreement, dated March 27, 2009, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd and Daiichi Sankyo Company, Ltd.	X			
10.9†	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.	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**	The following materials from the Biota Pharmaceuticals, Inc. Quarterly Report on Form 10-Q for the period ended March 31, 2013 formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Consolidated Balance Sheets as of March 31, 2013 and June 30, 2012, (ii) the Condensed Consolidated Statements of Operations for the Three and Nine Months Ended March 31, 2013, and March 31, 2012, (iii) the Condensed Statements of Stockholders' Equity for the Nine Months Ended March 31, 2013, and March 31, 2012, (iv) Condensed Consolidated Statements of Cash Flows for the Nine Months Ended March 31, 2013, and March 31, 2012, and (v) Notes to Condensed Consolidated Financial Statements	X			

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

** Furnished, not filed.

† Confidential treatment has been requested for certain information contained in this exhibit. Such information has been omitted and will be provided separately to the Securities and Exchange Commission.

Certain information contained in this document, marked by ***, is filed with the SEC pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended

00092

Collaboration and License Agreement

Between

Biota Holdings Limited

and

Sankyo Co., Ltd.

THIS AGREEMENT, effective as of September 29, 2003, between Biota Holdings Limited (Biota), a corporation organized and existing under the laws of Victoria, Australia, with offices at 616 St. Kilda Road Melbourne, Victoria, Australia, and Sankyo Co., Ltd. (Sankyo), a joint stock company organized and existing under the laws of Japan, with offices at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo, Japan sets forth the agreement between the parties as follows:

Recitals

1. Biota has expertise, know-how and patents in the field of long-acting neuraminidase inhibitors (LANI Compound[s]), and has synthesized and optimized several LANI Compounds which may be suitable for preclinical and clinical development, and wishes to collaborate with a key partner in the development of LANI Compounds for Commercialization (defined below) worldwide.

2. Sankyo also has expertise, know-how and patents in the field of LANI Compounds and has developed its own LANI Compound to the extent that it has completed Phase I clinical trials of one LANI Compound in the United Kingdom, and is preparing to submit the LANI Compound for Phase II clinical trials.

3. The Parties desire to collaborate and work together, using said expertise, know-how and patents to develop and market a product or products using the compounds described above for the treatment and prevention of influenza or other viral infections.

4. The Parties have executed a Letter of Intent which is dated May 23, 2003 which outlines the basic framework upon which the Parties will work together and which is now superceded in its entirety by the agreement set forth below.

NOW, THEREFORE, in consideration of the mutual covenants and

promises contained herein, and for other good and valuable consideration, the Parties hereto agree as follows:

Definitions

1. "Affiliate" of a Party hereto means any entity that controls, is controlled by or is under common control with such Party. For purposes of this definition, a Party shall be deemed to control another entity if it owns or controls, directly or indirectly, more than fifty percent (50%) of the voting equity of the other entity (or other comparable ownership interest for an entity other than a corporation) or if it has management control of the other entity.

2. "Agreement" means this document together with any appendixes, exhibits, schedules or specifications which are attached hereto and made a part of this document at the time of its execution, together with any amendments hereto which are signed by authorized representatives of the Parties and incorporated as a part of this document.

3. "API" means the active pharmaceutical ingredient using LANI Compounds and which is incorporated into the Products.

4. "Biota Technology" means, to the extent necessary or useful for the Development, Manufacture, use or sale of the LANI Compounds, (a) all Patents that Biota Controls as of the Effective Date or during the term of the Agreement and which shall be included in Appendix A, and (b) Information that is not included in the Patents described in the preceding clause (a) and that Biota Controls on the Effective Date or during the term of the Agreement.

5. "Clinical Development" means all clinical and regulatory work required from the Development Phase and up to Marketing Approval.

6. "Commercialization Phase" means the period after Marketing Approval through the term of the Agreement.

7. "Commercialize or Commercialization" means to promote, sell, distribute, and otherwise market a Product or Products, and to engage in Product Manufacturing.

8. "Control" means, with respect to any Information or intellectual property right, possession by a Party of the ability (whether by ownership, license or otherwise) to grant access, a license or a sub-license to such Information or intellectual property right without violating the terms of any agreement or other arrangement with any third party as of the time such Party would first be required hereunder to grant the other Party such access, license or sublicense.

9. "Development" means both the pre-clinical and clinical development of a LANI Compound.

10. "Development Candidate" means a LANI Compound listed in Appendix E or that is developed or optimized by Biota or Sankyo during the term of this Agreement and which shall be added to Appendix E, and that the Parties mutually agree is suitable for Clinical Development.

11. "Development Phase" means the period of this Agreement from the Effective Date to filing of a registration dossier for Marketing Approval.

12. "Effective Date" means the date shown in the first paragraph of this Agreement.

13. "Field" means the prevention and/or treatment of influenza virus types A and B and other viral infections with a LANI Compound.

14. "Information" means all tangible and intangible techniques, technology, practices, trade secrets, methods, knowledge, know-how, skill, experience, test data and results (including pharmacological, toxicological and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms relating to the LANI Products Controlled by a Party.

15. "Invention" means any idea, design, concept, technique, process, method, composition of matter or discovery, whether or not patentable, copyrightable, or otherwise protectable with intellectual property law which is conceived of, discovered, developed, created, made or reduced to practice during the term of this Agreement which is useful to the activities contemplated hereunder.

16. "LANI Compounds" means the less than once per day dosage neuraminidase inhibitor compounds set forth in Appendix D, and any such compounds which may be developed or optimized by Biota or Sankyo during the term of this Agreement and which shall be added to Appendix D.

17. "Laws" means collectively all laws, rules and regulations as amended from time to time applicable to the Development, Commercialization and Manufacture of LANI Compounds and the Product.

18. "Lead Compound" means the LANI Compound selected by the Parties for Development and Commercialization from among the Development Candidates, and which is shown in Appendix E, which may be amended from time to time as mutually agreed by the Parties.

19. "Licensee[s]" means a third party or parties which will be granted a license

from the Parties to develop, Manufacture and sell the Products in accordance with the terms and conditions which are set forth in the License Template.

20. "License Agreement" means, with respect to the Parties and a Licensee, an agreement executed between the Parties and a Licensee after negotiations based on the License Template.

21. "License Template" means the sample agreement which is attached hereto as Appendix F and which will be used to negotiate licensing terms with Licensees and which may only be modified upon mutual agreement by the Parties.

22. "Licensing Committee" means the joint committee established by Biota and Sankyo in accordance with this Agreement for the oversight and governance of the relationship between Biota and Sankyo on the one hand, and Licensees on the other.

23. "Manufacture or Manufactured" means with respect to each of API and Product, all the activities relating to production of API, LANI Compounds and/or Products, including, but not limited to, purchasing and release of raw materials, manufacturing, milling, quality control and assurance of all production steps, finishing, filling, labeling, packaging, release, holding and storage and the tests and analyses conducted in connection therewith.

24. "Marketing Approval" means any and all approvals (including, if required, price and reimbursement approvals), licenses, registrations, or authorizations of any regulatory agency, department, bureau or other government entity in a jurisdiction (or, if applicable, the European Union as a whole) that is necessary to market a Product in such jurisdiction.

25. "Net Sales" means the gross amount invoiced by a Party, its Affiliates and any respective Licensees to third parties that are not Affiliates or Licensees of the selling party (unless such Affiliate or Licensee is the end user of such Product, in which case the amount billed therefor shall be deemed to be the amount that would be billed to a third party in an arm's length transaction) for sales of Products to third parties, less the following items, as allocable to such Product (if not previously deducted from the amount invoiced): (i) trade discounts, credits or allowances; (ii) credits or allowances additionally granted upon returns, rejections or recalls (except where any such recall arises out of a Party's, its Affiliate's or Licensee's gross negligence, willful misconduct or fraud); (iii) freight, shipping and insurance charges; (iv) taxes, duties or other governmental tariffs (other than income taxes); and (v) government mandated rebates.

26. "Party" means either Biota or Sankyo. "Parties" means both Biota and

Sankyo.

27. "Patent[s]" means (a) patents filed in the country of origin, re-examinations, re-issues, renewals, extensions and term restorations, and including foreign counterparts of any of the foregoing, and (b) pending applications for patents filed in the country of origin, including, without limitation, provisional applications, continuations, continuations-in-part, divisional and substitute applications, including, without limitation, inventors' certificates, and foreign counterparts of any of the foregoing in each case to the extent they are applicable to the LANI Compounds and the Field that are owned or Controlled by a Party that either exist as of the effective date or claim Inventions owned or Controlled by a Party and that arise out of the activities contemplated under this Agreement. Existing Patents owned by Biota and Sankyo as of the Effective Date are set forth in Appendixes A and B, respectively. Any new Patents which come into existence during the term of this Agreement and which relate to a LANI Compound or Product shall be added to Appendix C (Joint Patents).

28. "Product[s]" means a finished pharmaceutical product that contains a LANI Compound.

29. "Regulatory Authority" means any health regulatory authority in any country that holds responsibility for approving applications or granting authorizations to commence human clinical testing of a drug and/or for granting regulatory Marketing Approval for a Product in such country, and any successor(s) thereto.

30. "Sankyo Technology" means, to the extent necessary or useful for the Development, Manufacture, use or sale of LANI Compounds, (a) all Patents that Sankyo Controls as of the Effective Date or during the term of the Agreement and which shall be included in Appendix B, and (b) Information that is not included in the Patents described in the preceding clause (a) and that Sankyo Controls on the Effective Date or during the term of the Agreement.

31. "Substance[s]" means compounds, compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material relating to the LANI Compounds.

1. Collaboration

1.1. The Parties will use their best efforts and work together to seek one or more Licensees to develop the Products on a worldwide basis using all the Patents, Information and Substances in order to maximize commercial return to the Parties through the safe and effective use of Products.

2. License Grants

2.1. Sankyo License

2.1.1. Biota hereby grants to Sankyo a license under the Biota Technology to develop, make, have made, use, sell, have sold, offer for sale and import Products worldwide for the Field (the "Sankyo License").

2.1.2. The Sankyo License shall be exclusive to Sankyo, except as provided hereunder, and shall include the right to sublicense under the terms and conditions provided herein.

2.2. Biota License

2.2.1. Sankyo hereby grants to Biota a license under the Sankyo Technology to develop, make, have made, use, sell, have sold, offer for sale and import Products worldwide, except in Japan, for the Field (the "Biota License").

2.2.2. The Biota License shall be exclusive to Biota, except as provided hereunder, and shall include the right to sublicense under the terms and conditions provided herein.

2.3 Immediate Disclosure and Cooperation

2.3.1 Upon execution of this Agreement, each Party will use its best efforts to immediately disclose and supply to the other Party in the English language its respective Technology, Information, Substances and any other materials that will assist the other Party in the performance of this Agreement.

2.3.2 Each Party will cooperate fully with the other Party in interpreting the materials disclosed and will assist the other Party in carrying out its duties under this Agreement.

2.4. Non-compete

2.4.1. During the term of this Agreement, unless otherwise

agreed between the Parties, each Party agrees that neither for itself or through its Affiliates will it develop, commercialize, or otherwise handle or deal with, directly or indirectly, or enter into any collaboration, license or development agreement or any other arrangement with any party other than the other Party to develop, Commercialize, or otherwise handle or deal with any Product for the Field ("Competitive Product") in any country. The restrictions in this Section 2.4.1 shall not apply to products already manufactured, distributed, sold, bought or otherwise dealt with by each Party or its Affiliates as of the Effective Date.

3. Development and Marketing Licensees

3.1. Licensing Committee

3.1.1. The Parties will collaborate to find appropriate Licensees on a worldwide basis, will negotiate and execute License Agreement(s) with the Licensees, and will establish the Licensing Committee. The Licensing Committee shall be comprised of four (4) members, with two (2) representatives appointed by each Party.

3.1.2. The Licensing Committee will oversee the selection of Licensees and the development of license terms within the scope of the License Template. Biota and Sankyo will cooperate in finding appropriate Licensees for each market and will have joint governance and equal opportunity to contribute to negotiations with Licensees through the Licensing Committee.

3.2 Meetings and decisions of Licensing Committee

3.2.1. Unless otherwise determined by the Licensing Committee, the Licensing Committee shall meet at least semi-annually alternately at locations to be determined, either Sankyo's offices in Japan or Biota's offices in California or Australia, the latter to be determined by Biota. At other times, the locations or manner of the meetings (e.g., telephone conferences) shall be determined by the Licensing Committee. All direct and indirect costs and expenses for representatives of the Parties to attend Licensing Committee meetings will be for each Party's account.

3.2.2. All actions and decisions reserved for the Licensing Committee will require the unanimous agreement of all of its members. If the Licensing Committee fails to reach unanimous agreement, then each individual member of the Licensing Committee shall have one vote to cast in resolving the matter by majority vote. If the Licensing Committee fails to reach a decision through majority vote, then the matter shall be referred to an executive at Biota and an executive at Sankyo with authority to settle the matter within thirty (30) days. If the matter is not resolved within the thirty (30) day period following submission of the matter to those executives, then the matter shall be referred to

the Chief Executive Officer of Biota and the Chief Executive Officer of Sankyo for final amicable settlement between the Parties.

3.3. Relationship with Licensees

3.3.1. The Parties will negotiate with Licensees subject to the license plans and policies determined by the Licensing Committee and within the terms and spirit of the License Template. The Parties acknowledge that Licensees may, at Licensees' discretion, implement certain activities, including but not limited to Development, Manufacture and sale of the Products subject to the terms and conditions of the License Agreement. However, to avoid confusion in dealing with Licensees, the Party who introduces the Licensee will take the lead in conducting negotiations with and supervising that Licensee, unless otherwise agreed by the Parties.

3.3.2. It is understood that both Parties have had preliminary discussions with potential Licensees and that each Party has disclosed all such discussions to the other. Each Party is encouraged to disclose to such potential Licensees the fact that the Parties have entered into this Agreement and the impact which this Agreement may have on any such discussion.

3.4. Guidance to Licensees

3.4.1. The Parties will offer their input and expertise to Licensees in accordance with the provisions of the License Template.

3.5. Commercialization Phase

3.5.1. Cooperation: The Parties agree to cooperate prior to and during the Commercialization Phase and to coordinate with, and with the exception of confidential business information, share information with the Licensee concerning any market data, marketing plans, promotional materials, labeling, selling messages, promotional strategies, pricing strategies, post-marketing studies, regulatory activities and any other regulatory, clinical or marketing data or plans.

3.5.2. Reporting: Each of Sankyo and Biota will provide the other with quarterly reports of Net Sales of the Products by such Party or its Affiliates worldwide.

4. Marketing by Sankyo and Biota

4.1. Japan

4.1.1. Sankyo may elect to have the exclusive right to market the Products in Japan, with a right to sublicense to a third party at its discretion.

4.2. USA

4.2.1. Although the parties intend to license the Products to a third party in the United States under an exclusive license, the parties will retain the right to designate a co-marketer and/or terminate the license to Licensees in the event that the Licensee does not achieve the goals agreed by the Parties and Licensees in that market. The Parties agree that either Party or its Affiliate may be designated as the co-marketer.

4.3 Other Markets

4.3.1. In all other markets where the Parties are able contractually to appoint exclusive Licensees, the Parties intend to appoint exclusive Licensees for each market, but will retain the right to terminate the Licensees and/or grant additional licenses to a third party (including, without limitation, Sankyo, Biota or one of their Affiliates) in any market, if the appointed Licensees do not meet the agreed goals in that market.

5. License Fees, Milestone Payments and Royalties

5.1. The Parties will divide all license fees, milestone payments, royalties, equity and other payments in cash or in kind (hereafter referred to as Consideration) received from Licensees on a fifty/fifty basis.

5.2. In addition, for any sales made by Sankyo in Japan or by either Party or its Affiliate in the USA, the Parties will pay each other non-refundable royalties at a rate which is fifty percent (50%) of the rate paid by any other Licensee in the same country. In the event there is no other Licensee in the country, the rate shall be fifty percent (50%) of the highest rate paid by any Licensee under this Agreement.

5.3. Records and Reports

5.3.1. The Parties agree that within sixty (60) days of the end of each calendar quarter after first commercial sale of the Product by a Party in the Territory, such party shall furnish to the other Party reports, in a form to be agreed upon, showing for the immediately preceding calendar quarter, among

other things, the gross sales and Net Sales of each Product sold and the royalties that have accrued hereunder with respect thereto and the amount of withholding taxes on the royalty payments. Such reports shall be rendered for the term of this Agreement and shall be due .

5.3.2. The Parties shall keep proper books of account with reference to their respective sales of any Product under this Agreement and with reference to any sales by Licensees that are reported to the Parties. When requested by the other Party, such books of account shall be made available at reasonable times during normal business hours for audit by a certified public accountant selected by the auditing party and acceptable to the audited party (such acceptance not to be unreasonably withheld) (including the right to inspect, copy, and make abstracts therefrom), solely for the purpose of verifying the royalties due or paid, or for determining compliance with other provisions of this Agreement. Any expense incurred by a Party conducting such audit shall be borne by said Party unless discrepancies attributable to the audited Party exceeding the cost of the audit are found, in which case the other Party shall pay the auditing party the discrepancy and reimburse the auditing Party for the costs of the audit.

5.4. The Party owing the royalty (the "Payor") shall permit its books of account or records of sale to be inspected at any reasonable time during normal business hours by a certified public accountant selected by the other Party (the "Payee") and acceptable to the Payor (such acceptance not to be unreasonably withheld) solely for the purpose of verifying the amounts due hereunder.

5.5. All payments under this Agreement shall be made payable in U.S. dollars and shall be by appropriate electronic funds transfer in immediately available funds to such bank accountant as the Payee shall designate and on a date no later than when royalty reports are due under Section 5.3.1 above. Each payment shall reference this Agreement and identify the obligation under this Agreement that the payment is to satisfy. Any and all expenses for such payment incurred by the Payee shall be borne by the Payee.

5.6. Any payments due hereunder that are not paid on or before the date such payments are due shall bear interest, at the lower of one percentage point above the Prime Rate of interest as reported in the New York edition of the Wall Street Journal on the date the payment is due or the maximum allowed by law, compounded monthly until such payment is made.

5.7. Any taxes or similar charges levied or assessed in a territory on the Payee on the royalty payments shall be borne by Payor. However, Payor has the right to deduct from the royalty payments such income taxes or charges paid thereon for which Payee is entitled to receive a credit under income tax laws in

effect as of the time payment is made. In these cases, Payor will promptly provide Payee with an original receipt for such tax payments (or a certified copy, if the original is not available). Payor's failure to provide Payee with such documentation as Payee determines is acceptable for tax purposes shall preclude Payor from deducting such taxes or charges from the gross royalty otherwise due.

5.8. Payee may require such other account statements or reports from Payor as may be reasonable.

6. Expenses

6.1. All direct and indirect costs and expenses, including travel and legal expenses associated with finding the Licensees and executing License Agreements, incurred under the negotiations with Licensees subject to the license plans and policies approved by the Licensing Committee will be borne by the Party who negotiates with the Licensees.

6.2. The Parties will negotiate with Licensee under the terms and conditions that all direct and indirect costs and expenses incurred under the activities contemplated under the License Agreement, including but not limited to Development, Manufacture and marketing of the Products, implemented by Licensees subject to the License Agreement shall be borne by Licensees as provided in the License Template.

7. Intellectual Property

7.1. Ownership and Treatment of Intellectual Properties

7.1.1. The Inventions, patent applications and the patents regarding the LANI Compounds or Products generated by Sankyo or Biota after the Effective Date of this Agreement (collectively, the "Joint Intellectual Properties") shall be owned by the Parties, jointly. Each of Biota and Sankyo shall own an undivided one-half interest in Joint Intellectual Properties, as defined under United States patent law.

7.1.2. In the case of Inventions owned jointly by the Parties in accordance with Section 7.1.1 ("Joint Inventions"), the Parties shall agree on whether or not to secure patent protection and which Party shall bear the primary responsibility for preparing, filing, prosecuting the Patents resulting therefrom. The Parties shall equally share all expenses related thereto. Each Party shall promptly render all necessary assistance reasonably requested by the other Party in applying for and prosecuting the patent applications. In the event that the Parties cannot agree whether or not to secure patent protection, the Party desiring to secure such protection may proceed to do so at its own expense and for

its own benefit, provided, however, that if the benefit proves to be to the advantage of both Parties, they shall negotiate in good faith the reasonable compensation which should be paid to the Party which has borne said expenses.

7.1.3 In the event applications for patents on Joint Inventions are filed, the Parties agree to cause, to the extent allowed by law, the inventors of such Joint Inventions to execute assignments to the Parties specifying that such Joint Inventions are to be owned equally and jointly as defined under United States patent law by the Parties.

7.2. Maintenance of Patents and Applications

7.2.1. Each Party shall, at its own expense, diligently take all steps necessary to maintain its own Patents, in full force and effect, including but not limited to a duty to diligently file and pursue any reissues and re-examinations, if applicable, and to diligently prosecute any pending patent applications. If either Party elects not to maintain any of its own Patents, it shall promptly notify the other of that election and shall, at the other Party's request, assign to the other Party all right, title and interest in and to such Patents of the first Party. In such case, the other Party shall bear the cost and responsibility for the maintenance of such Patents and the first Party shall render all necessary assistance reasonably requested by the other Party in maintaining such Patents.

7.2.2. In the event that Joint Inventions are registered, the Party who bears the primary responsibility for preparing, filing, prosecuting such Joint Inventions shall bear the primary responsibility for performing the obligation to maintain registered Patents resulting from such Joint Inventions ("Joint Patents") as set forth in Section 7.2.1. Each Party shall promptly render all necessary assistance reasonably requested by the other Party in performing such obligation. Any and all costs and expenses reasonably necessary and useful to perform such obligation on any and all Joint Patents shall be borne by both Parties equally.

7.2.3. Notwithstanding the provision of Section 7.2.1, each Party shall be relieved from its obligation to maintain its own Patents stipulated by Section 7.2.1, in the event that the Licensing Committee determines that any Products related to such Patents will not undergo Development or be Commercialized as a Development Candidate. If any Regulatory Authority grants Marketing Approval for a Product to a Party in any country, any and all costs and expenses reasonably necessary and useful to perform the obligation of the maintenances stipulated by Section 7.2.1 on any and all Patents related to such Product in said country shall be borne by both Parties equally.

7.2.4. The Parties agree to cooperate to obtain, to the fullest

extent allowed by Laws, an extension of exclusivity beyond the full term expiry date of any Patents subject to this Agreement which the Parties mutually agree may maximize commercial return of Products. The Parties shall provide all relevant patent information to the Regulatory Authority or other applicable agency as required by Laws.

7.2.5. Neither party shall take any legal action (whether by suit, proceedings or otherwise) against the other Party concerning any infringement of any Patents related to the LANI Compounds or the Products owned by the other Party during the term of the Agreement.

7.3. Patent Infringement

7.3.1. In the event that either Party is charged with the infringement of a patent or other intellectual properties, including but not limited to utility model, design or trademark owned by any third party or receives any filing of any claim or suit by any third party related to the LANI Compounds or the Products because of any of the activities necessary to the performance of its obligations under this Agreement, said Party shall notify the other Party fully and promptly in writing upon receipt of any knowledge or notice of the charge of infringement, specifying its nature and by whom it was raised. The Parties shall discuss and agree in good faith how such claim or suit should be handled, and which Party shall initiate the defense of said claim or suit. The initiating Party designated by said discussion ("Initiating Party") shall prosecute and control such claim or suit and periodically inform the other Party of its intended course of action and shall provide the other with the opportunity to comment on significant actions or elements of the Initiating Party. Neither Party shall settle any such claim or suit without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed, except as provided hereafter. Any costs and expenses, including reasonable attorneys' fees, incurred by Initiating Party in defending against such claim or suit shall be borne by both Parties equally. In the event the Parties cannot agree on the strategy for such action, including settlement, etc., the Initiating Party shall make the final determination.

7.3.2. In the event that either Party becomes aware that the Patents or other intellectual property, including but not limited to utility model, design or trademark (collectively, "Intellectual Properties" in this Section) are threatened to be infringed or disputed by any third party, such Party shall notify the other Party fully and promptly in writing, specifying the nature of the threat and by whom they are threatened to be infringed or disputed. The Party owning the Intellectual Property shall have the right, but not the obligation, to control any action for infringement or defense of such third party claim against the Intellectual Properties and the other Party shall provide reasonable and diligent cooperation with said Party in all matters concerning such claim, including, if

asked, to be a named party, and shall make available any relevant records, documents, power of attorney, or information if requested to do so. All expenses (including reasonable attorneys' fees) incurred by said Party in defending its Intellectual Properties against such infringement or legal action shall be for said Party's account, and said Party shall have full control over the conduct of defense of any such action. Said Party shall also indemnify the other Party for any liability which may arise from any judgment rendered in such action. If said Party does not exercise its right to control the conduct of defense of any such action in response to any such claim within thirty (30) days of becoming aware of or being notified of such infringement, then the other Party shall have the right, but not the obligation, to bring such action. Any monetary recovery in connection with an action brought or prosecuted by a Party under this Section 7.3.2 shall be kept solely by the Party initiating such action.

7.3.3. Notwithstanding the provision of Section 7.2.1 and Section 7.2.2, and Section 7.3.2, if the Patents or Intellectual Properties that are threatened to be infringed or disputed by any third party are (i) Joint Intellectual Properties including Joint Patents, (ii) any and all Patents related to the LANI Compounds or Products developed and Commercialized that is determined conclusively by the Licensing Committee to be the Development Candidate, or (iii) any and all Patents related to the Product for which the Regulatory Authority grants Marketing Approval, the Parties shall discuss and agree in good faith how such third party claim or suit against the Patents or Intellectual Properties should be defended and which party shall initiate the defense of said claim or suit. The initiating Party designated by said discussion ("Initiating Party") shall prosecute and control such claim or suit and periodically inform the other Party of its intended course of action and shall provide the other with the opportunity to comment on significant actions or elements of the Initiating Party. Neither Party shall settle any such claim or suit without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed, except as provided hereafter. Any costs and expenses, including reasonable attorneys' fees, incurred by Initiating Party in defending against such claim or suit shall be borne by both Parties equally. In the event the Parties cannot agree on the strategy for such action, including settlement, etc., the Initiating Party shall make the final determination.

7.3.4. Any monetary recovery in connection with an action brought or prosecuted by Sankyo or Biota under Sections 7.3.1 and 7.3.3 shall first be applied to reimburse each of the Parties for their out-of-pocket expenses (including reasonable attorneys' fees) in taking such action. Once the Parties have each been reimbursed for their out-of-pocket expenses, the remainder of any monetary recovery will be apportioned in proportion to damages actually incurred by the Parties.

7.4 Trademarks

7.4.1 It is the intent of the Parties that, where possible, each Product be sold under a single trademark worldwide which shall be selected by the Licensee with the approval of both Parties. It is understood that in some countries, other trademarks may be necessary or advisable or recommended by the Licensee. All trademarks used on Products under this Agreement (hereafter referred to as "Trademarks") will be owned and registered at the expense of the Licensee. (See License Template, Appendix F.) Upon any termination of the License Agreements, where Trademarks are to be returned to the Party that Controlled the LANI Compound being sold ("Originator"), the Originator may own and register that Trademark in its own name. All benefits and burdens relating to that Trademark shall be shared equally by the Parties during the term of this Agreement. If the Originator declines this right, the other Party may own and register the Trademarks in its name. Following the termination of this Agreement, and following the termination of a License Agreement in any country, either Party may use the Trademarks to sell the Products. The Party which has registered the Trademark shall cooperate with the other Party, including the execution of any necessary license agreements or other documents, to make it possible for the other Party or for both Parties, as the case may be, to market or co-promote the Products using the Trademarks.

8. Term and Termination

8.1. Term

8.1.1. This Agreement will commence on the Effective Date and continue on a country-by-country basis until the latter of (i) expiration of the last-to-expire Patent within the Biota Technology or the Sankyo Technology claiming the Manufacture, use or sale of the Products or (ii) expiration or termination of the last License Agreement.

8.2. Earlier termination

8.2.1. Either Party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement on a country-by-country basis prior to the end of the term, by giving the other Party sixty (60) days written notice ("Notice Period") upon occurrence of any of the following events:

8.2.1.1. "Material breach" defined as the default of any material obligation hereunder by the other Party, which has not been remedied within sixty (60) days after one Party sends written notice detailing the substance of the default to the defaulting Party, or

8.2.1.2. "Insolvency" meaning the insolvency, bankruptcy, dissolution or liquidation of the other Party, where such Party is subject to the filing or consents to the filing of a petition under any bankruptcy or insolvency law or has any such petition filed against it which has not been dismissed within ninety (90) days of such filing, appointment of a trustee, administrator, or receiver for all or substantially all of the assets of such Party, or assignment of the assets of such Party for the benefit of creditors, or attachment or expropriation of the business or assets of such Party, or

8.2.1.3. "Marketing Failure" meaning that the Product may not be sold as a result of a recall or market withdrawal and such inability to sell the Product continues for a period of twelve (12) months;

8.2.2. The right of a Party to terminate this Agreement as provided in this Section 8.2 shall not be affected in any way by its waiver or failure to take action with respect to any previous default.

8.3. Rights on termination

8.3.1. If either Party terminates this Agreement pursuant to Section 8.2, in those countries where such termination takes effect:

(a) all rights to the LANI Compounds and all relevant Patents, licenses and other rights granted or assigned to either Party at any time under this Agreement (collectively, "Rights") shall revert to the original Party; and

(b) both parties may use the Joint Intellectual Properties without any limitation and grant a license to any third party under the Joint Intellectual Properties without the prior written consent of the other Party. If either Party desires to acquire the other Party's right, title or interest in and to the Joint Patents, said Party may acquire such rights by paying to the other Party the amount which is agreed in good faith negotiation by the Parties in consideration of the transfer of such rights; and

(c) the Party who terminates this Agreement pursuant to Section 8.2. ("Terminating Party") and the other party shall negotiate in good faith a mechanism to allow the non-terminating Party, should it so wish, to continue to Develop, Manufacture, file for Marketing Approval, use, sale, offer for sale the Product in such country.

8.3.1.1. Without prejudice to any exclusive license granted herein, a Party that grants a license to a third party under a Joint Invention shall obtain the prior written consent of the other Party to such a license, such consent not to be unreasonably withheld or delayed.

8.3.2. The provisions of Section 8.3.1 and this Section 8.3.2 shall survive the termination for any reason of this Agreement. Except as specifically provided in this Agreement, neither Party shall be liable to the other based on, or as a result of, the termination of this Agreement as provided herein, whether in loss of good will, anticipated profits or otherwise.

9. Confidentiality

9.1. During the term of this Agreement and for a period of seven (7) years thereafter, each Party (a) shall hold the Technology, the Information and any marketing and other confidential information, whether in written, oral, visual, or machine readable form disclosed by either Party to the other under this Agreement (the "Confidential Information") and the Substances supplied by either Party to the other under this Agreement in confidence with the same degree of care it maintains the confidentiality of its own Confidential Information and Substances, (b) shall not disclose such Confidential Information and make Substances available to any third party without the prior written consent of the disclosing Party, and (c) shall not use such Confidential Information and Substances other than for exercising its rights and/or performance of its obligation under this Agreement except for any information which is evidenced that:

(i) was in the receiving party's possession at the time of disclosure,
(ii) was publicly known at the time of such disclosure,
(iii) becomes publicly known through no default of the receiving party,
(iv) was obtained legally by the receiving Party from a duly authorized third party, or
(v) was independently discovered without the aid or application of the information received.

9.2. Each Party may disclose the Confidential Information and make the Substances available only to those of its employees, contractors, and agents who have a need to know such Confidential Information and the Substances to implement the terms of this Agreement. The Parties agree to take reasonable precautions to preserve the confidential, proprietary or secret status of the Confidential Information and Substances and shall require that each of their respective employees, contractors, and agents understand and agree in writing to treat and to hold such Confidential Information and Substances in confidence consistent with the provisions herein.

9.3. Within thirty (30) days of the date of termination of this Agreement for any reason, the Parties shall provide each other with written notice specifying that through reasonable care and to the best of its knowledge: (a) all Confidential Information embodied in whole or in part in documents,

materials, things, and copies thereof have been destroyed or returned to the other Party, (b) the originals and all copies of any machine-readable documentation containing any portion of the Confidential Information have been destroyed or returned to the other Party, (c) all remaining Substances supplied by the either Party have been returned to the other Party or destroyed, unless otherwise agreed in writing between the Parties, and (d) all use of the Substances by the returning Party has ceased.

9.4. Neither Party may issue any press release, publication, or any other public announcement relating to this Agreement, the LANI Compounds or the Product without obtaining the other Party's prior written approval, which approval shall not be unreasonably withheld or delayed. The Parties shall in good faith prepare mutually acceptable announcements prior to such release, publication or announcement. Notwithstanding any of the foregoing, each Party may use the substance of previously approved public announcements and the substance of other public announcements of the other Party without prior notice.

10. Representations and Warranties

10.1. Each Party represents and warrants to the other that it possesses all of the requisite power and authority to enter into this Agreement and to perform each and every term, provision, and obligation of this Agreement, and that neither the execution or delivery of this Agreement nor the performance of the terms of this Agreement will conflict with or result in a breach of the terms, provisions, or obligations of, or constitute a default under, any other agreement or instrument under which such Party is obligated.

10.2. Each Party warrants that it is the owner of all right, title, and interest in the Patents and Information being licensed under this Agreement and that it has the right to grant the licenses described in this Agreement.

10.3. Notwithstanding the warranties of Section 10.1 and 10.2 above, neither Party warrants or makes any representation that the Patents are valid and enforceable, or that the Manufacture or sale of the Product or the LANI Compounds which are described and claimed in the Patents will not infringe the patent rights of others.

10.4. Each Party represents that it has not granted, and agrees that during the term of this Agreement it will not grant, to any other person, firm, or corporation any right or license with respect to the LANI Compounds which is described and claimed in the Patents.

10.5. Each Party warrants that there is no action, suit, investigation, claim, arbitration, or litigation pending, or to its knowledge, threatened against,

affecting, or involving said Party before any court, arbitrator, or governmental authority that is reasonably likely to result in a material adverse effect on the other Party's performance of its obligations under this Agreement.

10.6. Each Party warrants represents, and covenants that to the best of its actual knowledge after reasonable scientific investigation that,

(a) prior to the execution of this Agreement, the data that it has delivered to the other relating to the Information is scientifically true and accurate in all material respects, and that such data (i) contains no material errors or omissions, (ii) was compiled and prepared on a basis consistent with good scientific practices as applied by such Party, and (iii) presents fairly the condition of the Information and the LANI Compounds; and

(b) as of the Effective Date, that it has utilized its own scientific, marketing and distribution expertise and experience to analyze and evaluate both the scientific and commercial value of the Information and LANI Compound and has solely relied on such analysis and evaluations in deciding to enter into this Agreement; and

(c) after the Effective Date, the data that it will deliver to the other relating to the Technology will be scientifically true and accurate in all material respects, and that such data (i) will contain no material errors or omissions, (ii) will be compiled and prepared on a basis consistent with good scientific practices as implemented by such Party, and (iii) will present fairly the condition of the Information and the LANI Compounds and Products.

10.7. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THIS AGREEMENT.

10.8. SUBJECT TO ARTICLE 13, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER.

10.9. Sections 10.6, 10.7 and 10.8 shall survive any termination or expiration of this Agreement.

11. Liability and Indemnity

11.1. Sankyo shall indemnify, defend and hold harmless Biota, and its employees, agents, officers, directors, permitted licensees, successors and permitted assigns (collectively, the "Biota Indemnified Parties"), from and against any and all costs, liabilities, judgments, obligations, losses, expenses and damages (including reasonable attorneys' fees and expenses) of whatsoever kind or nature (collectively, "Losses") incurred by or imposed upon any Biota Indemnified Party as a result of any claims, actions, suits or proceedings (collectively, "Claims") arising out of or related to, in any way, the licensing, Development, Manufacture, marketing, promotion, importation, sale or other use (collectively, "Use") of the Product in any country by Sankyo pursuant to this Agreement or otherwise, regardless of whether such Claims or Losses are based upon theories of contract, tort, product liability, strict liability, infringement of any patent, trademark, trade name, logo, service mark, trade dress, trade secret, or any other legal or equitable theory; provided, however, that Sankyo shall have no obligation to indemnify Biota for Losses proven to have been caused solely from an intentional wrongdoing, negligent or grossly negligent omission by Biota.

11.2. Biota shall indemnify, defend and hold harmless Sankyo, and its employees, agents, officers, directors, permitted licensees, successors and permitted assigns (collectively, the "Sankyo Indemnified Parties"), from and against any and all costs, liabilities, judgments, obligations, losses, expenses and damages (including reasonable attorneys' fees and expenses) of whatsoever kind or nature (collectively, "Losses") incurred by or imposed upon any Sankyo Indemnified Party as a result of any claims, actions, suits or proceedings (collectively, "Claims") arising out of or related to, in any way, the licensing, Development, Manufacture, marketing, promotion, importation, sale or other use (collectively, "Use") of the Product in any country by Biota pursuant to this Agreement or otherwise, regardless of whether such Claims or Losses are based upon theories of contract, tort, product liability, strict liability, infringement of any patent, trademark, trade name, logo, service mark, trade dress, trade secret, or any other legal or equitable theory; provided, however, that Biota shall have no obligation to indemnify Sankyo for Losses proven to have been caused solely from an intentional wrongdoing, negligent or grossly negligent omission by Sankyo.

11.3. Each Party shall give prompt written notice to the other of any Claim asserted against such Party (in such capacity, the "Notifying Party") arising from or relating to the Product, regardless of whether the Notifying Party is entitled to seek indemnification from the other Party pursuant to either Section 11.1. or 11.2. The Parties shall, subject to the execution of an appropriate non-disclosure agreement, reasonably consult with, and share information with, each other regarding such Claim and shall reasonably cooperate and assist each other in the event that the Notifying Party wishes to pursue any claim against any third party in connection therewith, in each case at the sole cost and expense

of the Notifying Party. Each sublicense agreement entered into by a Party relating to any Product in accordance herewith shall contain a provision substantially similar to that set forth in this Section 11.3.

11.4. SUBJECT TO ARTICLE XIII (13), NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER, UNLESS SUCH DAMAGES ARE INFLICTED AS A RESULT OF THE GROSS NEGLIGENCE OR INTENTIONAL WRONGDOING OF THE OTHER PARTY.

12. Amendment

12.1. Except as otherwise provided in this Section, all amendments to this agreement must be in writing and signed by authorized representatives of both parties.

12.2. The Parties may agree in writing from time to time to add Development Candidates to this Agreement. This Agreement shall take effect with respect to such compounds whether or not they have been formally added to Appendix E, and all obligations of the Parties shall attach from such time as described therein.

13. Governing Law and Jurisdiction

13.1 Any claim, dispute or controversy of whatever nature arising out of or relating to this Agreement, including without limitation, any action based on tort, contract or statute, or concerning the interpretation, effect, termination, validity, performance or breach of this Agreement shall be construed in accordance with the laws of New York without regard to its conflict of law principles.

13.2 The Parties shall first negotiate in good faith to resolve any disputes which arise under this Agreement, but failing amicable solution, all unresolved disputes shall, at the request of either Party, be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators appointed in accordance with said Rules. The venue of the Arbitration shall be New York. The language of the arbitration shall be English.

14. Force Majeure

14.1. Neither Party hereto shall be liable for any failure or delay in performance of this agreement occasioned in whole or in part by acts of God, strike, lock-out, fire, earthquake, epidemic, inability to obtain materials or shipping space, breakdown, delay of carrier or regulation of any government or any other cause beyond its control, provided that said Party has exercised due and reasonable care and its best efforts to avoid any of the above-mentioned events.

15. Notices

15.1. Any notice or report pursuant to this Agreement shall be deemed duly given if delivered personally, sent by airmail, international recognized courier service, electronic mail (provided such electronic mail is followed by facsimile confirmation in accordance with this Section 15) or facsimile, addressed to the other Party at the address or facsimile number set forth below, or to such other address or facsimile number as shall have theretofore been furnished by one Party to the other in accordance with this Section, and shall be deemed to have been given when sent.

If to Sankyo:
Sankyo Company, Limited
3-5-1 Nihonbashi-Honcho, Chuo-ku,
Tokyo 103-8426, Japan
Attention: Director, Licensing Department
Fax: +81-3-5255-7086
Telephone: +81-3-5255-7084
e-mail: moriaki@hq.sankyo.co.jp

If to Biota:
Biota Holdings Limited
Level 4, 616 St Kilda Road
Melbourne 3004, Australia
Attention: Chief Executive Officer
Fax: +61-3-9529-2261
Telephone: +61-3-9529-2311
e-mail: info@biota.com.au

16. Assignment of Rights and Obligations

16.1. Either Party may assign all or any part of this Agreement to any Affiliate. In all other respects, neither Party shall voluntarily or by operation of law assign, hypothecate, give, transfer, mortgage, sublet, license, or otherwise transfer or encumber all or part of its rights, duties, or other interests in this Agreement or the proceeds thereof (collectively, "Assignment") in whole or in part to any third party without prior written consent of the other. Any attempt to make an Assignment in violation of this provision shall be a material default under this

Agreement and any Assignment in violation of this provision shall be null and void.

17. Entire Agreement

17.1. This Agreement, together with the Confidential Disclosure Agreement dated January 7, 2003, as amended August 5, 2003, and the Appendixes attached hereto, set forth the entire agreement and understanding between the Parties as to the subject matter hereof, and supercedes all agreements and understandings between the parties as to the subject matter, whether oral or in writing.

18. No Implied Waiver

18.1. No failure or delay on the part of either Party to exercise any right under this Agreement or provided for by Laws shall impair, prejudice or constitute a waiver of such right.

19. Severability

19.1. If and to the extent that any court or tribunal of competent jurisdiction holds any of the terms, provisions or conditions of this Agreement or parts thereof, or the application hereof to any circumstances, to be illegal, invalid or unenforceable in a final non-appealable order, (i) such provision shall be fully severable, (ii) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (iii) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (iv) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement, a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible.

20. No License

20.1. Nothing in this Agreement shall be deemed to constitute the grant of any license or other right in either Party to the other Party in respect of any product, patent, trademark, confidential information, trade secret or other data or any other intellectual property of the other Party except as expressly set forth herein.

21. Headings

21.1. The headings for each article and section in this Agreement have

been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular article or section nor to be used in construing or interpreting any of the provisions of this Agreement.

22. Appendixes

22.1. All Appendixes to this Agreement are by this reference incorporated herein and made a part of this Agreement.

23. Counterparts

23.1. This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed and effective as of the date first indicated above.

BIOTA HOLDINGS LTD.	SANKYO CO., LTD
By _____	By _____
Name PETER L. MOLLOY	Name Kouichirou Yamaguchi
Title CEO	Title Executive Corporate Officer
Date OCT 2 2003	Date Oct. 1, 2003

List of Appendixes

Appendix A:	Biota Patents
Appendix B:	Sankyo Patents
Appendix C:	Joint Patents
Appendix D:	LANI Compounds
Appendix E:	Development Candidates and Lead Compound
Appendix F:	License Template

Appendix A: Biota Patents

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*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

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Appendix C: Joint Patents

None as of the Effective Date of the Agreement)

Appendix D: LANI Compounds

Sankyo Compounds

R-118958

Biota Compounds

BTA938

BTA978

BTA929

Appendix E: Development Candidates and Lead Compound

Sankyo's Compounds:

R-118958(Lead Compound)

Biota's Compounds

BTA938

BTA978

BTA929

APPENDIX F

License Template

Between

Biota Holdings Limited

and

Sankyo Co., Ltd.

This License Template sets forth the basic understanding of Sankyo and Biota relating to the License Agreement to be executed with a Licensee or Licensees pertaining to the co-licensing of a Product or Products. This License Template shall be binding on both Sankyo and Biota. The terms of any Co-Licensing Agreement shall be consistent with the terms as described below.

* * *

THIS AGREEMENT, effective as of _____, 20 between **Biota Holdings Limited ("Biota"),** a corporation organized and existing under the laws of Victoria, Australia, with offices at 616 St. Kilda Road Melbourne, Victoria, Australia, and **Sankyo Co., Ltd. ("Sankyo"),** a joint stock company organized and existing under the laws of Japan, with offices at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo, Japan (collectively Biota and Sankyo are referred to as the "Licensors") on the one hand; and

[Licensee Name], a corporation organized and existing under the laws of (the "Licensee)

sets forth the agreement between the Licensors and the Licensee as follows:

Recitals

1. Biota and Sankyo both have expertise, know-how and patents in the field of long-acting neuraminidase inhibitors (LANI Compound[s]), and have synthesized and optimized several LANI Compounds which may be suitable for clinical development and commercialization worldwide as pharmaceutical products for human consumption.

2. Biota and Sankyo have executed a Collaboration and License Agreement under which the Licensors have agreed to pool their respective LANI Compound patents and technology and to collaborate and work together to license the LANI Compounds to one or more third parties for development and marketing.

3. Licensee has expertise and knowledge in the area of commercializing and marketing pharmaceutical products for human consumption and further desires to receive a license to develop and commercialize the LANI Compounds for the treatment and prevention of influenza or other viral infections.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein, and for other good and valuable consideration, all of the Parties hereto agree as follows:

Definitions

1. "Affiliate" of a Party hereto means any entity that controls, is controlled by or is under common control with such Party. For purposes of this definition, a Party shall be deemed to control another entity if it owns or controls, directly or indirectly, more than fifty percent (50%) of the voting equity of the other entity (or other comparable ownership interest for an entity other than a corporation) or if it has management control of the other entity.

2. "Agreement" means this document between the Licensee and the Licensors together with any exhibits, schedules or specifications which are attached hereto and made a part

of this document at the time of its execution, together with any amendments hereto which are signed by authorized representatives of the Parties and incorporated as a part of this document.

3. "API" means the active pharmaceutical ingredient using LANI Compounds and which is incorporated into the Products.

4. "API Manufacturing Development" means any raw material acquisition, process development and scale-up required to provide API of suitable quantity and quality for the agreed Clinical Development.

5. "Biota Technology" means, to the extent necessary or useful for the Development, Manufacture, use or sale of the LANI Compounds, (a) all Patents that Biota Controls as of the Effective Date or during the term of the Agreement and which shall be included in Appendix , and (b) Information that is not included in the Patents described in the preceding clause (a) and that Biota Controls on the Effective Date or during the term of the Agreement.

6. "Clinical Development" means all clinical and regulatory work required from the Development Phase and up to Marketing Approval.

7. "Commercialization Phase" means the period after Marketing Approval through the term of the Agreement.

8. "Commercialize or Commercialization" means to promote, sell, distribute, and otherwise market or promote a Product or Products, and to engage in Product Manufacturing for purposes of sale to a consumer.

9. "Competitive Product" means a product that is an antiviral agent targeted against influenza.

10. "Control" means, with respect to any Information or intellectual property right, possession by a Party of the ability (whether by ownership, license or otherwise) to grant access, a license or a sub-license to such Information or intellectual property right without violating the terms of any agreement or other arrangement with any third party as of the time such Party would first be required hereunder to grant the other Party such access,

license or sublicense.

11. "Co-Promotion" means the relationship in a country or countries in which two or more Parties to this Agreement collaborate in their promotional efforts to maximize sales of the Product under the same Trademark and a consistent marketing strategy and one Party books sales of the Product within that country.

12. "Co-Market" means the relationship in a country or countries in which two or more Parties to this Agreement market Products under different Trademarks, separate marketing channels and separate distribution channels, and in which both Parties book sales of the Product within that country.

13. "Development" means both the pre-clinical and clinical development of a LANI Compound.

14. "Development Candidate" means a LANI Compound from Appendix [ ] or another LANI compound that is developed or optimized by the Licensee during the term of this Agreement and that the Licensee determines is suitable for Clinical Development with the consent of the Licensors, which consent shall not be unreasonably withheld.

15. "Development Phase" means the period of this Agreement from the Effective Date to filing of a registration dossier for Marketing Approval.

16. "Development Plan" means a plan for developing the Products which is created and approved by the PDC on behalf of the Parties and which will guide the Parties in giving oversight and direction to the Licensees in developing the Products. The Development Plan shall be included as Appendix ____ to this Agreement, which may be amended from time to time as agreed by the Parties.

17. "Effective Date" means the date shown in the first paragraph of this Agreement.

18. "Field" means the prevention and/or treatment of influenza virus types A and B and other viral infections with a LANI Compound.

19. "First Commercial Sale" means the date on which the Product is first shipped by a Party to third parties for commercial sale in a country in the Territory.

20. "Information" means all tangible and intangible techniques, technology, practices, trade secrets, methods, knowledge, know-how, skill, experience, test data and results (including pharmacological, toxicological and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms relating to the LANI Products.

21. "Invention" means any idea, design, concept, technique, process, method, composition of matter or discovery, whether or not patentable, copyrightable, or otherwise protectable with intellectual property law which is conceived of, discovered, developed, created, made or reduced to practice during the term of this Agreement which is useful to the activities contemplated hereunder.

22. "LANI Compounds" means the less than once per day dosage neuraminidase inhibitor compounds set forth in Appendix _, which may be amended from time to time as agreed by the Parties..

23. "Laws" means collectively all laws, rules and regulations as amended from time to time applicable to the Development, Commercialization and Manufacture of LANI Compounds and the Product.

24. "Lead Compounds" means the LANI Compounds selected by the Parties for Development and marketing and shown in Appendix __ to the Agreement, which may be amended from time to time as agreed by the Parties.

25. "Licensors" means Sankyo and Biota.

26. "Licensed Patents" means those patents owned or controlled by either Sankyo or Biota, or Sankyo and Biota collectively as described on Appendix [ ].

27. "Manufacture or Manufactured" means with respect to each of API and Product, all the activities relating to production of API, LANI Compounds and/or Products, including, but not limited to, purchasing and release of raw materials, manufacturing, milling, quality control and assurance of all production steps, finishing, filling, labeling, packaging, release, holding and storage and the tests and analyses conducted in connection therewith.

28. "Marketing Approval" means any and all approvals (including, if required, price and reimbursement approvals), licenses, registrations, or authorizations of any regulatory agency, department, bureau or other government entity in a jurisdiction (or, if applicable, the European Union as a whole) that is necessary to market a Product in such jurisdiction.

29. "Net Sales" means the gross amount invoiced by a Party, its Affiliates and any respective Licensees to third parties that are not Affiliates or Licensees of the selling party (unless such Affiliate or Licensee is the end user of such Product, in which case the amount billed therefore shall be deemed to be the amount that would be billed to a third party in an arm's length transaction) for sales of Products to third parties, less the following items, as allocable to such Product (if not previously deducted from the amount invoiced): (i) trade discounts, credits or allowances; (ii) credits or allowances additionally granted upon returns, rejections or recalls (except where any such recall arises out of a Party's, its Affiliate's or Licensee's gross negligence, willful misconduct or fraud); (iii) freight, shipping and insurance charges; (iv) taxes, duties or other governmental tariffs (other than income taxes); and (v) government mandated rebates.

30. "Party" means Biota, Sankyo or a Licensee. "Parties" mean Biota, Sankyo and the Licensee.

31. "Patent[s]" means (a) patents filed in the country of origin, re-examinations, re-issues, renewals, extensions and term restorations, and including foreign counterparts of any of the foregoing, and (b) pending applications for patents filed in the country of origin, including, without limitation, provisional applications, continuations, continuations-in-part, divisional and substitute applications, including, without limitation, inventors' certificates, and foreign counterparts of any of the foregoing in each case to the extent they are applicable to the LANI Compounds and the Field that are owned or Controlled by a Party that either exist as of the effective date or claim Inventions owned or Controlled by a Party and that arise out of the activities contemplated under this Agreement. Existing Patents are set forth in Appendix [redacted] to this Agreement. Any new Patents which come into existence during the term of this Agreement shall be added to Appendix [redacted].

32. "Product[s]" means a finished pharmaceutical product that contains a LANI Compound.

33. "Product Development Committee" (PDC) means the joint committee established by the Parties in accordance with this Agreement which will oversee the Development of the LANI Compounds and Products in accordance with Article 3.

34. "Regulatory Authority" means any health regulatory authority(ies) in any country that holds responsibility for approving applications or granting authorization to commence human clinical testing of a drug and/or for granting regulatory Marketing Approval for a Product in such country, and any successor(s) thereto.

35. "Sankyo Technology" means, to the extent necessary or useful for the Development, Manufacture, use or sale of LANI Compounds, (a) all Patents that Sankyo Controls as of the Effective Date or during the term of the Agreement and which shall be included in Appendix [redacted], and (b) Information that is not included in the Patents described in the preceding clause (a) and that Sankyo Controls on the Effective Date or during the term of the Agreement.

36. "Substance[s]" means compounds, compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material relating to the LANI Compounds.

37. "Territory" means the countries listed in Appendix [redacted].

38. "Trademark" means the trademark or trademarks selected by the Licensee and approved in writing by the Licensors for use in connection with the commercialization, promotion and marketing of the Product in one or any of the countries in the Territory.

1. License Grant

1.1. Grant of Patent License. Until the last-to-expire Patent within the Territory expires the Licensors hereby grant to the Licensee under the Patents and Information owned by the Licensors, an exclusive license to develop, make, use, sell, offer for sale, and import the Product in the Field in each country in the Territory. For purposes of this Section 1, the term "exclusive" means to the exclusion of all other parties in the Territory, including Licensors.

1.2. Grant of Trademark License. After the last-to-expire Patent within the Territory expires, the Licensors shall grant to the Licensee under the Trademark owned by the Licensors, an exclusive license to use sell, offer for sale and import the Product in each country in the Territory.

1.3. Sublicenses. The licenses granted to the Licensee in Section 1.1 shall include the right to grant sublicenses to its Affiliates, in whole or in part; *provided, however, that* the Licensee shall be strictly liable for the performance of its Affiliates. The licenses granted to the Licensee in Section 1.1 and Section 1.2 shall not include the right to grant sublicenses to any third parties (other than a Licensee Affiliate) without the prior written consent of the Licensors.

1.4. Licensee Diligence. The Licensee shall diligently work to develop the LANI Compounds and to market the Product in such a way as to maximize Net Sales and operating income through the safe and effective use of the Product in compliance with all applicable Laws. The Licensee shall twice a year provide the Licensors with Development progress updates and, when requested by either of the Licensees, provide other material information relating to the Licensee's progress in Development and the eventual marketing of the Product.

2. Consideration

2.1. License Fee. In consideration for the Licensors' grants to the Licensee of the right to sell, market, and distribute Product, all pursuant to Section 1.1, the Licensors shall receive from the Licensee a one time non-refundable and non-creditable license fee of [ ] U.S. Dollars ([ ]) within seven (7) days of the Effective Date. Such License Fee shall be net of any taxes that might be payable in Japan or Australia to the Licensors.

2.2. Milestones. The Licensee will make the following payments to the Licensors in US Dollars upon the occurrence of the listed event in the Territory for each Product:

Event	Payment
Submission of IND	
Initiation of Phase II clinical trials (or equivalent)	
Initiation of Phase III clinical trials (or equivalent pivotal trial)	
Approval of an NDA (or equivalent)	
Launch of Licensed Product	
Date on which Net Sales of the Licensed Product exceed USD $_____ million in any 12-month period	
Date on which Net Sales of the Licensed Product exceed USD $_____million in any 12-month period	

2.3. Royalties. In consideration for the license granted under Section 2.1, the Licensee shall pay in U.S. dollars to the Licensors during the Term a royalty in each country in the Territory comprising XX percent (XX%) of Net Sales until this Agreement expires in accordance with its terms. In consideration for the license granted under Section 1.2, the Licensee shall pay in U.S. dollars to the Licensors after the expiration of the last Licensed Patent a royalty in each country in the Territory comprising XX percent (XX%) of Net Sales.

3. Development of the Products

3.1. Establishment and Membership of The Product Development Committee.

3.1.1. Upon execution of the License Agreement with the Licensee, the Licensors and Licensee shall establish a Product Development Committee (the "PDC") to provide oversight of the Development, and implementation of the Development Plan which is outlined in Appendix and which, when agreed upon and executed by representatives of the Licensors and Licensee, shall become a part of this Agreement.

3.1.2. The PDC shall be formed by the Licensee(s) and will allow for at least one voting representative of Biota and Sankyo, each at their respective option. The PDC formed under this Agreement shall cooperate with any PDC formed under other license agreements with other licensees relating to the Products in order to ensure maximum coordination in the development of the Products on a worldwide basis.

3.2. Duties of the PDC

3.2.1. The PDC shall provide oversight and governance of the Development Plan and monitor, manage and administer, as required, the Licensee Development of the Products. In general, the PDC will be responsible for project management.

3.2.1.1. Project management. The PDC shall (i) approve specific tasks, activities, resources, and expenditures under the Development Plan; (ii) establish objectives and milestones, and determine when and if objectives and milestones are met; and (iii) review progress made under the Development Plan and implement necessary changes to the Development Plan. It is the intention of the Parties that the PDC will review and discuss research plans, the design of studies, study protocols, selection of sites for preclinical and other Development studies, and other such matters that the Parties may deem necessary for the Development of the Products by the Licensees.

3.2.1.2. The PDC shall discuss regulatory strategy and the preparation, filing and prosecution of applications for Marketing Approvals and other regulatory issues.

3.3. Meetings and Decisions of the PDC

3.3.1. Meetings. Unless otherwise determined by the PDC, the PDC shall meet at least twice per year alternately at locations to be determined through negotiations between parties whose representatives participate in the PDC. At other times, the location or manner of the meeting (e.g., telephone conferences) will be determined by the PDC. Costs for representatives of the Parties to attend PDC meetings will be for each Party's account.

3.3.2. Decisions. All actions and decisions reserved for the PDC under Section 3.2 will require the unanimous consent of all of its voting members. If the PDC fails to reach unanimous agreement, the Parties shall attempt in good faith to reach an agreement on the unresolved matter within twenty (20) days, but if the issue cannot be resolved through good faith discussions, then the Licensee will have the right to make the final decision.

3.4. PDC Reporting and Information Sharing

3.4.1. Following each twice yearly meeting of the PDC, a representative of the PDC jointly appointed by its members shall prepare and deliver to all Parties a written report recording the issues, decisions, conclusions, recommendations and other actions taken by the PDC, as well as the general status of the Development Plan at that time. Any

exceptions or dissents from the report may be noted in writing by the dissenting Party.

3.4.2. The Parties shall nominate one person in each of their organizations to act as primary recipient for said written reports.

3.4.3. Except for confidential business information, the Parties agree to share with the PDC all clinical and regulatory data available to them from their Clinical Development activities that could assist the PDC in carrying out its responsibilities.

3.5. Development Phase

3.5.1. Development Expenses. All direct and indirect costs and expenses associated with Development of the Product will be borne by the Licensee.

3.5.2. Development Candidates. The Parties hereby agree that Sankyo's R-118958 shall be the Lead Compound and is nominated as the first Development Candidate. Biota's compound referenced as BTA938 shall be the back up Lead Compound.

3.5.3. The Development Candidate shall progress promptly into Development in accordance with the Development Plan.

3.5.4. If the first or a subsequent Development Candidate is not commercially viable as determined by the PDC, the PDC shall select the back up Lead Compound. If the back up Lead Compound is not commercially viable as determined by the PDC then the PDC may select another Lead Compound from Appendix [redacted] as a Development Candidate.

3.5.5. Due to the cost associated with Development, it is the intent of the Licensors that only one Lead Compound will be developed at a time. Notwithstanding the foregoing, the PDC may determine that more than one Development Candidate may progress into Development at any one time.

3.5.6. The Licensee shall ensure the integrity, quality and security of all Information; any technical, regulatory and clinical data, generated under the Development Plan, including any laboratory notes, technical data or specifications, test results, and any other relevant information or materials arising from the conduct of the Development Plan.

3.5.7. Clinical Trial Management: The Licensee shall prepare suitable applications for

approval or consent of commencement clinical trials, management of trials, handle reporting, analysis and all other aspects of the trial being conducted by it or on its behalf.

3.6. API Manufacturing Development Costs

3.6.1. All direct and indirect costs and/or third party charges associated with API Manufacturing Development shall be borne by the Licensee or its designee.

3.7. Regulatory Matters

3.7.1. The Licensee shall be responsible at its sole expense for filing, prosecuting, and obtaining Marketing Approvals in each country in the Territory. Subject to the provisions of this Agreement, the Licensors will use commercially reasonable efforts and reasonable scientific judgment to assist in preparing documents for obtaining Marketing Approval from a Regulatory Authority for each country in the Territory. The Licensors will, if required by a Regulatory Authority, provide certain information concerning the Manufacture of LANI Compound and/or Product directly to such Regulatory Authority to facilitate the Licensee's application for Marketing Approvals. If a Regulatory Authority requests that the Licensee conduct additional developmental activities to obtain Marketing Approval, the Licensee shall, after consultation with Licensors, conduct such additional developmental activities at its own expense. In each country in the Licensee Territory, the Licensee shall keep the Licensors reasonably informed as to the regulatory status of Marketing Approval. In addition, Licensee may, at its own expense, conduct developmental activities for promotional and marketing purposes upon securing the prior written consent of Licensors after obtaining Marketing Approval. The Licensee shall inform the Licensors of the First Commercial Sale of the Product by the Licensee in each country or region in the Territory within seven (7) days thereof. The Licensee shall promptly inform the Parties with respect to any regulatory action taken or notification regarding the Products either during the approval process or marketing of the Products in the Territory.

3.7.2. Regulatory Communications. Each Party agrees to provide the others with all reasonable assistance and take all actions reasonably requested by the others that are necessary or desirable to enable the others to comply with any Laws applicable to the Product, including, without limitation, to meet reporting and other obligations to

(i) maintain and update the Marketing Approval and any filings under Section 3.7.1;

(ii) submit adverse event reports to the appropriate Regulatory Authorities as

required to fulfill obligations under Laws; and

(iii) submit or file promotional materials with Regulatory Authorities, as appropriate.

4. Commercialization

4.1. Commercialization Committees. The Parties agree that they may form Co-Promotion Committees as necessary to coordinate the Co-Promotion of the Product in any applicable country in the Territory. Such committees, if formed by the Parties will allow for at least one voting representative from each of Biota and Sankyo, each at their respective option. Attendance of members at meetings shall be at the respective expense of the participating parties appointing such members.

4.1.1. Decisions of Commercialization Committees. All actions and decisions reserved for the Co-Promotion Committees will require the unanimous consent of all of its voting members. If the committee fails to reach unanimous agreement, the Parties shall attempt in good faith to reach an agreement on the unresolved matter within thirty (30) days, but if the issue cannot be resolved through good faith discussions, then the matter shall be referred to the executives of the representatives of those Parties unable to reach unanimity with authority to settle the matter within thirty (30) days. If the matter is not resolved within the thirty (30) day period following submission of the matter to those executives, then the Licensee will have the right to make the final decision.

4.2 Record Keeping; Reporting and Audit. The Licensee will provide Biota and Sankyo with quarterly reports of the Net Sales of the Products by the Licensee or its Affiliates in the Territory should Biota and/or Sankyo Co-Market or Co-Promote Products. The Licensee shall keep and complete records of costs associated with marketing and distribution costs, and expenses incurred for sale of the Product within the Territory should Biota and/or Sankyo Co-Promote Products. Such records shall be retained by the Licensee and shall be made available for inspection, review and audit, at any time within normal business hours during the applicable calendar year and for two (2) years thereafter, at the request and expense of the Licensors, by an independent certified public accountant appointed by the Licensors for the sole purpose of verifying the Licensee's accounting reports and payments made or to be made pursuant to this Agreement. Such accountants shall not reveal to the Licensors the details of its review, except for such information as is required to be disclosed under this Agreement. This right to audit shall remain in effect

throughout the life of this Agreement and for a period of two (2) years after the Term. If an error in favor of the Licensors of more than five percent (5%) is discovered, then the Licensees shall pay the audit expenses that discovered such error. The Parties shall settle all differences hereunder within thirty (30) days of notification.

4.3. The United States. Sankyo and Biota retain the right to designate a third party (including, without limitation, Sankyo, Biota or one of their Affiliates) to Co-Market the Product in the United States with the Licensee and/or terminate the license to the Licensee, if the Licensee does not meet reasonable annual minimum sales as agreed in writing within the six (6) months of the Product launch by the Parties for that country.

4.4 Other Markets. In all other countries where Sankyo and Biota have granted an exclusive license to the Licensee, Sankyo and Biota shall retain the right to terminate the Licensee and/or grant additional licenses to a third party (including, without limitation, Sankyo, Biota or one of their Affiliates), if the Licensee does not achieve reasonable annual minimum sales as agreed in writing within the six (6) months of the Product launch by the Parties for that country.

4.5 Non-Compete. During the term of this Agreement, unless otherwise agreed between the Parties, each Party agrees that neither for itself or through its Affiliates will it develop, Commercialize, or otherwise handle or deal with, directly or indirectly, or to enter into any collaboration, license or development agreement or any other arrangement with any party other than the other Parties to develop, Commercialize, or otherwise handle or deal with any Competitive Product in any country. The restrictions in this Section 4.5 shall not apply to Products already Manufactured, distributed, sold, bought or otherwise dealt with by each Party or its Affiliates as of the Effective Date.

5. Payments; Records and Reports

5.1. Royalty Reports

5.1.1. Frequency of Royalty Reports. Within sixty (60) days of the end of each calendar quarter after the First Commercial Sale of the Product by the Licensee in the Territory, the Licensee shall deliver to the Licensors a royalty report containing information concerning the immediately preceding calendar quarter. Each royalty report delivered by the Licensee to the Licensors shall contain at least the following information, denominated in local currency and US dollars as calculated for each applicable country in accordance

with the exchange rate published in the New York edition of the Wall Street Journal on the last day of the calendar quarter for which such payment accrues:

(i) Net Sales for the applicable calendar quarter in each country;

(ii) Amount of royalty earned for each country, and in total for the period;

(iii) Amount of withholding taxes, if any, required by Laws to be deducted in respect of such royalties; *provided, however, that* the Licensee will take reasonable action to minimize any such withholding tax in each country.

5.1.2. The Parties agree to furnish reports, in a form to be agreed upon, showing, among other things, (i) the gross sales and Net Sales of each Product sold and the royalties that have accrued hereunder with respect thereto and (ii) the amount of withholding taxes on the royalty payments.

5.1.3. The Parties shall keep proper books of account with reference to their respective sales of any Product under this Agreement and with reference to any sales by Licensees which are reported to the Parties. When requested by the other Party, such books of account shall be made available at reasonable times for audit by the other Party or its agents (including the right to inspect, copy, and make abstracts therefrom), solely for the purpose of verifying the royalties due or paid, or for determining compliance with other provisions of this Agreement. Any expense incurred by a Party conducting such audit shall be borne by said Party unless discrepancies attributable to the audited Party exceeding the cost of the audit are found, in which case the costs of the audit shall be reimbursed by the other Party.

5.1.4. The Party owing the royalty (the "Payor") shall permit its books of account or records of sale to be inspected at any reasonable time during normal business hours by a representative of the other Party (the "Payee") solely for the purpose of verifying the amounts due hereunder.

5.2. Method of Payment

5.2.1. All payments under this Agreement shall be made payable in U.S. dollars and shall be by appropriate electronic funds transfer in immediately available funds to such bank accountant as the Payee shall designate and on a date no later than when royalty reports are due under Section 5.1.1 above. Each payment shall reference this Agreement and identify the obligation under this Agreement that the payment is to satisfy. Any and all expenses for such payment incurred by the Payee shall be borne by the Payee.

5.2.2. Any payments due under this Agreement that are not paid on or before the date such payments are due shall bear interest, at the lower of one percentage point above the Prime Rate of interest as reported in the New York edition of the Wall Street Journal on the date the payment is due or the maximum allowed by law, compounded monthly until such payment is made.

5.2.3. Any taxes or similar charges levied or assessed in a territory on the Payee on the royalty payments shall be borne by Payor. However, Payor has the right to deduct from the royalty payments such income taxes or charges paid thereon for which Payee is entitled to receive a credit under income tax laws in effect as of the time payment is made. In these cases, Payor will promptly provide Payee with an original receipt for such tax payments (or a certified copy, if the original is not available). Payor's failure to provide Payee with such documentation as Payee determines is acceptable for tax purposes shall preclude Payor from deducting such taxes or charges from the gross royalty otherwise due.

5.2.4. Payee may require such other account statements or reports from Payor as may be reasonable.

6. Trademarks

6.1. To the extent commercially reasonable and appropriate, a single Trademark worldwide to be selected by the Licensee and approved in writing by the Licensors shall be used for each Product in all countries in the Territory, provided that Licensee shall cooperate with Licensors and other licensees relating to the Products in order to select said single Trademark for use on a worldwide basis. If the Trademark is not available in or inappropriate for the Territory, the Licensee shall propose an alternate Trademark to be approved in writing by the Licensors, such approval not to be unreasonably withheld. Each Trademark may be used by a Party only in connection with the applicable Product and shall not be used by any Party on, or in connection with, any other product. The Licensee shall own each Trademark used to promote Products in the Licensee's Territory and shall be responsible for searching, clearing, filing, prosecuting and maintaining, and all reasonable steps necessary in defending, each Product Trademark. In the case of countries in which the Licensors and Licensees Co-Market and/or Co-Promote Products, Sankyo and/or Biota, at their discretion, shall have the right to select and register

additional trademarks for use with the Product.

6.2. Until the last-to-expire Patent on a country-by-country basis within the Territory expires, Licensee shall hereby grant to the Licensors under the Trademark owned by the Licensee, an exclusive license, fully paid up, perpetual, royalty free, with the right to grant sublicenses, to make, use, sell, offer for sale and import the Product in any countries which said Trademark is registered outside the Territory. Upon any termination of this Agreement or expiration of the last-to-expire Patent on a country-by-country basis within the Territory , the Licensee shall, at the request of the Licensors, return all rights to and cooperate in transferring registrations of all Trademarks to the Licensors. Any and all costs and expenses necessary to transfer registrations of all Trademarks shall be borne by the Licensee.

7.Ownership and Treatment of Inventions

7.1 Ownership of Inventions

7.1.1. The Information and Inventions, and the right to file patent applications and the patents regarding the LANI Compounds or Products generated by the Licensors after the Effective Date (collectively, the "Licensor's Intellectual Properties") shall be owned by the Licensors.

7.1.2. The Information and Inventions, and the right to file patent applications and the patents regarding the LANI Compounds or Products generated by the Licensee after the Effective Date (collectively, the "Licensee's Intellectual Properties") shall be owned by the Licensee. Each of the Licensor's shall have an equal, undivided perpetual, paid up royalty free right to use Licensee's Intellectual Properties.

7.1.3. In the case of Inventions owned jointly by at least one employee of Biota or Sankyo and one employee of the Licensee ("Joint Inventions"), the Parties shall agree on whether or not to secure patent protection and which Party shall bear the primary responsibility for preparing, filing, prosecuting the Patents resulting therefrom. The Parties shall equally share all expenses related thereto. Each Party shall promptly render all necessary assistance reasonably requested by the other Party in applying for and prosecuting the patent applications. If any Party does not elect to participate in the expense of filing for such Joint Inventions, the other Party or Parties may do so at its own expense, excluding the declining Party from ownership.

7.2. Maintenance of Patents

7.2.1. Each Party shall, at its own expense, diligently take all steps necessary to maintain its own Patents, in full force and effect, including but not limited to a duty to diligently file and pursue any reissues and re-examinations, if applicable. If any Party elects not to maintain any of its own Patents, it shall promptly notify the others of that election and shall, at the other Parties request, assign to the other Parties all right, title and interest in and to such Patents of the assigning Party. In such case, the other Parties shall bear the cost and responsibility for the maintenance of such Patents and the assigning Party shall render all necessary assistance reasonably requested by the other Parties in maintaining such Patents.

7.2.2. In the event that Joint Inventions are registered, the Party who bears the primary responsibility for preparing, filing, prosecuting such Joint Inventions shall bear the primary responsibility for performing the obligation to maintain registered Patents resulting from such Joint Inventions ("Joint Patents") as set forth in Section 7.2.1. Each Party shall promptly render all necessary assistance reasonably requested by the other Parties in performing such obligation. Any and all costs and expenses reasonably necessary and useful to perform such obligation on any and all Joint Patents shall be borne by all Parties equally.

7.2.3. Notwithstanding the provision of Section 7.2.1, each Party shall be relieved from its obligation to maintain its own Patents stipulated by Section 7.2.1, in the event that the Licensors determine that any Products related to such Patents will not undergo Development or be Commercialized as a Development Candidate.

7.2.4. The Parties agree to cooperate to obtain, to the fullest extent allowed by Laws, an extension of exclusivity beyond the full term expiry date of any Patents subject to this Agreement which the Parties mutually agree may maximize commercial return of Products. The Parties shall provide all relevant patent information to the Regulatory Authority or other applicable agency as required by Laws.

7.3. Patent Infringement

7.3.1. In the event that the Licensee is charged with the infringement of a patent or other intellectual properties, including but not limited to utility model, design or trademark owned by any third party or receives any filing of any claim or suit by any third party

related to the Products because of any of the activities necessary to the performance of its obligations under this Agreement, the Licensee shall notify the other Parties fully and promptly in writing upon receipt of any knowledge or notice of the charge of infringement, specifying its nature and by whom it was raised. The Licensors shall in good faith offer the Licensee reasonable cooperation so that the Licensee may handle such claim or suit at its own expense and for its own account. The Licensee shall prosecute and control such claim or suit and periodically inform the other Parties of its intended course of action and shall provide the other Parties with the opportunity to comment on significant actions or elements of its course of action. The Licensee may not settle any such claim or suit without the prior written consent of the other Parties, which consent shall not be unreasonably withheld or delayed, except as provided hereafter. Any costs and expenses, including reasonable attorneys' fees, incurred by the Licensee in defending against such claim or suit shall be borne by the Licensee. Either Licensor shall have the option to take over the action at its discretion and its own expense, provided, however, that failure by the Licensee to diligently defend the action shall not relieve Licensee of responsibility for the expense of the action.

7.3.2. Infringement by Third Parties. In the event that any Party becomes aware that the Patents or other intellectual property, including but not limited to utility model, design or trademark (collectively, "Intellectual Properties" in this Section) are threatened to be infringed or disputed by any third party, such Party shall notify the other Parties fully and promptly in writing, specifying the nature of the threat and by whom they are threatened to be infringed or disputed. The Licensors shall in good faith offer the Licensee reasonable cooperation so that the Licensee may handle such claim or suit at its own expense and for its own account. The Licensee shall prosecute and control such claim or suit and periodically inform the other Parties of its intended course of action and shall provide the other Parties with the opportunity to comment on significant actions or elements of its course of action. The Licensee may not settle any such claim or suit without the prior written consent of the other Parties, which consent shall not be unreasonably withheld or delayed, except as provided hereafter. Any costs and expenses, including reasonable attorneys' fees, incurred by the Licensee in defending against such claim or suit shall be borne by the Licensee. If the Licensee does not exercise its right to control the conduct of defense of any such action in response to any such claim within XX (XX) days of becoming aware of or being notified of such infringement, then the Party owning or controlling such Intellectual Property shall have the right, but not the obligation, to bring such action.

8. Representations, Warranties, and Covenants

8.1. Mutual Representations, Warranties, and Covenants. Each of the Licensors and the Licensee each hereby represents, warrants, covenants acknowledges and agrees that the other is relying, and is entitled to rely, on the following representations, warranties, and covenants:

(a) Each Party has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement has been duly and validly authorized and approved by proper corporate action on the part of such Party. Each Party has taken all other action required to be taken by such Party under the Laws, its certificate of incorporation, by-laws or any agreement to which it is a party with respect to the execution, delivery and performance of this Agreement. Assuming due authorization, execution and delivery on the part of a Party, this Agreement constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as the enforceability thereof may be limited by applicable Laws or by bankruptcy, insolvency, reorganization or other similar Laws of general application relating to creditors' rights; and

(b) To the best of its knowledge as of the Effective Date, the execution and delivery of this Agreement by a Party and the performance by such Party contemplated hereunder shall not violate any Laws or any order of a court or a Regulatory Authority; and

(c) To the best of its knowledge as of the Effective Date, neither the execution and delivery of this Agreement nor the performance hereof by a Party requires such Party to obtain any permits, authorizations or consents from any governmental authority other than a Regulatory Authority or from any other person; and

(d) During the Term, each Party shall fulfill its obligations under this Agreement, in accordance with the terms of this Agreement and all applicable Laws; and

(e) During the Term, each Party shall retain and maintain compliance with all necessary government authorizations and permits necessary to Manufacture and supply the Product and to otherwise perform each Party's obligations under this

Agreement; and

(f) All of a Party's employees, officers and consultants participating in the performance of this Agreement are, to the extent permitted under applicable Laws, under obligations (i) to assign to such Party all Inventions made during the course of and as a result of their association with such Party, and (ii) to maintain as confidential the Confidential Information received from or on behalf of the other Party; and

(g) Each Party shall not knowingly employ any employee in performing the services hereunder who has been debarred or disqualified by a Regulatory Authority or any governmental agency.

8.2. Licensors' Representations, Warranties, and Covenants. Each Licensor for itself, hereby represents, warrants, covenants acknowledges and agrees that the Licensee is entitled to rely, on the following representations, warranties, and covenants:

(a) The execution, delivery and performance of this Agreement by each of the Licensors shall not result in the breach of or give rise to any termination of any agreement or contract relating to the Product to which each of the Licensors is a party; and

(b) To the best of each of the Licensor's knowledge, as of the Effective Date, the activities of the Licensee contemplated hereunder does not infringe any patent rights or any other proprietary rights of any third party; and

(c) As of and prior to the Effective Date, neither of the Licensors has granted to any third party a license under any Patent or Information owed or Controlled by each of the Licensors to make, use, sell, offer to sell, and/or import Product in the Licensee's Territory; and

(d) The Licensed Patents are duly and validly registered or applied for in the countries in the Licensee Territory with respect to each Licensed Patent and each Licensor agrees to continue to use commercially reasonable efforts to obtain and maintain the registrations of the Licensed Patents in full force and effect during the Term hereof at their sole cost and expense, taking into account the amount of revenues received from such Licensed Patents on a country-by-country basis.

8.3. No Other Warranty EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER LICENSOR MAKES ANY OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THIS AGREEMENT. THE LICENSE IS PROVIDED WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WARRANTY AS TO THE ENFORCEABILITY OR SCOPE OF ANY LICENSED PATENT IN THE FIELD, OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED. LICENSORS MAKE NO REPRESENTATION OR WARRANTY THAT LICENSEE'S ACTIVITIES UNDER THE LICENSE WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHT OF A THIRD PARTY. LICENSOR WILL NOT BE LIABLE FOR SUCH INFRINGEMENT, OR AN ALLEGATION THEREOF, NOR SHALL THE SAME BE AN EXCUSE FOR NONPERFORMANCE OF THE LICENSEE'S OBLIGATIONS HEREUNDER. THE LICENSORS ASSUME NO RESPONSIBILITIES OR LIABILITIES TOWARDS THE LICENSEE OR THIRD PARTIES WITH RESPECT TO THE RESEARCH, DEVELOPMENT, MANUFACTURE, USE, SALE OR DISPOSITION OF LICENSED PRODUCT IN THE FIELD. THE ENTIRE RISK AS TO LICENSED PRODUCT IN THE FIELD IS ASSUMED BY LICENSEE.

8.4. Limitation of Liability. SUBJECT TO ARTICLE XIII (13), NO PARTY SHALL BE ENTITLED TO RECOVER FROM ANOTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER, UNLESS SUCH DAMAGES ARE INFLICTED AS A RESULT OF THE NEGLIGENCE OR WRONGDOING OF THE OTHER PARTY.

8.5. Survival of Limitation of Liability. Sections 8.3 and 8.4 shall survive any termination or expiration of this Agreement.

9. Term and Termination

9.1. Term

9.1.1. The Agreement will commence on the Effective Date and, unless earlier terminated as provided for hereunder, continue until the expiration of the last-to-expire Patent within the Territory owned or Controlled by either or both of the Licensors

claiming the Manufacture, use, importation or sale of the Products on a country-by-country basis, and thereafter shall automatically be renewed each year for one (1) year periods unless either party gives at least six (6) months written notice of termination of this Agreement to the other before the expiration of the term of this Agreement. While this Agreement remains in force, the Licensee shall continue to have the right to use the Information owned by Licensors.

9.2. Earlier termination

9.2.1. Either the Licensors or the Licensee may, without prejudice to any other remedies available to it at law or in equity, terminate the Agreement on a country by country basis prior to the end of the term, by giving the other sixty (60) days written notice ("Notice Period") upon occurrence of any of the following events:

9.2.1.1. "Material breach" defined as the default of any material obligation hereunder by either the Licensor or the Licensee, which has not been remedied within sixty (60) days after one Party sends written notice detailing the substance of the default to the defaulting Party, or

9.2.1.2. "Insolvency" meaning the insolvency, bankruptcy, dissolution or liquidation of the other Party, where such Party is subject to the filing or consents to the filing of a petition under any bankruptcy or insolvency law or has any such petition filed against it which has not been dismissed within ninety (90) days of such filing, appointment of a trustee, administrator, or receiver for all or substantially all of the assets of such Party, or assignment of the assets of such Party for the benefit of creditors, or attachment or expropriation of the business or assets of such Party, or

9.2.1.3. "Unresolved Differences" meaning that despite the commercially reasonable efforts of the Parties, the Parties are unable to resolve disputes as provided herein.

9.2.1.4 "Development neglect" meaning that the Licensee ceases Development of the Product for more than six (6) consecutive months for reasons within its control until any Regulatory Authority grants Marketing Approval for the Product to the Licensee in the Territory.

9.2.1.5 "Marketing Failure" meaning that the Product may not be sold as a result of a recall or market withdrawal and such inability to sell the Product continues for a period of

twelve (12) months, provided, however, that if the Marketing Failure is applicable to a certain Territory, the termination shall only apply to that Territory and shall not affect the Agreement in other Territories.

9.2.1.6. The right of a Party to terminate this Agreement as provided in this Section 9.2 shall not be affected in any way by its waiver or failure to take action with respect to any previous default.

9.3. Rights on termination

9.3.1. If either Party terminates this Agreement pursuant to Section 9.2, in those countries where such termination takes effect:

(a) all rights to the LANI Compounds and all relevant Patents including the Licensor's Intellectual Properties, Trademarks, licenses and other rights granted or assigned to either Party at any time under this Agreement (collectively, "Rights") shall revert to the Licensors; and

(b) if this Agreement is terminated by the Licensors, the Licensors shall negotiate in good faith a mechanism to allow the Licensee, should it so wish, to continue to Develop, Manufacture, file for Marketing Approval, use, sell, offer for sale the Product in such country.

9.3.1.1. Without prejudice to any exclusive license granted herein, a Party that grants a license to a third party under a Joint Invention shall obtain the prior written consent of the other Party to such a license, such consent not to be unreasonably withheld or delayed.

9.3.2. The provisions of Section 9.3.1 and this Section 9.3.2 shall survive the termination for any reason of this Agreement. Except as specifically provided in this Agreement, neither Party shall be liable to the other based on, or as a result of, the termination of this Agreement as provided herein, whether in loss of good will, anticipated profits or otherwise.

10. Confidentiality

10.1. During the term of this Agreement and for a period of seven (7) years thereafter, each Party (a) shall hold the Technology, the Information and any marketing and other confidential information, whether in written, oral, visual, or machine readable form disclosed by either Party to the other under this Agreement (the "Confidential Information") and the Substances supplied by either Party to the other under this Agreement in confidence with the same degree of care it maintains the confidentiality of its own Confidential Information and Substances, (b) shall not disclose such Confidential Information and make Substances available to any third party without the prior written consent of the disclosing Party, and (c) shall not use such Confidential Information and Substances other than for exercising its rights and/or performance of its obligation under this Agreement except for any information which is evidenced that:

(i) was in the receiving party's possession at the time of disclosure,

(ii) was publicly known at the time of such disclosure,

(iii) becomes publicly known through no default of the receiving party,

(iv) was obtained legally by the receiving Party from a duly authorized third party, or

(v) was independently discovered without the aid or application of the information received.

10.2. Each Party may disclose the Confidential Information and make the Substances available only to those of its employees, contractors, and agents who have a need to know such Confidential Information and the Substances to implement the terms of this Agreement. The Parties agree to take reasonable precautions to preserve the confidential, proprietary or secret status of the Confidential Information and Substances and shall require that each of their respective employees, contractors, and agents understand and agree in writing to treat and to hold such Confidential Information and Substances in confidence consistent with the provisions herein.

10.3. Within thirty (30) days of the date of termination of this Agreement for any reason, the Parties shall provide each other with written notice specifying that through reasonable care and to the best of its knowledge: (a) all Confidential Information embodied in whole or in part in documents, materials, things, and copies thereof have been destroyed or returned to the other Party, (b) the originals and all copies of any machine-readable documentation containing any portion of the Confidential Information have been destroyed or returned to the other Party, (c) all remaining Substances supplied by the either Party have been returned to the other Party or destroyed, unless otherwise agreed in

writing between the Parties, and (d) all use of the Substances by the returning Party has ceased.

10.4. No Party may issue any press release, publication, or any other public announcement relating to this Agreement, the LANI Compounds or the Product without obtaining the other Parties' prior written approval, which approval shall not be unreasonably withheld or delayed. The Parties shall in good faith prepare mutually acceptable announcements prior to such release, publication or announcement. Notwithstanding any of the foregoing, each Party may use the substance of previously approved public announcements and the substance of other public announcements of the other Party without prior notice.

11. Liability and Indemnity

11.1. The Licensors shall indemnify, defend and hold harmless the Licensee, its employees, agents, officers, directors, permitted licensees, successors and permitted assigns (collectively, the "Licensee Indemnified Parties"), from and against any and all costs, liabilities, judgments, obligations, losses, expenses and damages (including reasonable attorneys' fees and expenses) of whatsoever kind or nature (collectively, "Losses") incurred by or imposed upon any Licensee Indemnified Party as a result of any claims, actions, suits or proceedings (collectively, "Claims") arising out of or related to, in any way, the licensing, Development, Manufacture, marketing, promotion, importation, sale or other use (collectively, "Use") of the Product in any country by the Licensor pursuant to this Agreement or otherwise, regardless of whether such Claims or Losses are based upon theories of contract, tort, product liability, strict liability, infringement of any patent, trademark, trade name, logo, service mark, trade dress, trade secret, or any other legal or equitable theory; provided, however, that the Licensee shall indemnify the Licensors for Losses proven to have been caused solely from an act or omission by Licensee.

11.2 The Licensee shall indemnify, defend and hold harmless each of the Licensors, and each of their employees, agents, officers, directors, permitted licensees, successors and permitted assigns (collectively, the "Licensor Indemnified Parties"), from and against any and all costs, liabilities, judgments, obligations, losses, expenses and damages (including reasonable attorneys' fees and expenses) of whatsoever kind or nature (collectively, "Losses") incurred by or imposed upon any Licensor Indemnified Party as a result of any

claims, actions, suits or proceedings (collectively, "Claims") arising out of or related to, in any way, the licensing, Development, Manufacture, marketing, promotion, importation, sale or other use (collectively, "Use") of the Product in any country by the Licensee pursuant to this Agreement or otherwise, regardless of whether such Claims or Losses are based upon theories of contract, tort, product liability, strict liability, infringement of any patent, trademark, trade name, logo, service mark, trade dress, trade secret, or any other legal or equitable theory; provided, however, that the Licensors shall indemnify Licensee for Losses proven to have been caused solely from an act or omission by the Licensors.

11.3. Each Party shall give prompt written notice to the other of any Claim asserted against such Party (in such capacity, the "Notifying Party") arising from or relating to the Product, regardless of whether the Notifying Party is entitled to seek indemnification from the other Party pursuant to either Section 11.1 or 11.2. The Parties shall, subject to the execution of an appropriate non-disclosure agreement, reasonably consult with, and share information with, each other regarding such Claim and shall reasonably cooperate and assist each other in the event that the Notifying Party wishes to pursue any claim against any third party in connection therewith, in each case at the sole cost and expense of the Notifying Party. Each sublicense agreement entered into by a Party relating to any Product in accordance herewith shall contain a provision substantially similar to that set forth in this Section 11.3.

11.4. SUBJECT TO ARTICLE XIII (13), NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER, UNLESS SUCH DAMAGES ARE INFLICTED AS A RESULT OF THE NEGLIGENCE OR WRONGDOING OF THE OTHER PARTY.

12. Amendment

12.1. Except as otherwise provided in this Section, all amendments to this agreement must be in writing and signed by authorized representatives of both parties.

13. Governing Law and Jurisdiction

13.1. Any claim, dispute or controversy of whatever nature arising out of or relating to this Agreement, including without limitation, any action based on tort, contract or statute, or concerning the interpretation, effect, termination, validity, performance or breach of this Agreement shall be construed in accordance with the laws of New York without regard to its conflict of law principles.

The Parties shall first negotiate in good faith to resolve any disputes which arise under this Agreement, but failing amicable solution, all unresolved disputes shall, at the request of either Party, be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators appointed in accordance with said Rules. The venue of the Arbitration shall be New York. The language of the arbitration shall be English.

14. Force Majeure

14.1. Neither Party hereto shall be liable for any failure or delay in performance of this agreement occasioned in whole or in part by acts of God, strike, lock-out, fire, earthquake, epidemic, inability to obtain materials or shipping space, breakdown, delay of carrier or regulation of any government or any other cause beyond its control, provided that said Party has exercised due and reasonable care and its best efforts to avoid any of the above-mentioned events.

15. Notices

15.1. Any notice or report pursuant to this Agreement shall be deemed duly given if delivered personally, sent by airmail, international recognized courier service, electronic mail (provided such electronic mail is followed by facsimile confirmation in accordance with this Section 15.1) or facsimile addressed to the other Party at the addressee facsimile number set forth below, or to such other address or facsimile number as shall have theretofore been furnished by one Party to the other in accordance with this Section, and shall be deemed to have been given when sent.

If to Sankyo: Sankyo Company, Limited
3-5-1 Nihonbashi-Honcho, Chuo-ku,
Tokyo 103-8426, Japan
Attention: Director, Licensing Department
Fax: +81-3-5255-7086
Telephone: +81-3-5255-7084
e-mail: moriaki@hq.sankyo.co.jp

If to Biota: _____
_____
_____
Attention:
Fax:
e-mail:

If to Licensee: _____
_____
_____
Attention:
Fax:
e-mail:

16. Assignment of Rights and Obligations

16.1. Either Party may assign all or any part of this Agreement to any Affiliate. In all other respects, neither Party shall voluntarily or by operation of law assign, hypothecate, give, transfer, mortgage, sublet, license, or otherwise transfer or encumber all or part of its rights, duties, or other interests in this Agreement or the proceeds thereof (collectively, "Assignment") in whole or in part to any third party without prior written consent of the other, provided, however that the Licensors may assign this Agreement in the event of an acquisition of the Licensor by a third party. In the event Licensee is acquired by a third party, either Licensor may terminate this Agreement upon reasonable notice to the other Parties. Any attempt to make an Assignment in violation of this provision shall be a material default under this Agreement and any Assignment in violation of this provision shall be null and void.

17. Entire Agreement

17.1. This Agreement, together with the Confidential Disclosure Agreement dated [redacted] and the Appendices attached hereto, set forth the entire agreement and understanding between the Parties as to the subject matter hereof, and supercedes all agreements and understandings between the parties as to the subject matter, whether oral

or in writing.

18. No Implied Waiver

18.1 No failure or delay on the part of either Party to exercise any right under this Agreement or provided for by Laws shall impair, prejudice or constitute a waiver of such right.

19. Severability.

19.1. If and to the extent that any court or tribunal of competent jurisdiction holds any of the terms, provisions or conditions of this Agreement or parts thereof, or the application hereof to any circumstances, to be illegal, invalid or unenforceable in a final non-appealable order, (i) such provision shall be fully severable, (ii) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (iii) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (iv) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement, a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible.

20. No License.

20.1. Nothing in this Agreement shall be deemed to constitute the grant of any license or other right in any Party to the other Party in respect of any product, patent, trademark, confidential information, trade secret or other data or any other intellectual property of the other Party except as expressly set forth herein.

21. Headings.

21.1. The headings for each article and section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular article or section nor to be used in construing or interpreting any of the provisions of this Agreement.

22. Appendixes

22.1. All Appendixes to this Agreement are by this reference incorporated herein and made a part of this Agreement.

23. Counterparts.

23.1. This Agreement may be executed in three or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed and effective as of the date first indicated above.

BIOTA HOLDINGS LTD.	**SANKYO CO., LTD**	**Licensee**
By_____	By_____	By_____
Name_____	Name_____	Name_____
Title_____	Title_____	Title_____
Date_____	Date_____	Date_____

Certain information contained in this document, marked by ***, is filed with the SEC pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended

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AMENDMENT #1

to

Collaboration and License Agreement

Between

Biota Holdings Limited,

Biota Scientific Management Pty. Ltd.

and

Sankyo Co., Ltd.

THIS AMENDMENT, effective as of June 30th, 2005 between Biota Holdings Limited and Biota Scientific Management Pty. Ltd. (jointly referred to as "Biota"), both being corporations organized and existing under the laws of Victoria, Australia, with offices at 616 St. Kilda Road Melbourne, Victoria, Australia, and Sankyo Company Limited ("Sankyo"), a joint stock company organized and existing under the laws of Japan, with offices at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo, Japan sets forth the agreement between the Parties as follows:

Recitals

1. Whereas, Biota Holdings Limited and Sankyo entered into a Collaboration and License Agreement dated September 29, 2003 (hereafter referred to as the "Agreement");

2. Whereas, Biota desires to expedite the clinical development of the LANI Compounds by providing funding of certain research and development work;

3. Whereas, Sankyo desires to cooperate with Biota in expediting such development; and

4. Whereas, the Parties desire to add Biota Scientific Management Pty. Ltd. as a Party to the Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein, and for other good and valuable consideration, the Parties hereto agree to amend the Agreement as follows:

1. Definitions

1.1 Any capitalized terms set forth in this Amendment shall have the same meanings as those set forth in the Agreement.

1.2 The "Activities" to be undertaken by Biota under this Amendment with respect to the LANI Compounds (specifically CS-8958) may include the following:

(a) Any Phase I studies with respect to the LANI Compounds,

(b) Proof of Concept (POC) studies in preparation for Phase II studies,

(c) Pre-clinical studies for Phase II,

(d) Phase II studies for which Biota has adequate funding,

(e) Development of the delivery device using a third party with expertise in such devices,

(f) Evaluating, applying for, registering and maintaining the Trademarks.

(g) Any other studies or development work agreed upon in writing by the Parties.

1.3 The "Activities" to be undertaken by Sankyo under this Amendment with respect to the LANI Compounds (specifically CS-8958) may include providing of API and its related compounds for the development and for the studies to be performed under the NIH study and for any other Activity agreed in writing by the Parties.

2. Funding of the Development

2.1 The Parties hereby agree that Biota may provide the funding for the Activities in an amount not to exceed [***] If Biota desires to invest more than [***] in funding for the Activities, the Parties will negotiate in good faith regarding the terms of such additional funding.

2.2 Sankyo may also provide funding toward the Activities in an amount up to [***] if it desires to do so. If Sankyo desires to invest more than [***] in funding for the Activities, the Parties will negotiate in good faith regarding the terms of such additional funding.

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

2.3 Any Party providing funding for compensation under this Amendment will keep accurate records of the nature and amount of all such expenses and will send reports of such expenses to the other Party within thirty (30) days of the end of each calendar quarter. Each Party shall have the right to audit the records of the other Party in accordance with the provisions of Section 5.3.2 of the Agreement. This right to audit shall remain in effect throughout the term of this Amendment and for a period of two (2) years after the termination of this Amendment. The Parties shall settle all differences arising from the audit within thirty (30) days after notification of any errors discovered during the audit.

3. Compensation for the Funding

3.1 Any Party which provides funding for the Activities shall be compensated as follows:

3.1.1 All funds for Activities shall be compensated to the Party making the investment by repaying double the amount of the investment.

3.1.2 The compensation shall be paid in a preferential manner out of proceeds received from any Licensee as upfront payments, milestone payments or royalties (hereafter referred to as "Licensee Payments").

3.1.3 The compensation shall be made using two-thirds (2/3) of any Licensee Payment which shall be paid in a preferential manner to the Party or Parties providing the funding in proportion to the funding provided by each Party. The remaining one-third (1/3) of any Licensee Payment will be considered as a "Profit Sharing" fee and shall be paid to Biota and Sankyo in equal amounts (50:50) as provided in the Agreement.

3.1.4 If the amount of the compensation to be paid to the Parties is less than two-thirds (2/3) of the amount of the Licensee Payment, then the balance of the Licensee Payment shall be paid as a Profit Sharing fee. If the amount of the compensation to be paid to the Parties is greater than two-thirds (2/3) of the amount of the Licensee Payment available, then the remainder of the compensation shall be carried forward until the next Licensee Payment is received. (See the attached "Example.")

3.1.5 The compensation will be paid within thirty (30) days of receipt of any Licensee Payment with respect to expenses incurred and reported in accordance with paragraph 2.3 above.

3.1.6 The costs and expenses to be compensated shall include (i) any third party expenses for the Activities paid after January 1st, 2005, (ii) the cost of

API for the Activities including intermediate incurred prior to the effective date of this Amendment, and (iii) the expenses for the NIH program as set forth in Section 5.1 below.

3.2 In the case of Biota, funding will be provided by, and compensation will be paid to, Biota Scientific Management Pty. Ltd.

3.3 The funding to be provided by the Parties, and which will be compensated as provided herein, will be allowed as follows:

(a) subcontract costs for clinical and pre-clinical studies performed by third party investigators under contract with Biota,
(b) the actual price charged by Sankyo's Affiliate for manufacturing API,
(c) the actual fees paid to consultants to help obtain the NIH grant,
(d) the cost of contracting the dry powder inhaler feasibility studies, including third-party consultants required to evaluate candidate inhalers,
(e) any third-party expenses required to evaluate, apply for, register and maintain the Trademarks,
(f) out-of-pocket expenses for other outside professional services and any other out-of-pocket expenses or costs required for the Activities or otherwise agreed by the Parties.

3.4 Sankyo will provide the necessary API for the Activities in the amounts and at a price to be agreed between the Parties. This price will be the actual price charged to Sankyo by its manufacturing Affiliate and will include the salaries and indirect costs of employees of the Affiliate, but will not include any profit margin for Sankyo. These amounts will be compensated as provided above.

3.5 In the event that either Party terminates the Agreement pursuant to Section 8.2 thereof, or the Agreement is terminated early upon mutual agreement, and one of the Parties continues to Develop, Manufacture, license or sell any of the LANI Compounds in any country (the "Continuing Party"), the Continuing Party shall compensate the other Party any of the funding provided for in this section, including the double funding provided for in Section 3.1.1 above. The compensation shall be paid in full within thirty (30) days after the Continuing Party receives from the other Party an invoice setting forth in detail the amount of any remaining funding which has not already been compensated. After the funding is fully compensated, the Continuing Party will pay the other Party (i) compensation, as profit sharing, in a range of twenty to forty percent (20-40%) of any Licensee Payments the Continuing Party may receive from Licensees, or (ii) in case of direct sales of the Product by the Continuing Party, a royalty on its Net Sales in a range of twenty to forty percent (20-40%) of the highest rate paid by any Licensee under the Agreement. The details of this arrangement shall be contained in a new agreement to be negotiated in good faith between the Parties.

3.6 Any disputes relating to the amount of the funding or the compensation to be paid under this section shall be resolved through good faith negotiations of the Parties. In the event of a failure to reach an agreement within sixty (60) days, the matter shall be resolved in accordance with Section 13 of the Agreement.

4. Management of Activities

4.1 Biota will take the lead in managing the Activities, provided, however, that important issues related to the Activities, such as study plans and protocol and the device selection, shall first be referred to the Licensing Committee.

4.2 In order to determine which issues need to be submitted to the Licensing Committee, each Party will submit an outline of any development plans to the Licensing Committee prior to commencing the Activities together with a proposed budget. If no objection is raised by a member of the Licensing Committee within fifteen (15) business days of receiving the development plan, the plan will be deemed to be approved. Urgent or emergency changes to the development plan may be made by Biota if, in its discretion, it is determined that such changes are required for medical or safety reasons or, based on study results, it is determined that changes must be made to accomplish the purpose of the development plan.

5. National Institute of Health (NIH) Study

5.1 The Parties agree that each has expended substantial sums of money to obtain the NIH grant and that each Party will be compensated under Section 3 above, *i.e.* double compensation, for any expenses paid to third parties to obtain the NIH grant or to complete the activities contemplated thereunder, including the cost of API provided by Sankyo, which are not paid by the NIH grant.

5.2 The Parties agree that any nebulizer or other results achieved by this NIH study will be considered to be Joint Intellectual Property or Joint Inventions under the Agreement and any proceeds arising from such Inventions will be shared 50:50 between the Parties.

6. Biota Scientific Management Pty. Ltd.

6.1 Biota Scientific Management Pty. Ltd. (BSM) is hereby added to the Agreement as a Party. Wherever, the term "Biota" appears in the Agreement or this Amendment, it shall apply to both Biota Holdings Limited and to BSM, unless the context otherwise requires.

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6.2 Recital 1 of the Agreement shall be amended as follows: Biota Scientific Management Pty. Ltd owns certain patents and, together with Biota Holdings Limited, has expertise and know-how in the field of long-acting neuraminidase inhibitors (LANI Compound[s]), and has synthesized and optimized several LANI Compounds which may be suitable for preclinical and clinical development, and wishes to collaborate with a key partner in the development of LANI Compounds for Commercialization (defined below) worldwide.

6.3 As the primary holder of the Biota Technology, BSM shall be responsible for carrying out Biota's responsibilities with respect to the Biota Technology under the Agreement and all payments to be made to Biota under the Agreement and this Amendment shall be made to BSM.

6.4 Any Joint Intellectual Property or Joint Inventions arising out of the Agreement (see Section 7 of the Agreement) may be, at Biota's option, owned or applied for in the name of BSM.

6.5 Any notices to be given to Biota in accordance with Section 15 of the Agreement shall be deemed to be given to both Biota Holdings Limited and to BSM if given in the manner prescribed in Section 15 thereof.

7. Trademarks

7.1 Section 7.4.1 of the Agreement is hereby amended to read as follows:
7.4.1 It is the intent of the Parties that, where possible, each Product be sold under a single trademark worldwide which shall be selected by Biota with the approval of Sankyo and, where feasible, in consultation with Licensees. It is understood that in some countries, other trademarks may be necessary or advisable or recommended by the Licensee. All trademarks used on Products under this Agreement (hereafter referred to as "Trademarks") will be owned and registered by Biota. Any royalties or other payments for the use of Trademarks paid by Licensee to Biota or Sankyo shall be considered as Consideration and shared equally between Biota and Sankyo during and following the term of this Agreement. Biota shall be responsible for evaluating, applying for, registering and maintaining the Trademarks. The expenses related thereto shall be a reimbursable expense under the Amendment until License Agreements are negotiated, at which time the Parties will use their best efforts to have Licensees take over the expenses related to the Trademarks. Upon any termination of this Agreement under Section 3.5 of the Amendment, the Parties shall cooperate with each other to execute appropriate licenses to make the Trademarks available to the Continuing Party royalty-free, unless otherwise agreed by the Parties. At the end of the full term of this Agreement, and following the termination of a License Agreement in any country in the Territory, either Party may use the Trademarks to sell the Products on a royalty-free basis, unless otherwise agreed by the Parties, because joint use of one Trademark is prohibited by

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local law or customary practice. The Parties shall cooperate with each other, including the execution of any necessary license agreements or other documents, to make it possible for each Party to market or co-promote the Products using the Trademarks. If co-marketing of the Products is not allowed under local law or not feasible under local customs in a certain country in the Territory, the Parties shall negotiate in good faith the use of the Trademarks and appropriate compensation therefore. This Section 7.4.1 shall survive the termination of this Agreement.

7.2 Appendix F of the Agreement (License Template Between Biota Holdings Limited and Sankyo Co., Ltd.) shall be amended as shown in this Amendment to Appendix F which is attached hereto and made a part of the Agreement.

8. Term and Termination

8.1 The term of this Amendment shall commence on the date first above written and shall remain in effect as long as the Agreement is in effect or until the Parties otherwise agree in writing to terminate this Amendment, except the Parties may not provide the funding as set forth in Sections 2.1 and 2.2 after a License Agreement is executed unless the Parties agree otherwise.

9. Entire Agreement

9.1. This Amendment, together with the Agreement, as hereby amended under Sections 6 and 7 referred to above and the Example attached hereto, set forth the entire agreement and understanding between the Parties as to the subject matter hereof, and supersedes all agreements and understandings between the Parties as to the subject matter, whether oral or in writing.

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IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed and effective as of the date first indicated above.

BIOTA HOLDINGS LTD.

By: _____
Name: Sterling C. Johnson
Title: Vice President, Business Development

Date: June 30, 2005

SANKYO COMPANY LIMITED

By: Akira Morita
Name: Akira Morita
Title: Director, Licensing Department
Corporate Officer

Date: June 30, 2005

BIOTA SCIENTIFIC
MANAGEMENT PTY. LTD.

By: _____
Name: Andrew Macdonald
Title: Chief Financial Officer/Company Secretary

Date: June 30, 2005

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EXAMPLE

FOR ILLUSTRATION PURPOSES ONLY

The following example is provided as an illustration to demonstrate how compensation would be handled under Section 3 of this Amendment.

In this example, the investment made by the parties is capped at [***] each.

[***]

Reimbursements will be in proportion to the investment made by each party at the time of the payment.

[***]

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*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

APPENDIX F

License Template

Between

Biota Scientific Management Pty. Ltd.

and

Sankyo Co., Ltd.

This License Template sets forth the basic understanding of Sankyo and Biota relating to the License Agreement to be executed with a Licensee or Licensees pertaining to the co-licensing of a Product or Products. This License Template shall be binding on both Sankyo and Biota. The terms of any Co-Licensing Agreement shall be consistent with the terms as described below.

* * *

THIS AGREEMENT, effective as of _____, 20__ between **Biota Scientific Management Pty. Ltd. ("Biota"),** a corporation organized and existing under the laws of Victoria, Australia, with offices at 616 St. Kilda Road Melbourne, Victoria, Australia, and **Sankyo Co., Ltd. ("Sankyo")**, a joint stock company organized and existing under the laws of Japan, with offices at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo, Japan (collectively Biota and Sankyo are referred to as the "Licensors") on the one hand; and

[Licensee Name], a corporation organized and existing under the laws of _____(the "Licensee) sets forth the agreement between the Licensors and the Licensee as follows:

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Recitals

1. Biota and Sankyo both have expertise, know-how and patents in the field of long-acting neuraminidase inhibitors (LANI Compound[s]), and have synthesized and optimized several LANI Compounds which may be suitable for clinical development and commercialization worldwide as pharmaceutical products for human consumption.

2. Biota and Sankyo have executed a Collaboration and License Agreement under which the Licensors have agreed to pool their respective LANI Compound patents and technology and to collaborate and work together to license the LANI Compounds to one or more third parties for development and marketing.

3. Licensee has expertise and knowledge in the area of commercializing and marketing pharmaceutical products for human consumption and further desires to receive a license to develop and commercialize the LANI Compounds for the treatment and prevention of influenza or other viral infections.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein, and for other good and valuable consideration, all of the Parties hereto agree as follows:

Definitions

1. "Affiliate" of a Party hereto means any entity that controls, is controlled by or is under common control with such Party. For purposes of this definition, a Party shall be deemed to control another entity if it owns or controls, directly or indirectly, more than fifty percent (50%) of the voting equity of the other entity (or other comparable ownership interest for an entity other than a corporation) or if it has management control of the other entity.

2. "Agreement" means this document between the Licensee and the Licensors together with any exhibits, schedules or specifications which are attached hereto and made a part of this document at the time of its execution, together with any amendments hereto which are

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signed by authorized representatives of the Parties and incorporated as a part of this document.

3. "API" means the active pharmaceutical ingredient using LANI Compounds and which is incorporated into the Products.

4. "API Manufacturing Development" means any raw material acquisition, process development and scale-up required to provide API of suitable quantity and quality for the agreed Clinical Development.

5. "Biota Technology" means, to the extent necessary or useful for the Development, Manufacture, use or sale of the LANI Compounds, (a) all Patents that Biota Controls as of the Effective Date or during the term of the Agreement and which shall be included in Appendix ___, and (b) Information that is not included in the Patents described in the preceding clause (a) and that Biota Controls on the Effective Date or during the term of the Agreement.

6. "Clinical Development" means all clinical and regulatory work required from the Development Phase and up to Marketing Approval.

7. "Commercialization Phase" means the period after Marketing Approval through the term of the Agreement.

8. "Commercialize or Commercialization" means to promote, sell, distribute, and otherwise market or promote a Product or Products, and to engage in Product Manufacturing for purposes of sale to a consumer.

9. "Competitive Product" means a product that is an antiviral agent targeted against influenza.

10. "Control" means, with respect to any Information or intellectual property right, possession by a Party of the ability (whether by ownership, license or otherwise) to grant access, a license or a sub-license to such Information or intellectual property right without violating the terms of any agreement or other arrangement with any third party as of the time such Party would first be required hereunder to grant the other Party such access, license or sublicense.

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11. "Co-Promotion" means the relationship in a country or countries in which two or more Parties to this Agreement collaborate in their promotional efforts to maximize sales of the Product under the same Trademark and a consistent marketing strategy and one Party books sales of the Product within that country.

12. "Co-Market" means the relationship in a country or countries in which two or more Parties to this Agreement market Products under different Trademarks, separate marketing channels and separate distribution channels, and in which both Parties book sales of the Product within that country.

13. "Development" means both the pre-clinical and clinical development of a LANI Compound.

14. "Development Candidate" means a LANI Compound from Appendix [ ] or another LANI compound that is developed or optimized by the Licensee during the term of this Agreement and that the Licensee determines is suitable for Clinical Development with the consent of the Licensors, which consent shall not be unreasonably withheld.

15. "Development Phase" means the period of this Agreement from the Effective Date to filing of a registration dossier for Marketing Approval.

16. "Development Plan" means a plan for developing the Products which is created and approved by the PDC on behalf of the Parties and which will guide the Parties in giving oversight and direction to the Licensees in developing the Products. The Development Plan shall be included as Appendix ___ to this Agreement, which may be amended from time to time as agreed by the Parties.

17. "Effective Date" means the date shown in the first paragraph of this Agreement.

18. "Field" means the prevention and/or treatment of influenza virus types A and B and other viral infections with a LANI Compound.

19. "First Commercial Sale" means the date on which the Product is first shipped by a Party to third parties for commercial sale in a country in the Territory.

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20. "Information" means all tangible and intangible techniques, technology, practices, trade secrets, methods, knowledge, know-how, skill, experience, test data and results (including pharmacological, toxicological and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms relating to the LANI Products.

21. "Invention" means any idea, design, concept, technique, process, method, composition of matter or discovery, whether or not patentable, copyrightable, or otherwise protectable with intellectual property law which is conceived of, discovered, developed, created, made or reduced to practice during the term of this Agreement which is useful to the activities contemplated hereunder.

22. "LANI Compounds" means the less than once per day dosage neuraminidase inhibitor compounds set forth in Appendix_, which may be amended from time to time as agreed by the Parties.

23. "Laws" means collectively all laws, rules and regulations as amended from time to time applicable to the Development, Commercialization and Manufacture of LANI Compounds and the Product.

24. "Lead Compounds" means the LANI Compounds selected by the Parties for Development and marketing and shown in Appendix [ ] to the Agreement, which may be amended from time to time as agreed by the Parties.

25. "Licensors" means Sankyo and Biota.

26. "Licensed Patents" means those patents owned or Controlled by either Sankyo or Biota, or Sankyo and Biota collectively as described on Appendix [ ].

27. "Manufacture or Manufactured" means with respect to each of API and Product, all the activities relating to production of API, LANI Compounds and/or Products, including, but not limited to, purchasing and release of raw materials, manufacturing, milling, quality control and assurance of all production steps, finishing, filling, labeling, packaging, release, holding and storage and the tests and analyses conducted in connection therewith.

28. "Marketing Approval" means any and all approvals (including, if required, price and

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reimbursement approvals), licenses, registrations, or authorizations of any regulatory agency, department, bureau or other government entity in a jurisdiction (or, if applicable, the European Union as a whole) that is necessary to market a Product in such jurisdiction.

29. "Net Sales" means the gross amount invoiced by a Party, its Affiliates and any respective Licensees to third parties that are not Affiliates or Licensees of the selling party (unless such Affiliate or Licensee is the end user of such Product, in which case the amount billed therefore shall be deemed to be the amount that would be billed to a third party in an arm's length transaction) for sales of Products to third parties, less the following items, as allocable to such Product (if not previously deducted from the amount invoiced): (i) trade discounts, credits or allowances; (ii) credits or allowances additionally granted upon returns, rejections or recalls (except where any such recall arises out of a Party's, its Affiliate's or Licensee's gross negligence, willful misconduct or fraud); (iii) freight, shipping and insurance charges; (iv) taxes, duties or other governmental tariffs (other than income taxes); and (v) government mandated rebates.

30. "Party" means Biota, Sankyo or a Licensee. "Parties" mean Biota, Sankyo and the Licensee.

31. "Patent[s]" means (a) patents filed in the country of origin, re-examinations, re-issues, renewals, extensions and term restorations, and including foreign counterparts of any of the foregoing, and (b) pending applications for patents filed in the country of origin, including, without limitation, provisional applications, continuations, continuations-in-part, divisional and substitute applications, including, without limitation, inventors' certificates, and foreign counterparts of any of the foregoing in each case to the extent they are applicable to the LANI Compounds and the Field that are owned or Controlled by a Party that either exist as of the effective date or claim Inventions owned or Controlled by a Party and that arise out of the activities contemplated under this Agreement. Existing Patents are set forth in Appendix [redacted] to this Agreement. Any new Patents which come into existence during the term of this Agreement shall be added to Appendix [redacted].

32. "Product[s]" means a finished pharmaceutical product that contains a LANI Compound.

33. "Product Development Committee" (PDC) means the joint committee established by

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the Parties in accordance with this Agreement which will oversee the Development of the LANI Compounds and Products in accordance with Article 3.

34. "Regulatory Authority" means any health regulatory authority(ies) in any country that holds responsibility for approving applications or granting authorization to commence human clinical testing of a drug and/or for granting regulatory Marketing Approval for a Product in such country, and any successor(s) thereto.

35. "Sankyo Technology" means, to the extent necessary or useful for the Development, Manufacture, use or sale of LANI Compounds, (a) all Patents that Sankyo Controls as of the Effective Date or during the term of the Agreement and which shall be included in Appendix [redacted], and (b) Information that is not included in the Patents described in the preceding clause (a) and that Sankyo Controls on the Effective Date or during the term of the Agreement.

36. "Substance[s]" means compounds, compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material relating to the LANI Compounds.

37. "Territory" means the countries listed in Appendix [redacted].

38. "Trademark" means the trademark or trademarks selected by the Licensors and for use in connection with the commercialization, promotion and marketing of the Product in one or any of the countries in the Territory.

1. License Grant

1.1. Grant of Patent License. Until the last-to-expire Patent within the Territory expires the Licensors hereby grant to the Licensee under the Patents and Information owned by the Licensors, an exclusive license to develop, make, use, sell, offer for sale, and import the Product in the Field in each country in the Territory. For purposes of this Section 1, the term "exclusive" means to the exclusion of all other parties in the Territory, including Licensors, unless the Parties agree to a co-marketing or co-promotion arrangement in the Territory.

1.2. Grant of Trademark License. After the last-to-expire Patent within the Territory

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expires, the Licensors may grant to the Licensee under the Trademark owned by the Licensors, an exclusive license to use sell, offer for sale and import the Product in each country in the Territory.

1.3. Sublicenses. The licenses granted to the Licensee in Section 1.1 shall include the right to grant sublicenses to its Affiliates, in whole or in part; *provided, however, that* the Licensee shall be strictly liable for the performance of its Affiliates. The licenses granted to the Licensee in Section 1.1 and Section 1.2 shall not include the right to grant sublicenses to any third parties (other than a Licensee Affiliate) without the prior written consent of the Licensors.

1.4. Licensee Diligence. The Licensee shall diligently work to develop the LANI Compounds and to market the Product in such a way as to maximize Net Sales and operating income through the safe and effective use of the Product in compliance with all applicable Laws. The Licensee shall twice a year provide the Licensors with Development progress updates and, when requested by either of the Licensees, provide other material information relating to the Licensee's progress in Development and the eventual marketing of the Product.

2. Consideration

2.1. License Fee. In consideration for the Licensors' grants to the Licensee of the right to sell, market, and distribute Product, all pursuant to Section 1.1, the Licensors shall receive from the Licensee a one time non-refundable and non-creditable license fee of [ ] U.S. Dollars ([ ]) within seven (7) days of the Effective Date. Such License Fee shall be net of any taxes that might be payable in Japan or Australia to the Licensors.

2.2. Milestones. The Licensee will make the following payments to the Licensors in US Dollars upon the occurrence of the listed event in the Territory for each Product:

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Event	Payment
Submission of IND	
Initiation of Phase II clinical trials (or equivalent)	
Initiation of Phase III clinical trials (or equivalent pivotal trial)	
Approval of an NDA (or equivalent)	
Launch of Licensed Product	
Date on which Net Sales of the Licensed Product exceed USD $___ 12-month period	
Date on which Net Sales of the Licensed Product exceed USD $___ 12-month period	

2.3. Royalties. In consideration for the license granted under Section 2.1, the Licensee shall pay in U.S. dollars to the Licensors during the Term a royalty in each country in the Territory comprising XX percent (XX%) of Net Sales until this Agreement expires in accordance with its terms. In consideration for the license which may be granted under Section 1.2, the Licensee shall pay in U.S. dollars to the Licensors after the expiration of the last Licensed Patent a royalty in each country in the Territory comprising XX percent (XX%) of Net Sales.

3. Development of the Products

3.1. Establishment and Membership of The Product Development Committee.

3.1.1. Upon execution of the License Agreement with the Licensee, the Licensors and Licensee shall establish a Product Development Committee (the "PDC") to provide oversight of the Development, and implementation of the Development Plan which is outlined in Appendix and which, when agreed upon and executed by representatives of the Licensors and Licensee, shall become a part of this Agreement.

3.1.2. The PDC shall be formed by the Licensee(s) and will allow for at least one voting representative of Biota and Sankyo, each at their respective option. The PDC formed under this Agreement shall cooperate with any PDC formed under other license agreements with other licensees relating to the Products in order to ensure maximum coordination in the development of the Products on a worldwide basis.

3.2. Duties of the PDC

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3.2.1. The PDC shall provide oversight and governance of the Development Plan and monitor, manage and administer, as required, the Licensee Development of the Products. In general, the PDC will be responsible for project management.

3.2.1.1. Project management. The PDC shall (i) approve specific tasks, activities, resources, and expenditures under the Development Plan; (ii) establish objectives and milestones, and determine when and if objectives and milestones are met; and (iii) review progress made under the Development Plan and implement necessary changes to the Development Plan. It is the intention of the Parties that the PDC will review and discuss research plans, the design of studies, study protocols, selection of sites for preclinical and other Development studies, and other such matters that the Parties may deem necessary for the Development of the Products by the Licensees.

3.2.1.2. The PDC shall discuss regulatory strategy and the preparation, filing and prosecution of applications for Marketing Approvals and other regulatory issues.

3.3. Meetings and Decisions of the PDC

3.3.1. Meetings. Unless otherwise determined by the PDC, the PDC shall meet at least twice per year alternately at locations to be determined through negotiations between parties whose representatives participate in the PDC. At other times, the location or manner of the meeting (e.g., telephone conferences) will be determined by the PDC. Costs for representatives of the Parties to attend PDC meetings will be for each Party's account.

3.3.2. Decisions. All actions and decisions reserved for the PDC under Section 3.2 will require the unanimous consent of all of its voting members. If the PDC fails to reach unanimous agreement, the Parties shall attempt in good faith to reach an agreement on the unresolved matter within twenty (20) days, but if the issue cannot be resolved through good faith discussions, then the Licensee will have the right to make the final decision.

3.4. PDC Reporting and Information Sharing

3.4.1. Following each twice yearly meeting of the PDC, a representative of the PDC jointly appointed by its members shall prepare and deliver to all Parties a written report recording the issues, decisions, conclusions, recommendations and other actions taken by the PDC, as well as the general status of the Development Plan at that time. Any exceptions or dissents from the report may be noted in writing by the dissenting Party.

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3.4.2. The Parties shall nominate one person in each of their organizations to act as primary recipient for said written reports.

3.4.3. Except for confidential business information, the Parties agree to share with the PDC all clinical and regulatory data available to them from their Clinical Development activities that could assist the PDC in carrying out its responsibilities.

3.5. Development Phase

3.5.1. Development Expenses. All direct and indirect costs and expenses associated with Development of the Product will be borne by the Licensee.

3.5.2. Development Candidates. The Parties hereby agree that Sankyo's R-118958 shall be the Lead Compound and is nominated as the first Development Candidate. Biota's compound referenced as BTA938 shall be the back up Lead Compound.

3.5.3. The Development Candidate shall progress promptly into Development in accordance with the Development Plan.

3.5.4. If the first or a subsequent Development Candidate is not commercially viable as determined by the PDC, the PDC shall select the back up Lead Compound. If the back up Lead Compound is not commercially viable as determined by the PDC then the PDC may select another Lead Compound from Appendix [redacted] as a Development Candidate.

3.5.5. Due to the cost associated with Development, it is the intent of the Licensors that only one Lead Compound will be developed at a time. Notwithstanding the foregoing, the PDC may determine that more than one Development Candidate may progress into Development at any one time.

3.5.6. The Licensee shall ensure the integrity, quality and security of all Information; any technical, regulatory and clinical data, generated under the Development Plan, including any laboratory notes, technical data or specifications, test results, and any other relevant information or materials arising from the conduct of the Development Plan.

3.5.7. Clinical Trial Management: The Licensee shall prepare suitable applications for approval or consent of commencement clinical trials, management of trials, handle

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reporting, analysis and all other aspects of the trial being conducted by it or on its behalf.

3.6. API Manufacturing Development Costs

3.6.1. All direct and indirect costs and/or third party charges associated with API Manufacturing Development shall be borne by the Licensee or its designee.

3.7. Regulatory Matters

3.7.1. The Licensee shall be responsible at its sole expense for filing, prosecuting, and obtaining Marketing Approvals in each country in the Territory. Subject to the provisions of this Agreement, the Licensors will use commercially reasonable efforts and reasonable scientific judgment to assist in preparing documents for obtaining Marketing Approval from a Regulatory Authority for each country in the Territory. The Licensors will, if required by a Regulatory Authority, provide certain information concerning the Manufacture of LANI Compound and/or Product directly to such Regulatory Authority to facilitate the Licensee's application for Marketing Approvals. If a Regulatory Authority requests that the Licensee conduct additional developmental activities to obtain Marketing Approval, the Licensee shall, after consultation with Licensors, conduct such additional developmental activities at its own expense. In each country in the Licensee Territory, the Licensee shall keep the Licensors reasonably informed as to the regulatory status of Marketing Approval. In addition, Licensee may, at its own expense, conduct developmental activities for promotional and marketing purposes upon securing the prior written consent of Licensors after obtaining Marketing Approval. The Licensee shall inform the Licensors of the First Commercial Sale of the Product by the Licensee in each country or region in the Territory within seven (7) days thereof. The Licensee shall promptly inform the Parties with respect to any regulatory action taken or notification regarding the Products either during the approval process or marketing of the Products in the Territory.

3.7.2. Regulatory Communications. Each Party agrees to provide the others with all reasonable assistance and take all actions reasonably requested by the others that are necessary or desirable to enable the others to comply with any Laws applicable to the Product, including, without limitation, to meet reporting and other obligations to

(i) maintain and update the Marketing Approval and any filings under Section 3.7.1;

(ii) submit adverse event reports to the appropriate Regulatory Authorities as required to fulfill obligations under Laws; and

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(iii) submit or file promotional materials with Regulatory Authorities, as appropriate.

4. Commercialization

4.1. Commercialization Committees. The Parties agree that they may form Co-Promotion Committees as necessary to coordinate the Co-Promotion of the Product in any applicable country in the Territory. Such committees, if formed by the Parties will allow for at least one voting representative from each of Biota and Sankyo, each at their respective option. Attendance of members at meetings shall be at the respective expense of the participating parties appointing such members.

4.1.1. Decisions of Commercialization Committees. All actions and decisions reserved for the Co-Promotion Committees will require the unanimous consent of all of its voting members. If the committee fails to reach unanimous agreement, the Parties shall attempt in good faith to reach an agreement on the unresolved matter within thirty (30) days, but if the issue cannot be resolved through good faith discussions, then the matter shall be referred to the executives of the representatives of those Parties unable to reach unanimity with authority to settle the matter within thirty (30) days. If the matter is not resolved within the thirty (30) day period following submission of the matter to those executives, then the Licensee will have the right to make the final decision.

4.2 Record Keeping; Reporting and Audit. The Licensee will provide Biota and Sankyo with quarterly reports of the Net Sales of the Products by the Licensee or its Affiliates in the Territory should Biota and/or Sankyo Co-Market or Co-Promote Products. The Licensee shall keep and complete records of costs associated with marketing and distribution costs, and expenses incurred for sale of the Product within the Territory should Biota and/or Sankyo Co-Promote Products. Such records shall be retained by the Licensee and shall be made available for inspection, review and audit, at any time within normal business hours during the applicable calendar year and for two (2) years thereafter, at the request and expense of the Licensors, by an independent certified public accountant appointed by the Licensors for the sole purpose of verifying the Licensee's accounting reports and payments made or to be made pursuant to this Agreement. Such accountants shall not reveal to the Licensors the details of its review, except for such information as is required to be disclosed under this Agreement. This right to audit shall remain in effect throughout the life of this Agreement and for a period of two (2) years after the Term. If an error in favor of the Licensors of more than five percent (5%) is discovered, then the

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Licensees shall pay the audit expenses that discovered such error. The Parties shall settle all differences hereunder within thirty (30) days of notification.

4.3. The United States. Sankyo and Biota retain the right to designate a third party (including, without limitation, Sankyo, Biota or one of their Affiliates) to Co-Market the Product in the United States with the Licensee and/or terminate the license to the Licensee, if the Licensee does not meet reasonable annual minimum sales as agreed in writing within the six (6) months of the Product launch by the Parties for that country.

4.4 Other Markets. In all other countries where Sankyo and Biota have granted an exclusive license to the Licensee, Sankyo and Biota shall retain the right to terminate the Licensee and/or grant additional licenses to a third party (including, without limitation, Sankyo, Biota or one of their Affiliates), if the Licensee does not achieve reasonable annual minimum sales as agreed in writing within the six (6) months of the Product launch by the Parties for that country.

4.5 Non-Compete. During the term of this Agreement, unless otherwise agreed between the Parties, each Party agrees that neither for itself or through its Affiliates will it develop, Commercialize, or otherwise handle or deal with, directly or indirectly, or to enter into any collaboration, license or development agreement or any other arrangement with any party other than the other Parties to develop, Commercialize, or otherwise handle or deal with any Competitive Product in any country. The restrictions in this Section 4.5 shall not apply to Products already Manufactured, distributed, sold, bought or otherwise dealt with by each Party or its Affiliates as of the Effective Date.

5. Payments; Records and Reports

5.1. Royalty Reports

5.1.1. Frequency of Royalty Reports. Within sixty (60) days of the end of each calendar quarter after the First Commercial Sale of the Product by the Licensee in the Territory, the Licensee shall deliver to the Licensors a royalty report containing information concerning the immediately preceding calendar quarter. Each royalty report delivered by the Licensee to the Licensors shall contain at least the following information, denominated in local currency and US dollars as calculated for each applicable country in accordance with the exchange rate published in the New York edition of the Wall Street Journal on the last day of the calendar quarter for which such payment accrues:

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(i) Net Sales for the applicable calendar quarter in each country;

(ii) Amount of royalty earned for each country, and in total for the period;

(iii) Amount of withholding taxes, if any, required by Laws to be deducted in respect of such royalties; *provided, however, that* the Licensee will take reasonable action to minimize any such withholding tax in each country.

5.1.2. The Parties agree to furnish reports, in a form to be agreed upon, showing, among other things, (i) the gross sales and Net Sales of each Product sold and the royalties that have accrued hereunder with respect thereto and (ii) the amount of withholding taxes on the royalty payments.

5.1.3. The Parties shall keep proper books of account with reference to their respective sales of any Product under this Agreement and with reference to any sales by Licensees which are reported to the Parties. When requested by the other Party, such books of account shall be made available at reasonable times for audit by the other Party or its agents (including the right to inspect, copy, and make abstracts therefrom), solely for the purpose of verifying the royalties due or paid, or for determining compliance with other provisions of this Agreement. Any expense incurred by a Party conducting such audit shall be borne by said Party unless discrepancies attributable to the audited Party exceeding the cost of the audit are found, in which case the costs of the audit shall be reimbursed by the other Party.

5.1.4. The Party owing the royalty (the "Payor") shall permit its books of account or records of sale to be inspected at any reasonable time during normal business hours by a representative of the other Party (the "Payee") solely for the purpose of verifying the amounts due hereunder.

5.2. Method of Payment

5.2.1. All payments under this Agreement shall be made payable in U.S. dollars and shall be by appropriate electronic funds transfer in immediately available funds to such bank accountant as the Payee shall designate and on a date no later than when royalty reports are due under Section 5.1.1 above. Each payment shall reference this Agreement and identify the obligation under this Agreement that the payment is to satisfy. Any and all expenses for such payment incurred by the Payee shall be borne by the Payee.

5.2.2. Any payments due under this Agreement that are not paid on or before the date such

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payments are due shall bear interest, at the lower of one percentage point above the Prime Rate of interest as reported in the New York edition of the Wall Street Journal on the date the payment is due or the maximum allowed by law, compounded monthly until such payment is made.

5.2.3. Any taxes or similar charges levied or assessed in a territory on the Payee on the royalty payments shall be borne by Payor. However, Payor has the right to deduct from the royalty payments such income taxes or charges paid thereon for which Payee is entitled to receive a credit under income tax laws in effect as of the time payment is made. In these cases, Payor will promptly provide Payee with an original receipt for such tax payments (or a certified copy, if the original is not available). Payor's failure to provide Payee with such documentation as Payee determines is acceptable for tax purposes shall preclude Payor from deducting such taxes or charges from the gross royalty otherwise due.

5.2.4. Payee may require such other account statements or reports from Payor as may be reasonable.

6. Trademarks

6.1. To the extent commercially reasonable and appropriate, a single Trademark worldwide to be selected and registered by the Licensors shall be used for each Product in all countries in the Territory, provided that Licensee shall cooperate with Licensors and other licensees relating to the Products in order to select said single Trademark for use on a worldwide basis. If the Trademark is not available in or inappropriate for the Territory, the Licensee shall propose an alternate Trademark to be approved in writing and registered by the Licensors, such approval not to be unreasonably withheld. Each Trademark may be used by a Party only in connection with the applicable Product and shall not be used by any Party on, or in connection with, any other product. The Licensors shall own each Trademark used to promote Products in the Licensee's Territory and shall be responsible for searching, clearing, filing, prosecuting and maintaining, and all reasonable steps necessary in defending, each Product Trademark, provided, however, that the actual expenses of maintaining the Trademarks in the Territory shall be borne by Licensee from the Effective Date. Such expenses shall be billed to Licensee by Licensors during the first quarter of each calendar year and shall be paid by Licensee within thirty (30) days of receipt of Licensors' invoice. In the case of countries in which the Licensors and

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Licensees Co-Market and/or Co-Promote Products, Sankyo and/or Biota, at their discretion, shall have the right to select and register additional trademarks for use with the Product.

7.Ownership and Treatment of Inventions

7.1 Ownership of Inventions

7.1.1. The Information and Inventions, and the right to file patent applications and the patents regarding the LANI Compounds or Products generated by the Licensors after the Effective Date (collectively, the "Licensor's Intellectual Properties") shall be owned by the Licensors.

7.1.2. The Information and Inventions, and the right to file patent applications and the patents regarding the LANI Compounds or Products generated by the Licensee after the Effective Date (collectively, the "Licensee's Intellectual Properties") shall be owned by the Licensee. Each of the Licensor's shall have an equal, undivided perpetual, paid up royalty free right to use Licensee's Intellectual Properties.

7.1.3. In the case of Inventions owned jointly by at least one employee of Biota or Sankyo and one employee of the Licensee ("Joint Inventions"), the Parties shall agree on whether or not to secure patent protection and which Party shall bear the primary responsibility for preparing, filing, prosecuting the Patents resulting therefrom. The Parties shall equally share all expenses related thereto. Each Party shall promptly render all necessary assistance reasonably requested by the other Party in applying for and prosecuting the patent applications. If any Party does not elect to participate in the expense of filing for such Joint Inventions, the other Party or Parties may do so at its own expense, excluding the declining Party from ownership.

7.2. Maintenance of Patents

7.2.1. Each Party shall, at its own expense, diligently take all steps necessary to maintain its own Patents, in full force and effect, including but not limited to a duty to diligently file and pursue any reissues and re-examinations, if applicable. If any Party elects not to maintain any of its own Patents, it shall promptly notify the others of that election and shall, at the other Parties request, assign to the other Parties all right, title and interest in and to such Patents of the assigning Party. In such case, the other Parties shall bear the cost and responsibility for the maintenance of such Patents and the assigning Party shall

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render all necessary assistance reasonably requested by the other Parties in maintaining such Patents.

7.2.2. In the event that Joint Inventions are registered, the Party who bears the primary responsibility for preparing, filing, prosecuting such Joint Inventions shall bear the primary responsibility for performing the obligation to maintain registered Patents resulting from such Joint Inventions ("Joint Patents") as set forth in Section 7.2.1. Each Party shall promptly render all necessary assistance reasonably requested by the other Parties in performing such obligation. Any and all costs and expenses reasonably necessary and useful to perform such obligation on any and all Joint Patents shall be borne by all Parties equally.

7.2.3. Notwithstanding the provision of Section 7.2.1, each Party shall be relieved from its obligation to maintain its own Patents stipulated by Section 7.2.1, in the event that the Licensors determine that any Products related to such Patents will not undergo Development or be Commercialized as a Development Candidate.

7.2.4. The Parties agree to cooperate to obtain, to the fullest extent allowed by Laws, an extension of exclusivity beyond the full term expiry date of any Patents subject to this Agreement which the Parties mutually agree may maximize commercial return of Products. The Parties shall provide all relevant patent information to the Regulatory Authority or other applicable agency as required by Laws.

7.3. Patent Infringement

7.3.1. In the event that the Licensee is charged with the infringement of a patent or other intellectual properties, including but not limited to utility model, design or trademark owned by any third party or receives any filing of any claim or suit by any third party related to the Products because of any of the activities necessary to the performance of its obligations under this Agreement, the Licensee shall notify the other Parties fully and promptly in writing upon receipt of any knowledge or notice of the charge of infringement, specifying its nature and by whom it was raised. The Licensors shall in good faith offer the Licensee reasonable cooperation so that the Licensee may handle such claim or suit at its own expense and for its own account. The Licensee shall prosecute and control such claim or suit and periodically inform the other Parties of its intended course of action and shall provide the other Parties with the opportunity to comment on significant actions or elements of its course of action. The Licensee may not settle any such claim or suit

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without the prior written consent of the other Parties, which consent shall not be unreasonably withheld or delayed, except as provided hereafter. Any costs and expenses, including reasonable attorneys' fees, incurred by the Licensee in defending against such claim or suit shall be borne by the Licensee. Either Licensor shall have the option to take over the action at its discretion and its own expense, provided, however, that failure by the Licensee to diligently defend the action shall not relieve Licensee of responsibility for the expense of the action.

7.3.2. Infringement by Third Parties. In the event that any Party becomes aware that the Patents or other intellectual property, including but not limited to utility model, design or trademark (collectively, "Intellectual Properties" in this Section) are threatened to be infringed or disputed by any third party, such Party shall notify the other Parties fully and promptly in writing, specifying the nature of the threat and by whom they are threatened to be infringed or disputed. The Licensors shall in good faith offer the Licensee reasonable cooperation so that the Licensee may handle such claim or suit at its own expense and for its own account. The Licensee shall prosecute and control such claim or suit and periodically inform the other Parties of its intended course of action and shall provide the other Parties with the opportunity to comment on significant actions or elements of its course of action. The Licensee may not settle any such claim or suit without the prior written consent of the other Parties, which consent shall not be unreasonably withheld or delayed, except as provided hereafter. Any costs and expenses, including reasonable attorneys' fees, incurred by the Licensee in defending against such claim or suit shall be borne by the Licensee. If the Licensee does not exercise its right to control the conduct of defense of any such action in response to any such claim within XX (XX) days of becoming aware of or being notified of such infringement, then the Party owning or Controlling such Intellectual Property shall have the right, but not the obligation, to bring such action.

8. Representations, Warranties, and Covenants

8.1. Mutual Representations, Warranties, and Covenants. Each of the Licensors and the Licensee each hereby represents, warrants, covenants acknowledges and agrees that the other is relying, and is entitled to rely, on the following representations, warranties, and covenants:

(a) Each Party has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery

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and performance of this Agreement has been duly and validly authorized and approved by proper corporate action on the part of such Party. Each Party has taken all other action required to be taken by such Party under the Laws, its certificate of incorporation, by-laws or any agreement to which it is a party with respect to the execution, delivery and performance of this Agreement. Assuming due authorization, execution and delivery on the part of a Party, this Agreement constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as the enforceability thereof may be limited by applicable Laws or by bankruptcy, insolvency, reorganization or other similar Laws of general application relating to creditors' rights; and

(b) To the best of its knowledge as of the Effective Date, the execution and delivery of this Agreement by a Party and the performance by such Party contemplated hereunder shall not violate any Laws or any order of a court or a Regulatory Authority; and

(c) To the best of its knowledge as of the Effective Date, neither the execution and delivery of this Agreement nor the performance hereof by a Party requires such Party to obtain any permits, authorizations or consents from any governmental authority other than a Regulatory Authority or from any other person; and

(d) During the Term, each Party shall fulfill its obligations under this Agreement, in accordance with the terms of this Agreement and all applicable Laws; and

(e) During the Term, each Party shall retain and maintain compliance with all necessary government authorizations and permits necessary to Manufacture and supply the Product and to otherwise perform each Party's obligations under this Agreement; and

(f) All of a Party's employees, officers and consultants participating in the performance of this Agreement are, to the extent permitted under applicable Laws, under obligations (i) to assign to such Party all Inventions made during the course of and as a result of their association with such Party, and (ii) to maintain as confidential the Confidential Information received from or on behalf of the other Party; and

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(g) Each Party shall not knowingly employ any employee in performing the services hereunder who has been debarred or disqualified by a Regulatory Authority or any governmental agency.

8.2. Licensors' Representations, Warranties, and Covenants. Each Licensor for itself, hereby represents, warrants, covenants acknowledges and agrees that the Licensee is entitled to rely, on the following representations, warranties, and covenants:

(a) The execution, delivery and performance of this Agreement by each of the Licensors shall not result in the breach of or give rise to any termination of any agreement or contract relating to the Product to which each of the Licensors is a party; and

(b) To the best of each of the Licensor's knowledge, as of the Effective Date, the activities of the Licensee contemplated hereunder does not infringe any patent rights or any other proprietary rights of any third party; and

(c) As of and prior to the Effective Date, neither of the Licensors has granted to any third party a license under any Patent or Information owed or Controlled by each of the Licensors to make, use, sell, offer to sell, and/or import Product in the Licensee's Territory; and

(d) The Licensed Patents are duly and validly registered or applied for in the countries in the Licensee Territory with respect to each Licensed Patent and each Licensor agrees to continue to use commercially reasonable efforts to obtain and maintain the registrations of the Licensed Patents in full force and effect during the Term hereof at their sole cost and expense, taking into account the amount of revenues received from such Licensed Patents on a country-by-country basis.

8.3. No Other Warranty EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER LICENSOR MAKES ANY OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THIS AGREEMENT. THE LICENSE IS PROVIDED WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WARRANTY AS TO THE ENFORCEABILITY OR SCOPE OF ANY LICENSED PATENT IN THE FIELD, OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED. LICENSORS MAKE NO REPRESENTATION OR WARRANTY THAT LICENSEE'S

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ACTIVITIES UNDER THE LICENSE WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHT OF A THIRD PARTY. LICENSOR WILL NOT BE LIABLE FOR SUCH INFRINGEMENT, OR AN ALLEGATION THEREOF, NOR SHALL THE SAME BE AN EXCUSE FOR NONPERFORMANCE OF THE LICENSEE'S OBLIGATIONS HEREUNDER. THE LICENSORS ASSUME NO RESPONSIBILITIES OR LIABILITIES TOWARDS THE LICENSEE OR THIRD PARTIES WITH RESPECT TO THE RESEARCH, DEVELOPMENT, MANUFACTURE, USE, SALE OR DISPOSITION OF LICENSED PRODUCT IN THE FIELD. THE ENTIRE RISK AS TO LICENSED PRODUCT IN THE FIELD IS ASSUMED BY LICENSEE.

8.4. Limitation of Liability. SUBJECT TO ARTICLE XIII (13), NO PARTY SHALL BE ENTITLED TO RECOVER FROM ANOTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER, UNLESS SUCH DAMAGES ARE INFLICTED AS A RESULT OF THE NEGLIGENCE OR WRONGDOING OF THE OTHER PARTY.

8.5. Survival of Limitation of Liability. Sections 8.3 and 8.4 shall survive any termination or expiration of this Agreement.

9. Term and Termination

9.1. Term

9.1.1. The Agreement will commence on the Effective Date and, unless earlier terminated as provided for hereunder, continue until the expiration of the last-to-expire Patent within the Territory owned or Controlled by either or both of the Licensors claiming the Manufacture, use, importation or sale of the Products on a country-by-country basis, and thereafter shall automatically be renewed each year for one (1) year periods unless either party gives at least six (6) months written notice of termination of this Agreement to the other before the expiration of the term of this Agreement. While this Agreement remains in force, the Licensee shall continue to have the right to use the Information owned by Licensors.

9.2. Earlier termination

9.2.1. Either the Licensors or the Licensee may, without prejudice to any other remedies available to it at law or in equity, terminate the Agreement on a country by country basis

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prior to the end of the term, by giving the other sixty (60) days written notice ("Notice Period") upon occurrence of any of the following events:

9.2.1.1. "Material breach" defined as the default of any material obligation hereunder by either the Licensor or the Licensee, which has not been remedied within sixty (60) days after one Party sends written notice detailing the substance of the default to the defaulting Party, or

9.2.1.2. "Insolvency" meaning the insolvency, bankruptcy, dissolution or liquidation of the other Party, where such Party is subject to the filing or consents to the filing of a petition under any bankruptcy or insolvency law or has any such petition filed against it which has not been dismissed within ninety (90) days of such filing, appointment of a trustee, administrator, or receiver for all or substantially all of the assets of such Party, or assignment of the assets of such Party for the benefit of creditors, or attachment or expropriation of the business or assets of such Party, or

9.2.1.3. "Unresolved Differences" meaning that despite the commercially reasonable efforts of the Parties, the Parties are unable to resolve disputes as provided herein.

9.2.1.4 "Development neglect" meaning that the Licensee ceases Development of the Product for more than six (6) consecutive months for reasons within its control until any Regulatory Authority grants Marketing Approval for the Product to the Licensee in the Territory.

9.2.1.5 "Marketing Failure" meaning that the Product may not be sold as a result of a recall or market withdrawal and such inability to sell the Product continues for a period of twelve (12) months, provided, however, that if the Marketing Failure is applicable to a certain Territory, the termination shall only apply to that Territory and shall not affect the Agreement in other Territories.

9.2.1.6. The right of a Party to terminate this Agreement as provided in this Section 9.2 shall not be affected in any way by its waiver or failure to take action with respect to any previous default.

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9.3. Rights on termination

9.3.1. If either Party terminates this Agreement pursuant to Section 9.2, in those countries where such termination takes effect:

(a) all rights to the LANI Compounds and all relevant Patents including the Licensor's Intellectual Properties, Trademarks, licenses and other rights granted or assigned to either Party at any time under this Agreement (collectively, "Rights") shall revert to the Licensors; and

(b) if this Agreement is terminated by the Licensors, the Licensors shall negotiate in good faith a mechanism to allow the Licensee, should it so wish, to continue to Develop, Manufacture, file for Marketing Approval, use, sell, offer for sale the Product in such country.

9.3.1.1. Without prejudice to any exclusive license granted herein, a Party that grants a license to a third party under a Joint Invention shall obtain the prior written consent of the other Party to such a license, such consent not to be unreasonably withheld or delayed.

9.3.2. The provisions of Section 9.3.1 and this Section 9.3.2 shall survive the termination for any reason of this Agreement. Except as specifically provided in this Agreement, neither Party shall be liable to the other based on, or as a result of, the termination of this Agreement as provided herein, whether in loss of good will, anticipated profits or otherwise.

10. Confidentiality

10.1. During the term of this Agreement and for a period of seven (7) years thereafter, each Party (a) shall hold the Technology, the Information and any marketing and other confidential information, whether in written, oral, visual, or machine readable form disclosed by either Party to the other under this Agreement (the "Confidential Information") and the Substances supplied by either Party to the other under this Agreement in confidence with the same degree of care it maintains the confidentiality of its own Confidential Information and Substances, (b) shall not disclose such Confidential Information and make Substances available to any third party without the prior written consent of the disclosing Party, and (c) shall not use such Confidential Information and Substances other than for exercising its rights and/or performance of its obligation under

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this Agreement except for any information which is evidenced that:

(i) was in the receiving party's possession at the time of disclosure,

(ii) was publicly known at the time of such disclosure,

(iii) becomes publicly known through no default of the receiving party,

(iv) was obtained legally by the receiving Party from a duly authorized third party, or

(v) was independently discovered without the aid or application of the information received.

10.2. Each Party may disclose the Confidential Information and make the Substances available only to those of its employees, contractors, and agents who have a need to know such Confidential Information and the Substances to implement the terms of this Agreement. The Parties agree to take reasonable precautions to preserve the confidential, proprietary or secret status of the Confidential Information and Substances and shall require that each of their respective employees, contractors, and agents understand and agree in writing to treat and to hold such Confidential Information and Substances in confidence consistent with the provisions herein.

10.3. Within thirty (30) days of the date of termination of this Agreement for any reason, the Parties shall provide each other with written notice specifying that through reasonable care and to the best of its knowledge: (a) all Confidential Information embodied in whole or in part in documents, materials, things, and copies thereof have been destroyed or returned to the other Party, (b) the originals and all copies of any machine-readable documentation containing any portion of the Confidential Information have been destroyed or returned to the other Party, (c) all remaining Substances supplied by the either Party have been returned to the other Party or destroyed, unless otherwise agreed in writing between the Parties, and (d) all use of the Substances by the returning Party has ceased.

10.4. No Party may issue any press release, publication, or any other public announcement relating to this Agreement, the LANI Compounds or the Product without obtaining the other Parties' prior written approval, which approval shall not be unreasonably withheld or delayed. The Parties shall in good faith prepare mutually acceptable announcements prior to such release, publication or announcement. Notwithstanding any of the foregoing, each Party may use the substance of previously approved public announcements and the substance of other public announcements of the

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other Party without prior notice.

11. Liability and Indemnity

11.1. The Licensors shall indemnify, defend and hold harmless the Licensee, its employees, agents, officers, directors, permitted licensees, successors and permitted assigns (collectively, the "Licensee Indemnified Parties"), from and against any and all costs, liabilities, judgments, obligations, losses, expenses and damages (including reasonable attorneys' fees and expenses) of whatsoever kind or nature (collectively, "Losses") incurred by or imposed upon any Licensee Indemnified Party as a result of any claims, actions, suits or proceedings (collectively, "Claims") arising out of or related to, in any way, the licensing, Development, Manufacture, marketing, promotion, importation, sale or other use (collectively, "Use") of the Product in any country by the Licensor pursuant to this Agreement or otherwise, regardless of whether such Claims or Losses are based upon theories of contract, tort, product liability, strict liability, infringement of any patent, trademark, trade name, logo, service mark, trade dress, trade secret, or any other legal or equitable theory; provided, however, that the Licensee shall indemnify the Licensors for Losses proven to have been caused solely from an act or omission by Licensee.

11.2 The Licensee shall indemnify, defend and hold harmless each of the Licensors, and each of their employees, agents, officers, directors, permitted licensees, successors and permitted assigns (collectively, the "Licensor Indemnified Parties"), from and against any and all costs, liabilities, judgments, obligations, losses, expenses and damages (including reasonable attorneys' fees and expenses) of whatsoever kind or nature (collectively, "Losses") incurred by or imposed upon any Licensor Indemnified Party as a result of any claims, actions, suits or proceedings (collectively, "Claims") arising out of or related to, in any way, the licensing, Development, Manufacture, marketing, promotion, importation, sale or other use (collectively, "Use") of the Product in any country by the Licensee pursuant to this Agreement or otherwise, regardless of whether such Claims or Losses are based upon theories of contract, tort, product liability, strict liability, infringement of any patent, trademark, trade name, logo, service mark, trade dress, trade secret, or any other legal or equitable theory; provided, however, that the Licensors shall indemnify Licensee for Losses proven to have been caused solely from an act or omission by the Licensors.

11.3. Each Party shall give prompt written notice to the other of any Claim asserted

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against such Party (in such capacity, the "Notifying Party") arising from or relating to the Product, regardless of whether the Notifying Party is entitled to seek indemnification from the other Party pursuant to either Section 11.1 or 11.2. The Parties shall, subject to the execution of an appropriate non-disclosure agreement, reasonably consult with, and share information with, each other regarding such Claim and shall reasonably cooperate and assist each other in the event that the Notifying Party wishes to pursue any claim against any third party in connection therewith, in each case at the sole cost and expense of the Notifying Party. Each sublicense agreement entered into by a Party relating to any Product in accordance herewith shall contain a provision substantially similar to that set forth in this Section 11.3.

11.4. SUBJECT TO ARTICLE XIII (13), NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER, UNLESS SUCH DAMAGES ARE INFLICTED AS A RESULT OF THE NEGLIGENCE OR WRONGDOING OF THE OTHER PARTY.

12. Amendment

12.1. Except as otherwise provided in this Section, all amendments to this agreement must be in writing and signed by authorized representatives of both parties.

13. Governing Law and Jurisdiction

13.1. Any claim, dispute or controversy of whatever nature arising out of or relating to this Agreement, including without limitation, any action based on tort, contract or statute, or concerning the interpretation, effect, termination, validity, performance or breach of this Agreement shall be construed in accordance with the laws of New York without regard to its conflict of law principles.

The Parties shall first negotiate in good faith to resolve any disputes which arise under this Agreement, but failing amicable solution, all unresolved disputes shall, at the request of either Party, be finally settled under the Rules of Arbitration of the International

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Chamber of Commerce by three (3) arbitrators appointed in accordance with said Rules. The venue of the Arbitration shall be New York. The language of the arbitration shall be English.

14. Force Majeure

14.1. Neither Party hereto shall be liable for any failure or delay in performance of this agreement occasioned in whole or in part by acts of God, strike, lock-out, fire, earthquake, epidemic, inability to obtain materials or shipping space, breakdown, delay of carrier or regulation of any government or any other cause beyond its control, provided that said Party has exercised due and reasonable care and its best efforts to avoid any of the above-mentioned events.

15. Notices

15.1. Any notice or report pursuant to this Agreement shall be deemed duly given if delivered personally, sent by airmail, international recognized courier service, electronic mail (provided such electronic mail is followed by facsimile confirmation in accordance with this Section 15.1) or facsimile addressed to the other Party at the addressee facsimile number set forth below, or to such other address or facsimile number as shall have theretofore been furnished by one Party to the other in accordance with this Section, and shall be deemed to have been given when sent.

If to Sankyo: Sankyo Company, Limited
3-5-1 Nihonbashi-Honcho, Chuo-ku,
Tokyo 103-8426, Japan
Attention: Director, Licensing
Fax: +81-3-5255-7086
Telephone: +81-3-5255-7084
e-mail: moriaki@hq.sankyo.co.jp

If to Biota: _____
_____
_____
Attention:
Fax:
e-mail:

If to Licensee: _____
_____
_____
Attention:
Fax:

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e-mail:

16. Assignment of Rights and Obligations

16.1. Either Party may assign all or any part of this Agreement to any Affiliate. In all other respects, neither Party shall voluntarily or by operation of law assign, hypothecate, give, transfer, mortgage, sublet, license, or otherwise transfer or encumber all or part of its rights, duties, or other interests in this Agreement or the proceeds thereof (collectively, "Assignment") in whole or in part to any third party without prior written consent of the other, provided, however that the Licensors may assign this Agreement in the event of an acquisition of the Licensor by a third party. In the event Licensee is acquired by a third party, either Licensor may terminate this Agreement upon reasonable notice to the other Parties. Any attempt to make an Assignment in violation of this provision shall be a material default under this Agreement and any Assignment in violation of this provision shall be null and void.

17. Entire Agreement

17.1. This Agreement, together with the Confidential Disclosure Agreement dated [redacted] and the Appendices attached hereto, set forth the entire agreement and understanding between the Parties as to the subject matter hereof, and supercedes all agreements and understandings between the parties as to the subject matter, whether oral or in writing.

18. No Implied Waiver

18.1 No failure or delay on the part of either Party to exercise any right under this Agreement or provided for by Laws shall impair, prejudice or constitute a waiver of such right.

19. Severability.

19.1. If and to the extent that any court or tribunal of competent jurisdiction holds any of the terms, provisions or conditions of this Agreement or parts thereof, or the application hereof to any circumstances, to be illegal, invalid or unenforceable in a final non-appealable order, (i) such provision shall be fully severable, (ii) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never

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comprised a part hereof, (iii) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (iv) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement, a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible.

20. No License.

20.1. Nothing in this Agreement shall be deemed to constitute the grant of any license or other right in any Party to any other Party in respect of any product, patent, trademark, confidential information, trade secret or other data or any other intellectual property of the other Party except as expressly set forth herein.

21. Headings.

21.1. The headings for each article and section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular article or section nor to be used in construing or interpreting any of the provisions of this Agreement.

22. Appendixes

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22.1. All Appendixes to this Agreement are by this reference incorporated herein and made a part of this Agreement.

23. Counterparts.

23.1. This Agreement may be executed in three or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed and effective as of the date first indicated above.

BIOTA SCIENTIFIC MANAGEMI	**SANKYO CO., LTD**	**Licensee**
By	By	By
Name	Name	Name
Title	Title	Title
Date	Date	Date

DocsOpen ID#772911

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AMENDMENT #2

to

Collaboration and License Agreement

between

Biota Holdings Limited,

Biota Scientific Management Pty. Ltd.

and

Daiichi Sankyo Company, Limited

THIS AMENDMENT #2, effective as of March 27th, 2009 ("Effective Date Amendment #2") between Biota Holdings Limited ("BHL") and Biota Scientific Management Pty. Ltd. ("BSM") (BHL and BSM being jointly referred to as "Biota"), both being corporations organized and existing under the laws of Victoria, Australia, with offices at 10/585 Blackburn Road, Notting Hill, 3168 Australia, and Daiichi Sankyo Company, Limited ("Daiichi Sankyo"), a joint stock company organized and existing under the laws of Japan, with offices at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo, Japan sets forth the agreement between the Parties as follows:

Recitals

1. Whereas, Biota Holdings Limited and Sankyo Company, Limited ("Sankyo") entered into a Collaboration and License Agreement dated September 29, 2003 ("CLA"); and,

2. Whereas, Biota and Sankyo executed an Amendment #1 to the CLA dated June 30, 2005 ("Amendment #1"); and,

3. Whereas, Daiichi Sankyo acquired all rights and obligations of Sankyo under the CLA and Amendment #1 as a result of merger dated April 1, 2007; and,

4. Whereas, the Parties have agreed to further amend the terms and conditions of the CLA and to replace Amendment #1 with this Amendment #2;

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein, and for other good and valuable consideration, the Parties hereto agree to amend the CLA, and specifically to replace Amendment #1 with this Amendment #2, as follows:

1. Definitions for this Amendment #2

1.1 Any capitalized terms set forth in this Amendment #2 shall have the same meanings as those set forth in the CLA.

2. Definitions in CLA

2.1 Any capitalized terms set forth in the CLA using "Sankyo" shall be hereby replaced with the equivalent terms using "Daiichi Sankyo."

2.2 The CLA shall be amended by inserting the following new definitions:

"CS-8958" means the LANI Compound listed under the heading "Daiichi Sankyo Compounds" in Appendix D as of the Effective Date Amendment #2.

"FLUNET Compounds" means the LANI Compounds listed under the heading "Biota Compounds" in Appendix D as of the Effective Date Amendment #2.

"FLUNET Option Deadline" means the earlier of (i) three (3) months after the cessation of CS-8958 Development, or (ii) six (6) months after the first launch date of CS-8958 in Japan.

"Third Party Licensee" means a Licensee other than one of the Parties.

3. Amendment # 1

3.1 Biota and Daiichi Sankyo agree that the amendments to the CLA effected by Amendment #1 will be regarded as having never been made, with the effect that the CLA, in the form executed by BHL and Sankyo on September 29, 2003, will be regarded by the Parties as in force between them from that date up until the time immediately before the Effective Date Amendment #2.

4. Biota Scientific Management Pty. Ltd.

4.1 BSM is hereby added to the CLA as a Party. Wherever, the term "Biota" appears in the CLA or this Amendment #2, it shall apply to both BHL and BSM, unless the context otherwise requires. For clarity, any statement like "shared equally between the Parties" in the CLA or this Amendment #2 refers to fifty-fifty sharing between BHL and BSM on the one hand and Daiichi Sankyo on the other hand.

4.2 Recital 1 of the CLA shall be amended as follows:

"1. Biota Scientific Management Pty. Ltd owns certain patents and, together with Biota Holdings Limited, has expertise and know-how in the field of long-acting neuraminidase inhibitors and has synthesized and optimized several LANI Compounds (defined below) which may be suitable for preclinical and clinical development, and wishes to collaborate with a key partner in the development of LANI Compounds for Commercialization (defined below) worldwide."

4.3 Daiichi Sankyo agrees that BSM, as the primary holder of the Biota Technology, shall be responsible for carrying out Biota's responsibilities with respect to the Biota Technology under the CLA and all payments to be made to Biota under the CLA and this Amendment #2 shall be made to BSM.

4.4 Any notices to be given to Biota in accordance with Section 15 of the CLA shall be deemed to be given to both BHL and to BSM if given in the manner prescribed in Section 15 thereof.

5. Collaboration and Licenses

5.1 Section 3 of the CLA is hereby deleted and replaced by the following:

"3. Collaboration and Licenses

3.1 Collaboration

3.1.1 The Parties will collaborate in the Development of LANI Compounds and the licensing of Biota Technology and Daiichi Sankyo Technology to appropriate licensees on a worldwide basis.

3.1.2 The Parties will endeavour to incorporate into any license with a Third Party Licensee a requirement that a committee comprised of representatives of the Parties and the Third Party Licensee (and any other Third Party Licensee) ("Global Development and Commercialization Committee") be established. The Global Development and Commercialization Committee shall be a forum to:

(i) exchange information concerning Development and Commercialization activities; and

(ii) facilitate the co-ordination of activities in the various jurisdictions.

3.2 Licensing Committee

3.2.1. Establishment of LC. To facilitate the licensing of Biota Technology and Daiichi Sankyo Technology and the supervision and oversight of Third Party Licensees, the Parties will establish a joint committee ("Licensing Committee" or "LC").

3.2.2 Responsibilities of the LC. The LC shall be responsible for:

(i) overseeing the selection of Third Party Licensees and the development of license terms within the scope of the License Template;

(ii) overseeing the performance of Third Party Licensees under the relevant License Agreements, liaising with Third Party Licensees and providing Third Party Licensees with a point of contact with the Parties; and

(iii) organizing meetings of the Global Development and Commercialization Committee and discussing the issues to be addressed by that Committee prior to its meetings.

3.2.3 Membership of LC. The LC shall be comprised of two (2) representatives from each of Biota and Daiichi Sankyo. Each Party's representatives, of which one (1) will be from the license or business development department and the other from the research and development or product development department, will have appropriate licensing and technical experience and knowledge, and ongoing familiarity with the LANI Compounds. Additional third party representatives, consultants or other employees representing technical or non-technical functional areas of a Party may from time to time, by mutual consent of the Parties, which consent shall not be unreasonably withheld, be invited to attend LC meetings (on a non-voting basis), subject to such representative's or consultant's written agreement to comply with the confidentiality requirements of Section 9. Unless otherwise agreed by the Parties, the LC shall have at least one representative with relevant decision-making authority from each Party such that the LC is able to effectuate all of its decisions within the scope of its responsibilities as described in Section 3.2.2 above. The representatives from each Party shall (i) coordinate and prepare the agenda and ensure the orderly conduct of the LC, (ii) attend (subject to below) each meeting of the LC, and (iii) prepare and issue minutes of each meeting within ten (10) business days thereafter accurately reflecting the discussions and decisions of the LC. Such minutes from each LC meeting shall not be finalized until the applicable representatives from each Party has reviewed and confirmed the accuracy of such minutes in writing. The representatives from each Party shall solicit agenda items from other LC members and provide an agenda along with appropriate information for such agenda reasonably in advance (to the extent possible) of any meeting. It is understood that such agenda shall include all items requested by either Party for inclusion therein.

3.3 Joint Project Team.

3.3.1. Establishment of JPT. To facilitate the collaboration referred to in Section 3.1.1 the Parties will establish a joint project team ("Joint Project Team" or "JPT").

3.3.2 Responsibilities of the JPT. The JPT shall be responsible for:

(i) providing strategic direction to the Parties' activities relating to the Development of LANI Compounds;

(ii) overseeing, reviewing and monitoring such activities and the progress thereof;

(iii) facilitating the exchange of information related to LANI Compounds between the Parties;

(iv) reporting regularly to the LC on the progress of the Development of LANI Compounds; and

(v) any other activities agreed to by the Parties from time to time.

3.3.3 Membership of JPT. The JPT shall be comprised of such number of representatives from Biota and Daiichi Sankyo as they agree from time to time.

3.4 Meetings of LC and JPT

The LC and JPT shall meet in accordance with the schedules established by mutual written agreement of the Parties, but no less frequently than once every six (6) months, with the location for in-person meetings alternating between Biota and Daiichi Sankyo facilities (or such other location that may be determined by the LC or the JPT as the case may be). Alternatively, the LC and the JPT may meet by means of teleconference, videoconference or other similar communications equipment. Each Party shall bear its own travel and lodging expenses related to the attendance of such meetings by its representatives. Each Party shall alternate the responsibility for the preparation of written minutes of the meetings of the LC and JPT, which shall become official only upon unanimous approval of the LC or the JPT as the case may be.

3.5 Decision Making of LC and JPT

Each of Biota and Daiichi Sankyo shall have collectively one (1) vote in all decisions within the purview of the LC and JPT (as specified in Sections 3.2.2 and 3.3.2) and the Parties shall attempt to make decisions by consensus. In the event that the LC or the JPT is unable to reach consensus with respect to a decision within its purview, either Party shall have the right, by written notice to the other Party, referencing this Section 3.5 and clearly stating the matter in dispute, to refer such dispute to the Parties' respective executives, in the case of Daiichi Sankyo, Vice President of the Licensing Department, and in the case of Biota the Chief Executive Officer for resolution. Notwithstanding anything herein to the contrary, the LC and the JPT shall not have any authority to amend, modify or waive compliance with any term or condition of this Agreement.

3.6 Relationship with Third Party Licensees

The Parties agree that negotiations with Third Party Licensees will be conducted on the basis of the license plans and policies determined by the LC and within the terms and spirit of the License Template. The LC will oversee the conduct of negotiations with potential Third Party Licensees but, to avoid confusion in dealing with Third Party Licensees, the Party who introduces the Third Party Licensee will take the lead in conducting negotiations with that Third Party Licensee, unless otherwise agreed by the Parties."

6. Intellectual Property

6.1 Section 7.1.1 of the CLA is hereby deleted and replaced by the

following:

"7.1.1 The Inventions, patent applications and the patents regarding the LANI Compounds or Products generated by or on behalf of a Party, either solely or jointly with third parties, after the Effective Date of the CLA shall be owned by such Party. Such patent applications and patents shall be regarded as such Party's Patents and included in Appendices A (Biota Patents) or B (Daiichi Sankyo Patents) to the CLA. The Parties confirm that the Inventions, patent applications and the patents referred to in this Section 7.1.1 generated by or on behalf of Daiichi Sankyo fall within the Biota License and the Inventions, patent applications and the patents referred to in this Section 7.1.1 generated by or on behalf of Biota fall within the Daiichi Sankyo License."

6.2 Sections 7.1.2, 7.1.3 and 7.2.2 of the CLA are hereby deleted.

6.3 Section 7.3.3 of the CLA is hereby deleted and replaced by:

"7.3.3 Notwithstanding the provision of Section 7.2.1 and Section 7.3.2, if the Patents or Intellectual Properties that are threatened to be infringed or disputed by any third party are (i) any and all Patents related to the LANI Compounds or Products developed and Commercialized that is determined conclusively by the Licensing Committee to be the Development Candidate, or (ii) any and all Patents related to the Product for which the Regulatory Authority grants Marketing Approval, the Parties shall discuss and agree in good faith how such third party claim or suit against the Patents or Intellectual Properties should be defended and which party shall initiate the defence of said claim or suit. The initiating Party designated by said discussion ("Initiating Party") shall prosecute and control such claim or suit and periodically inform the other Party of its intended course of action and shall provide the other with the opportunity to comment on significant actions or elements of the Initiating Party. Neither Party shall settle any such claim or suit without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed, except as provided hereafter. Any costs and expenses, including reasonable attorneys' fees, incurred by Initiating Party in defending against such claim or suit shall be borne by both Parties equally. In the event the Parties cannot agree on the strategy for such action, including settlement, etc., the Initiating Party shall make the final determination."

7. <u>FLUNET</u>

7.1 A new Section 4.4 shall be inserted into the CLA as follows:

"4.4 FLUNET

4.4.1 The Parties acknowledge that subject to Section 4.4.2 below, Daiichi Sankyo may elect to have the exclusive right to develop and market the FLUNET Compounds in Japan prior to the FLUNET Option Deadline.

4.4.2 If Daiichi Sankyo exercises its right of election in accordance with Section 4.4.1, the Parties will negotiate in good faith a license agreement that would confer such a right on Daiichi Sankyo and, if such negotiations result in agreement on the content of a license agreement, the Parties will execute such license agreement.

4.4.3 If, upon the expiration of three(3) months from Daiichi Sankyo giving Biota notice of its election under Section 4.4.1, Daiichi-Sankyo and Biota have not executed a FLUNET License Agreement the Parties' rights and obligations under Sections 4.4.1 and 4.4.2 will cease at that point.

4.4.4 In the event that Daiichi Sankyo does not exercise its right of election under Section 4.4.1 or the FLUNET License Agreement is not executed within three (3) months from Daiichi Sankyo giving Biota notice of its election under Section 4.4.1, the Parties will endeavour to enter into a license agreement with a potential Third Party Licensee to develop and market the FLUNET Compounds in Japan."

8. Non-compete

8.1 Section 2.4.1 of the CLA is hereby deleted and replaced by the following:

"2.4.1. During the term of this Agreement, unless otherwise agreed between the Parties, each Party agrees that neither for itself or through its Affiliates will it develop, commercialize, or otherwise handle or deal with, directly or indirectly, or enter into any collaboration, license or development agreement or any other arrangement with any party other than the other Party to develop, Commercialize, or otherwise handle or deal with any product for the Field ("Competitive Product") in any country. The restrictions in this Section 2.4.1 shall not apply to:

(i) products already manufactured, distributed, sold, bought or otherwise dealt with by each Party or its Affiliates as of the Effective Date;

(ii) arrangements entered into with Third Party Licensees in accordance with this Agreement; or

(iii) arrangements entered into by Daiichi Sankyo in accordance with any license or commercialization agreement entered into by Biota and Daiichi Sankyo in relation to any Product."

9. Term and Termination

9.1 The term of this Amendment #2 shall commence on the date first above written and shall remain in effect as long as the CLA is in effect or until the Parties otherwise agree in writing to terminate this Amendment #2.

10. Entire Agreement

10.1 This Amendment #2, together with the CLA, as hereby amended,

set forth the entire agreement and understanding between the Parties as to the subject matter hereof, and supersedes all agreements and understandings between the Parties as to the subject matter, whether oral or in writing. As provided in Section 2, the Amendment #1 is hereby deemed by the Parties to be of no effect.

IN WITNESS WHEREOF, the Parties have caused this Amendment #2 to be executed and effective as of the date first indicated above.

BIOTA HOLDINGS LTD.

By: _____
Name: Peter Cook
Title: Chief Executive Officer

Date: 30 March 2009

DAIICHI SANKYO COMPANY, LIMITED

By: _____
Name: Noriaki Ishida
Title: Vice President, Licensing

Date: 3/27/09

BIOTA SCIENTIFIC MANAGEMENT PTY. LTD.

By: _____
Name: Peter Cook
Title: Chief Executive Officer

Date: 30 March 2009

Certain information contained in this document, marked by ***, is filed with the SEC pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended

1663

Commercialization Agreement
Between
Biota Scientific Management Pty. Ltd.
and
Biota Holdings Limited
and
Daiichi Sankyo Company, Ltd.

THIS AGREEMENT, effective as of March 27th, 2009 between **Biota Scientific Management Pty. Ltd. ("BSM")** and **Biota Holdings Limited ("BHL")** (BSM and BHL being jointly referred to as **"Biota"**), both being corporations organized and existing under the laws of Victoria, Australia, with offices at 10/585 Blackburn Road, Notting Hill, 3168, Victoria, Australia, and on the one hand; and **Daiichi Sankyo Company, Ltd. ("Daiichi Sankyo")**, a joint stock company organized and existing under the laws of Japan, with offices at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo, Japan sets forth the agreement between Biota and Daiichi Sankyo as follows:

Recitals

1. Biota and Daiichi Sankyo both have expertise, know-how and patents in the field of long-acting neuraminidase inhibitors, and have synthesized and optimized several LANI Compounds (defined in the CLA) which may be suitable for clinical development and commercialization worldwide as pharmaceutical products for human consumption.

2. Biota and Daiichi Sankyo have executed a Collaboration and License Agreement, as amended and restated on March 27th, 2009 ("CLA"), under which Biota and Daiichi Sankyo have agreed to pool their respective LANI Compound patents and technology and to collaborate and work together to license the LANI Compounds to one or more third parties for development and marketing.

3. Daiichi Sankyo wishes to develop and commercialize in Japan CS-8958 (defined below) for the treatment and prevention of influenza or other viral infections.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein, and for other good and valuable consideration, all of the Parties hereto agree as follows:

Definitions and Interpretation

1. Unless clearly set forth herein otherwise, any capitalized terms set forth in this Agreement shall have the same meanings as those set forth in the CLA, provided where those definitions in the CLA refers "LANI Compound", it shall read "CS-8958" as appropriate.

2. "Agreement" means this document between Daiichi Sankyo and Biota together with any exhibits, schedules or specifications which are attached hereto and made a part of this document at the time of its execution, together with any amendments hereto which are signed by authorized representatives of the Parties and incorporated as a part of this document.

3. "Biota" means BSM and BHL.

4. "Commercialize or Commercialization" means to promote, sell, distribute, and otherwise market or promote a Product or Products, and to engage in Product Manufacturing for purposes of sale to a consumer.

5. "Commercially Reasonable Efforts" means with respect to a Party, the efforts and resources normally applied by such Party to its other programs, lead candidates and pharmaceutical products of similar commercial potential at a similar stage in its product life, but no less than a sustained, continued and active commitment of efforts and resources (financial and otherwise) consistent with those normally applied in the pharmaceutical industry for a novel, high-priority program and product of similar commercial potential at a similar stage in its product life. Without limiting the foregoing, Commercially Reasonable Efforts shall require the applicable Party to: (i) promptly assign responsibilities for activities for which it is responsible to specific employee(s) who are held accountable for the progress, monitoring and completion of such activities, (ii) set and consistently seek to achieve meaningful objectives for carrying out such activities, and (iii) consistently make and implement decisions and allocate the full complement of resources necessary or appropriate to advance progress with respect to and complete such objectives in an expeditious manner. In considering a pharmaceutical product's commercial potential, a Party shall not consider (A) any other pharmaceutical product such Party is then researching, developing or commercializing, alone or with one or more collaborators or (B) any payment required to be made by such Party hereunder.

6. "CS-8958" means the LANI Compound listed under the heading "Sankyo Compounds" in Appendix D to the CLA.

7. "Development Plan" means Daiichi Sankyo's plan in respect of Development activities and timelines which is included as Appendix A to this Agreement and which may be amended from time to time as reported to the REC.

8. "Effective Date" means the date shown in the first paragraph of this Agreement.

9. "First Commercial Date" means the date on which the Product is first shipped by Daiichi Sankyo to third parties for commercial sale in Japan.

10. "Generic Equivalent" means with respect to the Product, a product containing as its active pharmaceutical ingredient CS-8958 (or any organic or inorganic ester or salt of CS-8958).

11. "HIL" means Hovione International Limited.

12. "Hovione License Agreement" means the license relating to inhalation devices entered into by HIL, Daiichi Sankyo and BHL dated 25 January 2007.

13. "Manufacture" means with respect to each of API and Product, all the activities relating to production of API, CS-8958 and/or Products, including, but not limited to, purchasing and release of raw materials, manufacturing, milling, quality control and assurance of all production steps, finishing, filling, labeling, packaging, release, holding and storage and the tests and analyses conducted in connection therewith.

14. "Marketing Plan" means Daiichi Sankyo's plan in respect of Commercialization activities, which plan is to be developed in accordance with Section 5.1.

15. "Net Sales" means the gross amount invoiced by Daiichi Sankyo, its Affiliates and any third party collaboration as set forth in Section 1.2.1 below ("Collaborator") to third parties that are not Affiliates or Collaborator (unless such Affiliate or Collaborator is the end user of such Product, in which case the amount billed therefore shall be deemed to be the amount that would be billed to a third party in an arm's length transaction) for sales or other dispositions of Products to third parties, less the following items, as allocable to such Product (if not previously deducted from the amount invoiced): (i) trade discounts, credits or allowances commissions, rebates, chargebacks;

(ii) credits or allowances additionally granted upon returns, rejections or recalls (except where any such recall arises out of a Party's, its Affiliate's or Collaborator's gross negligence, wilful misconduct or fraud); (iii) freight, shipping and insurance charges; (iv) taxes, duties or other governmental tariffs (other than income taxes); and (v) government mandated rebates. For the avoidance of doubt, the Parties agree that Net Sales includes sales of the Product not sold under the Pricing and Reimbursement Approval, which includes but is not limited to sales to a governmental agency as inventory for a pandemic. Furthermore, Net Sales for a calendar quarter will be less any Product returned in that calendar quarter but sold in the preceding calendar quarter in Japan.

16. "Party" means BSM, BHL or Daiichi Sankyo. "Parties" mean BSM, BHL and Daiichi Sankyo.

17. "Pricing and Reimbursement Approval" means all approvals from any Pricing and Reimbursement Body necessary to enable sales of Products in Japan and, if applicable, for such sales to be the subject of valid claims for reimbursement.

18. "Pricing and Reimbursement Body" means any body with authority over granting approvals for the pricing and/or reimbursement of a Product in Japan.

19. "Review and Exchange Committee" or "REC" means the joint committee established by the Parties in accordance with this Agreement which will exchange information concerning, and in certain circumstances monitor, the Development and Commercialization of CS-8958 in accordance with Section 3.

20. "Term" means the period beginning on the Effective Date and ending on the later of (a) the expiration of the last-to-expire of Patents covering CS-8958 in Japan, and (b) twelve (12) years from the launch of such Product in Japan, unless sooner terminated pursuant to Section 8.2.

21. In this Agreement, the following rules apply unless the context requires otherwise:
    (a) The singular includes the plural, and the converse also applies.
    (b) A gender includes all genders.
    (c) If a word or phrase is defined, its other grammatical forms have a corresponding meaning.
    (d) A reference to a person includes a corporation, trust, partnership, unincorporated body or other entity, whether or not it comprises a separate legal

entity.

(e) A reference to a Section or Appendix is a reference to a section of or an appendix of this Agreement.

(f) A reference to an agreement or document (including a reference to this Agreement) is to the agreement or document as amended, supplemented, novated or replaced, except to the extent prohibited by this Agreement or that other agreement or document.

(g) A reference to writing includes any method of representing or reproducing words, figures, drawings, or symbols in a visible or tangible form.

(h) A reference to a party to this Agreement or another agreement or document includes the party's successors, permitted substitutes and permitted assigns (and, where applicable, the party's legal personal representatives).

(i) A reference to legislation or to a provision of legislation includes a modification or re-enactment of it, a legislative provision substituted for it and a regulation or statutory instrument issued under it.

(j) A reference to dollars and $ is to United States currency.

(k) A reference to a right or obligation of any two or more people comprising a single party confers that right, or imposes that obligation, as the case may be, on each of them severally and each two or more of them jointly. A reference to that party is a reference to each of those people separately (so that, for example, a representation or warranty by that party is given by each of them separately).

(l) Mentioning anything after includes, including, for example, or similar expressions, does not limit what else might be included.

(m) Nothing in this Agreement is to be interpreted against a party solely on the ground that the party put forward this Agreement or any part of it.

1. Commercialization in Japan

1.1. Exclusive Marketing. In accordance with Section 4.1.1 of CLA, Daiichi Sankyo hereby elects to have the exclusive right to market the Product in Japan. For the purposes of this Section 1, the term "exclusive" means to the exclusion of all other parties in Japan, including Biota. Daiichi Sankyo may undertake Clinical Development outside Japan for the sole purpose of obtaining a Marketing Approval in Japan, provided however, that except for Clinical Development ongoing as of the execution of this Agreement, Daiichi Sankyo shall obtain prior written confirmation from Biota that such Clinical Development does not conflict with the license agreement entered into with any Third Party Licensee.

1.2. Selection of Collaboration Partners.

1.2.1. The rights exercised by Daiichi Sankyo under Section 1.1 shall include the right to choose a third party collaborator for Development and/or Commercialization of the Product, in whole or in part; *provided, however, that*:

(i) Daiichi Sankyo shall continue to be strictly liable to Biota for the performance of Daiichi Sankyo's obligations under this Agreement, including, in particular Daiichi Sankyo's payment obligations under this Agreement; and

(ii) Daiichi Sankyo shall not grant a sublicense to any third party (other than a Licensee Affiliate) unless Biota is notified in advance of the proposed grant of sublicense and provided with an executive summary of the commercial terms of the proposed sublicense agreement.

1.2.2 If, in accordance with Section 1.2.1, Daiichi Sankyo grants a sub-license to a third party and the potential financial benefits that the sub-license provides Daiichi Sankyo are materially greater than the potential financial benefits that this License provides Biota, the Parties agree that they will negotiate in good faith amendments to the financial terms of this Agreement.

1.3. Daiichi Sankyo Diligence. Daiichi Sankyo shall use Commercially Reasonable Efforts to:

(i) implement the Development Plan and otherwise undertake all activities necessary for one or more Products to obtain Marketing Approval as soon as practicable;

(ii) implement the Marketing Plan and otherwise undertake all activities necessary to launch one or more Products in the Field in Japan as soon as practicable; and

(iii) market, promote and sell such Products in the Field in Japan with a view to maximizing Net Sales in accordance with the Marketing Plan.

Daiichi Sankyo shall twice a year (within a reasonable period prior to the twice yearly meetings of the REC envisaged by Section 3.3.1) provide Biota with comprehensive written (in English) Development and Commercialization progress updates and, when requested by Biota, provide other material information relating to the Daiichi Sankyo's progress in Development and Commercialization.

2. Consideration

2.1. Royalties. Notwithstanding Section 5.2 of CLA, Daiichi Sankyo shall pay in Australian dollars to Biota during the Term a royalty equivalent to the higher of:

(i) four percent (4%) of Net Sales; and

(ii) the lower of six percent (6%) of Net Sales or the royalty rate determined in

accordance with the following formula:

RPB = 50% x (GRR – HRR)

where:

RPB = Royalty payable to Biota by Daiichi Sankyo

GRR = Highest gross royalty rate paid by a Third Party Licensee to Biota and Daiichi Sankyo

HRR = Royalty rate payable to Hovione by that Third Party Licensee

For the avoidance of doubt, the royalty payable to Biota under this Section 2.1 is separate to any royalties or other amounts payable to HIL under any arrangements with HIL.

2.2. Donations. If, in any 12 month period from the First Commercial Date, or an anniversary thereof, Daiichi Sankyo and its collaborators (if any) make donations of Products which, by the number of units sold, represents in excess of 30% of the Products sold by Daiichi Sankyo in that period, then the number of units of Products equal to that excess will be deemed to have been sold by Daiichi Sankyo and its collaborators for the purposes of the definition of "Net Sales". The Parties agree to negotiate in good faith the deemed unit price of such sales for the purpose of the royalty calculation pursuant to Section 2.1.

2.3. Generic Competition. The royalty otherwise due under Section 2.1 shall be reduced in the event of generic competition in Japan in accordance with this provision. In the event that a Generic Equivalent has achieved more than twenty percent (20%) but less than fifty percent (50%) market share of the combined market share of Product and such Generic Equivalent (on a units sold basis) in Japan in any calendar quarter, the royalty rate for such calendar quarter shall be reduced to one-half (0.5) of the applicable royalty rate specified in Section 2.1 above for so long as such market share is within such thresholds. In the event that a Generic Equivalent has achieved equal to or more than fifty percent (50%) market share of the combined market share of Product and such Generic Equivalent (on a units sold basis) in Japan, the royalty rate shall be zero (0) of the applicable royalty rate specified in Section 2.1 above for so long as such market share exceeds such threshold. The measure of the market share will be made using data generated by IMS Health.

2.4. Sales Milestones. Daiichi Sankyo will make the following payments to Biota in US Dollars upon the occurrence of the listed event in Japan for each Product:

Event	Payment
1. The annual Net Sales of 10 billion Yen is first achieved.	[***]

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

2. The annual Net Sales of 20 billion Yen is first achieved. [***]

3. The annual Net Sales of 30 billion Yen is first achieved. [***]

3. Review and Exchange Committee

3.1. Establishment and Membership of the Review and Exchange Committee.

3.1.1. Upon execution of this Agreement, Biota and Daiichi Sankyo shall establish a Review and Exchange Committee (the "REC") to exchange information and discuss matters relevant to Development and Commercialization activities and progress, including the obtaining of Marketing Approvals and Pricing and Reimbursement Approvals.

3.1.2. The REC formed under this Agreement shall cooperate with the Licensing Committee formed under the CLA and any product development committee formed under other license agreements entered into by Biota and Daiichi Sankyo with other licensees relating to products containing LANI Compounds in order to ensure maximum coordination in the development and commercialization of such products on a worldwide basis.

3.1.3. The REC shall be comprised of two (2) representatives of Biota and two (2) representatives of Daiichi Sankyo. Each of Biota and Daiichi Sankyo shall make its designation of its representatives no later than thirty (30) days after the Effective Date. These representatives shall have appropriate technical credentials, experience and knowledge and each of Biota and Daiichi Sankyo may substitute one or more of its representatives, in its sole discretion, effective upon notice to the other of such change. Additional third party representatives, consultants or other employees representing technical or non-technical functional areas of a Party may from time to time, by mutual consent of the Parties, which consent shall not be unreasonably withheld, be invited to attend REC meetings (on a non-voting basis), subject to such representative's or consultant's written agreement to comply with the confidentiality requirements of Section 9.

3.2. Role of the REC.

3.2.1. The REC shall be a forum for:

(i) Biota and Daiichi Sankyo to exchange information concerning the development of CS-8958 and the Products,

(ii) Daiichi Sankyo to report to Biota on its progress in carrying out the Development Plan and Marketing Plan, its timing expectations for achievement of the milestones set out in both plans, obtaining Marketing Approvals and Pricing and Reimbursement Approvals,

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

(iii) review and approval of the proposed Development Plan and Marketing Plan as prepared by Daiichi Sankyo,

(iv) review of any proposal to make material changes to the Development Plan or the Marketing Plan, including any changes to the target dates for achievement of milestones set out in such plans,

(v) discussion of issues raised by Regulatory Authorities or Pricing and Reimbursement Bodies, and

(vi) discussion of any activities or proposed activities of Daiichi Sankyo in Japan in respect of the development of CS-8958 or the Products that, in the view of Biota, may have a material negative impact on the development of LANI Compounds outside Japan.

3.2.2. The REC shall discuss regulatory strategy and the preparation, filing and prosecution of applications for Marketing Approvals and Pricing and Reimbursement Approvals and other regulatory issues. Following any significant meeting with Regulatory Authorities or Pricing and Reimbursement Bodies, Daiichi Sankyo shall promptly provide Biota's representatives on the REC with a written update of the outcomes of the meeting.

3.3. Meetings of the REC.

3.3.1. Meetings. Unless otherwise determined by the REC, the REC shall meet at least twice per year at locations mutually agreed, including teleconferences or video conferences. Costs for representatives of the Parties to attend REC meetings will be for each Party's account.

3.3.2. Decisions.

3.3.2.1. Each of Biota and Daiichi Sankyo shall have collectively one (1) vote in all decisions within the purview of the REC (as specified in Section 3.2.1) and the Parties shall endeavour to make decisions by consensus.

3.3.2.2. If Biota and Daiichi Sankyo are unable to reach a consensus in respect of the content of the Development Plan or the Marketing Plan provided to the REC for review and approval under Section 3.2.1(iii) and (iv), Daiichi Sankyo will have the casting vote in addition to the vote to which it is already entitled. For the avoidance of doubt, in all circumstances, Daiichi Sankyo shall continue to comply with Section 1.3.

3.4. REC Reporting and Information Sharing.

3.4.1. Following each twice yearly meeting of the REC, a representative of the REC jointly appointed by its members shall prepare and deliver to all Parties a written report recording the issues, decisions, conclusions, recommendations and other actions taken by the REC, as well as

the general status of the Development Plan and the Marketing Plan at that time. Any exceptions or dissents from the report may be noted in writing by the dissenting Party.

3.4.2. The Parties shall nominate one person in each of their organizations to act as primary recipient for said written reports.

3.4.3. The Parties agree to share with the REC all clinical, regulatory, pricing and reimbursement data available to them from their Development, Clinical Development and Commercialization activities that could assist the REC in carrying out its responsibilities.

4. Development

4.1. Development Plan. By no later than March 31st of each year, Daiichi Sankyo must submit to the REC, for review and approval, the Development Plan and any proposed amendments. Notwithstanding this, if at any time, Daiichi Sankyo becomes aware that there is likely to be a material change to the Development Plan, Daiichi Sankyo must immediately notify the REC of such material change.

4.2. Development Expenses. All direct and indirect costs and expenses associated with Development of the Product will be borne by Daiichi Sankyo.

4.3. Information Quality. Daiichi Sankyo shall ensure the integrity, quality and security of all Information; any technical, regulatory and clinical data, generated under the Development Plan and Marketing Plan, including any laboratory notes, technical data or specifications, test results, and any other relevant information or materials arising from the conduct of the Development Plan and Marketing Plan.

4.4. Clinical Trial Management. Daiichi Sankyo shall prepare suitable applications for approval or consent to commencement of clinical trials and management of trials, and handle reporting, analysis and all other aspects of the trial being conducted by it or on its behalf. Daiichi Sankyo shall undertake all Clinical Development activities in accordance with all Laws, regulations and generally accepted standards or guidelines applicable to clinical trials of new drugs.

4.5. Development Delay. If Daiichi Sankyo becomes aware that there is likely to be a delay in the First Commercial Date, Daiichi Sankyo must immediately notify Biota of such delay.

4.6. API Manufacturing Development Costs. All direct and indirect costs and/or third party charges associated with any raw material acquisition, process development and scale-up

required to provide API of suitable quantity and quality for the agreed Clinical Development shall be borne by Daiichi Sankyo or its designee.

4.7. Regulatory, Pricing and Reimbursement Matters.

4.7.1. Daiichi Sankyo shall be responsible at its sole expense for filing, prosecuting, and obtaining Marketing Approvals and Pricing and Reimbursement Approvals in Japan. Subject to the provisions of this Agreement, Biota will use Commercially Reasonable Efforts and reasonable scientific judgment to assist in preparing documents for obtaining Marketing Approvals from Regulatory Authorities and Pricing and Reimbursement Approvals from Pricing and Reimbursement Bodies in Japan. Biota will, if required by a Regulatory Authority or a Pricing and Reimbursement Body, provide certain information concerning the Manufacture of CS-8958 and/or Product directly to such Regulatory Authority or Pricing and Reimbursement Body to facilitate Daiichi Sankyo's application. If a Regulatory Authority requests that Daiichi Sankyo conduct additional developmental activities to obtain Marketing Approval, Daiichi Sankyo shall, after consultation with Biota, conduct such additional developmental activities at its own expense. Daiichi Sankyo shall keep Biota reasonably informed as to the regulatory status of Marketing Approval and Pricing and Reimbursement Approvals. In addition, Daiichi Sankyo may, at its own expense and after consultation with Biota, conduct developmental activities for promotional and marketing purposes after obtaining Marketing Approval. Daiichi Sankyo shall inform Biota of the First Commercial Date within seven (7) days thereof. Daiichi Sankyo shall promptly inform Biota with respect to any regulatory action taken or notification regarding the Products either during the approval process or marketing of the Products in Japan.

4.7.2. Regulatory Communications. Each Party agrees to provide the others with all reasonable assistance and take all actions reasonably requested by the others that are necessary or desirable to enable the others to comply with any Laws applicable to the Product, including, without limitation, to meet reporting and other obligations to:

(i) maintain and update the Marketing Approval and any filings under Section 4.7.1;

(ii) submit adverse event reports to the appropriate Regulatory Authorities as required to fulfill obligations under Laws; and

(iii) submit or file promotional materials with Regulatory Authorities, as appropriate.

4.7.3. Without limiting the foregoing, Daiichi Sankyo must immediately provide to Biota any serious or unexpected adverse event report submitted to a Regulatory Authority in respect of CS-8958 or a Product.

5. Commercialization

5.1. Annual Sales Forecast. Daiichi Sankyo must submit to the REC, within three (3) months of the Pricing and Reimbursement Approval for the first calendar year and by no later than 30 September of every year thereafter, the Marketing Plan for review and approval. The Marketing Plan shall state the annual sales forecast, in Yen (¥) and number of units, for the fiscal year ending March including the First Commercial Date. The Marketing Plan must include a detailed description of the activities proposed to be undertaken by Daiichi Sankyo in respect of obtaining Pricing and Reimbursement Approvals and manufacturing, marketing, promoting, distributing and selling Products in Japan, including sales and marketing budgets, sale force numbers and timetables. All steps necessary to achieve Commercialization will be described in the Marketing Plan as milestones and a target date for achievement of the milestone will be included in the Marketing Plan.

5.2. Trademarks. Notwithstanding Section 7.4.1 of the CLA, Daiichi Sankyo may evaluate, select, apply, register, own and maintain any trademark for the Products in Japan at its expense, provided such trademarks conform to the global trademark strategy, to the extent possible, as determined by the Global Development and Commercialization Committee, if established at that time.

6. Payments; Records and Reports

6.1. Royalty Reports.

6.1.1. Frequency of Royalty Reports. Within sixty (60) days of the end of each calendar quarter after the First Commercial Date, Daiichi Sankyo shall deliver to Biota a royalty report containing information concerning the immediately preceding calendar quarter. Each royalty report delivered by Daiichi Sankyo to Biota shall contain at least the following information, denominated in local currency and Australian dollars as calculated using the average of the prevailing buy and sell rates at the end of the calendar quarter for which such payment accrues as published by the Westpac Banking Corporation:

(i) Net Sales for the applicable calendar quarter in Japan;

(ii) Amount of royalty earned for the period;

(iii) Amount of withholding taxes, if any, required by Laws to be deducted in respect of such royalties; *provided, however, that* Daiichi Sankyo will take reasonable action to minimize any such withholding tax.

6.1.2. Daiichi Sankyo agrees to furnish reports in English, in the form of a worksheet, showing, among other things:

(i) Gross sales (including sales of the Product not sold under the Pricing and Reimbursement Approval);
(ii) All permitted deductions (as set out in the definition of Net Sales) itemized separately;
(iii) Credits relating to Products sold in the preceding calendar quarter but returned in the calendar quarter being reported;
(iv) Net Sales of each Product sold;
(v) Number of units and gross sales of the Product shipped not for reimbursement under the Pricing and Reimbursement Approvals detailed by subcategories for (a) government stockpiles, (b) corporate stockpiles, (c) other private sales, and (d) donations;
(vi) Royalties that have accrued; and
(vii) The amount of withholding taxes on the royalty payments.

6.1.3. Daiichi Sankyo shall keep proper books of account with reference to its sales of any Product under this Agreement. When requested by Biota, such books of account shall be made available at reasonable times for audit by Biota or their agents (including the right to inspect, copy, and make abstracts therefrom), solely for the purpose of verifying the royalties due or paid, or for determining compliance with other provisions of this Agreement. Any expense incurred by Biota conducting such audit shall be borne by Biota unless discrepancies attributable to Daiichi Sankyo exceeding the cost of the audit are found, in which case the costs of the audit shall be reimbursed by Daiichi Sankyo.

6.2. Method of Payment.

6.2.1. All payments under this Agreement shall be made payable in Australian dollars and shall be by appropriate electronic funds transfer in immediately available funds to such bank account as the payee shall designate and on a date no later than when royalty reports are due under Section 6.1.1 above. Each payment shall reference this Agreement and identify the obligation under this Agreement that the payment is to satisfy. Any and all expenses for such payment incurred by the payee shall be borne by the payee.

6.2.2. Any payments due under this Agreement that are not paid on or before the date such payments are due shall bear interest, at the lower of one percentage point above the Prime Rate of interest as reported in the New York edition of the Wall Street Journal on the date the payment is due or the maximum allowed by law, compounded monthly until such payment is made.

6.2.3. Any taxes or similar charges levied or assessed in a territory on the payee on the royalty payments shall be borne by payor. However, payor has the right to deduct from the royalty

payments such income taxes or charges paid thereon for which payee is entitled to receive a credit under income tax laws in effect as of the time payment is made. In these cases, payor will promptly provide payee with an original receipt for such tax payments (or a certified copy, if the original is not available). Payor's failure to provide payee with such documentation as payee determines is acceptable for tax purposes shall preclude payor from deducting such taxes or charges from the gross royalty otherwise due.

6.2.4. Payee may require such other account statements or reports from payor as may be reasonable.

6.3. Payments due to HIL.

6.3.1. Where sales of Products or the achievement of other objectives set out in this Agreement result in BHL and Daiichi Sankyo having obligations to make payments to HIL under the Hovione License Agreement, Daiichi Sankyo shall notify BHL of those payment obligations, and provided BHL agrees with the payments, Daiichi Sankyo shall pay the amounts due to HIL and deduct BHL's share of such amounts from payments due to Biota under this Agreement.

7. Representations, Warranties, and Covenants

7.1. Mutual Representations, Warranties, and Covenants. Each of Biota and Daiichi Sankyo each hereby represents, warrants, covenants, acknowledges and agrees that the other is relying, and is entitled to rely, on the following representations, warranties, and covenants:

(a) Each Party has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement has been duly and validly authorized and approved by proper corporate action on the part of such Party. Each Party has taken all other action required to be taken by such Party under the Laws, its certificate of incorporation, by-laws or any agreement to which it is a party with respect to the execution, delivery and performance of this Agreement. Assuming due authorization, execution and delivery on the part of a Party, this Agreement constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as the enforceability thereof may be limited by applicable Laws or by bankruptcy, insolvency, reorganization or other similar Laws of general application relating to creditors' rights; and

(b) To the best of its knowledge as of the Effective Date, the execution and delivery of this Agreement by a Party and the performance by such Party contemplated

hereunder shall not violate any Laws or any order of a court or a Regulatory Authority; and

(c) To the best of its knowledge as of the Effective Date, neither the execution and delivery of this Agreement nor the performance hereof by a Party requires such Party to obtain any permits, authorizations or consents from any governmental authority other than a Regulatory Authority or from any other person; and

(d) During the Term, each Party shall fulfill its obligations under this Agreement, in accordance with the terms of this Agreement and all applicable Laws; and

(e) During the Term, each Party shall retain and maintain compliance with all necessary government authorizations and permits necessary to Manufacture and supply the Product and to otherwise perform each Party's obligations under this Agreement; and

(f) All of a Party's employees, officers and consultants participating in the performance of this Agreement are, to the extent permitted under applicable Laws, under obligations (i) to assign to such Party all Inventions made during the course of and as a result of their association with such Party, and (ii) to maintain as confidential the Confidential Information received from or on behalf of the other Party; and

(g) Each Party shall not knowingly employ any employee in performing the services hereunder who has been debarred or disqualified by a Regulatory Authority or any governmental agency.

7.2. Biota' Representations, Warranties, and Covenants. Biota hereby represents, warrants, covenants acknowledges and agrees that Daiichi Sankyo is entitled to rely, on the following representations, warranties, and covenants:

(a) The execution, delivery and performance of this Agreement by each of Biota shall not result in the breach of or give rise to any termination of any agreement or contract relating to the Product to which each of Biota is a party.

7.3. No Other Warranty. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THIS AGREEMENT. THE RIGHTS GRANTED HEREUNDER ARE PROVIDED WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED. BIOTA MAKES NO REPRESENTATION OR WARRANTY THAT DAIICHI SANKYO'S ACTIVITIES UNDER THIS AGREEMENT WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHT OF A THIRD PARTY. BIOTA WILL NOT BE LIABLE FOR SUCH INFRINGEMENT, OR AN

ALLEGATION THEREOF, NOR SHALL THE SAME BE AN EXCUSE FOR NON-PERFORMANCE OF DAIICHI SANKYO'S OBLIGATIONS HEREUNDER. BIOTA ASSUMES NO RESPONSIBILITIES OR LIABILITIES TOWARDS DAIICHI SANKYO OR THIRD PARTIES WITH RESPECT TO THE RESEARCH, DEVELOPMENT, MANUFACTURE, USE, SALE OR DISPOSITION OF THE PRODUCT IN THE FIELD. THE ENTIRE RISK AS TO THE PRODUCT IN THE FIELD IS ASSUMED BY DAIICHI SANKYO.

7.4. Limitation of Liability. SUBJECT TO SECTION 10, NO PARTY SHALL BE ENTITLED TO RECOVER FROM ANOTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT, UNLESS SUCH DAMAGES ARE INFLICTED AS A RESULT OF THE NEGLIGENCE OR WRONGDOING OF THE OTHER PARTY.

7.5. Survival of Limitation of Liability. Sections 7.3 and 7.4 shall survive any termination or expiration of this Agreement.

8. Term and Termination

8.1. Term.

8.1.1. This Agreement will commence on the Effective Date and, unless earlier terminated as provided for hereunder, continue for the Term. While this Agreement remains in force, Daiichi Sankyo shall continue to have the right to use the Information owned by Biota.

8.2. Earlier termination.

8.2.1. The Parties agree that provided the dispute resolution procedure under Section 12 is exhausted either Biota or Daiichi Sankyo may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement prior to the end of the term, by giving the other sixty (60) days written notice ("Notice Period") upon occurrence of any of the following events:

8.2.1.1. "Material breach" defined as the default of any material obligation hereunder by either Biota or Daiichi Sankyo, which has not been remedied within sixty (60) days after one Party sends written notice detailing the substance of the default to the defaulting Party, or

8.2.1.2. "Insolvency" meaning the insolvency, bankruptcy, dissolution or liquidation of the other Party, where such Party is subject to the filing or consents to the filing of a petition under any bankruptcy or insolvency law or has any such petition filed against it which has not been

dismissed within ninety (90) days of such filing, appointment of a trustee, administrator, or receiver for all or substantially all of the assets of such Party, or assignment of the assets of such Party for the benefit of creditors, or attachment or expropriation of the business or assets of such Party.

8.3. The right of a Party to terminate this Agreement as provided in Section 8.2 shall not be affected in any way by its waiver or failure to take action with respect to any previous default.

8.4. Rights on termination.

8.4.1. Except as specifically provided in this Agreement, none of the Parties shall be liable to the others based on, or as a result of, the termination of this Agreement as provided herein, whether in loss of good will, anticipated profits or otherwise. This Section 8.4.1 shall survive the termination for any reason of this Agreement.

9. Confidentiality

9.1. During the term of this Agreement and for a period of seven (7) years thereafter, each Party (a) shall hold the Information and any marketing and other confidential information, whether in written, oral, visual, or machine readable form disclosed by either Party to the other under this Agreement (the "Confidential Information") in confidence with the same degree of care it maintains the confidentiality of its own Confidential Information, (b) shall not disclose such Confidential Information without the prior written consent of the disclosing Party, and (c) shall not use such Confidential Information other than for exercising its rights and/or performance of its obligation under this Agreement except for any information which is evidenced that:

(i) was in the receiving Party's possession at the time of disclosure,
(ii) was publicly known at the time of such disclosure,
(iii) becomes publicly known through no default of the receiving Party,
(iv) was obtained legally by the receiving Party from a duly authorized third party, or
(v) was independently discovered without the aid or application of the information received.

9.2. Each Party may disclose the Confidential Information available only to those of its employees, contractors, and agents who have a need to know such Confidential Information to implement the terms of this Agreement. The Parties agree to take reasonable precautions to preserve the confidential, proprietary or secret status of the Confidential Information and shall require that each of their respective employees, contractors, and agents understand and agree in writing to treat and to hold such Confidential Information in confidence consistent with the

provisions herein.

9.3. Within thirty (30) days of the date of termination of this Agreement for any reason, each Party shall provide each other Party with written notice specifying that through reasonable care and to the best of its knowledge: (a) all Confidential Information embodied in whole or in part in documents, materials, things, and copies thereof have been destroyed or returned to the relevant Party, and (b) the originals and all copies of any machine-readable documentation containing any portion of the Confidential Information have been destroyed or returned to the relevant Party.

9.4. The Parties shall be entitled to issue a press release relating to this Agreement or activities conducted hereunder, as approved by the Parties. A Party may issue any subsequent press releases or other written public disclosures relating to this Agreement or activities conducted hereunder (each a **'Proposed Disclosure'**) upon prior written approval of the other Parties, such approval not to be unreasonably withheld; provided, however, that each Party will use Commercially Reasonably Efforts to submit to the other Parties a draft of such Proposed Disclosure for review and comment by the other Parties at least five (5) full business days prior to the date on which such Party would like to release such Proposed Disclosure. Biota will make good faith efforts to adhere to the five (5) day notice period, but Daiichi Sankyo acknowledges that there may be situations where under Australian laws or stock market listing rules Biota are required to immediately issue a disclosure concerning this Agreement or activities hereunder. In all situations, Biota will promptly inform Daiichi Sankyo of any required disclosure. No approval of the other Parties shall be required if a subsequent press release solely discloses information that has previously been approved. None of the Parties shall use the name, trademark, trade name or logo of the other Parties or their employees in any publicity or news release relating to this Agreement or its subject matter, without the prior express written permission of the other Parties.

10. Liability and Indemnity

10.1. Biota shall indemnify, defend and hold harmless Daiichi Sankyo, its employees, agents, officers, directors, permitted licensees, successors and permitted assigns (collectively, the "Daiichi Sankyo Indemnified Parties"), from and against any and all costs, liabilities, judgments, obligations, losses, expenses and damages (including reasonable attorneys' fees and expenses) of whatsoever kind or nature (collectively, "Losses") incurred by or imposed upon any Daiichi Sankyo Indemnified Party as a result of any claims, actions, suits or proceedings (collectively, "Claims") arising out of or related to, in any way, the Development, Manufacture, marketing, promotion, importation, sale or other use (collectively, "Use") of the

Product in Japan by Biota pursuant to this Agreement, regardless of whether such Claims or Losses are based upon theories of contract, tort, product liability, strict liability, infringement of any patent, trademark, trade name, logo, service mark, trade dress, trade secret, or any other legal or equitable theory; provided, however, that Daiichi Sankyo shall indemnify Biota for Losses proven to have been caused solely from an act or omission by Daiichi Sankyo.

10.2. Daiichi Sankyo shall indemnify, defend and hold harmless Biota, and each of their employees, agents, officers, directors, permitted licensees, successors and permitted assigns (collectively, the "Biota Indemnified Parties"), from and against any and all costs, liabilities, judgments, obligations, losses, expenses and damages (including reasonable attorneys' fees and expenses) of whatsoever kind or nature (collectively, "Losses") incurred by or imposed upon any Biota Indemnified Party as a result of any claims, actions, suits or proceedings (collectively, "Claims") arising out of or related to, in any way, the Development, Manufacture, marketing, promotion, importation, sale or other use (collectively, "Use") of the Product in Japan by Daiichi Sankyo pursuant to this Agreement, regardless of whether such Claims or Losses are based upon theories of contract, tort, product liability, strict liability, infringement of any patent, trademark, trade name, logo, service mark, trade dress, trade secret, or any other legal or equitable theory; provided, however, that the Biota shall indemnify Daiichi Sankyo for Losses proven to have been caused solely from an act or omission by Biota.

10.3. Each Party shall give prompt written notice to the other of any Claim asserted against such Party (in such capacity, the "Notifying Party") arising from or relating to the Product, regardless of whether the Notifying Party is entitled to seek indemnification from the other Party pursuant to either Section 10.1 or 10.2. The Parties shall, subject to the execution of an appropriate non-disclosure agreement, reasonably consult with, and share information with, each other regarding such Claim and shall reasonably cooperate and assist each other in the event that the Notifying Party wishes to pursue any claim against any third party in connection therewith, in each case at the sole cost and expense of the Notifying Party. Each sublicense agreement entered into by a Party relating to any Product in accordance herewith shall contain a provision substantially similar to that set forth in this Section 10.3.

10.4. SUBJECT TO SECTION 13, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER, UNLESS SUCH DAMAGES ARE INFLICTED AS A RESULT OF THE NEGLIGENCE OR WRONGDOING OF THE OTHER PARTY.

11. Amendment

11.1. All amendments to this Agreement must be in writing and signed by authorized representatives of both Parties.

12. Dispute Resolution

12.1. Disputes. If the Parties are unable to resolve any dispute or other matter arising out of or in connection with this Agreement, a Party may, by written notice to the other Parties (except as otherwise expressly provided herein), have such dispute referred to a panel consisting of the Head of Licensing of Daiichi Sankyo and the Chief Executive Officer of BHL or their senior delegates. Such persons shall be designated with plenary authority for attempted resolution by good faith negotiations within thirty (30) days after such notice is received. In such event, Biota and Daiichi Sankyo shall cause its member of that panel to meet (face-to-face or by teleconference) and be available to attempt to resolve such issue. If the Parties should resolve such dispute or claim, a memorandum setting forth their agreement and referencing this Section 12.1 will be prepared and signed by the Parties if requested by a Party. The Parties shall cooperate in an effort to limit the issues for consideration in such manner as narrowly as reasonably practicable in order to resolve the dispute.

12.2. Arbitration. If the Parties do not fully settle a dispute or other matter by the processes referred to in Section 12.1 and a Party wishes to further pursue the matter, each such dispute, controversy or claim shall be finally resolved by binding arbitration in accordance with the applicable rules of the American Arbitration Association by three (3) independent arbitrators in accordance with its Commercial Arbitration Rules. The arbitrators shall have substantial experience in commercial disputes in the pharmaceutical industry. Each of Biota and Daiichi Sankyo shall name one (1) arbitrator within thirty (30) days after the final closure of the process described in Section 12.1. The arbitration panel shall be headed by a partner practicing in an international law firm and who shall be selected by the two (2) chosen arbitrators. If the head of the arbitration panel is not nominated within thirty (30) days of the date of nomination of the later of the two (2) party-nominated arbitrators, he shall be selected according to the Commercial Arbitration Rules. Place of such arbitration shall be New York City, the State of New York, United States of America and the language (including of all testimony, evidence and written documentation) shall be English. In such arbitration the governing law to be applied is as described in Section 13.1. The Parties acknowledge that they desire for any arbitration to be conducted in an efficient, speedy and economical manner. In order to effectuate this desire, the arbitrators shall establish procedures to facilitate such goals and complete such arbitration as soon and efficiently as practicable. Unless the arbitrators otherwise expressly determine

otherwise, none of the Parties shall be required to give general discovery of documents, but may be required only to produce specific, identified documents which are relevant to the dispute. Further unless the arbitrators otherwise designate, each of Biota and Daiichi Sankyo shall bear fifty percent (50%) of the costs of any arbitration under this Section 12.2 and the arbitrators and all of its own costs (including attorney and expert fess) incurred with respect thereto.

12.3. Final Award. The award for arbitration under Section 12.2 shall be final and binding and may be enforced in any court of competent jurisdiction against any of the Parties. Notwithstanding the foregoing, the Parties shall each be entitled prior to or during any dispute resolution process under this Section 12 to seek and obtain injunctive or other equitable relief in any court of competent jurisdiction to preserve the status quo pending arbitration or to prevent the breach of this Agreement.

12.4. No Termination During Arbitration. The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments were not due.

12.5. Confidentiality. The Parties and the arbitrators, as applicable, shall maintain the fact of any dispute resolution proceeding and any settlement or award made to a Party under this Section 12 in strict confidence.

13. Governing Law

13.1. Any claim, dispute or controversy of whatever nature arising out of or relating to this Agreement, including without limitation, any action based on tort, contract or statute, or concerning the interpretation, effect, termination, validity, performance or breach of this Agreement shall be construed in accordance with the laws of New York without regard to any conflict of law principles.

14. Force Majeure

14.1. No Party shall be liable for any failure or delay in performance of this Agreement occasioned in whole or in part by acts of God, strike, lock-out, fire, earthquake, epidemic, inability to obtain materials or shipping space, breakdown, delay of carrier or regulation of any

government or any other cause beyond its control, provided that said Party has exercised due and reasonable care and its best efforts to avoid any of the above-mentioned events.

15. Notices

15.1. Any notice or report pursuant to this Agreement shall be deemed duly given if delivered personally, sent by airmail, international recognized courier service, electronic mail (provided such electronic mail is followed by facsimile confirmation in accordance with this Section 15.1) or facsimile addressed to the other Party at the addressee facsimile number set forth below, or to such other address or facsimile number as shall have theretofore been furnished by one Party to the other in accordance with this Section, and shall be deemed to have been given when sent.

If to BSM:

Attention: Mr Peter Cook
Chief Executive Officer
Biota Scientific Management Pty Ltd
10/585 Blackburn Road
Notting Hill, 3168
Victoria, Australia
Fax: +61 3 9915 3702
Telephone: +61 9915 3720
e-mail: p.cook@biota.com.au

Copy to be sent to:

Attention: Mr Damian Lismore
Company Secretary
Biota Scientific Management Pty Ltd
10/585 Blackburn Road
Notting Hill, 3168
Victoria, Australia
Fax: +61 3 9915 3702
Telephone: +61 3 9915 3721
e-mail: d.lismore@biota.com.au

If to BHL:	Attention: Mr Peter Cook Chief Executive Officer Biota Scientific Management Pty Ltd 10/585 Blackburn Road Notting Hill, 3168 Victoria, Australia Fax: +61 3 9915 3702 Telephone: +61 9915 3720 e-mail: p.cook@biota.com.au Copy to be sent to: Attention: Mr Damian Lismore Company Secretary Biota Scientific Management Pty Ltd 10/585 Blackburn Road Notting Hill, 3168 Victoria, Australia Fax: +61 3 9915 3702 Telephone: +61 3 9915 3721 e-mail: d.lismore@biota.com.au
If to Daiichi Sankyo:	Daiichi Sankyo Company, Limited 3-5-1 Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8426, Japan Attention: Vice President, Licensing Fax: +81-3-6225-1903 Telephone: +81-3-6225-1007 e-mail:ishida.noriaki.xe@daiichisankyo.co.jp

16. Assignment of Rights and Obligations

16.1. A Party may assign all or any part of this Agreement to any Affiliate. In all other respects, no Party shall voluntarily or by operation of law assign, hypothecate, give, transfer, mortgage, sublet, license, or otherwise transfer or encumber all or part of its rights, duties, or other interests in this Agreement or the proceeds thereof (collectively, "Assignment") in whole or in part to any third party without prior written consent of the other, provided, however that either Party may assign this Agreement in the event of an acquisition of such Party by a third party. Any attempt to make an Assignment in violation of this provision shall be a material default under this Agreement and any Assignment in violation of this provision shall be null and void.

17. Entire Agreement

17.1. This Agreement, together with the Appendices attached hereto, set forth the entire

agreement and understanding between the Parties as to the subject matter hereof, and supercedes all agreements and understandings between the Parties as to the subject matter, whether oral or in writing.

18. No Implied Waiver

18.1. No failure or delay on the part of a Party to exercise any right under this Agreement or provided for by Laws shall impair, prejudice or constitute a waiver of such right.

19. Severability

19.1. If and to the extent that any court or tribunal of competent jurisdiction holds any of the terms, provisions or conditions of this Agreement or parts thereof, or the application hereof to any circumstances, to be illegal, invalid or unenforceable in a final non-appealable order, (i) such provision shall be fully severable, (ii) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (iii) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (iv) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement, a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible.

20. No License

20.1. Nothing in this Agreement shall be deemed to constitute the grant of any license or other right in any Party to any other Party in respect of any product, patent, trademark, confidential information, trade secret or other data or any other intellectual property of the other Party except as expressly set forth herein.

21. Headings

21.1. The headings for each article and section in this Agreement have been inserted for convenience of reference only and are neither intended to limit or expand on the meaning of the language contained in the particular article or section nor to be used in construing or interpreting any of the provisions of this Agreement.

22. Appendices

22.1. All Appendices to this Agreement are by this reference incorporated herein and made a part of this Agreement.

23. Counterparts

23.1. This Agreement may be executed in three or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed and effective as of the Effective Date.

BIOTA SCIENTIFIC MANAGEMENT PTY. LTD.

By _____
Name: Peter Cook
Title: Chief Executive Officer
Date 30 March 2009

DAIICHI SANKYO CO., LTD.

By _____
Name: Noriaki Ishida
Title: Vice President, Licensing
Date 3/27/09

BIOTA HOLDINGS LTD.

By _____
Name: Peter Cook
Title: Chief Executive Officer
Date 30 March 2009

[***]

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*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

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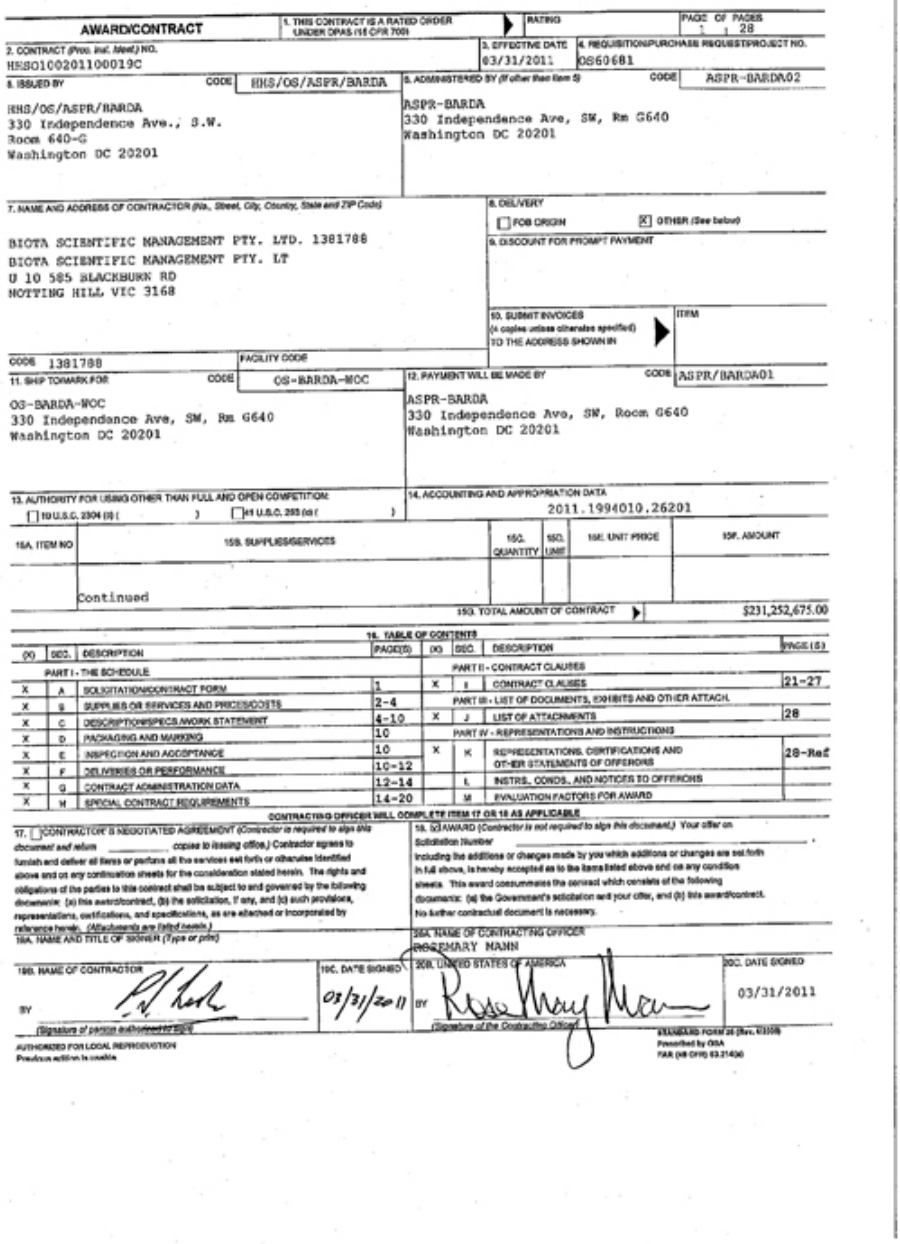
*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

Exhibit 10.9

Certain information contained in this document, marked by ***, is filed with the SEC pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended



AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) — RATING — PAGE OF PAGES 1 1 28

2. CONTRACT (Proc. Inst. Ident.) NO.: HHSO100201100019C

3. EFFECTIVE DATE: 03/31/2011

4. REQUISITION/PURCHASE REQUEST/PROJECT NO.: OS60681

5. ISSUED BY — CODE: HHS/OS/ASPR/BARDA

HHS/OS/ASPR/BARDA
330 Independence Ave., S.W.
Room 640-G
Washington DC 20201

6. ADMINISTERED BY (If other than Item 5) — CODE: ASPR-BARDA02

ASPR-BARDA
330 Independence Ave, SW, Rm G640
Washington DC 20201

7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, County, State and ZIP Code)

BIOTA SCIENTIFIC MANAGEMENT PTY. LTD. 1381788
BIOTA SCIENTIFIC MANAGEMENT PTY. LT
U 10 585 BLACKBURN RD
NOTTING HILL VIC 3168

8. DELIVERY: [ ] FOB ORIGIN [X] OTHER (See below)

9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN — ITEM

CODE 1381788 — FACILITY CODE

11. SHIP TO/MARK FOR — CODE: OS-BARDA-WOC

OS-BARDA-WOC
330 Independence Ave, SW, Rm G640
Washington DC 20201

12. PAYMENT WILL BE MADE BY — CODE: ASPR/BARDA01

ASPR-BARDA
330 Independence Ave, SW, Room G640
Washington DC 20201

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: [ ] 10 U.S.C. 2304 (c) ( ) [ ] 41 U.S.C. 253 (c) ( )

14. ACCOUNTING AND APPROPRIATION DATA: 2011.1994010.26201

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				

15G. TOTAL AMOUNT OF CONTRACT: $231,252,675.00

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. [ ] CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return ____ copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18A. NAME AND TITLE OF SIGNER (Type or print)

18B. NAME OF CONTRACTOR — BY (Signature of person authorized to sign) — 18C. DATE SIGNED: 03/31/2011

19. [X] AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Number ____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.

20A. NAME OF CONTRACTING OFFICER: ROSEMARY NANN

20B. UNITED STATES OF AMERICA — BY (Signature of the Contracting Officer) — 20C. DATE SIGNED: 03/31/2011

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is unusable

STANDARD FORM 26 (Rev. 4/2005)
Prescribed by GSA
FAR (48 CFR) 53.214(a)

SECTION B--SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The objective of this contract is to develop domestically manufactured antiviral drugs, oligomers, biologicals, antibody or immunoglobulins, humoral immune response modulators, Fab fragments or derivatives thereof, leading towards FDA-licensure and human usage. The scope of activities for which the Contractor may request funds may include manufacturing, clinical evaluation of pilot and commercial scale lots of drugs or biologicals, including but not limited to small molecules, enzymes, polypeptides, proteins and natural or synthetic antibodies and nucleic acids or derivatives thereof. Funds may also be used for scale-up development and manufacturing facility design but not facility construction.

ARTICLE B.2. CONTRACT LINE ITEM NUMBERS (CLINs)

ARTICLE B.2.1. Contract Type

This is a multiple year, Cost Plus Fixed Fee type contract.

ARTICLE B.2.2. Consideration and Payment (CPFF)

This is a cost plus fixed fee (CPFF) contract. In consideration for completion of work in accordance with the Statement of Work (Section C), the Contractor shall be paid an amount not to exceed $231,252,675 of which [***] represents the estimated reimbursable costs and [***] represents the fixed fee. The amount currently allotted for the contract shall cover a 60-month performance period.

[***]

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This section prohibits or restricts the use of contract funds, unless otherwise approved in writing by the Contracting Officer for the following:

a) Acquisition, by purchase or lease, of any interest in real property;
b) Rearrangement or alteration of facilities;
c) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value;
d) Travel Costs;
e) Consultant Costs;
f) Subcontract Costs;
g) Patient Care Costs; and
h) Accountable Government Property (defined as both real and personal property with an acquisition cost of $1,000 or more and a life expectancy of more than two years) and "sensitive items" (defined and listed in the Contractor's Guide of Government Property), regardless of acquisition value.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

ARTICLE B.4.1. Accounting System

The Contractor shall have an approved accounting system in position within six (6) months after contract award. If the Contractor fails to have a standing approved accounting system within six (6) months after contract award, the Government has the right to withhold payments until an approved accounting system is in place and/or terminate the contract in its entirety.

ARTICLE B.4.2. Daiichi-Sankyo Data and IP rights

HHS understands that Biota has free and unencumbered use of any data generated during the Daiichi-Sankyo–managed clinical trials for laninamivir registration in Japan, and that this data can be included to support an NDA submission for US registration. Biota shall obtain and use this data as needed for US FDA licensure.

ARTICLE B.4.3. In Process Review

In Process Reviews (IPR) will be conducted at the discretion of the Government to discuss the progression of the milestones. The Government reserves the right to revise the milestones and budget pending program development status. Deliverables may be required when the IPRs are conducted and may include, but not be limited to, the following:
Initial 24 months: The completion of the CMC-generated clinical lot and initiation of the Phase 2 adult clinical trial, that will conclude at the end of Year 2 in the contract and deliverables required will be the analytical or QA/QC reports or related documents on drug substance, drug products, device or final drug product and any Clinical Study Reports (CSRs) associated with pre-clinical and clinical studies completed by end of Year 2.
Months 25 through 36: The completion of the adult Phase 2 clinical trial and initiation of the Phase 3 adult clinical trials. The deliverables required at the end of Year 3, 4Q, are the adult Phase 2 study report, the Phase 2 pediatric CSR and any other study reports expected to be completed by the end of Year 3.
Months 37 through 60: The completion and qualification of the manufacturing validation lots and completion of the Phase 3 adult clinical trials. The deliverables required at the end of Year 5, 1Q, are the adult Phase 3 Clinical Study Reports and any other study reports expected to be completed by the end of Year 5, and the reports and documents associated with manufacturing lot qualification.

ARTICLE B.4.4. Termination of Contract

The Contractor's failure, in any material respect, to meet the milestones within the specified time periods as stated in the statement of work shall constitute an event of default entitling the Government to exercise its right to terminate the contract for default, in accordance with FAR 52.249-6, Termination (Cost-Reimbursement) (May 2004).

ARTICLE B.4.5. Consultant Rates

The Contractor agrees that the hourly rate of any individual, hired as a consultant against this contract, shall not exceed the federal Executive Schedule Level I hourly rate. If there is a need to pay a consultant in excess of this capped rate, the Contractor shall submit a request for Contracting Officer's approval which includes a justification for the higher hourly rate

and the number of hours for which this higher rate will be charged, along with backup documentation where the consultant has charged the higher rate on a regular basis. The Contracting Officer has the sole discretion to approve the higher rate for a limited number of hours.

SECTION C – STATEMENT OF WORK

Definitions –For the purpose of this Section

"Freedom to Operate" – ensures that the commercial production, marketing and use of the Contractor's new product, process and service do not infringe the intellectual property rights of others.

ARTICLE C.1. BACKGROUND

ARTICLE C.1.1. Introduction and Rationale

Preparedness for public health threats is a major goal of the U.S. Department of Health and Human Services (HHS). An influenza pandemic has a great potential to cause large numbers of deaths and illnesses over a short time period. A pandemic occurs when there is an antigenic shift in influenza A virus and transmission of a new strain to which most or all of the world's population is susceptible. Three pandemics occurred during the 20th century and one in the 21st century, the most severe of which, in 1918, caused over 500,000 U.S. deaths and more than 20 million deaths worldwide. Within the scientific community, it is generally believed that the occurrence of another influenza pandemic is most likely. Recent outbreaks of human disease caused by swine-origin H1N1in 2009 and avian H5, H9, and H7 influenza strains in Asia, Europe, and North America highlight the potential of new strains to be introduced into the population. Estimates for the next pandemic, extrapolating from those of the 20th and 21st centuries, range from about 100,000 to over 2 million deaths in the U.S. alone.

Influenza antiviral drugs and influenza vaccines are considered a primary means to decrease the mortality and morbidity associated with the next pandemic. HHS is pursuing multiple and parallel strategies to close the gap between current antiviral drug and influenza vaccine supply and the HHS goal of stockpiling licensed and new antiviral drugs and pre-pandemic vaccines as part of the strategic plan for pandemic preparedness.

Although vaccination is the primary strategy for the prevention of influenza, there are a number of likely scenarios for which vaccination will be unavailable or inadequate and effective antiviral agents would be of critical importance. Antiviral drugs form an important part of a strategy for dealing with an influenza pandemic with a new influenza virus of any origin, including avian influenza. In the event of a pandemic outbreak the infection will spread very quickly and the effective vaccine production and availability could be delayed several months, furthermore, the current classes of marketed products have limitations, contraindications and possible viral resistance development. New influenza compounds can target cells, innate immunity, or other immunity mechanism of the host or can act at different stages of the influenza virus life cycle and replication. HHS sees the advanced development of new influenza antivirals agents designed to affect different targets of influenza virus infection or to enhance effects of present classes of influenza antiviral drugs as necessary steps to counteract the limited supply, limited domestic production capacity, and rising possibility of resistant virus strains to licensed antivirals in the event of a pandemic outbreak.

ARTICLE C.1.2. Purpose

The purpose of this contract is to support advanced stage development of new antiviral agents for the treatment and prophylaxis of pandemic and seasonal influenza leading toward submission of a US FDA licensure application and development of required industrial capacity to support implementation of the influenza antivirals at full production capacity at or before the onset of a pandemic. Ultimately, these influenza antivirals shall be produced at one or more Food and Drug Administration (FDA)-approved manufacturing facilities and shall provide sufficient surge capacity to contribute substantially to U.S. and ideally global antiviral needs during an influenza pandemic.

ARTICLE C.1.3. Objectives

Using intellectual property to which the company has unencumbered, documented access and documents "freedom to operate," the successful Contractor shall accomplish the following objectives associated with advanced development of a new, influenza antiviral.

a) Conduct toxicology and clinical testing to assess the safety, of the new antiviral agent. The Contractor should consider the Fast Track Drug Development Programs – FDA's Guidance for Industry. Antiviral agents may be manufactured by the Contractor or subcontractor at a facility in compliance with current Good Manufacturing Practices (cGMP) guidelines.

b) Develop a clinical manufacturing and testing plan with the supportive regulatory development plan that will lead to submission of a licensure application. The Contractors should seek guidance from the FDA on the clinical development plan for their antiviral products and should indicate whether the clinical development plan reflects FDA's guidance.

c) Develop a plan to manufacture the antiviral drugs or products in an approved facility based in the U.S. (or, for a product with long-term stability that is suitable for stockpiling at an FDA-approved facility in the U.S. or at a foreign site with a capacity to support rapid stockpile purchases commensurate with U.S. pandemic influenza antiviral needs).

Activities that may be supported by this contract shall include drug toxicology studies in animals, clinical evaluation studies of the antiviral for safety process and manufacturing scale up development, product lot release assay development and process validation. U. S. Government (USG) support shall not be provided for building a manufacturing facility or purchasing an existing facility.

ARTICLE C.2. DESCRIPTION OF WORK

Independently and not as an agent of the government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities not otherwise provided by the government as needed to perform the work described below.

The Contractor Work Plan (CWP) that describes the activities to be performed and the Gantt chart to include all activities described in the CWP with a time-phased and task-linked budget (submitted in response to the RFP). The level of detail contained in the CWP and the corresponding Gantt chart must be sufficient to facilitate management and execution of the contract by the Contractor.

ARTICLE C.2.1. Milestones

I. Milestone 1: Within three (3) months of contract award, the Contractor shall provide to HHS for review and acceptance a comprehensive milestone-driven **Product Development Plan** for an influenza antiviral drug or therapeutic. The Plan should be inclusive of pre-clinical and clinical activities performed and completed prior to contract award and those clinical and manufacturing activities to be performed post-contract awarding. The Plan shall be a high-level overview and include the following:

   A. A Gantt chart timeline or equivalent.

   B. A description of the process development and scale-up of drug/therapeutic manufacturing.

   C. A description of clinical and consistency lot manufacturing for FDA Center for Biologics/Drugs Evaluation and Research (CBER/CDER) product licensure.

   D. A description of the general clinical development plan including development and validation of clinical sample assays.

   E. A description of product lot release assay development including lot release product assay specifications and validation.

   F. A regulatory master plan that focuses on the critical pathway to product licensure.

   G. A cost-accounting system based on original budget estimates (that includes earned value management) to monitor all costs related to the contract award for both prime- and sub-contractors on a real time basis.

II. Milestone 2: Within six (6) months of contract award, the Contractor shall submit to HHS for review and acceptance, a comprehensive, integrated **Clinical Development and Regulatory Plan**. The following issues shall be addressed in the Plan:

A. **A summary of pre-clinical studies** including consultation(s) with Center for Biologics/Drugs Evaluation and Research (CBER/CDER) at FDA which should be incorporated as an appendix to the milestone report.

B. **A detailed description of clinical evaluation** shall be integrated with the manufacturing plans using the most current and available information including consultation with CBER/CDER. Clinical trials performed as a result of this contract shall include any Phase 1, Phase 2, and Phase 3 trials needed to achieve U.S. FDA licensure. Trials should include adults and the elderly. Given the duration, cost, and importance of clinical trials, the plan for each clinical trial should clearly indicate key outcomes, populations, study sites and collaborators, analytic strategy, sample size, timelines, and other key components. A summary of clinical lot manufacturing results, provisional lot release specifications, toxicology data, completed Phase 1 trials and any additional stages of product development that have been completed should be incorporated as an appendix to the milestone report.

C. **A detailed description of regulatory activities** shall be integrated with all products, clinical testing and manufacturing activities using the most current and available information, including consultation with CBER/CDER. A risk assessment and mitigation plan addressing potential manufacturing, clinical and regulatory obstacles that might prevent or delay licensure as well as a plan for the production and distribution of drug/therapeutic in the case of Emergency Use Authorization (EUA) should be included. Issues suitable for risk assessment include pre-clinical and clinical toxicology and safety studies, process yields and facility management. Mitigation plans should include decision trees where applicable.

Many of the required elements may be satisfied by inclusion of the Contractor's Investigational New Drug (IND) application and relevant supplements.

III. Milestone 3: Within nine (9) months of contract award, the Contractor shall provide HHS for review and acceptance a plan to establish a **Manufacturing Facility Plan** describing the design, construction, commissioning, qualification and validation of a facility to produce the Contractor's antiviral drug or biological. The Plan shall contain appropriate information concerning the following elements:

A. **Site selection criteria**, including site user requirement specifications, descriptions of site utilities and infrastructure, descriptions of local, state and federal permitting issues and security planning considerations.

B. A **facility regulatory compliance plan** that addresses cGMP standards, USDA animal testing standards, National Fire Protection Agency standards, DHS security issues and OSHA compliance.

C. **Manufacturing processes** that includes descriptions of upstream and downstream processing, formulation, filling and finishing unit operations, bulk and finished product acceptance specifications, overall capacity needed to meet contract requirements, manufacturing support operations such as solution preparation, storage and distribution, glassware washing and sterilization, clean-in-place and steam-in-place operations, a risk management plan at each stage of production, process flow diagrams, equipment capacity calculations, an automation plan and an equipment list detailing sizing capacity criteria, utility requirements, dimensions, clearances weights, mounting and purchasing lead times.

D. **Architectural/ structural plans** that include concept functional designs, descriptions, and diagrams of space requirements, adjacency plans, floor plans, equipment layouts, material, product and personnel flows, solid, liquid contaminated and other waste flows, and an air balance description or diagram detailing zoning, pressurization, air flows and air quality classification.

E. **Process and building/ mechanical engineering** including energy balances, utility flow diagrams, automation plan, equipment lists and a preliminary layout.

F. A **proposed construction schedule** including installation, commissioning and installation/operational/ performance qualification and a risk mitigation analysis.

G. A **description of the manufacturing facility quality assurance and regulatory acceptance** including quality systems, the validation master plan and regulatory milestones.

The manufacturing facility and process shall be maintained in compliance with current Good Manufacturing Practices.

IV. Milestone 4: Within twelve (12) months of contract award, the Contractor shall provide HHS for review and acceptance a **Feasibility Plan** to manufacture, test, and release product containing antiviral drug. The Plan should include the following elements:

A. A **process description**, including a summary of process data that describes the yield of API and final product, addition of any excipients and purification efficiencies of key process steps.

B. A **comparison of process data** that describes the significance of process scale-up and yield/purity comparisons after scale-up.

C. **Proposed production schedules** including detailed timelines for each development step, conception of a manufacturing scheme, manufacture of proposed clinical lots, description of scale-up plans and manufacturing plant needs, receipt timelines for any virus strains that need importation clearance, QA/QC guidance and timelines, FDA inspection and clearance of manufacturing facilities and building or retrofitting schedules for manufacturing facility(s).

D. A bulk and fill-finish **manufacturing capacity analysis**.

E. A **description of process optimization activities**.

F. **Dose calculations and contingency plans** to address the need for higher dosages of the active pharmaceutical ingredient.

G. A **pre-pandemic facility management plan** including a pandemic preparedness plan and stockpiling contingencies of key ingredients.

H. A **pandemic facility management plan** including change procedures for post-pandemic operations and operation under Emergency Use Authorization (EUA).

V. Milestone 5: **Contractor-defined Milestones.** The Contractor shall provide a work breakdown structure including comprehensive and integrated timelines (Gantt chart) and major milestones to complete the remaining scope of work as relevant given the stage of drug development and evaluation toward product licensure. The Contractor shall propose milestones, at which time data will be presented, summarizing results of prior activities and new plans and protocols that will be submitted for review and approval in order to guide all subsequent activities. Potential milestones may include manufacturing of an investigational lot of API, validation of facilities, systems and equipment, validation of Quality Control product lot release methods, validation of manufacturing processes, stability study programs, consistency lot manufacturing, completion of a clinical trial and progress to a new phase of drug evaluation, submission of a license application, etc.

ARTICLE C.2.2. Project Management and Risk Management Objectives

The Contractor shall (deliver as a part of the Technical Proposal) and implement a **Management Plan** that explains how the Contractor will provide for the effective and efficient management of the technical, administrative, logistical, and support functions described in this statement of work, and shall use an **Earned Value Management System (EVMS)** in the management of this contract that is consistent with ANSI/EIA-STD-748 guidelines. The Contractor shall develop and implement a **Risk Management Plan** highlighting potential problems and/or issues that may arise during the life of the contract, their impact on cost, performance and timelines, and appropriate remediation plans. This plan should reference relevant WBS elements, where appropriate.

Integrated Baseline Review: The Contractor shall submit a plan for post-award Integrated Baseline Review (IBR) to occur within 90 days of contract award. At the IBR, the Contractor and HHS shall mutually agree upon cost, schedule and technical plan baseline (Performance Measurement Baseline). This baseline shall be the basis for monitoring and reporting progress throughout the life of the contract. The IBR is conducted to provide a mutual understanding of the inherent risks in Contractor's performance plans and the underlying management control systems, and it should formulate a plan to handle these risks.

Contract Performance Report: The Contractor shall deliver a Contract Performance Report (CPR) on a monthly basis consistent with the instruction in Department of Defense Data Item Description (DID) DI-MGMT-81466A. Contractor shall provide Format 1, Format 3 and/or Format 5 as negotiated. Format 1 will be reported at the Work Breakdown Structure level agreed to by HHS and the Contractor. Contractor shall provide preliminary CPR on the 15th day after end of Contractor reporting period and final CPR on the 20th day after contract end. EV Variance thresholds will be negotiated with the Contractor post-award but for planning purposes will likely be +/- 10%.

Integrated Master Schedule: The Contractor shall deliver (as a part of the Technical Proposal) a program level Integrated Master Schedule (IMS) that rolls up all time-phased WBS elements down to the activity level. This IMS shall include the dependencies that exist between tasks. The Contractor shall provide monthly delivery of the IMS status with performance data and should include actual start/finish and projected start/finish dates. The status schedule should be delivered 5 days after reporting month end.

Work Breakdown Structure: Work Breakdown Structures (WBS) shall be discernable and consistent. For example, HHS may require a contractor to furnish WBS data at the cost account level or at the work package level or at a lower level if there is significant complexity and risk associated with the task.

ARTICLE C.2.3. Security of Contract Operations and Information Technology

The work performed for development, manufacture, transport, storage and distribution will be performed under a detailed security plan that ensures against theft, tampering or destruction of the specific pertinent product-related material, equipment, documents, information, and data. The Contractor shall develop a written **Draft Security Plan**, for the protection of physical facilities, using, for example, fencing, controlled access, surveillance equipment, 2-person integrity rule, tamper evident packaging, and armed guards.

This plan shall ensure confidentiality, integrity of, and timely access by authorized individuals to data, information and information technology systems, consistent with OMB Circular A-130, Appendix III. This plan should also address the Contractor's security-related due diligence on public information, marketing, advertising, including use of web site(s) impacting product and supply chain security.

This plan shall also include the security measures to be used to protect the medical countermeasure to be stored at the Contractor's facility (e.g., refrigeration/freezer alarm systems, backup electrical power generator systems, etc.), and the contingency plan to accommodate any manufacturing and storage problems caused by natural or man-made disasters, power loss, refrigerant loss, equipment failures, etc.

The Contractor shall revise the Security Plan and submit a Final Security Plan to the Government within 30 days of notification. The COTR and the Information Protection and Systems Security (IPASS) Coordinator will review the plan and submit comments to the Contractor within 10 business days after receipt. Upon completion of all the required security measures, the Contractor shall supply to the COTR a letter certifying compliance. Performance of work under this contract shall be in accordance with this written Security Plan. The Final Security Plan will be incorporated as Attachment 5.

ARTICLE C.2.4. Meetings and conferences

The Contractor shall participate in regular meetings to coordinate and oversee the contract effort as directed by the COTR. Such meetings may include, but are not limited to, meetings of all Contractors and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale up manufacturing development, clinical sample assays development, preclinical/clinical study designs and regulatory issues; meetings with individual contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program; and meetings with technical consultants to discuss technical data provided by the Contractor. Monthly teleconferences with the Contractor and subcontractors with HHS officials will be held at times and dates to be determined to review technical and product development progress, except during clinical lot manufacturing when meetings shall be held on a weekly basis. The Contractor's Principal Investigator will discuss the activities during the reporting period, any problems that have arisen and the activities planned for the ensuing reporting period.

ARTICLE C.3. REPORTING REQUIREMENTS

In addition to those reports required by other terms of this contract, the Contractor(s) shall submit to the Contracting Officer and the COTR technical progress reports covering the work accomplished during each reporting period on a periodic basis as established by the COTR. These reports are subject to the technical inspection and requests for clarification by the COTR. These reports shall be brief and factual and prepared in accordance with the following format:

I. Technical Progress Reports: On the fifteenth day of each month for the previous calendar month or within fifteen days past the achievement of prescribed project milestones, the Contractor shall submit to the COTR and the Contracting Officer a Technical Progress Report. The frequency of Technical Progress Reporting will be determined by the

Contracting Officer and COTR during negotiations of the contract. The format and type of Technical Progress Report and Executive Summary will be provided by the COTR. Technical Progress Reports will include project timelines and milestones and summaries of product manufacturing, testing, and clinical evaluation. A Technical Progress Report will not be required for the period when the Final Report is due. The Contractor shall submit one copy of the Technical Progress Report electronically via e-mail. Any attachments to the e-mail report shall be submitted in Microsoft Word or Word Perfect, Microsoft Excel, Microsoft Project Manger, and/or Adobe Acrobat PDF files. Such reports shall include the following specific information:

A. Title page containing: *Technical Progress Report*, the contract number and title, the period of performance or milestone being reported, the Contractor's name, address, and other contact information, the author(s), and the date of submission;

B. Introduction/Background - An introduction covering the purpose and scope of the contract effort;

C. Progress - The report shall detail, document, and summarize the results of work performed, test results, and milestones achieved during the period covered. Also to be included is a summary of work planned for the next reporting period;

D. Issues - Issues resolved, new issues and outstanding issues are enumerated with options and recommendations for resolution. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and, if project activity is delinquent, then what corrective steps are planned. Revised timelines are provided.

E. Invoices – Summary of any invoices submitted during the reporting period.

F. Action Items – Summary table of activities or tasks to be accomplished by a certain date and by whom.

G. Distribution List – A list of persons receiving the Technical Progress Report

H. Attachments – Results on the project are provided as attachments

II. Earned Value Management System (EVMS) reports - including quantities needed, format, content, medium. The Contractor will be required to provide an Integrated Master Project Plan (including tabular & Gantt forms) that clearly indicate the critical path to support an Emergency Use Authorization (EUA) and licensure. The Contractor will be required to provide a Work Breakdown Structure (WBS) as part of their project plan. The preferred format will be the Department of Defense (DOD) MIL-HDBK-881A, as guidance in the creation of the WBS (http://www.acq.osd.mil/pm/).

The Contractor will be required to develop a Risk Management Plan highlighting potential problems and/or issues that may arise during the life of the contract, their impact on cost, performance and timelines, and appropriate remediation plans. This plan will reference relevant WBS elements, where appropriate. The Contractor will be required to provide an Earned Value Management System Plan that is consistent with ANSI/EIA-STD-748 guidelines, which will contain: (1) a plan for Integrated Baseline Reviews (IBRs), and (2) Integrated Master Schedule (IMS). This IMS is derived from the Integrated Master Project Plan that rolls up all time and cost phased WBS elements down to the activity level. The preferred format will be the Department of Defense DI-MGMT-81650, as guidance in the creation of the IMS (http://www.acq.osd.mil/pm/).

The Contractor will be required to provide an Earned Value Contract Performance Report (CPR) on a monthly basis. The preferred format will be the DOD DI-MGMT-81466A (http://www.acq.osd.mil/pm/). Earned Value Variance thresholds will be negotiated with the Contractor post-award but for planning purposes will likely be +/- 10%. In conjunction with the CPR, the Contractor shall provide a monthly update to the IMS with up to date performance data and should include actual start/finish and projected start/finish dates. EVMS requirements are incorporated as Attachment 4.

III. The Executive Summary, which shall accompany each Technical Progress Report, will be formatted in Microsoft Power Point presentations and include the following:

A. Title page containing Executive Title, the contract number and title, the period of performance or milestone being reported, the Contractor's name and the date of submission;

B. Project Progress presented as milestone events, test results, tasks, and other activities achieved during the reporting period as talking point bullets;

C. Project Issues presented headings and each item as a talking point bullet.

IV. Final Report – The Contractor shall submit a Draft Final Report to the COTR and Contracting Officer within 45 calendar days prior to the expiration date of the contract. The COTR will review the draft report and provide the Contracting Officer with comments within 15 calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary, and the final version delivered by the expiration date of the contract. The Contractor shall submit a comprehensive Final Report at the end of the contract that shall detail, document and summarize the results of the entire contract work. The report shall explain comprehensively the results achieved.

SECTION D--PACKAGING, MARKING AND SHIPPING

ARTICLE D.1. SHIPPING

I. Method of Delivery

Unless otherwise specified by the Contracting Officer or the Contracting Officer's Technical Representative (COTR), delivery of items, to be furnished to the government under this contract (including invoices), shall be made by first class mail.

II. Addressees – For all contract deliverables.

COTR
HHS/OS/ASPR/BARDA
330 Independence Avenue SW
Room G640
Washington, D.C. 20201

Contracting Officer
HHS/OS/ASPR/AMCG
330 Independence Avenue SW
Room G640
Washington, D.C. 20201

SECTION E--INSPECTION AND ACCEPTANCE

The Contracting Officer or the duly authorized representative will inspect and accept materials and services to be delivered under the contract. Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt. The following clause is incorporated by reference:

FAR Clause No.52.246-9, INSPECTION OF RESEARCH AND DEVELOPMENT (SHORT FORM) (APR 1984)

The COTR will perform the inspections at the Contractor's or subcontractors' facilities as necessary.

SECTION F--DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance shall be sixty (60) months from the effective date of contract award.

ARTICLE F.2. PLACE OF PERFORMANCE

All work shall be performed at the Contractor's and its subcontractors' facilities. Local travel within a 50-mile radius of the Contractor's office will not be reimbursed.

ARTICLE F.2. TECHNICAL REPORT DISTRIBUTION

Delivery will be required F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEE'S PREMISES (APR 1984), and in accordance with and by the dates specified elsewhere in the contract.

Item	Deliverable	Quantity	Due Date
1.	Technical Progress Report (including EVM report)	Original – C.O. 2 Copies – COTR 1 Electronic Copy	1st Report due on/before the 15th day of the month following the month of contract award; thereafter, due on/before the 15th of the month and within 15 days of achieving a milestone following each reporting period. Not due when Final is due.
2.	Executive Summary	Original – C.O. 2 Copies – COTR 1 Electronic Copy	1st Report due on/before the 15th day of the month following the month of contract award; thereafter, due on/before the 15th of the month following each anniversary date of the contract. Not due when Final is due.
3.	Final Report	Original – C.O. 2 Copies – COTR 1 Electronic Copy	Due on/before the completion date of the contract.

ARTICLE F.3. CONTRACT DELIVERABLES

Milestones	Deliverable	Quantity	Due Date
1.	**Product Development Plan** (Milestone 1)	Original – C.O. 2 Copies – COTR 1 Electronic Copy	Three (3) months after contract award.
2.	**Clinical Development and Regulatory Plan** (Milestone 2)	Original – C.O. 2 Copies – COTR 1 Electronic Copy	Within Six (6) months after contract award.
3.	**Manufacturing Facility Plan** (Milestone 3)	Original – C.O. 2 Copies – COTR 1 Electronic Copy	Within Nine (9) months after contract award.
4.	**Feasibility Plan** (Milestone 4)	Original – C.O. 2 Copies – COTR 1 Electronic Copy	Within Twelve (12) months after contract award.
5.	**Contractor Defined Milestones** (Milestone 5)	Original – C.O. 2 Copies – COTR 1 Electronic Copy	At contract award.
6.	**Final Security Plan**	Original – C.O. 2 Copies – COTR 1 Electronic Copy	30 Days after Government's Final Comments
7.	**Technical Progress & EVM Reports and Executive Summary**	Original – C.O. 2 Copies – COTR 1 Electronic Copy	See section C.3. Reporting Requirements.
8.	**Final Report**	Original – C.O. 2 Copies – COTR 1 Electronic Copy	See section C.3. Reporting Requirements.

ARTICLE F.4. STOP WORK ORDER

The following clause is incorporated herein by reference:

FAR CLAUSE 52.242-15, STOP WORK ORDER (AUG 1989) with ALTERNATE I (APR 1984)

SECTION G--CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER

1) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this contract.

2) The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; (5) obligate or deobligate funds into the contract; or (6) otherwise change any terms and conditions of this contract.

3) No information, other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

ARTICLE G.2. PROJECT OFFICER/CONTRACTING OFFICER'S TECHNICAL REPRESENTATIVE (COTR)

The Government's COTR for this contract is:

Ms. Julie Schafer

The COTR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Government may unilaterally change its designated COTR.

ARTICLE G.3. KEY PERSONNEL, HHSAR 352.270-5 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. Any cost associated with an unauthorized change in Contractor key personnel shall be at the cost of the Contractor and not the Government. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

Contractor personnel considered by the Government to be essential to contract performance will be identified here. The Contracting Officer must be notified prior to replacing any of these individuals on the contract.

[***]

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

ARTICLE G.4. ADVANCED APPROVAL OF TRAVEL

Requests for foreign travel must be submitted to the COTR at least six weeks in advance and shall contain the following: (a) meeting(s) and place(s) to be visited, with costs and dates; (b) name(s) and title(s) of Contractor personnel to travel and their functions in the contract project; (c) contract purposes to be served by the travel; (d) how travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of contract funds; (e) how such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and (f) what additional functions may be performed by the travelers to accomplish other purposes of the contract and thus further benefit the project. The Contractor will submit to the COTR on a monthly basis a list of all proposed business travel by its employees for the upcoming month with the understanding that there may be additional, necessary business travel that arises on an urgent basis. The COTR will review and respond in a timely basis to allow for efficient planning of travel. In the event the COTR does not respond to the proposed business travel plans within ten days after submission by the Contractor, the proposed business travel will be deemed accepted, provided that the costs of the travel are otherwise allowable under FAR 31.205-46. All travel will be in accordance with Federal Travel Regulations and will be pre-approved on a monthly basis by the COTR. Pre-approval must be submitted with the invoice for each request for reimbursement.

ARTICLE G.5. INDIRECT COST RATES

The Contractor shall bill in accordance with the indirect cost rates as indicated in the Contractor's Final Proposal dated March 2, 2011.

The indirect cost rates are as follows:

[***]

The indirect cost rates shall not exceed these ceiling rates and the Government is not obligated to pay any amounts that are in excess of these ceiling rates.

ARTICLE G.6. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

Invoice/Financing Request instructions are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment. Invoices shall be submitted to the Contracting Officer (Original) and the COTR (one copy). Invoices may be submitted electronically and hard copies mailed to the Contracting Officer.

The Contractor shall provide monthly invoices, together with documentation of costs in an acceptable format, and invoicing shall be in US dollars.

ARTICLE G.7. CONTRACT FINANCIAL REPORT

a. Financial reports will be submitted to the address specified in Block 7 of face page of the contract.

b. The first financial report shall cover the period consisting of the **first full three calendar months** following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

c. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

d. The financial report must be in compliance with EVMS requirements and the format should be approved by the government and include all negotiated budget elements.

e. The Government may unilaterally revise the expenditure categories to reflect the allotment of additional funds.

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

ARTICLE G.8. GOVERNMENT PROPERTY

If this contract will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes the acquisition of property (other than real property), this paragraph will include applicable provisions and incorporate the HHS Publication (OS) 686, entitled, **Contractor's Guide for Control of Government Property**, (1990), which can be found at:
http://www.hhs.gov/oamp/policies/contractors_guide_for_control_of_gov_property.pdf

ARTICLE G.9. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

Interim and final evaluations of Contractor performance shall be conducted on this contract in accordance with FAR 42.15. The final performance evaluation shall be completed at the time of completion of work. Interim and final evaluations will be submitted to the Contractor as soon as practicable. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement.

SECTION H--SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by the Department of Health and Human Services, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

ARTICLE H.2. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.3. CONFIDENTIALITY OF INFORMATION

The following information is covered by HHSAR Clause 352.224-70, Confidentiality of Information (January 2006): Data obtained from human subjects.

ARTICLE H.4. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at:
http://grants1.nih.gov/grants/olaw/references/phspol.htm

ARTICLE H.5. NEEDLE EXCHANGE

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ARTICLE H.6. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

The Contractor shall not conduct work involving select agents or toxins under this contract until it and any associated subcontractor(s) comply with the following:

For prime or subcontract awards to ***domestic institutions*** that possess, use, and/or transfer Select Agents under this contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) as required, before using HHS funds for work involving a *Select Agent or Toxin*. No HHS funds can be used for research involving a Select Agent or Toxin at a domestic institution without a valid registration certificate.

For prime or subcontract awards to ***foreign institutions*** that possess, use, and/or transfer a *Select Agent or Toxin* , before using HHS funds for any work directly involving a *Select Agent or Toxin* , the foreign institution must provide information satisfactory to the HHS that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 are in place and will be administered on behalf of all *Select Agent or Toxin* work supported by these funds. The process for making this determination includes inspection of the foreign laboratory facility by a HHS representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. No HHS funds can be used for work involving a Select Agent or Toxin at a foreign institution without written approval from the Contracting Officer.

Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at http://www.cdc.gov/od/sap/ and http://www.cdc.gov/od/sap/docs/salist.pdf .

Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at: http://www.aphis.usda.gov/programs/ag_selectagent/index.html and: http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_forms.html

For foreign institutions, see the HHS Select Agent Award information:
(http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm).

ARTICLE H.7. ANTI-LOBBYING

The Contractor is hereby notified of the restrictions on the use of Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 10, United States Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities see FAR Subpart 3.8, FAR Clause 52.203-12 and HHSAR 352.270-10.

In addition, the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such

recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or and State or Local legislature.

ARTICLE H.8. ACKNOWLEDGEMENT OF FEDERAL FUNDING

A. Section 507 of P.L. 104-208 mandates that contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal money, and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.

   This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

B. Publication and Publicity
   The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:
   "This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. *[insert #]*"

C. Press Releases
   Pursuant to Section 508 of Public Law 105-78, the Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.9. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

   1. The Small Business Subcontracting Plan, dated March 2, 2011, is attached hereto and made a part of this contract.

   2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

   The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov .

   1. Individual Subcontract Reports (ISR)

      Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

      April 30th
      October 30th
      Expiration Date of Contract

   2. Summary Subcontract Report (SSR)

      Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

      October 30th

For both the Individual and Summary Subcontract Reports, the [Contracting Officer/ Contract Specialist/title of alternate designee] shall be included as a contact for notification purposes at the following e-mail address:

_____
[Contracting Officer/Contract Specialist]

ARTICLE H.10. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in HHS funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.11. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

ARTICLE H.12. NOTICE PRIOR TO PUBLICATION

The Contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government, for additional information see HHSAR 352.270-6.

The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. Misrepresenting contract results or releasing information that is injurious to the integrity of HHS may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The Contractor shall ensure that the Contracting Officer and COTR has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

ARTICLE H.13. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (HHS). HHS reserves the right to review any other data reasonably determined by HHS to be relevant to this contract. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA. Except for data first produced in the performance of this contract or for which the Government is otherwise entitled to unlimited rights under the Rights in Data clause at Section I.4(3), such data (including but not limited to the data identified in Section 1.3 and Appendix IP1 of Contractor's Technical Proposal submitted on 15 December 2010) shall be treated as Limited Rights Data under such clause. Data submitted to the FDA in connection with Contractor's NDA submission shall be subject to the laws and regulations governing the confidentiality of data submitted to FDA, but shall not otherwise lose its treatment as Limited Rights Data by reason of it having been submitted to FDA.

ARTICLE H.14. MANUFACTURING STANDARDS

The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR Parts 210-211) will be the standard to be applied for manufacturing, processing and packing of this therapeutic product.

If at any time during the life of the contract, the Contractor fails to comply with cGMP in the manufacturing, processing and packaging of this therapeutic product and such failure results in a material adverse effect on the safety, purity or potency of this therapeutic product (a material failure) as identified by CBER and CDER, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the Contractor fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

ARTICLE H.15. EARNED VALUE MANAGEMENT SYSTEM (FAR 52.234-4) (Jul 2006)

(a) The Contractor shall use an earned value management system (EVMS) that has been determined by the Cognizant Federal Agency (CFA) to be compliant with the guidelines in ANSI/EIA Standard - 748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS has not been determined compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit reports in accordance with the requirements of this contract.

(b) If, at the time of award, the Contractor's EVM System has not been determined by the CFA as complying with EVMS guidelines or the Contractor does not have an existing cost/schedule control system that is compliant with the guidelines in ANSI/EIA Standard - 748 (current version at time of award), the Contractor shall—

  (1) Apply the current system to the contract; and

  (2) Take necessary actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

(c) The Government will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post award IBR shall be conducted as early as practicable after contract award.

(d) The Contracting Officer may require an IBR at—

  (1) Exercise of significant options; or

  (2) Incorporation of major modifications.

(e) Unless a waiver is granted by the CFA, Contractor proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.

(f) The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the performance criteria referenced in paragraph (a) of this clause.

(g) The Contractor shall require the subcontractors specified below to comply with the requirements of this clause:

[Insert list of applicable subcontractors.]

_____

_____

_____

ARTICLE H.16. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct or reporting of research funded under HHS contracts) will not be biased by any conflicting financial interest. 45 CFR Part 94 is available at the following Web site: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=9f130b6d2d48bb73803ca91ce943be3a;rgn=div5;view=text;node=45%3A1.0.1.1.53;idno=45;cc=ecfr

As required by 45 CFR Part 94, the Contractor shall, at a minimum:

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities and the applicable regulations. The Contractor

must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in HHS-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions shall be taken to manage, reduce or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a *Significant Financial Interest* could directly and significantly affect the design, conduct or reporting of the HHS-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct or reporting of the HHS-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research. If corrective action has not been taken or is not appropriate and the contract cannot be performed, the Government reserves the right to terminate the contract for default in accordance with FAR 52.249-6, Termination (Cost-Reimbursement) (May 2004).

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in HHS-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular conflict of interest will bias the objectivity of the HHS-funded research to such an extent that further corrective action is needed or that the Contractor has not managed, reduced or eliminated the conflict of interest. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that HHS-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment, has been designed, conducted or reported by an investigator with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

ARTICLE H.17. FDA AND HHS AUDITS

H.17.1. FDA Audits

Within thirty (30) calendar days of an FDA audit of Contractor or subcontractor facilities, the Contractor shall provide copies of the audit findings, final report, and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

H.17.2. HHS Site Visits/Audits

The United States Government (USG) reserves the right to conduct an audit of the Contractor with 48 hours notice. The USG reserves the right to accompany the Contractor on routine and for-cause site-visits/audits of subcontractors. At the discretion of the USG and independent of testing conducted by the Contractor, HHS reserves the right to conduct site visits/audits and collect samples of product held by the Contractor and subcontractors.

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FULL TEXT OF THESE CLAUSES MAY BE ACCESSED ELECTRONICALLY AT THESE ADDRESSES:

FAR CLAUSES: http://www.acquisition.gov/comp/far/index.html

HHSAR CLAUSES: http://www.dhhs.gov/oamp/dap/hhsar.html/

ARTICLE I.1. GENERAL CLAUSES

General Clauses for a Cost-Reimbursement Research and Development Contract

a. **FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:**

52.202-1	Jul 2004	Definitions (Over $100,000)
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Oct 2010	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.203-13	Apr 2010	Contractor Code of Business Ethics and Conduct
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.204-7	Apr 2008	Central Contractor Registration
52.209-6	Dec 2010	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $30,000)
52.215-2	Oct 2010	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 2010	Price Reduction for Defective Cost or Pricing Data (Over $650,000)
52.215-12	Oct 2010	Subcontractor Cost or Pricing Data (Over $650,000)
52.215-14	Oct 2010	Integrity of Unit Prices (Over $100,000)
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes

52.215-21	Oct 2010	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Jan 2011	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jan 2011	Small Business Subcontracting Plan (Over $550,000, $1,000,000 for Construction)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $550,000, $1,000,000 for Construction)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-21	Feb 1999	Prohibition of Segregated Facilities
52.222-26	Mar 2007	Equal Opportunity
52.222-35	Sep 2010	Equal Opportunity Veterans (Over $100,000)
52.222-36	Oct 2010	Affirmative Action for Workers with Disabilities
52.222-37	Sep 2010	Employment Reports Veterans (Over $100,000)
52.222-50	Feb 2009	Combating Trafficking in Persons
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over $100,000)
52.225-1	Jun 2003	Buy American Act - Supplies
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Dec 2007	Patent Rights—Ownership by the Contractor
52.229-8	Mar 1990	Taxes - Foreign Cost-Reimbursement Contracts
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Oct 2010	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Oct 2008	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Oct 2003	Payment by Electronic Funds Transfer--Central Contractor Registration
52.233-1	Jul 2002	Disputes

52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $650,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Oct 2010	Subcontracts, Alternate I (Jun 2007)
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.244-6	Dec 2010	Subcontracts for Commercial Items
52.245-1	Aug 2010	Government Property
52.245-9	Aug 2010	Use and Charges
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	May 2004	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

b. **DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES**

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2006	Definitions - with Alternate paragraph (h) (Jan 2006)
352.203-70	Jan 2006	Anti-Lobbying
352.216-70	Jan 2006	Additional Cost Principles
352.227-70	Jan 2006	Publications and Publicity
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.233-71	Jan 2006	Litigation and Claims
352.242-73	Jan 2006	Withholding of Contract Payments
352.242-74	Apr 1984	Final Decisions on Audit Findings

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

It is expected that the following substitution(s) will be made part of this contract:

N/A

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

(1) FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (April 2010).

(2) FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).
Any required posters may be obtained as follows:

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	http://oig.hhs.gov/fraud/hotline/OIG_Hotline_Poster.pdf

(3) FAR Clause **52.215-17, Waiver of Facilities Capital Cost of Money** (October 1997).

(4) FAR Clause **52.217-9, Option to Extend the Term of the Contract** (March 2000).

(a) The Government may extend the term of this contract by written notice to the Contractor within 90 calendar days provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 120 calendar days before the contract expires. The preliminary notice does not commit the Government to an extension.
(b) The total duration of this contract shall not exceed 60 months.

(5) FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

(6) FAR Clause **52.246-8. Inspection of Research and Development – Cost-Reimbursement** (May 2001)

(7) FAR Clause **52.252-2, Clauses Incorporated by Reference.** (February 1998)

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

(1) HHSAR Clause **352.223-70, Safety and Health** (January 2006).

(2) HHSAR Clause **352.201-70, Paperwork Reduction Act** (January 2006).

(3) HHSAR Clause **352.270-4 Protection of Human Subjects** (January 2006).

(4) HHSAR Clause **352.270-5(b), Care of Live Vertebrate Animals** (October 2009).

(5) HHSAR Clause **352.242-70, Key Personnel** (January 2006)

(6) HHSAR Clause **352.233-70 Choice of law (overseas)** (January 2010)
This contract shall be construed in accordance with the substantive laws of the United States of America. By the execution of this contract, the Contractor expressly agrees to waive any rights to invoke the jurisdiction of local national courts where this contract is performed and agrees to accept the exclusive jurisdiction of the Civilian Board of Contract Appeals and the United States Court of Federal Claims for hearing and determination of any and all disputes that may arise under the Disputes clause of this contract.
(End of clause)

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text.

(1) FAR Clause 52.227-3 Patent Indemnity. (Apr 1984)

(a) The Contractor shall indemnify the Government and its officers, agents, and employees against liability, including costs, for infringement of any United States patent (except a patent issued upon an application that is now or may hereafter be withheld from issue pursuant to a Secrecy Order under 35 U.S.C. 181) arising out of the manufacture or delivery of supplies, the performance of services, or the construction, alteration, modification, or repair of real

property (hereinafter referred to as "construction work") under this contract, or out of the use or disposal by or for the account of the Government of such supplies or construction work.

(b) This indemnity shall not apply unless the Contractor shall have been informed as soon as practicable by the Government of the suit or action alleging such infringement and shall have been given such opportunity as is afforded by applicable laws, rules, or regulations to participate in its defense. Further, this indemnity shall not apply to—

(1) An infringement resulting from compliance with specific written instructions of the Contracting Officer directing a change in the supplies to be delivered or in the materials or equipment to be used, or directing a manner of performance of the contract not normally used by the Contractor;
(2) An infringement resulting from addition to or change in supplies or components furnished or construction work performed that was made subsequent to delivery or performance; or
(3) A claimed infringement that is unreasonably settled without the consent of the Contractor, unless required by final decree of a court of competent jurisdiction.

(End of clause)

Alternate II (Apr 1984).
This patent indemnification shall only cover United States patents owned by Daiichi Sankyo Co. Ltd. that are relevant to the subject matter of this contract and listed below. For the purposes of this patent indemnification, "agents" shall not include any third party manufacturers or non-Government entities.

DAIICHI-SANKYO PATENTS PERTAINING TO LANINAMIVIR
Granted patents in the US

[***]

(2) 52.227-14 Rights in Data— (Dec 2007)

(a) Definitions. As used in this clause—
"Computer database" or "database means" a collection of recorded information in a form capable of, and for the purpose of, being stored in, processed, and operated on by a computer. The term does not include computer software.
"Computer software"—
(1) Means
(i) Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and
(ii) Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.
(2) Does not include computer databases or computer software documentation.
"Computer software documentation" means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.
"Data" means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.
"Form, fit, and function data" means data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, and data identifying source, size, configuration, mating and attachment characteristics, functional characteristics, and performance requirements. For computer software it means data identifying source, functional characteristics, and performance requirements but specifically excludes the source code, algorithms, processes, formulas, and flow charts of the software.
"Limited rights" means the rights of the Government in limited rights data as set forth in the Limited Rights Notice of paragraph (g)(3) if included in this clause.
"Limited rights data" means data, other than computer software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications.
"Restricted computer software" means computer software developed at private expense and that is a trade secret, is commercial or financial and confidential or privileged, or is copyrighted computer software, including minor modifications of the computer software.
"Restricted rights," as used in this clause, means the rights of the Government in restricted computer software, as set forth in a Restricted Rights Notice of paragraph (g) if included in this clause, or as otherwise may be provided in a collateral agreement incorporated in and made part of this contract, including minor modifications of such computer software.
"Technical data" means recorded information (regardless of the form or method of the recording) of a scientific or technical nature (including computer databases and computer software documentation). This term does not include computer software or financial, administrative, cost or pricing, or management data or other information incidental to contract administration. The term includes recorded information of a scientific or technical nature that is included in computer databases (See 41 U.S.C. 403(8)).
"Unlimited rights" means the rights of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

(b) Allocation of rights.
(1) Except as provided in paragraph (c) of this clause, the Government shall have unlimited rights in—
(i) Data first produced in the performance of this contract;
(ii) Form, fit, and function data delivered under this contract;
(iii) Data delivered under this contract (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or furnished for use under this contract; and
(iv) All other data delivered under this contract unless provided otherwise for limited rights data or restricted computer software in accordance with paragraph (g) of this clause.

(2) The Contractor shall have the right to—
(i) Assert copyright in data first produced in the performance of this contract to the extent provided in paragraph (c)(1) of this clause;

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

(ii) Use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, unless provided otherwise in paragraph (d) of this clause;
(iii) Substantiate the use of, add, or correct limited rights, restricted rights, or copyright notices and to take other appropriate action, in accordance with paragraphs (e) and (f) of this clause; and
(iv) Protect from unauthorized disclosure and use those data that are limited rights data or restricted computer software to the extent provided in paragraph (g) of this clause.

(c) Copyright—
(1) Data first produced in the performance of this contract.
(i) Unless provided otherwise in paragraph (d) of this clause, the Contractor may, without prior approval of the Contracting Officer, assert copyright in scientific and technical articles based on or containing data first produced in the performance of this contract and published in academic, technical or professional journals, symposia proceedings, or similar works. The prior, express written permission of the Contracting Officer is required to assert copyright in all other data first produced in the performance of this contract.
(ii) When authorized to assert copyright to the data, the Contractor shall affix the applicable copyright notices of 17 U.S.C. 401 or 402, and an acknowledgment of Government sponsorship (including contract number).
(iii) For data other than computer software, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly by or on behalf of the Government. For computer software, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted computer software to reproduce, prepare derivative works, and perform publicly and display publicly (but not to distribute copies to the public) by or on behalf of the Government.
(2) Data not first produced in the performance of this contract. The Contractor shall not, without the prior written permission of the Contracting Officer, incorporate in data delivered under this contract any data not first produced in the performance of this contract unless the Contractor—
(i) Identifies the data; and
(ii) Grants to the Government, or acquires on its behalf, a license of the same scope as set forth in paragraph (c)(1) of this clause or, if such data are restricted computer software, the Government shall acquire a copyright license as set forth in paragraph (g)(4) of this clause (if included in this contract) or as otherwise provided in a collateral agreement incorporated in or made part of this contract.
(3) Removal of copyright notices. The Government will not remove any authorized copyright notices placed on data pursuant to this paragraph (c), and will include such notices on all reproductions of the data.

(d) Release, publication, and use of data. The Contractor shall have the right to use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, except—
(1) As prohibited by Federal law or regulation (e.g., export control or national security laws or regulations);
(2) As expressly set forth in this contract; or
(3) If the Contractor receives or is given access to data necessary for the performance of this contract that contain restrictive markings, the Contractor shall treat the data in accordance with such markings unless specifically authorized otherwise in writing by the Contracting Officer.

(e) Unauthorized marking of data.
(1) Notwithstanding any other provisions of this contract concerning inspection or acceptance, if any data delivered under this contract are marked with the notices specified in paragraph (g)(3) or (g) (4) if included in this clause, and use of the notices is not authorized by this clause, or if the data bears any other restrictive or limiting markings not authorized by this contract, the Contracting Officer may at any time either return the data to the Contractor, or cancel or ignore the markings. However, pursuant to 41 U.S.C. 253d, the following procedures shall apply prior to canceling or ignoring the markings.
(i) The Contracting Officer will make written inquiry to the Contractor affording the Contractor 60 days from receipt of the inquiry to provide written justification to substantiate the propriety of the markings;
(ii) If the Contractor fails to respond or fails to provide written justification to substantiate the propriety of the markings within the 60-day period (or a longer time approved in writing by the Contracting Officer for good cause shown), the Government shall have the right to cancel or ignore the markings at any time after said period and the data will no longer be made subject to any disclosure prohibitions.
(iii) If the Contractor provides written justification to substantiate the propriety of the markings within the period set in paragraph (e)(1)(i) of this clause, the Contracting Officer will consider such written justification and determine whether or not the markings are to be cancelled or ignored. If the Contracting Officer determines that the markings are authorized, the Contractor will be so notified in writing. If the Contracting Officer determines, with concurrence of the head of the contracting activity, that the markings are not authorized, the Contracting Officer will furnish the Contractor a written determination, which determination will become the final agency decision regarding the appropriateness of the markings unless the Contractor files suit in a court of competent jurisdiction within 90 days of receipt of the Contracting Officer's decision. The Government will continue to abide by the markings under this paragraph (e)(1)(iii) until final resolution of the matter either by the Contracting Officer's determination becoming final (in which instance the Government will thereafter have the right to cancel or ignore the markings at any time and the data will no longer be made subject to any disclosure prohibitions), or by final disposition of the matter by court decision if suit is filed.
(2) The time limits in the procedures set forth in paragraph (e)(1) of this clause may be modified in accordance with agency regulations implementing the Freedom of Information Act (5 U.S.C. 552) if necessary to respond to a request thereunder.
(3) Except to the extent the Government's action occurs as the result of final disposition of the matter by a court of competent jurisdiction, the Contractor is not precluded by paragraph (e) of the clause from bringing a claim, in accordance with the Disputes clause of this contract, that may arise as the result of the Government removing or ignoring authorized markings on data delivered under this contract.

(f) Omitted or incorrect markings.
(1) Data delivered to the Government without any restrictive markings shall be deemed to have been furnished with unlimited rights. The Government is not liable for the disclosure, use, or reproduction of such data.
(2) If the unmarked data has not been disclosed without restriction outside the Government, the Contractor may request, within 6 months (or a longer time approved by the Contracting Officer in writing for good cause shown) after delivery of the data, permission to have authorized notices placed on the data at the Contractor's expense. The Contracting Officer may agree to do so if the Contractor—
(i) Identifies the data to which the omitted notice is to be applied;
(ii) Demonstrates that the omission of the notice was inadvertent;
(iii) Establishes that the proposed notice is authorized; and
(iv) Acknowledges that the Government has no liability for the disclosure, use, or reproduction of any data made prior to the addition of the notice or resulting from the omission of the notice.

(3) If data has been marked with an incorrect notice, the Contracting Officer may—

(i) Permit correction of the notice at the Contractor's expense if the Contractor identifies the data and demonstrates that the correct notice is authorized; or

(ii) Correct any incorrect notices.

(g) Protection of limited rights data and restricted computer software.

(1) The Contractor may withhold from delivery qualifying limited rights data or restricted computer software that are not data identified in paragraphs (b)(1)(i), (ii), and (iii) of this clause. As a condition to this withholding, the Contractor shall—

(i) Identify the data being withheld; and

(ii) Furnish form, fit, and function data instead.

(2) Limited rights data that are formatted as a computer database for delivery to the Government shall be treated as limited rights data and not restricted computer software.

(3) [Reserved]

(h) Subcontracting. The Contractor shall obtain from its subcontractors all data and rights therein necessary to fulfill the Contractor's obligations to the Government under this contract. If a subcontractor refuses to accept terms affording the Government those rights, the Contractor shall promptly notify the Contracting Officer of the refusal and shall not proceed with the subcontract award without authorization in writing from the Contracting Officer.

(i) Relationship to patents or other rights. Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government.

(End of clause)

Alternate II (Dec 2007).

(g)(3) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of limited rights data, or the Contracting Officer may require by written request the delivery of limited rights data that has been withheld or would otherwise be entitled to be withheld. If delivery of that data is required, the Contractor shall affix the following "Limited Rights Notice" to the data and the Government will treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with the notice:

Limited Rights Notice (Dec 2007)

(a) These data are submitted with limited rights under Government Contract No. HHSO100201100019C (and subcontract N/A, if appropriate). These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure: [Agencies may list additional purposes as set forth in 27.404-2(c)(1) or if none, so state.]

(b) This notice shall be marked on any reproduction of these data, in whole or in part.

(End of notice)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS

The following documents are incorporated into this contract and will be required during contract performance.

Attachment No.	Title	Location
Attachment 1:	Invoice/Financing Request Instructions—Cost-Reimbursement	See Attachment Section at the end of this contract
Attachment 2:	Gantt Chart	See Attachment Section at the end of this contract
Attachment 3:	Contractor Defined Milestones	See Attachment Section at the end of this contract
Attachment 4:	EVMS documents	See Attachment Section at the end of this contract
Attachment 5:	Security Plan/Checklist	See Attachment Section at the end of this contract

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K
REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The following documents are incorporated by reference in this contract:

Annual Representations and Certifications completed and located at the Online Representations and Certifications Application (ORCA) website. [This includes the changes, if any, identified in paragraph (b) of the FAR provision 52.204-8, Annual Representations and Certifications, contained in the contractor's proposal.]

Exhibit 31.1

Rule 13a-14(a)/15d-14(a) Certification

I, Russell H Plumb, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Biota Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 10, 2013

By: /s/ Russell H Plumb
Russell H Plumb
Chief Executive Officer and President
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

1350 CERTIFICATION PURSUANT TO TITLE 18 U.S.C. SECTION 1350

In connection with the Quarterly Report on Form 10-Q of Biota Pharmaceuticals, Inc. (the "Company") for the quarter ending March 31, 2013, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Russell H. Plumb, as Chief Executive Officer and President of the Company, hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

(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.

Dated: May 10, 2013

By: /s/ Russell H Plumb
Russell H Plumb
Chief Executive Officer and President
(Principal Executive Officer and Principal Financial Officer)

The purpose of this certification is solely to comply with Title 18, Chapter 63, Section 1350 of the United States Code, as amended by Section 906 of the Sarbanes-Oxley Act of 2002. This statement is not "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Act or any other federal or state law or regulation.