

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2007

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-32639

**Manhattan Pharmaceuticals, Inc.**  
(Exact Name of Registrant as Specified in Its Charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

36-3898269  
(I.R.S. Employer Identification No.)

810 Seventh Avenue, 4th Floor, New York, New York 10019  
(Address of principal executive offices)

(212) 582-3950  
(Issuer's telephone number)

Check whether the issuer: (1) 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 issuer was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

As of August 1, 2007 there were 70,474,232 shares of the issuer's common stock, \$.001 par value, outstanding.

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### Forward-Looking Statements

This quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities and Exchange Act of 1934. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “expect,” “may,” “intend” and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. These statements are therefore subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. Such risks and uncertainties relate to, among other factors:

- the development of our drug candidates;
- the regulatory approval of our drug candidates;
- our use of clinical research centers and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- acceptance of our products by doctors, patients or payers;
- our ability to market any of our products;
- our history of operating losses;
- our ability to compete against other companies and research institutions;
- our ability to secure adequate protection for our intellectual property;
- our ability to attract and retain key personnel;
- availability of reimbursement for our product candidates;
- the effect of potential strategic transactions on our business;
- our ability to obtain adequate financing; and
- the volatility of our stock price.

Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

## PART I – FINANCIAL INFORMATION

## Item 1. Unaudited Condensed Consolidated Financial Statements

**MANHATTAN PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
(A Development Stage Company)  
Condensed Consolidated Balance Sheets

	<u>June 30,</u> <u>2007</u> (Unaudited)	<u>December 31,</u> <u>2006</u> (See Note 1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 4,790,589	\$ 3,029,118
Prepaid expenses	352,657	264,586
Total current assets	<u>5,143,246</u>	<u>3,293,704</u>
Property and equipment, net	62,904	83,743
Other assets	70,506	70,506
Total assets	<u>\$ 5,276,656</u>	<u>\$ 3,447,953</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,001,849	\$ 1,393,296
Accrued expenses	1,528,406	550,029
Total liabilities	<u>2,530,255</u>	<u>1,943,325</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.001 par value. Authorized 1,500,000 shares; no shares issued and outstanding at June 30, 2007 and December 31, 2006	—	—
Common stock, \$.001 par value. Authorized 150,000,000 shares; 70,474,232 and 60,120,038 shares issued and outstanding at June 30, 2007 and December 31, 2006, respectively	70,474	60,120
Additional paid-in capital	53,101,402	44,411,326
Deficit accumulated during the development stage	<u>(50,425,475)</u>	<u>(42,966,818)</u>
Total stockholders' equity	<u>2,746,401</u>	<u>1,504,628</u>
Total liabilities and stockholders' equity	<u>\$ 5,276,656</u>	<u>\$ 3,447,953</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**MANHATTAN PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
(A Development Stage Company)  
Condensed Consolidated Statements of Operations  
(Unaudited)

	Three Months ended June 30,		Six months ended June 30,		Cumulative period from August 6, 2001 (inception) to June 30,
	2007	2006	2007	2006	2007
Revenue	\$ —	\$ —	\$ —	\$ —	\$ —
Costs and expenses:					
Research and development	3,871,634	1,570,905	5,551,082	3,257,346	23,504,438
General and administrative	1,052,374	786,391	1,967,098	1,597,336	12,211,191
In-process research and development charge	-	—	—	—	11,887,807
Impairment of intangible assets	-	—	—	—	1,248,230
Loss on disposition of intangible assets	-	—	—	—	1,213,878
Total operating expenses	4,924,008	2,357,296	7,518,180	4,854,682	50,065,544
Operating loss	(4,924,008)	(2,357,296)	(7,518,180)	(4,854,682)	(50,065,544)
Other (income) expense:					
Interest and other income	(29,608)	(86,483)	(59,998)	(185,189)	(769,714)
Interest expense	-	238	475	238	26,033
Realized gain on sale of marketable equity securities	-	—	—	(490)	(76,032)
Total other income	(29,608)	(86,245)	(59,523)	(185,441)	(819,713)
Net loss	(4,894,400)	(2,271,051)	(7,458,657)	(4,669,241)	(49,245,831)
Preferred stock dividends (including imputed amounts)	-	—	—	—	(1,179,644)
Net loss applicable to common shares	\$ (4,894,400)	\$ (2,271,051)	\$ (7,458,657)	\$ (4,669,241)	\$ (50,425,475)
Net loss per common share:					
Basic and diluted	\$ (0.07)	\$ (0.04)	\$ (0.11)	\$ (0.08)	
Weighted average shares of common stock outstanding:					
Basic and diluted	70,463,543	60,116,174	65,377,865	60,104,500	

See accompanying notes to unaudited condensed consolidated financial

statements.

Condensed Consolidated Statement of Stockholders' Equity (Deficiency)  
(Unaudited)

	Series A convertible preferred stock		Common stock		Additional paid-in capital	Subscription receivable	Deficit accumulated during development stage	Dividends payable in Series A preferred	Accumulated other comprehensive income (loss)	Unearned consulting services	Total stockholders' equity (deficiency)
	Shares	Amount	Shares	Amount							
		\$		\$							
Stock issued at \$0.0004 per share for subscription receivable	—	\$ —	10,167,741	\$ 10,168	\$ (6,168)	\$ (4,000)	\$ —	\$ —	\$ —	\$ —	\$ —
Net loss	—	—	—	—	—	—	(56,796)	—	—	—	(56,796)
Balance at December 31, 2001	—	—	10,167,741	10,168	(6,168)	(4,000)	(56,796)	—	—	—	(56,796)
Proceeds from subscription receivable	—	—	—	—	—	4,000	—	—	—	—	4,000
Stock issued at \$0.0004 per share for license rights	—	—	2,541,935	2,542	(1,542)	—	—	—	—	—	1,000
Stock options issued for consulting services	—	—	—	—	60,589	—	—	—	—	(60,589)	—
Amortization of unearned consulting services	—	—	—	—	—	—	—	—	—	22,721	22,721
Common stock issued at \$0.63 per share, net of expenses	—	—	3,043,332	3,043	1,701,275	—	—	—	—	—	1,704,318
Net loss	—	—	—	—	—	—	(1,037,320)	—	—	—	(1,037,320)
Balance at December 31, 2002	—	—	15,753,008	15,753	1,754,154	—	(1,094,116)	—	—	(37,868)	637,923
Common stock issued at \$0.63 per share, net of expenses	—	—	1,321,806	1,322	742,369	—	—	—	—	—	743,691
Effect of reverse acquisition	—	—	6,287,582	6,287	2,329,954	—	—	—	—	—	2,336,241
Amortization of unearned consulting costs	—	—	—	—	—	—	—	—	—	37,868	37,868
Unrealized loss on short-term investments	—	—	—	—	—	—	—	(7,760)	—	—	(7,760)
Payment for fractional shares for stock combination	—	—	—	—	(300)	—	—	—	—	—	(300)
Preferred stock issued at \$10 per share, net of expenses	1,000,000	1,000	—	—	9,045,176	—	—	—	—	—	9,046,176
Impaired preferred stock dividend	—	—	—	—	418,182	—	(418,182)	—	—	—	—
Net loss	—	—	—	—	—	—	(5,960,907)	—	—	—	(5,960,907)
Balance at December 31, 2003	1,000,000	1,000	23,362,396	23,362	14,289,535	—	(7,473,205)	(7,760)	—	—	6,832,932
Exercise of stock options	—	—	27,600	27	30,073	—	—	—	—	—	30,100
Common stock issued at \$1.10, net of expenses	—	—	3,368,952	3,369	3,358,349	—	—	—	—	—	3,361,718
Preferred stock dividend accrued	—	—	—	—	—	—	(585,799)	585,799	—	—	—
Preferred stock dividends paid by issuance of shares	24,901	25	—	—	281,073	—	—	(282,388)	—	—	(1,290)
Conversion of preferred stock to common stock at \$1.10 per share	(170,528)	(171)	1,550,239	1,551	(1,380)	—	—	—	—	—	—
Warrants issued for consulting services	—	—	—	—	125,558	—	—	—	—	(120,968)	4,590
Amortization of unearned consulting costs	—	—	—	—	—	—	—	—	—	100,800	100,800
Unrealized gain on short-term investments and reversal of unrealized loss on short-term investments	—	—	—	—	—	—	—	20,997	—	—	20,997
Net loss	—	—	—	—	—	—	(5,896,031)	—	—	—	(5,896,031)
Balance at December 31, 2004	854,373	854	28,309,187	28,309	18,083,208	—	(13,955,035)	303,411	13,237	(20,168)	4,453,816
Common stock issued at \$1.11 and \$1.15, net of expenses	—	—	11,917,680	11,918	12,238,291	—	—	—	—	—	12,250,209
Common stock issued to vendor at \$1.11 per share in satisfaction of accounts payable	—	—	675,675	676	749,324	—	—	—	—	—	750,000
Exercise of stock options	—	—	32,400	33	32,367	—	—	—	—	—	32,400
Exercise of warrants	—	—	279,845	279	68,212	—	—	—	—	—	68,491
Preferred stock dividend accrued	—	—	—	—	—	—	(175,663)	175,663	—	—	—
Preferred stock dividends paid by issuance of shares	41,781	42	—	—	477,736	—	—	(479,074)	—	—	(1,296)
Conversion of preferred stock to common stock at \$1.10 per share	(896,154)	(896)	8,146,858	8,147	(7,251)	—	—	—	—	—	—
Share-based compensation	—	—	—	—	66,971	—	—	—	—	20,168	87,139
Reversal of unrealized gain on short-term investments	—	—	—	—	—	—	—	(12,250)	—	—	(12,250)
Stock issued in connection with acquisition of Tapan Therapeutics, Inc.	—	—	10,731,052	10,731	11,042,253	—	—	—	—	—	11,052,984
Net loss	—	—	—	—	—	—	(19,140,997)	—	—	—	(19,140,997)
Balance at December 31, 2005	—	—	60,092,697	60,093	42,751,111	—	(33,271,695)	—	987	—	9,540,496
Cashless exercise of warrants	—	—	27,341	27	(27)	—	—	—	—	—	—
Share-based compensation	—	—	—	—	1,675,499	—	—	—	—	—	1,675,499
Unrealized loss on short-term investments	—	—	—	—	—	—	—	—	(987)	—	(987)
Costs associated with private placement	—	—	—	—	(15,257)	—	—	—	—	—	(15,257)
Net loss	—	—	—	—	—	—	(9,695,123)	—	—	—	(9,695,123)
Balance at December 31, 2006	—	—	60,120,038	60,120	44,411,326	—	(42,966,818)	—	—	—	1,504,628
Common stock issued at \$0.84 and \$0.90, net of expenses	—	—	10,185,502	10,186	7,843,967	—	—	—	—	—	7,854,153
Common stock issued to directors at \$0.72 per share in satisfaction of accounts payable	—	—	27,776	28	19,972	—	—	—	—	—	20,000
Common stock issued in connection with in-licensing agreement at \$0.90 per share	—	—	125,000	125	112,375	—	—	—	—	—	112,500
Share-based compensation	—	—	—	—	706,549	—	—	—	—	—	706,549
Exercise of warrants	—	—	10,327	15	7,219	—	—	—	—	—	7,234
Cashless exercise of warrants	—	—	5,589	—	(6)	—	—	—	—	—	(6)
Net loss	—	—	—	—	—	—	(7,458,657)	—	—	—	(7,458,657)
Balance at June 30, 2007	—	\$ —	70,474,232	\$ 70,474	\$ 53,101,402	\$ —	\$ (50,425,478)	\$ —	\$ —	\$ —	\$ 2,746,401

See accompanying notes to unaudited condensed consolidated financial statements.

MANHATTAN PHARMACEUTICALS, INC. AND SUBSIDIARIES

(A Development Stage Company)  
Condensed Consolidated Statements of Cash Flows  
(Unaudited)

	Six months ended June 30,		Cumulative period from August 6, 2001 (inception) to June 30,
	2007	2006	2007
<b>Cash flows from operating activities:</b>			
Net loss	\$ (7,458,657)	\$ (4,669,241)	\$ (49,245,831)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation	706,549	619,128	2,630,576
Shares issued in connection with in-licensing agreement	112,500	—	112,500
Amortization of intangible assets	—	—	145,162
Gain on sale of marketable equity securities	—	(490)	(76,032)
Depreciation	29,974	29,484	177,454
Non cash portion of in-process research and development charge	—	—	11,721,623
Loss on impairment and disposition of intangible assets	—	—	2,462,108
Other	—	—	5,590
Changes in operating assets and liabilities, net of acquisitions:			
Increase in prepaid expenses and other current assets	(88,071)	(780,863)	(294,412)
Increase in other assets	—	—	(70,506)
Increase/(decrease) in accounts payable	(371,447)	345,243	1,422,063
Increase in accrued expenses	978,377	203,778	988,085
Net cash used in operating activities	<u>(6,090,775)</u>	<u>(4,252,961)</u>	<u>(30,021,620)</u>
<b>Cash flows from investing activities:</b>			
Purchase of property and equipment	(9,135)	(12,832)	(230,636)
Cash acquired (paid) in connection with acquisitions, net	—	—	(26,031)
Proceeds from sale (payments for purchase) of short-term investments, net	—	500,000	435,938
Proceeds from sale of license	—	—	200,001
Net cash provided by (used in) investing activities	<u>(9,135)</u>	<u>487,168</u>	<u>379,272</u>
<b>Cash flows from financing activities:</b>			
Repayments of notes payable to stockholders	—	—	(884,902)
Payment for fractional shares for preferred stock dividends	—	—	(2,286)
Proceeds related to sale of common stock, net	7,854,153	(15,256)	25,898,230
Proceeds from sale of preferred stock, net	—	—	9,046,176
Proceeds from exercise of warrants and stock options	7,228	—	138,219
Other, net	—	—	237,500
Net cash (used in) provided by financing activities	<u>7,861,381</u>	<u>(15,256)</u>	<u>34,432,937</u>
Net (decrease) increase in cash and cash equivalents	<u>1,761,471</u>	<u>(3,781,049)</u>	<u>4,790,589</u>
Cash and cash equivalents at beginning of period	<u>3,029,118</u>	<u>9,826,336</u>	<u>—</u>
Cash and cash equivalents at end of period	<u>\$ 4,790,589</u>	<u>\$ 6,045,287</u>	<u>\$ 4,790,589</u>
<b>Supplemental disclosure of cash flow information:</b>			
Interest paid	\$ 475	\$ 238	\$ 26,033
<b>Supplemental disclosure of noncash investing and financing activities:</b>			
Common stock issued in satisfaction of accounts payable	\$ 20,000	\$ —	\$ 770,000
Imputed preferred stock dividend	—	—	418,182
Preferred stock dividends accrued	—	—	761,462
Conversion of preferred stock to common stock	—	—	9,046,176
Preferred stock dividends paid by issuance of shares	—	—	759,134
Issuance of common stock for acquisitions	—	—	13,389,226
Issuance of common stock in connection with in-licensing agreement	112,500	—	112,500
Marketable equity securities received in connection with sale of license	—	—	359,907
Net liabilities assumed over assets acquired in business combination	—	—	(675,416)
Cashless exercise of warrants	6	27	33

See accompanying notes to unaudited condensed consolidated financial statements.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

(1) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

***Basis of Presentation***

The accompanying unaudited condensed consolidated financial statements of Manhattan Pharmaceuticals, Inc. and its subsidiaries ("Manhattan" or the "Company") have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and the rules and regulations of the Securities and Exchange Commission. Accordingly, the unaudited condensed consolidated financial statements do not include all information and footnotes required by accounting principles generally accepted in the United States of America for complete annual financial statements. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments, consisting of only normal recurring adjustments, considered necessary for a fair presentation. Interim operating results are not necessarily indicative of results that may be expected for the year ending December 31, 2007 or for any other interim period. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements as of and for the year ended December 31, 2006, which are included in the Company's Annual Report on Form 10-KSB for such year. The condensed balance sheet as of December 31, 2006 has been derived from the audited financial statements included in the Form 10-KSB for that year.

As of December 31, 2006 all of the Company's subsidiaries had either been dissolved or merged into Manhattan. As a result, the Company had no subsidiaries during the three and six month periods ended June 30, 2007.

As of June 30, 2007, the Company has not generated any revenues from its operations and is considered to be a development stage company.

***Reclassifications***

Certain reclassifications have been made to prior-year amounts to conform to the current-year presentations.

***Segment Reporting***

The Company has determined that it operates in only one segment currently, which is biopharmaceutical research and development.

***Income Taxes***

Effective January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes - an interpretation of FASB No. 109*. The implementation of FIN 48 had no impact on the Company's financial statements as the Company has no unrecognized tax benefits. The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

***New Accounting Pronouncements***

In March 2007, the FASB issued FASB Staff Position EITF 07-03 ("FSP 07-03"), Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities. FSP 07-03 addresses whether nonrefundable advance payments for goods or services that will be used or rendered for research and development activities should be expensed when the advance payment is made or when the research and development activity has been performed. FSP 07-03 will be effective for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. The Company currently believes that the adoption of FSP 07-03 will have no material impact on its financial position or results of operations.

**(2) LIQUIDITY**

The Company incurred a net loss of \$7,458,657 and negative cash flows from operating activities of \$6,090,775 for the six months ended June 30, 2007. The net loss from date of inception, August 6, 2001 to June 30, 2007 amounts to \$49,245,831.

Management believes that the Company will continue to incur net losses through at least June 30, 2008, and for the foreseeable future thereafter. Based on the resources of the Company available at June 30, 2007, management believes that the Company will need additional equity or debt financing or will need to generate revenues through licensing of its products or entering into strategic alliances to be able to sustain its operations into 2008. Furthermore, we will need additional financing thereafter to complete development and commercialization of our product candidates.

The Company's continued operations will depend on its ability to raise additional funds through various potential sources such as equity and debt financing, collaborative agreements, strategic alliances and its ability to realize the full potential of its technology in development. Additional funds may not become available on acceptable terms, and there can be no assurance that any additional funding that the Company does obtain will be sufficient to meet the Company's needs in the long-term.

**(3) COMPUTATION OF NET LOSS PER COMMON SHARE**

Basic net loss per common share is calculated by dividing net loss applicable to common shares by the weighted-average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share, since potentially dilutive securities from the assumed exercise of stock options and stock warrants would have an antidilutive effect because the Company incurred a net loss during each period presented. The amounts of potentially dilutive securities excluded from the calculation of diluted net loss per share were 18,634,521 and 13,142,729 as of June 30, 2007 and 2006, respectively.

**(4) SHARE-BASED COMPENSATION**

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment," ("Statement 123(R)") for employee options using the modified prospective transition method. Statement 123(R) revised Statement 123 "Accounting for Stock-based Compensation" to eliminate the option to use the intrinsic value method and required the Company to expense the fair value of all employee options over the vesting period. Under the modified prospective transition method, the Company recognized compensation cost for the three and six month periods ending June 30, 2007 and 2006 based on the grant date fair value estimated in accordance with Statement 123(R). This includes (a) period compensation cost related to share-based payments granted prior to, but not yet vested, as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of Statement 123; and (b) period compensation cost related to share-based payments granted on or after January 1, 2006. In accordance with the modified prospective method, the Company has not restated prior period results.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

The Company recognized compensation expense related to stock option grants on a straight-line basis over the vesting period. The Company recognized share-based compensation cost of \$371,339 and \$307,216, for the three month periods ended June 30, 2007 and 2006 respectively, and \$706,549 and \$619,128 for the six month periods ended June 30, 2007 and 2006, respectively in accordance with Statement 123(R). The Company did not capitalize any share-based compensation cost.

Options granted to consultants and other non-employees are accounted for in accordance with Emerging Issues Task Force ("EITF") No. 96-18 "Accounting for Equity Instruments That Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services", and Financial Accounting Standards Board Interpretation No 28 "Accounting for Stock Appreciation Rights and Other Variable Option or Award Plans". Accordingly, such options are recorded at fair value at the date of grant and subsequently adjusted to fair value at the end of each reporting period until such options vest, and the fair value of the options, as adjusted, is amortized to consulting expense over the related vesting period. As a result of adjusting consultant and other non-employee options to fair value as of June 30, 2007 and 2006, net of amortization, the Company recognized general and administrative and research and development expenses of \$185 and \$3,556, respectively for the three-and six months ended June 30, 2007 and \$(50,292) and \$(26,321) for the three and six months ended June 30, 2006.

The Company has allocated share-based compensation costs to general and administrative and research and development expenses as follows:

MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

	Three months ended June 30,		Six months ended June 30,	
	2007	2006	2007	2006
General and administrative expense:				
Share-based employee compensation cost	\$ 249,623	\$ 252,361	\$ 471,544	\$ 444,977
Share-based consultant and non-employee (credit) cost	—	(28,450)	10,550	(22,861)
	<u>\$ 249,623</u>	<u>\$ 223,911</u>	<u>\$ 482,094</u>	<u>\$ 422,116</u>
Research and development expense				
Share-based employee compensation cost	\$ 121,531	\$ 105,147	\$ 231,449	\$ 200,472
Share-based consultant and non-employee (credit) cost	185	(21,842)	(6,994)	(3,460)
	<u>\$ 121,716</u>	<u>\$ 83,305</u>	<u>\$ 224,455</u>	<u>\$ 197,012</u>
Total share-based cost	<u>\$ 371,339</u>	<u>\$ 307,216</u>	<u>\$ 706,549</u>	<u>\$ 619,128</u>

The Company has shareholder-approved stock incentive plans for employees under which it has granted non-qualified and incentive stock options. In December 2003, the Company established the 2003 Stock Option Plan (the "2003 Plan"), which provided for the granting of up to 5,400,000 options to officers, directors, employees and consultants for the purchase of stock. The Company increased the number of shares of common stock reserved for issuance under the 2003 Plan in August 2005 by 2,000,000 shares and in May 2007 by 3,000,000 shares. At June 30, 2007, 10,400,000 shares were authorized for issuance. Under the 2003 Plan at June 30, 2007 options to purchase 7,096,598 shares were outstanding and 27,776 shares of common stock have been issued leaving a total of 3,275,626 shares reserved for future stock option grants. The options have a maximum term of 10 years and vest over a period determined by the Company's Board of Directors (generally three years) and are issued at an exercise price equal to or greater than the fair market value of the shares at the date of grant. The 2003 Plan expires on December 10, 2013 or when all options have been granted, whichever is sooner. Under the 2003 Plan, the Company granted options to purchase an aggregate of 1,342,500 shares of common stock during the six months ended June 30, 2007 of which options to purchase 300,000 and 97,500 shares of common stock were granted at an exercise price of \$0.72 per share to directors and employees, respectively, options to purchase 75,000 shares of common stock were granted to an employee at an exercise price of \$0.82 per share, and options to purchase 870,000 shares of common stock were granted to officers at an exercise price of \$0.95 per share. Additionally, on January 30, 2007, the Company's non-employee directors agreed to accept an aggregate of 27,776 shares of the Company's common stock, each valued at \$0.72 per share (the closing sale price of the common stock on such date), in lieu of receiving \$20,000 in aggregate cash fees owed to such directors for their services in 2006. Such shares were issued pursuant to the 2003 plan.

In July 1995, the Company established the 1995 Stock Option Plan (the "1995 Plan"), which provided for the granting of options to purchase up to 130,000 shares of the Company's common stock to officers, directors, employees and consultants. The 1995 Plan was amended several times to increase the number shares reserved for stock option grants. In June 2005, the 1995 Plan expired and no further options can be granted. As of June 30, 2007, options to purchase 1,137,240 shares were outstanding under the 1995 Plan and no shares were reserved for future stock option grants.

MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

To compute compensation expense in 2007 and 2006, the Company estimated the fair value of each option award on the date of grant using the Black-Scholes model. The Company based the expected volatility assumption on a volatility index of peer companies as the Company did not have a sufficient number of years of historical volatility of its common stock for the application of Statement 123(R). The expected term of options granted represents the period of time that options are expected to be outstanding. The Company estimated the expected term of stock options by the simplified method as prescribed in The Securities and Exchange Commission's Staff Accounting Bulletin No. 107. The expected forfeiture rates are based on the historical forfeiture experiences. To determine the risk-free interest rate, the Company utilized the U.S. Treasury yield curve in effect at the time of grant with a term consistent with the expected term of the Company's awards. The Company has not declared a dividend on its common stock since its inception and has no intentions of declaring a dividend in the foreseeable future and therefore used a dividend yield of zero.

The following table shows the weighted average assumptions the Company used to develop the fair value estimates for the determination of the compensation charges in 2007 and 2006:

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2007</u>	<u>2006</u>	<u>2007</u>	<u>2006</u>
Expected Volatility	79.7 - 93.2%	55%	79.7 - 93.2%	55%
Dividend yield	—	—	—	—
Expected term (in years)	6 - 8	4	6 - 8	4
Risk-free interest rate	4.56% - 4.96%	4.88%	4.56% - 4.96%	4.88%

MANHATTAN PHARMACEUTICALS, INC. and SUBSIDIARIES  
(A Development Stage Company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

A summary of the status of the Company's outstanding stock options as of June 30, 2007 and changes during the six months then ended is presented below:

	Shares	Weighted average exercise price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2006	7,000,504	\$ 1.31		
Granted				
Officers	870,000			
Directors	300,000			
Employees	172,500			
Total Granted	1,342,500	0.88		
Exercised	-	-		
Cancelled	(109,166)	0.95		
Outstanding at June 30, 2007	<u>8,233,838</u>	<u>\$ 1.25</u>	<u>7.43</u>	<u>\$ 387,171</u>
Options exercisable at June 30, 2007	<u>5,102,546</u>	<u>\$ 1.30</u>	<u>6.95</u>	<u>\$ 341,821</u>
Weighted-average fair value of options granted during the six months ended June 30, 2007	<u>\$ 0.63</u>			

As of June 30, 2007, the total compensation cost related to non-vested option awards not yet recognized is \$1,419,413. The weighted average period over which it is expected to be recognized is approximately 1.2 years.

In November 2005, the FASB issued FASB Staff Position No. FAS 123(R)-3 ("FSP 123(R)-3"), "Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards". The Company has adopted this alternative transition method provided in FSP 123(R)-3 for calculating the tax effects of stock-based compensation pursuant to SFAS 123(R) in 2006. The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee stock-based compensation, and to determine the subsequent impact on the APIC pool and consolidated statements of cash flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of SFAS 123(R). The adoption did not have a material impact on our results of operations and financial condition.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

(5) COMMITMENTS

The Company often contracts with third parties to facilitate, coordinate and perform agreed-upon research and development of its product candidates. To ensure that research and development costs are expensed as incurred, the Company records monthly accruals for clinical trials and preclinical testing costs based on the work performed under the contracts.

These contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain milestones. This method of payment often does not match the related expense recognition resulting in either a prepayment, when the amounts paid are greater than the related research and development costs expensed, or an accrued liability, when the amounts paid are less than the related research and development costs expensed.

Expenses associated with the recently concluded clinical trials of Oleoyl-estrone in common obesity and morbid obesity were recognized on this activity-based basis. At June 30, 2007 we recognized prepaid expense of \$9,000 and accrued expenses of \$267,000 related to these clinical trials. The remaining financial commitments for these clinical trials are negligible.

(6) RECENTLY COMPLETED IN-LICENSING TRANSACTIONS

*Altoderm License Agreement*

On April 3, 2007, the Company entered into a license agreement for "Altoderm" (the "Altoderm Agreement") with Thornton & Ross LTD ("T&R"). Pursuant to the Altoderm Agreement, the Company acquired an exclusive North American license to certain patent rights and other intellectual property relating to Altoderm, a topical skin lotion product candidate using sodium cromoglicate for the treatment of atopic dermatitis. In accordance with the terms of the Altoderm Agreement, the Company issued 125,000 shares of its common stock, valued at \$112,500, and made a cash payment of \$475,000 to T&R upon the execution of the agreement. These amounts have been included in research and development as fees associated with the in-licensing agreement. Further, the Company agreed to make future milestone payments to T&R comprised of various combinations of cash and common stock in respective aggregate amounts of \$5,675,000 and 875,000 shares of common stock upon the achievement of various clinical and regulatory milestones. The Company also agreed to pay royalties on net sales of products using the licensed patent rights at rates ranging from 10% to 20%, depending on the level of annual net sales, and subject to an annual minimum royalty payment of \$1 million in each year following the first commercial sale of Altoderm. The Company may sublicense the patent rights. The Company agreed to pay T&R 30% the royalties received by the Company under such sublicense agreements.

*Altolyn License Agreement*

On April 3, 2007, the Company and T&R also entered into a license agreement for "Altolyn" (the "Altolyn Agreement"). Pursuant to the Altolyn Agreement, the Company acquired an exclusive North American license to certain patent rights and other intellectual property relating to Altolyn, an oral formulation product candidate using sodium cromoglicate for the treatment of mastocytosis, food allergies, and inflammatory bowel disorder. In accordance with the terms of the Altolyn Agreement, the Company made a cash payment of \$475,000 to T&R upon the execution of the agreement. This amount is included in research and development as a fee associated with the in-licensing agreement. Further, the Company agreed to make future cash milestone payments to T&R in an aggregate amount of \$5,675,000 upon the achievement of various clinical and regulatory milestones. The Company also agreed to pay royalties on net sales of products using the licensed patent rights at rates ranging from 10% to 20%, depending on the level of annual net sales, and subject to an annual minimum royalty payment of \$1 million in each year following the first commercial sale of Altolyn. The Company may sublicense the patent rights. The Company agreed to pay T&R 30% of the royalties received by the Company under such sublicense agreements.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

***Hedrin License Agreement***

On June 26, 2007, the Company entered into an exclusive license agreement for "Hedrin" (the "Hedrin Agreement") with T&R and Kerris, S.A. ("Kerris"). Pursuant to the Hedrin Agreement, the Company has acquired an exclusive North American license to certain patent rights and other intellectual property relating to Hedrin(TM), a non-insecticide product candidate for the treatment of head lice. In addition, on June 26, 2007, the Company entered into a Supply Agreement with T&R pursuant to which T&R will be the Company's exclusive supplier of Hedrin product.

In consideration for the license, the Company agreed to issue to T&R and Kerris (jointly, the "Licensor") a combined total of 150,000 shares of its common stock upon the execution of the Hedrin Agreement, which were issued in August 2007. In addition, the Company also agreed to make a cash payment of \$600,000 to the Licensor no later than July 3, 2007. These amounts have been accrued and included in research and development as fees associated with the in-licensing agreement. Further, the Company agreed to make future milestone payments to the Licensor in the aggregate amount of \$2,500,000 upon the achievement of various clinical, regulatory, and patent issuance milestones, as well as up to \$2,500,000 in a one-time success fee based on aggregate sales of the product by the Company and its licensees of at least \$50,000,000. The Company also agreed to pay royalties of 8% (or, under certain circumstances, 4%) on net sales of licensed products. On a country-by-country basis, in the event there are no patent issues covering the Hedrin product, the obligation to pay royalties ends 10 years from the date of first commercial sale. The Company's exclusivity under the License Agreement is subject to an annual minimum royalty payment of \$1,000,000 (or, under certain circumstances, \$500,000) in each of the third through seventh years following the first commercial sale of Hedrin. The Company may sublicense its rights under the Hedrin Agreement with the consent of Licensor and the proceeds resulting from such sublicenses will be shared with the Licensor.

Pursuant to the Supply Agreement, the Company has agreed that it and its sublicensees will purchase their respective requirements of the Hedrin product from T&R at agreed upon prices. Under certain circumstances where T&R is unable to supply Hedrin products in accordance with the terms and conditions of the Supply Agreement, the Company may obtain products from an alternative supplier subject to certain conditions. The term of the Supply Agreement ends upon termination of the Hedrin Agreement.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

(7) PRIVATE PLACEMENT OF COMMON SHARES

On March 30, 2007, the Company entered into a series of subscription agreements with various institutional and other accredited investors for the issuance and sale in a private placement of an aggregate of 10,185,502 shares of its common stock for total net proceeds of approximately \$7.85 million, after deducting commissions and other costs of the transaction. Of the total amount of shares issued, 10,129,947 were sold at a per share price of \$0.84, and an additional 55,555 shares were sold to an entity affiliated with a director of the Company, at a per share price of \$0.90, the closing sale price of the common stock on March 29, 2007. Pursuant to the subscription agreements, the Company also issued to the investors 5-year warrants to purchase an aggregate of 3,564,897 shares of common stock at an exercise price of \$1.00 per share. The warrants are exercisable during the period commencing September 30, 2007 and ending March 30, 2012.

Pursuant to these subscription agreements the Company filed a registration statement covering the resale of the shares issued in the private placement, including the shares issuable upon exercise of the investor warrants and the placement agent warrants, with the Securities and Exchange Commission on May 9, 2007, which was declared effective by the Securities and Exchange Commission on May 18, 2007.

The Company engaged Paramount BioCapital, Inc., an affiliate of a significant stockholder of the Company, as its placement agent in connection with the private placement. In consideration for its services, the Company paid aggregate cash commissions of approximately \$600,000 and issued to Paramount a 5-year warrant to purchase an aggregate of 509,275 shares at an exercise price of \$1.00 per share.

(8) SUBSEQUENT EVENTS

*Oleoyl-estrone – results of Phase 2a studies*

On July 9, 2007 the Company announced the results of its two Phase 2a clinical trials of oral Oleoyl-estrone (“OE”). The results of both randomized, double-blind, placebo controlled studies, one in common obesity and the other in morbid obesity, demonstrated no statistically or clinically meaningful placebo adjusted weight loss for any of the treatment arms evaluated. Based on these results, the Company is discontinuing its Oleoyl-estrone programs in both common obesity and morbid obesity.

*Propofol Lingual Spray*

On July 9, 2007 the Company announced that it is discontinuing development and intends to pursue appropriate out-licensing opportunities for Propofol Lingual Spray for pre-procedural sedation.

**Item 2. Management's Discussion and Analysis Financial Condition and Results of Operations**

**You should read the following discussion of our results of operations and financial condition in conjunction with our Annual Report on Form 10-KSB for the year ended December 31, 2006 (the "Annual Report") and our financial statements as of and for the three and six month periods ended June 30, 2007 included elsewhere in this report.**

We were incorporated in Delaware in 1993 under the name Atlantic Pharmaceuticals, Inc. and, in March 2000, we changed our name to Atlantic Technology Ventures, Inc. In 2003, we completed a "reverse acquisition" of privately held Manhattan Research Development, Inc. In connection with this transaction, we also changed our name to Manhattan Pharmaceuticals, Inc. From an accounting perspective, the accounting acquirer is considered to be Manhattan Research Development, Inc. and accordingly, the historical financial statements are those of Manhattan Research Development, Inc.

During 2005 we merged with Tarpan Therapeutics, Inc. ("Tarpan"). Tarpan was a privately held New York based biopharmaceutical company developing dermatological therapeutics. Through the merger, we acquired Tarpan's primary product candidate, topical PTH (1-34) for the treatment of psoriasis. In consideration for their shares of Tarpan's capital stock, the stockholders of Tarpan received an aggregate of approximately 10,731,000 shares of our common stock, representing approximately 20% of our then outstanding common shares. This transaction was accounted for as a purchase of Tarpan by the Company.

We are a development stage biopharmaceutical company focused on developing and commercializing innovative pharmaceutical therapies for underserved patient populations. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually either bringing the technologies to market or out-licensing. We currently have four product candidates in development:

- Topical PTH (1-34) for the treatment of psoriasis;
- Altoderm, a proprietary formulation of topical cromolyn sodium for the treatment of atopic dermatitis;
- Altolyn, a proprietary site specific tablet formulation of oral cromolyn sodium for the treatment of mastocytosis;
- and Hedrin, a novel, non-insecticide treatment for head lice.

We have not received regulatory approval for, or generated commercial revenues from marketing or selling any drugs.

We have recently announced that we are discontinuing development of two product candidates, oral OE and Propofol Lingual Spray.

You should read the following discussion of our results of operations and financial condition in conjunction with the consolidated financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q. This discussion includes "forward-looking" statements that reflect our current views with respect to future events and financial performance. We use words such as we "expect," "anticipate," "believe," and "intend" and similar expressions to identify forward-looking statements. You should be aware that actual results may differ materially from our expressed expectations because of risks and uncertainties inherent in future events, particularly those risks identified under the heading "Risk Factors" following Item 1 in the Annual Report, and should not unduly rely on these forward looking statements.

## RESULTS OF OPERATIONS

SIX-MONTH PERIOD ENDED JUNE 30, 2007 VS 2006

	Six month period ended June 30, 2007	Six month period ended June 30, 2006	Increase (decrease)	% Increase (decrease)
<b>Costs and expenses</b>				
<b>Research and development</b>				
Stock based compensation	\$ 224,000	\$ 197,000	\$ 27,000	13.7%
In-license and related fees	\$ 1,803,000	\$ 250,000	\$ 1,553,000	621.2%
Other research and development expense	\$ 3,524,000	\$ 2,810,000	\$ 714,000	25.4%
Total research and development expense	\$ 5,551,000	\$ 3,257,000	\$ 2,294,000	70.4%
<b>General and administrative</b>				
Stock based compensation	\$ 482,000	\$ 422,000	\$ 60,000	14.2%
Other general and administrative expense	\$ 1,485,000	\$ 1,175,000	\$ 310,000	26.4%
Total general and administrative expense	\$ 1,967,000	\$ 1,597,000	\$ 370,000	23.2%
<b>Other income</b>	\$ 60,000	\$ 185,000	\$ (125,000)	(67.6)%
<b>Net loss</b>	\$ 7,458,000	\$ 4,669,000	\$ 2,789,000	59.7%

During each of the six months ended June 30, 2007 and 2006, we had no revenues, and are considered a development stage company. We do not expect to have revenues relating to our technologies prior to June 30, 2008, if at all.

For the six months ended June 30, 2007 total research and development expense was \$5,551,000 as compared to \$3,257,000 for the six months ended June 30, 2006. The increase of \$2,294,000, or 70.4% is primarily comprised of an increase of \$1,553,000 in in-license and associated fees, an increase of \$740,000 in clinical activities of Oleoyl-estrone and an increase in development costs for Altoderm, Altolyn and Hedrin of \$251,000, partially offset by decreases in development costs for PTH of \$253,000 and for Propofol of \$25,000.

For the six months ended June 30, 2007, total general and administrative expense was \$1,967,000 as compared to \$1,597,000 for the six months ended June 30, 2006. The increase of \$370,000, or 23.2%, is primarily due to increases of \$60,000 in stock based compensation, of \$107,000 in spending on business development activities, of \$82,000 in payroll and related costs, of \$63,000 in director compensation costs, of \$35,000 in insurance costs and of \$30,000 in office expenses.

For the six months ended June 30, 2007, other income was \$60,000 as compared to \$185,000 for the six months ended June 30, 2006. The decrease of \$125,000, or 67.6%, is due primarily to a decrease in interest income which resulted from lower average balances in interest bearing cash and short-term investment accounts.

Net loss for the six months ended June 30, 2007, was \$7,458,000 as compared to \$4,669,000 for the six months ended June 30, 2006. The increase of \$2,789,000, or 59.7%, in net loss is attributable to an increase in research and development expense of \$2,294,000, an increase in general and administrative expense of \$370,000 and a decrease in other income of \$125,000.

	Quarter ended June 30, 2007	Quarter ended June 30, 2006	Increase (decrease)	% Increase (decrease)
<b>Costs and expenses</b>				
<b>Research and development</b>				
Stock based compensation	\$ 122,000	\$ 83,000	\$ 39,000	47.0%
In-license and related fees	\$ 1,803,000	\$ 250,000	\$ 1,553,000	621.2%
Other research and development expense	\$ 1,947,000	\$ 1,238,000	\$ 709,000	57.3%
Total research and development expense	\$ 3,872,000	\$ 1,571,000	\$ 2,301,000	146.5%
<b>General and administrative</b>				
Stock based compensation	\$ 250,000	\$ 224,000	\$ 26,000	11.6%
Other general and administrative expense	\$ 802,000	\$ 562,000	\$ 240,000	42.7%
Total general and administrative expense	\$ 1,052,000	\$ 786,000	\$ 266,000	33.8%
<b>Other income</b>	\$ 30,000	\$ 86,000	\$ (56,000)	(65.1)%
<b>Net loss</b>	\$ 4,894,000	\$ 2,271,000	\$ 2,623,000	115.5%

During each of the quarters ended June 30, 2007 and 2006, we had no revenues, and are considered a development stage company. We do not expect to have revenues relating to our technologies prior to June 30, 2008, if at all.

For the quarter ended June 30, 2007 total research and development expense was \$3,872,000 as compared to \$1,571,000 for the quarter ended June 30, 2006. The increase of \$2,301,000, or 146.5%, is primarily attributable to a \$1,553,000 increase in in-license and associated fees, an increase of \$174,000 in clinical activities of Oleoyl-estrone, an increase of \$318,000 in development costs for PTH and an increase in development costs for Altoderm, Altolyn and Hedrin of \$251,000, partially offset by a decreases in development costs for Propofol of \$20,000.

For the three months ended June 30, 2007, total general and administrative expense was \$1,052,000 as compared to \$786,000 for the three months ended June 30, 2006. The increase of \$266,000, or 33.8%, is primarily due to increases of \$26,000 in stock based compensation, of \$63,000 in spending on business development activities, of \$33,000 in payroll and related costs, of \$36,000 in director compensation costs, of \$26,000 in insurance costs, of \$42,000 in professional fees and of \$22,000 in investor relations costs.

For the three months ended June 30, 2007, other income was \$30,000 as compared to \$86,000 for the three months ended June 30, 2006. The decrease of \$56,000, or 65.1%, is due primarily to a decrease in interest income which resulted from lower average balances in interest bearing cash and short-term investment accounts.

Net loss for the three months ended June 30, 2007, was \$4,894,000 as compared to \$2,271,000 for the three months ended June 30, 2006. The increase of \$2,623,000, or 115.5%, in net loss is attributable to an increase in research and development expense of \$2,301,000, an increase in general and administrative expense of \$266,000 and a decrease in other income of \$56,000.

## LIQUIDITY AND CAPITAL RESOURCES

From inception to June 30, 2007, we incurred a deficit during the development stage of \$50.4 million primarily as a result of our net losses and preferred stock dividends. We expect to continue to incur additional losses through at least June 30, 2008 and for the foreseeable future thereafter. These losses have been incurred through a combination of research and development activities related to the various technologies under our control and expenses supporting those activities.

We have financed our operations since inception primarily through equity financing and our licensing and sale of certain residual royalty rights. During the six months ended June 30, 2007, we had a net increase in cash and cash equivalents of \$1.8 million. This increase resulted largely from net proceeds related to the sale of common stock of \$7.9 million partially offset by net cash used in operating activities of \$6.1 million. Total liquid resources as of June 30, 2007 were \$4.8 million compared to \$3.0 million at December 31, 2006.

### *Liquidity*

As of June 30, 2007, we had working capital of \$2.6 million compared to \$1.4 million at December 31, 2006. This \$1.2 million increase in working capital is primarily due to net proceeds related to the sale of common stock of approximately \$7.9 million offset by net cash used in operating activities of \$6.1 million during the six months ended June 30, 2007 and an increase in accounts payable and accrued expenses of \$0.6 million.

### *March 2007 Private Placement*

On March 30, 2007, we entered into a series of subscription agreements with various institutional and other accredited investors for the issuance and sale in a private placement of an aggregate of 10,185,502 shares of our common stock for net proceeds of approximately \$7.9 million. Of the total amount of shares issued, 10,129,947 were sold at a per share price of \$0.84, and an additional 55,555 shares were sold to an entity affiliated with a director of the Company, at a per share price of \$0.90, the closing sale price of the common stock on March 29, 2007. Pursuant to the subscription agreements, we also issued to the investors 5-year warrants to purchase an aggregate of 3,564,897 shares of our common stock at an exercise price of \$1.00 per share. The warrants are exercisable during the period commencing September 30, 2007 and ending March 30, 2012.

Pursuant to these subscription agreements the Company filed a registration statement covering the resale of the shares issued in the private placement, including the shares issuable upon exercise of the investor warrants and the placement agent warrants, with the Securities and Exchange Commission on May 9, 2007, which was declared effective by the Securities and Exchange Commission on May 18, 2007.

The Company engaged Paramount BioCapital, Inc., a related party, as its placement agent in connection with the private placement. In consideration for its services, we paid aggregate cash commissions of approximately \$600,000 and issued to Paramount a 5-year warrant to purchase an aggregate of 509,275 shares at an exercise price of \$1.00 per share.

### *Commitments*

We often contract with third parties to facilitate, coordinate and perform agreed upon research and development of our product candidates. To ensure that research and development costs are expensed as incurred, we record monthly accruals for clinical trials and preclinical testing costs based on the work performed under the contracts.

These contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain milestones. This method of payment often does not match the related expense recognition resulting in either a prepayment, when the amounts paid are greater than the related research and development costs recognized, or an accrued liability, when the amounts paid are less than the related research and development costs recognized.

Expenses associated with the recently concluded clinical trials in common obesity and morbid obesity were recognized on this activity based basis. At June 30, 2007 we recognized prepaid expense of \$9,000 and accrued expenses of \$267,000 related to these clinical trials. The remaining financial commitments for these clinical trials are negligible.

#### *Capital Resources*

Our available working capital and capital requirements will depend upon numerous factors, including progress of our research and development programs, our progress in and the cost of ongoing and planned pre-clinical and clinical testing, the timing and cost of obtaining regulatory approvals, the cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights, competing technological and market developments, changes in our existing collaborative and licensing relationships, the resources that we devote to commercializing capabilities, the status of our competitors, our ability to establish collaborative arrangements with other organizations and our need to purchase additional capital equipment.

Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing, other collaborative agreements, strategic alliances, and our ability to realize the full potential of our technology in development. Such additional funds may not become available on acceptable terms and there can be no assurance that any additional funding that we do obtain will be sufficient to meet our needs in the long term. Through June 30, 2007, a significant portion of our financing has been through private placements of common stock, preferred stock and warrants to purchase common stock. Until our operations generate significant revenues and cash flows from operating activities, we will continue to fund operations from cash on hand and through the similar sources of capital previously described. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. Management believes that we will continue to incur net losses and negative cash flows from operating activities for the foreseeable future. Based on the resources available to us at June 30, 2007, management believes that we will need additional equity or debt financing or will need to generate revenues through licensing our products or entering into strategic alliances to be able to sustain our operations into 2008 and we will need additional financing thereafter until we can achieve profitability, if ever.

Although we currently have sufficient capital to fund our anticipated 2007 expenditures, we will need to raise additional capital in order to complete the anticipated development programs for each of our research and development projects. If we are unable to raise such additional capital, we may have to sublicense our rights to a third party as a means of continuing development, or, although less likely, we may be required to abandon further development efforts altogether, either of which would have a material adverse effect on the prospects of our business.

In January 2007 we received notice from the staff of the American Stock Exchange, or AMEX, indicating that we were not in compliance with certain continued listing standards set forth in the American Stock Exchange Company Guide. Specifically, the American Stock Exchange notice cited our failure to comply, as of September 30, 2006, with section 1003(a)(ii) of the AMEX Company Guide as we had less than the \$4,000,000 of stockholders' equity and had losses from continuing operations and/or net losses in three of our four most recent fiscal years and with section 1003(a) (iii) which requires us to maintain \$6,000,000 of stockholders' equity if we have experienced losses from continuing operations and /or net losses in its five most recent fiscal years.

In order to maintain our AMEX listing, we were required to submit a plan to AMEX advising the exchange of the actions we have taken, or will take, that would bring us into compliance with all the continued listing standards by April 16, 2008. We submitted such a plan in February 2007. AMEX accepted our plan in March 2007, so we are now able to continue our listing during the period ending April 16, 2008, during which time we will be subject to periodic review to determine if we are making progress consistent with the plan. If we are not in compliance with the continued listing standards at the end of the plan period, or if we do not make progress consistent with the plan during the plan period, AMEX staff may initiate delisting proceedings. There can be no assurance that we will be able to make progress consistent with such plan.

If we fail to make sufficient progress under our plan, AMEX may initiate delisting proceedings. If our common stock is delisted from AMEX, trading in our common stock would likely be conducted on the OTC Bulletin Board, a regulated quotation service. If our common stock is delisted from the AMEX, the liquidity of our common stock may be reduced, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and reduction in security analysts' and the media's coverage of us. This may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and asked prices for our common stock. Further, if we are delisted from AMEX, we may find it more difficult to raise additional capital through sales of our common stock or other equity securities.

#### RESEARCH AND DEVELOPMENT PROJECTS

Our success in developing each of our research and development projects is dependent on numerous factors, including raising further capital, unforeseen safety issues, lack of effectiveness, significant unforeseen delays in the clinical trial and regulatory approval process, both of which could be extremely costly, and inability to monitor patients adequately before and after treatments. The existence of any of these factors could increase our development costs or make successful completion of development impractical, which would have a material adverse affect on the prospects of our business.

#### ***PTH (1-34)***

We are developing PTH (1-34) as a topical treatment for psoriasis. In 2003, researchers, led by Michael Holick, PhD, MD, Professor of Medicine, Physiology, and Biophysics at Boston University Medical Center, reported positive results from a US Phase 1 and 2 clinical trial evaluating the safety and efficacy of PTH (1-34) as a topical treatment for psoriasis. This double-blind, controlled trial in 15 patients compared PTH (1-34) formulated in the Novasome® Technology versus the Novasome® vehicle alone. Following 8 weeks of treatment, the topical application of PTH (1-34) resulted in complete clearing of the treated lesion in 60% of patients and partial clearing in 85% of patients. Additionally, there was a statistically significant improvement in the global severity score. Ten patients continued receiving PTH (1-34) in an open label extension study in which the Psoriasis Area and Severity Index (PASI) was measured; PASI improvement across all 10 patients achieved statistically significant improvement compared to baseline. This study showed PTH (1-34) to be well tolerated and efficacious for the treatment of plaque psoriasis with no patients experiencing any clinically significant adverse events.

Due to the high response rate seen in patients in the initial trial with PTH (1-34), we believe that it may have an important clinical advantage over current topical psoriasis treatments. A physician sponsored Investigative New Drug application Phase 2a trial involving PTH (1-34) was initiated in December 2005 under the auspices of Boston University. In April 2006, we reported a delay in this planned Phase 2a clinical study of topical PTH (1-34) due to a formulation issue. We believe we have identified and resolved this issue. An improved formulation has been produced and several patent applications are being prepared. We expect to initiate clinical activities during 2007.

To date, we have incurred \$3,676,000 of project costs related to our development of PTH (1-34). These project costs have been incurred since April 1, 2005, the date of the Tarpan Therapeutics acquisition, \$961,000 of which was incurred in the first six months of 2007.

#### **Altoderm**

In April 2007 we entered into a license agreement with Thornton & Ross LTD, or T&R, pursuant to which we acquired exclusive North American rights to a dermatology product candidate called Altoderm™. Altoderm™ is a novel, proprietary formulation of topical cromolyn sodium and is designed to enhance the absorption of cromolyn sodium in order to treat atopic dermatitis, or "eczema." This product candidate is currently being tested in a Phase 3 clinical trial in the United Kingdom. In a previously completed randomized, double-blind, placebo-controlled, parallel-group, Phase 3 clinical study in the United Kingdom the compound was administered for 12 weeks to 114 child subjects with moderately severe atopic dermatitis. In the study results, published in the British Journal of Dermatology in February 2005, Altoderm demonstrated a statistically significant reduction in symptoms. During the study, subjects were permitted to continue with their existing treatment, in most cases this consisted of emollients and topical steroids. A positive secondary outcome of the study was a reduction in the use of topical steroids for the Altoderm-treated subjects.

To date, we have incurred \$681,000 of project costs related to our development of Altoderm, all of which was incurred in the first six months of 2007.

#### **Altolyn**

In addition to the Altoderm™ license agreement, we entered into a separate license agreement with T&R pursuant to which we acquired exclusive North American rights to develop and commercialize Altolyn™. Altolyn™ is a proprietary, site specific, tablet formulation of oral cromolyn sodium for the treatment of mastocytosis. This novel formulation is designed to provide optimal availability by preferentially releasing the drug in the upper part of the small intestine, the purported site of action. In addition to mastocytosis early clinical experience in the United Kingdom suggests promising activity in patients with various allergic disorders, including inflammatory bowel conditions. Oral cromolyn sodium is the active ingredient in Gastrocrom® an oral liquid solution that is currently FDA approved for the treatment of mastocytosis.

To date, we have incurred \$526,000 of project costs related to our development of Altolyn, all of which was incurred in the first six months of 2007.

#### **Hedrin**

In June 2007, we entered into an exclusive license agreement for Hedrin with T&R and Kerris, S.A. ("Kerris"). We previously entered into exclusive license agreements with T&R with respect to two other products, Altoderm and Altolyn, with respect to rights in North America. We acquired an exclusive North American license to certain patent rights and other intellectual property relating to Hedrin(TM), a non-insecticide product candidate for the treatment of head lice. In addition, and at the same time, we also entered into a Supply Agreement with T&R pursuant to which T&R will be the Company's exclusive supplier of Hedrin product.

To date, we have incurred \$872,000 of project costs related to our development of Hedrin, all of which was incurred in the first six months of 2007.

#### ***Oleoyl-estrone***

On July 9, 2007 we announced the results of our two Phase 2a clinical trials of oral Oleoyl-estrone. The results of both randomized, double-blind, placebo controlled studies, one in common obesity and the other in morbid obesity, demonstrated no statistically or clinically meaningful placebo adjusted weight loss for any of the treatment arms evaluated. Based on these results, we will discontinue our Oleoyl-estrone programs in both common obesity and morbid obesity.

To date, we have incurred \$14,784,000 of project costs related to our development of Oleoyl-estrone, including milestone payments triggered under our license agreement for Oleoyl-estrone, of which \$2,499,000 was incurred in the first six months of 2007.

#### ***Lingual spray propofol***

On July 9, 2007 we announced that we will discontinue development and we intend to pursue appropriate out-licensing opportunities for Propofol Lingual Spray for pre-procedural sedation.

To date, we have incurred \$2,966,000 of project costs related to our development of propofol lingual spray, of which \$12,000 was incurred in the first six months of 2007.

#### **Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements.

#### **New Accounting Pronouncements**

In March 2007, the FASB issued FASB Staff Position EITF 07-03 ("FSP 07-03"), Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities. FSP 07-03 addresses whether nonrefundable advance payments for goods or services that will be used or rendered for research and development activities should be expensed when the advance payment is made or when the research and development activity has been performed. FSP 07-03 will be effective for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. We currently believe that the adoption of FSP 07-03 will have no material impact on our financial position or results of operations.

**Item 3. Quantitative and Qualitative Disclosure About Market Risk**

Our exposure to market risk is confined to our cash and cash equivalents. We have attempted to minimize risk by investing in high-quality financial instruments, primarily money market funds with no security having an effective duration longer than 90 days. If the market interest rate decreases by 100 basis points or 1%, the fair value of our cash and cash equivalents portfolio would have minimal to no impact on the carrying value of our portfolio. We did not hold any derivative instruments as of June 30, 2007, and we have never held such instruments in the past.

**Item 4. Controls and Procedures****Evaluation of Disclosure Controls and Procedures**

As of June 30, 2007, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of that date were effective to ensure that information required to be disclosed in the reports we file under the Securities and Exchange Act is recorded, processed, summarized and reported on an accurate and timely basis.

The Company's management, including its Chief Executive Officer and its Chief Financial Officer, does not expect that disclosure controls or internal controls over financial reporting will prevent all errors or all instances of fraud, even as the same are improved to address any deficiencies. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected.

Because of the inherent limitation of a cost-effective control system, misstatements due to error or fraud may occur and not be detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls.

**Changes in Internal Control**

During the quarter ended June 30, 2007, there were no changes in internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**Item 1A. Risk Factors**

We have not had material changes to our risk factor disclosure in our Annual Report on Form 10-KSB for the year ended December 31, 2006 under the caption "Risk Factors" following Item 1 of such report.

**Item 4. Submission of matters to a vote of security holders.**

We held our Annual Meeting of Stockholders at the American Stock Exchange, 86 Trinity Place, New York, New York on May 24, 2007. The stockholders took the following actions:

(i) The stockholders elected seven directors to serve until the next Annual Meeting of Stockholders. The stockholders present in person or by proxy cast the following numbers of votes in connection with the election of directors, resulting in the election of all nominees:

<b>Nominee</b>	<b>Votes For</b>	<b>Votes Withheld</b>
Douglas Abel	35,536,892	65,132
Neil Herskowitz	35,376,093	225,931
Malcolm Hoenlein	35,518,495	83,529
Timothy McInerney	35,538,692	63,332
Joan Pons Gimbert	35,154,378	447,646
Richard I. Steinhart	35,529,736	72,288
Michael Weiser	34,493,245	1,108,779

(ii) The stockholders ratified the amendment to our 2003 Stock Option Plan increasing the number of shares available for issuance thereunder from 7,400,000 to 10,400,000. 34,440,971 votes were cast for the proposal; 1,107,853 votes were cast against the proposal, shares representing 53,200 votes abstained; and there were no broker non-votes.

(iii) The stockholders ratified the appointment of J.H. Cohn LLP as our independent registered public accounting firm for fiscal 2007. 35,519,099 votes were cast for the proposal; 8,205 votes were cast against the proposal, shares representing 74,720 votes abstained; and there were no broker non-votes.

**Item 6. Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
4.1	Form of warrant issued to investors in March 30, 2007 private placement (incorporated by reference to Exhibit 4.1 of the Company's Form 8-K filed April 5, 2007).
4.2	Form of warrant issued to placement agent in connection with the March 30, 2007 private placement (incorporated by reference to Exhibit 4.2 of the Company's Form 8-K filed April 5, 2007).
10.1	Summary of terms of non-employee director compensation (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed February 5, 2007).

10.2	Form of subscription agreement between the Company and investors in the March 30, 2007 private placement (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed April 5, 2007).
10.3	Exclusive License Agreement for "Altoderm" between Thornton & Ross Ltd. and Manhattan Pharmaceuticals, Inc. dated April 3, 2007.
10.4	Exclusive License Agreement for "Altolyn" between Thornton & Ross Ltd. and Manhattan Pharmaceuticals, Inc. dated April 3, 2007.
10.5	Exclusive License Agreement for "Hedrin" between Thornton & Ross Ltd., Kerris, S.A. and Manhattan Pharmaceuticals, Inc. dated June 26, 2007.
10.6	Supply Agreement for "Hedrin" between Thornton & Ross Ltd. and Manhattan Pharmaceuticals, Inc. dated June 26, 2007.
31.1	Certification of Chief Executive Officer
31.2	Certification of Chief Financial Officer
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**SIGNATURES**

In accordance with the requirements of the Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MANHATTAN PHARMACEUTICALS, INC.

Date: August 14, 2007

By: /s/ Douglas Abel

\_\_\_\_\_  
Douglas Abel  
President and Chief Executive Officer

Date: August 14, 2007

By: /s/ Michael G. McGuinness

\_\_\_\_\_  
Michael G. McGuinness  
Chief Financial Officer

**Index to Exhibits Filed with this Report**

Exhibit No.	Description
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32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**EXECUTION COPY**

**EXCLUSIVE LICENSE AGREEMENT**

**FOR "ALTODERM"**

**between**

**THORNTON & ROSS LTD.**

**and**

**MANHATTAN PHARMACEUTICALS, INC.**

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EXCLUSIVE LICENSE AGREEMENT FOR "ALTODERM"

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## EXCLUSIVE LICENSE AGREEMENT FOR "ALTODERM"

This Exclusive License Agreement for "Altoderm" (hereinafter referred to as this "Agreement"), effective as April 3, 2007 (the "Effective Date"), is entered into by and between **THORNTON & ROSS LTD.**, a company duly incorporated under the laws of England and having a place of business at Lintwaite, Huddersfield, HD7 5QH ("Licensor"), and **MANHATTAN PHARMACEUTICALS, INC.**, a corporation duly organized and existing under the laws of the State of Delaware having a place of business at 810 Seventh Avenue, 4<sup>th</sup> Floor, New York, New York 10019 (the "Company").

**WHEREAS**, Licensor is the sole owner of all right, title and interest in the Patent Rights (as defined below), and Know How (as defined below) related thereto used in the formulation of and to manufacture the Licensed Product (as defined below);

**WHEREAS**, the Company is interested in obtaining exclusive license under the Patent Rights and Know How in the Field of Use (as defined below) to make, have made, use, have used, lease, import and export, offer to sell, sell have sold, produce, manufacture, distribute and market products made in accordance with such rights; and

**WHEREAS**, Licensor wishes to grant to the Company an exclusive license under the Patent Rights and Know How, in the Field of Use (as defined below) to make, have made, use, have used, lease, import and export, offer to sell, sell have sold, produce, manufacture, distribute and market products made in accordance with such rights;

**NOW, THEREFORE**, in consideration of the foregoing recitals, the premises and the mutual covenants contained herein, the parties hereto, intending to be legally bound, agree as follows:

### Article 1 Definitions

For the purposes of this Agreement, the following words and phrases shall have the following meanings:

#### 1.1 "Affiliate"

means, with respect to any Person, any other Person which directly or indirectly controls, is controlled by, or is under common control with, such Person. A Person shall be regarded as in control of another Person if it owns, or directly or indirectly controls, at least fifty percent (50%) of the voting stock or other ownership interest of the other Person, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other Person by any means whatsoever.

#### 1.2 "Applicable Law(s)"

means, with respect to the United States, the FDCA (as defined below), all regulations promulgated thereunder, and all other applicable laws, rules, regulations and guidelines within the Territory that apply to the import, export, research and development, manufacture, marketing, distribution, or sale of Licensed Products in the Field of Use in the Territory and the use of the Trade Mark in relation thereto or the performance of either party's obligations under this Agreement (including disclosure obligations as required by the United States Securities and Exchange Commission or other comparable exchange or securities commission having authority over a party) to the extent applicable and relevant to such party.

#### 1.3 "Competent Authority(ies)"

means collectively the entities in each country in the Territory responsible for (a) the regulation of medicinal products or medical devices, as applicable, intended for human use or the establishment, maintenance and/or protection of rights related to the Patent Rights, including but not limited to the FDA and any other applicable administrative agency in any country in the Territory having the aforementioned responsibilities, and any successor entities thereto, (b) the establishment, maintenance and/or protection of rights related to the Patent Rights, including the United States Patent and Trademark Office ("USPTO"), and (c) any other applicable regulatory or administrative agency in any country in the Territory that is comparable to, or a counterpart of, the foregoing.

**1.4 "Development"**

means the Company's, its Affiliates', or Sublicensees' use of commercially reasonable efforts to secure Marketing Authorizations for Licensed Products in the Territory.

**1.5 "DMF"**

means a drug master file, as provided for in 21 CFR § 314.420, or similar submission to or file maintained with the FDA or other Competent Authority that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.

**1.6 "FDCA"**

means the United States' Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated with respect thereto.

**1.7 "FDA"**

means the United States Food and Drug Administration and any successor entity thereto.

**1.8 "Field of Use"**

means all fields of use.

**1.9 "First Commercial Sale"**

means, with respect to any Licensed Product, the first sale of such Licensed Product after all applicable Marketing Authorizations (if any) have been granted by the applicable Competent Authority(ies).

**1.10 "Governmental Approval(s)"**

means any and all permits, licenses, approvals, and authorizations required by any Competent Authority as a prerequisite to the development, manufacturing, packaging, marketing, and selling of a Licensed Product in the Field of Use in the Territory.

**1.11 "IND(s)"**

means an investigational new drug application as defined in *21 C.F.R. Part 312* et seq in the United States (as may be amended, supplemented or replaced from time to time), or equivalent application to any Competent Authority of any other country in the Territory, to commence clinical testing of a drug, including but not limited to any amendments, supplements, or supporting correspondence with respect thereto.

**1.12 “Improvements”**

shall mean any modification, enhancement, or improvement of a Licensed Product, or any inventions, discoveries, improvements (whether patentable or not), information, and data, owned or controlled by Licensor or the Company (as the case may be) any time during the Term, which would be useful or necessary in the manufacture, use, or sale of any Licensed Product, such improvements to be designated “Licensor Improvements” or “Company Improvements,” as the case may be.

**1.13 “Know-how”**

shall mean all tangible or intangible information and know-how (other than that which is the subject of a Valid Claim in the Patent Rights), whether patentable or not (but which has not been patented), related to the Licensed Product, or any Licensor Improvement or which is useful to or necessary for the Company to develop or commercialize any Licensed Product (including but not limited to: trade secrets, formulations, protocol, results of experimentation, in vitro, preclinical or clinical design, information or results, other proprietary materials, processes, including but not limited to manufacturing processes, data, drawings and sketches, designs, testing and test results, regulatory information of a like nature), owned or controlled by Licensor as of the Effective Date or which Licensor obtains the right to disclose and license to the Company during the Term.

**1.14 “Licensed Product(s)”**

shall mean any product including but not limited to a topical skin lotion product using sodium cromoglicate for use in the treatment of atopic dermatitis which is made in accordance with the Patent Rights. For the avoidance of doubt, the “Licensed Products” include, without limitation, that certain topical skin lotion product for the treatment of atopic dermatitis known as “Altoderm,” for which Licensor is seeking regulatory approval in the United Kingdom and other jurisdictions outside the Territory.

**1.15 “Licensor IND(s)”**

means the INDs, whether now existing or previously submitted, described on [Exhibit 1.15](#), and any filings, updates, material correspondence, or material communications to or from any applicable Competent Authority with respect thereto.

**1.16 “Marketing Authorization”**

means all necessary and appropriate regulatory approvals, including but not limited to NDAs and reimbursement and pricing approvals, to allow a Licensed Product to be marketed and sold in the Field of Use in a particular country in the Territory.

**1.17 “Milestone Payment”**

means the payments set out in Article 6.6 and "Milestone" means any one of the steps to be taken as set out in Article 6.6.

**1.18 "NDA"**

means a New Drug Application as defined in *21 C.F.R. Part 314.50* et seq. in the United States (as may be amended, supplemented or replaced from time to time), or equivalent application to any Competent Authority of any other country in the Territory, to commence commercial sale and marketing of a drug for human use, including but not limited to any amendments, supplements, or supporting correspondence with respect thereto.

**1.19 "Net Sales"**

shall have the meaning set out below:

- 1.19.1 "Net Sales" shall mean the total gross receipts for sales of Licensed Products to customers who are not Affiliates (or are Affiliates, but are end users of the Licensed Products) by or on behalf of the Company or any of its Affiliates (and, to the extent included pursuant to Article 6.2 below, its Sublicensees), whether invoiced or not, less only the sum of the following:
- (a) usual trade discounts to customers, including but not limited to cash, quantity and trade discounts, rebates and other price reductions for such Licensed Product given to such customers;
  - (b) sales, tariff duties, value-added tax and/or use taxes directly imposed and with reference to particular sales;
  - (c) amounts allowed or credited on charge-backs and/or returns;
  - (d) bad debt deductions and uncollectible amounts actually written off during the accounting period;
  - (e) outbound transportation prepaid or allowed and transportation insurance;
  - (f) sales commissions;
  - (g) packaging, freight, and insurance charges;
  - (h) customs duties, surcharges and other governmental charges incurred in exporting or importing such Licensed Product to such customers; and
  - (i) wholesaler discounts and government chargebacks
- 1.19.2 Components of Net Sales (and the deductions listed above) shall be determined in the ordinary course of business in accordance with U.S. GAAP.
- 1.19.3 Notwithstanding anything herein to the contrary, the transfer of a Licensed Product to an Affiliate, Sublicensee, or other Third Party in connection with the research, development or testing of a Licensed Product or for purposes of resale shall not be

considered a sale of a Licensed Product under this Agreement. Nor shall the transfer of Licensed Product solely for indigent or similar public support or compassionate use programs be considered a sale of Licensed Product under this Agreement.

- 1.19.4 In the case of discounts on "bundles" of separate products or services which include Licensed Products, the Company may discount (or enable its Affiliates and Sublicensees to discount) the bona fide list price of a Licensed Product by the average percentage discount of all products of the Company and/or its Affiliates and Sublicensees in a particular "bundle", calculated as follows:

$$\text{Average percentage discount on a particular "bundle"} = 1 - (X/Y) \times 100$$

where X equals the total discounted price of a particular "bundle" of products, and Y equals the sum of the undiscounted bona fide list prices of each unit of every product in such "bundle". The Company shall provide Licensor documentation reasonably supporting such average discount with respect to each "bundle." If a Licensed Product in a "bundle" is not sold separately, and no bona fide list price exists for such Licensed Product, the Company shall determine in good faith a reasonable imputed list price for such Licensed Product and Net Sales with respect thereto shall be based on such imputed list price.

**1.20 "Non-Royalty Sublicensing Income" or "NRSI"**

means, aggregate cash consideration received from a Sublicensee in consideration for grant of a sublicense under the rights granted to the Company hereunder, which shall include sublicense issue fees and non-sales related sublicense milestone payments received by the Company as consideration for the sublicensing by the Company of its rights under this Agreement to commercialize Licensed Products, but shall exclude the following payments as determined by the Company in good faith and subject as provided in Article 6.4 (a) payments received from the sale, issuance or exchange of debt or equity securities of the Company; (b) payments received by the Company that are specifically designated in any agreement with a Third Party to be dedicated to the research and development of the Technology or the establishment of a direct sales force; (c) payments resulting from or calculated on the basis of the sale of one or more Licensed Products, including sales milestones and royalties; and (d) payments received to reimburse Company's or its Affiliates' cost to perform research, development or similar services conducted for such Licensed Product after signing the agreement with the Third Party, or in reimbursement of patent or other out-of-pocket expenses relating to such Licensed Product.

**1.21 "Patent Rights"**

means

- 1.21.1 all U.S. and Canadian patents and patent applications set forth in Schedule 1.21;
- 1.21.2 any and all US or Canadian patents, patent applications, or other rights issuing from, or filed subsequent to the date of this Agreement, based on or claiming priority to or from the applications, patents, and rights listed on Schedule 1.21, including but not limited to continuations, continuations in part, divisionals, reexaminations, extensions, reissues, substitutions, renewals, supplementary protection certificates, registrations,

and confirmations of any of the foregoing, and any patents resulting from any application or right included in Articles 1.21.1 or 1.21.2;

- 1.21.3 any other intellectual property rights in the Territory relating to any topical skin lotion product using sodium cromoglicate for use in the treatment of atopic dermatitis (except where the rights involve the use of sodium cromoglicate with another active ingredient which produces a product which requires its own Government Approval) that are owned or controlled by the Licensor or that Licensor has the ability to license to the Company as of the date of this Agreement, or which Licensor acquires, or acquires the right to license to Company, after the Effective Date, and any and all US or Canadian patents, patent applications, or other rights, including continuations, continuations in part, divisionals, reexaminations, extensions, reissues, substitutions, renewals, supplementary protection certificates, registrations, and confirmations of such rights claiming or relating to, in each case, any topical skin lotion product using sodium cromoglicate for use in the treatment of atopic dermatitis except as aforesaid;
- 1.21.4 any other intellectual property rights in the Territory owned or controlled by the Licensor at any time during the Term of this Agreement relating to or claiming an Improvement or that Licensor has the ability to license or gains the ability to license to the Company relating to or claiming an Improvement (except where such improvement produces a product which requires its own separate Government Approval); and any and all US or Canadian patents, patent applications, or other rights, including continuations, continuations in part, divisionals, reexaminations, extensions, reissues, substitutions, renewals, supplementary protection certificates, registrations, and confirmations of such rights relating to or claiming, in each case, an Improvement; and
- 1.21.5 any Licensor information useful or necessary to file and obtain issuance in the Territory of valid patent claims relating to the use, manufacture, development, administration, delivery, formulation, dosing, packaging, and handling of the Know-how, the Licensed Products or any other topical skin lotion product using sodium cromoglicate for use in the treatment of atopic dermatitis (except where such information produces a product which requires its own separate Government Approval).

The parties shall use commercially reasonable efforts to ensure that Schedule 1.21 shall be amended in writing from time to time to reflect the foregoing, provided that any failure to do so shall not limit the scope of the definition of Patent Rights established above.

**1.22 "Person"**

means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint venture, non-profit organization, pool, syndicate, sole proprietorship, unincorporated organization, university, governmental authority or any other form of entity not specifically listed herein

**1.23 "Phase I Trial"**

means a clinical trial that generally provides for the first introduction into humans of a Licensed Product with the primary purpose of determining safety, metabolism and pharmacokinetic properties and clinical pharmacology of the Licensed Product, and generally consistent with 21 CFR § 312.21(a).

**1.24 “Phase II Trial”**

means a clinical trial of a Licensed Product on patients, including possibly pharmacokinetic studies, the principal purpose of which is to make a preliminary determination that such Licensed Product is safe for its intended use and to obtain sufficient information about such Licensed Product’s efficacy to permit the design of further clinical trials, and generally consistent with 21 CFR § 312.21(b).

**1.25 “Phase III Trial”**

means a pivotal human clinical trial of a Licensed Product, which trial is designed to: (a) establish that a Licensed Product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed; (c) support Marketing Authorization of such Licensed Product; and (d) generally consistent with 21 CFR § 312.21(c).

**1.26 “Registration(s)”**

means any and all permits, licenses, authorizations, registrations or regulatory approvals (including, but not limited to, IND or NDA) required and/or granted by any Competent Authority as a prerequisite to the development, manufacturing, packaging, shipping, marketing and/or selling of any product.

**1.27 “Royalty Term”**

means, on a country-by-country and Licensed Product-by-Licensed Product basis, the period commencing on the date of the applicable First Commercial Sale and ending on the date of the last to expire Patent Right covering a Licensed Product in such country.

**1.28 “Sublicensee”**

means a Third Party that has entered in to an agreement with the Company licensing to such Third Party any of the rights granted to the Company by the Licensor pursuant to Article 2.1, or a Third Party that has entered into a license agreement with any such Sublicensee licensing such Third Party the rights granted to the Company by the Licensor and granted to such subsequent Third Party licensee by the Sublicensee.

**1.29 “Successful Outcome”**

means an outcome of a Phase III Trial with data reasonably determined by Company to be sufficient to support final approval by the FDA of an NDA with respect to the Licensed Product (including, but not limited to, data from any supporting pharmacokinetic studies and toxicology studies (including, but not limited to any carcinogenicity, and developmental and reproductive toxicology studies)).

**1.30 “Term”**

has the meaning set out in Article 11.1.

**1.31 “Territory”**

means: (i) the United States, its territories and possessions and United States military bases throughout the world and (ii) Canada.

**1.32 "Third Party"**

mean any Person other than Licensor, Company and their respective Affiliates.

**1.33 "Trade Mark"**

means the trade mark "Altoderm," including, but not limited to, all rights under any trademark applications and registrations with respect thereto in the Territory.

**1.34 "Valid Claim"**

means any pending or issued claim included within the Patent Rights that has been filed in good faith and has not been withdrawn, permanently revoked, abandoned nor deemed unenforceable, unpatentable, or invalid by a decision of a court or other governmental agency of competent jurisdiction that is unappealable or unappealed in the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

**Article 2 License Grant**

**2.1 Grant of License**

Licensor hereby grants to the Company an exclusive license, with rights to grant sublicense as further described below, in the Field of Use to practice under the Patent Rights and to utilize the Know-how and the "Altoderm" mark and name in the Territory, including to:

- 2.1.1 conduct research, make, have made, use, have used, import, have imported, export, have exported, offer for sale, have sold, sell, produce, manufacture, distribute and market Licensed Products to the full end of the Royalty Term, unless sooner terminated as hereinafter provided; and
- 2.1.2 sublicense to third parties, through multiple tiers, in accordance with Article 2.2 below, the rights granted under Article 2.1.1.

**2.2 Sublicenses**

- 2.2.1 The Company shall have the right to sublicense rights granted in Article 2.1 in its sole discretion with the prior consent in writing of Licensor, which consent should not be unreasonably withheld or delayed, and Sublicensees shall have the right to grant further sublicenses in their sole discretion with the prior consent of the Licensor; which consent shall not be unreasonably withheld or delayed, but the Company shall continue to remain responsible for the performance of its obligations under this Agreement if a Sublicensee is appointed. Each sublicense agreement: (i) shall contain terms and conditions requiring the applicable sublicensee to provide Data (as defined in Section 11.5 below) created by or on behalf of such sublicensee to the Licensor, on terms and under circumstances analogous to those set forth herein (namely Articles 3.1, 5.5, 11.2, 11.5 and 11.6), in the event the applicable sublicense agreement with the Sublicensee is terminated after having been assigned to and assumed by Licensor (as provided below in this Article 2.2.1), (ii) shall otherwise not conflict with the terms and conditions set forth herein and (iii) shall name Licensor as

a third party beneficiary of the sublicense agreement. The Company will keep Licensor reasonably apprised of the status of negotiations with prospective Sublicensees. All sublicenses granted under this Article 2.2.1 by the Company shall survive and be automatically assigned to and assumed by Licensor upon termination of this Agreement, *provided however*, Licensor shall not be obligated to incur any obligations in excess of those of Licensor contained herein.

- 2.2.2 Notwithstanding the foregoing, if the Company believes that Licensor has terminated this Agreement for the primary purpose of doing business directly with the Sublicensee, the termination may be disputed under the provisions of Article 10.

### **Article 3 Technology and Regulatory Transfer**

#### **3.1 Technology and Regulatory Transfer**

Upon execution of this Agreement, (i) Licensor shall transfer to the Company, at no additional cost, all Know-how, which shall include but not be limited to copies of all pre-clinical or clinical data, trade secrets, human safety data, preliminary efficacy data (further including, but not limited to, any of the foregoing data relating to any Licensor applications for regulatory approval of the Licensed Product in the United Kingdom, European Union and any other jurisdictions outside the Territory), and other regulatory data related to any Licensed Product in its possession, and (ii) Licensor hereby assigns all right, title, and interest in the Licensor IND(s), if any, to the Company, free and clear of all liens, claims, and encumbrances.

Licensor shall, at Licensor's cost, take any and all actions requested by the Company to effect the purposes of the foregoing as promptly as practicable following the execution of this Agreement and on an ongoing basis thereafter, which shall include but not be limited to (i) preparing and filing whatever filings, requests or applications are required or deemed advisable to be filed with any Regulatory Authority, if any, in connection with the assignment of any Licensor IND(s) (including but not limited to, if applicable with respect to the FDA, a "transfer of ownership letter") and (ii) taking all reasonable actions necessary to enable the Company to undertake the manufacture, development and commercialization of Licensed Products under this Agreement. Such actions shall include providing the Company with the following items relating to the Licensed Products (regardless of whether such item relates to the Territory or any jurisdiction outside the Territory), to the extent such items are within the possession or control of Licensor as of the Effective Date or come within the possession or control of Licensor at any time thereafter and the Licensor has the right to transfer or communicate the same (and the Licensor will notify the Company of any potential limitations on its right to transfer or communicate any of the foregoing to the Company and will use commercially reasonable efforts to overcome any such limitations):

- a. copies of all regulatory submissions;
- b. any communications with Competent Authorities and the minutes of any meetings with Competent Authorities, as well as any communications with and minutes of any meetings with any analogous regulatory authorities outside the Territory;
- c. DMFs and any trial, drug, device, or other master files relating to any Licensed Product, including copies of all case report forms;

- d. copies of all listings and tables of results from the clinical trials relating to any Licensed Product;
- e. copies of all treatment-related serious adverse event reports from the clinical trials relating to any Licensed Product;
- f. storage of and access permission to any retained samples of materials used in clinical trials relating to any Licensed Product;
- g. access to contract and clinical research organizations involved in the preclinical studies and clinical trials relating to any Licensed Product;
- h. the data, files and results of any chemistry, manufacturing, or control-related activities regarding any Licensed Product; and
- i. all other information that the Company may reasonably request that may be useful to the Company for the manufacturing of Licensed Products or conducting preclinical studies and clinical trials and other development activities with respect to each Licensed Product, and the commercialization of Licensed Products.

The Company shall during the Term keep Licensor reasonably informed of any data developed by or on behalf of Company that may be used in support of regulatory filings for the Licensed Product (including, but not limited to, pre-clinical and clinical trial data, human safety data and efficacy data) (the "Company Data"), as well as any regulatory filings made and approvals obtained by the Company with respect to the Licensed Product in the Territory and the Company shall deposit, at Licensor's expense, copies of the Company Data and such regulatory filings with its lawyers or an agreed third party escrow agent together with the necessary permission to allow right of reference to such material by Licensor and shall issue an irrevocable instruction to release such items to the Licensor if this Agreement is terminated pursuant to Article 11.2 and the Company shall procure that all sub-licensees accept this obligation to the Licensor. In addition the Company shall confirm to the Licensor from time to time that it has so deposited such items as provided in this Article 3.1, and the Company shall procure that all sub-licensees accept this obligation to the Licensor. Licensor will notify Company if it wishes to obtain a nonexclusive license to the Company Data (or portion thereof) and/or rights of reference to such regulatory filings and approvals, in each case solely for use in connection with regulatory filings outside the Territory. Provided that Company has the right to grant such license and/or rights of reference, upon receipt of such notice from Licensor, the parties will negotiate in good faith with respect to the terms and conditions of such license and/or rights of reference (including commercially reasonable compensation to be paid to Company for such license and/or rights of reference). Any such terms and conditions agreed upon by the parties shall be set forth in writing and signed by authorized representatives of both parties.

### **3.2 Technical Assistance**

Without limiting Licensor's other obligations hereunder, Licensor shall provide such technical assistance to Company as Company reasonably requests regarding the Patent Rights, Know-how and Licensed Products, including without limitation: (i) providing Company with reasonable access to Licensor's employees and consultants involved in the development, formulation and regulatory approval outside the Territory of the Licensed Products and (ii) providing to Company all or part of Licensor's inventory of GMP and non-GMP Licensed Products, as the parties mutually agree. Company shall pay to Licensor its documented reasonable out-of-pocket costs of providing such technical assistance, subject to Company's prior, written approval of such costs in each case.

## Article 4 Regulatory Compliance

### 4.1 Ownership and Maintenance of Governmental Approvals

- 4.1.1 The Company will own all Marketing Authorizations for each country in the Territory for Licensed Products. Without limiting the generality of the foregoing, the Company shall prepare and submit in its own name and at its expense NDAs with the FDA in the U.S. and any other equivalent application with the Competent Authorities in other countries in the Territory.
- 4.1.2 The Company shall secure and maintain in good standing, at its sole cost and expense, any and all Governmental Approvals (including, Marketing Authorizations, licenses, permits and consents, facility licenses and permits required by Applicable Laws or by the applicable Competent Authorities) necessary and/or required for the Company to perform its obligations under this Agreement and use commercially reasonable efforts at its cost and expense to secure and maintain any variations and renewals thereof. Licensor shall promptly notify Company of any written or oral notices received from, or inspections by, any Competent Authority relating to any such Governmental Approvals.
- 4.1.3 To the extent Licensor is or becomes the holder of any Governmental Approval referred to in Article 4.1.2 above, during the time that Licensor holds such Governmental Approval, Licensor shall (i) promptly provide Company an advance draft of any proposed responses to such written notices or inspections and the resolution of any issue raised by such Competent Authority and (ii) make such reasonable changes to such proposed response as may be recommended by Company, and the Company shall be entitled to attend any and all meetings and participate in telephone calls with the Competent Authorities, including without limitation any meeting preparation, meeting co-ordination and preparation of minutes.

### 4.2 Rights of Reference

Licensor shall grant and hereby grants Company a free-of-charge right to reference and use and have full access to all preclinical and clinical data, information, and results, Governmental Approvals, and all other regulatory documents relating to or useful for the Development of the Licensed Products, including but not limited to any IND, NDA, DMF (whether as an independent document or as part of any Governmental Approval), and all chemistry, manufacturing and controls information, and any supplements, amendments or updates to the foregoing, where such regulatory documents are owned, licensed, or controlled by Licensor and the Licensor has the right to transfer or communicate the same, and all analogs to any of the foregoing outside the Territory (for the purposes of this Article, the "Right of Reference"). The Licensor will notify the Company of any potential limitations on its right to transfer or communicate any Right of Reference to the Company and will use commercially reasonable efforts to overcome any such limitations. The Company may license the Right of Reference to Affiliates and to Sublicensees.

### 4.3 Access to Manufacturers

Licensors grants to the Company a free of charge, worldwide right to access and/or sublicense any suppliers of the Licensed Product and any form, component, or ingredient of or precursor to the Technology or any Licensed Product, and shall, if and as requested by the Company, reasonably assist Company in establishing supply relationships with such suppliers on commercially reasonable terms and/or assigning any relevant supply agreements to the Company. In addition, if requested by Company, the parties will negotiate in good faith for commercially reasonable terms on which Licensor would supply Licensed Products (and/or ingredients thereof) to the Company.

#### **Article 5 Development and Commercialization**

##### **5.1 Development**

The Company shall use commercially reasonable efforts, itself or through the activities of its Sublicensees and Affiliates, to perform the Development and secure the Marketing Authorizations for Licensed Products.

##### **5.2 Commercialization**

The Company shall, following receipt of the necessary Marketing Authorizations, use commercially reasonable efforts to, itself or through the activities of its Sublicensees and Affiliates, commence marketing of, and to promote, market, sell and commercialize thereafter, Licensed Products in the Territory. For the avoidance of doubt, Company and the Sublicensees may market the Licensed Products under the "Altoderm" name or such other brand as may be selected by the Company and/or the Sublicensees, provided that if the "Altoderm" name is used it is identified as a registered trade mark of Licensor and the Licensor is accorded all rights under Applicable Laws usually accorded to owners of trade marks in the Territory.

##### **5.3 Clinical Trial Cooperation.**

The parties shall discuss in good faith opportunities to avoid duplication of effort and achieve cost savings and other efficiencies with respect to any clinical trials to be conducted by the Company for the Licensed Products.

##### **5.4 Non-Compete.**

During the term of this Agreement, other than sales of Licensed Products by Company and Sublicensees hereunder, neither party nor any of their respective Affiliates shall market or sell (or license any third party to market or sell) in the Territory: (i) any topical product that contains sodium cromoglicate as an active pharmaceutical ingredient (whether the sole active pharmaceutical ingredient or in combination with any another active pharmaceutical ingredients) or (ii) any other product for the treatment of atopic dermatitis.

##### **5.5 Company Improvements.**

Company will keep Licensor reasonably informed of any Company Improvements it makes in the course of the Development. Licensor will notify Company if it wishes to obtain a nonexclusive license to any such Company Improvement, in each case solely for use in connection with Licensed Products to be sold

in countries outside the Territory. Provided that Company has the right to grant such license, upon receipt of such notice from Licensor, the parties will negotiate in good faith with respect to the terms and conditions of such license (including commercially reasonable royalties and other compensation to be paid to Company for such license).

**5.6 Annual Review Meetings.**

Executive-level personnel of both parties shall meet at least once per year during the Term (either in person or telephonically, and at times and places as are mutually acceptable to the parties) for the purpose of reviewing the status of Licensed Product commercialization in the Territory, including, but not limited to regulatory approval status, development and production issues and market conditions. The parties will discuss in good faith any amendments suggested by either party to the timelines set forth in Section 11.6, royalty rates and/or other provisions of this Agreement as may be fair and reasonable in light of changed conditions. Any agreed upon amendments to this Agreement must be in writing and signed by authorized representatives of both parties.

**Article 6 Royalties and Other Consideration**

**6.1 Royalties on Net Sales; Minimum Royalties**

6.1.1 During the Royalty Term, on a country-by-country and Licensed Product-by-Licensed Product basis, the Company shall pay Licensor royalties in amounts as set forth in the below table, with the applicable Royalty rate determined based on the amount of Net Sales received during the applicable Royalty Term Year (as defined below), subject to further adjustment as described in this Article 6. For the purposes hereof, a "Royalty Term Year" means: (i) the period that begins on the date of the applicable First Commercial Sale and ends on December 31 of the same year and (ii) each calendar year thereafter during the Royalty Term.

<b>Net Sales Received During the Applicable Royalty Term Year (in U.S. Dollars)</b>	<b>Royalty</b>
\$0 to \$100,000,000	10% of Net Sales received during the applicable Royalty Year
\$100,000,001 to \$200,000,000	15% of Net Sales received during the applicable Royalty Year
equal to or over \$200,000,001	20% of Net Sales received during the applicable Royalty Year

For the avoidance of doubt, the Royalty rates set forth in the above table are incremental, *i.e.*, each Royalty rate is applicable to only the portion of annual Net Sales exceeding the respective values (for example, in the case of annual Net Sales of \$300 million U.S. Dollars, a Royalty rate of 10% is applicable to \$100 million U.S. Dollars, a Royalty rate of 15% is applicable to the next \$100 million U.S. Dollars and a Royalty rate of 20% is applicable to last \$100 million U.S. Dollars). The Royalty rates set forth in the above table also are calculated on: (i) a Licensed Product-by-

Licensed Product basis, i.e., Net Sales achieved with one Licensed Product are not added to Net Sales achieved with other Licensed Products and therefore do not influence the Royalty rate applicable to other Licensed Products and (ii) a country-by-country basis, i.e., Net Sales achieved with respect to sales in one country in the Territory are not added to Net Sales achieved with other Licensed Products and therefore do not influence the Royalty rate applicable to other Licensed Products. For the purposes of clause (i) of the preceding sentence, any distinctions between multiple Licensed Products shall be made by the Company acting in good faith and in consultation with Licensor, and shall be based upon objective criteria, such as differences in dosage strength, formulation or branding.

- 6.1.2 The exclusivity granted to Company pursuant to Section 2.1 is subject to Company paying Licensor, with respect to each of the second, third, fourth, fifth and sixth full calendar years during the Royalty Term, minimum Royalties of One Million U.S. Dollars (\$1,000,000) (the "Minimum Royalties"). Company may cure any failure to meet its Minimum Royalty obligation for any such calendar year by paying the amount of the shortfall to Licensor within sixty (60) days after the end of such calendar year. If Company fails to meet its Minimum Royalty obligation for a particular calendar year (and does not cure such failure as provided in the preceding sentence), Licensor, as its sole and exclusive remedy for such failure, may at any time thereafter, upon thirty (30) days prior, written notice to Company, terminate the license granted to Company under Section 2.1 above

## **6.2 Sublicensing Royalties**

During the Royalty Term, on a country-by-country and Licensed Product-by-Licensed Product basis, the Company shall pay Licensor royalties for Licensed Products sold by any Sublicensee(s) during a particular Royalty Term Year equal to the lesser of: (a) thirty percent (30%) of all sales-based royalties including sales milestones received by the Company or its Affiliates from such Sublicensee(s) with respect to such Licensed Products pursuant to the applicable sublicense agreement(s) and (b) the Royalties that would be due under Article 6.1 above for the Sublicensee's Net Sales of such Licensed Products; provided, however, that notwithstanding any of the foregoing, in no event shall such royalties payable to the Licensor be less than four-and-one-half percent (4.5%) of the Sublicensee's Net Sales of such Licensed Products.

## **6.3 No Multiple Royalties**

No multiple royalties shall be payable because the use, lease or sale of any Licensed Product is, or shall be, covered by more than one Valid Claim contained in the Patent Rights. Additionally, royalties shall be paid to Licensor for the sale of a Licensed Product based upon only one of Articles 6.1 or 6.2 above, but in no case both (that is, royalties due to Licensor on direct sales of a Licensed Product by the Company or its Affiliates to a Third Party shall be based only on Article 6.1, while royalties on sales of a Licensed Product by the Company's Sublicensees to a Third Party shall be based only on either clause (a) or clause (b) of Article 6.2, so as to avoid double counting).

## **6.4 Non Royalty Sublicensing Income**

The Company shall pay to Licensor thirty percent (30%) of NRSI received by the Company or its Affiliates, subject to any deductions therefrom described in Article 1.20 and subject as provided below in this Article 6.4. If requested by Licensor, the Company will provide Licensor with reasonable documentation (including copies of the relevant agreements with the Sublicensee and documentation of costs incurred to provide services to the Sublicensee) to support the Company's determination and establish on an objective basis that a payment received from a Sublicensee falls within the definition of NRSI or within an exclusion thereto. The parties agree that any dispute in this respect shall be dealt with under Article 10. Notwithstanding anything to the contrary, Milestone Payments paid by the Company after its execution of any such sublicense agreement shall be fully creditable against payments due with respect to NRSI.

#### **6.5 Combination Products**

In the event that a Licensed Product is sold in the form of a combination product containing one or more technologies which, if incorporated into a product by themselves, would not render a product a Licensed Product, the Net Sales for such combination product shall be calculated by multiplying the sales price of such combination product by the fraction  $A/(A+B)$  where (i) A is the invoice price of a Licensed Product incorporating solely the technology which renders such product a Licensed Product, or, if such Licensed Product is not sold separately, the fair market value of a Licensed Product incorporating solely such technology, and (ii) B is the total invoice price of products incorporating solely the other technologies or, if such products are not sold separately, the fair market value of such products. Company shall not sell or permit any Sublicensee to sell any such combination product without the prior, written approval of Licensor, such approval not to be unreasonably withheld or delayed.

#### **6.6 Milestone Payments**

As further consideration for the license granted hereunder, the Company will make the following one time Milestone Payments to Licensor:

- 6.6.1 (a) 125,000 shares of the Company's common stock and (b) four hundred and seventy-five thousand US Dollars (\$475,000), upon execution of the License Agreement (which payment shall be made within seven (7) days of execution of the License Agreement, but which payment obligation shall be irrevocable, regardless of any termination of this Agreement by the Company);
- 6.6.2 four hundred and fifty thousand US Dollars (\$450,000) upon acceptance for filing by the FDA of the first IND for the Licensed Product filed by Company or a Sublicensee;
- 6.6.3 125,000 shares of the Company's common stock upon first dosing of a patient with a Licensed Product in the first Phase II Trial conducted with a Licensed Product under the first Company-sponsored (or Sublicensee-sponsored) IND;
- 6.6.4 (a) 250,000 shares of the Company's common stock and (b) six hundred and twenty-five thousand US Dollars (\$625,000) upon first dosing of a patient with a Licensed Product in the first Phase III Trial conducted with a Licensed Product under the first Company-sponsored (or Sublicensee-sponsored) IND;
- 6.6.5 One million US Dollars (\$1,000,000) upon the Successful Outcome of the Phase III Trial conducted with a Licensed Product under the first Company-sponsored (or Sublicensee-sponsored) IND;

- 6.6.6 One million and one hundred thousand US Dollars (\$1,100,000) upon the acceptance for filing of the first Company-sponsored (or Sublicensee-sponsored) NDA by a Competent Authority for a Licensed Product;
- 6.6.7 (a) 500,000 shares of the Company's common stock and (b) two million US Dollars (\$2,000,000) upon the final approval by a FDA of the first Company-sponsored (or Sublicensee-sponsored) NDA for a Licensed Product;
- 6.6.8 Five hundred thousand US Dollars (\$500,000) upon receipt by the Company or a Sublicensee of the first Marketing Authorization for a Licensed Product in Canada; and
- 6.6.9 a one-time success fee of ten million US Dollars (\$10,000,000) upon achieving a target of cumulative Net Sales in the United States of the Licensed Products by the Company and all its sub-licensees of one hundred million US Dollars (\$100,000,000) (respectively the "Success Fee" and the "Net Sales Target"), payable as follows:
- (a) if the said Net Sales Target shall be achieved within the first two (2) years of the Royalty Term in respect of the USA, such Success Fee to be paid out over the five (5) year period following the achievement of such milestone in equal installments of two million US Dollars (\$2,000,000) per year;
  - (b) if the Net Sales Target is achieved during the third (3rd) years of the Royalty Term in respect of USA, the Success Fee shall be paid out over the four (4) year period following the achievement of such milestone in equal installments of two million five hundred thousand US Dollars (\$2,500,000) per year; and
  - (c) if the Net Sales Target is achieved during the fourth (4<sup>th</sup>) year of the Royalty Term in respect of USA, the Success Fee shall be paid out over the three (3) year period following the achievement of such milestone in equal installments of three million three hundred and thirty three thousand, three hundred and thirty three US Dollars and thirty-three cents (\$3,333,333.33) per year; and
  - (d) if the Net Sales Target is achieved during or after the fifth (5th) year of the Royalty Term in respect of USA, the Success Fee shall be paid out over the two (2) year period following the achievement of such milestone in equal installments of five million US Dollars (\$5,000,000) per year.

Each of the Milestone Payments described above shall only be paid once upon their respective accomplishments, regardless of the number of times each of such milestones is achieved.

If any of the Milestone Payments set out above are not paid because the Company shall decide it is not necessary to take that step giving rise to the Milestone Payment, the Milestone Payment shall nonetheless be due and shall be paid at the time the Company shall decide not to take the particular step or when the next Milestone Payment is due whichever shall first occur.

## **6.7 Equity Consideration**

It is understood and agreed that, notwithstanding anything to the contrary in this Agreement, the shares provided to Licensor from time to time under this Agreement (the "Shares") are non-refundable. The Shares are not registered under the Securities Act of 1933, as amended, and may not be transferred unless and until registered or the Company has received an opinion of counsel or other evidence satisfactory to the Company and its counsel that such registration is not required. Each time Shares are required to be issued under this Agreement, such Shares will be issued pursuant to a subscription agreement, in the form attached hereto as Exhibit 6.7. Licensor agrees to enter into reasonable or customary agreements required by any future equity investors regarding subjecting the Shares to rights of first refusal and co-sale, such rights to terminate on an initial public offering of Company stock pursuant to a registration statement filed pursuant to the Securities Act of 1933, as amended.

#### **6.8 Place of Payment, Taxes and Conversions**

All payments under this Agreement shall be paid in United States dollars, unless otherwise required by law, at such place as Licensor may reasonably designate consistent with applicable laws and regulations. Any taxes, duties, or other levies which the Company, its Affiliate or any Sublicensee shall, in its reasonable discretion, be required by law to pay or withhold on remittance of any payment(s) due under this Agreement shall be deducted from such payment(s) to Licensor. Any such taxes, levies, or duties required under applicable law to be paid or withheld shall be an expense of, and borne solely by, Licensor. The Company will use commercially reasonable efforts to secure and send to Licensor proof of any such taxes, duties or other levies withheld and paid by the Company for the benefit of Licensor, and cooperate, at Licensor's expense, with any reasonable request to help ensure that amounts withheld and/or paid are reduced and/or recovered to the extent permitted by the relevant jurisdiction. If any currency conversion shall be required in connection with the payment of royalties hereunder, such conversion shall be made by using the exchange rate prevailing at Citibank, N.A. in New York, New York on the last business day of the calendar quarterly reporting period to which such royalty payments relate. In each country where the local currency is blocked and cannot be removed from the country under such country's applicable law, royalties accrued with respect to that country shall be paid to Licensor in such country in local currency by deposit in a local bank designated by Licensor, unless the parties otherwise agree.

#### **6.9 Time for Payment**

- 6.9.1 The Company shall pay to Licensor the royalties due and payable under this Agreement on a quarterly basis, and shall provide the Royalty Statement referred to in Article 7.2 along with such payment. Payments pursuant to this Article 6.9.1 are due with respect to a particular calendar quarter's Net Sales and receipts of NSRI and sales-based royalties sixty (60) days after the conclusion of such calendar quarter.
- 6.9.2 Milestone Payments payable to Licensor shall, notwithstanding the use of the word "upon" throughout Article 6.6, become due and payable within thirty (30) days after achievement of the indicated milestone.
- 6.9.3 Even if no royalties or other payments that may be due to Licensor under this Agreement shall be due, the Company shall be required to make a report pursuant to Article 7.2 to state that no payments are due.

#### **6.10 Interest**

Amounts which are not paid when due shall accrue interest from the due date until paid, at a rate equal to the then prevailing prime rate of Citibank, N.A., plus two percent (2%).

#### **6.11 Royalty Adjustments**

- 6.11.1 Notwithstanding anything to the contrary herein, if the Company obtains (or has obtained) one or more licenses under patents or patent applications owned by a Third Party: (i) to avoid infringement thereof by the manufacture, use, or sale of any Licensed Product, (ii) to reasonably avoid infringement-related litigation regarding a Licensed Product, or (iii) with the prior approval in writing of Licensor (which approval shall not be unreasonably withheld) to make, use or sell any technology that could improve, enhance, or modify a Licensed Product, as determined by the Company in its reasonable discretion, then the Company may deduct fifty percent (50%) of any fees, milestones or royalties paid under such license(s) (even if paid in settlement or judgment of any claim for infringement) from the payments otherwise due Licensor under this Agreement (including any royalty payments, minimum royalty payments and Success Fee payments, but excluding any other Milestone Payments); provided, however, that, notwithstanding the foregoing, the total amount due Licensor under this Agreement in any particular calendar quarter shall not be reduced by more than fifty percent (50%) as a result of any such deduction, and any amounts not deducted in a calendar quarter shall be carried forward for deduction in the subsequent calendar quarter(s), subject to such fifty percent (50%) limitation in each case.
- 6.11.2 Should a compulsory license be granted, or be the subject of a possible grant, to a Third Party under the applicable laws of any country in the Territory under the rights licensed under this Agreement, the Company shall notify Licensor, including any material information concerning such compulsory license, and the running royalty rate payable under this Article 6 for sales of Licensed Products in such country will be adjusted to equal any lower royalty rate granted to such Third Party for such country with respect to the sales of such Licensed Products therein (the "Compulsory Royalty") during such periods such third parties sell or offer for sale under the compulsory license articles that compete with the Licensed Products then marketed and sold by the Company, its Affiliates, or Sublicensees in that country, provided that such Compulsory Royalty shall remain subject to further adjustment consistent with this Article 6.

#### **6.12 Invalidity, Unenforceability or Revocation of Patents**

Notwithstanding anything to the contrary, if any of the Patent Rights are declared or held invalid or unenforceable or are revoked by court or tribunal of competent jurisdiction, then all Royalties shall cease to be payable with respect to Licensed Products covered by such Patent Rights sold in the part of the Territory in which such declaration, holding or revocation is effective, as from the date of such declaration, holding or revocation, but if the decision of the court or tribunal making such declaration, holding or revocation shall be reversed on appeal, the Royalties shall become payable from the date of such reversal together with all Royalties which would have been payable but for the adverse decision.

#### **Article 7 Reports and Records**

## 7.1 Records and Audits

The Company shall keep full, true and accurate books of account containing all particulars that may be reasonably necessary for the purpose of showing the amounts payable to Licensor under this Agreement. Said books of account shall be kept at the Company's principal place of business and the supporting data shall be opened up to Licensor once per year upon reasonable notice to the Company for inspection by Licensor's internal audit division or by another designated auditor selected by Licensor, except one to whom the Company has reasonable objection, for the purpose of verifying the Company's Royalty Statement (as defined below) or compliance in other respects with this Agreement. If an inspection shows an under reporting or underpayment in excess of five percent (5%) of remuneration payable, then the Company shall reimburse Licensor for the reasonable, documented cost of the inspection at the time the Company pays the unreported royalties, including any late charges as required by Article 6.10 of this Agreement. Said books of account and the supporting data shall be made available to Licensor for one (1) year following the expiration of the Term. All payments required under this Article 7.1 shall be due within thirty (30) days of the date Licensor provides the Company notice of the payment due. Licensor shall cause its accounting firm to retain all financial information subject to review under this Article 7.1 in strict confidence; provided, however, that Company shall have the right to require that such accounting firm, prior to conducting such audit, enter into an appropriate non-disclosure agreement with Company regarding such financial information. The accounting firm shall disclose to Licensor only whether the Company's Royalty Statement is correct or not and the amount of any discrepancy. No other information shall be shared. Licensor shall treat all such financial information as Company's Confidential Information.

## 7.2 Royalty Statements

Within 45 days from the end of each of the first, second and third calendar quarters (and within 60 days from the end of the fourth calendar quarter) of each calendar year, the Company shall deliver to Licensor complete and accurate reports, giving such particulars of the business conducted by the Company during the preceding quarter under this Agreement as shall be pertinent to an accounting of royalties and other payments that may be due to Licensor under this Agreement (the "Royalty Statement"). The Royalty Statement shall include at least the following:

- 7.2.1 Net Sales for each Licensed Product by the Company, each Affiliate, and each Sublicensee;
- 7.2.2 cumulative Net Sales for the applicable calendar quarter;
- 7.2.3 a breakdown of deductions applicable in computing Net Sales and taxes paid or withheld, if any;
- 7.2.4 a breakdown of royalties due based on Net Sales by or for the Company or its Affiliates;
- 7.2.5 a breakdown of royalties due on NRST;
- 7.2.6 names and addresses of all Sublicensees and Affiliates of the Company; and
- 7.2.7 a copy of each report from each Sublicensee as may be pertinent to an accounting of royalties and other payments that may be due to Licensor.

### **7.3 Confidential Treatment of Reports**

Licensor agrees to hold in confidence each Royalty Statement delivered by the Company pursuant to this Article 7 for a period of five (5) years following termination of this Agreement. Notwithstanding the foregoing, Licensor may disclose any such information required to be disclosed in its financial statements or as required by any stock exchange or similar regulatory authority, or pursuant to any Applicable Laws, provided that Licensor take reasonable steps to provide and assist the Company with the opportunity, where reasonably appropriate, to (i) contest such subpoena, requirement or order or (ii) seek protective or confidential treatment thereof, including but not limited to reasonable advance notice to the Company of any such required disclosure, to the extent reasonably practicable. The Licensor understands that it is the intention of the Company to become publicly traded and that any information disclosed to Licensor under this Agreement, including the Royalty Statement, may be deemed "material non-public information" under the state and federal securities laws.

## **Article 8 Patent Prosecution and Maintenance**

### **8.1 Prosecution and Maintenance**

Following the Effective Date, the Company shall, at its expense, diligently file, prepare, prosecute and maintain the Patent Rights as set forth in Schedule 1.21 hereto (as the same may be amended or supplemented in writing from time to time after the date hereof), including, but not limited to, the filing of patent applications, extensions, continuations, continuations in part, divisionals, re-examinations, or re-issue applications that the Company determines, in consultation with Licensor, may be required to advance the purposes of this Agreement or otherwise to protect the rights and licenses granted hereunder. The Company shall control such prosecution and maintenance, using counsel of its choosing, in the name of Licensor, and agrees to keep Licensor reasonably informed with respect to the status and progress of any such applications, prosecutions and maintenance activities and to consult in good faith with Licensor and take into account Licensor's reasonable comments and requests with respect thereto prior to the filing of any such documents. Licensor shall notify Company in writing and reasonable detail of any Improvements and assist Company in filing, prosecuting, and maintaining Patent Rights claiming the same. Both parties agree to provide reasonable cooperation to each other to facilitate the application and prosecution of patents pursuant to this Agreement and the Licensor shall execute all lawful papers and instruments and make all rightful oaths and declarations as may be necessary in the preparation, prosecution and maintenance of all patents and other filings referred to in this Article 8.

### **8.2 Patent Term Extensions**

The Company shall promptly notify Licensor of the issuance of each Governmental Approval and, where reasonably possible and reasonably useful or valuable in the commercialization of Licensed Products, use commercially reasonable efforts to apply or enable Licensor to apply for a patent term extension, adjustment or restoration, supplementary protection certificate, or other form of market exclusivity conferred by Applicable Laws (collectively, "Patent Term Extensions") in the relevant country of the Territory. Licensor shall, to the extent reasonably possible and reasonably useful or valuable in the commercialization of Licensed Products, use commercially reasonable efforts to, if and as requested by the Company, obtain (or assist the Company in obtaining) all available Patent Term Extensions. The Parties shall cooperate with each other in obtaining Patent Term Extensions wherever and whenever applicable, reasonably possible to obtain, and reasonably useful or valuable in the commercialization of Licensed Products.

### **8.3 Abandonment**

The Company may, in its discretion, elect to abandon any patent applications or issued patent in the Patent Rights provided that it shall have informed Licensor in writing prior to doing so. Following such abandonment, Licensor shall have the right, but not the obligation, to commence or continue such prosecution and to maintain any such patent or patent application under its own control and at its own expense and such patent or patent application shall thereafter be excluded from the definition of Patent Rights for purposes of this Agreement. Prior to any such abandonment, the Company shall give Licensor at least sixty (60) days notice and a reasonable opportunity to take over prosecution of such patent or patent application. The Company agrees to cooperate in such activities including execution of any documents necessary to enable Licensor to retain ownership and control of such patent or patent application.

## **Article 9 Infringement, Enforcement and Other Actions**

### **9.1 Notice of Infringement of Patent Rights**

The Company and Licensor shall promptly provide written notice, to the other party, of any alleged infringement or any challenge or threatened challenge to the validity, enforceability or priority of any of the Patent Rights, and provide each other with any available evidence of such infringement, challenge or threatened challenge by a Third Party of the Patent Rights and provide such other party with any available evidence of such infringement.

### **9.2 Option to Prosecute or Defend Patent Rights**

During the term of this Agreement, the Company shall have the first right, but not the obligation, to take (or refrain from taking) appropriate action to enforce Patent Rights, to defend any declaratory judgments seeking to invalidate or hold the Patent Rights unenforceable, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation, declaratory judgments or other enforcement action pertaining to Patent Rights, with respect to any potential, threatened, alleged, or actual infringement of, or challenge, to, the Patent Rights (all of the foregoing, collectively "Enforcement Actions"), at its own expense and with counsel of its choosing. In furtherance of such right, Licensor hereby agrees that the Licensor will, if requested by Company, join with Company as a party in any such suit. If, within twelve (12) months of the written notice described in Article 9.1 above, the Company (i) shall have been unsuccessful in persuading the alleged infringer to desist, (ii) shall not have brought and shall not be diligently prosecuting an infringement action, or (iii) has not entered into settlement discussions with respect to such infringement, or if the Company notifies Licensor that it has decided not to undertake any of the foregoing against any such alleged infringer, then Licensor shall then have the right to bring suit to enforce such Patent Rights, at its own expense. Any recovery of damages or amounts received in settlement pursuant to this Article 9.2, as well as costs and expenses incurred in connection therewith, shall be allocated pursuant to Article 9.5 below.

### **9.3 Infringement by Licensed Product**

In the event that a claim or suit is asserted or brought against the Company alleging that the manufacture or sale of any Licensed Product by the Company, an Affiliate of the Company, or any Sublicensee, or the use of such Licensed Product by any customer of any of the foregoing, infringes proprietary rights of a Third Party, the Company shall give written notice thereof to Licensor. The Company may, in its sole discretion, modify such Licensed Product to avoid such infringement and/or may settle on terms that it deems advisable in its sole discretion, provided that any final disposition of the litigation that will restrict the claims in or admit any invalidity of any Patent Rights(s) shall not be made without consultation with and approval by Licensor, such approval not to be unreasonably withheld. Otherwise, the Company shall

have the first right, but not the obligation, to defend any such claim or suit. If the Company has not exercised such right to defend or entered into settlement discussions concerning such alleged infringement within the sooner of (i) twelve (12) months of the assertion of such a claim or (ii) thirty (30) days of the filing of such a suit, or if the Company notifies Licensor that it has decided not to undertake such defense or enter into settlement discussions with respect to its alleged infringement, then Licensor shall then have the right to defend such alleged infringement, at its sole expense, provided however that no settlement affecting Patent Rights will be agreed upon without Company's written consent.

#### **9.4 Control of Infringement Action**

The party controlling any action, suit, or defense under Article 9.2 or 9.3 (the "Controlling Party") shall be free to enter into a settlement, consent judgment, or other voluntary disposition of any such action, provided, however, that (i) the Controlling Party shall consult with the other party (the "Secondary Party") prior to entering into any settlement thereof and (ii) any settlement, consent judgment or other voluntary disposition of such actions which (1) materially limits the scope, validity, or enforceability of any Patent Rights or, if the Company is the Secondary Party, patents or patent applications owned or controlled by the Company, (2) subjects the Secondary Party to any non-indemnified liability, payment obligation, or injunction, or (3) admits fault or wrongdoing on the part of Secondary Party must be approved in writing by Secondary Party, such approval not to be unreasonably withheld. Secondary Party shall provide the Controlling Party notice of its approval or denial of such approval within fifteen (15) business days of any request for such approval by the Controlling Party, provided that (i) in the event Secondary Party wishes to deny such approval, such notice shall include a written description of Secondary Party's reasonable objections to the proposed settlement, consent judgment, or other voluntary disposition and (ii) Secondary Party shall be deemed to have approved such proposed settlement, consent judgment, or other voluntary disposition in the event it fails to provide such notice within such fifteen (15) business day period.

#### **9.5 Allocation of Costs Incurred and Damages Recovered in Enforcement Action**

Each party (the "Prosecuting Party") will promptly notify the other party in writing in the event the Prosecuting Party chooses to take any Enforcement Action pursuant to its rights under Article 9.2 above and such other party will, within thirty (30) days after the date of such notice, provide the Prosecuting Party with written notice as to whether or not such other party elects to enter into an arrangement pursuant to which such other party will pay for fifty percent (50%) of the parties' aggregate attorneys' fees and other costs and expenses incurred in connection with such Enforcement Action (such costs to be allocated between and paid by the parties as incurred), and in exchange receive fifty percent (50%) of any cash payments awarded to the Prosecuting Party or received by the Prosecuting Party in settlement of such Enforcement Action (a "Risk/Reward Sharing Arrangement"). If such other party fails to provide the above-described notice to the Prosecuting Party within such thirty (30) day period, such other party shall be deemed to have elected not to enter into the Risk/Reward Sharing Arrangement. If such other party elects not to (or is deemed to have elected not to) enter into the Risk/Reward Sharing Arrangement, the Prosecuting Party shall be solely responsible for all of its costs of the Enforcement Action (together with any reasonable, documented out-of-pocket costs incurred by the other party to provide any assistance requested by the Prosecuting Party in connection with such Enforcement Action), and shall be entitled to retain all awards and other proceeds of such Enforcement Action.

#### **9.6 Cooperation**

In any suit to enforce and/or defend the Patent Rights pursuant to this Agreement, or defend any alleged infringement of Third Party intellectual property rights by the manufacture, use, sale, or import of a

Licensed Product, the Secondary Party shall, at the request of the Controlling Party, cooperate in all respects and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens, and the like.

#### Article 10 Dispute Resolution

##### 10.1 Disputes

- 10.1.1 The parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either party's rights and/or obligations hereunder or to the interpretation, performance, breach, or termination of this Agreement, (a "Dispute"). It is the objective of the parties to establish procedures to facilitate the resolution of a Dispute in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the parties agree to follow the procedures set forth in this Article 10 if and when a Dispute arises under this Agreement.
- 10.1.2 A Dispute among the parties will be resolved as recited in this Article 10. Any Disputes relating to this Agreement shall be promptly presented to the Chief Executive Officers of Licensor and the Company, or their respective designees (who must be members of a party's senior management) for resolution. From the date of referral of a Dispute to the Chief Executive Officers or their designees of the parties and until such time as any matter has been resolved by the parties or has been finally settled by arbitration hereunder, the running of the cure periods (if any) as to which a party must cure a breach that is part of the subject matter of any Dispute shall be suspended. In the event that the Chief Executive Officers of Licensor and the Company, or their respective designees, cannot after good faith negotiations resolve the Dispute within thirty (30) days (or such other period of time as mutually agreed to by the parties in writing) of being requested by a party to resolve a Dispute, the parties agree that such Dispute shall be resolved by binding arbitration in accordance with this Article 10.1.
- 10.1.3 If a party intends to begin arbitration to resolve such Dispute, such party shall provide written notice (the "Arbitration Notice") to the other party informing such other party of such intention and the issues to be resolved. Any arbitration hereunder shall be conducted pursuant to the Commercial Arbitration Rules of the American Arbitration Association ("AAA"; such rules, the "AAA Rules"), except as modified herein. The arbitration shall be conducted by a panel of three (3) independent, neutral arbitrators that are industry experts experienced in the issues comprising the Dispute and have no past, present or reasonably anticipated future affiliation with either party (the "Panel"). Company and Licensor shall each be entitled to select one (1) such arbitrator, with the two such arbitrators so selected selecting the third such arbitrator. In the event either party fails to select its arbitrator within such ten (10) day period, the arbitrator selected by the other party within such ten (10) day period shall be entitled to select such arbitrator. The arbitration shall take place in New York, New York and be conducted in English. The Panel shall apply the laws of the State of New York, without regard to its conflicts of laws provisions. The Panel shall issue appropriate protective orders to protect each party's Confidential Information. If a party can demonstrate to the Panel that the complexity of the issue or other reasons warrant the extension of one or more timetables in the AAA Rules, the Panel may

extend such timetables but in no event shall the proceeding extend more than twelve (12) months from the date of filing of the arbitration notice with the AAA. The Panel's decision shall be in writing. The Panel shall have the authority to award any remedy allowed by law, including but not limited to compensatory damages, pre-judgment interest, but not punitive or other damages and each party shall be deemed to have waived any right to such excluded damages. Each party shall bear its own costs, fees and expenses in the arbitration and shall share equally the Panel's fees, unless the Panel determines that its fees are to be paid by the non-prevailing party. Notwithstanding anything to the contrary, without prejudice to the above procedures, either party may seek injunctive relief or other provisional judicial relief if, in its reasonable judgment, such action is necessary to avoid irreparable damage or otherwise enforce its rights hereunder

#### **10.2 Performance to Continue**

Each party shall continue to perform its obligations, and shall be permitted to continue to exercise its rights, under this Agreement pending final resolution of any Dispute arising out of or related to this Agreement, provided, however, that a party may suspend performance of its obligations during any period in which the other party fails or refuses to perform its obligations.

#### **10.3 Determination of Patents and Other Intellectual Property**

Notwithstanding the foregoing, any dispute relating to the determination of validity of claims, infringement or claim interpretation relating to Licensor's Patent Rights shall be submitted exclusively to the United States District Court for the Southern District of New York and the appropriate appellate courts thereof. Each of the parties hereby irrevocably consents and submits to the exclusive jurisdiction of such courts with respect to any such disputes and waives any objections to the laying of venue in such courts.

#### **10.4 Statute of Limitation and Time-Based Defenses Tolloed**

All applicable statutes of limitation and time-based defenses (such as estoppel and laches) shall be tolled while any arbitration proceedings are pending and during any arbitration proceedings. The parties shall cooperate in taking any actions necessary to achieve this result.

### **Article 11 Term and Termination**

#### **11.1 Term**

This Agreement shall become effective on the Effective Date and shall expire on the date of the expiration of the last to expire Royalty Term in any country in the Territory (the "Term"), unless earlier terminated as provided in Articles 11.2, 11.3, or 11.5.

#### **11.2 Termination for Insolvency**

If the Company shall become bankrupt, or shall file a petition in bankruptcy, or if the business of the Company shall be placed in the hands of a receiver, assignee or trustee for the benefit of creditors, whether by the voluntary act of the Company or otherwise, Company shall provide notice thereof to Licensor and Licensee may, subject to the effects of and protections of any applicable bankruptcy-related laws, rules, or regulations, terminate this Agreement upon notice to Company given within thirty (30)

business days of Licensor's receipt of such notice whereupon Licensor shall be entitled to exercise the right of reference to Company Data as defined in Article 3.1 and on the basis set out in Articles 3.1 and 11.5.

### **11.3 Termination for Material Breach**

Upon any material breach or default of this Agreement by the Company, Licensor shall have the right to terminate this Agreement and the rights, privileges and license granted hereunder by giving ninety (90) days prior written notice to the Company. Upon the expiration of the ninety (90) day period, if the Company shall have not cured such breach or default, this Agreement shall, at the option of Licensor, terminate upon written notice of Licensor. In the event of a bona fide dispute over any material breach, the parties shall attempt to resolve such dispute in good faith through negotiation, or if agreed to by the parties, mediation, in each case to include the senior executive of both parties hereto. Notwithstanding anything herein to the contrary, if the nature of the breach is such that additional time is reasonably needed to cure such breach, and Company has commenced with good faith efforts to cure such breach, then Licensor shall provide Company with additional time in which to cure such breach. If a dispute regarding termination is addressed pursuant to Article 10, this license shall remain in full force and effect until such dispute is resolved. All applicable statutes of limitation and time-based defenses (such as estoppel and laches) shall be tolled while any good faith negotiation or mediation procedures are pending or ongoing. The parties shall reasonably cooperate in taking any actions necessary to achieve this result.

### **11.4 Expiration of Royalty Term on a Country by Country Basis**

Upon the expiration of the Royalty Term in each country in the Territory, the Company will have an irrevocable, perpetual, paid up, royalty-free non-exclusive license, with rights of sublicense (through multiple tiers), under all rights granted under this Agreement to make, have made, use, have used, lease, import and export, offer to sell, sell have sold, produce, manufacture, distribute and market Licensed Products in such country.

### **11.5 Termination for Convenience**

The Company shall have the right at any time to terminate this Agreement in its entirety or on a country-by-country basis, for any reason or no reason, by giving thirty (30) days notice thereof in writing to Licensor. In the event of any termination pursuant to this Article 11.5, at the request of Licensor, Company shall transfer to Licensor any and all clinical study data, INDs and Governmental Approvals relating to the Licensed Product (the "Data") that the Company has the right to transfer.

If such notice of termination shall be given prior to the First Commercial Sale such transfer shall be free. If notice shall be given after the First Commercial Sale, the Licensor shall reimburse the Company for all costs incurred in connection with the creation of the Data (including, but not limited to, costs of clinical studies and costs associated with filing for and obtaining regulatory approval) (the "Data Costs"), as follows:

- (i) to the extent Licensor or any of its Affiliates licenses the Licensed Product and/or the Data to one or more third parties (the "New Licensees"), after Licensor or its Affiliates have received aggregate payments from the New Licensees equal to the Threshold Amount (as defined below), Licensor will reimburse the Company for the Data Costs out of any subsequent payments received from the New Licensees, as follows: (A) Licensor will pay Company fifty percent (50%) of any such payments (other than royalties) that Licensor or any of its Affiliates receives from the New Licensees, including, but not

limited to, milestone payments and lump sum payments for use of the Data, and (B) Licensor will pay Company a percentage of any royalties that Licensor or any of its Affiliates receives from the New Licensees, such percentage to be determined using the formula set forth in Section 6.2 hereof, *mutatis mutandis*; and

- (ii) to the extent Licensor or any of its Affiliates sells the Licensed Product itself (as opposed to licensing a New Licensee to do so), Licensor will reimburse the Company for the Data Costs pursuant to such payment schedule as shall be negotiated in good faith and agreed upon in writing by the parties.

For the purposes of the foregoing, the "Threshold Amount" means an amount equal to: (A) five million U.S. Dollars (\$5,000,000) minus (B) the aggregate amount of all Minimum Royalties paid by Company hereunder. The Company will take all steps that may be necessary to ensure that the benefit of the Data is transferred to the Licensor

#### 11.6 Termination by Licensor

11.6.1 Subject to Section 11.6.2 below, Licensor shall be entitled to terminate this Agreement if the Company (or its Sublicensee) does not:

- 11.6.1.1 request a Pre-IND Meeting with the FDA within ninety (90) days after the Effective Date;
- 11.6.1.2 file an IND in respect of the first Licensed Product in the United States by, as applicable: (A) three (3) months after the date of the Pre-IND Meeting with the FDA or (B) if no such meeting is held, within one (1) month after receipt of notice from the FDA that no such meeting is required or (C) if the FDA fails to notify the Company as to whether or not such a meeting is required, within eighteen (18) months after the Effective Date;
- 11.6.1.3 initiate a Phase II Trial in the United States within six (6) months of the FDA approval of an IND for such Licensed Product;
- 11.6.1.4 initiate a Phase III Trial in the United States within nine (9) months of the date of the End-of-Phase II Meeting with the FDA with respect to such Licensed Product (such meeting to be requested within two (2) months after Company completes full analysis of Phase II data);
- 11.6.1.5 complete the Phase III Trial within twenty-four (24) months of the commencement of the Phase III Trial;
- 11.6.1.6 file the first application for NDA for a Licensed Product in the United States within nine (9) months of Successful Outcome;
- 11.6.1.7 achieve the First Commercial Sale in the United States within six (6) months of obtaining the final approval by the FDA of the NDA for a Licensed Product in the United States.

If Licensor terminates this Agreement under any of the provisions set out above in this Section 11.6.1, the Company shall transfer the Data to Licensor free of charge.

11.6.2 The timelines and termination right described in Article 11.6.1 are subject to the following provisions:

11.6.2.1 For the avoidance of doubt, the timelines and termination right under Article 11.6.1 apply only with respect to the first Licensed Product for which the Company seeks regulatory approval in the United States. To the extent the Company seeks regulatory approval for any additional Licensed Products and/or seeks regulatory approval in Canada, Licensor shall not have any right to terminate this Agreement on the basis of delays associated with such activities.

11.6.2.2 The timelines specified in Article 11.6.1 are based on the following assumptions:

- (i) the documentation regarding the Licensed Product provided to Company by the Licensor will be deemed sufficient by the FDA for filing an IND for the Licensed Product, without any material supplement or change;
- (ii) the Toxicology Package relating to the Licensed Product that has been provided to the Company by Licensor will be suitable to the FDA without any material supplement or change;
- (iii) no additional non-clinical studies (*i.e.*, other than those studies that have already been conducted by Licensor prior to the Effective Date) are required by the FDA with respect to the Licensed Product during the clinical development program;
- (iv) the FDA will not require any additional pre-clinical studies, toxicology studies, pharmacology studies, CMC data, formulation or clinical supplies production activities to be completed to support the Phase III Trial, and
- (v) no safety, toxicity, technical or other issues will arise during the conduct of any studies relating to the Licensed Product.

11.6.2.3 The periods specified in Article 11.6.1 above shall be extended after consultation with Licensor and the parties' mutual agreement as to the length of the each extension (such agreement not to be unreasonably withheld), to the extent that delay is incurred on account of: (i) the failure of any of the assumptions listed in Article 11.6.2.2 above or (ii) any reasons outside the reasonable control of the Company including any delays caused by Competent Authorities or any requirement to conduct further clinical studies of the Licensed Product.

11.6.3 Licensor shall be entitled to terminate this Agreement upon written notice to the Company if the Company (or any of its Affiliates or Sublicensees) commences any litigation challenging the validity or enforceability of any of the Patent Rights.

#### **11.7 Consequences of Termination**

Upon the early termination of this Agreement by either party, the following shall occur:

- 11.7.1 Subject to Article 11.7.2, the Company and its Affiliates (as the case may be) shall have no right to practice within the Patent Rights or use any of the Patent Rights and Know-how, and all rights, title or interest in, or other incidents of ownership under, the Patent Rights and Know-how shall revert to and become the sole property of Licensor, and the licenses granted under Article 2.1 shall automatically terminate.
- 11.7.2 Notwithstanding Article 11.7.1, if this Agreement is terminated other than pursuant to Article 11.5, the Company and its Affiliates may, after the effective date of such termination and continuing for a period not to exceed twelve (12) months thereafter, sell all completed Licensed Products, and complete (or have completed) any Licensed Products in the process of manufacture at the time of such termination and sell the same, provided that the Company:
- (a) notifies Licensor of its decision within thirty (30) days after the date it receives a notice of termination by Licensor or the date it provides a notice of termination to Licensor, as the case may be;
  - (b) pays or cause to be paid to Licensor the royalties and other payments thereon as required by Article 6 of this Agreement; and
  - (c) submits the reports required by Article 7 hereof.
- 11.7.3 If the Company does not elect pursuant to Article 11.7.2 to sell-off or distribute, as applicable, any existing inventory of Licensed Product, the Company shall, at Licensor's election, either:
- (a) sell all existing inventory of Licensed Product to Licensor at fair market value; or
  - (b) destroy all remaining inventory of Licensed Product in accordance with Applicable Laws and provide Licensor with written proof of destruction sufficient to comply with Applicable Laws.
- 11.7.4 Notwithstanding anything to the contrary, each sublicense granted under this Agreement by the Company or its Affiliates to a Sublicensee shall, to the extent not imposing obligations on Licensor in excess of those contained herein, survive such termination and be automatically assigned to Licensor as provided for in Article 2, in order to provide for the applicable Sub licensees' continued enjoyment of their rights under such sublicenses.

#### **11.8 Partial Termination**

Upon the early termination of this Agreement by either party in respect of a country, the terms of Article 11.7 shall apply in respect of such country.

#### **11.9 Survival**

Upon termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination, or such party's

obligations under Articles 6 and 7, and the following provisions shall survive such termination: Articles 7.3, 9 (with respect to infringement occurring prior to such termination), 10, 11, 13, 14, 15, and 16.

## Article 12 Representations and Warranties

### 12.1 Licensor Warranties

Licensor represents and warrants that:

- 12.1.1 Licensor owns all right, title, and interest in and to the Patent Rights and Know-how, including the exclusive, absolute, irrevocable right, title and interest thereto, free and clear of all liens, charges, encumbrances or other restrictions or limitations of any kind whatsoever.
- 12.1.2 There are no licenses, options, restrictions, liens, rights of third parties, disputes, royalty obligations, proceedings or claims relating to, affecting, or limiting Licensor's rights or the rights of the Company under this Agreement, or which may lead to a claim of infringement by or invalidity regarding, any part or all of the Patent Rights or Know-how or their use.
- 12.1.3 There is no claim, pending or threatened, of infringement, interference or invalidity regarding any part or all of the Patent Rights or Know-how or their use.
- 12.1.4 The US and foreign patent applications and patents itemized on Schedule 1.21 set forth all of the patents and patent applications owned by or licensed to Licensor or any of its Affiliates relating to the Licensed Products in respect of the Territory (including, but not limited to, the manufacture, formulation, composition or use thereof) on the date of this Agreement.
- 12.1.5 There are no inventors of Patent Rights other than those listed as inventors on applications filed for such Patent Rights.
- 12.1.6 The development of the Patent Rights, and Know-how were not supported in whole or part by funding or grants by any governmental agency or philanthropic or charitable organization.
- 12.1.7 The Licensor is a company duly organized, validly existing and in good standing under the laws of England. The Licensor has the requisite power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement and the performance and consummation of the transactions contemplated hereby by the Licensor have been duly authorized by all necessary action on the part of the Licensor. This Agreement has been duly executed and delivered by the Licensor and, subject to the due authorization, execution and delivery of this Agreements by the Company, this Agreement constitutes a valid and binding obligation of the Licensor, enforceable against the Licensor in accordance with its terms, except as such enforcement may be affected by bankruptcy, reorganization, insolvency, moratorium or similar laws affecting creditor's rights generally and except for general principles of equity.

- 12.1.8 The execution and delivery of this Agreement does not, the consummation of the transactions contemplated hereby, and the performance of Licensor's obligations hereunder will not, (i) conflict with, or result in any violation or breach of any provision of the organizational documents of the Licensor, (ii) so far as Licensor is aware conflict with or violate any applicable foreign, Federal, state and local statutes, judgments, decrees, laws, ordinances, rules, regulations, injunctions and orders ("Laws") of any U.S. Federal, state, foreign or local government or any court, tribunal, administrative agency or commission or other governmental or regulatory authority, body or agency, including any self-regulatory organization ("Governmental Authorities") applicable to the Licensor or any of its assets or operations or any permit applicable to the Licensor or (iii) result in (x) any violation or breach of, constitute (with or without notice or lapse of time or both) a default under or conflict with (or give rise to a right of termination, amendment, cancellation or acceleration of any material obligation or loss of any benefit under) the provisions of any lease, contract or other agreement to which the Licensor is a party or by which it or any of its properties or assets is otherwise bound or (y) the imposition of any lien, pledge, hypothecation, mortgage, security interest, claim, lease, charge, option, right of first refusal or first offer, easement, servitude, transfer restriction, voting requirement or any other encumbrance, restriction or limitation on any of the properties or assets of the Licensor.
- 12.1.9 No consent, approval or authorization of, or declaration or filing with, any Governmental Authority or other Third Party (a "Consent") is required on the part of the Licensor in connection with its execution, delivery, and performance of this Agreement or the consummation of the transactions contemplated hereby.
- 12.1.10 No written communication has been received by the Licensor, and no investigation, regulatory enforcement action (including seizure, injunction, civil penalty or criminal action) or any related Governmental Authority review is or, in respect of any Licensed Product, to the knowledge of the Licensor, was at any time pending or is threatened by any Governmental Authority with respect to (i) any alleged or actual violation by the Licensor of any permit, Law or other requirement of any Governmental Authority relating to the operations conducted by the Licensor with respect to any Licensed Product or (ii) any alleged or actual failure to have or maintain in effect all permits required in connection with the operations conducted by the Licensor with respect to any Licensed Product. The Licensor has not received from the FDA, the U.S. Drug Enforcement Administration ("DEA"), or any similar state, local, federal, or foreign Governmental Authority any written notice regarding the approvability or approval of any of the Licensed Products. No Licensed Product has been withdrawn, suspended or discontinued by the Licensor as a result of any action by the FDA, the DEA or any similar state, local, federal, or foreign Governmental Authority, either within or outside the U.S. (whether voluntarily or otherwise). With respect to any Licensed Products, no officer, employee or, to the knowledge of the Licensor, agent of the Licensor has made any untrue statement of a material fact or a fraudulent statement to the FDA, DEA or any similar state, local, federal, or foreign Governmental Authority, failed to disclose any material fact required to be disclosed to the FDA, the DEA or any similar state, local, federal, or foreign Governmental Authority, or committed an act, made a statement or failed to make a statement that, at the time such act, statement or omission was made, could reasonably be expected to provide a basis for the FDA, the DEA or any similar state, local, federal or foreign Governmental

Authority to invoke the FDA's policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" set forth in 56 Fed. Reg. 46191 (September 10, 1991) or any similar policy, nor has any director, officer, employee or, to the knowledge of the Licensor, agent of the Licensor been convicted of any crime or engaged in any conduct for which debarment is mandated by 21 U.S.C. Article 335a(a) (or any similar Law) or authorized by 21 U.S.C. Article 335a(b) (or any similar Law).

- 12.1.11 There are no suits or actions, administrative, arbitration or other proceedings, or governmental investigations pending or, to the knowledge of the Licensor, threatened against or affecting the Licensor with respect to Licensed Products or the Patent Rights. No Entity has notified the Licensor in writing of any material claim against the Licensor alleging any personal property or economic injury, loss or damage incurred as a result of or relating to the use of any Licensed Products. There is no judgment, order, injunction, decree, writ or award against the Licensor that is not satisfied and remains outstanding with respect to Patent Rights or any Licensed Product.
- 12.1.12 Schedule 12.1.12 hereto sets forth a true and complete list of each material license, contract or other agreements (together with certain other agreements and any amendments to any of the foregoing) to which the Licensor is a party or by or to which any property of the Licensor is otherwise bound or subject that relates to the Licensed Products or the Patent Rights (collectively, the "Material Agreements"). True and complete copies of all Material Agreements have been previously delivered to the Company. Each of the Material Agreements is valid, binding and in full force and effect, and enforceable by the Licensor, or has expired, in each case in accordance with its respective terms. No Person (other than the Licensor) that is a party to any Material Agreement or is otherwise bound thereby is, to the knowledge of the Licensor, in default or breach thereof and, to the Licensor's knowledge, no event, condition or act exists that, with the giving of notice or the lapse of time or both, would give rise to such a default or breach thereof or a right of cancellation by the Licensor thereunder. The Licensor is not in default or breach in any material respect of any of the Material Agreements and, to the knowledge of the Licensor, no event, condition or act exists that, with the giving of notice or the lapse of time or both, would give rise to a default or breach by the Licensor thereof or a right of cancellation thereunder by any other party thereto.
- 12.1.13 To the knowledge of the Licensor, none of the Patent Rights or Licensed Products, nor the practice, development, use, manufacture, sale, or import of any of the foregoing, infringes or conflicts in any material respect with (and the Licensor has not received any notice of infringement of, or conflict with) any license, patent, copyright, trademark, service mark or other intellectual property right of any Third Party and, to the knowledge of the Licensor, there has not been and is not currently any infringement or unauthorized use by any Third Party of any of the Patent Rights, Know-how, or Licensed Products. The validity or enforceability of any of the Patent Rights and or the title of the Licensor thereto has not been questioned in any litigation, governmental inquiry or proceeding to which the Licensor is a party and, to the knowledge of the Licensor, no such litigation, governmental inquiry or proceeding is threatened.

- 12.1.14 To the knowledge of the Licensor, the Licensor has taken all reasonable actions necessary or appropriate to preserve the confidentiality of all trade secrets, proprietary and other confidential information material to the Licensed Products, Know-how, and Patent Rights.
- 12.1.15 Licensor is not aware of any Third Party activities which would constitute misappropriation or infringement of the Patent Rights.
- 12.1.16 Licensor owns all right, title, and interest to the Licensor IND(s) (if any) free and clear of all liens, claims, and encumbrances, the Licensor IND(s) constitute the only INDs or regulatory filings of any kind concerning any Licensed Product, and there are no Governmental Approvals in place or effective in any jurisdiction with respect to any Licensed Product.
- 12.1.17 Schedule 12.1.17 contains a complete and accurate list of any and all regulatory approvals and filings for regulatory approval, worldwide, with respect to any Licensed Products (the "Worldwide Regulatory Filings and Approvals"). Licensor represents that it has provided Company with copies of all correspondence with the Governmental Authority with respect to each of the Worldwide Regulatory Filings and Approvals, as well as all other data and information of which Licensor is aware that would reasonably be expected to be material to the safety or efficacy of the Licensed Product.

## 12.2 Company Warranties

The Company represents and warrants that:-

- 12.2.1 The Company is a corporation duly organized, validly existing and in good standing under the laws of Delaware. The Company has the requisite power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement and the performance and consummation of the transactions contemplated hereby by the Company have been duly authorized by all necessary action on the part of the Company. This Agreement has been duly executed and delivered by the Company and, subject to the due authorization, execution and delivery of this Agreements by the Licensor, this Agreement constitutes a valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except as such enforcement may be affected by bankruptcy, reorganization, insolvency, moratorium or similar laws affecting creditor's rights generally and except for general principles of equity.
- 12.2.2 The execution and delivery of this Agreement does not, the consummation of the transactions contemplated hereby, and the performance of Company's obligations hereunder will not, (i) conflict with, or result in any violation or breach of any provision of the organizational documents of the Company, (ii) so far as the Company is aware conflict with or violate any applicable Laws of any Governmental Authorities applicable to the Company or any of its assets or operations or any permit applicable to the Company or (iii) result in (x) any violation or breach of, constitute (with or without notice or lapse of time or both) a default under or conflict with (or give rise to a right of termination, amendment, cancellation or acceleration of any material obligation or loss of any benefit under) the provisions of any lease, contract or other agreement to which the

Company is a party or by which it or any of its properties or assets is otherwise bound or (y) the imposition of any lien, pledge, hypothecation, mortgage, security interest, claim, lease, charge, option, right of first refusal or first offer, easement, servitude, transfer restriction, voting requirement or any other encumbrance, restriction or limitation on any of the properties or assets of the Company.

- 12.2.3 No Consent is required on the part of the Company in connection with its execution, delivery, and performance of this Agreement or the consummation of the transactions contemplated hereby.
- 12.2.4 Except as set forth on Schedule 12.2.4, as of the Effective Date: (i) there are no suits or actions, administrative, arbitration or other proceedings, or governmental investigations pending or, to the knowledge of the Company, threatened against or affecting the Company, (ii) no Entity has notified the Company in writing of any material claim against the Company alleging any personal property or economic injury, loss or damage incurred as a result of relating any action by the Company and (iii) there is no judgment, order, injunction, decree, writ or award against the Company that is not satisfied and remains outstanding with respect to any matter affecting the Company the Patent Rights, or any Licensed Product.
- 12.2.5 Company is not bound by any non-competition covenant or other agreement containing restrictions on Company which would reasonably be expected to have a material adverse affect on the ability of Company to perform its obligations under this Agreement.
- 12.2.6 To the actual knowledge of the Company, the sale in the Territory of the Licensed Product (in the form initially contemplated by the Company as of the Effective Date), does not infringe any third party patent issued in the Territory as of the Effective Date.

### **12.3 No Impairment**

Each party hereby covenants and agrees with the other that, during the Term, it will not, by act or failure to act, impair or otherwise adversely affect, or cause any occurrence which would reasonably anticipated to impair or otherwise adversely affect, the rights of the other under this Agreement or ability of the other party to freely exercise such rights.

## **Article 13 Limitation of Liability, Indemnity**

### **13.1 NO IMPLIED WARRANTIES**

- 13.1.1 EXCEPT AS SET FORTH IN ARTICLE 12, NEITHER PARTY MAKES AND EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND VALIDITY OF PATENTED RIGHTS CLAIMS, ISSUED OR PENDING.
- 13.1.2 EXCEPT AS SET FORTH IN ARTICLE 12, NOTHING HEREIN SHALL BE CONSTRUED AS A REPRESENTATION OR WARRANTY BY EITHER PARTY TO THE OTHER PARTY THAT THE PATENT RIGHTS AND KNOW-HOW ARE NOT INFRINGED BY ANY THIRD PARTY, OR THAT THE PRACTICE OF

SUCH RIGHTS DOES NOT INFRINGE ANY INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

**13.2 Indemnity**

13.2.1 The Company agrees to defend, indemnify and hold harmless Licensor, its Affiliates, and each of their respective directors, employees and officers (collectively, the "Licensor Indemnitees") from and against all liability, demands, damages, costs and expenses (including, without limitation, reasonable legal fees and expenses) and losses (collectively, "Losses") in connection with any third party claim arising out of or relating to: (i) any breach of this Agreement by Company, (ii) negligence, willful misconduct, or failure to comply with Applicable Laws by any Company Indemnitee in connection with this Agreement or (iii) any Company Indemnitee's use, manufacture, sale, or other disposition of Licensed Products under the terms of this Agreement (including, but not limited to, any claims for personal injury or property damage arising from the use thereof); in each of the foregoing cases to the extent not resulting from any Licensor Indemnitee's breach of this Agreement, negligence, willful misconduct, or failure to comply with Applicable Laws.

13.2.2 Licensor agrees to defend, indemnify and hold harmless the Company and its Affiliates and each of their respective directors, employees, and officers (collectively, the "Company Indemnitees") from and against all Losses in connection with any third party claim arising out of or relating to: (i) any breach of this Agreement by Licensor, (ii) negligence, willful misconduct, or failure to comply with Applicable Laws by any Licensor Indemnitee in connection with this Agreement, (iii) any Licensed Products sold by Licensor or any of its sublicensees or distributors following any termination of this Agreement, including, but not limited to, any claims for personal injury or property damage arising from the use thereof or (iv) any claims by any Sublicensees under any sublicense agreement assigned to Licensor following any termination of this Agreement, to the extent such claim relates to the period following the date of such termination.

13.2.3 In the event that either party intends to seek indemnification for any claim under Article 13.2.1 or 13.2.2, it shall inform the other party of the claim promptly after receiving notice of the claim.

In the case of a claim for which Licensor seeks indemnification under Article 13.2.1, Licensor shall permit the Company to direct and control the defense of the claim and shall provide such reasonable assistance as is reasonably requested by the Company (at the Company's cost) in the defense of the claim, provided that nothing in this Article 13.2.3 shall permit the Company to make any admission on behalf of Licensor, or to settle any claim or litigation which would impose any financial obligations on Licensor without the prior written consent of Licensor, such consent not to be unreasonably withheld or delayed.

In the case of a claim for which the Company seeks indemnification under Article 13.2.2, the Company shall permit Licensor to direct and control the defense of the claim and shall provide such reasonable assistance as is reasonably requested by Licensor (at Licensor's cost) in the defense of the claim, provided that nothing in this Article 13.2.3 shall permit Licensor to make any admission on behalf of the Company,

or to settle any claim or litigation which would impose any financial obligations on the Company without the prior written consent of the Company, such consent not to be unreasonably withheld or delayed.

### **13.3 LIMITATION OF LIABILITY**

EXCEPT WITH REGARD TO DAMAGES ARISING FOR INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS, BREACHES OF ARTICLE 14.3 OR 15, AND ANY DUTY TO INDEMNIFY FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES UNDER ARTICLE 13.2.1 OR 13.2.2, IN NO EVENT SHALL EITHER PARTY OR THEIR AFFILIATES BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY AND IRRESPECTIVE OF WHETHER SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF ANY SUCH LOSS OR DAMAGE.

## **Article 14 Use of Names and Publication**

### **14.1 Use of Name**

Nothing contained in this Agreement shall be construed as granting any right to the Company or its Affiliates to use in advertising, publicity, or other promotional activities any name, trade name, trademark, or other designation of Licensor or any of its units (including contraction, abbreviation or simulation of any of the foregoing) without the prior, written consent of Licensor; provided that Company may identify Licensor as the licensor under this Agreement without such consent to actual or potential investors, investment bankers, acquirers, acquisition targets, and strategic partners, and where the use of such names may be required by Applicable Law.

### **14.2 No Agency**

Nothing herein shall be deemed to establish a relationship of principal and agent between Licensor and the Company, nor any of their agents or employees for any purpose whatsoever. This Agreement shall not be construed as creating a partnership between the Licensor and the Company, or as creating any other form of legal association or arrangement, which would impose liability upon one party for the act or failure to act of the other party.

### **14.3 Publication**

In the event that Licensor or any Affiliate, employee, officer, director, or shareholder thereof desires to publish or disclose, by written, oral or other presentation, any information included in the Patent Rights, Know-how, or any material information related thereto, Licensor shall provide the Company with a copy of the proposed publication, presentation, or disclosure at least sixty (60) days prior to its submission for presentation, publication, or disclosure. The Company may request that Licensor, no later than sixty (60) days following the receipt of such proposed publication, presentation, or disclosure, (i) delay such presentation, publication or disclosure for up to an additional ninety (90) days in order to enable the Company to file, or have filed on their behalf, a patent application, copyright or other appropriate form of intellectual property protection related to the information to be disclosed or request that Licensor do so, (ii) remove the Company's Confidential Information from such presentation, publication or disclosure, and/or (iii) make any other reasonable changes to such proposed publication, presentation, or disclosure, as applicable. Upon receipt of such request, Licensor shall (i) arrange for a delay of such presentation, publication or disclosure until such time as the Company or Licensor have filed, or had filed on its behalf,

such patent application, copyright or other appropriate form of intellectual property protection in form and in substance reasonably satisfactory to the Company and Licensor, (ii) remove the Company's Confidential Information from such presentation, publication or disclosure, and/or (iii) reasonably consider any other reasonable changes proposed by the Company. If Licensor does not receive any request from the Company to delay such presentation, publication or disclosure, Licensor may submit such material for presentation, publication or other form of disclosure, subject to Licensor's obligations under Article 15.

#### **Article 15 Confidentiality**

##### **15.1 Confidentiality and Non-Use**

Any proprietary or confidential information relating to the Technology, Patent Rights, Know-how (including but not limited to patent prosecution documents relating to Patent Rights), reports and records provided under Article 7, and any other reasonably confidential or proprietary information concerning a party's business or technology disclosed to the other party under this Agreement collectively constitute the "Confidential Information." Neither party will use the Confidential Information for any purpose unrelated to the exercise of their rights or fulfillment of their obligations under this Agreement, and will hold it in confidence during the Term and for a period of five (5) years after the termination or expiration date of this Agreement. Each party shall exercise with respect to such the Confidential Information the same degree of care as the party exercises with respect to its own confidential or proprietary information of a similar nature, but in no event less than reasonable care, and shall not disclose it or permit its disclosure to any Third Party (except to those of its employees, consultants, or agents who are bound by a substantially similar obligation of confidentiality of this Agreement). However, such undertaking of confidentiality shall not apply to any information or data which:

- 15.1.1 The receiving party receives without obligation of confidentiality at any time from a third-party lawfully in possession of same and having the right to disclose same;
- 15.1.2 is, as of the date of this Agreement, in the public domain, or subsequently enters the public domain through no fault of the receiving party;
- 15.1.3 is independently developed by the receiving party as demonstrated by written evidence without reference to or benefit of information disclosed to the receiving party by the disclosing party;
- 15.1.4 is disclosed pursuant to the prior written approval of the disclosing party; or
- 15.1.5 is required to be disclosed pursuant to Applicable Law or legal process (including, without limitation, to a governmental authority) provided that recipient will (i) give prior written notice of such required disclosure to the other party, to the extent reasonably practicable, (ii) give reasonable assistance to the other party, as requested thereby, seeking confidential or protective treatment thereof, and (iii) only disclose such Confidential Information to the extent required by such Applicable Law or legal process.

##### **15.2 Limited Disclosure by Licensor**

Licensor acknowledges and agrees that the Know-how licensed to the Company has value to the Company in being maintained as confidential. Therefore, Licensor shall not disclose the Know-how to

any Third Party" (i) for use in the Territory without the Company's prior written consent or (ii) for use outside the Territory other than to recipients who have agreed in writing with Company to maintain the confidentiality of such Know-how.

**15.3 Material Non-Public Information**

The Licensor understands that it is the intent of the Company to register its capital stock on a national securities exchange, on the National Association of Securities Dealers, Inc. Automated Quotation System (collectively "NASDAQ"), or the Over The Counter Bulletin Board and accordingly, the Licensor understands that confidential information provided to it by the Company pursuant to the terms of this Agreement may constitute "material non-public information" concerning the Company.

**Article 16 Miscellaneous Provisions**

**16.1 Assignment**

This Agreement and the rights and duties appertaining hereto may not be assigned by either party without first obtaining the written consent of the other party, which consent shall not be unreasonably withheld. Any such purported assignment without the written consent of the other party shall be null and of no effect. Notwithstanding the foregoing, either party (the "Assigning Party") may assign this Agreement without the consent of the other party (i) to a purchaser, merging, or consolidating corporation, or acquirer of all or substantially all of the Assigning Party's assets or business (or that portion thereof to which this Agreement relates) and/or pursuant to any reorganization of the Assigning Party or (ii) to an Affiliate of the Assigning Party.

**16.2 Binding Nature and Inurement**

This Agreement will not be binding upon the parties until it has been signed below on behalf of each party, in which event, it shall be effective as of the Effective Date. As of the Effective Date, this Agreement is binding upon and inures to the benefit of the parties and their respective permitted successors and assigns.

**16.3 Counterparts; Facsimile**

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be signed and delivered to the other party by facsimile signature; such transmission will be deemed a valid signature.

**16.4 Entire Agreement; Amendment**

The parties hereto acknowledge that this Agreement, including the Exhibits, Schedules and documents incorporated by reference, sets forth the entire agreement and understanding of the parties hereto as to the subject matter hereof, and shall not be subject to any change of modification except by the execution of a written instrument subscribed to by the parties hereto and shall supersede all previous communications, representations or understandings, either oral or written, between the parties relating to the subject matter hereof. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the parties hereto unless reduced to writing and signed by the respective authorized officers of the parties.

**16.5 Force Majeure**

Neither party is responsible for delays resulting from causes beyond its reasonable control, including without limitation fire, explosion, flood, war, strike, or riot, provided that the nonperforming party uses commercially reasonable efforts to avoid or remove those causes of nonperformance and continues performance under this Agreement with reasonable dispatch whenever the causes are removed.

#### **16.6 Further Assurances**

From time to time during the Term, at the request of either party, the other party shall execute and deliver such documents and take such other action as the requesting party may reasonably request to consummate more effectively the transactions contemplated hereby.

#### **16.7 Headings**

The headings of the several articles are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

#### **16.8 Law**

This Agreement, and any and all disputes directly or indirectly arising from or relating to this Agreement, shall be construed, governed, interpreted and applied in accordance with the laws of the State of New York, without regard to principles of conflicts of laws.

#### **16.9 Payments, Notices and Other Communications**

Any payment, notice or other communication required or permitted to be given pursuant to this Agreement shall be in writing and sent by certified first class mail, postage prepaid, by hand delivery or by facsimile if confirmed in writing, in each case effective upon receipt, at the addresses below or as otherwise designated by written notice given to the other party:

In the case of Licensor:

Thornton & Ross Limited  
Linthwaite  
Huddersfield  
HD7 5QH  
Attn: Chairman  
Tel. No: 01484 842217  
Fax No: 01484 847201

With a copy to: Knif Steinart Levy  
3 St Mary's Parsonage  
Manchester M3 2RD  
United Kingdom

In the case of the Company:

Manhattan Pharmaceuticals, Inc.  
810 Seventh Avenue, 4<sup>th</sup> Floor  
New York, New York 10019  
USA  
Attn: President

Tel: (212) 582-3950  
Fax: (212) 582-3957

**16.10 Payment of Own Fees and Expenses**

Each of the Company and Licensor shall be responsible for their own expenses relating to the preparation and consummation of this Agreement and, except as specified herein, the agreements and transactions contemplated hereby.

**16.11 Severability**

The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions hereof.

**16.12 Waiver**

The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party. Any waiver of any rights or failure to act in a specific instance relates only to that instance and is not an agreement to waive any rights or fail to act in any other instance.

[Signature page to follow.]

**IN WITNESS WHEREOF**, the parties hereto have executed this Agreement, in triplicate by proper persons thereunto duly authorized.

**THORNTON & ROSS LTD.**

**MANHATTAN PHARMACEUTICALS, INC.**

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

**Schedule 1.15: Licensor IND(s)**

None.

**Schedule 1.21: Patent Rights**

United States Patent No. 7,109,246 titled "Pharmaceutical compositions comprising an amphoteric surfactant an alkoxylated cetyl alcohol and a polar drug"

Canadian Patent Application No. 2,330,330 titled "Pharmaceutical compositions comprising an amphoteric surfactant an alkoxylated cetyl alcohol and a polar drug"

**Exhibit 6.7**

**FORM OF  
SUBSCRIPTION AGREEMENT**

This Subscription Agreement, dated \_\_\_\_\_, 20\_\_ (the "*Agreement*"), by and between Manhattan Pharmaceuticals, Inc., a Delaware corporation having a place of business at 810 Seventh Avenue, 4th Floor, New York, New York 10019 (the "*Company*"), and Thornton & Ross, Ltd., a company duly incorporated under the laws of England and having a place of business at Linthwaite, Huddersfield, HD7 5QH (the "*Subscriber*").

**WITNESSETH**

WHEREAS, on April 3, 2007, Subscriber and the Company entered into an Exclusive License Agreement for "Altoderm" (the "*License Agreement*"), and the shares of common stock being issued hereby are being issued pursuant to Section 6.7 of the License Agreement in full satisfaction of a milestone payment earned by Subscriber pursuant to the subsection of Section 6.6 of the License Agreement described in Section 1 hereof.

NOW THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, each of the parties hereto agrees as follows:

*Section 1. Issuance of Common Stock.*

Pursuant to Section 6.6\_\_ of the License Agreement, and in full satisfaction of the milestone payment described in that subsection, the Company hereby sells, assigns, transfers, conveys and agrees to deliver to Subscriber \_\_\_\_\_ of the Company's common stock (the "*Shares*"), and Subscriber hereby accepts such Shares.

*Section 2. Subscriber Representations and Warranties.*

Subscriber hereby represents and warrants to the Company, as of the date hereof, as follows:

(a) Organization; Authority; Enforceability. Subscriber is a company duly organized, validly existing and in good standing under the laws of England. Subscriber has the requisite power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement and the performance and consummation of the transactions contemplated hereby by Subscriber have been duly authorized by all necessary action on the part of Subscriber. This Agreement has been duly executed and delivered by Subscriber and, subject to the due authorization, execution and delivery of this Agreement by the Company, this Agreement constitutes a valid and binding obligation of Subscriber, enforceable against Subscriber in accordance with its terms, except as such enforcement may be affected by bankruptcy, reorganization, insolvency, moratorium or similar laws affecting creditor's rights generally and except for general principles of equity.

(b) Purchase Entirely for Own Account. The Shares acquired by Subscriber hereunder are being acquired for investment for Subscriber's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof. Subscriber has no present intention of selling, granting any participation in, or otherwise distributing the same. Subscriber does not presently

have any contract, undertaking, agreement or arrangement with any person or entity to sell, transfer or grant participations to such person or entity or to any third party, with respect to any of the Shares. Subscriber has not been formed for the specific purpose of acquiring the Shares.

(c) Disclosure of Information. Subscriber hereby acknowledges that it has been furnished with, or has had an opportunity to acquire and carefully review, (i) the Company's most recently filed Annual Report on Form 10-KSB or 10-K (the "*10-KSB*"), (ii) the Company's Quarterly Reports on Form 10-QSB or 10-Q for the quarters ended after the date of the latest 10-KSB (the "*10-QSBs*"), (iii) the Company's Current Reports on Form 8-K filed with the U.S. Securities and Exchange Commission ("*SEC*") following the date of the latest 10-QSB, (iv) such other reports on filed by the Company with the SEC subsequent to the date of the 10-KSB. Subscriber further represents that Subscriber has been furnished by the Company during the course of this transaction with all information regarding the Company which Subscriber, his, her or its investment advisor, attorney and/or accountant has requested or desired to know, has been afforded the opportunity to ask questions of and receive answers from duly authorized officers or other representatives of the Company concerning the Company, and has received any additional information which the Subscriber has requested.

(d) Restricted Securities. Subscriber understands that Rule 144 promulgated under the U.S. Securities Act of 1933, as amended (the "*Securities Act*") requires, among other conditions, a minimum holding period of one-year prior to the resale (in limited amounts) of securities acquired in a non-public offering without having to satisfy the registration requirements under the Securities Act. Subscriber understands that the Shares have not been, and will not be, registered under the Securities Act or any state securities or "blue sky" law by reason of a specific exemption from the registration provisions of that act which depends upon, among other things, the bona fide nature of the investment intent and the accuracy of the Subscriber's representations as expressed herein. Subscriber understands that the Shares are "restricted securities" under applicable U.S. federal and state securities laws and that, pursuant to these laws, Subscriber must hold the Shares indefinitely unless they are registered with the U.S. Securities and Exchange Commission and qualified by state authorities, or an exemption from such registration and qualification requirements is available. Subscriber acknowledges that the Company has no obligation to register or qualify the Shares for resale. Subscriber further acknowledges that if an exemption from registration or qualification is available, it may be conditioned on various requirements including, but not limited to, the time and manner of sale, the holding period for the securities, and on requirements relating to the Company which are outside of Subscriber's control, and which the Company is under no obligation and may not be able to satisfy.

(e) Illiquidity. Subscriber understands, acknowledges and agrees with the Company that there can be no assurance that Subscriber will be able to sell or dispose of the Shares. It is understood that in order not to jeopardize the exempt status under Section 4(2) of the Securities Act, and Regulation D promulgated thereunder, of the issuance of the Shares hereunder, any transferee may, at a minimum, be required to fulfill the investor suitability requirements thereunder.

(f) Legends. Subscriber understands, acknowledges and agrees that the issuance of the Shares hereunder has not been reviewed, recommended or endorsed by the SEC or any state securities regulatory authority or other governmental body or agency, since the such issuance is intended to be exempt from the registration requirements of Section 5 of the Securities Act pursuant to Regulation D promulgated under the Securities Act. Subscriber understands that the Shares shall bear a "restricted securities" legend similar to the following (and any other legend required by U.S. federal or state securities laws):

"THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE U.S. SECURITIES ACT OF 1933, AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH TRANSFER MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL IN A FORM SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933."

(g) Accredited Investor. Subscriber is an accredited investor as defined in Rule 501(a) of Regulation D promulgated under the Securities Act.

(h) No General Solicitation. Subscriber represents that no Shares were offered or sold to it by means of any form of general solicitation or general advertising, and in connection therewith Subscriber did not: (A) receive or review any advertisement, article, notice or other communication published in a newspaper or magazine or similar media or broadcast over television or radio whether closed circuit, or generally available; or (B) attend any seminar meeting or industry investor conference whose attendees were invited by any general solicitation or general advertising.

Section 3. Deliveries. Promptly after the Company's receipt of the executed signature page hereof, and the Company's determination that the Company is required to deliver the Shares to satisfy the milestone payment referenced in Section 1 hereof, the Company shall deliver to Subscriber (i) an executed counterpart of this Agreement and (ii) a certificate representing the Shares registered in the name of the Subscriber.

Section 4. Miscellaneous.

(a) This Agreement and any controversy arising, directly or indirectly, out of or relating to this Agreement shall be governed by and construed in accordance with the General Corporation Law of the State of Delaware as to matters within the scope thereof, and as to all other matters shall be governed by and construed in accordance with the internal laws of State of New York, without regard to conflict of law principles that would result in the application of any law other than the law of the State of New York. The parties hereto (i) hereby irrevocably and unconditionally submit to the jurisdiction of the state courts of New York and to the jurisdiction of the United States District Court for the Southern District of New York for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (ii) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the state courts of New York or the United States District Court for the Southern District of New York, and (iii) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

(b) Any notice or other communication required or permitted to be given pursuant to this Agreement shall be in writing and sent by certified first class mail, postage prepaid, by hand delivery or by facsimile if confirmed in writing, in each case effective upon receipt, at the addresses set forth in the preamble hereof, or as otherwise designated by written notice given to the other party.

(c) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and may be amended only by a writing executed by both parties hereto.

(d) This Agreement may be executed in counterparts, each of which shall be deemed an original instrument, but all of which shall together constitute one and the same instrument.

[Signature Page Follows.]

IN WITNESS WHEREOF, the parties hereto have executed this Subscription Agreement as of the date first above written.

MANHATTAN PHARMACEUTICALS, INC.

By: \_\_\_\_\_

Name:

Title:

THORNTON & ROSS, LTD.

By: \_\_\_\_\_

Name:

Title:

**Schedule 12.1.12: Material Agreements**

None.

**Schedule 12.1.17 Worldwide Regulatory Filings and Approvals**

Application for approval filed in the United Kingdom.

**Schedule 12.2.4: Company Claims**

In February 2007, a former employee of the Company alleged an ownership interest in two of the Company's provisional patent applications. Also, without articulating precise legal claims, the former employee contends that the Company wrongfully characterized the former employee's separation from employment as a resignation instead of a dismissal in an effort to harm the former employee's immigration sponsorship efforts, and, further, to wrongfully deprive the former employee of the former employee's alleged rights in two of the Company's provisional patent applications. The former employee is seeking an unspecified amount in damages. The Company refutes the former employee's contentions and intends to vigorously defend itself should the former employee file claims against the Company.

**EXECUTION COPY**

**EXCLUSIVE LICENSE AGREEMENT**

**FOR "ALTOLYN"**

**between**

**THORNTON & ROSS LTD.**

**and**

**MANHATTAN PHARMACEUTICALS, INC.**

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EXCLUSIVE LICENSE AGREEMENT FOR "ALTOLYN"

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## EXCLUSIVE LICENSE AGREEMENT FOR "ALTOLYN"

This Exclusive License Agreement for "Altolyn" (hereinafter referred to as this "Agreement"), effective as April 3, 2007 (the "Effective Date"), is entered into by and between **THORNTON & ROSS LTD.**, a company duly incorporated under the laws of England and having a place of business at Linthwaite, Huddersfield, HD7 5QH ("Licensor"), and **MANHATTAN PHARMACEUTICALS, INC.**, a corporation duly organized and existing under the laws of the State of Delaware having a place of business at 810 Seventh Avenue, 4<sup>th</sup> Floor, New York, New York 10019 (the "Company").

**WHEREAS**, Licensor is the sole owner of all right, title and interest in the Patent Rights (as defined below), and Know How (as defined below) related thereto used in the formulation of and to manufacture the Licensed Product (as defined below);

**WHEREAS**, the Company is interested in obtaining exclusive license under the Patent Rights and Know How in the Field of Use (as defined below) to make, have made, use, have used, lease, import and export, offer to sell, sell have sold, produce, manufacture, distribute and market products made in accordance with such rights; and

**WHEREAS**, Licensor wishes to grant to the Company an exclusive license under the Patent Rights and Know How, in the Field of Use (as defined below) to make, have made, use, have used, lease, import and export, offer to sell, sell have sold, produce, manufacture, distribute and market products made in accordance with such rights;

**NOW, THEREFORE**, in consideration of the foregoing recitals, the premises and the mutual covenants contained herein, the parties hereto, intending to be legally bound, agree as follows:

### Article 1 Definitions

For the purposes of this Agreement, the following words and phrases shall have the following meanings:

#### 1.1 "Affiliate"

means, with respect to any Person, any other Person which directly or indirectly controls, is controlled by, or is under common control with, such Person. A Person shall be regarded as in control of another Person if it owns, or directly or indirectly controls, at least fifty percent (50%) of the voting stock or other ownership interest of the other Person, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other Person by any means whatsoever.

#### 1.2 "Applicable Law(s)"

means, with respect to the United States, the FDCA (as defined below), all regulations promulgated thereunder, and all other applicable laws, rules, regulations and guidelines within the Territory that apply to the import, export, research and development, manufacture, marketing, distribution, or sale of Licensed Products in the Field of Use in the Territory and the use of the Trade Mark in relation thereto or the performance of either party's obligations under this Agreement (including disclosure obligations as required by the United States Securities and Exchange Commission or other comparable exchange or securities commission having authority over a party) to the extent applicable and relevant to such party.

#### 1.3 "Competent Authority(ies)"

means collectively the entities in each country in the Territory responsible for (a) the regulation of medicinal products or medical devices, as applicable, intended for human use or the establishment, maintenance and/or protection of rights related to the Patent Rights, including but not limited to the FDA and any other applicable administrative agency in any country in the Territory having the aforementioned responsibilities, and any successor entities thereto, (b) the establishment, maintenance and/or protection of rights related to the Patent Rights, including the United States Patent and Trademark Office ("USPTO"), and (c) any other applicable regulatory or administrative agency in any country in the Territory that is comparable to, or a counterpart of, the foregoing.

**1.4 "Development"**

means the Company's, its Affiliates', or Sublicensees' use of commercially reasonable efforts to secure Marketing Authorizations for Licensed Products in the Territory.

**1.5 "DMF"**

means a drug master file, as provided for in 21 CFR § 314.420, or similar submission to or file maintained with the FDA or other Competent Authority that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.

**1.6 "FDCA"**

means the United States' Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated with respect thereto.

**1.7 "FDA"**

means the United States Food and Drug Administration and any successor entity thereto.

**1.8 "Field of Use"**

means all fields of use.

**1.9 "First Commercial Sale"**

means, with respect to any Licensed Product, the first sale of such Licensed Product after all applicable Marketing Authorizations (if any) have been granted by the applicable Competent Authority(ies).

**1.10 "Governmental Approval(s)"**

means any and all permits, licenses, approvals, and authorizations required by any Competent Authority as a prerequisite to the development, manufacturing, packaging, marketing, and selling of a Licensed Product in the Field of Use in the Territory.

**1.11 "IND(s)"**

means an investigational new drug application as defined in 21 C.F.R. Part 312 et seq in the United States (as may be amended, supplemented or replaced from time to time), or equivalent application to any Competent Authority of any other country in the Territory, to commence clinical testing of a drug,

including but not limited to any amendments, supplements, or supporting correspondence with respect thereto.

**1.12 “Improvements”**

shall mean any modification, enhancement, or improvement of a Licensed Product, or any inventions, discoveries, improvements (whether patentable or not), information, and data, owned or controlled by Licensor or the Company (as the case may be) any time during the Term, which would be useful or necessary in the manufacture, use, or sale of any Licensed Product, such improvements to be designated “Licensor Improvements” or “Company Improvements,” as the case may be.

**1.13 “Know-how”**

shall mean all tangible or intangible information and know-how (other than that which is the subject of a Valid Claim in the Patent Rights), whether patentable or not (but which has not been patented), related to the Licensed Product, or any Licensor Improvement or which is useful to or necessary for the Company to develop or commercialize any Licensed Product (including but not limited to: trade secrets, formulations, protocol, results of experimentation, in vitro, preclinical or clinical design, information or results, other proprietary materials, processes, including but not limited to manufacturing processes, data, drawings and sketches, designs, testing and test results, regulatory information of a like nature), owned or controlled by Licensor as of the Effective Date or which Licensor obtains the right to disclose and license to the Company during the Term.

**1.14 “Licensed Product(s)”**

shall mean any product (including but not limited to an oral formulation product using sodium cromoglicate for use in the treatment of mastocytosis, food allergies, inflammatory bowel disorder, or any other conditions) which is made in accordance with the Patent Rights. For the avoidance of doubt, the “Licensed Products” include, without limitation, that certain oral formulation product using sodium cromoglicate known as “Altolyn,” for which Licensor intends to seek regulatory approval in the United Kingdom and other jurisdictions outside the Territory.

**1.15 “Licensor IND(s)”**

means the INDs, whether now existing or previously submitted, described on [Exhibit 1.15](#), and any filings, updates, material correspondence, or material communications to or from any applicable Competent Authority with respect thereto.

**1.16 “Marketing Authorization”**

means all necessary and appropriate regulatory approvals, including but not limited to NDAs and reimbursement and pricing approvals, to allow a Licensed Product to be marketed and sold in the Field of Use in a particular country in the Territory.

**1.17 “Milestone Payment”**

means the payments set out in Article 6.6 and “Milestone” means any one of the steps to be taken as set out in Article 6.6.

**1.18 “NDA”**

means a New Drug Application as defined in 21 C.F.R. Part 314.50 et seq. in the United States (as may be amended, supplemented or replaced from time to time), or equivalent application to any Competent Authority of any other country in the Territory, to commence commercial sale and marketing of a drug for human use, including but not limited to any amendments, supplements, or supporting correspondence with respect thereto.

**1.19 "Net Sales"**

shall have the meaning set out below:

- 1.19.1 "Net Sales" shall mean the total gross receipts for sales of Licensed Products to customers who are not Affiliates (or are Affiliates, but are end users of the Licensed Products) by or on behalf of the Company or any of its Affiliates (and, to the extent included pursuant to Article 6.2 below, its Sublicensees), whether invoiced or not, less only the sum of the following:
- (a) usual trade discounts to customers, including but not limited to cash, quantity and trade discounts, rebates and other price reductions for such Licensed Product given to such customers;
  - (b) sales, tariff duties, value-added tax and/or use taxes directly imposed and with reference to particular sales;
  - (c) amounts allowed or credited on charge-backs and/or returns;
  - (d) bad debt deductions and uncollectible amounts actually written off during the accounting period;
  - (e) outbound transportation prepaid or allowed and transportation insurance;
  - (f) sales commissions;
  - (g) packaging, freight, and insurance charges;
  - (h) customs duties, surcharges and other governmental charges incurred in exporting or importing such Licensed Product to such customers; and
  - (i) wholesaler discounts and government chargebacks
- 1.19.2 Components of Net Sales (and the deductions listed above) shall be determined in the ordinary course of business in accordance with U.S. GAAP.
- 1.19.3 Notwithstanding anything herein to the contrary, the transfer of a Licensed Product to an Affiliate, Sublicensee, or other Third Party in connection with the research, development or testing of a Licensed Product or for purposes of resale shall not be considered a sale of a Licensed Product under this Agreement. Nor shall the transfer of Licensed Product solely for indigent or similar public support or compassionate use programs be considered a sale of Licensed Product under this Agreement.

- 1.19.4 In the case of discounts on “bundles” of separate products or services which include Licensed Products, the Company may discount (or enable its Affiliates and Sublicensees to discount) the bona fide list price of a Licensed Product by the average percentage discount of all products of the Company and/or its Affiliates and Sublicensees in a particular “bundle”, calculated as follows:

$$\text{Average percentage discount on a particular "bundle"} = 1 - (X/Y) \times 100$$

where X equals the total discounted price of a particular “bundle” of products, and Y equals the sum of the undiscounted bona fide list prices of each unit of every product in such “bundle”. The Company shall provide Licensor documentation reasonably supporting such average discount with respect to each “bundle.” If a Licensed Product in a “bundle” is not sold separately, and no bona fide list price exists for such Licensed Product, the Company shall determine in good faith a reasonable imputed list price for such Licensed Product and Net Sales with respect thereto shall be based on such imputed list price.

#### 1.20 “Non-Royalty Sublicensing Income” or “NRSI”

means, aggregate cash consideration received from a Sublicensee in consideration for grant of a sublicense under the rights granted to the Company hereunder, which shall include sublicense issue fees and non-sales related sublicense milestone payments received by the Company as consideration for the sublicensing by the Company of its rights under this Agreement to commercialize Licensed Products, but shall exclude the following payments as determined by the Company in good faith and subject as provided in Article 6.4 (a) payments received from the sale, issuance or exchange of debt or equity securities of the Company; (b) payments received by the Company that are specifically designated in any agreement with a Third Party to be dedicated to the research and development of the Technology or the establishment of a direct sales force; (c) payments resulting from or calculated on the basis of the sale of one or more Licensed Products, including sales milestones and royalties; and (d) payments received to reimburse Company’s or its Affiliates’ cost to perform research, development or similar services conducted for such Licensed Product after signing the agreement with the Third Party, or in reimbursement of patent or other out-of-pocket expenses relating to such Licensed Product.

#### 1.21 “Patent Rights”

means

- 1.21.1 all U.S. and Canadian patents and patent applications set forth in Schedule 1.21;
- 1.21.2 any and all US or Canadian patents, patent applications, or other rights issuing from, or filed subsequent to the date of this Agreement, based on or claiming priority to or from the applications, patents, and rights listed on Schedule 1.21, including but not limited to continuations, continuations in part, divisionals, reexaminations, extensions, reissues, substitutions, renewals, supplementary protection certificates, registrations, and confirmations of any of the foregoing, and any patents resulting from any application or right included in Articles 1.21.1 or 1.21.2;

- 1.21.3 any other intellectual property rights in the Territory relating to any oral formulation product using sodium cromoglicate for use in the treatment of mastocytosis, food allergies, inflammatory bowel disorder or any other conditions (except where the rights involve the use of sodium cromoglicate with another active ingredient which produces a product which requires its own Government Approval) that are owned or controlled by the Licensor or that Licensor has the ability to license to the Company as of the date of this Agreement, or which Licensor acquires, or acquires the right to license to Company, after the Effective Date, and any and all US or Canadian patents, patent applications, or other rights, including continuations, continuations in part, divisionals, reexaminations, extensions, reissues, substitutions, renewals, supplementary protection certificates, registrations, and confirmations of such rights claiming or relating to, in each case, any oral formulation product using sodium cromoglicate for use in the treatment of mastocytosis, food allergies, inflammatory bowel disorder or any other conditions except as aforesaid;
- 1.21.4 any other intellectual property rights in the Territory owned or controlled by the Licensor at any time during the Term of this Agreement relating to or claiming an Improvement or that Licensor has the ability to license or gains the ability to license to the Company relating to or claiming an Improvement (except where such improvement produces a product which requires its own separate Government Approval); and any and all US or Canadian patents, patent applications, or other rights, including continuations, continuations in part, divisionals, reexaminations, extensions, reissues, substitutions, renewals, supplementary protection certificates, registrations, and confirmations of such rights relating to or claiming, in each case, an Improvement; and
- 1.21.5 any Licensor information useful or necessary to file and obtain issuance in the Territory of valid patent claims relating to the use, manufacture, development, administration, delivery, formulation, dosing, packaging, and handling of the Know-how, the Licensed Products or any other oral formulation product using sodium cromoglicate for use in the treatment of mastocytosis, food allergies, inflammatory bowel disorder or any other conditions (except where such information produces a product which requires its own separate Government Approval).

The parties shall use commercially reasonable efforts to ensure that Schedule 1.21 shall be amended in writing from time to time to reflect the foregoing, provided that any failure to do so shall not limit the scope of the definition of Patent Rights established above.

**1.22 "Person"**

means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint venture, non-profit organization, pool, syndicate, sole proprietorship, unincorporated organization, university, governmental authority or any other form of entity not specifically listed herein

**1.23 "Phase I Trial"**

means a clinical trial that generally provides for the first introduction into humans of a Licensed Product with the primary purpose of determining safety, metabolism and pharmacokinetic properties and clinical pharmacology of the Licensed Product, and generally consistent with 21 CFR § 312.21(a).

**1.24 “Phase II Trial”**

means a clinical trial of a Licensed Product on patients, including possibly pharmacokinetic studies, the principal purpose of which is to make a preliminary determination that such Licensed Product is safe for its intended use and to obtain sufficient information about such Licensed Product’s efficacy to permit the design of further clinical trials, and generally consistent with 21 CFR § 312.21(b).

**1.25 “Phase III Trial”**

means a pivotal human clinical trial of a Licensed Product, which trial is designed to: (a) establish that a Licensed Product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed; (c) support Marketing Authorization of such Licensed Product; and (d) generally consistent with 21 CFR § 312.21(c).

**1.26 “Registration(s)”**

means any and all permits, licenses, authorizations, registrations or regulatory approvals (including, but not limited to, IND or NDA) required and/or granted by any Competent Authority as a prerequisite to the development, manufacturing, packaging, shipping, marketing and/or selling of any product.

**1.27 “Royalty Term”**

means, on a country-by-country and Licensed Product-by-Licensed Product basis, the period commencing on the date of the applicable First Commercial Sale and ending on the date of the last to expire Patent Right covering a Licensed Product in such country.

**1.28 “Sublicensee”**

means a Third Party that has entered in to an agreement with the Company licensing to such Third Party any of the rights granted to the Company by the Licensor pursuant to Article 2.1, or a Third Party that has entered into a license agreement with any such Sublicensee licensing such Third Party the rights granted to the Company by the Licensor and granted to such subsequent Third Party licensee by the Sublicensee.

**1.29 “Successful Outcome”**

means an outcome of a Phase III Trial with data reasonably determined by Company to be sufficient to support final approval by the FDA of an NDA with respect to the Licensed Product (including, but not limited to, data from any supporting pharmacokinetic studies and toxicology studies (including, but not limited to any carcinogenicity, and developmental and reproductive toxicology studies)).

**1.30 “Term”**

has the meaning set out in Article 11.1.

**1.31 “Territory”**

means: (i) the United States, its territories and possessions and United States military bases throughout the world and (ii) Canada.

**1.32 “Third Party”**

mean any Person other than Licensor, Company and their respective Affiliates.

**1.33 “Trade Mark”**

means the trade mark “Altolyn,” including, but not limited to, all rights under any trademark applications and registrations with respect thereto in the Territory.

**1.34 “Valid Claim”**

means any pending or issued claim included within the Patent Rights that has been filed in good faith and has not been withdrawn, permanently revoked, abandoned nor deemed unenforceable, unpatentable, or invalid by a decision of a court or other governmental agency of competent jurisdiction that is unappealable or unappealed in the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

**Article 2 License Grant**

**2.1 Grant of License**

Licensor hereby grants to the Company an exclusive license, with rights to grant sublicense as further described below, in the Field of Use to practice under the Patent Rights and to utilize the Know-how and the “Altolyn” mark and name in the Territory, including to:

- 2.1.1 conduct research, make, have made, use, have used, import, have imported, export, have exported, offer for sale, have sold, sell, produce, manufacture, distribute and market Licensed Products to the full end of the Royalty Term, unless sooner terminated as hereinafter provided; and
- 2.1.2 sublicense to third parties, through multiple tiers, in accordance with Article 2.2 below, the rights granted under Article 2.1.1.

**2.2 Sublicenses**

- 2.2.1 The Company shall have the right to sublicense rights granted in Article 2.1 in its sole discretion with the prior consent in writing of Licensor, which consent should not be unreasonably withheld or delayed, and Sublicensees shall have the right to grant further sublicenses in their sole discretion with the prior consent of the Licensor, which consent shall not be unreasonably withheld or delayed, but the Company shall continue to remain responsible for the performance of its obligations under this Agreement if a Sublicensee is appointed. Each sublicense agreement: (i) shall contain terms and conditions requiring the applicable sublicensee to provide Data (as defined in Section 11.5 below) created by or on behalf of such sublicensee to the Licensor, on terms and under circumstances analogous to those set forth herein (namely Articles 3.1, 5.5, 11.2, 11.5 and 11.6), in the event the applicable sublicense agreement with the Sublicensee is terminated after having been assigned to and assumed by Licensor (as provided below in this Article 2.2.1), (ii) shall otherwise not conflict with the terms and conditions set forth herein and (iii) shall name Licensor as a third party beneficiary of the sublicense agreement. The Company will keep

Licensor reasonably apprised of the status of negotiations with prospective Sublicensees. All sublicenses granted under this Article 2.2.1 by the Company shall survive and be automatically assigned to and assumed by Licensor upon termination of this Agreement, *provided however*, Licensor shall not be obligated to incur any obligations in excess of those of Licensor contained herein.

- 2.2.2 Notwithstanding the foregoing, if the Company believes that Licensor has terminated this Agreement for the primary purpose of doing business directly with the Sublicensee, the termination may be disputed under the provisions of Article 10.

### Article 3 Technology and Regulatory Transfer

#### 3.1 Technology and Regulatory Transfer

Upon execution of this Agreement, (i) Licensor shall transfer to the Company, at no additional cost, all Know-how, which shall include but not be limited to copies of all pre-clinical or clinical data, trade secrets, human safety data, preliminary efficacy data (further including, but not limited to, any of the foregoing data relating to any Licensor applications for regulatory approval of the Licensed Product in the United Kingdom, European Union and any other jurisdictions outside the Territory), and other regulatory data related to any Licensed Product in its possession, and (ii) Licensor hereby assigns all right, title, and interest in the Licensor IND(s), if any, to the Company, free and clear of all liens, claims, and encumbrances.

Licensor shall, at Licensor's cost, take any and all actions requested by the Company to effect the purposes of the foregoing as promptly as practicable following the execution of this Agreement and on an ongoing basis thereafter, which shall include but not be limited to (i) preparing and filing whatever filings, requests or applications are required or deemed advisable to be filed with any Regulatory Authority, if any, in connection with the assignment of any Licensor IND(s) (including but not limited to, if applicable with respect to the FDA, a "transfer of ownership letter") and (ii) taking all reasonable actions necessary to enable the Company to undertake the manufacture, development and commercialization of Licensed Products under this Agreement. Such actions shall include providing the Company with the following items relating to the Licensed Products (regardless of whether such item relates to the Territory or any jurisdiction outside the Territory), to the extent such items are within the possession or control of Licensor as of the Effective Date or come within the possession or control of Licensor at any time thereafter and the Licensor has the right to transfer or communicate the same (and the Licensor will notify the Company of any potential limitations on its right to transfer or communicate any of the foregoing to the Company and will use commercially reasonable efforts to overcome any such limitations):

- a. copies of all regulatory submissions;
- b. any communications with Competent Authorities and the minutes of any meetings with Competent Authorities, as well as any communications with and minutes of any meetings with any analogous regulatory authorities outside the Territory;
- c. DMFs and any trial, drug, device, or other master files relating to any Licensed Product, including copies of all case report forms;
- d. copies of all listings and tables of results from the clinical trials relating to any Licensed Product;

- e. copies of all treatment-related serious adverse event reports from the clinical trials relating to any Licensed Product;
- f. storage of and access permission to any retained samples of materials used in clinical trials relating to any Licensed Product;
- g. access to contract and clinical research organizations involved in the preclinical studies and clinical trials relating to any Licensed Product;
- h. the data, files and results of any chemistry, manufacturing, or control-related activities regarding any Licensed Product; and
- i. all other information that the Company may reasonably request that may be useful to the Company for the manufacturing of Licensed Products or conducting preclinical studies and clinical trials and other development activities with respect to each Licensed Product, and the commercialization of Licensed Products.

The Company shall during the Term keep Licensor reasonably informed of any data developed by or on behalf of Company that may be used in support of regulatory filings for the Licensed Product (including, but not limited to, pre-clinical and clinical trial data, human safety data and efficacy data) (the "Company Data"), as well as any regulatory filings made and approvals obtained by the Company with respect to the Licensed Product in the Territory and the Company shall deposit, at Licensor's expense, copies of the Company Data and such regulatory filings with its lawyers or an agreed third party escrow agent together with the necessary permission to allow right of reference to such material by Licensor and shall issue an irrevocable instruction to release such items to the Licensor if this Agreement is terminated pursuant to Article 11.2 and the Company shall procure that all sub-licensees accept this obligation to the Licensor. In addition the Company shall confirm to the Licensor from time to time that it has so deposited such items as provided in this Article 3.1, and the Company shall procure that all sub-licensees accept this obligation to the Licensor. Licensor will notify Company if it wishes to obtain a nonexclusive license to the Company Data (or portion thereof) and/or rights of reference to such regulatory filings and approvals, in each case solely for use in connection with regulatory filings outside the Territory. Provided that Company has the right to grant such license and/or rights of reference, upon receipt of such notice from Licensor, the parties will negotiate in good faith with respect to the terms and conditions of such license and/or rights of reference (including commercially reasonable compensation to be paid to Company for such license and/or rights of reference). Any such terms and conditions agreed upon by the parties shall be set forth in writing and signed by authorized representatives of both parties.

### **3.2 Technical Assistance**

Without limiting Licensor's other obligations hereunder, Licensor shall provide such technical assistance to Company as Company reasonably requests regarding the Patent Rights, Know-how and Licensed Products, including without limitation: (i) providing Company with reasonable access to Licensor's employees and consultants involved in the development, formulation and regulatory approval outside the Territory of the Licensed Products and (ii) providing to Company all or part of Licensor's inventory of GMP and non-GMP Licensed Products, as the parties mutually agree. Company shall pay to Licensor its documented reasonable out-of-pocket costs of providing such technical assistance, subject to Company's prior, written approval of such costs in each case.

## Article 4 Regulatory Compliance

### 4.1 Ownership and Maintenance of Governmental Approvals

- 4.1.1 The Company will own all Marketing Authorizations for each country in the Territory for Licensed Products. Without limiting the generality of the foregoing, the Company shall prepare and submit in its own name and at its expense NDAs with the FDA in the U.S. and any other equivalent application with the Competent Authorities in other countries in the Territory.
- 4.1.2 The Company shall secure and maintain in good standing, at its sole cost and expense, any and all Governmental Approvals (including, Marketing Authorizations, licenses, permits and consents, facility licenses and permits required by Applicable Laws or by the applicable Competent Authorities) necessary and/or required for the Company to perform its obligations under this Agreement and use commercially reasonable efforts at its cost and expense to secure and maintain any variations and renewals thereof. Licensor shall promptly notify Company of any written or oral notices received from, or inspections by, any Competent Authority relating to any such Governmental Approvals.
- 4.1.3 To the extent Licensor is or becomes the holder of any Governmental Approval referred to in Article 4.1.2 above, during the time that Licensor holds such Governmental Approval, Licensor shall (i) promptly provide Company an advance draft of any proposed responses to such written notices or inspections and the resolution of any issue raised by such Competent Authority and (ii) make such reasonable changes to such proposed response as may be recommended by Company, and the Company shall be entitled to attend any and all meetings and participate in telephone calls with the Competent Authorities, including without limitation any meeting preparation, meeting co-ordination and preparation of minutes.

### 4.2 Rights of Reference

Licensor shall grant and hereby grants Company a free-of-charge right to reference and use and have full access to all preclinical and clinical data, information, and results, Governmental Approvals, and all other regulatory documents relating to or useful for the Development of the Licensed Products, including but not limited to any IND, NDA, DMF (whether as an independent document or as part of any Governmental Approval), and all chemistry, manufacturing and controls information, and any supplements, amendments or updates to the foregoing, where such regulatory documents are owned, licensed, or controlled by Licensor and the Licensor has the right to transfer or communicate the same, and all analogs to any of the foregoing outside the Territory (for the purposes of this Article, the "Right of Reference"). The Licensor will notify the Company of any potential limitations on its right to transfer or communicate any Right of Reference to the Company and will use commercially reasonable efforts to overcome any such limitations. The Company may license the Right of Reference to Affiliates and to Sublicensees.

### 4.3 Access to Manufacturers

Licensor grants to the Company a free of charge, worldwide right to access and/or sublicense any suppliers of the Licensed Product and any form, component, or ingredient of or precursor to the Technology or any Licensed Product, and shall, if and as requested by the Company, reasonably assist

Company in establishing supply relationships with such suppliers on commercially reasonable terms and/or assigning any relevant supply agreements to the Company. In addition, if requested by Company, the parties will negotiate in good faith for commercially reasonable terms on which Licensor would supply Licensed Products (and/or ingredients thereof) to the Company.

## **Article 5 Development and Commercialization**

### **5.1 Development**

The Company shall use commercially reasonable efforts, itself or through the activities of its Sublicensees and Affiliates, to perform the Development and secure the Marketing Authorizations for Licensed Products. For the avoidance of doubt, the Company's development obligations under this Agreement (including, but not limited to, the development timelines set forth in Section 11.6 below) shall apply only with respect to the development of an initial Licensed Product for the treatment of mastocytosis. The Company shall have the right, but not the obligation, to develop Licensed Products for other indications in its sole discretion.

### **5.2 Commercialization**

The Company shall, following receipt of the necessary Marketing Authorizations, use commercially reasonable efforts to, itself or through the activities of its Sublicensees and Affiliates, commence marketing of, and to promote, market, sell and commercialize thereafter, Licensed Products in the Territory. For the avoidance of doubt, Company and the Sublicensees may market the Licensed Products under the "Altolyn" name or such other brand as may be selected by the Company and/or the Sublicensees, provided that if the "Altolyn" name is used it is identified as a registered trade mark of Licensor and the Licensor is accorded all rights under Applicable Laws usually accorded to owners of trade marks in the Territory.

### **5.3 Clinical Trial Cooperation**

The parties shall discuss in good faith opportunities to avoid duplication of effort and achieve cost savings and other efficiencies with respect to any clinical trials to be conducted by the Company for the Licensed Products.

### **5.4 Non-Compete**

During the term of this Agreement, other than sales of Licensed Products by Company and Sublicensees hereunder, neither party nor any of their respective Affiliates shall market or sell (or license any third party to market or sell) in the Territory: (i) any oral formulation product that contains sodium cromoglicate as an active pharmaceutical ingredient (whether the sole active pharmaceutical ingredient or in combination with any another active pharmaceutical ingredients) or (ii) any other product for the treatment of mastocytosis, food allergies and/or inflammatory bowel disease.

### **5.5 Company Improvements**

Company will keep Licensor reasonably informed of any Company Improvements it makes in the course of the Development. Licensor will notify Company if it wishes to obtain a nonexclusive license to any

such Company Improvement, in each case solely for use in connection with Licensed Products to be sold in countries outside the Territory. Provided that Company has the right to grant such license, upon receipt of such notice from Licensor, the parties will negotiate in good faith with respect to the terms and conditions of such license (including commercially reasonable royalties and other compensation to be paid to Company for such license).

**5.6 Annual Review Meetings.**

Executive-level personnel of both parties shall meet at least once per year during the Term (either in person or telephonically, and at times and places as are mutually acceptable to the parties) for the purpose of reviewing the status of Licensed Product commercialization in the Territory, including, but not limited to regulatory approval status, development and production issues and market conditions. The parties will discuss in good faith any amendments suggested by either party to the timelines set forth in Section 11.6, royalty rates and/or other provisions of this Agreement as may be fair and reasonable in light of changed conditions. Any agreed upon amendments to this Agreement must be in writing and signed by authorized representatives of both parties.

**Article 6 Royalties and Other Consideration**

**6.1 Royalties on Net Sales; Minimum Royalties**

6.1.1 During the Royalty Term, on a country-by-country and Licensed Product-by-Licensed Product basis, the Company shall pay Licensor royalties in amounts as set forth in the below table, with the applicable Royalty rate determined based on the amount of Net Sales received during the applicable Royalty Term Year (as defined below), subject to further adjustment as described in this Article 6. For the purposes hereof, a "Royalty Term Year" means: (i) the period that begins on the date of the applicable First Commercial Sale and ends on December 31 of the same year and (ii) each calendar year thereafter during the Royalty Term.

<b>Net Sales Received During the Applicable Royalty Term Year (in U.S. Dollars)</b>	<b>Royalty</b>
\$0 to \$100,000,000	10% of Net Sales received during the applicable Royalty Year
\$100,000,001 to \$200,000,000	15% of Net Sales received during the applicable Royalty Year
equal to or over \$200,000,001	20% of Net Sales received during the applicable Royalty Year

For the avoidance of doubt, the Royalty rates set forth in the above table are incremental, *i.e.* each Royalty rate is applicable to only the portion of annual Net Sales exceeding the respective values (for example, in the case of annual Net Sales of \$300 million U.S. Dollars, a Royalty rate of 10% is applicable to \$100 million U.S. Dollars, a Royalty rate of 15% is applicable to the next \$100 million U.S. Dollars and a Royalty rate of 20% is applicable to last \$100 million U.S. Dollars). The Royalty

rates set forth in the above table also are calculated on: (i) a Licensed Product-by-Licensed Product basis, i.e. Net Sales achieved with one Licensed Product are not added to Net Sales achieved with other Licensed Products and therefore do not influence the Royalty rate applicable to other Licensed Products and (ii) a country-by-country basis, i.e. Net Sales achieved with respect to sales in one country in the Territory are not added to Net Sales achieved with other Licensed Products and therefore do not influence the Royalty rate applicable to other Licensed Products. For the purposes of clause (i) of the preceding sentence, any distinctions between multiple Licensed Products shall be made by the Company acting in good faith and in consultation with Licensor, and shall be based upon objective criteria, such as differences in dosage strength, formulation or branding.

- 6.1.2 The exclusivity granted to Company pursuant to Section 2.1 is subject to Company paying Licensor, with respect to each of the second, third, fourth, fifth and sixth full calendar years during the Royalty Term, minimum Royalties of One Million U.S. Dollars (\$1,000,000) (the "Minimum Royalties"). Company may cure any failure to meet its Minimum Royalty obligation for any such calendar year by paying the amount of the shortfall to Licensor within sixty (60) days after the end of such calendar year. If Company fails to meet its Minimum Royalty obligation for a particular calendar year (and does not cure such failure as provided in the preceding sentence), Licensor, as its sole and exclusive remedy for such failure, may at any time thereafter, upon thirty (30) days prior, written notice to Company, terminate the license granted to Company under Section 2.1 above

## **6.2 Sublicensing Royalties**

During the Royalty Term, on a country-by-country and Licensed Product-by-Licensed Product basis, the Company shall pay Licensor royalties for Licensed Products sold by any Sublicensee(s) during a particular Royalty Term Year equal to the lesser of: (a) thirty percent (30%) of all sales-based royalties including sales milestones received by the Company or its Affiliates from such Sublicensee(s) with respect to such Licensed Products pursuant to the applicable sublicense agreement(s) and (b) the Royalties that would be due under Article 6.1 above for the Sublicensee's Net Sales of such Licensed Products; provided, however, that notwithstanding any of the foregoing, in no event shall such royalties payable to the Licensor be less than four-and-one-half percent (4.5%) of the Sublicensee's Net Sales of such Licensed Products.

## **6.3 No Multiple Royalties**

No multiple royalties shall be payable because the use, lease or sale of any Licensed Product is, or shall be, covered by more than one Valid Claim contained in the Patent Rights. Additionally, royalties shall be paid to Licensor for the sale of a Licensed Product based upon only one of Articles 6.1 or 6.2 above, but in no case both (that is, royalties due to Licensor on direct sales of a Licensed Product by the Company or its Affiliates to a Third Party shall be based only on Article 6.1, while royalties on sales of a Licensed Product by the Company's Sublicensees to a Third Party shall be based only on either clause (a) or clause (b) of Article 6.2, so as to avoid double counting).

## **6.4 Non Royalty Sublicensing Income**

The Company shall pay to Licensor thirty percent (30%) of NRSI received by the Company or its Affiliates, subject to any deductions therefrom described in Article 1.20 and subject as provided below in

this Article 6.4. If requested by Licensor, the Company will provide Licensor with reasonable documentation (including copies of the relevant agreements with the Sublicensee and documentation of costs incurred to provide services to the Sublicensee) to support the Company's determination and establish on an objective basis that a payment received from a Sublicensee falls within the definition of NRSI or within an exclusion thereto. The parties agree that any dispute in this respect shall be dealt with under Article 10. Notwithstanding anything to the contrary, Milestone Payments paid by the Company after its execution of any such sublicense agreement shall be fully creditable against payments due with respect to NRSI.

#### **6.5 Combination Products**

In the event that a Licensed Product is sold in the form of a combination product containing one or more technologies which, if incorporated into a product by themselves, would not render a product a Licensed Product, the Net Sales for such combination product shall be calculated by multiplying the sales price of such combination product by the fraction  $A/(A+B)$  where (i) A is the invoice price of a Licensed Product incorporating solely the technology which renders such product a Licensed Product, or, if such Licensed Product is not sold separately, the fair market value of a Licensed Product incorporating solely such technology, and (ii) B is the total invoice price of products incorporating solely the other technologies or, if such products are not sold separately, the fair market value of such products. Company shall not sell or permit any Sublicensee to sell any such combination product without the prior, written approval of Licensor, such approval not to be unreasonably withheld or delayed.

#### **6.6 Milestone Payments**

As further consideration for the license granted hereunder, the Company will make the following one time Milestone Payments to Licensor.

- 6.6.1 four hundred and seventy-five thousand US Dollars (\$475,000), upon execution of the License Agreement (which payment shall be made within seven (7) days of execution of the License Agreement, but which payment obligation shall be irrevocable, regardless of any termination of this Agreement by the Company);
- 6.6.2 four hundred and fifty thousand US Dollars (\$450,000) upon acceptance for filing by the FDA of the first IND for the Licensed Product filed by Company or a Sublicensee;
- 6.6.4 six hundred and twenty-five thousand US Dollars (\$625,000) upon first dosing of a patient with a Licensed Product in the first Phase III Trial conducted with a Licensed Product under the first Company-sponsored (or Sublicensee-sponsored) IND;
- 6.6.5 One million US Dollars (\$1,000,000) upon the Successful Outcome of the Phase III Trial conducted with a Licensed Product under the first Company-sponsored (or Sublicensee-sponsored) IND;
- 6.6.6 One million and one hundred thousand US Dollars (\$1,100,000) upon the acceptance for filing of the first Company-sponsored (or Sublicensee-sponsored) NDA by a Competent Authority for a Licensed Product;
- 6.6.7 two million US Dollars (\$2,000,000) upon the final approval by a FDA of the first Company-sponsored (or Sublicensee-sponsored) NDA for a Licensed Product;

- 6.6.8 Five hundred thousand US Dollars (\$500,000) upon receipt by the Company or a Sublicensee of the first Marketing Authorization for a Licensed Product in Canada; and
- 6.6.9 a one-time success fee of ten million US Dollars (\$10,000,000) upon achieving a target of cumulative Net Sales in the United States of the Licensed Products by the Company and all its sub-licensees of one hundred million US Dollars (\$100,000,000) (respectively the "Success Fee" and the "Net Sales Target"), payable as follows:
- (a) if the said Net Sales Target shall be achieved within the first two (2) years of the Royalty Term in respect of the USA, such Success Fee to be paid out over the five (5) year period following the achievement of such milestone in equal installments of two million US Dollars (\$2,000,000) per year;
  - (b) if the Net Sales Target is achieved during the third (3rd) years of the Royalty Term in respect of USA, the Success Fee shall be paid out over the four (4) year period following the achievement of such milestone in equal installments of two million five hundred thousand US Dollars (\$2,500,000) per year; and
  - (c) if the Net Sales Target is achieved during the fourth (4<sup>th</sup>) year of the Royalty Term in respect of USA, the Success Fee shall be paid out over the three (3) year period following the achievement of such milestone in equal installments of three million three hundred and thirty three thousand, three hundred and thirty three US Dollars and thirty-three cents (\$3,333,333.33) per year; and
  - (d) if the Net Sales Target is achieved during or after the fifth (5th) year of the Royalty Term in respect of USA, the Success Fee shall be paid out over the two (2) year period following the achievement of such milestone in equal installments of five million US Dollars (\$5,000,000) per year.

Each of the Milestone Payments described above shall only be paid once upon their respective accomplishments, regardless of the number of times each of such milestones is achieved.

If any of the Milestone Payments set out above are not paid because the Company shall decide it is not necessary to take that step giving rise to the Milestone Payment, the Milestone Payment shall nonetheless be due and shall be paid at the time the Company shall decide not to take the particular step or when the next Milestone Payment is due whichever shall first occur.

#### 6.7 [INTENTIONALLY OMITTED]

#### 6.8 Place of Payment, Taxes and Conversions

All payments under this Agreement shall be paid in United States dollars, unless otherwise required by law, at such place as Licensor may reasonably designate consistent with applicable laws and regulations. Any taxes, duties, or other levies which the Company, its Affiliate or any Sublicensee shall, in its reasonable discretion, be required by law to pay or withhold on remittance of any payment(s) due under this Agreement shall be deducted from such payment(s) to Licensor. Any such taxes, levies, or duties

required under applicable law to be paid or withheld shall be an expense of, and borne solely by, Licensor. The Company will use commercially reasonable efforts to secure and send to Licensor proof of any such taxes, duties or other levies withheld and paid by the Company for the benefit of Licensor, and cooperate, at Licensor's expense, with any reasonable request to help ensure that amounts withheld and/or paid are reduced and/or recovered to the extent permitted by the relevant jurisdiction. If any currency conversion shall be required in connection with the payment of royalties hereunder, such conversion shall be made by using the exchange rate prevailing at Citibank, N.A. in New York, New York on the last business day of the calendar quarterly reporting period to which such royalty payments relate. In each country where the local currency is blocked and cannot be removed from the country under such country's applicable law, royalties accrued with respect to that country shall be paid to Licensor in such country in local currency by deposit in a local bank designated by Licensor, unless the parties otherwise agree

#### **6.9 Time for Payment**

- 6.9.1 The Company shall pay to Licensor the royalties due and payable under this Agreement on a quarterly basis, and shall provide the Royalty Statement referred to in Article 7.2 along with such payment. Payments pursuant to this Article 6.9.1 are due with respect to a particular calendar quarter's Net Sales and receipts of NSRI and sales-based royalties sixty (60) days after the conclusion of such calendar quarter.
- 6.9.2 Milestone Payments payable to Licensor shall, notwithstanding the use of the word "upon" throughout Article 6.6, become due and payable within thirty (30) days after achievement of the indicated milestone.
- 6.9.3 Even if no royalties or other payments that may be due to Licensor under this Agreement shall be due, the Company shall be required to make a report pursuant to Article 7.2 to state that no payments are due.

#### **6.10 Interest**

Amounts which are not paid when due shall accrue interest from the due date until paid, at a rate equal to the then prevailing prime rate of Citibank, N.A., plus two percent (2%).

#### **6.11 Royalty Adjustments**

- 6.11.1 Notwithstanding anything to the contrary herein, if the Company obtains (or has obtained) one or more licenses under patents or patent applications owned by a Third Party: (i) to avoid infringement thereof by the manufacture, use, or sale of any Licensed Product, (ii) to reasonably avoid infringement-related litigation regarding a Licensed Product, or (iii) with the prior approval in writing of Licensor (which approval shall not be unreasonably withheld) to make, use or sell any technology that could improve, enhance, or modify a Licensed Product, as determined by the Company in its reasonable discretion, then the Company may deduct fifty percent (50%) of any fees, milestones or royalties paid under such license(s) (even if paid in settlement or judgment of any claim for infringement) from the payments otherwise due Licensor under this Agreement (including any royalty payments, minimum royalty payments and Success Fee payments, but excluding any other Milestone Payments); provided, however, that, notwithstanding the foregoing, the total amount due Licensor under this Agreement in any particular calendar quarter shall not be reduced by more than fifty percent (50%) as a result of any such deduction, and any

amounts not deducted in a calendar quarter shall be carried forward for deduction in the subsequent calendar quarter(s), subject to such fifty percent (50%) limitation in each case.

- 6.11.2 Should a compulsory license be granted, or be the subject of a possible grant, to a Third Party under the applicable laws of any country in the Territory under the rights licensed under this Agreement, the Company shall notify Licensor, including any material information concerning such compulsory license, and the running royalty rate payable under this Article 6 for sales of Licensed Products in such country will be adjusted to equal any lower royalty rate granted to such Third Party for such country with respect to the sales of such Licensed Products therein (the "Compulsory Royalty") during such periods such third parties sell or offer for sale under the compulsory license articles that compete with the Licensed Products then marketed and sold by the Company, its Affiliates, or Sublicensees in that country, provided that such Compulsory Royalty shall remain subject to further adjustment consistent with this Article 6.

#### **6.12 Invalidity, Unenforceability or Revocation of Patents**

Notwithstanding anything to the contrary, if any of the Patent Rights are declared or held invalid or unenforceable or are revoked by court or tribunal of competent jurisdiction, then all Royalties shall cease to be payable with respect to Licensed Products covered by such Patent Rights sold in the part of the Territory in which such declaration, holding or revocation is effective, as from the date of such declaration, holding or revocation, but if the decision of the court or tribunal making such declaration, holding or revocation shall be reversed on appeal, the Royalties shall become payable from the date of such reversal together with all Royalties which would have been payable but for the adverse decision.

### **Article 7 Reports and Records**

#### **7.1 Records and Audits**

The Company shall keep full, true and accurate books of account containing all particulars that may be reasonably necessary for the purpose of showing the amounts payable to Licensor under this Agreement. Said books of account shall be kept at the Company's principal place of business and the supporting data shall be opened up to Licensor once per year upon reasonable notice to the Company for inspection by Licensor's internal audit division or by another designated auditor selected by Licensor, except one to whom the Company has reasonable objection, for the purpose of verifying the Company's Royalty Statement (as defined below) or compliance in other respects with this Agreement. If an inspection shows an under reporting or underpayment in excess of five percent (5%) of remuneration payable, then the Company shall reimburse Licensor for the reasonable, documented cost of the inspection at the time the Company pays the unreported royalties, including any late charges as required by Article 6.10 of this Agreement. Said books of account and the supporting data shall be made available to Licensor for one (1) year following the expiration of the Term. All payments required under this Article 7.1 shall be due within thirty (30) days of the date Licensor provides the Company notice of the payment due. Licensor shall cause its accounting firm to retain all financial information subject to review under this Article 7.1 in strict confidence; provided, however, that Company shall have the right to require that such accounting firm, prior to conducting such audit, enter into an appropriate non-disclosure agreement with Company regarding such financial information. The accounting firm shall disclose to Licensor only whether the

Company's Royalty Statement is correct or not and the amount of any discrepancy. No other information shall be shared. Licensor shall treat all such financial information as Company's Confidential Information

## **7.2 Royalty Statements**

Within 45 days from the end of each of the first, second and third calendar quarters (and within 60 days from the end of the fourth calendar quarter) of each calendar year, the Company shall deliver to Licensor complete and accurate reports, giving such particulars of the business conducted by the Company during the preceding quarter under this Agreement as shall be pertinent to an accounting of royalties and other payments that may be due to Licensor under this Agreement (the "Royalty Statement"). The Royalty Statement shall include at least the following:

- 7.2.1 Net Sales for each Licensed Product by the Company, each Affiliate, and each Sublicensee;
- 7.2.2 cumulative Net Sales for the applicable calendar quarter;
- 7.2.3 a breakdown of deductions applicable in computing Net Sales and taxes paid or withheld, if any;
- 7.2.4 a breakdown of royalties due based on Net Sales by or for the Company or its Affiliates;
- 7.2.5 a breakdown of royalties due on NRSI;
- 7.2.6 names and addresses of all Sublicensees and Affiliates of the Company; and
- 7.2.7 a copy of each report from each Sublicensee as may be pertinent to an accounting of royalties and other payments that may be due to Licensor.

## **7.3 Confidential Treatment of Reports**

Licensor agrees to hold in confidence each Royalty Statement delivered by the Company pursuant to this Article 7 for a period of five (5) years following termination of this Agreement. Notwithstanding the foregoing, Licensor may disclose any such information required to be disclosed in its financial statements or as required by any stock exchange or similar regulatory authority, or pursuant to any Applicable Laws, provided that Licensor take reasonable steps to provide and assist the Company with the opportunity, where reasonably appropriate, to (i) contest such subpoena, requirement or order or (ii) seek protective or confidential treatment thereof, including but not limited to reasonable advance notice to the Company of any such required disclosure, to the extent reasonably practicable. The Licensor understands that it is the intention of the Company to become publicly traded and that any information disclosed to Licensor under this Agreement, including the Royalty Statement, may be deemed "material non-public information" under the state and federal securities laws.

## **Article 8 Patent Prosecution and Maintenance**

### **8.1 Prosecution and Maintenance**

Following the Effective Date, the Company shall, at its expense, diligently file, prepare, prosecute and maintain the Patent Rights as set forth in Schedule 1.21 hereto (as the same may be amended or supplemented in writing from time to time after the date hereof), including, but not limited to, the filing of patent applications, extensions, continuations, continuations in part, divisionals, re-examinations, or re-issue applications that the Company determines, in consultation with Licensor, may be required to advance the purposes of this Agreement or otherwise to protect the rights and licenses granted hereunder. The Company shall control such prosecution and maintenance, using counsel of its choosing, in the name of Licensor, and agrees to keep Licensor reasonably informed with respect to the status and progress of any such applications, prosecutions and maintenance activities and to consult in good faith with Licensor and take into account Licensor's reasonable comments and requests with respect thereto prior to the filing of any such documents. Licensor shall notify Company in writing and reasonable detail of any Improvements and assist Company in filing, prosecuting, and maintaining Patent Rights claiming the same. Both parties agree to provide reasonable cooperation to each other to facilitate the application and prosecution of patents pursuant to this Agreement and the Licensor shall execute all lawful papers and instruments and make all rightful oaths and declarations as may be necessary in the preparation, prosecution and maintenance of all patents and other filings referred to in this Article 8.

#### **8.2 Patent Term Extensions**

The Company shall promptly notify Licensor of the issuance of each Governmental Approval and, where reasonably possible and reasonably useful or valuable in the commercialization of Licensed Products, use commercially reasonable efforts to apply or enable Licensor to apply for a patent term extension, adjustment or restoration, supplementary protection certificate, or other form of market exclusivity conferred by Applicable Laws (collectively, "Patent Term Extensions") in the relevant country of the Territory. Licensor shall, to the extent reasonably possible and reasonably useful or valuable in the commercialization of Licensed Products, use commercially reasonable efforts to, if and as requested by the Company, obtain (or assist the Company in obtaining) all available Patent Term Extensions. The Parties shall cooperate with each other in obtaining Patent Term Extensions wherever and whenever applicable, reasonably possible to obtain, and reasonably useful or valuable in the commercialization of Licensed Products.

#### **8.3 Abandonment**

The Company may, in its discretion, elect to abandon any patent applications or issued patent in the Patent Rights provided that it shall have informed Licensor in writing prior to doing so. Following such abandonment, Licensor shall have the right, but not the obligation, to commence or continue such prosecution and to maintain any such patent or patent application under its own control and at its own expense and such patent or patent application shall thereafter be excluded from the definition of Patent Rights for purposes of this Agreement. Prior to any such abandonment, the Company shall give Licensor at least sixty (60) days notice and a reasonable opportunity to take over prosecution of such patent or patent application. The Company agrees to cooperate in such activities including execution of any documents necessary to enable Licensor to retain ownership and control of such patent or patent application.

### **Article 9 Infringement, Enforcement and Other Actions**

#### **9.1 Notice of Infringement of Patent Rights**

The Company and Licensor shall promptly provide written notice, to the other party, of any alleged infringement or any challenge or threatened challenge to the validity, enforceability or priority of any of

the Patent Rights, and provide each other with any available evidence of such infringement, challenge or threatened challenge by a Third Party of the Patent Rights and provide such other party with any available evidence of such infringement.

### **9.2 Option to Prosecute or Defend Patent Rights**

During the term of this Agreement, the Company shall have the first right, but not the obligation, to take (or refrain from taking) appropriate action to enforce Patent Rights, to defend any declaratory judgments seeking to invalidate or hold the Patent Rights unenforceable, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation, declaratory judgments or other enforcement action pertaining to Patent Rights, with respect to any potential, threatened, alleged, or actual infringement of, or challenge, to, the Patent Rights (all of the foregoing, collectively "Enforcement Actions"), at its own expense and with counsel of its choosing. In furtherance of such right, Licensor hereby agrees that the Licensor will, if requested by Company, join with Company as a party in any such suit. If, within twelve (12) months of the written notice described in Article 9.1 above, the Company (i) shall have been unsuccessful in persuading the alleged infringer to desist, (ii) shall not have brought and shall not be diligently prosecuting an infringement action, or (iii) has not entered into settlement discussions with respect to such infringement, or if the Company notifies Licensor that it has decided not to undertake any of the foregoing against any such alleged infringer, then Licensor shall then have the right to bring suit to enforce such Patent Rights, at its own expense. Any recovery of damages or amounts received in settlement pursuant to this Article 9.2, as well as costs and expenses incurred in connection therewith, shall be allocated pursuant to Article 9.5 below.

### **9.3 Infringement by Licensed Product**

In the event that a claim or suit is asserted or brought against the Company alleging that the manufacture or sale of any Licensed Product by the Company, an Affiliate of the Company, or any Sublicensee, or the use of such Licensed Product by any customer of any of the foregoing, infringes proprietary rights of a Third Party, the Company shall give written notice thereof to Licensor. The Company may, in its sole discretion, modify such Licensed Product to avoid such infringement and/or may settle on terms that it deems advisable in its sole discretion, provided that any final disposition of the litigation that will restrict the claims in or admit any invalidity of any Patent Rights(s) shall not be made without consultation with and approval by Licensor, such approval not to be unreasonably withheld. Otherwise, the Company shall have the first right, but not the obligation, to defend any such claim or suit. If the Company has not exercised such right to defend or entered into settlement discussions concerning such alleged infringement within the sooner of (i) twelve (12) months of the assertion of such a claim or (ii) thirty (30) days of the filing of such a suit, or if the Company notifies Licensor that it has decided not to undertake such defense or enter into settlement discussions with respect to its alleged infringement, then Licensor shall then have the right to defend such alleged infringement, at its sole expense, provided however that no settlement affecting Patent Rights will be agreed upon without Company's written consent.

### **9.4 Control of Infringement Action**

The party controlling any action, suit, or defense under Article 9.2 or 9.3 (the "Controlling Party") shall be free to enter into a settlement, consent judgment, or other voluntary disposition of any such action, provided, however, that (i) the Controlling Party shall consult with the other party (the "Secondary Party") prior to entering into any settlement thereof and (ii) any settlement, consent judgment or other voluntary disposition of such actions which (1) materially limits the scope, validity, or enforceability of any Patent Rights or, if the Company is the Secondary Party, patents or patent applications owned or controlled by the Company, (2) subjects the Secondary Party to any non-indemnified liability, payment

obligation, or injunction, or (3) admits fault or wrongdoing on the part of Secondary Party must be approved in writing by Secondary Party, such approval not to be unreasonably withheld. Secondary Party shall provide the Controlling Party notice of its approval or denial of such approval within fifteen (15) business days of any request for such approval by the Controlling Party, provided that (i) in the event Secondary Party wishes to deny such approval, such notice shall include a written description of Secondary Party's reasonable objections to the proposed settlement, consent judgment, or other voluntary disposition and (ii) Secondary Party shall be deemed to have approved such proposed settlement, consent judgment, or other voluntary disposition in the event it fails to provide such notice within such fifteen (15) business day period.

#### **9.5 Allocation of Costs Incurred and Damages Recovered in Enforcement Action**

Each party (the "Prosecuting Party") will promptly notify the other party in writing in the event the Prosecuting Party chooses to take any Enforcement Action pursuant to its rights under Article 9.2 above and such other party will, within thirty (30) days after the date of such notice, provide the Prosecuting Party with written notice as to whether or not such other party elects to enter into an arrangement pursuant to which such other party will pay for fifty percent (50%) of the parties' aggregate attorneys' fees and other costs and expenses incurred in connection with such Enforcement Action (such costs to be allocated between and paid by the parties as incurred), and in exchange receive fifty percent (50%) of any cash payments awarded to the Prosecuting Party or received by the Prosecuting Party in settlement of such Enforcement Action (a "Risk/Reward Sharing Arrangement"). If such other party fails to provide the above-described notice to the Prosecuting Party within such thirty (30) day period, such other party shall be deemed to have elected not to enter into the Risk/Reward Sharing Arrangement. If such other party elects not to (or is deemed to have elected not to) enter into the Risk/Reward Sharing Arrangement, the Prosecuting Party shall be solely responsible for all of its costs of the Enforcement Action (together with any reasonable, documented out-of-pocket costs incurred by the other party to provide any assistance requested by the Prosecuting Party in connection with such Enforcement Action), and shall be entitled to retain all awards and other proceeds of such Enforcement Action.

#### **9.6 Cooperation**

In any suit to enforce and/or defend the Patent Rights pursuant to this Agreement, or defend any alleged infringement of Third Party intellectual property rights by the manufacture, use, sale, or import of a Licensed Product, the Secondary Party shall, at the request of the Controlling Party, cooperate in all respects and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens, and the like.

### **Article 10 Dispute Resolution**

#### **10.1 Disputes**

- 10.1.1 The parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either party's rights and/or obligations hereunder or to the interpretation, performance, breach, or termination of this Agreement, (a "Dispute"). It is the objective of the parties to establish procedures to facilitate the resolution of a Dispute in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the parties agree to follow the procedures set forth in this Article 10 if and when a Dispute arises under this Agreement.

- 10.1.2 A Dispute among the parties will be resolved as recited in this Article 10. Any Disputes relating to this Agreement shall be promptly presented to the Chief Executive Officers of Licensor and the Company, or their respective designees (who must be members of a party's senior management) for resolution. From the date of referral of a Dispute to the Chief Executive Officers or their designees of the parties and until such time as any matter has been resolved by the parties or has been finally settled by arbitration hereunder, the running of the cure periods (if any) as to which a party must cure a breach that is part of the subject matter of any Dispute shall be suspended. In the event that the Chief Executive Officers of Licensor and the Company, or their respective designees, cannot after good faith negotiations resolve the Dispute within thirty (30) days (or such other period of time as mutually agreed to by the parties in writing) of being requested by a party to resolve a Dispute, the parties agree that such Dispute shall be resolved by binding arbitration in accordance with this Article 10.1.
- 10.1.3 If a party intends to begin arbitration to resolve such Dispute, such party shall provide written notice (the "Arbitration Notice") to the other party informing such other party of such intention and the issues to be resolved. Any arbitration hereunder shall be conducted pursuant to the Commercial Arbitration Rules of the American Arbitration Association ("AAA"; such rules, the "AAA Rules"), except as modified herein. The arbitration shall be conducted by a panel of three (3) independent, neutral arbitrators that are industry experts experienced in the issues comprising the Dispute and have no past, present or reasonably anticipated future affiliation with either party (the "Panel"). Company and Licensor shall each be entitled to select one (1) such arbitrator, with the two such arbitrators so selected selecting the third such arbitrator. In the event either party fails to select its arbitrator within such ten (10) day period, the arbitrator selected by the other party within such ten (10) day period shall be entitled to select such arbitrator. The arbitration shall take place in New York, New York and be conducted in English. The Panel shall apply the laws of the State of New York, without regard to its conflicts of laws provisions. The Panel shall issue appropriate protective orders to protect each party's Confidential Information. If a party can demonstrate to the Panel that the complexity of the issue or other reasons warrant the extension of one or more timetables in the AAA Rules, the Panel may extend such timetables but in no event shall the proceeding extend more than twelve (12) months from the date of filing of the arbitration notice with the AAA. The Panel's decision shall be in writing. The Panel shall have the authority to award any remedy allowed by law, including but not limited to compensatory damages, pre-judgment interest, but not punitive or other damages and each party shall be deemed to have waived any right to such excluded damages. Each party shall bear its own costs, fees and expenses in the arbitration and shall share equally the Panel's fees, unless the Panel determines that its fees are to be paid by the non-prevailing party. Notwithstanding anything to the contrary, without prejudice to the above procedures, either party may seek injunctive relief or other provisional judicial relief if, in its reasonable judgment, such action is necessary to avoid irreparable damage or otherwise enforce its rights hereunder

## 10.2 Performance to Continue

Each party shall continue to perform its obligations, and shall be permitted to continue to exercise its rights, under this Agreement pending final resolution of any Dispute arising out of or related to this

Agreement; provided, however, that a party may suspend performance of its obligations during any period in which the other party fails or refuses to perform its obligations.

### **10.3 Determination of Patents and Other Intellectual Property**

Notwithstanding the foregoing, any dispute relating to the determination of validity of claims, infringement or claim interpretation relating to Licensor's Patent Rights shall be submitted exclusively to the United States District Court for the Southern District of New York and the appropriate appellate courts thereof. Each of the parties hereby irrevocably consents and submits to the exclusive jurisdiction of such courts with respect to any such disputes and waives any objections to the laying of venue in such courts.

### **10.4 Statute of Limitation and Time-Based Defenses Tolerated**

All applicable statutes of limitation and time-based defenses (such as estoppel and laches) shall be tolled while any arbitration proceedings are pending and during any arbitration proceedings. The parties shall cooperate in taking any actions necessary to achieve this result.

## **Article 11 Term and Termination**

### **11.1 Term**

This Agreement shall become effective on the Effective Date and shall expire on the date of the expiration of the last to expire Royalty Term in any country in the Territory (the "Term"), unless earlier terminated as provided in Articles 11.2, 11.3, or 11.5.

### **11.2 Termination for Insolvency**

If the Company shall become bankrupt, or shall file a petition in bankruptcy, or if the business of the Company shall be placed in the hands of a receiver, assignee or trustee for the benefit of creditors, whether by the voluntary act of the Company or otherwise, Company shall provide notice thereof to Licensor and Licensee may, subject to the effects of and protections of any applicable bankruptcy-related laws, rules, or regulations, terminate this Agreement upon notice to Company given within thirty (30) business days of Licensor's receipt of such notice whereupon Licensor shall be entitled to exercise the right of reference to Company Data as defined in Article 3.1 and on the basis set out in Articles 3.1 and 11.5.

### **11.3 Termination for Material Breach**

Upon any material breach or default of this Agreement by the Company, Licensor shall have the right to terminate this Agreement and the rights, privileges and license granted hereunder by giving ninety (90) days prior written notice to the Company. Upon the expiration of the ninety (90) day period, if the Company shall have not cured such breach or default, this Agreement shall, at the option of Licensor, terminate upon written notice of Licensor. In the event of a bona fide dispute over any material breach, the parties shall attempt to resolve such dispute in good faith through negotiation, or if agreed to by the parties, mediation, in each case to include the senior executive of both parties hereto. Notwithstanding anything herein to the contrary, if the nature of the breach is such that additional time is reasonably needed to cure such breach, and Company has commenced with good faith efforts to cure such breach, then Licensor shall provide Company with additional time in which to cure such breach. If a dispute regarding termination is addressed pursuant to Article 10, this license shall remain in full force and effect

until such dispute is resolved. All applicable statutes of limitation and time-based defenses (such as estoppel and laches) shall be tolled while any good faith negotiation or mediation procedures are pending or ongoing. The parties shall reasonably cooperate in taking any actions necessary to achieve this result.

#### **11.4 Expiration of Royalty Term on a Country by Country Basis**

Upon the expiration of the Royalty Term in each country in the Territory, the Company will have an irrevocable, perpetual, paid up, royalty-free non-exclusive license, with rights of sublicense (through multiple tiers), under all rights granted under this Agreement to make, have made, use, have used, lease, import and export, offer to sell, sell have sold, produce, manufacture, distribute and market Licensed Products in such country.

#### **11.5 Termination for Convenience**

The Company shall have the right at any time to terminate this Agreement in its entirety or on a country-by-country basis, for any reason or no reason, by giving thirty (30) days notice thereof in writing to Licensor. In the event of any termination pursuant to this Article 11.5, at the request of Licensor, Company shall transfer to Licensor any and all clinical study data, INDs and Governmental Approvals relating to the Licensed Product (the "Data") that the Company has the right to transfer.

If such notice of termination shall be given prior to the First Commercial Sale such transfer shall be free. If notice shall be given after the First Commercial Sale, the Licensor shall reimburse the Company for all costs incurred in connection with the creation of the Data (including, but not limited to, costs of clinical studies and costs associated with filing for and obtaining regulatory approval) (the "Data Costs"), as follows:

- (i) to the extent Licensor or any of its Affiliates licenses the Licensed Product and/or the Data to one or more third parties (the "New Licensees"), after Licensor or its Affiliates have received aggregate payments from the New Licensees equal to the Threshold Amount (as defined below), Licensor will reimburse the Company for the Data Costs out of any subsequent payments received from the New Licensees, as follows: (A) Licensor will pay Company fifty percent (50%) of any such payments (other than royalties) that Licensor or any of its Affiliates receives from the New Licensees, including, but not limited to, milestone payments and lump sum payments for use of the Data, and (B) Licensor will pay Company a percentage of any royalties that Licensor or any of its Affiliates receives from the New Licensees, such percentage to be determined using the formula set forth in Section 6.2 hereof, *mutatis mutandis*; and
- (ii) to the extent Licensor or any of its Affiliates sells the Licensed Product itself (as opposed to licensing a New Licensee to do so), Licensor will reimburse the Company for the Data Costs pursuant to such payment schedule as shall be negotiated in good faith and agreed upon in writing by the parties.

For the purposes of the foregoing, the "Threshold Amount" means an amount equal to: (A) five million U.S. Dollars (\$5,000,000) minus (B) the aggregate amount of all Minimum Royalties paid by Company hereunder. The Company will take all steps that may be necessary to ensure that the benefit of the Data is transferred to the Licensor

#### **11.6 Termination by Licensor**

- 11.6.1 Subject to Section 11.6.2 below, Licensor shall be entitled to terminate this Agreement if the Company (or its Sublicensee) does not:
- 11.6.1.1 request a Pre-IND Meeting with the FDA within ninety (90) days after the Effective Date;
  - 11.6.1.2 file an IND in respect of the first Licensed Product in the United States by, as applicable: (A) three (3) months after the date of the Pre-IND Meeting with the FDA or (B) if no such meeting is held, within one (1) month after receipt of notice from the FDA that no such meeting is required or (C) if the FDA fails to notify the Company as to whether or not such a meeting is required, within eighteen (18) months after the Effective Date;
  - 11.6.1.3 initiate a Phase II Trial in the United States within six (6) months of the FDA approval of an IND for such Licensed Product;
  - 11.6.1.4 initiate a Phase III Trial in the United States within nine (9) months of the date of the End-of-Phase II Meeting with the FDA with respect to such Licensed Product (such meeting to be requested within two (2) months after Company completes full analysis of Phase II data);
  - 11.6.1.5 complete the Phase III Trial within twenty-four (24) months of the commencement of the Phase III Trial;
  - 11.6.1.6 file the first application for NDA for a Licensed Product in the United States within nine (9) months of Successful Outcome; or
  - 11.6.1.7 achieve the First Commercial Sale in the United States within six (6) months of obtaining the final approval by the FDA of the NDA for a Licensed Product in the United States.

If Licensor terminates this Agreement under any of the provisions set out above in this Section 11.6.1, the Company shall transfer the Data to Licensor free of charge.

- 11.6.2 The timelines and termination right described in Article 11.6.1 are subject to the following provisions:
- 11.6.2.1 For the avoidance of doubt, the timelines and termination right under Article 11.6.1 apply only with respect to the first Licensed Product for which the Company seeks regulatory approval in the United States. To the extent the Company seeks regulatory approval for any additional Licensed Products and/or seeks regulatory approval in Canada, Licensor shall not have any right to terminate this Agreement on the basis of delays associated with such activities.
  - 11.6.2.2 The timelines specified in Article 11.6.1 are based on the following assumptions:
    - (i) the documentation regarding the Licensed Product provided to Company by the Licensor will be deemed sufficient by the FDA for filing an IND for the Licensed Product, without any material supplement or change;

- (ii) the Toxicology Package relating to the Licensed Product that has been provided to the Company by Licensor will be suitable to the FDA without any material supplement or change;
- (iii) no additional non-clinical studies (i.e., other than those studies that have already been conducted by Licensor prior to the Effective Date) are required by the FDA with respect to the Licensed Product during the clinical development program;
- (iv) the FDA will not require any additional pre-clinical studies, toxicology studies, pharmacology studies, CMC data, formulation or clinical supplies production activities to be completed to support the Phase III Trial; and
- (v) no safety, toxicity, technical or other issues will arise during the conduct of any studies relating to the Licensed Product.

11.6.2.3 The periods specified in Article 11.6.1 above shall be extended after consultation with Licensor and the parties' mutual agreement as to the length of the each extension (such agreement not to be unreasonably withheld), to the extent that delay is incurred on account of: (i) the failure of any of the assumptions listed in Article 11.6.2.2 above or (ii) any reasons outside the reasonable control of the Company including any delays caused by Competent Authorities or any requirement to conduct further clinical studies of the Licensed Product.

11.6.3 Licensor shall be entitled to terminate this Agreement upon written notice to the Company if the Company (or any of its Affiliates or Sublicensees) commences any litigation challenging the validity or enforceability of any of the Patent Rights.

## 11.7 Consequences of Termination

Upon the early termination of this Agreement by either party, the following shall occur:

- 11.7.1 Subject to Article 11.7.2, the Company and its Affiliates (as the case may be) shall have no right to practice within the Patent Rights or use any of the Patent Rights and Know-how, and all rights, title or interest in, or other incidents of ownership under, the Patent Rights and Know-how shall revert to and become the sole property of Licensor, and the licenses granted under Article 2.1 shall automatically terminate.
- 11.7.2 Notwithstanding Article 11.7.1, if this Agreement is terminated other than pursuant to Article 11.5, the Company and its Affiliates may, after the effective date of such termination and continuing for a period not to exceed twelve (12) months thereafter, sell all completed Licensed Products, and complete (or have completed) any Licensed Products in the process of manufacture at the time of such termination and sell the same, provided that the Company:
  - (a) notifies Licensor of its decision within thirty (30) days after the date it receives a notice of termination by Licensor or the date it provides a notice of termination to Licensor, as the case may be;

- (b) pays or cause to be paid to Licensor the royalties and other payments thereon as required by Article 6 of this Agreement; and
  - (c) submits the reports required by Article 7 hereof.
- 11.7.3 If the Company does not elect pursuant to Article 11.7.2 to sell-off or distribute, as applicable, any existing inventory of Licensed Product, the Company shall, at Licensor's election, either:
- (a) sell all existing inventory of Licensed Product to Licensor at fair market value; or
  - (b) destroy all remaining inventory of Licensed Product in accordance with Applicable Laws and provide Licensor with written proof of destruction sufficient to comply with Applicable Laws.
- 11.7.4 Notwithstanding anything to the contrary, each sublicense granted under this Agreement by the Company or its Affiliates to a Sublicensee shall, to the extent not imposing obligations on Licensor in excess of those contained herein, survive such termination and be automatically assigned to Licensor as provided for in Article 2, in order to provide for the applicable Sub licensees' continued enjoyment of their rights under such sublicenses.

#### **11.8 Partial Termination**

Upon the early termination of this Agreement by either party in respect of a country, the terms of Article 11.7 shall apply in respect of such country.

#### **11.9 Survival**

Upon termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination, or such party's obligations under Articles 6 and 7, and the following provisions shall survive such termination: Articles 7.3, 9 (with respect to infringement occurring prior to such termination), 10, 11, 13, 14, 15, and 16.

### **Article 12 Representations and Warranties**

#### **12.1 Licensor Warranties**

Licensor represents and warrants that:

- 12.1.1 Licensor owns all right, title, and interest in and to the Patent Rights and Know-how, including the exclusive, absolute, irrevocable right, title and interest thereto, free and clear of all liens, charges, encumbrances or other restrictions or limitations of any kind whatsoever.
- 12.1.2 There are no licenses, options, restrictions, liens, rights of third parties, disputes, royalty obligations, proceedings or claims relating to, affecting, or limiting Licensor's rights or the rights of the Company under this Agreement, or which may lead to a

claim of infringement by or invalidity regarding, any part or all of the Patent Rights or Know-how or their use.

- 12.1.3 There is no claim, pending or threatened, of infringement, interference or invalidity regarding any part or all of the Patent Rights or Know-how or their use.
- 12.1.4 The US and foreign patent applications and patents itemized on Schedule 1.21 set forth all of the patents and patent applications owned by or licensed to Licensor or any of its Affiliates relating to the Licensed Products in respect of the Territory (including, but not limited to, the manufacture, formulation, composition or use thereof) on the date of this Agreement.
- 12.1.5 There are no inventors of Patent Rights other than those listed as inventors on applications filed for such Patent Rights.
- 12.1.6 The development of the Patent Rights, and Know-how were not supported in whole or part by funding or grants by any governmental agency or philanthropic or charitable organization.
- 12.1.7 The Licensor is a company duly organized, validly existing and in good standing under the laws of England. The Licensor has the requisite power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement and the performance and consummation of the transactions contemplated hereby by the Licensor have been duly authorized by all necessary action on the part of the Licensor. This Agreement has been duly executed and delivered by the Licensor and, subject to the due authorization, execution and delivery of this Agreements by the Company, this Agreement constitutes a valid and binding obligation of the Licensor, enforceable against the Licensor in accordance with its terms, except as such enforcement may be affected by bankruptcy, reorganization, insolvency, moratorium or similar laws affecting creditor's rights generally and except for general principles of equity.
- 12.1.8 The execution and delivery of this Agreement does not, the consummation of the transactions contemplated hereby, and the performance of Licensor's obligations hereunder will not, (i) conflict with, or result in any violation or breach of any provision of the organizational documents of the Licensor, (ii) so far as Licensor is aware conflict with or violate any applicable foreign, Federal, state and local statutes, judgments, decrees, laws, ordinances, rules, regulations, injunctions and orders ("Laws") of any U.S. Federal, state, foreign or local government or any court, tribunal, administrative agency or commission or other governmental or regulatory authority, body or agency, including any self-regulatory organization ("Governmental Authorities") applicable to the Licensor or any of its assets or operations or any permit applicable to the Licensor or (iii) result in (x) any violation or breach of, constitute (with or without notice or lapse of time or both) a default under or conflict with (or give rise to a right of termination, amendment, cancellation or acceleration of any material obligation or loss of any benefit under) the provisions of any lease, contract or other agreement to which the Licensor is a party or by which it or any of its properties or assets is otherwise bound or (y) the imposition of any lien, pledge, hypothecation, mortgage, security interest, claim, lease, charge, option, right of first refusal or first offer, easement, servitude, transfer restriction, voting requirement or

any other encumbrance, restriction or limitation on any of the properties or assets of the Licensor.

- 12.1.9 No consent, approval or authorization of, or declaration or filing with, any Governmental Authority or other Third Party (a "Consent") is required on the part of the Licensor in connection with its execution, delivery, and performance of this Agreement or the consummation of the transactions contemplated hereby.
- 12.1.10 No written communication has been received by the Licensor, and no investigation, regulatory enforcement action (including seizure, injunction, civil penalty or criminal action) or any related Governmental Authority review is or, in respect of any Licensed Product, to the knowledge of the Licensor, was at any time pending or is threatened by any Governmental Authority with respect to (i) any alleged or actual violation by the Licensor of any permit, Law or other requirement of any Governmental Authority relating to the operations conducted by the Licensor with respect to any Licensed Product or (ii) any alleged or actual failure to have or maintain in effect all permits required in connection with the operations conducted by the Licensor with respect to any Licensed Product. The Licensor has not received from the FDA, the U.S. Drug Enforcement Administration ("DEA"), or any similar state, local, federal, or foreign Governmental Authority any written notice regarding the approvability or approval of any of the Licensed Products. No Licensed Product has been withdrawn, suspended or discontinued by the Licensor as a result of any action by the FDA, the DEA or any similar state, local, federal, or foreign Governmental Authority, either within or outside the U.S. (whether voluntarily or otherwise). With respect to any Licensed Products, no officer, employee or, to the knowledge of the Licensor, agent of the Licensor has made any untrue statement of a material fact or a fraudulent statement to the FDA, DEA or any similar state, local, federal, or foreign Governmental Authority, failed to disclose any material fact required to be disclosed to the FDA, the DEA or any similar state, local, federal, or foreign Governmental Authority, or committed an act, made a statement or failed to make a statement that, at the time such act, statement or omission was made, could reasonably be expected to provide a basis for the FDA, the DEA or any similar state, local, federal or foreign Governmental Authority to invoke the FDA's policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" set forth in 56 Fed. Reg. 46191 (September 10, 1991) or any similar policy, nor has any director, officer, employee or, to the knowledge of the Licensor, agent of the Licensor been convicted of any crime or engaged in any conduct for which debarment is mandated by 21 U.S.C. Article 335a(a) (or any similar Law) or authorized by 21 U.S.C. Article 335a(b) (or any similar Law).
- 12.1.11 There are no suits or actions, administrative, arbitration or other proceedings, or governmental investigations pending or, to the knowledge of the Licensor, threatened against or affecting the Licensor with respect to Licensed Products or the Patent Rights. No Entity has notified the Licensor in writing of any material claim against the Licensor alleging any personal property or economic injury, loss or damage incurred as a result of or relating to the use of any Licensed Products. There is no judgment, order, injunction, decree, writ or award against the Licensor that is not satisfied and remains outstanding with respect to Patent Rights or any Licensed Product.

- 12.1.12 Schedule 12.1.12 hereto sets forth a true and complete list of each material license, contract or other agreements (together with certain other agreements and any amendments to any of the foregoing) to which the Licensor is a party or by or to which any property of the Licensor is otherwise bound or subject that relates to the Licensed Products or the Patent Rights (collectively, the "Material Agreements"). True and complete copies of all Material Agreements have been previously delivered to the Company. Each of the Material Agreements is valid, binding and in full force and effect, and enforceable by the Licensor, or has expired, in each case in accordance with its respective terms. No Person (other than the Licensor) that is a party to any Material Agreement or is otherwise bound thereby is, to the knowledge of the Licensor, in default or breach thereof and, to the Licensor's knowledge, no event, condition or act exists that, with the giving of notice or the lapse of time or both, would give rise to such a default or breach thereof or a right of cancellation by the Licensor thereunder. The Licensor is not in default or breach in any material respect of any of the Material Agreements and, to the knowledge of the Licensor, no event, condition or act exists that, with the giving of notice or the lapse of time or both, would give rise to a default or breach by the Licensor thereof or a right of cancellation thereunder by any other party thereto.
- 12.1.13 To the knowledge of the Licensor, none of the Patent Rights or Licensed Products, nor the practice, development, use, manufacture, sale, or import of any of the foregoing, infringes or conflicts in any material respect with (and the Licensor has not received any notice of infringement of, or conflict with) any license, patent, copyright, trademark, service mark or other intellectual property right of any Third Party and, to the knowledge of the Licensor, there has not been and is not currently any infringement or unauthorized use by any Third Party of any of the Patent Rights, Know-how, or Licensed Products. The validity or enforceability of any of the Patent Rights and or the title of the Licensor thereto has not been questioned in any litigation, governmental inquiry or proceeding to which the Licensor is a party and, to the knowledge of the Licensor, no such litigation, governmental inquiry or proceeding is threatened.
- 12.1.14 To the knowledge of the Licensor, the Licensor has taken all reasonable actions necessary or appropriate to preserve the confidentiality of all trade secrets, proprietary and other confidential information material to the Licensed Products, Know-how, and Patent Rights.
- 12.1.15 Licensor is not aware of any Third Party activities which would constitute misappropriation or infringement of the Patent Rights.
- 12.1.16 Licensor owns all right, title, and interest to the Licensor IND(s) (if any) free and clear of all liens, claims, and encumbrances, the Licensor IND(s) constitute the only INDs or regulatory filings of any kind concerning any Licensed Product, and there are no Governmental Approvals in place or effective in any jurisdiction with respect to any Licensed Product.
- 12.1.17 Schedule 12.1.17 contains a complete and accurate list of any and all regulatory approvals and filings for regulatory approval, worldwide, with respect to any Licensed Products (the "Worldwide Regulatory Filings and Approvals"). Licensor represents that it has provided Company with copies of all correspondence with the

Governmental Authority with respect to each of the Worldwide Regulatory Filings and Approvals, as well as all other data and information of which Licensor is aware that would reasonably be expected to be material to the safety or efficacy of the Licensed Product.

## 12.2 Company Warranties

The Company represents and warrants that:-

- 12.2.1 The Company is a corporation duly organized, validly existing and in good standing under the laws of Delaware. The Company has the requisite power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement and the performance and consummation of the transactions contemplated hereby by the Company have been duly authorized by all necessary action on the part of the Company. This Agreement has been duly executed and delivered by the Company and, subject to the due authorization, execution and delivery of this Agreements by the Licensor, this Agreement constitutes a valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except as such enforcement may be affected by bankruptcy, reorganization, insolvency, moratorium or similar laws affecting creditor's rights generally and except for general principles of equity.
- 12.2.2 The execution and delivery of this Agreement does not, the consummation of the transactions contemplated hereby, and the performance of Company's obligations hereunder will not, (i) conflict with, or result in any violation or breach of any provision of the organizational documents of the Company, (ii) so far as the Company is aware conflict with or violate any applicable Laws of any Governmental Authorities applicable to the Company or any of its assets or operations or any permit applicable to the Company or (iii) result in (x) any violation or breach of, constitute (with or without notice or lapse of time or both) a default under or conflict with (or give rise to a right of termination, amendment, cancellation or acceleration of any material obligation or loss of any benefit under) the provisions of any lease, contract or other agreement to which the Company is a party or by which it or any of its properties or assets is otherwise bound or (y) the imposition of any lien, pledge, hypothecation, mortgage, security interest, claim, lease, charge, option, right of first refusal or first offer, easement, servitude, transfer restriction, voting requirement or any other encumbrance, restriction or limitation on any of the properties or assets of the Company.
- 12.2.3 No Consent is required on the part of the Company in connection with its execution, delivery, and performance of this Agreement or the consummation of the transactions contemplated hereby.
- 12.2.4 Except as set forth on Schedule 12.2.4, as of the Effective Date: (i) there are no suits or actions, administrative, arbitration or other proceedings, or governmental investigations pending or, to the knowledge of the Company, threatened against or affecting the Company, (ii) no Entity has notified the Company in writing of any material claim against the Company alleging any personal property or economic injury, loss or damage incurred as a result of relating any action by the Company and (iii) there is no judgment, order, injunction, decree, writ or award against the Company that is not satisfied and

remains outstanding with respect to any matter affecting the Company the Patent Rights, or any Licensed Product.

12.2.5 Company is not bound by any non-competition covenant or other agreement containing restrictions on Company which would reasonably be expected to have a material adverse affect on the ability of Company to perform its obligations under this Agreement.

12.2.6 To the actual knowledge of the Company, the sale in the Territory of the Licensed Product (in the form initially contemplated by the Company as of the Effective Date), does not infringe any third party patent issued in the Territory as of the Effective Date.

### **12.3 No Impairment**

Each party hereby covenants and agrees with the other that, during the Term, it will not, by act or failure to act, impair or otherwise adversely affect, or cause any occurrence which would reasonably anticipated to impair or otherwise adversely affect, the rights of the other under this Agreement or ability of the other party to freely exercise such rights.

## **Article 13 Limitation of Liability, Indemnity**

### **13.1 NO IMPLIED WARRANTIES**

13.1.1 EXCEPT AS SET FORTH IN ARTICLE 12, NEITHER PARTY MAKES AND EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND VALIDITY OF PATENTED RIGHTS CLAIMS, ISSUED OR PENDING.

13.1.2 EXCEPT AS SET FORTH IN ARTICLE 12, NOTHING HEREIN SHALL BE CONSTRUED AS A REPRESENTATION OR WARRANTY BY EITHER PARTY TO THE OTHER PARTY THAT THE PATENT RIGHTS AND KNOW-HOW ARE NOT INFRINGED BY ANY THIRD PARTY, OR THAT THE PRACTICE OF SUCH RIGHTS DOES NOT INFRINGE ANY INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

### **13.2 Indemnity**

13.2.1 The Company agrees to defend, indemnify and hold harmless Licensor, its Affiliates, and each of their respective directors, employees and officers (collectively, the "Licensor Indemnitees") from and against all liability, demands, damages, costs and expenses (including, without limitation, reasonable legal fees and expenses) and losses (collectively, "Losses") in connection with any third party claim arising out of or relating to: (i) any breach of this Agreement by Company, (ii) negligence, willful misconduct, or failure to comply with Applicable Laws by any Company Indemnitee in connection with this Agreement or (iii) any Company Indemnitee's use, manufacture, sale, or other disposition of Licensed Products under the terms of this Agreement (including, but not limited to, any claims for personal injury or property damage arising from the use thereof); in each of the foregoing cases to the extent not

resulting from any Licensor Indemnitee's breach of this Agreement, negligence, willful misconduct, or failure to comply with Applicable Laws.

13.2.2 Licensor agrees to defend, indemnify and hold harmless the Company and its Affiliates and each of their respective directors, employees, and officers (collectively, the "Company Indemnitees") from and against all Losses in connection with any third party claim arising out of or relating to: (i) any breach of this Agreement by Licensor, (ii) negligence, willful misconduct, or failure to comply with Applicable Laws by any Licensor Indemnitee in connection with this Agreement, (iii) any Licensed Products sold by Licensor or any of its sublicensees or distributors following any termination of this Agreement, including, but not limited to, any claims for personal injury or property damage arising from the use thereof or (iv) any claims by any Sublicensees under any sublicense agreement assigned to Licensor following any termination of this Agreement, to the extent such claim relates to the period following the date of such termination.

13.2.3 In the event that either party intends to seek indemnification for any claim under Article 13.2.1 or 13.2.2, it shall inform the other party of the claim promptly after receiving notice of the claim.

In the case of a claim for which Licensor seeks indemnification under Article 13.2.1, Licensor shall permit the Company to direct and control the defense of the claim and shall provide such reasonable assistance as is reasonably requested by the Company (at the Company's cost) in the defense of the claim, provided that nothing in this Article 13.2.3 shall permit the Company to make any admission on behalf of Licensor, or to settle any claim or litigation which would impose any financial obligations on Licensor without the prior written consent of Licensor, such consent not to be unreasonably withheld or delayed.

In the case of a claim for which the Company seeks indemnification under Article 13.2.2, the Company shall permit Licensor to direct and control the defense of the claim and shall provide such reasonable assistance as is reasonably requested by Licensor (at Licensor's cost) in the defense of the claim, provided that nothing in this Article 13.2.3 shall permit Licensor to make any admission on behalf of the Company, or to settle any claim or litigation which would impose any financial obligations on the Company without the prior written consent of the Company, such consent not to be unreasonably withheld or delayed.

### 13.3 LIMITATION OF LIABILITY

EXCEPT WITH REGARD TO DAMAGES ARISING FOR INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS, BREACHES OF ARTICLE 14.3 OR 15, AND ANY DUTY TO INDEMNIFY FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES UNDER ARTICLE 13.2.1 OR 13.2.2, IN NO EVENT SHALL EITHER PARTY OR THEIR AFFILIATES BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY AND IRRESPECTIVE OF WHETHER SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF ANY SUCH LOSS OR DAMAGE.

### Article 14 Use of Names and Publication

#### **14.1 Use of Name**

Nothing contained in this Agreement shall be construed as granting any right to the Company or its Affiliates to use in advertising, publicity, or other promotional activities any name, trade name, trademark, or other designation of Licensor or any of its units (including contraction, abbreviation or simulation of any of the foregoing) without the prior, written consent of Licensor; provided that Company may identify Licensor as the licensor under this Agreement without such consent to actual or potential investors, investment bankers, acquirers, acquisition targets, and strategic partners, and where the use of such names may be required by Applicable Law.

#### **14.2 No Agency**

Nothing herein shall be deemed to establish a relationship of principal and agent between Licensor and the Company, nor any of their agents or employees for any purpose whatsoever. This Agreement shall not be construed as creating a partnership between the Licensor and the Company, or as creating any other form of legal association or arrangement, which would impose liability upon one party for the act or failure to act of the other party.

#### **14.3 Publication**

In the event that Licensor or any Affiliate, employee, officer, director, or shareholder thereof desires to publish or disclose, by written, oral or other presentation, any information included in the Patent Rights, Know-how, or any material information related thereto, Licensor shall provide the Company with a copy of the proposed publication, presentation, or disclosure at least sixty (60) days prior to its submission for presentation, publication, or disclosure. The Company may request that Licensor, no later than sixty (60) days following the receipt of such proposed publication, presentation, or disclosure, (i) delay such presentation, publication or disclosure for up to an additional ninety (90) days in order to enable the Company to file, or have filed on their behalf, a patent application, copyright or other appropriate form of intellectual property protection related to the information to be disclosed or request that Licensor do so, (ii) remove the Company's Confidential Information from such presentation, publication or disclosure, and/or (iii) make any other reasonable changes to such proposed publication, presentation, or disclosure, as applicable. Upon receipt of such request, Licensor shall (i) arrange for a delay of such presentation, publication or disclosure until such time as the Company or Licensor have filed, or had filed on its behalf, such patent application, copyright or other appropriate form of intellectual property protection in form and in substance reasonably satisfactory to the Company and Licensor, (ii) remove the Company's Confidential Information from such presentation, publication or disclosure, and/or (iii) reasonably consider any other reasonable changes proposed by the Company. If Licensor does not receive any request from the Company to delay such presentation, publication or disclosure, Licensor may submit such material for presentation, publication or other form of disclosure, subject to Licensor's obligations under Article 15.

### **Article 15 Confidentiality**

#### **15.1 Confidentiality and Non-Use**

Any proprietary or confidential information relating to the Technology, Patent Rights, Know-how (including but not limited to patent prosecution documents relating to Patent Rights), reports and records provided under Article 7, and any other reasonably confidential or proprietary information concerning a party's business or technology disclosed to the other party under this Agreement collectively constitute

the "Confidential Information." Neither party will use the Confidential Information for any purpose unrelated to the exercise of their rights or fulfillment of their obligations under this Agreement, and will hold it in confidence during the Term and for a period of five (5) years after the termination or expiration date of this Agreement. Each party shall exercise with respect to such the Confidential Information the same degree of care as the party exercises with respect to its own confidential or proprietary information of a similar nature, but in no event less than reasonable care, and shall not disclose it or permit its disclosure to any Third Party (except to those of its employees, consultants, or agents who are bound by a substantially similar obligation of confidentiality of this Agreement). However, such undertaking of confidentiality shall not apply to any information or data which:

- 15.1.1 The receiving party receives without obligation of confidentiality at any time from a third-party lawfully in possession of same and having the right to disclose same;
- 15.1.2 is, as of the date of this Agreement, in the public domain, or subsequently enters the public domain through no fault of the receiving party;
- 15.1.3 is independently developed by the receiving party as demonstrated by written evidence without reference to or benefit of information disclosed to the receiving party by the disclosing party;
- 15.1.4 is disclosed pursuant to the prior written approval of the disclosing party; or
- 15.1.5 is required to be disclosed pursuant to Applicable Law or legal process (including, without limitation, to a governmental authority) provided that recipient will (i) give prior written notice of such required disclosure to the other party, to the extent reasonably practicable, (ii) give reasonable assistance to the other party, as requested thereby, seeking confidential or protective treatment thereof, and (iii) only disclose such Confidential Information to the extent required by such Applicable Law or legal process.

#### **15.2 Limited Disclosure by Licensor**

Licensor acknowledges and agrees that the Know-how licensed to the Company has value to the Company in being maintained as confidential. Therefore, Licensor shall not disclose the Know-how to any Third Party" (i) for use in the Territory without the Company's prior written consent or (ii) for use outside the Territory other than to recipients who have agreed in writing with Company to maintain the confidentiality of such Know-how.

#### **15.3 Material Non-Public Information**

The Licensor understands that it is the intent of the Company to register its capital stock on a national securities exchange, on the National Association of Securities Dealers, Inc. Automated Quotation System (collectively "NASDAQ"), or the Over The Counter Bulletin Board and accordingly, the Licensor understands that confidential information provided to it by the Company pursuant to the terms of this Agreement may constitute "material non-public information" concerning the Company.

### **Article 16 Miscellaneous Provisions**

#### **16.1 Assignment**

This Agreement and the rights and duties appertaining hereto may not be assigned by either party without first obtaining the written consent of the other party, which consent shall not be unreasonably withheld. Any such purported assignment without the written consent of the other party shall be null and of no effect. Notwithstanding the foregoing, either party (the "Assigning Party") may assign this Agreement without the consent of the other party (i) to a purchaser, merging, or consolidating corporation, or acquirer of all or substantially all of the Assigning Party's assets or business (or that portion thereof to which this Agreement relates) and/or pursuant to any reorganization of the Assigning Party or (ii) to an Affiliate of the Assigning Party.

**16.2 Binding Nature and Inurement**

This Agreement will not be binding upon the parties until it has been signed below on behalf of each party, in which event, it shall be effective as of the Effective Date. As of the Effective Date, this Agreement is binding upon and inures to the benefit of the parties and their respective permitted successors and assigns.

**16.3 Counterparts; Facsimile**

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be signed and delivered to the other party by facsimile signature; such transmission will be deemed a valid signature.

**16.4 Entire Agreement; Amendment**

The parties hereto acknowledge that this Agreement, including the Exhibits, Schedules and documents incorporated by reference, sets forth the entire agreement and understanding of the parties hereto as to the subject matter hereof, and shall not be subject to any change of modification except by the execution of a written instrument subscribed to by the parties hereto and shall supersede all previous communications, representations or understandings, either oral or written, between the parties relating to the subject matter hereof. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the parties hereto unless reduced to writing and signed by the respective authorized officers of the parties.

**16.5 Force Majeure**

Neither party is responsible for delays resulting from causes beyond its reasonable control, including without limitation fire, explosion, flood, war, strike, or riot, provided that the nonperforming party uses commercially reasonable efforts to avoid or remove those causes of nonperformance and continues performance under this Agreement with reasonable dispatch whenever the causes are removed.

**16.6 Further Assurances**

From time to time during the Term, at the request of either party, the other party shall execute and deliver such documents and take such other action as the requesting party may reasonably request to consummate more effectively the transactions contemplated hereby.

**16.7 Headings**

The headings of the several articles are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

#### **16.8 Law**

This Agreement, and any and all disputes directly or indirectly arising from or relating to this Agreement, shall be construed, governed, interpreted and applied in accordance with the laws of the State of New York, without regard to principles of conflicts of laws.

#### **16.9 Payments, Notices and Other Communications**

Any payment, notice or other communication required or permitted to be given pursuant to this Agreement shall be in writing and sent by certified first class mail, postage prepaid, by hand delivery or by facsimile if confirmed in writing, in each case effective upon receipt, at the addresses below or as otherwise designated by written notice given to the other party:

In the case of Licensor:

Thornton & Ross Limited  
Linthwaite  
Huddersfield  
HD7 5QH  
Attn: Chairman  
Tel. No: 01484 842217  
Fax No: 01484 847201

With a copy to: Kuit Steinart Levy  
3 St Mary's Parsonage  
Manchester M3 2RD  
United Kingdom

In the case of the Company:

Manhattan Pharmaceuticals, Inc.  
810 Seventh Avenue, 4<sup>th</sup> Floor  
New York, New York 10019  
USA  
Attn: President  
Tel: (212) 582-3950  
Fax: (212) 582-3957

#### **16.10 Payment of Own Fees and Expenses**

Each of the Company and Licensor shall be responsible for their own expenses relating to the preparation and consummation of this Agreement and, except as specified herein, the agreements and transactions contemplated hereby.

#### **16.11 Severability**

The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions hereof.

**16.12 Waiver**

The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party. Any waiver of any rights or failure to act in a specific instance relates only to that instance and is not an agreement to waive any rights or fail to act in any other instance.

[Signature page to follow.]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement, in triplicate by proper persons thereunto duly authorized.

**THORNTON & ROSS LTD.**

**MANHATTAN PHARMACEUTICALS, INC.**

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

**Schedule 1.15: Licensor IND(s)**

None.

**Schedule 1.21: Patent Rights**

United States Patent Application Serial No. 09/831,681 titled "Chromone Enteric Release Formulation."

United States Patent Application Serial No. 11/580,511 titled "Treatment of Allergic Conditions" published February 15, 2007.

Canadian Patent Application No. 2,350,519 titled "Chromone Enteric Release Formulation."

Any and all other patent applications and patents in the Territory claiming priority from International Patent Application No. PCT/GB99/03731 filed on November 9, 1999 titled "Chromone Enteric Release Formulation."

**Schedule 12.1.12: Material Agreements**

None.

**Schedule 12.1.17 Worldwide Regulatory Filings and Approvals**

None.

#### **Schedule 12.2.4: Company Claims**

In February 2007, a former employee of the Company alleged an ownership interest in two of the Company's provisional patent applications. Also, without articulating precise legal claims, the former employee contends that the Company wrongfully characterized the former employee's separation from employment as a resignation instead of a dismissal in an effort to harm the former employee's immigration sponsorship efforts, and, further, to wrongfully deprive the former employee of the former employee's alleged rights in two of the Company's provisional patent applications. The former employee is seeking an unspecified amount in damages. The Company refutes the former employee's contentions and intends to vigorously defend itself should the former employee file claims against the Company.

EXCLUSIVE LICENSE AGREEMENT

FOR "HEDRIN"

between

THORNTON & ROSS LTD.,

KERRIS, S.A.

and

MANHATTAN PHARMACEUTICALS, INC.

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EXCLUSIVE LICENSE AGREEMENT FOR "HEDRIN"

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## EXCLUSIVE LICENSE AGREEMENT FOR "HEDRIN"

This Exclusive License Agreement for "Hedrin" (hereinafter referred to as this "Agreement"), effective as of June 26, 2007 (the "Effective Date"), is entered into by and between **THORNTON & ROSS LTD.**, a company duly incorporated under the laws of England and having a place of business at Linthwaite, Huddersfield, HD7 5QH ("Thornton & Ross"), **KERRIS, S.A.**, a company duly organized under the laws of Luxembourg and having a place of business at 127 rue de Mühlenbach, L – 2168, Luxembourg ("Kerris," and collectively with Thornton & Ross, "Licensor"), and **MANHATTAN PHARMACEUTICALS, INC.**, a corporation duly organized and existing under the laws of the State of Delaware having a place of business at 810 Seventh Avenue, 4<sup>th</sup> Floor, New York, New York 10019 (the "Company").

**WHEREAS**, Durminster Limited, a company organized under the laws of British Virgin Islands ("Durminster") is the sole owner of the patent applications and patents included in the Patent Rights (as defined below), and has granted exclusive licenses in the Territory to such Patent Rights to Thornton & Ross and to Kerris pursuant to that certain Patent Licence Agreement dated 25 May, 2007 (the "Durminster Agreement"), a true and complete copy of which has been provided to the Company;

**WHEREAS**, Durminster and Thornton & Ross are the sole owners of the Know How (as defined below) used in the formulation of and to manufacture the Licensed Product (as defined below), and the Know How owned by Durminster is exclusively licensed to Thornton & Ross and Kerris pursuant to the Durminster Agreement;

**WHEREAS**, Thornton & Ross is the sole owner of the Trademark (as defined below);

**WHEREAS**, the Company is interested in obtaining exclusive license under the Patent Rights, the Know How and the Trademark in the Field of Use (as defined below) to make, have made, use, have used, lease, import and export, offer to sell, sell, have sold, produce, manufacture, distribute and market products made in accordance with such rights; and

**WHEREAS**, Licensor wishes to grant to the Company an exclusive license under the Patent Rights, the Know How, and the Trademark in the Field of Use to make, have made, use, have used, lease, import and export, offer to sell, sell have sold, produce, manufacture, distribute and market products made in accordance with such rights;

**NOW, THEREFORE**, in consideration of the foregoing recitals, the premises and the mutual covenants contained herein, the parties hereto, intending to be legally bound, agree as follows:

### Article 1 Definitions

For the purposes of this Agreement, the following words and phrases shall have the following meanings:

#### 1.1 "Affiliate"

means, with respect to any Person, any other Person which directly or indirectly controls, is controlled by, or is under common control with, such Person. A Person shall be regarded as in control of another Person if it owns, or directly or indirectly controls, at least fifty percent (50%) of the voting stock or other ownership interest of the other Person, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other Person by any means whatsoever.

**1.2 "Applicable Law(s)"**

means, with respect to the United States, the FDCA (as defined below), all regulations promulgated thereunder, and all other applicable laws, rules, regulations and guidelines within the Territory that apply to the import, export, research and development, manufacture, marketing, distribution, or sale of Licensed Products in the Field of Use in the Territory and the use of the Trade Mark in relation thereto or the performance of either party's obligations under this Agreement (including disclosure obligations as required by the United States Securities and Exchange Commission or other comparable exchange or securities commission having authority over a party) to the extent applicable and relevant to such party.

**1.3 "Competent Authority(ies)"**

means collectively the entities in each country in the Territory responsible for (a) the regulation of medicinal products or medical devices, as applicable, intended for human use, including but not limited to the FDA and any other applicable administrative agency in any country in the Territory having the aforementioned responsibilities, and any successor entities thereto, (b) the establishment, maintenance and/or protection of rights related to the Patent Rights, including the United States Patent and Trademark Office ("USPTO"), and (c) any other applicable regulatory or administrative agency in any country in the Territory that is comparable to, or a counterpart of, the foregoing.

**1.4 "Development"**

means the Company's, its Affiliates', or Sublicensees' use of commercially reasonable efforts to secure Marketing Authorizations for Licensed Products in the Territory.

**1.5 "DMF"**

means a drug master file, as provided for in 21 CFR § 314.420, device master file, as defined in 21 CFR § 814.3, or similar submission to or file maintained with the FDA or other Competent Authority that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs or medical devices.

**1.6 "FDCA"**

means the United States' Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated with respect thereto.

**1.7 "FDA"**

means the United States Food and Drug Administration and any successor entity thereto.

**1.8 "Field of Use"**

means the use of the Licensed Products for the treatment of humans.

**1.9 "First Commercial Sale"**

means, with respect to any Licensed Product, the first sale of such Licensed Product after all applicable Marketing Authorizations (if any) have been granted by the applicable Competent Authority(ies).

**1.10 "Governmental Approval(s)"**

means any and all permits, licenses, approvals, and authorizations required by any Competent Authority as a prerequisite to the development, manufacturing, packaging, marketing, and selling of a Licensed Product in the Field of Use in the Territory.

#### **1.11 "IND(s)"**

means, as applicable, either:

- (a) an investigational new drug application as defined in *21 C.F.R. Part 312* et seq in the United States (as may be amended, supplemented or replaced from time to time), or equivalent application to any Competent Authority of any other country in the Territory, to commence clinical testing of a drug, including but not limited to any amendments, supplements, or supporting correspondence with respect thereto; or
- (b) an investigational device exemption application as defined in *21 C.F.R. Part 812* in the United States (as may be amended, supplemented or replaced from time to time), or equivalent application to any Competent Authority of any other country in the Territory, to commence clinical testing of a medical device, including but not limited to any amendments, supplements, or supporting correspondence with respect thereto.

#### **1.12 "Improvements"**

shall mean any modification, enhancement, or improvement of a Licensed Product, or any inventions, discoveries, improvements (whether patentable or not), information, and data, owned or controlled by Licensor or the Company (as the case may be) any time during the Term (or which Licensor or the Company, as applicable, obtains the right to disclose and license to the other party during the Term), which would be useful or necessary in the manufacture, use, or sale of any Licensed Product, such improvements to be designated "Licensor Improvements" or "Company Improvements," as the case may be.

#### **1.13 "Know-how"**

shall mean all tangible or intangible information and know-how (other than that which is the subject of a Valid Claim in the Patent Rights), whether patentable or not (but which has not been patented), related to the Licensed Product, or any Licensor Improvement or which is useful to or necessary for the Company to develop or commercialize any Licensed Product (including but not limited to: trade secrets, formulations, protocol, results of experimentation, in vitro, preclinical or clinical design, information or results, other proprietary materials, processes, including but not limited to manufacturing processes, data, drawings and sketches, designs, testing and test results, regulatory information of a like nature), owned or controlled by Licensor as of the Effective Date or which Licensor obtains the right to disclose and license to the Company during the Term. The Know How includes, without limitation, all copyrights, know how and other intellectual property rights (other than the Patent Rights) that are licensed to Licensor pursuant to the Durminster Agreement.

#### **1.14 "Licensed Product(s)"**

shall mean any product, including but not limited to a product for the treatment of head lice, pubic lice, body lice and/or scabies infestations (collectively, "Infestations"), which is claimed in or covered by any of the Patent Rights. For the avoidance of doubt, the "Licensed Products" include, without limitation, that certain product for the treatment of Infestations known as "Hedrin," which is marketed in the United Kingdom and other jurisdictions outside the Territory.

**1.15 “Licensor IND(s)”**

means the INDs, whether now existing or previously submitted, described on Exhibit 1.15, and any filings, updates, material correspondence, or material communications to or from any applicable Competent Authority with respect thereto.

**1.16 “Marketing Authorization”**

means all necessary and appropriate regulatory approvals, including but not limited to NDAs and reimbursement and pricing approvals, to allow a Licensed Product to be marketed and sold in the Field of Use in a particular country in the Territory.

**1.17 “Milestone Payment”**

means the payments set out in Article 6.6 and “Milestone” means any one of the steps to be taken as set out in Article 6.6.

**1.18 “NDA”**

means, as applicable, either:

- (a) a New Drug Application as defined in *21 C.F.R. Part 314.50* et seq. in the United States (as may be amended, supplemented or replaced from time to time), or equivalent application to any Competent Authority of any other country in the Territory, to commence commercial sale and marketing of a drug for human use, including but not limited to any amendments, supplements, or supporting correspondence with respect thereto;
- (b) a Premarketing Approval application, as defined in *21 C.F.R. Part 814* in the United States (as it may be amended, supplemented or replaced from time to time), or equivalent application to any Competent Authority of any other country in the Territory, to commence commercial sale and marketing of a medical device for human use, including but not limited to any amendments, supplements, or supporting correspondence with respect thereto; or
- (c) a Premarket Notification submitted in accordance with *21 C.F.R. Part 807* in the United States (as it may be amended, supplemented or replaced from time to time), or equivalent notification or application to any Competent Authority of any other country in the Territory, to commence commercial sale and marketing of a medical device for human use, including but not limited to any amendments, supplements, or supporting correspondence with respect thereto.

**1.19 “Net Sales”**

shall have the meaning set out below:

- 1.19.1 “Net Sales” shall mean the total gross receipts for sales of Licensed Products to customers who are not Affiliates (or are Affiliates, but are end users of the Licensed Products) by or on behalf of the Company or any of its Affiliates (and, to the extent included pursuant to Article 6.2 below, its Sublicensees), whether invoiced or not, less only the sum of the following:

- (a) usual trade discounts to customers, including but not limited to cash, quantity and trade discounts, rebates and other price reductions for such Licensed Product given to such customers;
- (b) sales, tariff duties, value-added tax and/or use taxes directly imposed and with reference to particular sales;
- (c) amounts allowed or credited on charge-backs and/or returns;
- (d) bad debt deductions and uncollectible amounts actually written off during the accounting period;
- (e) outbound transportation prepaid or allowed and transportation insurance;
- (f) sales commissions;
- (g) packaging, freight, and insurance charges;
- (h) customs duties, surcharges and other governmental charges incurred in exporting or importing such Licensed Product to such customers; and
- (i) wholesaler discounts and government chargebacks

1.19.2 Components of Net Sales (and the deductions listed above) shall be determined in the ordinary course of business in accordance with U.S. GAAP.

1.19.3 Notwithstanding anything herein to the contrary, the transfer of a Licensed Product to an Affiliate, Sublicensee, or other Third Party in connection with the research, development or testing of a Licensed Product or for purposes of resale shall not be considered a sale of a Licensed Product under this Agreement. Nor shall the transfer of Licensed Product solely for indigent or similar public support or compassionate use programs be considered a sale of Licensed Product under this Agreement.

1.19.4 In the case of discounts on "bundles" of separate products or services which include Licensed Products, the Company may discount (or enable its Affiliates and Sublicensees to discount) the bona fide list price of a Licensed Product by the average percentage discount of all products of the Company and/or its Affiliates and Sublicensees in a particular "bundle", calculated as follows:

$$\text{Average percentage discount on a particular "bundle"} = 1 - (X/Y) \times 100$$

where X equals the total discounted price of a particular "bundle" of products, and Y equals the sum of the undiscounted bona fide list prices of each unit of every product in such "bundle". The Company shall provide Licensor documentation reasonably supporting such average discount with respect to each "bundle." If a Licensed Product in a "bundle" is not sold separately, and no bona fide list price exists for such Licensed Product, the Company shall determine in good faith a reasonable imputed list price for such Licensed Product and Net Sales with respect thereto shall be based on such imputed list price.

**1.20 "Non-Royalty Sublicensing Income" or "NRSI"**

means, aggregate cash consideration received from a Sublicensee in consideration for grant of a sublicense under the rights granted to the Company hereunder, which shall include sublicense issue fees and non-sales related sublicense milestone payments received by the Company as consideration for the sublicensing by the Company of its rights under this Agreement to commercialize Licensed Products, but shall exclude the following payments as determined by the Company in good faith and subject as provided in Article 6.4 (a) payments received from the sale, issuance or exchange of debt or equity securities of the Company; (b) payments received by the Company that are specifically designated in any agreement with a Third Party to be dedicated to the research and development of the Technology or the establishment of a direct sales force; (c) payments resulting from or calculated on the basis of the sale of one or more Licensed Products, including sales milestones and royalties; and (d) payments received to reimburse Company's or its Affiliates' cost to perform research, development or similar services conducted for such Licensed Product after signing the agreement with the Third Party, or in reimbursement of patent or other out-of-pocket expenses relating to such Licensed Product.

**1.21 "Patent Rights"**

means

- 1.21.1 The U.S. and Canadian patent applications set forth on Schedule 1.21 (the "Key Patent Applications");
- 1.21.2 any and all US or Canadian patents, patent applications, or other rights issuing from, or filed subsequent to the date of this Agreement, based on or claiming priority to or from the applications, patents, and rights listed on Schedule 1.21, including but not limited to continuations, continuations in part, divisionals, reexaminations, extensions, reissues, substitutions, renewals, supplementary protection certificates, registrations, and confirmations of any of the foregoing, and any patents resulting from any application or right included in Articles 1.21.1 or 1.21.2;
- 1.21.3 any other intellectual property rights in the Territory relating to any product for the treatment of Infestations (except where the rights involve the use of the Licensed Product initially to be marketed hereunder with another active ingredient which produces a product which requires its own Government Approval) that are owned or controlled by the Licensor or that Licensor has the ability to license to the Company as of the date of this Agreement, or which Licensor acquires, or acquires the right to license to Company, after the Effective Date, and any and all US or Canadian patents, patent applications, or other rights, including continuations, continuations in part, divisionals, reexaminations, extensions, reissues, substitutions, renewals, supplementary protection certificates, registrations, and confirmations of such rights claiming or relating to, in each case, any product for the treatment of Infestations except as aforesaid;
- 1.21.4 any other intellectual property rights in the Territory owned or controlled by the Licensor at any time during the Term of this Agreement relating to or claiming an Improvement or that Licensor has the ability to license or gains the ability to license to the Company relating to or claiming an Improvement (except where the rights involve the use of the Licensed Product initially to be marketed hereunder with another active ingredient which produces a product which requires its own Government Approval); and any and all US or Canadian patents, patent applications, or other rights, including

continuations, continuations in part, divisionals, reexaminations, extensions, reissues, substitutions, renewals, supplementary protection certificates, registrations, and confirmations of such rights relating to or claiming, in each case, an Improvement; and

- 1.21.5 any Licensor information useful or necessary to file and obtain issuance in the Territory of valid patent claims relating to the use, manufacture, development, administration, delivery, formulation, dosing, packaging, and handling of the Know-how, the Licensed Products or any other product for the treatment of Infestations (except where such information produces a product which requires its own separate Government Approval).

For the avoidance of doubt, and notwithstanding anything to the contrary, the Patent Rights shall include rights to any Improvements relating to any spray-on or other delivery forms of any product for the treatment of Infestations. The parties shall use commercially reasonable efforts to ensure that Schedule 1.21 shall be amended in writing from time to time to reflect the foregoing, provided that any failure to do so shall not limit the scope of the definition of Patent Rights established above.

**1.22 "Person"**

means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint venture, non-profit organization, pool, syndicate, sole proprietorship, unincorporated organization, university, governmental authority or any other form of entity not specifically listed herein

**1.23 "Phase I Trial"**

means a clinical trial that generally provides for the first introduction into humans of a Licensed Product with the primary purpose of determining safety, metabolism and pharmacokinetic properties and clinical pharmacology of the Licensed Product, and generally consistent with 21 CFR § 312.21(a).

**1.24 "Phase II Trial"**

means a clinical trial of a Licensed Product on patients, including possibly pharmacokinetic studies, the principal purpose of which is to make a preliminary determination that such Licensed Product is safe for its intended use and to obtain sufficient information about such Licensed Product's efficacy to permit the design of further clinical trials, and generally consistent with 21 CFR § 312.21(b).

**1.25 "Phase III Trial"**

means a pivotal human clinical trial of a Licensed Product, which trial is designed to: (a) establish that a Licensed Product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed; (c) support Marketing Authorization of such Licensed Product; and (d) generally consistent with 21 CFR § 312.21(c).

**1.26 "Registration(s)"**

means any and all permits, licenses, authorizations, registrations or regulatory approvals (including, but not limited to, IND or NDA) required and/or granted by any Competent Authority as a prerequisite to the development, manufacturing, packaging, shipping, marketing and/or selling of any product.

**1.27 "Royalty Term"**

means, on a country-by-country and Licensed Product-by-Licensed Product basis, the period commencing on the date of the applicable First Commercial Sale and ending on the date of the last to expire patent included in the Patent Rights covering a Licensed Product in such country.

**1.28 "Sublicensee"**

means a Third Party that has entered in to an agreement with the Company licensing to such Third Party any of the rights granted to the Company by the Licensor pursuant to Article 2.1, or a Third Party that has entered into a license agreement with any such Sublicensee licensing such Third Party the rights granted to the Company by the Licensor and granted to such subsequent Third Party licensee by the Sublicensee.

**1.29 "Successful Outcome"**

means an outcome of a Phase III Trial with data reasonably determined by Company to be sufficient to support final approval by the FDA of an NDA with respect to the Licensed Product (including, but not limited to, data from any supporting pharmacokinetic studies and toxicology studies (including, but not limited to any carcinogenicity, and developmental and reproductive toxicology studies)).

**1.30 "Term"**

has the meaning set out in Article 11.1.

**1.31 "Territory"**

means: (i) the United States, its territories and possessions and United States military bases throughout the world and (ii) Canada.

**1.32 "Third Party"**

mean any Person other than Licensor, Company and their respective Affiliates.

**1.33 "Trade Mark"**

means the trade mark "Hedrin," including, but not limited to, all rights under any trademark applications and registrations with respect thereto in the Territory.

**1.34 "Valid Claim"**

means any pending or issued claim included within the Patent Rights that has been filed in good faith and has not been withdrawn, permanently revoked, abandoned nor deemed unenforceable, unpatentable, or invalid by a decision of a court or other governmental agency of competent jurisdiction that is unappealable or unappealed in the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

**Article 2 License Grant**

## 2.1 Grant of License

Licensors hereby grants to the Company an exclusive license, with rights to grant sublicense as further described below, in the Field of Use to practice under the Patent Rights and to utilize the Know-how and the "Hedrin" mark and name in the Territory, including to:

- 2.1.1 conduct research, make, have made, use, have used, import, have imported, export and have exported (except for export to countries outside the Territory), offer for sale, have sold, sell, produce, manufacture, distribute and market Licensed Products to the full end of the Royalty Term, unless sooner terminated as hereinafter provided; and
- 2.1.2 sublicense to third parties, through multiple tiers, in accordance with Article 2.2 below, the rights granted under Article 2.1.1.

The parties acknowledge that Licensor is the licensee of the Patent Rights and certain Know How pursuant to the Durminster Agreement. Licensor represents that it has provided the Company with a true and complete copy of the Durminster Agreement prior to the date hereof. For the avoidance of doubt, the parties acknowledge and agree that: (i) this Agreement is the sole and exclusive statement of the Company's rights and obligations with respect to the Licensed Product and the other matters set forth herein and (ii) the rights expressly granted to the Company under this Agreement shall in no event be modified or limited by any provision of the Durminster Agreement. For the avoidance of doubt, the rights licensed to the Company hereunder include, but are not limited to, all rights that are licensed to Licensor pursuant to the Durminster Agreement (the "Durminster IP").

## 2.2 Sublicenses

- 2.2.1 The Company shall have the right to sublicense rights granted in Article 2.1 in its sole discretion with the prior consent in writing of Licensor, which consent should not be unreasonably withheld or delayed, and Sublicensees shall have the right to grant further sublicenses in their sole discretion with the prior consent of the Licensor, which consent shall not be unreasonably withheld or delayed, but the Company shall continue to remain responsible for the performance of its obligations under this Agreement if a Sublicensee is appointed. Each sublicense agreement: (i) shall contain terms and conditions requiring the applicable sublicensee to provide Data (as defined in Section 11.5 below) created by or on behalf of such sublicensee to the Licensor, on terms and under circumstances analogous to those set forth herein (namely Articles 3.1, 5.5, 11.2, 11.5 and 11.6), in the event the applicable sublicense agreement with the Sublicensee is terminated after having been assigned to and assumed by Licensor (as provided below in this Article 2.2.1), (ii) shall otherwise not conflict with the terms and conditions set forth herein and (iii) shall name Licensor as a third party beneficiary of the sublicense agreement. The Company will keep Licensor reasonably apprised of the status of negotiations with prospective Sublicensees. All sublicenses granted under this Article 2.2.1 by the Company shall survive and be automatically assigned to and assumed by Licensor upon termination of this Agreement, *provided however*, Licensor shall not be obligated to incur any obligations in excess of those of Licensor contained herein.
- 2.2.2 Notwithstanding the foregoing, if the Company believes that Licensor has terminated this Agreement for the primary purpose of doing business directly with the Sublicensee, the termination may be disputed under the provisions of Article 10.

## Article 3 Technology and Regulatory Transfer

### 3.1 Technology and Regulatory Transfer

Upon execution of this Agreement, (i) Licensor shall transfer to the Company, at no additional cost, all Know-how, which shall include but not be limited to copies of all pre-clinical or clinical data, trade secrets, human safety data, preliminary efficacy data (further including, but not limited to, any of the foregoing data relating to any Licensor applications for regulatory approval of the Licensed Product in the United Kingdom, European Union and any other jurisdictions outside the Territory), and other regulatory data related to any Licensed Product in its possession, and (ii) Licensor hereby assigns all right, title, and interest in the Licensor IND(s), if any, to the Company, free and clear of all liens, claims, and encumbrances.

Licensor shall, at Licensor's cost, take any and all actions requested by the Company to effect the purposes of the foregoing as promptly as practicable following the execution of this Agreement and on an ongoing basis thereafter, which shall include but not be limited to (i) preparing and filing whatever filings, requests or applications are required or deemed advisable to be filed with any Regulatory Authority, if any, in connection with the assignment of any Licensor IND(s) (including but not limited to, if applicable with respect to the FDA, a "transfer of ownership letter") and (ii) taking all reasonable actions necessary to enable the Company to undertake the manufacture, development and commercialization of Licensed Products under this Agreement. Such actions shall include providing the Company with the following items relating to the Licensed Products (regardless of whether such item relates to the Territory or any jurisdiction outside the Territory), to the extent such items are within the possession or control of Licensor as of the Effective Date or come within the possession or control of Licensor at any time thereafter and the Licensor has the right to transfer or communicate the same (and the Licensor will notify the Company of any potential limitations on its right to transfer or communicate any of the foregoing to the Company and will use commercially reasonable efforts to overcome any such limitations):

- a. copies of all regulatory submissions;
- b. any communications with Competent Authorities and the minutes of any meetings with Competent Authorities, as well as any communications with and minutes of any meetings with any analogous regulatory authorities outside the Territory;
- c. DMFs and any trial, drug, device, or other master files relating to any Licensed Product, including copies of all case report forms;
- d. copies of all listings and tables of results from the clinical trials relating to any Licensed Product;
- e. copies of all treatment-related serious adverse event reports from the clinical trials relating to any Licensed Product;
- f. storage of and access permission to any retained samples of materials used in clinical trials relating to any Licensed Product;
- g. access to contract and clinical research organizations involved in the preclinical studies and clinical trials relating to any Licensed Product;

- h. the data, files and results of any chemistry, manufacturing, or control-related activities regarding any Licensed Product; and
- i. all other information that the Company may reasonably request that may be useful to the Company for the manufacturing of Licensed Products or conducting preclinical studies and clinical trials and other development activities with respect to each Licensed Product, and the commercialization of Licensed Products.

The Company shall during the Term keep Licensor reasonably informed of any data developed by or on behalf of Company that may be used in support of regulatory filings for the Licensed Product (including, but not limited to, pre-clinical and clinical trial data, human safety data and efficacy data) (the "Company Data"), as well as any regulatory filings made and approvals obtained by the Company with respect to the Licensed Product in the Territory and the Company shall deposit, at Licensor's expense, copies of the Company Data and such regulatory filings with its lawyers or an agreed third party escrow agent together with the necessary permission to allow right of reference to such material by Licensor and shall issue an irrevocable instruction to release such items to the Licensor if this Agreement is terminated pursuant to Article 11.2 and the Company shall procure that all sub-licensees accept this obligation to the Licensor. In addition the Company shall confirm to the Licensor from time to time that it has so deposited such items as provided in this Article 3.1, and the Company shall procure that all sub-licensees accept this obligation to the Licensor. Licensor will notify Company if it wishes to obtain a nonexclusive license to the Company Data (or portion thereof) and/or rights of reference to such regulatory filings and approvals, in each case solely for use in connection with regulatory filings outside the Territory. Provided that Company has the right to grant such license and/or rights of reference, upon receipt of such notice from Licensor, the parties will negotiate in good faith with respect to the terms and conditions of such license and/or rights of reference (including commercially reasonable compensation to be paid to Company for such license and/or rights of reference). Any such terms and conditions agreed upon by the parties shall be set forth in writing and signed by authorized representatives of both parties.

### **3.2 Technical Assistance**

Without limiting Licensor's other obligations hereunder, Licensor shall provide such technical assistance to Company as Company reasonably requests regarding the Patent Rights, Know-how and Licensed Products, including without limitation: (i) providing Company with reasonable access to Licensor's employees and consultants involved in the development, formulation and regulatory approval outside the Territory of the Licensed Products and (ii) providing to Company all or part of Licensor's inventory of GMP and non-GMP Licensed Products, as the parties mutually agree. Company shall pay to Licensor its documented reasonable out-of-pocket costs of providing such technical assistance, subject to Company's prior, written approval of such costs in each case.

### **3.3 Maintenance of Durminster Agreement**

Licensor shall not without the prior written approval of Company: (i) amend the Durminster Agreement in any way that relates to the any of Company's rights to grant the license and other rights granted hereunder in the Territory, or (ii) make any election or exercise any right or option to terminate in whole or in part the Durminster Agreement as it relates to the Territory. Licensor shall notify the Company in writing promptly upon receiving any notice that Licensor is in default of the Durminster Agreement (including, but not limited for any failure to pay royalties thereunder) and the Company may, in its sole discretion, elect to cure such breach on behalf of Licensor. Company shall have the right to exercise the exclusive license granted to it by Durminster pursuant to that certain Deed of License dated as of the date hereof between Company, Licensor and Durminster in the event the Durminster Agreement is terminated or certain other events as set forth in such Deed of License.

3.4 Certain Matters Regarding the Relationship Between the Parties

- 3.4.1 Thornton & Ross and Kerris shall be jointly and severally responsible for all obligations and liabilities of Licensor under this Agreement except in relation to the Trade Mark for which only Thornton & Ross shall be responsible.
- 3.4.2 For the avoidance of doubt, all Patent Rights, Know-how, Improvements, Trade Marks, rights to data, rights of reference, Licensor INDs and other rights and assets that are provided or licensed to Company under this Agreement shall include all such rights and assets, whether held solely by either one of the, or jointly by both, Licensor parties.
- 3.4.3 Kerris hereby irrevocably designates, makes, constitutes and appoints Thornton & Ross, its successors or assigns, the true and lawful attorney (and agent-in-fact) of Kerris with full power of substitution, for the benefit of Thornton & Ross, to take any and all actions, to execute and deliver any and all documents and instruments, which Thornton & Ross may deem proper in connection with this Agreement, and to do all such acts and things in relation thereto as Thornton & Ross shall deem advisable. Kerris acknowledges that the foregoing powers are coupled with an interest and shall be irrevocable by Kerris in any manner or for any reason.
- 3.4.4 Notwithstanding anything to the contrary: (i) Kerris shall be deemed to have notice of and to have received all notices, royalty statements, other communications and information provided by Company to Thornton & Ross under this Agreement (and Company will use commercially reasonable efforts to provide Kerris a courtesy copy of all notices under this Agreement as set forth in Section 16.9), (ii) any consents and approvals given by Thornton & Ross under this Agreement shall be deemed to also constitute the consent and approval of Kerris and (iii) any enforcement or exercise of rights under this Agreement by Kerris shall be enforced or exercised only through Thornton & Ross, which enforcement or exercise shall be pursuant to the terms of this Agreement.
- 3.4.5 For the avoidance of doubt, all amounts payable by Company under this Agreement represent single payments to be made to the joint account of Kerris and Thornton & Ross, as directed by Thornton & Ross. By way of example, the \$600,000 Milestone Payment to Licensor described in Section 6.6.1 below is a single payment to be made to the joint account of Kerris and Thornton & Ross (and in no event shall be construed to be a \$600,000 Milestone Payment to Kerris with another \$600,000 Milestone Payment to Thornton & Ross).
- 3.4.6 If either Kerris or Thornton & Ross (as applicable, the "Affected Licensor Party") ceases to conduct business in the ordinary course, become insolvent, is dissolved, becomes bankrupt, files or has filed against it a petition in bankruptcy, or if the business of the Affected Licensor Party is placed in the hands of a receiver, assignee or trustee for the benefit of creditors, whether by the voluntary act of the Affected Licensor Party or otherwise, that Affected Licensor Party shall cease to be a "Licensor" for the purposes of this Agreement, and the Agreement shall continue in force with the Licensor which is not the Affected Licensor Party.

#### Article 4 Regulatory Compliance

##### 4.1 Ownership and Maintenance of Governmental Approvals

- 4.1.1 The Company will own all Marketing Authorizations for each country in the Territory for Licensed Products. Without limiting the generality of the foregoing, the Company shall prepare and submit in its own name and at its expense NDAs with the FDA in the U.S. and any other equivalent application with the Competent Authorities in other countries in the Territory.
- 4.1.2 The Company shall secure and maintain in good standing, at its sole cost and expense, any and all Governmental Approvals (including, Marketing Authorizations, licenses, permits and consents, facility licenses and permits required by Applicable Laws or by the applicable Competent Authorities) necessary and/or required for the Company to perform its obligations under this Agreement and use commercially reasonable efforts at its cost and expense to secure and maintain any variations and renewals thereof. Licensor shall promptly notify Company of any written or oral notices received from, or inspections by, any Competent Authority relating to any such Governmental Approvals.
- 4.1.3 To the extent Licensor is or becomes the holder of any Governmental Approval referred to in Article 4.1.2 above, during the time that Licensor holds such Governmental Approval, Licensor shall (i) promptly provide Company an advance draft of any proposed responses to such written notices or inspections and the resolution of any issue raised by such Competent Authority and (ii) make such reasonable changes to such proposed response as may be recommended by Company, and the Company shall be entitled to attend any and all meetings and participate in telephone calls with the Competent Authorities, including without limitation any meeting preparation, meeting co-ordination and preparation of minutes.

##### 4.2 Rights of Reference

Licensor shall grant and hereby grants Company a free-of-charge right to reference and use and have full access to all preclinical and clinical data, information, and results, Governmental Approvals, and all other regulatory documents relating to or useful for the Development of the Licensed Products, including but not limited to any IND, NDA, DMF (whether as an independent document or as part of any Governmental Approval), and all chemistry, manufacturing and controls information, and any supplements, amendments or updates to the foregoing, where such regulatory documents are owned, licensed, or controlled by Licensor and the Licensor has the right to transfer or communicate the same, and all analogs to any of the foregoing outside the Territory (for the purposes of this Article, the "Right of Reference"). The Licensor will notify the Company of any potential limitations on its right to transfer or communicate any Right of Reference to the Company and will use commercially reasonable efforts to overcome any such limitations. The Company may license the Right of Reference to Affiliates and to Sublicensees.

#### Article 5 Development and Commercialization

##### 5.1 Development

The Company shall use commercially reasonable efforts, itself or through the activities of its Sublicensees and Affiliates, to perform the Development and secure the Marketing Authorizations for Licensed Products.

#### **5.2 Commercialization**

The Company shall, following receipt of the necessary Marketing Authorizations, use commercially reasonable efforts to, itself or through the activities of its Sublicensees and Affiliates, commence marketing of, and to promote, market, sell and commercialize thereafter, Licensed Products in the Territory. For the avoidance of doubt, Company and the Sublicensees may market the Licensed Products under the "Hedrin" name or such other brand as may be selected by the Company and/or the Sublicensees, provided that if the "Hedrin" name is used it is identified as a registered trade mark of Licensor and the Licensor is accorded all rights under Applicable Laws usually accorded to owners of trade marks in the Territory.

#### **5.3 Clinical Trial Cooperation.**

The parties shall discuss in good faith opportunities to avoid duplication of effort and achieve cost savings and other efficiencies with respect to any clinical trials to be conducted by the Company for the Licensed Products.

#### **5.4 Non-Compete; Trademark Exclusivity.**

During the term of this Agreement, other than sales of Licensed Products by Company and Sublicensees hereunder, neither party nor any of their respective Affiliates shall market or sell (or license any third party to market or sell) in the Territory any product for the treatment of Infestations. In addition, during the term of this Agreement, neither Licensor nor any of its Affiliates shall use (or license any third party to use) the Trade Mark (or any other marks or names containing or confusingly similar to, the Trade Mark) in the Territory in any field of use whatsoever (whether or not in the Field of Use).

#### **5.5 Company Improvements.**

Company will keep Licensor reasonably informed of any Company Improvements it makes in the course of the Development. Licensor will notify Company if it wishes to obtain a nonexclusive license to any such Company Improvement, in each case solely for use in connection with Licensed Products to be sold in countries outside the Territory. Provided that Company has the right to grant such license, upon receipt of such notice from Licensor, the parties will negotiate in good faith with respect to the terms and conditions of such license (including commercially reasonable royalties and other compensation to be paid to Company for such license).

#### **5.6 Annual Review Meetings.**

Executive-level personnel of both parties shall meet at least once per year during the Term (either in person or telephonically, and at times and places as are mutually acceptable to the parties) for the purpose of reviewing the status of Licensed Product commercialization in the Territory, including, but not limited to regulatory approval status, development and production issues and market conditions. The parties will discuss in good faith any amendments suggested by either party to the timelines set forth in Section 11.6, royalty rates and/or other provisions of this Agreement as may be fair and reasonable in light of changed

conditions. Any agreed upon amendments to this Agreement must be in writing and signed by authorized representatives of both parties.

#### Article 6 Royalties and Other Consideration

##### 6.1 Royalties on Net Sales; Minimum Royalties

6.1.1 During the Royalty Term, the Company shall pay Licensor a royalty at the Applicable Rate (as defined below) of Net Sales received during the applicable Royalty Term Year (as defined below), subject to further adjustment as described in this Article 6. For the purposes hereof, a "Royalty Term Year" means: (i) the period that begins on the date of the applicable First Commercial Sale and ends on December 31 of the same year and (ii) each calendar year thereafter during the Royalty Term. For the purposes hereof, the "Applicable Rate" means either: (i) eight percent (8%) or (ii) if an Adverse Event (as defined below) occurs, four percent (4%). If an Adverse Event occurs the Company shall notify Licensor and the parties shall agree that an Adverse Event has occurred and the month in which it occurred and thereafter the four percent (4%) royalty rate shall apply retroactively to all Net Sales received since the month during the calendar year in which the Adverse Event occurs, and Licensor shall pay any applicable refund to Company within thirty (30) days of the occurrence of the Adverse Event. If the Parties fail to agree this shall be dealt with as provided in Article 10.

6.1.2 (a) An Adverse Event shall be determined, and any royalty rate reductions under Section 6.1.1 above shall be applied, on a country-by-country basis in the Territory. For the purposes hereof, an "Adverse Event" means the date of first commercial sale of a Substantially Similar Product (as defined below) in the United States market or Canadian market, as applicable, which has been approved by the applicable Competent Authorities as a medical device or drug.

(b) For the purposes hereof, a "Substantially Similar Product" means any product for the treatment of head lice in humans that either: (i) is identical (in terms of formulation) to a Licensed Product and/or (ii) contains the compound known as "dimeticone" or "dimethicone" (irrespective of whether it is supplied as dimethicone or under a trade name) as the active ingredient up to and including a concentration of 10% w/w. Notwithstanding the foregoing, Substantially Similar Products do not include any current product marketed at the date hereof (other than Hedrin). For the avoidance of doubt combination products that include siloxanes, in combination with any one or more of the following active ingredients are not Substantially Similar Products: (i) any neurotoxin, (ii) any other solvents and/or alcohol in a concentration of more than 10% w/w and/or (iii) any fatty esters. The parties from time to time will discuss in good faith other new products for the treatment of head lice as they enter the marketplace and, as a result of such good faith discussions, may agree in writing upon other products that shall be excluded from the definition of Substantially Similar Products. Products requiring combing the hair as part of the treatment regime are also excluded.

6.1.3 Notwithstanding anything to the contrary, on a country-by-country basis in the Territory, if no patent issues from the Key Patent Application with respect to a country in the Territory (or if any such patent issues, but is subsequently invalidated,

deemed unenforceable, abandoned or revoked), the Company's obligation to pay Royalties under this Agreement and the Royalty Term (with respect to that country of the Territory in which the patent does not issue or is subsequently invalidated, deemed unenforceable, abandoned or revoked) shall end ten (10) years after the date of First Commercial Sale in such country.

6.1.4 The exclusivity granted to Company pursuant to Section 2.1 is subject to Company paying Licensor, with respect to each of the third, fourth, fifth, sixth and seventh full calendar years during the Royalty Term, minimum Royalties of One Million U.S. Dollars (\$1,000,000) (the "Minimum Royalties"); provided, however, that notwithstanding the foregoing, if an Adverse Event occurs, the Minimum Royalties in the calendar year in which the Adverse Event occurs and each of the above mentioned full calendar years thereafter shall be reduced to Five Hundred Thousand U.S. Dollars (\$500,000). Company may cure any failure to meet its Minimum Royalty obligation for any such calendar year by paying the amount of the shortfall to Licensor within sixty (60) days after the end of such calendar year. If Company fails to meet its Minimum Royalty obligation for a particular calendar year (and does not cure such failure as provided in the preceding sentence), Licensor, as its sole and exclusive remedy for such failure, may at any time thereafter, upon thirty (30) days prior, written notice to Company, convert the license granted to Company under Section 2.1 above to a semi-exclusive license (i.e., whereby Licensor shall have the right to grant a license to the Patent Rights, Know-How and Trademarks to no more than one (1) other party in the Territory in addition to the Company).

## 6.2 Sublicensing Royalties

During the Royalty Term, the Company shall pay Licensor royalties for Licensed Products sold by any Sublicensee(s) during a particular Royalty Term Year equal to the lesser of: (a) thirty percent (30%) of all sales-based royalties including sales milestones received by the Company or its Affiliates from such Sublicensee(s) with respect to such Licensed Products pursuant to the applicable sublicense agreement(s) and (b) the Royalties that would be due under Article 6.1 above for the Sublicensee's Net Sales of such Licensed Products; provided, however, that notwithstanding any of the foregoing, in no event shall such royalties payable to the Licensor be less than four and a half (4½%) percent of the Sublicensee's Net Sales of such Licensed Products.

## 6.3 No Multiple Royalties

No multiple royalties shall be payable because the use, lease or sale of any Licensed Product is, or shall be, covered by more than one Valid Claim contained in the Patent Rights. Additionally, royalties shall be paid to Licensor for the sale of a Licensed Product based upon only one of Articles 6.1 or 6.2 above, but in no case both (that is, royalties due to Licensor on direct sales of a Licensed Product by the Company or its Affiliates to a Third Party shall be based only on Article 6.1, while royalties on sales of a Licensed Product by the Company's Sublicensees to a Third Party shall be based only on either clause (a) or clause (b) of Article 6.2 (but in neither case shall such royalty be less than four and a half percent (4½%) of the Sublicensee's Net Sales), so as to avoid double counting).

## 6.4 Non Royalty Sublicensing Income

The Company shall pay to Licensor thirty percent (30%) of NRSI received by the Company or its Affiliates, subject to any deductions therefrom described in Article 1.20 and subject as provided below in this Article 6.4. If requested by Licensor, the Company will provide Licensor with reasonable

documentation (including copies of the relevant agreements with the Sublicensee and documentation of costs incurred to provide services to the Sublicensee) to support the Company's determination and establish on an objective basis that a payment received from a Sublicensee falls within the definition of NRSI or within an exclusion thereto. The parties agree that any dispute in this respect shall be dealt with under Article 10. Notwithstanding anything to the contrary, Milestone Payments paid by the Company after its execution of any such sublicense agreement shall be fully creditable against payments due with respect to NRSI.

#### 6.5 Combination Products

In the event that a Licensed Product is sold in the form of a combination product containing one or more technologies which, if incorporated into a product by themselves, would not render a product a Licensed Product, the Net Sales for such combination product shall be calculated by multiplying the sales price of such combination product by the fraction  $A/(A+B)$  where (i) A is the invoice price of a Licensed Product incorporating solely the technology which renders such product a Licensed Product, or, if such Licensed Product is not sold separately, the fair market value of a Licensed Product incorporating solely such technology, and (ii) B is the total invoice price of products incorporating solely the other technologies or, if such products are not sold separately, the fair market value of such products. Company shall not sell or permit any Sublicensee to sell any such combination product without the prior, written approval of Licensor, such approval not to be unreasonably withheld or delayed.

#### 6.6 Milestone Payments

As further consideration for the license granted hereunder, the Company will make the following one time Milestone Payments to Licensor.

- 6.6.1 (a) 150,000 shares of the Company's common stock (of which 75,000 shares shall be issued to Thornton & Ross and 75,000 shares issued to Kerris) and (b) six hundred thousand US Dollars (\$600,000), upon execution of the License Agreement (which payment shall be made within seven (7) days of execution of the License Agreement, but which payment obligation shall be irrevocable, regardless of any termination of this Agreement by the Company);
- 6.6.2 two hundred and fifty thousand US Dollars (\$250,000) upon acceptance for filing by the FDA of the first IND for the Licensed Product filed by Company or a Sublicensee;
- 6.6.3 One million US Dollars (\$1,000,000) upon the Successful Outcome of the Phase III Trial (if any) conducted with a Licensed Product under the first Company-sponsored (or Sublicensee-sponsored) IND (the "Phase III Milestone Payment"); provided, however, that if a Phase III Trial is not required the Phase III Milestone Payment shall not be payable until such time as the Approval (as defined below) issues;
- 6.6.4 Seven Hundred Thousand US Dollars (\$700,000) upon the final approval by a FDA of the first Company-sponsored (or Sublicensee-sponsored) NDA for a Licensed Product (the "Approval");
- 6.6.5 Three Hundred Thousand US Dollars (\$300,000) if, on or before the date that is thirty-six (36) months after the date Government Approval is received in the United States, a U.S. patent is issued from the Key Patent Application;

- 6.6.6 Two hundred fifty thousand US Dollars (\$250,000) upon receipt by the Company or a Sublicensee of the first Marketing Authorization for a Licensed Product in Canada; and
- 6.6.7 a one-time success fee of two million five hundred thousand US Dollars (\$2,500,000) upon achieving a target of cumulative Net Sales in the United States of the Licensed Products by the Company and all its sub-licensees of fifty million US Dollars (\$50,000,000) (respectively the "Success Fee" and the "Net Sales Target"), payable as follows:
- (a) if the said Net Sales Target shall be achieved within the first two (2) years of the Royalty Term in respect of the USA, such Success Fee to be paid out over the five (5) year period following the achievement of such milestone in equal installments of five hundred thousand US Dollars (\$500,000) per year;
  - (b) if the Net Sales Target is achieved during the third (3rd) years of the Royalty Term in respect of USA, the Success Fee shall be paid out over the four (4) year period following the achievement of such milestone in equal installments of six hundred twenty-five thousand US Dollars (\$625,000) per year; and
  - (c) if the Net Sales Target is achieved during the fourth (4<sup>th</sup>) year of the Royalty Term in respect of USA, the Success Fee shall be paid out over the three (3) year period following the achievement of such milestone in equal installments of eight hundred and thirty-three thousand, three hundred and thirty three US Dollars and thirty-three cents (\$833,333.33) per year; and
  - (d) if the Net Sales Target is achieved during or after the fifth (5th) year of the Royalty Term in respect of USA, the Success Fee shall be paid out over the two (2) year period following the achievement of such milestone in equal installments of one million two hundred fifty thousand US Dollars (\$1,250,000) per year.

Each of the Milestone Payments described above shall only be paid once upon their respective accomplishments, regardless of the number of times each of such milestones is achieved.

If any of the Milestone Payments set out above are not paid because the Company shall decide it is not necessary to take that step giving rise to the Milestone Payment, the Milestone Payment shall nonetheless be due and shall be paid at the time the Company shall decide not to take the particular step or when the next Milestone Payment is due whichever shall first occur.

#### **6.7 Equity Consideration**

It is understood and agreed that, notwithstanding anything to the contrary in this Agreement, the shares provided to Thornton & Ross and Kerris under this Agreement (the "Shares") are non-refundable. The Shares are not registered under the Securities Act of 1933, as amended, and may not be transferred unless and until registered or the Company has received an opinion of counsel or other evidence satisfactory to the Company and its counsel that such registration is not required. Each time Shares are required to be

issued under this Agreement, such Shares will be issued pursuant to a subscription agreement, in the form attached hereto as Exhibit 6.7.

#### **6.8 Place of Payment, Taxes and Conversions**

All payments under this Agreement shall be paid in United States dollars, unless otherwise required by law, into a joint account of Thornton & Ross and Kerris, at such place as Thornton & Ross may reasonably designate consistent with applicable laws and regulations. Any taxes, duties, or other levies which the Company, its Affiliate or any Sublicensee shall, in its reasonable discretion, be required by law to pay or withhold on remittance of any payment(s) due under this Agreement shall be deducted from such payment(s) to Licensor. Any such taxes, levies, or duties required under applicable law to be paid or withheld shall be an expense of, and borne solely by, Licensor. The Company will use commercially reasonable efforts to secure and send to Licensor proof of any such taxes, duties or other levies withheld and paid by the Company for the benefit of Licensor, and cooperate, at Licensor's expense, with any reasonable request to help ensure that amounts withheld and/or paid are reduced and/or recovered to the extent permitted by the relevant jurisdiction. If any currency conversion shall be required in connection with the payment of royalties hereunder, such conversion shall be made by using the exchange rate prevailing at Citibank, N.A. in New York, New York on the last business day of the calendar quarterly reporting period to which such royalty payments relate. In each country where the local currency is blocked and cannot be removed from the country under such country's applicable law, royalties accrued with respect to that country shall be paid to Licensor in such country in local currency by deposit in a local bank designated by Licensor, unless the parties otherwise agree.

#### **6.9 Time for Payment**

- 6.9.1 The Company shall pay to Licensor the royalties due and payable under this Agreement on a quarterly basis, and shall provide the Royalty Statement referred to in Article 7.2 along with such payment. Payments pursuant to this Article 6.9.1 are due with respect to a particular calendar quarter's Net Sales and receipts of NSRI and sales-based royalties sixty (60) days after the conclusion of such calendar quarter.
- 6.9.2 Milestone Payments payable to Licensor shall, notwithstanding the use of the word "upon" throughout Article 6.6, become due and payable within thirty (30) days after achievement of the indicated milestone.
- 6.9.3 Even if no royalties or other payments that may be due to Licensor under this Agreement shall be due, the Company shall be required to make a report pursuant to Article 7.2 to state that no payments are due.

#### **6.10 Interest**

Amounts which are not paid when due shall accrue interest from the due date until paid, at a rate equal to the then prevailing prime rate of Citibank, N.A., plus two percent (2%).

#### **6.11 Royalty Adjustments**

- 6.11.1 Notwithstanding anything to the contrary herein, if the Company obtains (or has obtained) one or more licenses under patents or patent applications owned by a Third Party: (i) to avoid infringement thereof by the manufacture, use, or sale of any Licensed Product, (ii) to reasonably avoid infringement-related litigation regarding a Licensed Product, or (iii) with the prior approval in writing of Licensor (which

approval shall not be unreasonably withheld) to make, use or sell any technology that could improve, enhance, or modify a Licensed Product, as determined by the Company in its reasonable discretion, then the Company may deduct fifty percent (50%) of any fees, milestones or royalties paid under such license(s) (even if paid in settlement or judgment of any claim for infringement) from the payments otherwise due Licensor under this Agreement (including any royalty payments, minimum royalty payments and Success Fee payments, but excluding any other Milestone Payments); provided, however, that, notwithstanding the foregoing, the total amount due Licensor under this Agreement in any particular calendar quarter shall not be reduced by more than fifty percent (50%) as a result of any such deduction, and any amounts not deducted in a calendar quarter shall be carried forward for deduction in the subsequent calendar quarter(s), subject to such fifty percent (50%) limitation in each case.

- 6.11.2 Should a compulsory license be granted, or be the subject of a possible grant, to a Third Party under the applicable laws of any country in the Territory under the rights licensed under this Agreement, the Company shall notify Licensor, including any material information concerning such compulsory license, and the running royalty rate payable under this Article 6 for sales of Licensed Products in such country will be adjusted to equal any lower royalty rate granted to such Third Party for such country with respect to the sales of such Licensed Products therein (the "Compulsory Royalty") during such periods such third parties sell or offer for sale under the compulsory license articles that compete with the Licensed Products then marketed and sold by the Company, its Affiliates, or Sublicensees in that country, provided that such Compulsory Royalty shall remain subject to further adjustment consistent with this Article 6, but such royalty rate shall not be less than four and a half percent (4½%).

#### **Article 7 Reports and Records**

##### **7.1 Records and Audits**

The Company shall keep full, true and accurate books of account containing all particulars that may be reasonably necessary for the purpose of showing the amounts payable to Licensor under this Agreement. Said books of account shall be kept at the Company's principal place of business and the supporting data shall be opened up to Licensor once per year upon reasonable notice to the Company for inspection by Licensor's internal audit division or by another designated auditor selected by Licensor, except one to whom the Company has reasonable objection, for the purpose of verifying the Company's Royalty Statement (as defined below) or compliance in other respects with this Agreement. If an inspection shows an under reporting or underpayment in excess of five percent (5%) of remuneration payable, then the Company shall reimburse Licensor for the reasonable, documented cost of the inspection at the time the Company pays the unreported royalties, including any late charges as required by Article 6.10 of this Agreement. Said books of account and the supporting data shall be made available to Licensor for one (1) year following the expiration of the Term. All payments required under this Article 7.1 shall be due within thirty (30) days of the date Licensor provides the Company notice of the payment due. Licensor shall cause its accounting firm to retain all financial information subject to review under this Article 7.1 in strict confidence; provided, however, that Company shall have the right to require that such accounting firm, prior to conducting such audit, enter into an appropriate non-disclosure agreement with Company regarding such financial information. The accounting firm shall disclose to Licensor only whether the

Company's Royalty Statement is correct or not and the amount of any discrepancy. No other information shall be shared. Licensor shall treat all such financial information as Company's Confidential Information

## **7.2 Royalty Statements**

Within 45 days from the end of each of the first, second and third calendar quarters (and within 60 days from the end of the fourth calendar quarter) of each calendar year, the Company shall deliver to Licensor complete and accurate reports, giving such particulars of the business conducted by the Company during the preceding quarter under this Agreement as shall be pertinent to an accounting of royalties and other payments that may be due to Licensor under this Agreement (the "Royalty Statement"). The Royalty Statement shall include at least the following:

- 7.2.1 Net Sales for each Licensed Product by the Company, each Affiliate, and each Sublicensee;
- 7.2.2 cumulative Net Sales for the applicable calendar quarter;
- 7.2.3 a breakdown of deductions applicable in computing Net Sales and taxes paid or withheld, if any;
- 7.2.4 a breakdown of royalties due based on Net Sales by or for the Company or its Affiliates;
- 7.2.5 a breakdown of royalties due on NRSE;
- 7.2.6 names and addresses of all Sublicensees and Affiliates of the Company; and
- 7.2.7 a copy of each report from each Sublicensee as may be pertinent to an accounting of royalties and other payments that may be due to Licensor.

## **7.3 Confidential Treatment of Reports**

Licensor agrees to hold in confidence each Royalty Statement delivered by the Company pursuant to this Article 7 for a period of five (5) years following termination of this Agreement. Notwithstanding the foregoing, Licensor may disclose any such information required to be disclosed in its financial statements or as required by any stock exchange or similar regulatory authority, or pursuant to any Applicable Laws, provided that Licensor take reasonable steps to provide and assist the Company with the opportunity, where reasonably appropriate, to (i) contest such subpoena, requirement or order or (ii) seek protective or confidential treatment thereof, including but not limited to reasonable advance notice to the Company of any such required disclosure, to the extent reasonably practicable. The Licensor understands that it is the intention of the Company to become publicly traded and that any information disclosed to Licensor under this Agreement, including the Royalty Statement, may be deemed "material non-public information" under the state and federal securities laws.

## **Article 8 Patent Prosecution and Maintenance**

### **8.1 Prosecution and Maintenance**

Following the Effective Date, the Company shall, at its expense, diligently file, prepare, prosecute and maintain the Patent Rights as set forth in Schedule 1.21 hereto (as the same may be amended or

supplemented in writing from time to time after the date hereof), including, but not limited to, the filing of patent applications, extensions, continuations, continuations in part, divisionals, re-examinations, or re-issue applications that the Company determines, in consultation with Licensor, may be required to advance the purposes of this Agreement or otherwise to protect the rights and licenses granted hereunder. The Company shall control such prosecution and maintenance, using counsel of its choosing, in the name of Licensor, and agrees to keep Licensor reasonably informed with respect to the status and progress of any such applications, prosecutions and maintenance activities and to consult in good faith with Licensor and take into account Licensor's reasonable comments and requests with respect thereto prior to the filing of any such documents. Licensor shall notify Company in writing and reasonable detail of any Improvements and assist Company in filing, prosecuting, and maintaining Patent Rights claiming the same. Both parties agree to provide reasonable cooperation to each other to facilitate the application and prosecution of patents pursuant to this Agreement and the Licensor shall execute all lawful papers and instruments and make all rightful oaths and declarations as may be necessary in the preparation, prosecution and maintenance of all patents and other filings referred to in this Article 8.

## **8.2 Patent Term Extensions**

The Company shall promptly notify Licensor of the issuance of each Governmental Approval and, where reasonably possible and reasonably useful or valuable in the commercialization of Licensed Products, use commercially reasonable efforts to apply or enable Licensor to apply for a patent term extension, adjustment or restoration, supplementary protection certificate, or other form of market exclusivity conferred by Applicable Laws (collectively, "Patent Term Extensions") in the relevant country of the Territory. Licensor shall, to the extent reasonably possible and reasonably useful or valuable in the commercialization of Licensed Products, use commercially reasonable efforts to, if and as requested by the Company, obtain (or assist the Company in obtaining) all available Patent Term Extensions. The Parties shall cooperate with each other in obtaining Patent Term Extensions wherever and whenever applicable, reasonably possible to obtain, and reasonably useful or valuable in the commercialization of Licensed Products.

## **8.3 Abandonment**

The Company may, in its discretion, elect to abandon any patent applications or issued patent in the Patent Rights provided that it shall have informed Licensor in writing prior to doing so. Following such abandonment, Licensor shall have the right, but not the obligation, to commence or continue such prosecution and to maintain any such patent or patent application under its own control and at its own expense and such patent or patent application shall thereafter be excluded from the definition of Patent Rights for purposes of this Agreement. Prior to any such abandonment, the Company shall give Licensor at least sixty (60) days notice and a reasonable opportunity to take over prosecution of such patent or patent application. The Company agrees to cooperate in such activities including execution of any documents necessary to enable Licensor to retain ownership and control of such patent or patent application.

## **Article 9 Infringement, Enforcement and Other Actions**

### **9.1 Notice of Infringement of Patent Rights**

The Company and Licensor shall promptly provide written notice, to the other party, of any alleged infringement or any challenge or threatened challenge to the validity, enforceability or priority of any of the Patent Rights, and provide each other with any available evidence of such infringement, challenge or threatened challenge by a Third Party of the Patent Rights and provide such other party with any available evidence of such infringement.

## **9.2 Option to Prosecute or Defend Patent Rights**

During the term of this Agreement, the Company shall have the first right, but not the obligation, to take (or refrain from taking) appropriate action to enforce Patent Rights, to defend any declaratory judgments seeking to invalidate or hold the Patent Rights unenforceable, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation, declaratory judgments or other enforcement action pertaining to Patent Rights, with respect to any potential, threatened, alleged, or actual infringement of, or challenge, to, the Patent Rights (all of the foregoing, collectively "Enforcement Actions"), at its own expense and with counsel of its choosing. In furtherance of such right, Licensor hereby agrees that the Licensor will, if requested by Company, join with Company as a party in any such suit, and cause its licensor and the owner of the patent to join such suit. If, within twelve (12) months of the written notice described in Article 9.1 above, the Company (i) shall have been unsuccessful in persuading the alleged infringer to desist, (ii) shall not have brought and shall not be diligently prosecuting an infringement action, or (iii) has not entered into settlement discussions with respect to such infringement, or if the Company notifies Licensor that it has decided not to undertake any of the foregoing against any such alleged infringer, then Licensor shall then have the right to bring suit to enforce such Patent Rights, at its own expense. Any recovery of damages or amounts received in settlement pursuant to this Article 9.2, as well as costs and expenses incurred in connection therewith, shall be allocated pursuant to Article 9.5 below.

## **9.3 Infringement by Licensed Product**

In the event that a claim or suit is asserted or brought against the Company alleging that the manufacture or sale of any Licensed Product by the Company, an Affiliate of the Company, or any Sublicensee, or the use of such Licensed Product by any customer of any of the foregoing, infringes proprietary rights of a Third Party, the Company shall give written notice thereof to Licensor. The Company may, in its sole discretion, modify such Licensed Product to avoid such infringement and/or may settle on terms that it deems advisable in its sole discretion, provided that any final disposition of the litigation that will restrict the claims in or admit any invalidity of any Patent Rights(s) shall not be made without consultation with and approval by Licensor, such approval not to be unreasonably withheld. Otherwise, the Company shall have the first right, but not the obligation, to defend any such claim or suit. If the Company has not exercised such right to defend or entered into settlement discussions concerning such alleged infringement within the sooner of (i) twelve (12) months of the assertion of such a claim or (ii) thirty (30) days of the filing of such a suit, or if the Company notifies Licensor that it has decided not to undertake such defense or enter into settlement discussions with respect to its alleged infringement, then Licensor shall then have the right to defend such alleged infringement, at its sole expense, provided however that no settlement affecting Patent Rights will be agreed upon without Company's written consent.

## **9.4 Control of Infringement Action**

The party controlling any action, suit, or defense under Article 9.2 or 9.3 (the "Controlling Party") shall be free to enter into a settlement, consent judgment, or other voluntary disposition of any such action, provided, however, that (i) the Controlling Party shall consult with the other party (the "Secondary Party") prior to entering into any settlement thereof and (ii) any settlement, consent judgment or other voluntary disposition of such actions which (1) materially limits the scope, validity, or enforceability of any Patent Rights or, if the Company is the Secondary Party, patents or patent applications owned or controlled by the Company, (2) subjects the Secondary Party to any non-indemnified liability, payment obligation, or injunction, or (3) admits fault or wrongdoing on the part of Secondary Party must be approved in writing by Secondary Party, such approval not to be unreasonably withheld. Secondary Party shall provide the Controlling Party notice of its approval or denial of such approval within fifteen (15) business days of any request for such approval by the Controlling Party, provided that (i) in the event

Secondary Party wishes to deny such approval, such notice shall include a written description of Secondary Party's reasonable objections to the proposed settlement, consent judgment, or other voluntary disposition and (ii) Secondary Party shall be deemed to have approved such proposed settlement, consent judgment, or other voluntary disposition in the event it fails to provide such notice within such fifteen (15) business day period.

#### **9.5 Allocation of Costs Incurred and Damages Recovered in Enforcement Action**

Each party (the "Prosecuting Party") will promptly notify the other party in writing in the event the Prosecuting Party chooses to take any Enforcement Action pursuant to its rights under Article 9.2 above and such other party will, within thirty (30) days after the date of such notice, provide the Prosecuting Party with written notice as to whether or not such other party elects to enter into an arrangement pursuant to which such other party will pay for fifty percent (50%) of the parties' aggregate attorneys' fees and other costs and expenses incurred in connection with such Enforcement Action (such costs to be allocated between and paid by the parties as incurred), and in exchange receive fifty percent (50%) of any cash payments awarded to the Prosecuting Party or received by the Prosecuting Party in settlement of such Enforcement Action (a "Risk/Reward Sharing Arrangement"). If such other party fails to provide the above-described notice to the Prosecuting Party within such thirty (30) day period, such other party shall be deemed to have elected not to enter into the Risk/Reward Sharing Arrangement. If such other party elects not to (or is deemed to have elected not to) enter into the Risk/Reward Sharing Arrangement, the Prosecuting Party shall be solely responsible for all of its costs of the Enforcement Action (together with any reasonable, documented out-of-pocket costs incurred by the other party to provide any assistance requested by the Prosecuting Party in connection with such Enforcement Action), and shall be entitled to retain all awards and other proceeds of such Enforcement Action.

#### **9.6 Cooperation**

In any suit to enforce and/or defend the Patent Rights pursuant to this Agreement, or defend any alleged infringement of Third Party intellectual property rights by the manufacture, use, sale, or import of a Licensed Product, the Secondary Party shall, at the request of the Controlling Party, cooperate in all respects and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens, and the like.

### **Article 10 Dispute Resolution**

#### **10.1 Disputes**

- 10.1.1 The parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either party's rights and/or obligations hereunder or to the interpretation, performance, breach, or termination of this Agreement, (a "Dispute"). It is the objective of the parties to establish procedures to facilitate the resolution of a Dispute in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the parties agree to follow the procedures set forth in this Article 10 if and when a Dispute arises under this Agreement.
- 10.1.2 A Dispute among the parties will be resolved as recited in this Article 10. Any Disputes relating to this Agreement shall be promptly presented to the Chief Executive Officers of Licensor and the Company, or their respective designees (who must be members of a party's senior management) for resolution. From the date of referral of a Dispute to the Chief Executive Officers or their designees of the parties

and until such time as any matter has been resolved by the parties or has been finally settled by arbitration hereunder, the running of the cure periods (if any) as to which a party must cure a breach that is part of the subject matter of any Dispute shall be suspended. In the event that the Chief Executive Officers of Licensor and the Company, or their respective designees, cannot after good faith negotiations resolve the Dispute within thirty (30) days (or such other period of time as mutually agreed to by the parties in writing) of being requested by a party to resolve a Dispute, the parties agree that such Dispute shall be resolved by binding arbitration in accordance with this Article 10.1.

- 10.1.3 If a party intends to begin arbitration to resolve such Dispute, such party shall provide written notice (the "Arbitration Notice") to the other party informing such other party of such intention and the issues to be resolved. Any arbitration hereunder shall be conducted pursuant to the Commercial Arbitration Rules of the American Arbitration Association ("AAA"; such rules, the "AAA Rules"), except as modified herein. The arbitration shall be conducted by a panel of three (3) independent, neutral arbitrators that are industry experts experienced in the issues comprising the Dispute and have no past, present or reasonably anticipated future affiliation with either party (the "Panel"). Company and Licensor shall each be entitled to select one (1) such arbitrator, with the two such arbitrators so selected selecting the third such arbitrator. In the event either party fails to select its arbitrator within such ten (10) day period, the arbitrator selected by the other party within such ten (10) day period shall be entitled to select such arbitrator. The arbitration shall take place in New York, New York and be conducted in English. The Panel shall apply the laws of the State of New York, without regard to its conflicts of laws provisions. The Panel shall issue appropriate protective orders to protect each party's Confidential Information. If a party can demonstrate to the Panel that the complexity of the issue or other reasons warrant the extension of one or more timetables in the AAA Rules, the Panel may extend such timetables but in no event shall the proceeding extend more than twelve (12) months from the date of filing of the arbitration notice with the AAA. The Panel's decision shall be in writing. The Panel shall have the authority to award any remedy allowed by law, including but not limited to compensatory damages, pre-judgment interest, but not punitive or other damages and each party shall be deemed to have waived any right to such excluded damages. Each party shall bear its own costs, fees and expenses in the arbitration and shall share equally the Panel's fees, unless the Panel determines that its fees are to be paid by the non-prevailing party. Notwithstanding anything to the contrary, without prejudice to the above procedures, either party may seek injunctive relief or other provisional judicial relief if, in its reasonable judgment, such action is necessary to avoid irreparable damage or otherwise enforce its rights hereunder

## **10.2 Performance to Continue**

Each party shall continue to perform its obligations, and shall be permitted to continue to exercise its rights, under this Agreement pending final resolution of any Dispute arising out of or related to this Agreement; provided, however, that a party may suspend performance of its obligations during any period in which the other party fails or refuses to perform its obligations.

## **10.3 Determination of Patents and Other Intellectual Property**

Notwithstanding the foregoing, any dispute relating to the determination of validity of claims, infringement or claim interpretation relating to Licensor's Patent Rights shall be submitted exclusively to the United States District Court for the Southern District of New York and the appropriate appellate courts thereof. Each of the parties hereby irrevocably consents and submits to the exclusive jurisdiction of such courts with respect to any such disputes and waives any objections to the laying of venue in such courts.

#### **10.4 Statute of Limitation and Time-Based Defenses Tolloed**

All applicable statutes of limitation and time-based defenses (such as estoppel and laches) shall be tolled while any arbitration proceedings are pending and during any arbitration proceedings. The parties shall cooperate in taking any actions necessary to achieve this result.

### **Article 11 Term and Termination**

#### **11.1 Term**

This Agreement shall become effective on the Effective Date and shall expire on the date of the expiration of the last to expire Royalty Term in any country in the Territory (the "Term"), unless earlier terminated as provided in Articles 6.1.3, 11.2, 11.3, or 11.5.

#### **11.2 Termination for Insolvency**

If the Company shall become bankrupt, or shall file a petition in bankruptcy, or if the business of the Company shall be placed in the hands of a receiver, assignee or trustee for the benefit of creditors, whether by the voluntary act of the Company or otherwise, Company shall provide notice thereof to Licensor and Licensor may, subject to the effects of and protections of any applicable bankruptcy-related laws, rules, or regulations, terminate this Agreement upon notice to Company given within thirty (30) business days of Licensor's receipt of such notice whereupon Licensor shall be entitled to exercise the right of reference to Company Data as defined in Article 3.1 and on the basis set out in Articles 3.1 and 11.5.

#### **11.3 Termination for Material Breach**

Upon any material breach or default of this Agreement by the Company, Licensor shall have the right to terminate this Agreement and the rights, privileges and license granted hereunder by giving ninety (90) days prior written notice to the Company. Upon the expiration of the ninety (90) day period, if the Company shall have not cured such breach or default, this Agreement shall, at the option of Licensor, terminate upon written notice of Licensor. In the event of a bona fide dispute over any material breach, the parties shall attempt to resolve such dispute in good faith through negotiation, or if agreed to by the parties, mediation, in each case to include the senior executive of both parties hereto. Notwithstanding anything herein to the contrary, if the nature of the breach is such that additional time is reasonably needed to cure such breach, and Company has commenced with good faith efforts to cure such breach, then Licensor shall provide Company with additional time in which to cure such breach. If a dispute regarding termination is addressed pursuant to Article 10, this license shall remain in full force and effect until such dispute is resolved. All applicable statutes of limitation and time-based defenses (such as estoppel and laches) shall be tolled while any good faith negotiation or mediation procedures are pending or ongoing. The parties shall reasonably cooperate in taking any actions necessary to achieve this result.

#### **11.4 Expiration of Royalty Term on a Country by Country Basis**

Upon the expiration of the Royalty Term in each country in the Territory, the Company will have an irrevocable, perpetual, paid up, royalty-free non-exclusive license, with rights of sublicense (through multiple tiers), under all rights granted under this Agreement to make, have made, use, have used, lease, import and export, offer to sell, sell have sold, produce, manufacture, distribute and market Licensed Products in such country.

#### 11.5 Termination for Convenience

The Company shall have the right at any time to terminate this Agreement in its entirety or on a country-by-country basis, for any reason or no reason, by giving thirty (30) days notice thereof in writing to Licensor. In the event of any termination pursuant to this Article 11.5, at the request of Licensor, Company shall transfer to Licensor any and all clinical study data, INDs and Governmental Approvals relating to the Licensed Product (the "Data") that the Company has the right to transfer.

If such notice of termination shall be given prior to the First Commercial Sale such transfer shall be free. If notice shall be given after the First Commercial Sale, the Licensor shall reimburse the Company for all costs incurred in connection with the creation of the Data (including, but not limited to, costs of clinical studies and costs associated with filing for and obtaining regulatory approval) (the "Data Costs"), as follows:

- (i) to the extent Licensor or any of its Affiliates licenses the Licensed Product and/or the Data to one or more third parties (the "New Licensees"), after Licensor or its Affiliates have received aggregate payments from the New Licensees equal to the Threshold Amount (as defined below), Licensor will reimburse the Company for the Data Costs out of any subsequent payments received from the New Licensees, as follows: (A) Licensor will pay Company fifty percent (50%) of any such payments (other than royalties) that Licensor or any of its Affiliates receives from the New Licensees, including, but not limited to, milestone payments and lump sum payments for use of the Data, and (B) Licensor will pay Company a percentage of any royalties that Licensor or any of its Affiliates receives from the New Licensees, such percentage to be determined using the formula set forth in Section 6.2 hereof, *mutatis mutandis*; and
- (ii) to the extent Licensor or any of its Affiliates sells the Licensed Product itself (as opposed to licensing a New Licensee to do so), Licensor will reimburse the Company for the Data Costs pursuant to such payment schedule as shall be negotiated in good faith and agreed upon in writing by the parties.

For the purposes of the foregoing, the "Threshold Amount" means an amount equal to: (A) five million U.S. Dollars (\$5,000,000) minus (B) the aggregate amount of all Minimum Royalties paid by Company hereunder. The Company will take all steps that may be necessary to ensure that the benefit of the Data is transferred to the Licensor

#### 11.6 Termination by Licensor

11.6.1 Subject to Section 11.6.2 below, Licensor shall be entitled to terminate this Agreement if the Company (or its Sublicensee) does not:

- 11.6.1.1 request a Pre-IND Meeting with the FDA within ninety (90) days after the Effective Date;

- 11.6.1.2 file an IND in respect of the first Licensed Product in the United States by, as applicable: (A) three (3) months after the date of the Pre-IND Meeting with the FDA or (B) if no such meeting is held, within one (1) month after receipt of notice from the FDA that no such meeting is required or (C) if the FDA fails to notify the Company as to whether or not such a meeting is required, within eighteen (18) months after the Effective Date;
- 11.6.1.3 to the extent that Company or its Sublicensee is seeking approval for the Licensed Product as a drug, initiate a Phase III Trial in the United States within nine (9) months of the date of the End-of-Phase II Meeting with the FDA with respect to such Licensed Product (such meeting to be requested within two (2) months after Company completes full analysis of Phase II data);
- 11.6.1.4 to the extent that Company or its Sublicensee is seeking approval for the Licensed Product as a drug, complete the Phase III Trial within twenty-four (24) months of the commencement of the Phase III Trial;
- 11.6.1.5 to the extent that Company or its Sublicensee is seeking approval for the Licensed Product as a drug, file the first application for NDA for a Licensed Product in the United States within nine (9) months of Successful Outcome.
- 11.6.1.6 achieve the First Commercial Sale in the United States within twelve (12) months of obtaining the final approval by the FDA of the NDA for a Licensed Product in the United States.

If Licensor terminates this Agreement under any of the provisions set out above in this Section 11.6.1, the Company shall transfer the Data to Licensor free of charge.

- 11.6.2 The timelines and termination right described in Article 11.6.1 are subject to the following provisions:
  - 11.6.2.1 For the avoidance of doubt, the timelines and termination right under Article 11.6.1 apply only with respect to the first Licensed Product for which the Company seeks regulatory approval in the United States. To the extent the Company seeks regulatory approval for any additional Licensed Products and/or seeks regulatory approval in Canada, Licensor shall not have any right to terminate this Agreement on the basis of delays associated with such activities.
  - 11.6.2.2 The timelines specified in Article 11.6.1 are based on the following assumptions:
    - (i) the documentation regarding the Licensed Product provided to Company by the Licensor will be deemed sufficient by the FDA for filing an IND for the Licensed Product, and proceeding directly to Phase III Trials, without any material supplement or change;
    - (ii) the FDA will allow any required toxicology studies to be conducted in parallel with the Phase III Trial (as opposed to prior to beginning the Phase III Trial);
    - (iii) no additional non-clinical studies (i.e., other than those studies that have already been conducted by Licensor prior to the Effective Date) are

required by the FDA with respect to the Licensed Product during the clinical development program;

- (iv) the FDA will not require any additional pre-clinical studies, toxicology studies (other than as described in clause (ii) above), pharmacology studies, CMC data, formulation or clinical supplies production activities to be completed to support the Phase III Trial; and
- (v) no safety, toxicity, technical or other issues will arise during the conduct of any studies relating to the Licensed Product.

11.6.2.3 The periods specified in Article 11.6.1 above shall be extended after consultation with Licensor and the parties' mutual agreement as to the length of the each extension (such agreement not to be unreasonably withheld), to the extent that delay is incurred on account of: (i) the failure of any of the assumptions listed in Article 11.6.2.2 above, (ii) any reasons outside the reasonable control of the Company including any delays caused by Competent Authorities or any requirement to conduct further clinical studies of the Licensed Product or (iii) any failure of Thornton & Ross to supply GMP-compliant quantities of the Licensed Product for use in clinical trials and/or for commercial sale.

11.6.3 Licensor shall be entitled to terminate this Agreement upon written notice to the Company if the Company (or any of its Affiliates or Sublicensees) commences any litigation challenging the validity or enforceability of any of the Patent Rights.

## 11.7 Consequences of Termination

Upon the early termination of this Agreement by either party, the following shall occur:

11.7.1 Subject to Article 11.7.2, the Company and its Affiliates (as the case may be) shall have no right to practice within the Patent Rights or use any of the Patent Rights and Know-how, and all rights, title or interest in, or other incidents of ownership under, the Patent Rights and Know-how shall revert to and become the sole property of Licensor, and the licenses granted under Article 2.1 shall automatically terminate.

11.7.2 Notwithstanding Article 11.7.1, if this Agreement is terminated other than pursuant to Article 11.5, the Company and its Affiliates may, after the effective date of such termination and continuing for a period not to exceed twelve (12) months thereafter, sell all completed Licensed Products, and complete (or have completed) any Licensed Products in the process of manufacture at the time of such termination and sell the same, provided that the Company:

- (a) notifies Licensor of its decision within thirty (30) days after the date it receives a notice of termination by Licensor or the date it provides a notice of termination to Licensor, as the case may be;
- (b) pays or cause to be paid to Licensor the royalties and other payments thereon as required by Article 6 of this Agreement; and
- (c) submits the reports required by Article 7 hereof.

- 11.7.3 If the Company does not elect pursuant to Article 11.7.2 to sell-off or distribute, as applicable, any existing inventory of Licensed Product, the Company shall, at Licensor's election, either:
- (a) sell all existing inventory of Licensed Product to Licensor at fair market value; or
  - (b) destroy all remaining inventory of Licensed Product in accordance with Applicable Laws and provide Licensor with written proof of destruction sufficient to comply with Applicable Laws.
- 11.7.4 Notwithstanding anything to the contrary, each sublicense granted under this Agreement by the Company or its Affiliates to a Sublicensee shall, to the extent not imposing obligations on Licensor in excess of those contained herein, survive such termination and be automatically assigned to Licensor as provided for in Article 2, in order to provide for the applicable Sub licensees' continued enjoyment of their rights under such sublicenses.

#### **11.8 Partial Termination**

Upon the early termination of this Agreement by either party in respect of a country, the terms of Article 11.7 shall apply in respect of such country.

#### **11.9 Survival**

Upon termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination, or such party's obligations under Articles 6 and 7, and the following provisions shall survive such termination: Articles 7.3, 9 (with respect to infringement occurring prior to such termination), 10, 11, 13, 14, 15, and 16.

### **Article 12 Representations and Warranties**

#### **12.1 Licensor Warranties**

For the avoidance of doubt, all references to Licensor in this Section 12.1 shall mean Thornton & Ross and/or Kerris, as the context requires. Thornton & Ross and Kerris (jointly and severally) each represents and warrants that:

- 12.1.1 Licensor owns all right, title, and interest in and to, or has an exclusive license under the Durminster Agreement to, the Patent Rights and Know-how, free and clear of all liens, charges, encumbrances or other restrictions or limitations of any kind whatsoever, except for those restrictions that are expressly set forth in the Durminster Agreement, none of which conflict with the terms and conditions of this Agreement. Licensor has licensed sufficient rights to the Patent Rights and Know-how under the Durminster Agreement for it to grant the rights (including, but not limited to, the exclusive license to the Patent Rights and Know-How) granted hereunder to the Company.
- 12.1.2 There are no licenses, options, restrictions, liens, rights of third parties, disputes, royalty obligations, proceedings or claims relating to, affecting, or limiting Licensor's rights or the rights of the Company under this Agreement, or which may lead to a

claim of infringement by or invalidity regarding, any part or all of the Patent Rights or Know-how or their use.

- 12.1.3 There is no claim, pending or threatened, of infringement, interference or invalidity regarding any part or all of the Patent Rights or Know-how or their use.
- 12.1.4 The US and foreign patent applications and patents itemized on Schedule 1.21 set forth all of the patents and patent applications owned by or licensed to Licensor or any of its Affiliates relating to the Licensed Products in respect of the Territory (including, but not limited to, the manufacture, formulation, composition or use thereof) on the date of this Agreement.
- 12.1.5 There are no inventors of Patent Rights other than those listed as inventors on applications filed for such Patent Rights.
- 12.1.6 The development of the Patent Rights, and Know-how were not supported in whole or part by funding or grants by any governmental agency or philanthropic or charitable organization.
- 12.1.7 Thornton & Ross is a company duly organized, validly existing and in good standing under the laws of England. Kerris is a company duly organized, validly existing and in good standing under the laws of Luxembourg. The Licensor has the requisite power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement and the performance and consummation of the transactions contemplated hereby by the Licensor have been duly authorized by all necessary action on the part of the Licensor. This Agreement has been duly executed and delivered by the Licensor and, subject to the due authorization, execution and delivery of this Agreements by the Company, this Agreement constitutes a valid and binding obligation of the Licensor, enforceable against the Licensor in accordance with its terms, except as such enforcement may be affected by bankruptcy, reorganization, insolvency, moratorium or similar laws affecting creditor's rights generally and except for general principles of equity.
- 12.1.8 The execution and delivery of this Agreement does not, the consummation of the transactions contemplated hereby, and the performance of Licensor's obligations hereunder will not, (i) conflict with, or result in any violation or breach of any provision of the organizational documents of the Licensor, (ii) so far as Licensor is aware conflict with or violate any applicable foreign, Federal, state and local statutes, judgments, decrees, laws, ordinances, rules, regulations, injunctions and orders ("Laws") of any U.S. Federal, state, foreign or local government or any court, tribunal, administrative agency or commission or other governmental or regulatory authority, body or agency, including any self-regulatory organization ("Governmental Authorities") applicable to the Licensor or any of its assets or operations or any permit applicable to the Licensor or (iii) result in (x) any violation or breach of, constitute (with or without notice or lapse of time or both) a default under or conflict with (or give rise to a right of termination, amendment, cancellation or acceleration of any material obligation or loss of any benefit under) the provisions of any lease, contract or other agreement to which the Licensor is a party or by which it or any of its properties or assets is otherwise bound or (y) the imposition of any lien, pledge, hypothecation, mortgage, security interest, claim, lease, charge, option, right of first refusal or first offer, easement, servitude, transfer restriction, voting requirement or

any other encumbrance, restriction or limitation on any of the properties or assets of the Licensor.

- 12.1.9 No consent, approval or authorization of, or declaration or filing with, any Governmental Authority or other Third Party (a "Consent") is required on the part of the Licensor in connection with its execution, delivery, and performance of this Agreement or the consummation of the transactions contemplated hereby.
- 12.1.10 No written communication has been received by the Licensor, and no investigation, regulatory enforcement action (including seizure, injunction, civil penalty or criminal action) or any related Governmental Authority review is or, in respect of any Licensed Product, to the knowledge of the Licensor, was at any time pending or is threatened by any Governmental Authority with respect to (i) any alleged or actual violation by the Licensor of any permit, Law or other requirement of any Governmental Authority relating to the operations conducted by the Licensor with respect to any Licensed Product or (ii) any alleged or actual failure to have or maintain in effect all permits required in connection with the operations conducted by the Licensor with respect to any Licensed Product. The Licensor has not received from the FDA, the U.S. Drug Enforcement Administration ("DEA"), or any similar state, local, federal, or foreign Governmental Authority any written notice regarding the approvability or approval of any of the Licensed Products. No Licensed Product has been withdrawn, suspended or discontinued by the Licensor as a result of any action by the FDA, the DEA or any similar state, local, federal, or foreign Governmental Authority, either within or outside the U.S. (whether voluntarily or otherwise). With respect to any Licensed Products, no officer, employee or, to the knowledge of the Licensor, agent of the Licensor has made any untrue statement of a material fact or a fraudulent statement to the FDA, DEA or any similar state, local, federal, or foreign Governmental Authority, failed to disclose any material fact required to be disclosed to the FDA, the DEA or any similar state, local, federal, or foreign Governmental Authority, or committed an act, made a statement or failed to make a statement that, at the time such act, statement or omission was made, could reasonably be expected to provide a basis for the FDA, the DEA or any similar state, local, federal or foreign Governmental Authority to invoke the FDA's policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" set forth in 56 Fed. Reg. 46191 (September 10, 1991) or any similar policy, nor has any director, officer, employee or, to the knowledge of the Licensor, agent of the Licensor been convicted of any crime or engaged in any conduct for which debarment is mandated by 21 U.S.C. Article 335a(a) (or any similar Law) or authorized by 21 U.S.C. Article 335a(b) (or any similar Law).
- 12.1.11 Except as set forth in Schedule 12.1.11 as of the Effective Date there are no suits or actions, administrative, arbitration or other proceedings, or governmental investigations pending or, to the knowledge of the Licensor, threatened against or affecting the Licensor with respect to Licensed Products or the Patent Rights. No Entity has notified the Licensor in writing of any material claim against the Licensor alleging any personal property or economic injury, loss or damage incurred as a result of or relating to the use of any Licensed Products. There is no judgment, order, injunction, decree, writ or award against the Licensor that is not satisfied and remains outstanding with respect to Patent Rights or any Licensed Product.

- 12.1.12 Schedule 12.1.12 hereto sets forth a true and complete list of each material license, contract or other agreements (together with certain other agreements and any amendments to any of the foregoing) to which the Licensor is a party or by or to which any property of the Licensor is otherwise bound or subject that relates to the Licensed Products or the Patent Rights, including but not limited to the Dumminster Agreement (collectively, the "Material Agreements"). True and complete copies of all Material Agreements have been previously delivered to the Company. Each of the Material Agreements is valid, binding and in full force and effect, and enforceable by the Licensor, or has expired, in each case in accordance with its respective terms. No Person (other than the Licensor) that is a party to any Material Agreement or is otherwise bound thereby is, to the knowledge of the Licensor, in default or breach thereof and, to the Licensor's knowledge, no event, condition or act exists that, with the giving of notice or the lapse of time or both, would give rise to such a default or breach thereof or a right of cancellation by the Licensor thereunder. The Licensor is not in default or breach in any material respect of any of the Material Agreements and, to the knowledge of the Licensor, no event, condition or act exists that, with the giving of notice or the lapse of time or both, would give rise to a default or breach by the Licensor thereof or a right of cancellation thereunder by any other party thereto.
- 12.1.13 To the knowledge of the Licensor, none of the Patent Rights or Licensed Products, nor the practice, development, use, manufacture, sale, or import of any of the foregoing, infringes or conflicts in any material respect with (and the Licensor has not received any notice of infringement of, or conflict with) any license, patent, copyright, trademark, service mark or other intellectual property right of any Third Party and, to the knowledge of the Licensor, there has not been and is not currently any infringement or unauthorized use by any Third Party of any of the Patent Rights, Know-how, or Licensed Products. The validity or enforceability of any of the Patent Rights and or the title of the Licensor thereto has not been questioned in any litigation, governmental inquiry or proceeding to which the Licensor is a party and, to the knowledge of the Licensor, no such litigation, governmental inquiry or proceeding is threatened.
- 12.1.14 To the knowledge of the Licensor, the Licensor and its licensors have taken all reasonable actions necessary or appropriate to preserve the confidentiality of all trade secrets, proprietary and other confidential information material to the Licensed Products, Know-how, and Patent Rights.
- 12.1.15 Licensor is not aware of any Third Party activities which would constitute misappropriation or infringement of the Patent Rights.
- 12.1.16 Licensor owns all right, title, and interest to the Licensor IND(s) (if any) free and clear of all liens, claims, and encumbrances, the Licensor IND(s) constitute the only INDs or regulatory filings of any kind concerning any Licensed Product, and there are no Governmental Approvals in place or effective in any jurisdiction with respect to any Licensed Product.
- 12.1.17 Schedule 12.1.17 contains a complete and accurate list of any and all regulatory approvals and filings for regulatory approval, worldwide, with respect to any Licensed Products (the "Worldwide Regulatory Filings and Approvals"). Licensor represents that it has provided Company with copies of all correspondence with the Governmental Authority with respect to each of the Worldwide Regulatory Filings

and Approvals, as well as all other data and information of which Licensor is aware that would reasonably be expected to be material to the safety or efficacy of the Licensed Product.

## 12.2 Company Warranties

The Company represents and warrants that:

- 12.2.1 The Company is a corporation duly organized, validly existing and in good standing under the laws of Delaware. The Company has the requisite power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement and the performance and consummation of the transactions contemplated hereby by the Company have been duly authorized by all necessary action on the part of the Company. This Agreement has been duly executed and delivered by the Company and, subject to the due authorization, execution and delivery of this Agreement by the Licensor, this Agreement constitutes a valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except as such enforcement may be affected by bankruptcy, reorganization, insolvency, moratorium or similar laws affecting creditor's rights generally and except for general principles of equity.
- 12.2.2 The execution and delivery of this Agreement does not, the consummation of the transactions contemplated hereby, and the performance of Company's obligations hereunder will not, (i) conflict with, or result in any violation or breach of any provision of the organizational documents of the Company, (ii) so far as the Company is aware conflict with or violate any applicable Laws of any Governmental Authorities applicable to the Company or any of its assets or operations or any permit applicable to the Company or (iii) result in (x) any violation or breach of, constitute (with or without notice or lapse of time or both) a default under or conflict with (or give rise to a right of termination, amendment, cancellation or acceleration of any material obligation or loss of any benefit under) the provisions of any lease, contract or other agreement to which the Company is a party or by which it or any of its properties or assets is otherwise bound or (y) the imposition of any lien, pledge, hypothecation, mortgage, security interest, claim, lease, charge, option, right of first refusal or first offer, easement, servitude, transfer restriction, voting requirement or any other encumbrance, restriction or limitation on any of the properties or assets of the Company.
- 12.2.3 No Consent is required on the part of the Company in connection with its execution, delivery, and performance of this Agreement or the consummation of the transactions contemplated hereby.
- 12.2.4 Except as set forth on Schedule 12.2.4, as of the Effective Date: (i) there are no suits or actions, administrative, arbitration or other proceedings, or governmental investigations pending or, to the knowledge of the Company, threatened against or affecting the Company, (ii) no Entity has notified the Company in writing of any material claim against the Company alleging any personal property or economic injury, loss or damage incurred as a result of relating any action by the Company and (iii) there is no judgment, order, injunction, decree, writ or award against the Company that is not satisfied and remains outstanding with respect to any matter affecting the Company, the Patent Rights, or any Licensed Product.

12.2.5 Company is not bound by any non-competition covenant or other agreement containing restrictions on Company which would reasonably be expected to have a material adverse effect on the ability of Company to perform its obligations under this Agreement.

12.2.6 To the actual knowledge of the Company, the sale in the Territory of the Licensed Product (in the form initially contemplated by the Company as of the Effective Date), does not infringe any third party patent issued in the Territory as of the Effective Date.

### 12.3 No Impairment

Each party hereby covenants and agrees with the other that, during the Term, it will not, by act or failure to act, impair or otherwise adversely affect, or cause any occurrence which would reasonably anticipated to impair or otherwise adversely affect, the rights of the other under this Agreement or ability of the other party to freely exercise such rights.

## Article 13 Limitation of Liability, Indemnity

### 13.1 NO IMPLIED WARRANTIES

13.1.1 EXCEPT AS SET FORTH IN ARTICLE 12, NEITHER PARTY MAKES AND EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND VALIDITY OF PATENTED RIGHTS CLAIMS, ISSUED OR PENDING.

13.1.2 EXCEPT AS SET FORTH IN ARTICLE 12, NOTHING HEREIN SHALL BE CONSTRUED AS A REPRESENTATION OR WARRANTY BY EITHER PARTY TO THE OTHER PARTY THAT THE PATENT RIGHTS AND KNOW-HOW ARE NOT INFRINGED BY ANY THIRD PARTY, OR THAT THE PRACTICE OF SUCH RIGHTS DOES NOT INFRINGE ANY INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

### 13.2 Indemnity

13.2.1 The Company agrees to defend, indemnify and hold harmless Licensor, its Affiliates, and each of their respective directors, employees and officers (collectively, the "Licensor Indemnitees") from and against all liability, demands, damages, costs and expenses (including, without limitation, reasonable legal fees and expenses) and losses (collectively, "Losses") in connection with any third party claim arising out of or relating to: (i) any breach of this Agreement by Company, (ii) negligence, willful misconduct, or failure to comply with Applicable Laws by any Company Indemnitee in connection with this Agreement or (iii) any Company Indemnitee's use, manufacture, sale, or other disposition of Licensed Products under the terms of this Agreement (including, but not limited to, any claims for personal injury or property damage arising from the use thereof); in each of the foregoing cases to the extent: (i) not resulting from any Licensor Indemnitee's breach of this Agreement, negligence, willful misconduct, or failure to comply with Applicable Laws and/or (ii) not covered

by any indemnity provided to Company by a Licensor Indemnitee pursuant to a separate agreement.

13.2.2 Licensor agrees to defend, indemnify and hold harmless the Company and its Affiliates and each of their respective directors, employees, and officers (collectively, the "Company Indemnitees") from and against all Losses in connection with any third party claim arising out of or relating to: (i) any breach of this Agreement by Licensor, (ii) negligence, willful misconduct, or failure to comply with Applicable Laws by any Licensor Indemnitee in connection with this Agreement, (iii) any Licensed Products sold by Licensor or any of its sublicensees or distributors following any termination of this Agreement, including, but not limited to, any claims for personal injury or property damage arising from the use thereof or (iv) any claims by any Sublicensees under any sublicense agreement assigned to Licensor following any termination of this Agreement, to the extent such claim relates to the period following the date of such termination.

13.2.3 In the event that either party intends to seek indemnification for any claim under Article 13.2.1 or 13.2.2, it shall inform the other party of the claim promptly after receiving notice of the claim.

In the case of a claim for which Licensor seeks indemnification under Article 13.2.1, Licensor shall permit the Company to direct and control the defense of the claim and shall provide such reasonable assistance as is reasonably requested by the Company (at the Company's cost) in the defense of the claim, provided that nothing in this Article 13.2.3 shall permit the Company to make any admission on behalf of Licensor, or to settle any claim or litigation which would impose any financial obligations on Licensor without the prior written consent of Licensor, such consent not to be unreasonably withheld or delayed.

In the case of a claim for which the Company seeks indemnification under Article 13.2.2, the Company shall permit Licensor to direct and control the defense of the claim and shall provide such reasonable assistance as is reasonably requested by Licensor (at Licensor's cost) in the defense of the claim, provided that nothing in this Article 13.2.3 shall permit Licensor to make any admission on behalf of the Company, or to settle any claim or litigation which would impose any financial obligations on the Company without the prior written consent of the Company, such consent not to be unreasonably withheld or delayed.

### 13.3 LIMITATION OF LIABILITY

EXCEPT WITH REGARD TO DAMAGES ARISING FOR INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS, BREACHES OF ARTICLE 14.3 OR 15, AND ANY DUTY TO INDEMNIFY FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES UNDER ARTICLE 13.2.1 OR 13.2.2, IN NO EVENT SHALL EITHER PARTY OR THEIR AFFILIATES BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY AND IRRESPECTIVE OF WHETHER SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF ANY SUCH LOSS OR DAMAGE.

### Article 14 Use of Names and Publication

#### **14.1 Use of Name**

Nothing contained in this Agreement shall be construed as granting any right to the Company or its Affiliates to use in advertising, publicity, or other promotional activities any name, trade name, trademark, or other designation of Licensor or any of its units (including contraction, abbreviation or simulation of any of the foregoing) without the prior, written consent of Licensor; provided that Company may identify Licensor as the licensor under this Agreement without such consent to actual or potential investors, investment bankers, acquirers, acquisition targets, and strategic partners, and where the use of such names may be required by Applicable Law.

#### **14.2 No Agency**

Nothing herein shall be deemed to establish a relationship of principal and agent between Licensor and the Company, nor any of their agents or employees for any purpose whatsoever. This Agreement shall not be construed as creating a partnership between the Licensor and the Company, or as creating any other form of legal association or arrangement, which would impose liability upon one party for the act or failure to act of the other party.

#### **14.3 Publication**

In the event that Licensor or any Affiliate, employee, officer, director, or shareholder thereof desires to publish or disclose, by written, oral or other presentation, any information included in the Patent Rights, Know-how, or any material information related thereto, Licensor shall provide the Company with a copy of the proposed publication, presentation, or disclosure at least sixty (60) days prior to its submission for presentation, publication, or disclosure. The Company may request that Licensor, no later than sixty (60) days following the receipt of such proposed publication, presentation, or disclosure, (i) delay such presentation, publication or disclosure for up to an additional ninety (90) days in order to enable the Company to file, or have filed on their behalf, a patent application, copyright or other appropriate form of intellectual property protection related to the information to be disclosed or request that Licensor do so, (ii) remove the Company's Confidential Information from such presentation, publication or disclosure, and/or (iii) make any other reasonable changes to such proposed publication, presentation, or disclosure, as applicable. Upon receipt of such request, Licensor shall (i) arrange for a delay of such presentation, publication or disclosure until such time as the Company or Licensor have filed, or had filed on its behalf, such patent application, copyright or other appropriate form of intellectual property protection in form and in substance reasonably satisfactory to the Company and Licensor, (ii) remove the Company's Confidential Information from such presentation, publication or disclosure, and/or (iii) reasonably consider any other reasonable changes proposed by the Company. If Licensor does not receive any request from the Company to delay such presentation, publication or disclosure, Licensor may submit such material for presentation, publication or other form of disclosure, subject to Licensor's obligations under Article 15.

### **Article 15 Confidentiality**

#### **15.1 Confidentiality and Non-Use**

Any proprietary or confidential information relating to the Technology, Patent Rights, Know-how (including but not limited to patent prosecution documents relating to Patent Rights), reports and records provided under Article 7, and any other reasonably confidential or proprietary information concerning a party's business or technology disclosed to the other party under this Agreement collectively constitute the "Confidential Information." Neither party will use the Confidential Information for any purpose unrelated to the exercise of their rights or fulfillment of their obligations under this Agreement, and will

hold it in confidence during the Term and for a period of five (5) years after the termination or expiration date of this Agreement. Each party shall exercise with respect to such the Confidential Information the same degree of care as the party exercises with respect to its own confidential or proprietary information of a similar nature, but in no event less than reasonable care, and shall not disclose it or permit its disclosure to any Third Party (except to those of its employees, consultants, or agents who are bound by a substantially similar obligation of confidentiality of this Agreement). However, such undertaking of confidentiality shall not apply to any information or data which:

- 15.1.1 The receiving party receives without obligation of confidentiality at any time from a third-party lawfully in possession of same and having the right to disclose same;
- 15.1.2 is, as of the date of this Agreement, in the public domain, or subsequently enters the public domain through no fault of the receiving party;
- 15.1.3 is independently developed by the receiving party as demonstrated by written evidence without reference to or benefit of information disclosed to the receiving party by the disclosing party;
- 15.1.4 is disclosed pursuant to the prior written approval of the disclosing party; or
- 15.1.5 is required to be disclosed pursuant to Applicable Law or legal process (including, without limitation, to a governmental authority) provided that recipient will (i) give prior written notice of such required disclosure to the other party, to the extent reasonably practicable, (ii) give reasonable assistance to the other party, as requested thereby, seeking confidential or protective treatment thereof, and (iii) only disclose such Confidential Information to the extent required by such Applicable Law or legal process.

#### **15.2 Limited Disclosure by Licensor**

Licensor acknowledges and agrees that the Know-how licensed to the Company has value to the Company in being maintained as confidential. Therefore, Licensor shall not disclose the Know-how to any Third Party (i) for use in the Territory without the Company's prior written consent or (ii) for use outside the Territory other than to recipients who have agreed in writing with Company to maintain the confidentiality of such Know-how.

#### **15.3 Material Non-Public Information**

The Licensor understands that it is the intent of the Company to register its capital stock on a national securities exchange, on the National Association of Securities Dealers, Inc. Automated Quotation System (collectively "NASDAQ"), or the Over The Counter Bulletin Board and accordingly, the Licensor understands that confidential information provided to it by the Company pursuant to the terms of this Agreement may constitute "material non-public information" concerning the Company.

### **Article 16 Miscellaneous Provisions**

#### **16.1 Assignment**

This Agreement and the rights and duties appertaining hereto may not be assigned by either party without first obtaining the written consent of the other party, which consent shall not be unreasonably withheld. Any such purported assignment without the written consent of the other party shall be null and of no

effect. Notwithstanding the foregoing, either party (the "Assigning Party") may assign this Agreement without the consent of the other party (i) to a purchaser, merging, or consolidating corporation, or acquirer of all or substantially all of the Assigning Party's assets or business (or that portion thereof to which this Agreement relates) and/or pursuant to any reorganization of the Assigning Party or (ii) to an Affiliate of the Assigning Party.

#### **16.2 Binding Nature and Inurement**

This Agreement will not be binding upon the parties until it has been signed below on behalf of each party, in which event, it shall be effective as of the Effective Date. As of the Effective Date, this Agreement is binding upon and inures to the benefit of the parties and their respective permitted successors and assigns.

#### **16.3 Counterparts; Facsimile**

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be signed and delivered to the other party by facsimile signature; such transmission will be deemed a valid signature.

#### **16.4 Entire Agreement; Amendment**

The parties hereto acknowledge that this Agreement, including the Exhibits, Schedules and documents incorporated by reference, sets forth the entire agreement and understanding of the parties hereto as to the subject matter hereof, and shall not be subject to any change of modification except by the execution of a written instrument subscribed to by the parties hereto and shall supersede all previous communications, representations or understandings, either oral or written, between the parties relating to the subject matter hereof. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the parties hereto unless reduced to writing and signed by the respective authorized officers of the parties.

#### **16.5 Force Majeure**

Neither party is responsible for delays resulting from causes beyond its reasonable control, including without limitation fire, explosion, flood, war, strike, or riot, provided that the nonperforming party uses commercially reasonable efforts to avoid or remove those causes of nonperformance and continues performance under this Agreement with reasonable dispatch whenever the causes are removed.

#### **16.6 Further Assurances**

From time to time during the Term, at the request of either party, the other party shall execute and deliver such documents and take such other action as the requesting party may reasonably request to consummate more effectively the transactions contemplated hereby.

#### **16.7 Headings**

The headings of the several articles are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

#### **16.8 Law**

This Agreement, and any and all disputes directly or indirectly arising from or relating to this Agreement, shall be construed, governed, interpreted and applied in accordance with the laws of the State of New York, without regard to principles of conflicts of laws.

#### **16.9 Payments, Notices and Other Communications**

Any payment, notice or other communication required or permitted to be given pursuant to this Agreement shall be in writing and sent by certified first class mail, postage prepaid, by hand delivery or by facsimile if confirmed in writing, in each case effective upon receipt, at the addresses below or as otherwise designated by written notice given to the other party:

In the case of Licensor:

Thornton & Ross Limited  
Linthwaite  
Huddersfield  
HD7 5QH  
Attn: Chairman

Tel. No: +44 (0) 01484 842217  
Fax No: +44 (0) 01484 847201

With a copy to: Kuit Steinart Levy  
3 St Mary's Parsonage  
Manchester M3 2RD  
United Kingdom

And with a courtesy copy to (which copy shall not be required in order to give effective notice):  
Kerris S.A., 127 rue de Mühlenbach, L - 2168 Luxembourg

Tel. No: +44 (0) 1534 767 777  
Fax No: +44 (0) 1534 618 617

In the case of the Company:

Manhattan Pharmaceuticals, Inc.  
810 Seventh Avenue, 4<sup>th</sup> Floor  
New York, New York 10019  
USA  
Attn: President  
Tel: (212) 582-3950  
Fax: (212) 582-3957

#### **16.10 Payment of Own Fees and Expenses**

Each of the Company and Licensor shall be responsible for their own expenses relating to the preparation and consummation of this Agreement and, except as specified herein, the agreements and transactions contemplated hereby.

**16.11 Severability**

The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions hereof.

**16.12 Waiver**

The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party. Any waiver of any rights or failure to act in a specific instance relates only to that instance and is not an agreement to waive any rights or fail to act in any other instance.

[Signature page to follow.]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement, in triplicate by proper persons thereunto duly authorized.

**THORNTON & ROSS LTD.**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

**MANHATTAN PHARMACEUTICALS, INC.**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

**KERRIS, S.A.**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

Schedule 1.15: Licensor IND(s)

None.

**Schedule 1.21: Patent Rights**

USA Patent Application No. 11/705,389 a divisional application divided out of the original application No. 10/097,615 with the original application filing date.

Canadian Patent Application 2381106 filed on 12<sup>th</sup> September 2002.

Exhibit 6.7

FORM OF  
SUBSCRIPTION AGREEMENT

This Subscription Agreement, dated \_\_\_\_\_, 20\_\_ (the "*Agreement*"), by and between Manhattan Pharmaceuticals, Inc., a Delaware corporation having a place of business at 810 Seventh Avenue, 4th Floor, New York, New York 10019 (the "*Company*"), and \_\_\_\_\_, a \_\_\_\_\_ (the "*Subscriber*"),

WITNESSETH

WHEREAS, on \_\_\_\_\_, 2007, Subscriber, \_\_\_\_\_ and the Company entered into an Exclusive License Agreement for "Hedrin" (the "*License Agreement*"), and the shares of common stock being issued hereby are being issued pursuant to Section 6.7 of the License Agreement in full satisfaction of a milestone payment earned by Subscriber pursuant to the subsection of Section 6.6.1 of the License Agreement described in Section 1 hereof.

NOW THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, each of the parties hereto agrees as follows:

*Section 1. Issuance of Common Stock.*

Pursuant to Section 6.6.1 of the License Agreement, and in full satisfaction of the milestone payment described in that subsection, the Company hereby sells, assigns, transfers, conveys and agrees to deliver to Subscriber seventy-five thousand (75,000) shares of the Company's common stock (the "*Shares*"), and Subscriber hereby accepts such Shares.

*Section 2. Subscriber Representations and Warranties.*

Subscriber hereby represents and warrants to the Company, as of the date hereof, as follows:

(a) Organization; Authority; Enforceability. Subscriber is a company duly organized, validly existing and in good standing under the laws of England. Subscriber has the requisite power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement and the performance and consummation of the transactions contemplated hereby by Subscriber have been duly authorized by all necessary action on the part of Subscriber. This Agreement has been duly executed and delivered by Subscriber and, subject to the due authorization, execution and delivery of this Agreement by the Company, this Agreement constitutes a valid and binding obligation of Subscriber, enforceable against Subscriber in accordance with its terms, except as such enforcement may be affected by bankruptcy, reorganization, insolvency, moratorium or similar laws affecting creditor's rights generally and except for general principles of equity.

(b) Purchase Entirely for Own Account. The Shares acquired by Subscriber hereunder are being acquired for investment for Subscriber's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof; Subscriber has no present intention of selling, granting any participation in, or otherwise distributing the same. Subscriber does not presently

have any contract, undertaking, agreement or arrangement with any person or entity to sell, transfer or grant participations to such person or entity or to any third party, with respect to any of the Shares. Subscriber has not been formed for the specific purpose of acquiring the Shares.

(c) Disclosure of Information. Subscriber hereby acknowledges that it has been furnished with, or has had an opportunity to acquire and carefully review, (i) the Company's most recently filed Annual Report on Form 10-KSB or 10-K (the "*10-KSB*"), (ii) the Company's Quarterly Reports on Form 10-QSB or 10-Q for the quarters ended after the date of the latest 10-KSB (the "*10-QSBs*"), (iii) the Company's Current Reports on Form 8-K filed with the U.S. Securities and Exchange Commission ("*SEC*") following the date of the latest 10-QSB, (iv) such other reports on filed by the Company with the SEC subsequent to the date of the 10-KSB. Subscriber further represents that Subscriber has been furnished by the Company during the course of this transaction with all information regarding the Company which Subscriber, his, her or its investment advisor, attorney and/or accountant has requested or desired to know, has been afforded the opportunity to ask questions of and receive answers from duly authorized officers or other representatives of the Company concerning the Company, and has received any additional information which the Subscriber has requested.

(d) Restricted Securities. Subscriber understands that Rule 144 promulgated under the U.S. Securities Act of 1933, as amended (the "*Securities Act*") requires, among other conditions, a minimum holding period of one-year prior to the resale (in limited amounts) of securities acquired in a non-public offering without having to satisfy the registration requirements under the Securities Act. Subscriber understands that the Shares have not been, and will not be, registered under the Securities Act or any state securities or "blue sky" law by reason of a specific exemption from the registration provisions of that act which depends upon, among other things, the bona fide nature of the investment intent and the accuracy of the Subscriber's representations as expressed herein. Subscriber understands that the Shares are "restricted securities" under applicable U.S. federal and state securities laws and that, pursuant to these laws, Subscriber must hold the Shares indefinitely unless they are registered with the U.S. Securities and Exchange Commission and qualified by state authorities, or an exemption from such registration and qualification requirements is available. Subscriber acknowledges that the Company has no obligation to register or qualify the Shares for resale. Subscriber further acknowledges that if an exemption from registration or qualification is available, it may be conditioned on various requirements including, but not limited to, the time and manner of sale, the holding period for the securities, and on requirements relating to the Company which are outside of Subscriber's control, and which the Company is under no obligation and may not be able to satisfy.

(e) Illiquidity. Subscriber understands, acknowledges and agrees with the Company that there can be no assurance that Subscriber will be able to sell or dispose of the Shares. It is understood that in order not to jeopardize the exempt status under Section 4(2) of the Securities Act, and Regulation D promulgated thereunder, of the issuance of the Shares hereunder, any transferee may, at a minimum, be required to fulfill the investor suitability requirements thereunder.

(f) Legends. Subscriber understands, acknowledges and agrees that the issuance of the Shares hereunder has not been reviewed, recommended or endorsed by the SEC or any state securities regulatory authority or other governmental body or agency, since the such issuance is intended to be exempt from the registration requirements of Section 5 of the Securities Act pursuant to Regulation D promulgated under the Securities Act. Subscriber understands that the Shares shall bear a "restricted securities" legend similar to the following (and any other legend required by U.S. federal or state securities laws):

"THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE U.S. SECURITIES ACT OF 1933, AND HAVE BEEN ACQUIRED FOR INVESTMENT

AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH TRANSFER MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL IN A FORM SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933.”

(g) Accredited Investor. Subscriber is an accredited investor as defined in Rule 501(a) of Regulation D promulgated under the Securities Act.

(h) No General Solicitation. Subscriber represents that no Shares were offered or sold to it by means of any form of general solicitation or general advertising, and in connection therewith Subscriber did not: (A) receive or review any advertisement, article, notice or other communication published in a newspaper or magazine or similar media or broadcast over television or radio whether closed circuit, or generally available; or (B) attend any seminar meeting or industry investor conference whose attendees were invited by any general solicitation or general advertising.

Section 3. *Deliveries*. Promptly after the Company's receipt of the executed signature page hereof, and the Company's determination that the Company is required to deliver the Shares to satisfy the milestone payment referenced in Section 1 hereof, the Company shall deliver to Subscriber (i) an executed counterpart of this Agreement and (ii) a certificate representing the Shares registered in the name of the Subscriber.

Section 4. *Miscellaneous*.

(a) This Agreement and any controversy arising, directly or indirectly, out of or relating to this Agreement shall be governed by and construed in accordance with the General Corporation Law of the State of Delaware as to matters within the scope thereof, and as to all other matters shall be governed by and construed in accordance with the internal laws of State of New York, without regard to conflict of law principles that would result in the application of any law other than the law of the State of New York. The parties hereto (i) hereby irrevocably and unconditionally submit to the jurisdiction of the state courts of New York and to the jurisdiction of the United States District Court for the Southern District of New York for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (ii) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the state courts of New York or the United States District Court for the Southern District of New York, and (iii) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

(b) Any notice or other communication required or permitted to be given pursuant to this Agreement shall be in writing and sent by certified first class mail, postage prepaid, by hand delivery or by facsimile if confirmed in writing, in each case effective upon receipt, at the addresses set forth in the preamble hereof, or as otherwise designated by written notice given to the other party

(c) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and may be amended only by a writing executed by both parties hereto.

(d) This Agreement may be executed in counterparts, each of which shall be deemed an original instrument, but all of which shall together constitute one and the same instrument.

[Signature Page Follows.]

IN WITNESS WHEREOF, the parties hereto have executed this Subscription Agreement as of the date first above written.

MANHATTAN PHARMACEUTICALS, INC.

By: \_\_\_\_\_

Name:

Title:

[ \_\_\_\_\_ ]

By: \_\_\_\_\_

Name:

Title:

**Schedule 12.1.11: Disclosed Claims Against Licensor**

Two incidents have been reported by Thornton & Ross to its insurers.

In October 2006 it is alleged that after using Hedrin a girl lost some of her hair.

In April 2007 a boy was playing with a lighter after using Hedrin and allegedly set his hair on fire.

In both cases Thornton & Ross is disputing that the incidents were caused by Hedrin. Thornton & Ross is also disputing that the labelling and product information was incorrect.

**Schedule 12.1.12: Material Agreements**

1. New Patent Licence dated 25<sup>th</sup> May 2007 between:-
  - (1) Durminster Limited
  - (2) Thornton & Ross Limited and Kerris S.A.

**Medicine Licence**

Country	Approval Date
United Kingdom	November 2005
Austria	Pending
Canada	Pending
Israel	Pending
Jamaica	Pending
Portugal	Pending
Spain (pediculicide)	January 2007
Tunisia	Pending
Ukraine	Pending

**Medical Device**

Country	Approval Date
Eire	October 2005
Austria	July 2006
Belgium	September 2006
Cyprus	Pending
Czech Republic	Pending
Denmark	July 2006
Finland	July 2006
France	May 2006
Germany	Pending
Holland	June 2006

Hungary	Pending
Iceland	Pending
Italy	February 2007
Mauritius	Pending
Norway	Pending
Poland	Pending
Sweden	February 2007
Switzerland	July 2006

Licensors can only provide copies of correspondence in respect of application it has made in U.K. and Eire. Such copies are contained in the information sent to Manhattan 14<sup>th</sup> March 2007 as listed below:

1. CD – Hedrin Bible UK launch presentation
2. DVD – Hedrin Training Presentation
3. CD – Latest UK Launch update and examples of TV advertising
4. Presentation of examples of UK Promotional Material and Trade Print Advertising
5. Latest IRI Market Share Graphs
6. Accolades from UK Launch
7. Accolade from French Launch
8. Copy of article from BMJ publication
9. Copy of Clinical Report by Ian Burgess comparing Hedrin with Derbac-M
10. Copy of Ian Burgess Ex-vivo Study of Hedrin in Malathion resistant lice
11. CD – Copy of Hedrin Licence Dossier Modules 1 – 5
12. Hedrin in Europe

**Updates/ Information available**

1. Licence variation to amend the specification of the Dimeticone 100,000 to meet the requirements of the Ph.Eur. – Still pending
2. Licence variation to change classification from P to GSL – Withdrawn 02.05.07.
3. Final report from the Medical Entomology Centre on “Activity of 4% Dimeticone lotion against head lice and their eggs” – dated 29<sup>th</sup> May 2007

**Schedule 12.2.4: Disclosed Claims Against Company**

In February 2007, a former employee of the Company alleged an ownership interest in two of the Company's provisional patent applications. Also, without articulating precise legal claims, the former employee contends that the Company wrongfully characterized the former employee's separation from employment as a resignation instead of a dismissal in an effort to harm the former employee's immigration sponsorship efforts, and, further, to wrongfully deprive the former employee of the former employee's alleged rights in two of the Company's provisional patent applications. The former employee is seeking an unspecified amount in damages. The Company refutes the former employee's contentions and intends to vigorously defend itself should the former employee file claims against the Company.

## CERTIFICATIONS

I, Douglas Abel, certify that:

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

Date: August 14, 2007

/s/ Douglas Abel

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Douglas Abel  
President and Chief Executive Officer

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## CERTIFICATIONS

I, Michael G. McGuinness, certify that:

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

Date: August 14, 2007

/s/ Douglas Abel

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Michael G. McGuinness  
Chief Financial Officer

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**CERTIFICATION  
OF  
CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Manhattan Pharmaceuticals, Inc. do hereby certify that, to the best of their knowledge:

- (a) the Quarterly Report on Form 10-Q of Manhattan Pharmaceuticals, Inc. for the quarter ended June 30, 2007 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (b) information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Manhattan Pharmaceuticals, Inc.

Date: August 14, 2007

*/s/ Douglas Abel*

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Douglas Abel  
President and Chief Executive Officer

Date: August 14, 2007

*/s/ Michael G. McGuinness*

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Michael G. McGuinness  
Chief Financial Officer

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