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

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FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2004  $^{\circ}$ 

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

Commission file number 0-12957

ENZON PHARMACEUTICALS, INC. (Exact Name of Registrant as Specified in Its Charter)

Delaware 22-2372868

(State or Other Jurisdiction of Incorporation or Organization)

(I.R.S. Employer Identification No.)

685 Route 202/206, Bridgewater, New Jersey 08807 (Address of Principal Executive Offices) (Zip Code)

(908) 541-8600

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes |X| No | |

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes |X| No  $|_{-}|$ 

As of May 10, 2004, there were 43,848,057 shares of Common Stock, par value \$.01 per share, outstanding.

PART I FINANCIAL INFORMATION Item 1. Financial Statements

ENZON PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except shares and per share amounts)
(Unaudited)

	March 31, 2004	June 30, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 83,370	\$ 66,752
Short-term investments	9,741	25,047
Accounts receivable, net	29,623	33,173
Inventories	10,586	11,786
Deferred tax and other current assets	20,798	16,089
Total current assets	154,118	152,847

Property and equipment	48,287	43,896
Less: Accumulated depreciation and amortization	14,109	11,303
	34,178	32,593
Other assets:	01 250	61 450
Marketable securities Investments in equity securities and convertible note	81,358 65,274	61,452 56,364
Amortizable intangible assets, net	198,544	211,975
Goodwill	150,985	150,985
Deferred tax and other assets	53,132	62,350
	549,293	543,126
Total assets	\$ 737,589	\$ 728,566
TOTAL ASSETS		=======
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities: Accounts payable	ė 0 001	\$ 12,809
Accrued expenses	18,516	21,536
Accided expenses		
Total current liabilities	26,517	34,345
Notes payable	400,000	400,000
Other liabilities	6,671 	2,637
	406,671	402,637
Commitments and contingencies Stockholders' equity: Common stock-\$.01 par value, authorized 90,000,000 shares; issued and outstanding 43,840,746 shares at March 31, 2004		
and 43,518,359 shares at June 30, 2003	438	435
Additional paid-in capital	326,170	322,488
Accumulated other comprehensive income (loss)	1,446	(159)
Deferred compensation	(6,702)	(4,040)
Accumulated deficit	(16,951)	(27,140)
Total stockholders' equity	304,401	291,584
Total liabilities and stockholders' equity	\$ 737 <b>,</b> 589	\$ 728 <b>,</b> 566
	=======	=======

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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ENZON PHARMACEUTICALS, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS Three and Nine Months Ended March 31, 2004 and 2003 (In thousands, except per share data) (Unaudited)

	Three months ended March 31,		Nine months ended March 31,	
	2004	2003	2004	2003
Revenues:				
Product sales, net	\$ 27,993	\$ 21,875	\$ 80,665	\$ 36,250
Manufacturing revenue	5,035	4,762	8,826	5,496
Royalties	11,103	16,242	36,461	57,565
Contract revenue	248	284	769	417
Total revenues	44,379	43,163	126,721	99,728
Costs and expenses:				
Cost of sales and manufacturing revenue	12,458	11,080	35,195	17,859
Research and development	10,772	5,132	24,711	14,886
Acquired in-process research and development	12,000		12,000	

Selling, general and administrative Merger expenses Amortization of acquired intangible assets Write-down of carrying value of investments	12,500  3,358 	9,481 1,398 3,960	35,187  10,074 	20,786 1,398 5,288 27,237
Total costs and expenses	51,088		117,167	
Operating income (loss)	(6,709)	12,112	9,554	12,274
Other income (expense):     Investment income, net     Interest expense     Other, net	(4,957) (337)	(4,957) 3	12,744 (14,871) 71  (2,056)	(14,871)
Income (loss) before tax provision Income tax provision (benefit)	(439) (5,505)	156	7,498 (2,691)	662
Net income	\$ 5,066 		\$ 10,189	
Basic earnings per common share	\$ 0.12	,		
Diluted earnings per common share	\$ 0.12		\$ 0.23	
Weighted average number of common shares outstanding-basic	43,368		43,322	
Weighted average number of common shares and dilutive potential common shares outstanding	43,817	43,634	43,657	

The accompanying notes are an integral part of these unaudited consolidated condensed financial statements.

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# ENZON PHARMACEUTICALS, INC. AND SUBSIDIARIES Condensed Consolidated Statement of Cash Flows (In thousands) (Unaudited)

	Nine Month March	-
	2004	2003
Cash flows from operating activities:		
Net income	S 10.189	\$ 5,174
Adjustments to reconcile net income to net cash provided by operating activities:	,,	, ,,,,,,,
Depreciation and amortization	16,487	7,895
Non-cash expense for issuance of common stock	1,132	468
Non-cash income relating to equity collar arrangement	(82)	
Gain on sale of equity investments	(10,997)	
Amortization of bond premium/discount	409	1,154
Non-cash write-down of carrying value of investment		27,237
Deferred income taxes	(4,618)	(2,272)
Changes in operating assets and liabilities	(4,062)	1,255
Net cash provided by operating activities	8,458	40,911
Cash flows from investing activities:		
Purchase of property and equipment	(4,640)	(5,306)
Purchase of ABELCET business		(369,062)
Purchase of DEPOCYT product		(12,181)
Proceeds from sale of NEKTAR equity investment	17,375	
Proceeds from sale of marketable securities	32,444	350,318
Maturities of marketable securities		53,000
Purchases of marketable securities	(37,450)	(101,203)
Net cash provided by (used in) investing activities	7,729	(84, 434)
Cash flows from financing activities:		
Proceeds from exercise of common stock options	431	1,472
Net increase (decrease) in cash and cash equivalents	16,618	(42,051)
Cash and cash equivalents at beginning of period	66,752	113,858
Cash and cash equivalents at end of period	\$ 83,370	\$ 71,807

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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# ENZON PHARMACEUTICALS, INC. AND SUBSIDIARIES Notes To Condensed Consolidated Financial Statements (Unaudited)

# (1) Organization and Basis of Presentation

The unaudited condensed consolidated financial statements have been prepared from the books and records of Enzon Pharmaceuticals, Inc. (the "Company") and its subsidiaries in accordance with accounting principles generally accepted in the United States of America for interim financial information pursuant to Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required for complete annual financial statements. In the opinion of management, all adjustments (consisting only of normal and recurring adjustments) considered necessary for a fair presentation have been included. Interim results are not necessarily indicative of the results that may be expected for the year. The interim consolidated financial statements should be read in conjunction with the consolidated financial statements and the notes thereto included in the Company's latest annual report on Form 10-K.

### (2) Comprehensive Income

Statement of Financial Accounting Standards ("SFAS") No. 130, "Reporting Comprehensive Income", requires unrealized gains and losses on the Company's available-for-sale securities to be included in other comprehensive income.

The following table reconciles net income to comprehensive income (loss) (in thousands):

	Three months ended  March 31,		Nine months ended March 31,	
		2003	2004	2003
Net income Other comprehensive income:	\$ 5,066	\$ 7,634	\$ 10,189	\$ 5,174
Unrealized gain (loss) on marketable securities arising during the period, net of tax	324	167	3	966
Unrealized gain on NPS investment arising during the period, net of tax (see note 13)			1,824	
Reclassification adjustment for net gain realized in net				
income, net of tax	227	(203)	(222)	(2,318)
Total other comprehensive income (loss)	551 	(36)	1,605	(1,352)
Comprehensive income	\$ 5,617	\$ 7,598	\$ 11,794 ======	\$ 3,822 ======

### (3) New Accounting Pronouncements

In December 2003, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 46 (revised December 2003) ("FIN46-R"), Consolidation of Variable Interest Entities, which addresses how a business enterprise should evaluate whether it has a controlling financial interest in an entity through means other than voting rights and accordingly should consolidate the entity. FIN 46-R replaces FASB Interpretation No. 46, Consolidation of Variable Interest Entities ("FIN 46"), which was issued in January 2003. FIN 46-R requires that if an entity has a controlling financial interest in a variable interest entity, the assets, liabilities and results of activities of the variable interest entity should be included in the consolidated financial statements of the entity. The provisions of FIN 46-R are effective immediately to those entities that are considered to be special-purpose entities. For all other arrangements, the FIN 46-R provisions are required to be adopted at the beginning of the first interim or annual period ending after March 15, 2004. As of March 31, 2004 the Company is not a party to transactions contemplated under FIN 46-R.

In November 2002, the Emerging Issues Task Force ("EITF") reached a consensus opinion on EITF 00-21, Revenue Arrangements with Multiple Deliverables. The consensus provides that revenue arrangements with multiple deliverables should be divided into separate units of accounting if certain criteria are met. The consideration for the arrangement should be allocated to the separate units of accounting based on their relative fair values, with different provisions if the fair value of all deliverables is not known or if the fair value is contingent on delivery of specified items or performance conditions. Applicable revenue recognition criteria should be considered separately for each separate unit of accounting. EITF 00-21 is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. This adoption did not have any impact on our financial position or results of operations.

# (4) Earnings Per Common Share

Basic earnings per share is computed by dividing the net income available to common shareholders adjusted for cumulative undeclared preferred stock dividends for the relevant period, by the weighted average number of shares of Common Stock issued and outstanding during the periods. For purposes of calculating diluted earnings per share for the three and nine months ended March 31, 2004 and 2003, the denominator includes both the weighted average number of shares of Common Stock outstanding and the number of dilutive Common Stock equivalents. The number of dilutive Common Stock equivalents includes the effect of non-qualified stock options calculated using the treasury stock method and the number of shares issuable upon conversion of certain Series A Preferred Stock that were outstanding as of March 31, 2003. The number of shares issuable upon conversion of the Company's 4.5% Convertible Subordinated Notes due 2008 (the "Notes") and the effect of the vesting of certain restricted stock using the treasury stock method have not been included as the effect of their inclusion would be antidilutive. As of March 31, 2004, the Company had 10,797,000 dilutive common shares outstanding that could potentially dilute future earnings per share calculations.

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# ENZON PHARMACEUTICALS, INC. AND SUBSIDIARIES Notes To Condensed Consolidated Financial Statements (Unaudited)

The following table reconciles the basic and diluted earnings per share calculations (in thousands):

	Three months ended March 31,		Nine months ended March 31,	
	2004	2003	2004	2003
Net income Less: Preferred stock dividends	\$ 5,066 	\$ 7,634 4	\$ 10,189 	\$ 5,174 11

Net income available to common

stockholders	\$ 5,066	\$ 7,630	\$ 10,189	\$ 5,163
	======	======	======	======
Weighted average number of				
<pre>common shares outstanding - basic Effect of dilutive securities:</pre>	43,368	43,192	43,322	43,061
Conversion of preferred stock Assumed exercise of non- qualified stock options and		16		16
restricted stock	449	426	335	534
Weighted average number of common shares outstanding and				
dilutive potential common shares	43,817 ======	43,634 =====	43,657 =====	43,611

# (5) Stock Based Compensation

As permitted by Statement of Financial Accounting Standards ("SFAS") No. 123, "Accounting for Stock Based Compensation", the Company accounts for stock-based compensation arrangements in accordance with the provisions of Accounting Principals Board ("APB") Opinion No. 25 "Accounting for Stock Issued to Employees". Compensation expense for stock options issued to employees is based on the difference on the date of grant between the fair value of the Company's stock and the exercise price of the option. No stock option-based employee compensation cost is reflected in net income, as all options granted to employees had exercise prices equal to the market value of the underlying common stock at the date of grant.

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# ENZON PHARMACEUTICALS, INC. AND SUBSIDIARIES Notes To Condensed Consolidated Financial Statements (Unaudited)

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock based compensation (in thousands, except per share data):

	Three months ended March 31,		Nine months end March 31,	
	2004	2003	2004	2003
Net income Less: Preferred stock dividends	\$ 5,066 	\$ 7,634 4	\$ 10,189 	\$ 5,174 11
Net income available to common stockholders	\$ 5,066 =====	\$ 7,630	\$ 10,189	\$ 5,163
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects  Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(3,040)	250 (4,609)	718 (8,588)	458 (11,844)
Pro forma net income (loss) available to common stockholders	\$ 2,303	\$ 3,271 ======	\$ 2,319	(\$6,223) =====
Earnings (loss) per common share - basic: as reported	\$ 0.12	\$ 0.18	\$ 0.24	\$ 0.12
pro forma	\$ 0.05 ======	\$ 0.08 ======	\$ 0.05 ======	(\$0.14)
Earnings (loss) per common share - diluted: as reported	\$ 0.12	\$ 0.17	\$ 0.23	\$ 0.12

pro forma \$ 0.05 \$ 0.08 \$ 0.05 (\$0.14)

During the nine months ended March 31, 2004, the Company issued 312,500 shares of restricted common stock and restricted common stock units to certain members of management. Total compensation expense of approximately \$3.7 million is being recognized over a five year vesting period.

During the nine months ended March 31, 2004, the Company granted 2,028,000 stock options to its employees at an average exercise price of \$13.82 under its stock option plans (fair value on the date of grants) of which 300,000 were granted to executive officers and 25,000 were granted to non-employee directors of the Company. The options vest over a period between one and four years.

In December 2003, the stockholders of the Company approved amendments to the Company's 2001 Incentive Stock Plan ("Plan") to increase the number of shares of common stock available for issuance under the Plan from 2,000,000 to 6,000,000 and to limit the maximum number of shares of restricted stock and restricted stock units that may be granted under the Plan to 50% of the total number of shares available for issuance.

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# ENZON PHARMACEUTICALS, INC. AND SUBSIDIARIES Notes To Condensed Consolidated Financial Statements (Unaudited)

# (6) Inventories

The composition of inventories is as follows (in thousands):

	March 31, 2004	June 30, 2003
Raw materials	\$ 3,960	\$ 4,349
Work in process	3,446	3,392
Finished goods	3,180	4,045
	\$10,586	\$11,786
	======	======

# (7) Acquisition of the ABELCET Product Line

On November 22, 2002, the Company acquired the North American rights and operational assets associated with the development, manufacture, sales and marketing of ABELCET(R) (Amphotericin B Lipid Complex Injection) (the "ABELCET Product Line") from Elan Corporation, plc, for \$360.0 million plus acquisition costs of approximately \$9.3 million.

The following unaudited pro forma results of operations of the Company for the nine month period ended March 31, 2003, assumes the acquisition of the ABELCET Product Line occurred as of July 1, 2002 and assumes the purchase price has been allocated to the assets purchased based on fair values at the date of acquisition (in thousands, except per share amounts):

	Nine months ended March 31,
	2003
Product Sales, net Total revenues Net income (loss)	\$ 78,148 136,130 (8,028)
Pro forma earnings (loss) per share:    Basic    Diluted	\$ (0.19) \$ (0.19)

# (8) Intangible Assets

The Company's intangible assets are primarily related to its November 22, 2002 acquisition of the ABELCET Product Line, DEPOCYT and ONCASPAR and are amortized over their estimated useful lives. The gross carrying amount,

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# ENZON PHARMACEUTICALS, INC. AND SUBSIDIARIES Notes To Condensed Consolidated Financial Statements (Unaudited)

	Estimated Lives	Gross Carrying Amount	Accumulated Amortization	Net Assets
Product patented technology	12 years	\$ 64,400	\$ 7,156	\$ 57,244
Manufacturing patent	12 years	18,300	2,033	16,267
NDA Approval	12 years	31,100	3,455	27,645
Trade name and other				
product rights	15 years	80,000	7,111	72,889
Product acquisition costs	10-14 years	26,194	3,274	22,920
Patents	1-5 years	2,092	1,735	357
Manufacturing contract	3 years	2,200	978	1,222
Total		\$224,286	\$25,742	\$198,544
		======		

Amortization of intangible assets for the three and nine month period ended March 31, 2004 was \$4.5 million and \$13.4 million, respectively, a portion of which is included in cost of goods sold. Assuming no changes in the gross carrying amount of intangible assets, the amortization of intangible assets for the next five fiscal years is estimated to be approximately \$17.9 million per year. Amortization of intangible assets for both the three and nine month period ended March 31, 2003 was \$4.5 million and \$6.3 million, respectively.

# (9) Goodwill

The amount assigned to goodwill in connection with the ABELCET Product Line acquisition was recorded at \$151.0 million. In accordance with SFAS No. 142, "Goodwill and Other Intangible Assets," goodwill is not amortized, but rather is reviewed at least annually for impairment.

# (10) Cash Flow Information

The Company considers all highly liquid securities with original maturities of three months or less to be cash equivalents. Cash payments for interest were approximately \$9.0 million for the nine months ended March 31, 2004 and 2003. Income tax payments for the nine months ended March 31, 2004 were \$3.6 million. There were no income tax payments made for the nine months ended March 31, 2003.

# (11) Income Taxes

During the three months ended March 31, 2004 the Company recorded a net tax benefit of approximately \$5.5 million related primarily to the reversal of a deferred tax asset valuation allowance of approximately \$3.8 million for the write-down in a prior year of our investment in NEKTAR Therapeutics Convertible Preferred Stock which was converted and the underlying common stock was sold during the quarter, resulting in a financial reporting gain of approximately \$11.0 million. The benefit was also due to the reduction of our estimated taxable income and effective tax rate to 29% as compared to 35% used in the previous two quarters, due to a payment during the three months ended March 31, 2004 of \$12.0 million to INEX Pharmaceuticals related to acquired in-process research and development for Onco TCS (See Note 14). The tax provision recognized for the nine months ended March 31, 2004 is based on the estimated annual effective tax rate of 29%. In addition, the tax effect of the financial reporting gain on the sale of NEKTAR Convertible Preferred Stock and the acquired in process research and development charge was recognized during the three months ended March 31, 2004, the period in which the items occurred.

# Notes To Condensed Consolidated Financial Statements (Unaudited)

At June 30, 2003, the Company recognized approximately \$67.5 million as a net deferred tax asset related to expected future profits, because management concluded that it is more likely than not that the deferred tax assets will be realized, including the net operating losses from operating activities and stock option exercises, based on future operations. As of June 30, 2003 the Company retained a valuation allowance of \$12.8 million with respect to certain capital losses and federal research and development credits as the ultimate utilization of such losses and credits is uncertain. As discussed above, during February 2004, the Company reversed a portion of the valuation allowance associated with the NEKTAR investment. The Company will continue to reassess the need for such valuation allowance based on the future operating performance of the Company.

The tax provision for the three and nine month period ended March 31, 2003 represents the Company's anticipated Alternative Minimum Tax liability based on the anticipated taxable income for the full fiscal year.

During the three and nine month period ended March 31, 2004, the Company received \$254,000 for the sale of certain New Jersey state net operating loss carryforwards and also purchased certain New Jersey state net operating loss carryforwards for \$1.5 million.

# (12) Business Segments

A single management team that reports to the Chief Executive Officer comprehensively manages the business operations. The Company does not operate separate lines of business or separate business entities with respect to any of its approved products or product candidates. In addition, the Company does not conduct any operations outside of the United States and Canada. The Company does not prepare discrete financial statements with respect to separate product areas. Accordingly, the Company does not have separately reportable segments as defined by SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information".

# (13) Derivative Instruments

In August 2003, the Company entered into a Zero Cost Protective Collar arrangement (the "Collar") with a financial institution to reduce the exposure associated with the 1.5 million shares of common stock of NPS Pharmaceuticals, Inc. ("NPS") it received as part of the merger termination agreement between the Company and NPS. By entering into this equity collar arrangement and taking into consideration the underlying put and call option strike prices, the terms are structured so that the Company's investment in NPS stock, when combined with the value of the Collar, should secure ultimate cash proceeds in the range of 85%-108% of the negotiated fair value per share of \$23.47 (representing a 4.85% discount off of the closing price of NPS common stock on the day before the Company executed the Collar). The Collar is considered a derivative hedging instrument under SFAS No. 133 and as such, the Company periodically measures its fair value and recognizes the derivative as an asset or a liability. The change in fair value is recorded in other comprehensive income (See Note 2) or in the Statement of Operations depending on its effectiveness. As of March 31, 2004, the market value of NPS' common stock was \$28.52 per share. When the underlying shares become unrestricted and freely tradable, the Company is required to deliver to the financial institution as posted collateral, a corresponding number of shares of NPS common stock. During the three and nine month period ended March 31, 2004, the Company sold and re-purchased 315,100 shares and 690,100 shares, respectively, of common stock of NPS. The unrealized gain previously recognized under other comprehensive income with respect to these shares aggregating \$504,000 and \$1.1 million for the three and nine months ended March 31, 2004, respectively, was recognized in the Statements of Operations and is being shown as "Other Income". With respect to the remaining 809,900 shares of NPS common stock as of March 31, 2004, the increase in the aggregate value above the base price of \$23.47 per share up to the \$25.35 per share Collar limit, or \$989,000, has been recorded in comprehensive income for the nine months ended March 31, 2004, net of income taxes. The fair value of the Collar above the \$25.35 per share dollar limit represented a liability of \$4.8 million at March 31, 2004, which is included under "Other Liabilities" in the Condensed Consolidated Balance Sheet. In addition, the difference in the fair value of the Collar compared to the fair market value of the NPS common stock

# ENZON PHARMACEUTICALS, INC. AND SUBSIDIARIES Notes To Condensed Consolidated Financial Statements (Unaudited)

representing a loss of \$318,000 for the three months ended March 31, 2004 and a gain of \$83,000 for the nine month period ended March 31, 2004, was recorded as "Other Income" in the Statement of Operations. The Collar will mature in four separate three-month intervals beginning November 2004 through August 2005, at which time the Company will receive the proceeds from the sale of the securities. The amount due at each maturity date will be determined based on the market value of NPS' common stock on such maturity date. The contract requires the Company to maintain a minimum cash balance of \$30.0 million and additional collateral up to \$10.0 million (as defined) under certain circumstances with the financial institution. The strike prices of the put and call options are subject to certain adjustments in the event the Company receives a dividend from NPS.

# (14) INEX Agreement

During January 2004, the Company and Inex Pharmaceuticals Corporation ("INEX") entered into a strategic partnership to develop and commercialize INEX's proprietary oncology product Onco TCS. The Company and INEX entered into a Product Supply Agreement, a Development Agreement, and a Co-Promotion Agreement. The agreements contain cross termination provisions under which termination of one agreement triggers termination of all the agreements.

Under the terms of the agreements, the Company received the exclusive commercialization rights for Onco TCS for all indications in the United States, Canada and Mexico. The lead indication for Onco TCS is relapsed aggressive non-Hodgkin's lymphoma (NHL) for which a "rolling" New Drug Application (NDA) to the United States Food and Drug Administration (FDA) was filed on March 15, 2004. The product is also in numerous phase II clinical trials for several other cancer indications, including first-line NHL.

Upon execution of the related agreements the Company made a \$12.0 million up-front payment to INEX which has been determined to be an acquisition of in-process research and development as the payment was made prior to FDA approval, and therefore expensed in the Company's Statement of Operations for the quarter ended March 31, 2004. In addition, the Company will be required to pay up to \$20.0 million upon Onco TCS being approved by the FDA and development milestones and sales based bonus payments could total \$43.75 million, of which \$10.0 million is payable upon annual sales first reaching \$125.0 million, and \$15.0 million is payable upon annual sales first reaching \$250.0 million. The Company will also be required to pay INEX a percentage of commercial sales of Onco TCS and this percentage will increase as sales reach certain predetermined thresholds.

The Company and INEX will share equally the future development costs to obtain and maintain marketing approvals in North America for Onco TCS, and the Company will pay all sales and marketing costs and certain other post-approval clinical development costs typically associated with commercialization activities. The Company plans to market Onco TCS to the oncology market through its North American sales force, which currently markets ABELCET(R), ONCASPAR(R), and DEPOCYT(R). INEX has the option of complementing the Company's sales efforts by co-promoting Onco TCS through the formation of a dedicated North American sales and medical science liaison force. The costs of building INEX's co-promotion force will be shared equally by both companies and the Company will record all sales in the licensed territories. INEX retains manufacturing rights and the Company will reimburse INEX for the manufacture and supply of the drug at manufacturing cost plus five percent.

The agreements will expire on a country by country basis upon the expiration of the last patent covering the licensed product in each particular country or 15 years after the first commercial sale in such country, whichever is later. The agreements are also subject to earlier termination under various circumstances. The Company may terminate the agreements at any time upon 90 days notice, in connection with which the Company must pay a \$2.0 million termination fee. INEX has completed the submission of its NDA, therefore if Enzon terminates it must pay the \$2.0 million fee. In addition, if at any time the Company determines that it has no interest in commercializing the product in any country, then INEX may terminate the agreement with respect to such country. Either party may

# ENZON PHARMACEUTICALS, INC. AND SUBSIDIARIES Notes To Condensed Consolidated Financial Statements (Unaudited)

terminate the agreements upon a materialbreach and failure to cure by the other party. In addition, either party may terminate the agreements upon the other party's bankruptcy. Generally, the termination of the agreements with respect to a particular country shall terminate the Company's license with respect to Onco TCS, and preclude the Company from marketing the product, in that country. However, if the Company terminates the agreements because of INEX's breach or bankruptcy, INEX will be obligated to provide the Company a right of reference to INEX's regulatory dossiers and facilitate a transfer to the Company of the technology necessary to manufacture the product. In addition, after such termination, INEX will be obligated to exercise commercially reasonable efforts to ensure that the Company has a continuous supply of product until the Company, exercising commercially reasonable efforts, has secured an alternative source of supply.

# (15) Elan/Medeus Manufacturing Agreements

During February 2004 Elan Corporation, plc, sold its ABELCET and MYOCET European business to Medeus Pharma, Ltd. ("Medeus") As part of this transaction the Company's long-term manufacturing and supply agreement with Elan was assigned to Medeus. In connection with the closing of this sale the Company and Elan settled a dispute over the manufacturing cost of products produced for Elan resulting in the payment and recognition of manufacturing revenue related to approximately \$1.7 million of revenue not previously recognized given the uncertainty of the contractual amount.

# (16) Investment Income

During the three months ended March 31, 2004, the Company converted 20,055 shares or approximately 50% of its Nektar Therapeutics convertible preferred stock investment to common stock which it sold resulting in gross proceeds of approximately \$17.4 million and a net gain of approximately \$11.0 million.

# (17) Subsequent Events

In connection with Mr. Higgins' departure as the Company's CEO the board appointed a committee of four independent directors (Dr. Rosina Dixon, Robert LeBuhn, Dr. David Golde and Robert Parkinson) to review and approve the terms of Mr. Higgins departure. This committee negotiated and approved a separation payment of \$1.25 million, which is payable to Mr. Higgins upon his departure in May 2004. Concurrent with Mr. Higgins' departure as CEO in May 2004, the Company will reverse approximately \$1.29 million of compensation expense previously recorded related to restricted stock of the Company that will be forfeited by Mr. Higgins as a result of his departure as the Company's CEO.

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

Information contained herein contains forward-looking statements which can be identified by the use of forward-looking terminology such as "believes," "expects," "may," "will," "should," or "anticipates" or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy. These forward looking statements are subject to various risks and uncertainties that may cause actual results to differ materially from the results predicted by the forward looking statements. The matters set forth in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2003, which is incorporated herein by reference, contain cautionary statements identifying important risks, uncertainties and other factors, that could prevent the future results indicated in such forward-looking statements from being achieved. Other factors could also cause actual results to vary materially from the future results indicated in such forward-looking statements.

# Liquidity and Capital Resources

Total cash reserves, which include cash, cash equivalents, short-term investments, and marketable securities, were \$174.5 million as of March 31,

2004, as compared to \$153.3 million as of June 30, 2003. The increase is primarily due to net proceeds from the sale of shares of common stock issuable upon our conversion of preferred shares of Nektar Therapeutics of approximately \$17.4 million and cash flow from operations. We invest our excess cash primarily in United States government-backed securities and investment-grade corporate debt securities.

During the nine months ended March 31, 2004, net cash generated from operating activities was \$8.5 million, compared to \$40.9 million for the nine months ended March 31, 2003. The reduction in net cash generated operating activities in 2004 compared to 2003 was primarily due to a reduction in net income related to the deduction of a non-cash write-down of the carrying value of investments in 2003 as well as purchase of \$12.0 million of acquired in process research and development related to the Onco TCS strategic partnership and a decrease in income. During the nine months ended March 31, 2003, we recorded as a non-cash write-down of approximately \$27.2 million of our investment in NEKTAR Therapeutics

Cash provided by investing activities totaled \$7.7 million for the nine months ended March 31, 2004 compared to cash utilization of \$84.4 million for the nine months ended March 31, 2003. Cash provided by investing activities during the nine months ended March 31, 2004, was principally due to purchases and sales from investments and marketable securities of \$12.3 million principally due to the sale of Nektar Therapeutics stock of \$17.4 million offset by \$4.6 million of capital expenditures.

As of March 31, 2004, we had \$400.0 million of 4.5% convertible subordinated notes outstanding. The notes bear interest at an annual rate of 4.5%. Interest is payable on January 1 and July 1 of each year. Accrued interest on the notes was \$4.5 million as of March 31, 2004. The holders may convert all or a portion of the notes into common stock at any time on or before July 1, 2008. The notes are convertible into our common stock at a conversion price of \$70.98 per share, subject to adjustment in certain events. The notes are subordinated to all existing and future senior indebtedness. On or after July 7, 2004, we may redeem any or all of the notes at specified redemption prices, plus accrued and unpaid interest to the day preceding the redemption date. The notes will mature on July 1, 2008 unless earlier converted, redeemed at our option or redeemed at the option of the note-holder upon a fundamental change, as described in the indenture for the notes. Neither we nor any of our subsidiaries are subject to any financial covenants under the indenture. In addition, neither we nor any of our subsidiaries are restricted under the indenture from paying dividends, incurring debt, or issuing or repurchasing our securities.

In August 2003, we entered into a Zero Cost Protective Collar arrangement with a financial institution to reduce the exposure associated with the 1.5 million shares of common stock of NPS we received as part of the merger termination agreement with NPS. By entering into this equity collar arrangement and taking into consideration the underlying put and call option strike prices, the terms are structured so that our investment in NPS stock, when combined with the value of the Collar, should secure ultimate cash proceeds in the range of 85%-108%

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of the negotiated fair value per share of \$23.47 (representing a 4.85% discount off of the closing price of NPS common stock on the day before we executed the Collar). The Collar is considered a derivative hedging instrument under SFAS No. 133 and as such, we periodically measure its fair value and recognizes the derivative as an asset or a liability. The change in fair value is recorded in other comprehensive income (See Note 2) or in the Statement of Operations depending on its effectiveness. As of March 31, 2004, the market value of NPS' common stock was \$28.52 per share. When the underlying shares become unrestricted and freely tradable, we are required to deliver to the financial institution as posted collateral, a corresponding number of shares of NPS common stock. During the three and nine month period ended March 31, 2004, we sold and re-purchased 315,100 shares and 690,100 shares respectively of common stock of NPS. The unrealized gain previously recognized under other comprehensive income with respect to these shares aggregating \$504,000 and \$1.1 million for the three and nine months ended March 31, 2004, respectively, was recognized in the Statements of Operations and is being shown as "Other Income". With respect to the remaining 809,900 shares of NPS common stock as of March 31, 2004, the increase in the aggregate value above the base price of \$23.47 per share up to the \$25.35 per share Collar limit, or \$989,000, has been recorded in

comprehensive income for the nine months ended March 31, 2004, net of income taxes. The fair value of the Collar above the \$25.35 per share Collar limit represented a liability of \$4.8 million at March 31, 2004, which is included under "Other Liabilities" in the Condensed Consolidated Balance Sheet. In addition, the difference in the fair value of the Collar compared to the fair market value of the NPS common stock representing a loss of \$318,000 for the three months ended March 31, 2004 and a gain of \$83,000 for the nine month period ended March 31, 2004, was recorded as "Other Income" in the Statement of Operations. The Collar will mature in four separate three-month intervals beginning November 2004 through August 2005, at which time we will receive the proceeds from the sale of the securities. The amount due at each maturity date will be determined based on the market value of NPS' common stock on such maturity date. The contract requires us to maintain a minimum cash balance of \$30.0 million and additional collateral up to \$10.0 million (as defined) under certain circumstances with the financial institution. The strike prices of the put and call options are subject to certain adjustments in the event we receive a dividend from NPS.

Our current sources of liquidity are our cash reserves, and interest earned on such cash reserves, short-term investments, marketable securities, sales of ADAGEN(R), ONCASPAR(R), DEPOCYT(R) and ABELCET(R), royalties earned primarily on sales of PEG-INTRON(R), sales of our products for research purposes and license fees. Based upon our currently planned research and development activities and related costs and our current sources of liquidity, we anticipate our current cash reserves and expected cash flow from operations will be sufficient to meet our capital, debt service and operational requirements for the foreseeable future.

While we believe that our cash, cash reserves and investments will be adequate to satisfy our capital needs for the foreseeable future, we may seek additional financing, such as through future offerings of equity or debt securities or agreements with collaborators with respect to the development and commercialization of products, to fund future operations and potential acquisitions. We cannot assure you, however, that we will be able to obtain additional funds on acceptable terms, if at all.

# Off-Balance Sheet Arrangements

As part of our ongoing business, we do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities ("SPE"), which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow limited purposes. As of March 31, 2004, we are not involved in any SPE transactions.

# Contractual Obligations

Our major outstanding contractual obligations relate to our operating leases, our convertible debt and our license and development agreements with collaborative partners. Under our strategic partnership with INEX which was entered into during the three months ended March 31, 2004 we are obligated to pay up to \$20.0 million payment upon Onco TCS receiving approval from the FDA and additional development milestones and sales based bonus

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payments could total \$43.75 million, of which \$10.0 million is payable upon annual sales first reaching \$125.0 million and \$15.0 million is payable upon annual sales first reaching \$250.0 million. INEX will also receive a percentage of commercial sales of Onco TCS and this percentage will increase as sales reach certain predetermined thresholds. Other than the additional INEX contracted obligations our contractual obligations as of March 31, 2004 are not materially different from our contractual obligations as of June 30, 2003 as disclosed under "Management's Discussion and Analysis of Financial Condition and Results of Operations - Contractual Obligations" in our annual report on Form 10-K for the fiscal year ended June 30, 2003.

# Results of Operations

Three months ended March 31, 2004 and March 31, 2003

Revenues. Total revenues for the three months ended March 31, 2004

increased by 3% to \$44.4 million, as compared to \$43.2 million for the three months ended March 31, 2003. The components of revenues are product sales and certain contract manufacturing revenues, royalties we earn on the sale of products by others and contract revenues.

Net product sales and manufacturing revenue increased by 24% to \$33.0million for the three months ended March 31, 2004, as compared to \$26.6 million for the three months ended March 31, 2003. The increase in net sales was due to increased sales of ABELCET and DEPOCYT in North America and increased sales of ONCASPAR. During the three months ended March 31, 2004, we recorded \$22.6million of sales related to the ABELCET Product Line as compared to \$18.3 million for the corresponding period in the prior year. Of the total ABELCET Product Line sales, sales in North America accounted for \$17.6 million for the three months ended March 31, 2004 as compared to \$13.5 for the three months ended March 31, 2003. Contract manufacturing revenue related to the manufacture and sale of ABELCET for the international market and other contract manufacturing revenue was \$5.0 million for the three month period ended March 31, 2004 as compared to \$4.8 for the three months ended March 31, 2003. Approximately \$1.7 million of the \$5.0 million of revenues recorded during the three months ended March 31, 2004 related to the settlement of amounts previously disputed by Elan. During the three months ended March 31, 2004, we recorded DEPOCYT sales of \$1.4 million as compared to \$1.2 million in the corresponding period in the prior year. Sales of ONCASPAR increased by 73% to \$4.9 million for the three months ended March 31, 2004 from \$2.8 million in the corresponding period in the prior year. This was a result of our resumption of marketing efforts in connection with our reacquiring from Aventis in June 2002 the right to market and distribute ONCASPAR for certain territories previously licensed to Aventis. Sales of ADAGEN decreased by 4% for the three months ended March 31, 2004 to \$4.1 million as compared to \$4.3 million for the three months ended March 31, 2003 due to the timing of shipments.

Royalties for the three months ended March 31, 2004, decreased to \$11.1 million as compared to \$16.2 million in the same period in the prior year. The decrease was primarily due to decreased sales of PEG-INTRON by Schering-Plough, our marketing partner, due to sales of a competitive product, PEGASYS(R).

During December 2002, Hoffman-LaRoche launched PEGASYS(R), a pegylated version of its interferon product ROFERON-A(R). Since its launch, PEGASYS has taken market share away from PEG-INTRON. As a result, quarterly sales of PEG-INTRON and the royalties we receive on those sales have declined in recent quarters. We have no involvement in the marketing and sales of PEG-INTRON, which are the responsibility of Schering-Plough. We cannot assure you that PEGASYS will not continue to gain market share at the expense of PEG-INTRON, which could result in lower PEG-INTRON sales and lower royalties.

As a result of our focused marketing efforts for ABELCET, we believe that we have been able to stabilize the pressure from the introduction of new products in the antifungal market and that the product is now back on a growth pattern. We expect sales of DEPOCYT, which are currently running at an annual rate of approximately \$5.0 million, to increase as we continue to roll out our focused marketing efforts. We expect ADAGEN and ONCASPAR sales to grow in this fiscal year at levels similar to those achieved during the last fiscal year. However, we cannot assure you that any particular sales levels of ABELCET, ADAGEN, ONCASPAR, DEPOCYT or PEG-INTRON will be achieved or maintained.

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Contract revenues for the three months ended March 31, 2004, remained relatively stable at \$248,000 as compared to \$284,000 in the corresponding period in the previous year. Contract revenue is principally comprised of a portion of the \$3.5 million licensing payment received in January 2003 from the licensing of our PEG technology to SkyePharma which is being recognized as revenue over the term of the related agreement.

During the three months ended March 31, 2004, we had export sales and royalties on export sales of \$9.0 million, of which \$7.4 million were sales in Europe or royalties on sales in Europe. Export sales and royalties on export sales for the three months ended March 31, 2003 were \$8.6 million, of which \$7.5 million were in Europe.

Cost of Sales and Manufacturing Revenue. Cost of sales and manufacturing revenue, as a percentage of net sales and manufacturing revenue decreased to 38% for the three months ended March 31, 2004 as compared to 42% for the same period

last year. The decrease was principally due to higher 2003 inventory costs as a result of certain purchase accounting adjustments to the inventory acquired with the ABELCET Product Line, which was sold during the three months ended March 31, 2003, as well as lower cost of manufacturing revenue due to the settlement of \$1.7 million in disputed Elan invoices previously discussed.

Research and Development. Research and development expenses increased by 110% to \$10.8 million for the three months ended March 31, 2004 from \$5.1 million for the same period last year. The increase was primarily due to (i) increased spending of approximately \$1.6 million related to our strategic partnership with INEX on INEX's proprietary oncology product Onco TCS, (ii) increased spending of approximately \$819,000 related to our single chain antibody collaboration with Micromet AG, (iii) increased spending on our two late stage development programs, Pegamotecan and ATG Fresenius S, of approximately \$1.4 million, and (iv) increased payroll related expenses of approximately \$1.8 million.

Selling, General and Administrative. Selling, general and administrative expenses for the three months ended March 31, 2004 increased by 32% to \$12.5 million, as compared to \$9.5 million in the same period last year. The increase was primarily due to (i) increased sales and marketing expense of approximately \$970,000 related to the ABELCET Product Line including the lunch of the Clear II registry, (ii) increased sales and marketing expense of approximately \$272,000 related to our oncology sales force for ONCASPAR and DEPOCYT, and (iii) increased general and administrative personnel and other costs of approximately \$1.8 million.

Merger Expenses. Merger expenses represent costs incurred related to our mutual termination of the merger agreement with NPS Pharmaceuticals. During the three months ended March 31, 2003, we incurred \$1.4 million of merger related expenses. There were no such costs in the current period.

Amortization. Amortization expense for the three months ended March 31, 2004 was \$3.4 million as compared to \$4.0 million in the comparable period last year. Amortization relates principally to the intangible assets acquired in November 2002 as part of the ABELCET Product Line. Amortization of intangible assets is provided over their estimated lives ranging from 1-15 years on a straight-line basis.

Acquired In Process Research and Development. Acquired in process research and development for the three months ended March 31, 2004 of \$12.0 million was due to the up-front payment for the execution of a strategic partnership agreements entered into with INEX related to Onco TCS.

Other Income/Expense. Investment income for the three months ended March 31, 2004 increased to \$11.6 million, as compared to \$632,000 for the prior year. The increase was primarily due to the sale of Nektar Therapeutics stock and the sale of the shares of common stock issued upon such conversion. Interest expense remained unchanged from the comparable period last year. Interest expense is related to the \$400.0 million in 4.5% convertible subordinated notes, which were outstanding for both periods. Other expense of \$337,000 for the three months ended March 31, 2004 was principally due to a loss recognized with respect to the collar associated with the 1.5 million shares of NPS common stock we hold.

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Income Taxes. During the three months ended March 31, 2004 the Company recorded a net tax benefit of approximately \$5.5 million related primarily to the reversal of a deferred tax asset valuation allowance of approximately \$3.8 million for the write-down in a prior year of our investment in NEKTAR Convertible Preferred Stock which was converted and the underlying common stock was sold during the quarter resulting in a financial reporting gain of approximately \$11.0 million. The benefit was also due the reduction of our estimated taxable income and effective tax rate to 29% as compared to 35% used in the previous two quarters, due to a payment during the three months ended March 31, 2004 of \$12.0 million to INEX Pharmaceuticals related to acquired in-process research and development for Onco TCS. The tax provision for the three months ended March 31, 2003 represented our anticipated Alternative Minimum Tax liability based on the anticipated taxable income for the full fiscal year.

On November 22, 2002, we acquired the North American rights and operational assets associated with the development, manufacture, sales and marketing of ABELCET(R) (Amphotericin B Lipid Complex Injection) ("the ABELCET Product Line") from Elan Corporation, plc ("Elan") for \$360.0 million, plus approximately \$9.3 million of acquisition costs. This transaction was accounted for as a business combination.

Unless otherwise indicated, the discussions in Management's Discussion and Analysis of Financial Condition and Results of Operations for the three months ended March 31, 2004 and 2003 and the nine months ended March 31, 2004 and financial condition at March 31, 2004 include the results of operations of the ABELCET Product Line. Comparisons are made to the results of operations and the financial condition for the nine months ended March 31, 2003, which include approximately only four months of operations, of the ABELCET Product Line commencing from our acquisition of the Product Line on November 22, 2002.

Nine months ended March 31, 2004 and March 31, 2003

Revenues. Total revenues for the nine months ended March 31, 2004 increased by 27% to \$126.7 million, as compared to \$99.7 million for the nine months ended March 31, 2003. The components of revenues are product sales and certain contract manufacturing revenues, royalties we earn on the sale of products by others and contract revenues.

Net product sales and manufacturing revenue increased by 114% to \$89.5 million for the nine months ended March 31, 2004, as compared to \$41.7 million for the nine months ended March 31, 2003. The increase in net sales was due to increased sales of ABELCET and DEPOCYT during the entire nine months ended March 31, 2004, and increased sales of ADAGEN and ONCASPAR. During November 2002, we acquired the ABELCET Product Line from Elan. During the nine months ended March 31, 2004, we recorded \$59.4 million of sales related to the ABELCET Product Line as compared to \$19.6 million for the prior year. Of the total ABELCET Product Line sales, sales in North America accounted for \$50.6 million for the nine months ended March 31, 2004 as compared to \$14.1 for the nine months ended March 31, 2003. Contract manufacturing revenue related to the manufacture and sale of ABELCET to Elan for the international market and other contract manufacturing revenue was \$8.8 million for the nine month period ended March 31, 2004 as compared to \$5.5 for the comparable period of the prior year. Approximately \$1.7 million of the \$8.8 million of revenues recorded during the nine months related to the settlement of amounts previously disputed by Elan. In January 2003, we obtained an exclusive license to sell, market and distribute SkyePharma's DEPOCYT. During the nine months ended March 31, 2004, we recorded DEPOCYT sales of \$4.0 million as compared to \$1.2 million for the same period last year. Sales of ONCASPAR increased by 53% to \$13.3 million for the nine months ended March 31, 2004 from \$8.7 million in the corresponding period in the prior year. This was a result of our resumption of our marketing efforts subsequent to our reacquiring from Aventis in June 2002 the right to market and distribute ONCASPAR for certain territories which we had previously licensed to Aventis. Sales of ADAGEN increased by 4% for the nine months ended March 31, 2004 to \$12.8 million as compared to \$12.2 million for the nine months ended March 31, 2003 due to the timing of shipments.

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Royalties for the nine months ended March 31, 2004, decreased to \$36.5 million as compared to \$57.6 million in the same period in the prior year. The decrease was primarily due to decreased sales of PEG-INTRON by Schering-Plough, our marketing partner, due to the introduction of a competitive product, PEGASYS.

Contract revenues for the nine months ended March 31, 2004 increased to \$769,000 as compared to \$417,000 in the corresponding period in the previous year. The increase was related to revenue received from the licensing of our PEG technology to SkyePharma. In connection with such licensing, we received a payment of \$3.5 million in January 2003 which is being recognized as revenue over the term of the related agreement.

During the nine months ended March 31, 2004, we had export sales and royalties on export sales of \$27.0 million, of which \$22.5 million were sales in Europe or royalties on sales in Europe. Export sales and royalties recognized on export sales for the corresponding period in the prior year were \$24.2 million, of which \$21.5 million were in Europe.

Cost of Sales and Manufacturing Revenue. Cost of sales and manufacturing revenue, as a percentage of net sales and manufacturing revenue decreased to 39% for the nine months ended March 31, 2004 as compared to 43% for the comparable period last year. The decrease was due to certain purchase accounting adjustments to the inventory acquired with the ABELCET Product Line, which was sold during nine months ended March 31, 2003.

Research and Development. Research and development expenses increased by 66% to \$24.7 million for the nine months ended March 31, 2004 from \$14.9 million for the comparable period last year. The increase was primarily due to (i) increased spending of approximately \$2.4 million related to our single chain antibody collaboration with Micromet AG, (ii) increased spending on our two late stage development programs, Pegamotecan and ATG Fresenius S, of approximately \$2.8 million, (iii) increased spending of approximately \$1.6 million related to our strategic partnership with INEX on INEX's proprietary oncology product Onco TCS, and (iv) increased payroll related expenses of approximately \$3.0 million.

Selling, General and Administrative. Selling, general and administrative expenses for the nine months ended March 31, 2004 increased by 69% to \$35.2 million, as compared to \$20.8 million in the comparable period last year. The increase was primarily due to (i) increased sales and marketing expense of approximately \$10.5 million related to the sales force acquired from Elan as part of our acquisition of the ABELCET Product Line, (ii) increased sales and marketing expense of approximately \$2.1 million related to the establishment of an oncology sales force for ONCASPAR and DEPOCYT and (iii) increased general and administrative personnel and other costs of approximately \$1.8 million.

Merger Expenses. Merger expenses represent costs incurred related to our mutual termination of the merger agreement with NPS Pharmaceuticals. During the nine months ended March 31, 2003, we incurred \$1.4 million of merger related expenses. There were no such expenses in the current period.

Amortization. Amortization expense increased to \$10.1 million for the nine months ended March 31, 2004 as compared to \$5.3 million in the same period last year as a result of the amortization of the intangible assets acquired in November 2002 as part of the ABELCET Product Line. Amortization of intangible assets is provided over their estimated lives ranging from 1-15 years on a straight-line basis.

Acquired In Process Research and Development. Acquired in process research and development for the nine months ended March 31, 2004 of \$12.0 million was due to an up-front payment for the execution of a strategic partnership agreements entered into with INEX related to Onco TCS.

Other Income/Expense. Investment income for the nine months ended March 31, 2004 increased to \$12.7 million, as compared to \$8.4 million for the prior year. The increase was primarily due to the sale of Nektar Therapeutics stock and the sale of the shares of common stock issued upon such conversions. Interest expense

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remained unchanged from the comparable period last year. Interest expense is related to the \$400.0 million in 4.5% convertible subordinated notes, which were outstanding for both periods. Other income of \$71,000 for the nine months ended March 31, 2004, represents the gain recognized on the Collar arrangement related to the 1.5 million shares of NPS common stock we hold.

Income Taxes. During the nine months ended March 31, 2004 the Company recorded a net tax benefit of approximately \$2.7 million related primarily to the reversal of a deferred tax asset valuation allowance of approximately \$3.8 million for the write-down in a prior year of our investment in NEKTAR Therapeutics Convertible Preferred Stock which was converted and the underlying common stock was sold during the nine months resulting in a financial reporting gain of approximately \$11.0 million. The benefit was also due to the reduction of our estimated taxable income and effective tax rate to 29% as compared to 35% used in the previous two quarters, due to a payment during the nine months ended March 31, 2004 of \$12.0 million to INEX Pharmaceuticals related to acquired in-process research and development for Onco TCS (See Note 14). The tax provision recognized for the nine months ended March 31, 2004 is based on the estimated annual effective tax rate of 29%.

In December 2001, the SEC requested that all registrants discuss their most "critical accounting policies" in Management's Discussion and Analysis of Financial Condition and Results of Operations. The SEC indicated that a "critical accounting policy" is one which is both important to the portrayal of the company's financial condition and results of operations and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

Our consolidated financial statements are presented in accordance with accounting principles that are generally accepted in the United States. All professional accounting standards effective as of December 31, 2003 have been taken into consideration in preparing the consolidated financial statements. The preparation of the consolidated financial statements requires estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. Some of those estimates are subjective and complex, and, consequently, actual results could differ from those estimates. The following accounting policies have been highlighted as significant because changes to certain judgments and assumptions inherent in these policies could affect our consolidated financial statements.

Revenues from product sales and manufacturing revenue are recognized based on shipping terms and a provision is made at that time for estimated future credits, chargebacks, sales discounts, rebates and returns. These sales provision accruals are presented as a reduction of the accounts receivable balances. We continually monitor the adequacy of the accruals by comparing the actual payments to the estimates used in establishing the accruals. We utilize the following criteria to determine appropriate revenue recognition: pervasive evidence of an arrangement exists, delivery has occurred, selling price is fixed and determinable and collection is reasonably assured.

Royalties under our license agreements with third parties are recognized when earned through the sale of the product by the licensor net of any estimated future credits, chargebacks, sales discount rebates and refunds. Since we do not sell or market the products, we rely on disclosures from our marketing partners to estimate such sales allowances.

Contract revenues are recorded as the earnings process is completed. Non-refundable milestone payments that represent the completion of a separate earnings process are recognized as revenue when earned, upon the occurrence of contract-specified events and when the milestone has substance. Non-refundable payments received upon entering into license and other collaborative agreements where we have continuing involvement are recorded as deferred revenue and recognized ratably over the estimated service period.

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Under the asset and liability method of Statement of Financial Accounting Standards ("SFAS") No. 109, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance on net deferred tax assets is provided for when it is more likely than not that some portion or all of the deferred tax assets will not be realized. We have significant net deferred tax assets, primarily related to net operating loss carryforwards, and continue to analyze the level of the valuation allowance needed taking into consideration the expected future performance of the Company.

We assess the carrying value of our investments in accordance with SFAS No. 115 and SEC Staff Accounting Bulletin No. 59. An impairment write-down is recorded when a decline in the value of an investment is determined to be other-than-temporary. These determinations involve a significant degree of judgment and are subject to change as facts and circumstances change.

In accordance with the provisions of SFAS No. 142, goodwill and intangible assets determined to have an indefinite useful life acquired in a purchase business combination are not subject to amortization, are tested at least annually for impairment, and are tested for impairment more frequently if events and circumstances indicate that the asset might be impaired. Goodwill is reviewed for impairment by comparing the carrying value to its fair value.

Recoverability of amortizable intangible assets is determined by comparing the carrying amount of the asset to the future undiscounted net cash flow to be generated by the asset. The evaluations involve amounts that are based on management's best estimate and judgment. Actual results may differ from these estimates. If recorded values are less than the fair values, no impairment is indicated. SFAS No. 142 also requires that intangible assets with estimated useful lives be amortized over their respective estimated useful lives.

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# Item 3. Quantitative and Qualitative Disclosures About Market Risk

The following discussion about our exposure to market risk of financial instruments contains forward-looking statements. Actual results may differ materially from those described.

Our holdings of financial instruments are comprised of debt securities and time deposits. All such instruments are classified as securities available-for-sale. We do not invest in portfolio equity securities or commodities or use financial derivatives for trading purposes. Our debt security portfolio represents funds held temporarily pending use in our business and operations. We manage these funds accordingly. We seek reasonable assuredness of the safety of principal and market liquidity by investing in rated investment grade fixed income securities while at the same time seeking to achieve a favorable rate of return. Our market risk exposure consists principally of exposure to changes in interest rates. Our holdings are also exposed to the risks of changes in the credit quality of issuers. We typically invest the majority of our investments in the shorter-end of the maturity spectrum, and at March 31, 2004 all of our holdings were in instruments maturing in three years or less.

The table below presents the principal amounts and related weighted average interest rates by year of maturity for our investment portfolio as of March 31, 2004 (in thousands):

2004	2005	2006	2007	2008	Total	Fair Value
4,569	\$27,602	\$38,458	\$12,274	\$ 8,015	\$90,918	\$91,099
2.52%	2.22%	2.18%	2.29%	3.38%	2.33%	
\$ 4,569	\$27,602	\$38,458	\$12 <b>,</b> 274	\$ 8,015	\$90,918	\$91,099
	4,569 2.52% 	4,569 \$27,602 2.52% 2.22% 	4,569 \$27,602 \$38,458 2.52% 2.22% 2.18% 	4,569 \$27,602 \$38,458 \$12,274 2.52% 2.22% 2.18% 2.29%	4,569 \$27,602 \$38,458 \$12,274 \$ 8,015 2.52% 2.22% 2.18% 2.29% 3.38%	4,569 \$27,602 \$38,458 \$12,274 \$ 8,015 \$90,918 2.52% 2.22% 2.18% 2.29% 3.38% 2.33%

Our 4.5% convertible subordinated notes in the principal amount of \$400.0 million due July 1, 2008 have a fixed interest rate. The fair value of the notes was approximately \$383.9 million at March 31, 2004. The fair value of fixed interest rate convertible notes is affected by changes in interest rates and by changes in the price of our common stock.

As discussed in Liquidity and Capital Resources, in August 2003, we entered into a Zero Cost Protective Collar arrangement with a financial institution to reduce the exposure associated with the 1.5 million shares of common stock of NPS we received as part of the merger termination agreement with NPS.

# Item 4. Controls and Procedures

# (a) Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of December 31, 2003, the end of the period covered by this report (the "Evaluation Date"). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of the Evaluation Date, our disclosure controls and procedures were effective in timely alerting them to the material information relating to us required to be included in our periodic SEC filings.

(b) Changes in internal controls over financial reporting.

There were no changes in our internal controls over financial reporting during the period covered by this report that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

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Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits (numbered in accordance with Item 601 of Regulation S-K).

		Page Number
		or
Exhibit		Incorporation
Number	Description	By Reference
3.1	Certificate of Incorporation, as amended	^^^
3.2	Amendment to Certificate of Incorporation	\\
3.3	By laws, as amended	^^
4.1	Indenture dated as of June 26, 2001, between the Company and	
4.1	Wilmington Trust Company, as trustee, including the form of 41/2%	
	Convertible Subordinated Notes due 2008 attached as Exhibit A thereto	++++
4.2		****
4.2	Rights Agreement dated May 17, 2002 between the Company and	^
4.3	Continental Stock Transfer Trust Company, as rights agent	*
	First Amendment to Rights Agreement, dated as of February 19, 2003	^
10.27	Separation Agreement with Arthur Higgins	0
	dated as of March 16, 2004	@
10.28	Development Agreement between Inex Pharmaceuticals, Inc. and the	
	Company dated January 19, 2004**	@
10.29	Product Supply Agreement between Inex Pharmaceuticals, Inc. and	
	The Company dated January 19, 2004**	@
10.30	Co-Promotion Agreement between Inex Pharmaceuticals, Inc. and the	
	Company dated January 19, 2004**	@
31.1	Rule 13a-14(a) Certifications	@
31.2	Rule 13a-14(a) Certifications	@
32.1	Section 1350 Certifications	@
32.2	Section 1350 Certifications	@

- @ Filed herewith.
- ^^^ Previously filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended June 30, 2002 and incorporated herein by reference thereto.
- \\ Previously filed as an exhibit to the Company's Current Report on Form 8-K filed on December 10, 2002 and incorporated herein by reference thereto.
- ^^ Previously filed as an exhibit to the Company's Current Report on Form 8-K filed with the Commission on May 22, 2002 and incorporated herein by reference thereto.
- ++++ Previously filed as an exhibit to the Company's Registration Statement on Form S-3 (File No. 333-67509) filed with the Commission and incorporated herein by reference thereto.
  - ^ Previously filed as an exhibit to the Company's Form 8-A (File No. 000-12957) filed with the Commission on May 22, 2002 and incorporated herein by reference thereto.
  - \* Previously filed as an exhibit to the Company's Form 8-A12 G/A (File No. 000-12957) filed with the Commission on February 20, 2003 and incorporated herein by reference thereto.(b) Reports on Form 8-K
  - \*\* Certain portions of this document have been omitted and filed separately with the Commission pursuant to a confidential treatment request.

### (b) Reports on Form 8-K

On January 8, 2004, we filed with the Commission a Current Report on Form 8-K dated January 2, 2004 reporting David S. Barlow's resignation from our Board of Directors.

On January 21, 2004, we filed with the Commission a Current Report on Form 8-K dated January 19, 2004 reporting our agreement with Inex Pharmaceuticals Corporation ("INEX") to develop and commercialize INEX's proprietary oncology product Onco TCS.

On February 4, 2004, we filed with the Commission a Current Report on Form 8-K/A dated January 19, 2004 amending our report on Form 8-K, filed with the Securities and Exchange Commission on January 21, 2004, to correct a typographical error.

On February 4, 2004, we filed with the Commission a Current Report on Form 8-K dated February 4, 2004 reporting our financial results for the quarter ended December 31, 2003.

On March 18, 2004, we filed with the Commission a Current Report on Form 8-K dated March 16, 2004 reporting that effective May 10, 2004 Arthur J. Higgins will resign from his position as chief executive officer of Enzon and become chairman and chief executive officer of Bayer Healthcare.

On March 18, 2004, we filed with the Commission a Current Report on Form 8-K dated March 15, 2004 reporting that Enzon and Inex submitted the final section of a "rolling submission" of a New Drug Application (NDA) to the United States Food and Drug Administration (FDA).

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# SIGNATURES

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

Date: May 10, 2004

By: /s/Arthur J. Higgins

\_\_\_\_\_

Arthur J. Higgins Chairman, President and Chief Executive Officer (Principal Executive Officer)

Date: May 10, 2004

By: /s/Kenneth J. Zuerblis

Kenneth J. Zuerblis

Vice President, Finance, Chief Financial Officer (Principal Financial and Accounting Officer) and Corporate Secretary

### SEPARATION AGREEMENT

This Separation Agreement (the "Separation Agreement") is made and entered into as of March 16, 2004 between Enzon Pharmaceuticals, Inc., a Delaware corporation with its executive offices located in Bridgewater, New Jersey (the "Company") and Arthur Higgins, residing in Libertyville, Illinois ("Executive").

#### WITNESSETH:

WHEREAS, Executive has been employed as the Company's President and Chief Executive Officer since May, 2001, has been a member of the Company's Board of Directors since May, 2001 and has been Chairman of the Company's Board of Directors since December, 2001;

WHEREAS, Executive and the Company have been party to an employment agreement dated as of May 9, 2001 and as amended as of May 23, 2001 and as of December 3, 2003 (the "Employment Agreement");

WHEREAS, Executive and the Company have been party to a Restricted Stock Award Agreement entered into June 2001 (the "2001 Stock Agreement") and a Restricted Stock Award Agreement dated as of December 3, 2002 (the "2002 Stock Agreement" and together with the 2001 Stock Agreement, the "Stock Agreements") pursuant to which the Company made restricted stock awards of shares of the Company's common stock (the "Restricted Stock") to Executive;

WHEREAS, on February 6, 2004, the Compensation Committee of the Company's Board of Directors voted to grant Mr. Higgins 50,000 restricted stock units on June 30, 2004 (the "2004 Restricted Stock Units");

WHEREAS, the Company granted Executive options to purchase shares of the Company's common stock pursuant to the Employment Agreement, pursuant to the resolutions of the Compensation Committee adopted in April 2002 and pursuant to a Non-Incentive Stock Option Agreement dated as of December 3, 2002 (the "December 2002 Option Agreement");

WHEREAS, Executive has informed the Company's Board of Directors (the "Board") that he intends to voluntarily terminate his employment with the Company and resign as President and Chief Executive Officer of the Company;

WHEREAS, Executive has informed the Board that he wishes to remain a member of the Board and as Chairman of the Board, and the Board has advised Executive of its desire to have Executive remain a member of the Board and Chairman of the Board;

WHEREAS, the Company and Executive wish to set forth (i) the terms and conditions of Executive's continued employment as the Company's President and Chief Executive Officer through the date Executive's employment with the Company terminates, (ii) Executive's role as Chairman of the Executive Committee of the Board until the Company employs a successor Chief Executive Officer (the "Successor CEO"), and (iii) the compensation payable to Executive upon the termination of his employment as the Company's President and Chief Executive Officer.

NOW THEREFORE, in consideration of the premises, the mutual agreements set forth below and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties agree as follows:

- 1. Executive's full-time employment as the Company's President and Chief Executive Officer shall continue from the date of this Separation Agreement through the close of business on May 10, 2004 (the "Remaining Term"). During the Remaining Term, Executive shall continue to serve as the Company's President and Chief Executive Officer in accordance the provisions of Section 3 of the Employment Agreement.
- 2. Executive agrees to serve as Chairman of the Board until such time as the Board determines it is appropriate to appoint a new Chairman.
  - 3. Executive will assist the Company in searching for a Successor CEO.
  - 4. Executive will serve as a member, and Chairman, of the Executive

Committee of the Board until such time as the Company employs a Successor CEO or such earlier time as may be determined by the Board. In the event the Company has not employed a Successor CEO prior to the expiration of the Remaining Term, the Executive Committee of the Board shall be responsible for the supervision and direction of the Company's business until such time as the Company employs a Successor CEO, provided that notwithstanding the foregoing, the Board shall have the power in its sole discretion to determine the members, powers and role of the Executive Committee.

- 5. It is understood and agreed that the termination of Executive's employment with the Company is the result of a voluntary resignation by the Executive and not the result of Good Reason (as defined in the Employment Agreement) or any breach of the Employment Agreement by the Company.
- 6. Executive will continue to receive his current base salary and his current medical, dental and life insurance benefits during the Remaining Term. Executive will be entitled to any deferred compensation and other unpaid amounts and benefits earned and vested prior to the end of the Remaining Term. In recognition of the accomplishments of Executive and the Company to date during the Company's current fiscal year ending June 30, 2004, within fifteen (15) days after the end of the Remaining Term the Company shall pay to Executive a cash bonus of \$216,000. The Company shall be entitled to make all required tax and other customary withholdings from such cash payment.
- 7. Executive shall retain the 10,000 shares of Restricted Stock granted pursuant to the 2001 Stock Agreement that will have vested under the terms of the 2001 Stock Agreement as of the end of the Remaining Term. To the extent not previously done, the Company shall deliver certificates for such 10,000 shares to Executive and such certificates shall not contain any restrictive legend. The remaining 15,000 shares of Restricted Stock granted pursuant to the 2001 Stock Agreement and the entire 200,000 shares of Restricted Stock granted pursuant to the 2002 Stock Agreement will not have vested as of the end of the Remaining Term and will be forfeited by Executive back to the Company. The certificates for such 215,000 unvested shares shall be delivered to the Company together with any stock powers relating to such certificates executed by Executive. To the extent necessary Executive will execute and deliver to the Company or its transfer agent any additional stock powers or other documents required to effect the forfeiture of such shares to the Company and allow the Company to cancel such shares. The 2004 Restricted

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Stock Units shall not be granted to Executive and Executive shall forfeit all rights he may have in and to the 2004 Restricted Stock Units.

- 8. Any options granted to Executive which have not vested in accordance with their terms as of the last day of the Remaining Term shall terminate and be of no further force and effect as of the last day of the Remaining Term. Any options granted to Executive which have vested as of the last day of the Remaining Term shall remain exercisable in accordance with their terms through the close of business on November 10, 2004, at which time any of such options which remain unexercised shall terminate and be of no further force and effect. Attached hereto as Exhibit A is the vesting schedule of all options held by Executive. It is agreed that the transfer restrictions set forth in Section 3(f) of the December 2002 Option Agreement are hereby waived and of no further force and effect.
- 9. In order to acknowledge Executive's forfeiture of certain restricted stock of Executive's prior employer when he joined the Company and in recognition of Executive's many valuable contributions to the Company, within fifteen (15) days after the end of the Remaining Term, the Company shall make a cash payment of \$1,250,000 to Executive. The Company shall be entitled to make all required tax and other customary withholdings from such lump sum cash payment.
- 10. In consideration of the compensation and benefits provided to Executive under the Employment Agreement and the additional compensation payable to Executive under this Separation Agreement, it is agreed that the non-competition provisions set forth in Section 5(a) of the Employment Agreement, the confidentiality provisions set forth in Section 5(b) of the Employment Agreement and the non-solicitation of employees provisions set forth in Section 5(c) of the Employment Agreement shall remain in full force and effect in accordance with their terms, provided that the "Non-Compete Period" as

defined in Section 5 (a) of the Employment Agreement and as applicable in Section 5(c) of the Employment Agreement shall extend through May 10, 2007.

- 11. Each party agrees not to directly or indirectly make any disparaging, untrue or defamatory statements or communications (regardless of medium) about the other.
- 12. Except as provided in the next sentence, the Employment Agreement is terminated and of no further force and effect as of the date of this Separation Agreement. Notwithstanding the preceding sentence, the following sections of the Employment Agreement shall survive in accordance with their terms, as such sections may be amended by the terms of this Separation Agreement: Sections 3, 5, 7, 8 and 11.
- 13. The terms and conditions of this Separation Agreement may not be altered, amended or modified except by a writing duly executed by both the Company and Executive.
- 14. If any provision of this Separation Agreement or the application thereof is held invalid by a court of law, the invalid provision shall not affect any other provision or the application thereof which can be given effect without the invalid provision or application, and to this end the provisions of this Separation Agreement are declared to be severable.
- 15. Courts situated within the State of New Jersey shall have sole jurisdiction over any disputes arising out of or concerning this Separation Agreement. The rights and obligations of the parties under this Separation Agreement shall be construed and enforced in accordance

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with, and governed by, the laws of the State of New Jersey without regard to principles of conflict of laws.

- 16. No waiver of any breach of any term or provision of this Separation Agreement shall be construed to be, nor shall it be, a waiver of any other breach of this Separation Agreement.
- 17. This Separation Agreement contains the entire understanding between the parties hereto with respect to the subject matter hereof and supersedes any prior understandings, agreements or representations, written or oral, relating to the subject matter hereof.

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

# COMPANY:

Enzon Pharmaceuticals, Inc.

By: /s/ Kenneth J. Zuerblis

Kenneth J. Zuerblis, Vice President Finance and Chief Executive Officer

EXECUTIVE:

By: /s/ Arthur J. Higgins

-----

Arthur J. Higgins

# DEVELOPMENT AGREEMENT

# BETWEEN

INEX PHARMACEUTICALS, INC.

AND

ENZON PHARMACEUTICALS, INC.

January 19, 2004

# Development Agreement

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\*\*\* Indicates the omission of confidential material pursuant to a request for confidential treatment made in accordance with Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The Confidential material is being filed separately with the Secretary to the Securities and Exchange Commission.

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# Development Agreement

This DEVELOPMENT AGREEMENT dated as of the 19th day of January, 2004 between Inex Pharmaceuticals, Inc., a corporation duly incorporated pursuant to the laws of Delaware, USA, having a registered office at Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801 (hereinafter referred to as "Inex"), and Enzon Pharmaceuticals, Inc., a corporation duly incorporated pursuant to the laws of Delaware, having a principal place of business at 685 Route 202/206, Bridgewater, New Jersey 08807, USA (hereinafter referred to as "Enzon").

# INTRODUCTION

A. Enzon is a pharmaceutical company with operations in research and development, import, export, manufacture and sale of pharmaceutical products;

- B. Inex is in the business of developing, manufacturing and selling certain pharmaceutical products, including Vincristine Sulfate Liposomes Injection (as further defined in this Agreement);
- C. Of even date hereof, the Parties have entered into a Product Supply Agreement for the supply from Inex to Enzon of Vincristine Sulfate Liposomes Injection, and incidental thereto, the Parties must complete the development of Vincristine Sulfate Liposomes Injection;
- D. Inex and Enzon desire to set out in this Agreement the terms which will govern the development of Vincristine Sulfate Liposomes Injection and to provide for licenses for the right to develop, market and distribute Vincristine Sulfate Liposomes Injection, which licenses are granted solely for the Parties' legal protection and for the purpose of enabling Enzon to acquire rights to develop, market, distribute and sell Inex's Vincristine Sulfate Liposomes Injection product in the Territory for the Term;
- E. The execution of this Agreement is ancillary to and a necessary pre-condition for the establishment of both a market and a product for Inex's business with respect to manufacturing and selling Vincristine Sulfate Liposomes Injection.

In consideration of the mutual covenants and promises contained in this Agreement and other good and valuable consideration, and intending to be legally bound, Inex and Enzon agree as follows:

# Article 1 Interpretation

# 1.1 Definitions

Unless otherwise defined in this Agreement, capitalized terms used in this Agreement shall have the meaning set out therefor in the Product Supply Agreement. As used in this Agreement, the following terms, whether used in the singular or plural, shall have the following meanings:

- 1.1.1 "Adverse Drug Event" will have the meaning set forth in Exhibit 1.1.1.
- \*\*\* Indicates the omission of confidential material pursuant to a request for confidential treatment made in accordance with Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The Confidential material is being filed separately with the Secretary to the Securities and Exchange Commission.

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- 1.1.2 "Affiliate" means any corporation, company, partnership, joint venture or other person or entity which controls, is controlled by or is under common control with a Party. For purposes of this Section 1.1.1, "control" shall mean (a) in the case of corporate entities, direct or indirect ownership of at least 50% of the stock or shares (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) entitled to vote for the election of directors or otherwise having the power to vote on or direct the affairs of such Party; and (b) in the case of non-corporate entities, direct or indirect ownership of at least 50% of the equity interest or the power to direct the management and policies of such non-corporate entities.
- 1.1.3 "Agreement" means this Development Agreement including all exhibits attached to this Agreement.
- 1.1.4 "Applicable Laws" means all applicable federal, provincial, state and local laws, ordinances, rules and regulations of any kind whatsoever in the Territory, including, without limitation, pharmaceutical and environmental rules and regulations, including cGMP Requirements, GCP Requirements, GLP Requirements and the General Biological Products Standards of the FDA, and the Federal Food, Drug and Cosmetic Act, as amended, or any successor act thereto ("FDCA").
- 1.1.5 "Business Day" means any day other than a day which is a Saturday, a Sunday or a statutory holiday in New York City, New York, USA.

- 1.1.6 "cGMP Requirements" shall mean the current Good Manufacturing Practices standards required by the FDA, the TPD and the equivalent Regulatory Authority elsewhere in the Territory, and the applicable regulations, policies or guidelines of each of them in effect for the manufacture and testing of pharmaceutical materials, active ingredients, or excipients, as applicable.
- 1.1.7 "Clinical Activity" and "Clinical Activities" mean any one or more of the activities associated with drug testing in humans, including trial design and execution, payment of investigators', institutional, and contractors' fees, drug distribution and accountability, analytical testing, data management, statistical analysis, adverse event reporting, and scientific publication, performed or to be performed by the Parties or their Representatives in pursuit of the Development of the Product or post-Regulatory Approval commercialization of the Product.
- 1.1.8 "Code" or "Codes" means the Code on Interactions with Healthcare Professionals promulgated by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the American Medical Association (AMA) Guidelines on Gifts to Physicians from Industry, as either of the foregoing may be amended from time to time.
- 1.1.9 "Commercially Reasonable Efforts" means efforts which are not less than those efforts a Party makes with respect to other pharmaceutical products in its portfolio (but, in any event, not less than the efforts that would be exerted by a reasonably prudent and diligent pharmaceutical company similarly situated and seeking to accomplish similar objectives),
- \*\*\* Indicates the omission of confidential material pursuant to a request for confidential treatment made in accordance with Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The Confidential material is being filed separately with the Secretary to the Securities and Exchange Commission.

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taking into account the product's market potential, level of competition, number of prescribers and other relevant factors.

- 1.1.10 "Compendium Listing" means the listing in any two or more publications or directories including Drugdex Information Service, AHFS Drug Information, or US Pharmacopoeia Drug Information, recognized by the US government for coverage under Medicaid, Medicare or other like health insurance programs, for use of VSLI in the treatment of Firstline NHL.
- 1.1.11 "Confidential Information" means:
  - (a) all proprietary information and materials, patentable or otherwise, of a Party which is disclosed in writing by or on behalf of such Party to the other Party and marked as confidential or proprietary, including DNA sequences, vectors, cells, substances, formulations, techniques, methodology, equipment, data, reports, know-how, preclinical and clinical trials and the results thereof, sources of supply, patent positioning, marketing plans and business plans, including any negative developments;
  - (b) any other information, oral or written, designated in writing by the disclosing Party to the other Party as confidential or proprietary within ten (10) days after such disclosure, whether or not related to the making, use, importing or selling of the Product; and
  - (c) the Data, the Inex Technology, the Regulatory Approvals and Regulatory Submissions, and the Licensed Patents (all of which are deemed to be Confidential Information of Inex);

provided that Confidential Information shall not include such information which:

- (d) was known or used by the receiving Party or its Affiliates prior to its date of disclosure to the receiving Party, as evidenced by the prior written records of the receiving Party or its Affiliates; or
- (e) either before or after the date of the disclosure to the receiving Party is lawfully disclosed to the receiving Party or its Affiliates by an independent, unaffiliated Third Party rightfully in possession of the Confidential Information; or
- (f) either before or after the date of the disclosure to the receiving Party becomes published or generally known to the public through no fault or omission on the part of the receiving Party or its Affiliates; or
- (g) the receiving Party can verify, by written documentation, results from research and development by the receiving Party or any of its Affiliates independent of disclosure by the other Party thereof.
- 1.1.12 "Co-Promotion Agreement" means the Co-Promotion Agreement between Inex and Enzon of even date herewith.
- \*\*\* Indicates the omission of confidential material pursuant to a request for confidential treatment made in accordance with Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The Confidential material is being filed separately with the Secretary to the Securities and Exchange Commission.

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- 1.1.13 "Data" has the meaning set out in Section 10.3.2.
- 1.1.14 "DDMAC Activities" mean all jointly agreed-to activities performed or to be performed by one or both Parties in accordance with the requirements of the Division of Drug Marketing, Advertising and Communications, Center for Drug Evaluation and Research of the FDA, and the Office of the Inspector General of the Department of Health and Human Services of the United States.
- 1.1.15 "Development" means:
  - (a) all activities set forth in the Development Plan; and
  - (b) all activities necessary to obtain and maintain Regulatory Approvals in each country in the Territory;

including Development Clinical Activities, Regulatory Activities and Technical and Manufacturing Support Activities.

- 1.1.16 "Development Clinical Activities" has the meaning set out in Section 5.2.
- 1.1.17 "Development Costs" means, with respect to Development of the Product in respect of the Territory:
  - the Development FTE Costs and Out-of-Pocket Costs utilized or incurred by a Party in fulfilling its obligations under the then-current Development Plan;
  - (b) all Development FTE Costs and Out of Pocket costs incurred in excess of the budget in the then-current Development Plan, provided that any such excess costs have been approved in advance by the Joint Steering Committee; and
  - (c) the Manufacturing Cost of Product produced for the Development.

For greater certainty, Development Costs do not include Commercialization Costs as defined in the Product Supply Agreement.

- 1.1.18 "Development FTE" means a scientific or technical person employed by a Party or a Party's Affiliates and assigned to work on Development with such time and effort to constitute one person working on Development on a full time basis consistent with normal business and scientific practice (e.g., having appropriate education, training and experience and working \*\*\* hours per year of dedicated effort).
- 1.1.19 "Development FTE Costs" means the price of Development FTEs to be used for the purposes of determining the costs incurred with respect to personnel performing work on the Development in accordance with the then-approved Development Plan. The price per Development FTE shall initially be \*\*\* per Development FTE year or pro-rata portion thereof incurred on the Development. The Development FTE rate includes all the fully burdened cost of salary, employee benefits, incidental materials, travel, lodging and other expenses including support staff and direct and indirect overhead for or associated with a Development FTE. On each anniversary of the Effective Date, the FTE rate shall be

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raised by a percentage equal to the percentage increase in the Index (defined below) for the twelve (12) month period ending with December of the calendar year immediately preceding such anniversary date (such increase, the "CPI Increase"). For purposes of this Agreement, the term "Index" shall mean the Consumer Price Index for all Urban Consumers (CPI-U) - - U.S. City Average. All Items (1982-1984 = 100), as published by the United States Bureau of Labor Statistics, or if such index is no longer published, then the index most comparable thereto.

- 1.1.20 "Development Plan" means the Development Plan for obtaining and maintaining Regulatory Approvals for the Product in the Territory, together with a corresponding budget accounting for the anticipated Development Costs to be expended or incurred by each Party in conducting the Development. The definitive Development Plan adopted in accordance with Section 4.4 will form a part of this Agreement.
- 1.1.21 "Dollar" and "\$" means United States Dollars.
- 1.1.22 "Effective Date" means the date shown on page one of this  $$\operatorname{Agreement.}$$
- 1.1.23 "Elan" means Elan Pharmaceuticals, Inc.
- 1.1.24 "Elan Consent" means the consent by Elan to the execution and delivery of the Related Agreements and the subsequent grant of manufacturing rights contemplated herein.
- 1.1.25 "Elan Improvements" has the meaning set out therefor in the Elan License.
- 1.1.26 "Elan License" means the Amended and Restated License Agreement made as of April 3, 2003 between Elan, IE Oncology Company Limited and Inex Pharmaceuticals Corporation.
- 1.1.27 "Elan Patents" means the Patents set out in Exhibit 1.1.27.
- 1.1.28 "FDA" means the United States Food and Drug Administration or any successor thereto.
- 1.1.29 "Field" means VSLI for all indications in humans.
- 1.1.30 "First Commercial Sale" means (a) with respect to a country in the

Territory, the first sale by Enzon, its sublicensees or Affiliates for use, consumption or resale of the Product in such country (excluding any sales for clinical trials, compassionate uses or other non-commercial purposes) and (b) with respect to the Territory, the First Commercial Sale in any country within the Territory. A sale to a sublicensee or an Affiliate shall not constitute a First Commercial Sale unless the sublicensee or Affiliate is the end user of the Product.

- 1.1.31 "Firstline NHL" means the treatment of aggressive non-Hodgkin's lymphoma in patients not previously treated for aggressive non-Hodgkin's lymphoma.
- 1.1.32 "GCP Requirements" or "Good Clinical Practices" means the then current standards for clinical trials for pharmaceuticals as required by the FDA, the TPD and the equivalent Regulatory Authority elsewhere in the Territory, and as applicable, the policies and

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guidelines of the International Conference on Harmonization in effect for the clinical testing of pharmaceutical materials.

- 1.1.33 "GLP Requirements" or "Good Laboratory Practices" means the current Good Laboratory Practices standards required by the FDA, the TPD and the equivalent Regulatory Authority elsewhere in the Territory in effect for the testing of pharmaceutical materials as applied to raw materials and finished products.
- 1.1.34 "include" and "including" (and the like) means "including, without limitation".
- 1.1.35 "IND" means an Investigational New Drug application in accordance with the rules and regulations of the FDA.
- 1.1.36 "Inex Patents" means the Patents set out in Exhibit 1.1.36.
- 1.1.37 "Inex Technology" means all technical information and know-how owned or controlled by Inex which relates to the Product and is necessary or useful for the development and commercialization of the Product, and shall include:
  - (a) as of the Effective Date, all biological, chemical, pharmacological, toxicological, clinical, assay, control and manufacturing data and any other information owned or controlled by Inex and necessary or useful for the development and commercialization of the Product;
  - (b) any Data referred to in Section 10.3; and
  - (c) any Data referred to in Section 12.3 of the Product Supply Agreement.
- 1.1.38 "Intellectual Property Rights" means any rights to any Patents and
  copyrights and registrations and applications for registration of
  the foregoing rights, and trade secrets and moral rights.
  "Intellectual Property Rights" do not include trademark, domain
  name or trade name rights.
- 1.1.39 "Joint Steering Committee" means the committee formed pursuant to Article 6. The Joint Steering Committee formed under this Agreement shall be the same as the Joint Steering Committee formed under the Product Supply Agreement.
- 1.1.40 "Licensed Patents" means the Patents owned or controlled by Inex relating to VSLI, and necessary or useful for the development and commercialization of the Product, and shall include:

- (a) as of the Effective Date, the Inex Patents and the Elan Patents;
- (b) to the extent of Inex's legal right to grant rights to same, as of the Effective Date, the Regents' Patents;
- (c) any Patents on inventions referred to in Section 10.3; and

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- (d) any Patents on inventions referred to in Section 12.3 of the Product Supply Agreement.
- 1.1.41 "NDA" means a New Drug Application in accordance with the rules and regulations of the FDA.
- 1.1.42 "NHL" means non-Hodgkin's Lymphoma.
- 1.1.43 "not to be unreasonably withheld" and the like means not to be unreasonably withheld or delayed.
- 1.1.44 "Out-of-Pocket Cost" means an out-of-pocket payment made by a Party or its Representatives to a Third Party but only to the extent such payment relates to costs which are incurred by a Party or its Representatives with respect to fulfilling its obligations under the Development Plan.
- 1.1.45 "Party" means Inex or Enzon and "Parties" means Inex and Enzon.
- 1.1.46 "Patent" means (a) all patent applications filed or having legal force in any country; (b) all patents that have issued or in the future issue therefrom, including without limitation utility, model and design patents and certificates of invention; and (c) all divisionals, continuations, continuations—in—part, reissues, renewals, extensions (including supplemental protection certificates), additions, registrations or confirmations to or of any such patent applications and patents.
- 1.1.47 "Person" means and includes any individual, corporation, partnership, firm, joint venture, syndicate, association, trust, government body, and any other form of entity or organization.
- 1.1.48 "Permitted Exception" means any or all of the following:
  - (a) any termination of the license between \*\*\*and the \*\*\* by either \*\*\* or the \*\*\* before or after the Effective Date; or
  - (b) any inability of IE Oncology Company Limited or Inex to grant sublicenses under the \*\*\* License, or the absence of a consent to such sublicense from \*\*\* or the \*\*\*; or
  - any inability of \*\*\* to grant Intellectual Property
    Rights under the \*\*\*to IE Oncology Company Limited
    ("IE"), or of IE to grant such rights to Inex, or of
    Inex to grant such rights to Enzon, which rights in each
    case are at least co-extensive (within the Field and
    within the Territory as defined in the Related
    Agreements) with the scope of Intellectual Property
    Rights under the \*\*\* purported to be granted by \*\*\* to
    IE pursuant to the \*\*\* License;

or the like respecting the \*\*\*.

Exchange Act of 1934, as amended. The Confidential material is being filed separately with the Secretary to the Securities and Exchange Commission.

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- 1.1.49 "Pharmacovigilance" means all the activities associated with maintaining an effective drug safety monitoring system and adverse events reporting system in compliance with the requirements of Regulatory Authorities.
- 1.1.50 "Post-Approval Clinical Activities" has the meaning set out in Section 5.3.
- 1.1.51 "Prime Rate" means the prime or equivalent rate quoted by Citibank, N.A. from time to time.
- 1.1.52 "Product" means VSLI.
- 1.1.53 "Product Supply Agreement" means the agreement for the supply of the Product from Inex to Enzon entered into as of the Effective Date.
- 1.1.54 "QA" means Quality Assurance, being that part of each management system, within Inex and Enzon separately, having responsibility for assuring the quality of the Product in respect of compliance with Regulatory Requirements.
- 1.1.55 "Quality/Technical Agreement" has the meaning set out in the Product Supply Agreement.
- 1.1.56 \*\*\*
- 1.1.57 "Regulatory Activity" and "Regulatory Activities" mean any one or more of the regulatory activities to be performed by the Parties, or their Representatives in pursuit of the Development of the Product, including writing, translation, compilation, notification, submission, filing, defense, maintenance and renewal of Regulatory Approvals and payment of fees associated therewith, and meeting with Regulatory Authorities.
- 1.1.58 "Regulatory Approvals" means all necessary and appropriate regulatory approvals which must be obtained before placing the Product on the market in the Field in any country in the Territory in which such approval is required, including without limitation, INDs, NDAs, and any other comparable terms as applicable with regard to any such approvals in any other country in the Territory.
- 1.1.59 "Regulatory Authority" or "Regulatory Authorities" means:
  - (a) the FDA, the TPD and any other like governmental authorities, whether federal, provincial, state or municipal, regulating the importation, distribution, marketing and/or sale of therapeutic substances in the Territory; and
  - (b) the corresponding governmental authorities, whether federal, provincial, state or municipal, of each other applicable jurisdiction outside the Territory in which the Product will be developed, used or sold.
- 1.1.60 "Regulatory Requirements" means:
  - (a) Applicable Laws, rules, regulations, guidances, and the Codes and Standards in respect of all activities of the Parties and their permitted Representatives under
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the Related Agreements, including guidances in respect of quality control and QA procedures and processes, manufacturing and production batch records (including the Master Production Record), packaging, handling, storage, delivery and retention of raw material and Product samples and associated support data, and all licenses, certificates, authorizations or requirements from Regulatory Authorities; and

- (b) the corresponding laws, rules, regulations and guidances of each other applicable jurisdiction outside the Territory in which such activities take place.
- 1.1.61 "Regulatory Submissions" means all submissions and filings made in furtherance of obtaining and maintaining any Regulatory Approvals.
- 1.1.62 "Related Agreements" means, collectively, this Agreement, the Product Supply Agreement, the Quality/Technical Agreement and the Co-Promotion Agreement.
- 1.1.63 "Representatives" means, in respect of a Party, that Party's
  Affiliates and their respective directors, officers, employees,
  consultants, subcontractors, sublicensees, agents, representatives
  and other persons acting under their authority.
- 1.1.64 "Standards" means the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of Continuing Medical Education, as they may be amended from time to time.
- 1.1.65 "Sublicensee" means a Third Party which is not an Affiliate of Enzon and to whom Enzon has granted a sublicense for the purpose of developing, using, selling, having sold, distributing, importing or exporting the Product in one or more countries of the Territory.
- 1.1.66 "Technical and Manufacturing Support Activity" or "Technical and Manufacturing Support Activities" mean any one or more of the activities to be performed by the Parties or their Representatives in the area of analytical development, process development, manufacturing, and quality control, in pursuit of manufacturing scale-up and the Regulatory Approvals of the Product, including the design, testing, analysis, qualification, and validation of methods, equipment and/or processes.
- 1.1.67 "Term" has the meaning set out in Section 11.1.
- 1.1.68 "Territory" means Canada, Mexico and the USA.
- 1.1.69 "Third Party(ies)" means any Person other than Inex or Enzon or an Affiliate of either of them.
- 1.1.70 "TPD" means the Therapeutic Products Directorate Organization of Health Canada.
- 1.1.71 "Trademarks" means trademarks, trade names, and domain names identified in Exhibit 1.1.71 and all applications and registrations thereof in the Territory.
- 1.1.72 "USA" means the United States of America, including its territories, possessions and the Commonwealth of Puerto Rico.
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- (a) a claim of an issued and unexpired patent which has not been held unenforceable, unpatentable or invalid by a court or other governmental agency of competent jurisdiction, and which has not been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or
- (b) a claim in a patent application, provided that if such pending claim has not issued as a claim of an issued patent within seven years after the national filing date of such patent application in a country, such pending claim shall not be a Valid Claim for purposes of this Agreement.

In the event that a claim of an issued patent is held by a court or other governmental agency of competent jurisdiction to be unenforceable, unpatentable or invalid, and such holding is reversed on appeal by a higher court or agency of competition jurisdiction, such claim shall be reinstated as a Valid Claim hereunder.

- 1.1.74 "Vincristine" means the chemical compound known as vincristine sulfate.
- 1.1.75 "Vincristine Sulfate Liposomes Injection" or "VSLI" means
  Vincristine encapsulated in sphingomyelin/cholesterol liposomes or
  a kit for production of same.

# 1.2 Entire Agreement; Conflicts

The Parties hereby agree that, except as expressly modified hereby, the following Articles of the Product Supply Agreement shall be part of this Agreement as if set out herein: Sections 12.6 through 12.10 inclusive, Articles 13, 14, 15 and 16. This Agreement, together with the other Related Agreements, constitutes the entire agreement between the Parties concerning the subject matter hereof. In the event of a conflict between the terms and conditions set out in any of the Related Agreements, the following agreements shall govern in the following priority:

- 1.2.1 the Product Supply Agreement;
- 1.2.2 the Quality/Technical Agreement;
- 1.2.3 this Development Agreement; and
- 1.2.4 the Co-Promotion Agreement

# 1.3 Governing Law

This Agreement shall be governed by and construed in accordance with the laws of Delaware in force therein without regard to its conflict of law rules.

# 1.4 Headings

The headings contained in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. References to Articles are references to Articles of this

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Agreement and the Sections contained therein, and references to Sections are references to Sections of this Agreement.

# 1.5 Severability

If a court or other tribunal of competent jurisdiction should hold any term or provision of this agreement to be excessive, invalid, void or unenforceable, the offending term or provision shall be deemed inoperative to the extent it

conflicts with such holding and shall be deemed to be modified to the extent necessary to conform with such statute or rule of law, while still preserving, to the extent practicable, the legitimate aims of the Parties, provided that the remaining portions hereof shall remain in full force and effect. In the event that the terms and conditions of this Agreement are materially altered as a result of the above, the Parties will renegotiate the terms and conditions of this Agreement to resolve any inequities.

Article 2 Grant and Reservation of Rights

### 2.1 Grant of Licenses

In furtherance of the Product Supply Agreement, and subject to the reservation set forth in Section 2.2 of this Agreement, Inex hereby grants to Enzon:

- 2.1.1 an exclusive license for the Field in the Territory under the Inex Patents;
- 2.1.2 subject to the terms, conditions and limitations set out in the
   \*\*\*, an exclusive sublicense for the Field in the Territory under
   the \*\*\*;
- 2.1.3 subject to Section Error! Reference source not found., to the extent of Inex's legal right to grant same, a non-exclusive sublicense for the Field in the Territory under the \*\*\*;
- 2.1.4 an exclusive license for the Field in the Territory under the Inex Technology; and

for the sole purpose of developing (solely in accordance with the Development Plan), using, selling, having sold, offering for sale, distributing, importing and exporting the Product for the Field in the Territory, including the right to grant sublicenses under these rights in accordance with Section 2.4. Enzon shall not use or exploit for any purpose of any Licensed Patents or Inex Technology except as permitted in this Agreement.

# 2.2 Reservation of Rights

- 2.2.1 Except as otherwise expressly licensed to Enzon hereunder, Inex may exploit the Licensed Patents and Inex Technology for any purpose, including using, making, having made, selling, having sold, distributing and importing the Product:
  - (a) outside the Territory;
  - (b) inside the Territory but outside the Field;
  - (c) inside the Territory and inside the Field, for the purpose of sales to Enzon; and
  - (d) in accordance with Section 11.3.

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- - (a) to practice the Licensed Patents and the Inex Technology for internal research purposes for the Field;
  - (b) to Co-Promote the Product in the Territory in accordance with the Co-Promotion Agreement; and
  - (c) to undertake Development as contemplated herein.
- 2.2.3 For avoidance of doubt, Inex may exploit the Licensed Patents and Inex Technology in any territory for any liposomal product which

### 2.3 \*\*\*

# 2.4 Sublicenses

- 2.4.1 Enzon shall have the right to sublicense all the rights granted in Section 2.1 to its Affiliates. Enzon hereby unconditionally guarantees the performance of any such Affiliates hereunder as if they were signatories to this Agreement to the extent the performance or lack of performance is a breach of this Agreement. A breach by any such Affiliate of any such obligation shall constitute a breach by Enzon of this Agreement and shall entitle Inex to exercise its rights hereunder, in addition to any other rights and remedies to which Inex may be entitled.
- 2.4.2 Enzon shall also have the right to sublicense all the rights granted in Section 2.1 to Third Parties, subject to the following:
  - (a) Prior to the execution of any sublicense, Enzon shall provide Inex with at least the following information with respect to each potential Sublicensee: (i) the identity of the Sublicensee; (ii) the territory in which the Product will be sold; and (iii) a copy of the draft sublicense.
  - (b) Each sublicense shall contain covenants by the Sublicensee for the benefit of Inex to observe and perform similar terms and conditions to those in this Agreement. All sublicenses granted by Enzon shall be personal to the Sublicensee and shall not be further sublicensable or assignable without the prior written consent of Inex. Such sublicenses shall terminate upon the termination of Enzon's rights granted herein unless events of default are cured by Enzon or Sublicensee within sixty (60) days after notification by Inex of default and/or as provided by the terms of this Agreement.
  - (c) Enzon may grant such sublicenses only with the prior written consent of Inex, which shall not be unreasonably withheld.

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- (d) Unless otherwise agreed in the Elan Consent, Enzon may grant such sublicenses only with the prior written consent of Elan, which consent may be withheld in Elan's absolute discretion.
- (e) Any Sublicensee which wishes to grant a further sublicense shall comply with the terms of this Section as if the further sublicense were a sublicense hereunder, including providing to Enzon and Inex the information described in this Section with respect to each potential sub-sublicensee, and obtaining the consent referred to in this Section, prior to the execution of any such sub-sublicense.
- (f) In the event that Enzon becomes aware of a material breach of any such sublicense by the Sublicensee, Enzon shall promptly notify Inex of the particulars of same and take all reasonable steps to enforce the terms of such sublicense. Enzon shall remain responsible to Inex for the compliance of each such Sublicensee with the financial and other obligations due under this Agreement. Upon the request of Inex, Enzon shall act reasonably in considering any request of Inex for Enzon

to terminate such sublicense.

## Article 3 Milestone Payments for Development

### 3.1 Signing and Regulatory Milestone Payments

As payments to facilitate the development of the Product and the establishment of Inex's manufacturing and commercialization business, and as consideration for the rights granted by Inex to Enzon under this Agreement, Enzon shall make the following signing and regulatory milestone payments to Inex:

\_\_\_\_\_\_

Milestone:		Payment:
3.1.1	Execution of the Product Supply Agreement, this Agreement and the Co-Promotion Agreement	\$12.0 million
3.1.2	NDA Accelerated Approval ("AA") in the USA within eighteen (18) months of completed NDA submission date	\$20.0 million
3.1.3	***	\$***
3.1.4	***	\$***
3.1.5	***	\$***
3.1.6	***	\$***
3.1.7	***	\$***
3.1.8	***	\$***
3.1.9	***	\$*** ========

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### Provided that:

- 3.1.10 Enzon shall make the milestone payment referred to in Section 3.1.1 to Inex on execution and delivery of this Agreement by the Parties, in payment for Inex's prior development work and other rights granted herein;
- 3.1.11 Enzon shall make the milestone payments other than the ones referred to in Sections 3.1.1 and Error! Reference source not found. to Inex within thirty (30) days after achievement of each milestone by a Party, or by an Affiliate or a Sublicensee;
- 3.1.12 Enzon shall make the milestone payments referred to in Section Error! Reference source not found. to Inex on the dates set out for occurrence of such milestone in Section Error! Reference source not found.;
- 3.1.13 except for the payments set out in Section Error! Reference source not found., each milestone payment hereunder shall be made only one time, based upon the Product achieving a particular milestone regardless of how many times such milestone is achieved;
- 3.1.14 only one of the three alternative milestone payments referred to in Sections 3.1.2, Error! Reference source not found. and Error! Reference source not found. will be paid;
- 3.1.15 payment shall not be owed for a milestone which is not reached;

- 3.1.16 except as expressly set out in this Agreement, each payment shall be made without setoff, deduction or similar right;
- 3.1.17 with the exception of payment referred to in Section 3.1.9, which is creditable in accordance with its terms, any milestone payment described herein shall be non-refundable and non-creditable against any other payment due from Enzon to Inex under this Agreement;
- 3.1.18 \*\*\*
- 3.1.19 \*\*\*
- 3.1.20 \*\*\*
- 3.1.21 \*\*\*
- 3.1.22 \*\*\*

### 3.2 Withholding Taxes

The Parties contemplate that there will be no payment or withholding by Enzon of taxes on any payments made by Enzon to Inex pursuant to this Agreement. In the event that either Party takes any action, or if the circumstances applicable to either Party change with the result that taxes must be paid or withheld on the payments due pursuant to this Agreement, then such taxes shall be borne by such Party. Without limiting the generality of the foregoing:

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- 3.2.1 if Enzon assigns or sublicenses its rights hereunder, undergoes a reorganization or otherwise changes its structure, or changes its domicile, and thereafter taxes must be paid or withheld on the payments hereunder, such payments shall be grossed up so that Inex receives the actual amounts set out in this Agreement; and
- 3.2.2 if Inex assigns or sublicenses its rights hereunder, undergoes a reorganization or otherwise changes its structure, or changes its domicile, and thereafter taxes must be paid or withheld on the payments hereunder, then such tax or withholding payments shall be deducted from the amounts set forth herein, and Enzon shall assist Inex as may be reasonably required, including providing proof of such payment of such tax payment, in order to allow Inex to claim the benefit of, exemption from or repayment such tax payment, as may be applicable; and
- 3.2.3 in the event that payment or withholding by Enzon of taxes becomes necessary on any payments made by Enzon to Inex pursuant to this Agreement when neither Section 3.2.1 nor Section 3.2.2 applies, then such tax or withholding payments shall be deducted from the amounts set forth herein, and Enzon shall assist Inex as may be reasonably required, including providing proof of such payment of such tax payment, in order to allow Inex to claim the benefit of, exemption from or repayment such tax payment, as may be applicable.

Notwithstanding the foregoing, if Inex is able to credit the grossed up portion of any payment made by Enzon pursuant to Section 3.2.1 against taxes payable by Inex, or gain exemption from or repayment of such tax payment, Inex will promptly pay the equivalent of the benefit received by Inex to Enzon.

# 3.3 Late Payments

Any payment by Enzon or Inex that is not paid on or before the date such payment is due under this Agreement shall bear interest at a rate equal to the lesser of:

3.3.1 Prime Rate plus \*\*\* per year, or

# 3.3.2 the maximum rate permitted by law;

calculated based on the number of days that payment is delinquent.

## Article 4 Development

### 4.1 Development Activities in accordance with the Development Plan

Inex and Enzon will undertake Development as set out in the Development Plan and as amended from time to time by the Parties in accordance with this Article 4. Subject to Sections 5.2 and 5.8, from the Effective Date until the Parties' agreement to the terms of the definitive Development Plan, Inex and Enzon will undertake the Development acting reasonably. If either Party fails to perform its responsibilities under the Development Plan (the "Non-performing Party") after reasonable notice of such failure from the other Party (the "Performing Party"), the Performing Party's sole remedy shall be that the Performing Party may assume conduct of such responsibilities and the Development Plan shall be amended to reflect such change. The cost of any such responsibilities so assumed shall be borne by the Parties as set out in this Agreement.

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## 4.2 Overview of Development

The Parties intend to work cooperatively to pursue the Development in accordance with the terms of this Agreement. Unless otherwise set out in this Agreement, the Parties will conduct the Development as directed by the Joint Steering Committee and in conformance with the Development Plan. The Parties shall collaborate closely, through the Joint Steering Committee, to assign responsibility for conducting the various aspects of such Development. Unless otherwise agreed by the Parties, the Parties will conduct the activities assigned to them in the Development Plan.

# 4.3 Development Diligence

- 4.3.1 Inex shall make its third submission to the FDA for an NDA for the Product as soon as reasonably possible.
- 4.3.2 Each of the Parties, directly and through its permitted
  Representatives, shall use Commercially Reasonable Efforts to
  Develop the Product for the USA and Canada, including carrying out
  its respective responsibilities under the Development Plan,
  including to:
  - (a) conduct or cause to be conducted the necessary and appropriate clinical trials as necessary to obtain and maintain Regulatory Approvals for the Product; and
  - (b) prepare, file and prosecute or cause to be prepared, filed and prosecuted the Regulatory Submissions for the Product in the USA and Canada.
- 4.3.3 Each of the Parties, directly and through its permitted Representatives, shall perform the Development in compliance with Regulatory Requirements.
- 4.3.4 Each Party shall ensure none of its Representatives who participate in any activities under the Related Agreements:
  - (a) is or has been suspended, debarred or disqualified by the FDA:
  - (b) has been convicted of any offence that would form the basis for any debarment; or
  - (c) is or has been subject to any proceedings for the suspension, disqualification or debarment of such Party

### 4.4 Development Plans

- 4.4.1 Within ninety (90) days after the Effective Date, the Joint Steering Committee shall prepare, review and submit to the Parties for approval a detailed Development Plan for the Development of the Product.
- 4.4.2 Development of the Product shall be conducted by the Parties in conformance with the Development Plan.

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- 4.4.3 The Development Plan may be updated by the Joint Steering Committee and the Parties as provided herein.
- 4.4.4 At a minimum, the Development Plan as amended from time to time shall describe the specific activities to be performed in the Territory for a twelve (12) month period, with a summary of development activities to be performed thereafter. The Development Plan will be reviewed on at least a semi-annual basis by the Joint Steering Committee to update the specific activities to be performed for the rolling twelve (12) month period, as well as to reflect the revised Development as the Joint Steering Committee reasonably determines to be necessary or useful. Notwithstanding the above, no amendment to any Development Plan shall be construed to be final unless it has been made in accordance with the provisions of Article 6.

# 4.5 Reports on Development

Each Party will keep the other Party fully informed on the progress of the Development in respect of the Territory, using reasonable reporting requirements mutually established by the Parties. As a minimum requirement, the Joint Steering Committee shall receive and review and approve quarterly progress reports.

### 4.6 Attendance at Regulatory Meetings

Each Party will inform the other Party of planned meetings between its representatives and governmental or Regulatory Authorities regarding Regulatory Approvals and Regulatory Submissions for the Product in the Territory and, where appropriate to do so, make reasonable efforts to include the other Party in such meetings.

# 4.7 Subcontractors

Either Party may subcontract to any of its Representatives any of its obligations in respect of the Development with the consent of the other Party, such consent not to be unreasonably withheld; provided however, that the subcontracting Party shall be responsible for the performance of its Representatives and shall remain fully responsible and obligated to the other Party for all activities undertaken by its Representatives.

Article 5 Development Responsibility and Funding

# 5.1 Shared Funding of Certain Development Costs

Each Party shall bear the initial responsibility for funding all Development Costs required to support the conduct of all such Party's responsibilities in pursuit of Regulatory Approvals for the Product in the Territory in accordance with the Development Plan, subject to allocation and reimbursement for such expenses in accordance with this Article 5.

# 5.2 Development Clinical Activities

5.2.1 Subject to Section 5.2.2, Enzon will fund 50%, and Inex 50% of

Development Costs for all the following Clinical Activities (the "Development Clinical Activities"):

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- (a) obtaining and maintaining Regulatory Approval for the first label claim for the Product in each country in the Territory, including any FDA mandated Phase III confirmatory trials for the first label claim if VSLI receives NDA Accelerated Approval in the USA;
- (b) any jointly agreed-to trials designed to obtain additional Regulatory Approvals for the Product in the Territory;
- (c) all Phase II clinical trials for the Product ongoing as of the Effective Date, a listing of which is set out in Exhibit 5.2.1(c); and
- (d) all jointly agreed-to trials sponsored by either of the Parties to explore new indications or dosing regimens for the Product.
- 5.2.2 Notwithstanding anything herein to the contrary, Enzon's contribution to Development Costs for Development Clinical Activities under this Section 5.2 from the Effective Date through June 30, 2004 shall be limited to \*\*\* of the first \*\*\* of Development Costs incurred. Inex shall pay \*\*\* of the Development Costs incurred during this period in excess of \*\*\*, if any.

# 5.3 Post-Approval Clinical Activities

Enzon will be responsible for and fund \*\*\* of the costs for all the following Clinical Activities (the "Post-Approval Clinical Activities"):

- 5.3.1 Clinical Activities typically associated with post-Regulatory Approval commercialization, including Phase IV clinical trials and post-Regulatory Approval Compendium Listings;
- 5.3.2 physician-sponsored studies; and
- 5.3.3 any Clinical Activities undertaken by the Parties not required by a Regulatory Authority in order to obtain any Regulatory Approval or as a condition of obtaining or maintaining a Regulatory Approval.

# 5.4 Regulatory Activities

- The Parties will coordinate their activities with each other with respect to the overall regulatory strategy for the Product in the Territory, and with respect to Inex's overall regulatory strategy for the Product outside the Territory.
- 5.4.2 Inex will have primary responsibility for Regulatory Activities in the Territory, with Enzon's input and advice.
- 5.4.3 Enzon will fund \*\*\*, and Inex \*\*\* of all Development Costs for Regulatory Activities associated with obtaining and maintaining Regulatory Approval for the Product in the Territory.
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- 5.5 Filing of Regulatory Submissions
  - 5.5.1 Inex or an Affiliate of Inex designated by Inex shall be named as the applicant for all Regulatory Submissions and holder of all Regulatory Approvals in all countries, including the countries in the Territory, and all such Regulatory Approvals and Regulatory Submissions shall be owned as set out in Section 10.4.
- 5.6 Technical and Manufacturing Support Activities
  - 5.6.1 Each Party will have responsibility for Technical and Manufacturing Support Activities in the Territory as set out in the Development Plan, with input and advice from the other Party.
  - 5.6.2 Enzon will fund \*\*\*, and Inex \*\*\* of all Development Costs including Costs for Technical and Manufacturing Support Activities and the following additional activities, if mutually agreed upon, shall be Technical and Manufacturing Support Activities:
    - (a) manufacturing scale up activities;
    - (b) the contracting of secondary suppliers and testing laboratories;
    - (c) the establishment of secondary manufacturing sites; and
    - (d) the establishment of secondary suppliers and/or alternate sources of raw materials.
- 5.7 Funding of Development Costs
  - 5.7.1 From and after the Effective Date, in respect of each calendar quarter in which Development Costs are incurred, the Parties shall bear their proportionate share of Development Costs as set out in this Article.
  - 5.7.2 Within twelve Business (12) Days after of the end of each calendar quarter, each Party shall provide the other Party with a reasonably detailed invoice setting forth such Party's Development Costs.
  - 5.7.3 Such invoices shall be accompanied by appropriate documentation ("Supporting Documentation"), including a listing of expenditures in reasonably specific detail to support the Party's determination of the actual Development Costs incurred in conducting Development work during such calendar quarter.
  - 5.7.4 If the invoices and Supporting Documentation (as verified by the Joint Steering Committee) demonstrate that one Party, in completing tasks assigned for such quarter under the Development Plan (but excluding tasks each Party is to perform at its own expense hereunder) has borne more of the Development Costs than the share set out for such Party in this Article 5, then within 30 days after the exchange of invoices and Supporting Documentation, there shall be an accounting and payment between the Parties to bring the Development Costs incurred by them respectively during such quarter into conformity with this Article 5.

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5.7.5 Each Party shall use Commercially Reasonable Efforts to comply with the applicable budget for each activity set out in the Development Plan for such Party during the each calendar year. In the event that a Party incurs any Development FTE Costs for a particular activity that exceed the amount budgeted therefor, such event shall not be considered a breach of this Agreement by such Party, but the other Party shall not be responsible for funding

any such excess amount, unless otherwise agreed to in writing by the Parties. If a Party believes that completion of the assigned Development tasks will exceed the portion of such budget that is allocated for such Party's efforts, such Party will contact the Joint Steering Committee promptly after such determination in order to initiate discussion by the Joint Steering Committee of such matter and appropriate means of resolving same.

### 5.8 Transition

From the Effective Date until the Parties' agreement to the terms of the definitive Development Plan, Inex and Enzon will fund their respective shares of Development Costs incurred as contemplated by this Agreement. If the Parties fail to agree on the terms of the definitive Development Plan within 90 days of the Effective Date, until the terms of the definitive Development Plan are determined, the Parties shall fund their respective shares of Development Costs incurred by the Parties, acting reasonably. Notwithstanding the foregoing, after the Effective Date, in the absence of a definitive Development Plan agreed upon by the Parties, no more than an aggregate of US\$\*\*\* in Development Costs will be incurred without the review of the Joint Steering Committee and the agreement of the Parties.

# 5.9 Records

Both Parties shall keep full, true and accurate books of accounts and other records containing all information and data which may be necessary to ascertain and verify:

- 5.9.1 the Development Costs incurred by each of them and their respective Representatives for a period of three (3) years after the completion of the Development; and
- 5.9.2 any other amount payable hereunder for a period of three (3) years after the completion of the Term.

### 5.10 Audits

5.10.1 During the Development and for a period of one (1) year following the completion of the Development, Enzon shall have the right from time to time (not to exceed once during each calendar year) to have either its internal financial audit personnel or an independent firm of accountants (i.e., a certified public accountant or like person reasonably acceptable to Inex) inspect the books, records and supporting data of Inex referred to in Section 5.9. Such independent firm of accountants shall perform these audits at Enzon's expense upon reasonable prior notice and during Inex's regular business hours, and shall agree as a condition to such audit to maintain the confidentiality of all information disclosed or observed in connection with such audit and to disclose to Enzon only whether Inex has complied with its obligations under this Agreement with respect to Development Costs. If the result of such audit demonstrates an overpayment or underpayment, there shall be a prompt (but in no event more than 60 days after

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completion of the audit) accounting between the parties to reconcile such overpayment or underpayment. If the result of such audit demonstrates an overpayment by Enzon of \*\*\* or more, Inex shall pay Enzon the reasonable costs of such audit.

5.10.2 During the Term and for a period of one (1) year thereafter, Inex shall have the right from time to time (not to exceed once during each calendar year) to have either its internal financial audit personnel or an independent firm of accountants (i.e., a certified public accountant or like person reasonably acceptable to Enzon) inspect the books, records and supporting data of Enzon referred

to in Section 5.9. Such independent firm of accountants shall perform these audits at Inex's expense upon reasonable prior notice and during Enzon's regular business hours, and shall agree as a condition to such audit to maintain the confidentiality of all information disclosed or observed in connection with such audit and to disclose to Inex only whether Enzon has complied with its obligations under this Agreement with respect to the payment of money owing pursuant to this Agreement. If the result of such audit demonstrates an overpayment or underpayment, there shall be a prompt (but in no event more than 60 days after completion of the audit) accounting between the parties to reconcile such overpayment or underpayment. If the result of such audit demonstrates an underpayment of \*\*\* or more, Enzon shall pay Inex the reasonable costs of such audit.

5.10.3 The provisions of Sections 5.10.1 and 5.10.2 are based on the assumption that the net flow of payments under Section 5.7 will be from Enzon to Inex. If this assumption proves incorrect, the provisions of Sections 5.10.1 and 5.10.2 will be deemed modified to permit an appropriate accounting between Inex and Enzon to correct for any underpayment or overpayment by Inex.

Article 6 Joint Steering Committee

## 6.1 Joint Steering Committee

- Committee shall be formed and shall be constituted of four representatives from each Party. The members of the Joint Steering Committee as of the Effective Date are as set forth on Exhibit 6.1. The Chairperson of the Joint Steering Committee at the first meeting of the Joint Steering Committee shall be an Enzon member of the Joint Steering Committee, and thereafter, the Chairperson will alternate at each meeting between a representative of Inex and a representative of Enzon. The Chairperson shall be responsible for issuing an agenda for the meeting, conducting and chairing the meeting and preparing the minutes for the meeting, and such other tasks as assigned by the committee. The Joint Steering Committee shall meet regularly at least quarterly during the period when Development in respect of the Territory is occurring, or more frequently if necessary.
- 6.1.2 Each Party shall bear its own expenses associated with its participation in the Joint Steering Committee and its administration and oversight of the activities contemplated by the Agreement. Such expenses shall not be included in Development Costs.
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# 6.2 Meetings of the Joint Steering Committee

The Joint Steering Committee should meet at least once per year at 6.2.1 the location of Inex or an Affiliate of Inex, and once per year at a location of Enzon or an Affiliate of Enzon. All other meetings of the Joint Steering Committee may occur by telephone, video conference or other acceptable means or location if requested by a Party. The Joint Steering Committee shall oversee all Development activities of the Parties under this Agreement, including coordinating the overall strategy for Development. The Joint Steering Committee shall have the responsibilities as set forth generally in Exhibit 6.1. Each Party may appoint its representatives to the Joint Steering Committee and other members of its project team at its discretion. It is the intent of the Parties to assign responsibilities for the various operational aspects of the Development Plan to those portions of their respective organizations which have the appropriate resources, expertise and responsibility for such functions. The Joint

Steering Committee shall act only as a body making recommendations to the Parties, and neither Party is bound by any recommendation of the Joint Steering Committee. The members of the Joint Steering Committee shall attempt, in good faith, to reach consensus on all matters before the committee and make a consensus recommendation to the Parties. In the event that the Joint Steering Committee cannot make a consensus recommendation to the Parties which is acceptable to the Parties, either Party may refer the matter for resolution in accordance with the terms of Article 16 of the Product Supply Agreement.

6.2.2 The Joint Steering Committee shall cause there to be recorded reasonably detailed minutes of its meetings. The Party providing the chairperson of each meeting shall be responsible for preparing draft minutes of such meeting and distributing same to the other members of the committee within five Business Days after such meeting. If the other Party desires to revise the draft minutes it will provide comments on such minutes within ten Business Days after receiving the minutes. If such comments are provided, members of the Joint Steering Committee designated by each Party shall confer promptly and in good faith to resolve such comments and finalize the minutes. If the members of the Joint Steering Committee are unable to finalize the minutes within 30 days after the date of the meeting, either Party may refer the matter for resolution in accordance with the terms of Article 16 of the Product Supply Agreement.

## 6.3 Working Committees

The Joint Steering Committee may establish working committees to manage actively the Development. Such working committees will conduct at a minimum quarterly planning and review meetings as well as ad hoc meetings as necessary. The primary method of meeting will be teleconference. Responsibilities of the working committees may include overseeing the planning and monitoring of the clinical development process and the regulatory and commercialization processes.

Article 7 Pharmacovigilance, DDMAC and Recalls

# 7.1 Regulatory Responsibilities

Inex will be responsible for maintaining and fulfilling all Regulatory Requirements with respect to the Product that are imposed upon Inex as the manufacturer and holder of the Regulatory Approvals. Subject

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to the other express terms of the Related Agreements, Enzon and its designees will have sole responsibility for the advertising and other promotion of the Product and for maintaining and fulfilling all Regulatory Requirements with respect to the Product that are imposed upon Enzon as the advertiser, marketer and distributor thereof.

### 7.2 Pharmacovigilance Agent

7.2.1 Unless the Parties agree to establish the agency referred to in Section 7.2.2 on an accelerated basis, Inex shall be responsible for performing Pharmacovigilance in respect of all pre-Regulatory Approval Clinical Activities (in addition to all other Regulatory Activities for which Inex is responsible). Until this agency is established, if Enzon receives any information of any type whatsoever that may constitute a complaint regarding the Product or indicates that the Product in any way relates to an Adverse Drug Event, then it will record the information set forth on Exhibit 1.1.1 and transmit the completed form to Inex as soon as possible, and in any event at least in time to allow Inex to meet its reporting obligations under Regulatory Requirements. Inex will then report the Adverse Drug Event in accordance with Regulatory Requirements, and provide Enzon with a copy(ies) of all

documentation provided to Regulatory Authorities in respect of such complaint or Adverse Drug Event. Further, until this agency is established, if Inex receives any information of any type whatsoever that may constitute a complaint regarding the Product or indicates that the Product in any way relates to an Adverse Drug Event, then it will record the information set forth on Exhibit 1.1.1, provide a copy of the completed form to Enzon (if possible, prior to submitting it to Regulatory Authorities) and report the Adverse Drug Event in accordance with Regulatory Requirements.

7.2.2 After Regulatory Approval of the Products by a Regulatory Authority (or sooner if and to the extent agreed to by the Parties), Enzon shall be appointed by Inex as Inex's agent with respect to the regulatory dossier for the Product in the Field in the Territory for the sole purpose of conducting Pharmacovigilance. After this agency has been established, Enzon shall manage and carry out on behalf of Inex all relevant communications and relations with Regulatory Authorities to the extent related to Pharmacovigilance with respect to the Product. Inex shall be entitled to participate in all negotiations and discussions between Enzon and Regulatory Authorities relating to Pharmacovigilance with respect to the Product. Without limiting the generality of the foregoing, after this agency has been established, if Inex receives any information of any type whatsoever that may constitute a complaint regarding the Product or indicates that the Product in any way relates to an Adverse Drug Event, then it will record the information set forth on Exhibit 1.1.1 and transmit the completed form to Enzon as soon as possible, and in any event at least in time to allow Enzon to meet its reporting obligations under Regulatory Requirements. Enzon will then report the Adverse Drug Event in accordance with Regulatory Requirements, and provide Inex with a copy(ies) of all documentation provided to Regulatory Authorities in respect of such complaint or Adverse Drug Event. Further, after this agency has been established, if Enzon receives any information of any type whatsoever that may constitute a complaint regarding the Product or indicates that the Product in any way relates to an Adverse Drug Event, then it will record the information set forth on Exhibit 1.1.1, provide a copy of the completed form to Inex (if possible, prior to submitting it to Regulatory Authorities) and report the Adverse Drug Event in accordance with Regulatory Requirements.

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# 7.3 Agency for DDMAC Activities

- 7.3.1 Inex hereby appoints Enzon as its agent for the Product in the Field in the Territory for the sole purpose of conducting all DDMAC Activities in the USA and the foreign equivalents in the remainder of the Territory.
- 7.3.2 Enzon shall perform the DDMAC Activities in the USA and the foreign equivalents in the remainder of the Territory in compliance with Regulatory Requirements.
- 7.3.3 Enzon will perform all DDMAC Activities in the USA and the foreign equivalents in the remainder of the Territory and subject to Section 7.1, be responsible for all post-approval Pharmacovigilance activities, and assume all the costs associated therewith.
- 7.3.4 In each country for which Inex is the holder of the Regulatory Approval, Enzon shall regularly inform Inex of Enzon's DDMAC Activities and foreign equivalents and obtain Inex's prior consent to Enzon's DDMAC Activities and foreign equivalents and plans respecting any of them. In the event Enzon informs Inex of its

DDMAC Activities, foreign equivalents and plans, and does not receive a written objection from Inex within 10 Business Days, Inex shall be deemed to have consented to such activities and plans.

- 7.4 Agent for Regulatory Authorities Generally
  - 7.4.1 Nothing in Section 7.1 or this Section 7.4 precludes Inex from appointing an agent for Regulatory Authorities for products other than the Product, or for territories outside the Territory.
  - 7.4.2 All activities, communications and relations as well as Enzon's role as agent for Regulatory Authorities shall be performed by Enzon in close coordination with Inex, as holder of the Regulatory Approvals.
  - 7.4.3 In respect of all of the foregoing under Section 7.1 or this Section 7.4, except as required by Regulatory Requirements and except for those reporting requirements which have timeliness requirements that make it impossible to seek and obtain Inex's consent prior to making such report, any communications with Regulatory Authorities by Enzon under Section 7.1 or this Section 7.4 are subject to the consent of the Inex, such consent not to be unreasonably withheld.
- 7.5 Recalls and Withdrawals of Product
  - 7.5.1 If Inex or Enzon will be required or requested by any Regulatory Authority to recall any Product for any reason, or should Enzon decide voluntarily to withdraw any Product:
    - (a) Enzon will be responsible for co-coordinating such recall or withdrawal;
    - (b) Enzon shall pay the costs and expenses of such recall or withdrawal, subject to recovery of some or all of same in accordance with the terms of Section 7.5.2;
    - (c) unless Inex is liable for such costs and expenses in accordance with the terms of Section 7.5.2, Enzon will remain responsible to Inex for the Purchase Price for

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such Product and will reimburse Inex for all of the reasonable costs and expenses actually incurred by Inex in connection with such recall or withdrawal including, but not limited to, administration of the recall or withdrawal and such other reasonable costs as may be reasonably related to the recall or withdrawal; and

- (d) both Parties will cooperate fully with one another in connection with any such recall or withdrawal.
- 7.5.2 if a recall or withdrawal is due to Inex's negligence, willful misconduct or breach of this Agreement or Inex's failure to Manufacture the Product in conformity with the Specifications or the provisions of the Product Supply Agreement or the Quality/Technical Agreement, Inex will reimburse Enzon for all of Enzon's reasonable costs and expenses actually incurred by Enzon in connection with the recall or withdrawal, including the Purchase Price for the recalled or withdrawn Product, costs of retrieving Product already delivered to customers, costs and expenses Enzon is required to pay for notification, shipping and handling charges, destruction or return of the defective Product or Product and such other reasonable costs as may be reasonably related to the recall or withdrawal.
- 7.5.3 If the Parties are unable to agree on whether or not a recall or withdrawal is due to Inex's negligence, willful misconduct or breach of this Agreement, either Party may refer the matter for resolution pursuant to Article 16 of the Product Supply Agreement.

# 8.1 Pipeline Drug

For a reasonable period after the Effective Date, the Parties will make good faith efforts to work together to identify and secure rights to one other oncology or hematology product from within or to be added to Enzon's current pipeline. The Parties' intention is that the development and commercialization of such new product in the Territory would be on the basis of a 50:50 funding and profit sharing split.

### 8.2 Legal Effect

The matters set forth in this Article 8 constitute merely an expression of the desire of the Parties to negotiate with each other regarding the terms of an agreement regarding the subject matter of this Article 8, and nothing in this Article 8 will have any legal or binding effect unless set out in writing in a separate agreement and signed by the duly authorized representatives of the Parties.

## Article 9 Representations and Warranties

#### 9.1 By Enzon

Enzon hereby represents and warrants to Inex that, as of the Effective Date:

- 9.1.1 Enzon has full legal right, power and authority to execute, deliver and perform its obligations under the Related Agreements;
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- 9.1.2 the execution, delivery and performance by Enzon of the Related Agreements does not contravene or constitute a default under any provision of Applicable Law or its articles or by-laws (or equivalent documents) or of any judgment, injunction, order, decree or other instrument binding upon Enzon;
- 9.1.3 all licenses, consents, authorizations and approvals, if any, required for the execution, delivery and performance by Enzon of the Related Agreements have been obtained and to the best knowledge of Enzon are in full force and effect and all conditions thereof have been complied with, and, except for appropriate disclosure regarding the Related Agreements under the Securities Exchange Act of 1934, as amended, no other action by or with respect to, or filing with, any governmental authority or any other person or entity is required in connection with the execution, delivery and performance by Enzon of the Related Agreements;
- 9.1.4 except for the Permitted Exception, to the best knowledge of Enzon, the exploitation by Enzon of the rights granted to Enzon hereunder in pursuit of the Development, Manufacture and Commercialization of the Product do not infringe the Intellectual Property Rights of any Third Party;
- 9.1.5 assuming each is a valid, binding and enforceable agreement of Inex, each of the Related Agreements constitutes a valid and binding agreement of Enzon, enforceable against Enzon in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, moratorium or creditors' rights generally;
- 9.1.6 the execution, delivery and performance by Enzon of each Related Agreement does not and will not conflict with or result in a material breach of any of the terms and provisions of any Third Party agreement of Enzon entered into as of the Effective Date;
- 9.1.7 except for the Permitted Exception, Enzon is not aware of any

impediment, including without limitation any Third Party agreement of Enzon, which would prevent Enzon from performing its obligations under the Related Agreements;

- 9.1.8 Enzon will not enter into any Third Party agreement after the Effective Date which, in any way, will limit its ability to perform all of the obligations undertaken by Enzon under the Related Agreements; and
- 9.1.9 except for Intellectual Property Rights owned by Elan and licensed to Enzon, Enzon does not own or control any Intellectual Property Rights which could be asserted against Inex for Inex's performance under the Related Agreements, or which could be infringed by the developing, using, selling, having sold, distributing and importing of the Product in the Territory.

### 9.2 By Inex

Inex hereby represents and warrants to Enzon that, as of the Effective Date:

- 9.2.1 Inex has full legal right, power and authority to execute, deliver and perform its obligations under the Related Agreements;
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- 9.2.2 the execution, delivery and performance by Inex of the Related Agreements does not contravene or constitute a default under any provision of Applicable Law or its articles or by-laws (or equivalent documents) or of any judgment, injunction, order, decree or other instrument binding upon Inex;
- 9.2.3 all licenses, consents, authorizations and approvals, if any, required for the execution, delivery and performance by Inex of the Related Agreements, including the Elan Consent, have been obtained and, except for the Permitted Exception, to the best knowledge of Inex, are in full force and effect and all conditions thereof have been complied with, and, except for appropriate disclosure regarding the Related Agreements required by any stock exchange having authority, except for the Permitted Exception, to the best knowledge of Inex no other action by or with respect to, or filing with, any governmental authority or any other person or entity is required in connection with the execution, delivery and performance by Inex of the Related Agreements;
- 9.2.4 except for the Permitted Exception, and the rights granted by Inex outside the Field or outside the Territory, Inex is the exclusive owner or licensee of all legal and beneficial right, title and interest in and to the Licensed Patents;
- 9.2.5 except for the Permitted Exception, Inex has the rights to the Elan Patents necessary to grant the sublicenses granted in the Related Agreements and the Elan License has not been breached by Inex or its Affiliates or, to the best knowledge of Inex, by Elan and its Affiliates;
- 9.2.6 except for rights granted by Inex outside the Field or outside the Territory, Inex is the sole and exclusive owner or licensee of the Inex Technology, free and clear of any lien, claim or encumbrance or rights of any other person or entity;
- 9.2.7 except for the Permitted Exception, to the best knowledge of Inex, the exploitation by Enzon of the rights granted to Enzon under the Related Agreements in pursuit of the Development, Manufacture and Commercialization of the Product do not infringe the Intellectual Property Rights of any Third Party;
- 9.2.8 assuming each is a valid, binding and enforceable agreement of Enzon, each of the Related Agreements constitutes a valid and

binding agreement of Inex, enforceable against Inex in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, moratorium or creditors' rights generally;

- 9.2.9 the execution, delivery and performance by Inex of the Related Agreements does not and will not conflict with or result in a material breach of any of the terms and provisions of any Third Party agreement of Inex entered into as of the Effective Date;
- 9.2.10 except for the Permitted Exception, Inex is not aware of any impediment, including without limitation any Third Party agreement of Inex, which would prevent Inex from performing its obligations under the Related Agreement;

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- 9.2.11 Inex will not enter into any Third Party agreement after the Effective Date which, in any way, will limit its ability to perform all of the obligations undertaken by Inex under the Related Agreements;
- 9.2.12 except for the Licensed Patents and Inex Technology, Inex does not own or control any Intellectual Property Rights which could be asserted against Enzon for Enzon's performance under the Related Agreements, or which could be infringed by the developing, using, selling, having sold, distributing and importing of the Product in the Territory; and
- 9.2.13 at the time delivered to Enzon, all Product:
  - (a) will fully conform to the Regulatory Requirements, the Specifications and the Master Production Record; and
  - (b) will not, as the result of Inex's undertakings or failure to perform its undertakings as set out in this Agreement, be adulterated or misbranded within the meaning of Section 501[351] and 502[352] of the Federal Food, Drug and Cosmetic Act, as amended, and the regulations issued thereunder or within the meaning of any applicable state or local law, the adulteration and misbranding provisions of which are similar to the Federal Food, Drug and Cosmetic Act.

# 9.3 Survival of Representations and Warranties

The representations and warranties contained herein shall survive the execution, delivery and performance of this Agreement by the Parties, notwithstanding any investigation at any time made by or on behalf of any Party or Parties.

### 9.4 DISCLAIMER

EXCEPT FOR THE EXPRESS WARRANTIES AND REPRESENTATIONS CONTAINED IN THIS AGREEMENT, NEITHER INEX NOR ENZON MAKES, AND EACH HEREBY EXPRESSLY DISCLAIMS, ANY WARRANTIES OR REPRESENTATIONS, EITHER EXPRESS OR IMPLIED, WHETHER IN FACT OR IN LAW, INCLUDING WITHOUT LIMITATION IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR VALIDITY OR SCOPE OR NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS.

# Article 10 Intellectual Property Rights

# 10.1 Injunctive Relief

Each party acknowledges the competitive and technical value of the Licensed Patents and Inex Technology, and the sensitive and confidential nature of the Confidential Information and agrees that monetary damages alone will be inadequate to protect the other party's interests against any actual or threatened material breach of this Agreement. Accordingly, each party consents to the granting of specific performance and injunctive or other equitable relief

to the other party in respect of any actual or threatened breach of this Agreement, without proof of actual damages.

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10.2 Ownership of Pre-Existing Intellectual Property Rights

Any Intellectual Property Rights or trademark rights owned by either Party prior to the Effective Date shall remain solely owned by such Party.

10.3 Ownership of Intellectual Property Rights in the Product

All Intellectual Property Rights arising from and during the course of the Development, including all Intellectual Property Rights:

- 10.3.2 to all data, information, know-how and results and the like
   created as part of the Development (the "Data"); and
- 10.3.3 relating to the Product or improvements thereto or the process for manufacturing the Product;

shall be solely owned by Inex or its designee, regardless of:

- 10.3.4 which Party(ies) created or invented the same; and
- 10.3.5 whether or not such Intellectual Property Rights are required to
   obtain and maintain Regulatory Approvals;

and shall be licensed to Enzon hereunder as Licensed Patents and Inex Technology without additional consideration or formality during the Term. Without limiting the generality of the foregoing, any Elan Improvements made by Enzon, or its Representatives, regardless of whether or not arising from and during the course of the Development, shall be solely owned by Elan and sublicensed (within the Field and within the Territory) without additional consideration to Enzon through Inex on the terms set out in this Section. Enzon shall cooperate, and shall cause its Representatives to cooperate, with Inex and Elan, at Elan's expense, in perfecting Elan's ownership and other proprietary rights in respect of any Elan Improvements and Enzon hereby assigns same to Elan and shall execute and deliver, and cause its Representatives to execute and deliver, to Elan any documents that Elan may reasonably require with respect thereto. If at any time Elan does not exercise its rights under this Section, such rights may be exercised by Inex as if Inex were Elan under this Section.

10.4 Ownership of Regulatory Approvals and Regulatory Submissions

Notwithstanding the terms of Section 10.3:

- 10.4.1 Inex or its Representatives will own all Regulatory Approvals and Regulatory Submissions made as part of the Development in respect of the Product in the Territory and all Intellectual Property Rights in same; and
- 10.4.2 Inex or its Representatives may use all Data and Regulatory Approvals and Regulatory Submissions, in Inex or its Representative's efforts to register and commercialize the Product outside the Territory and inside the Territory but outside the Field.

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10.5 Ownership of Intellectual Property Rights Outside the Development

Except as otherwise provided in Sections 10.3 and 10.4, each Party shall have and retain sole and exclusive title to all inventions, discoveries and know-how which are made, conceived, reduced to practice or generated by its Representatives. For greater certainty, Intellectual Property Rights or inventions or creations generated outside the Development and without access to the other Party's Confidential Information shall not be licensed hereunder or included in the Licensed Patents or Inex Technology.

## Article 11 Termination

# 11.1 Term

This Agreement shall become effective on the Effective Date and, unless earlier terminated as provided for herein, shall expire, on a country-by-country basis, upon the later of:

- 11.1.1 expiration of the last to expire of the Licensed Patents containing Valid Claims covering the Product in such country in the Territory; and
- 11.1.2 fifteen years from the date of the First Commercial Sale in that country;

and such period shall be the "Term" under this Agreement.

#### 11.2 Renewal

On or before six months before the expiration of this Agreement in accordance with its terms, Enzon may notify Inex in writing that Enzon wishes to renew this Agreement. In the event that Enzon so notifies Inex, the Parties will negotiate in good faith for the extension of the Term. If the Parties have not reached agreement in writing to extend the Term on or before the expiry of the Term, this Section 11.2 shall be of no further force or effect.

## 11.3 Voluntary Termination

- 11.3.1 In the event that Enzon does not have a significant interest in obtaining or maintaining Regulatory Approval of and marketing Product in any country of the Territory, Enzon shall promptly notify Inex in writing. If Inex requests in writing that Enzon indicate whether or not Enzon has an interest in obtaining or maintaining Regulatory Approval of and marketing Product in a country(ies) of the Territory, within thirty (30) days thereafter Enzon shall notify Inex in writing as to whether or not Enzon has such an interest. In the event that:
  - (a) Enzon notifies Inex that it does not have a significant interest in obtaining or maintaining Regulatory Approval of and marketing Product in any country(ies) of the Territory; or
  - (b) Enzon does not respond in writing within thirty (30) days of Enzon's receipt of Inex's query;
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- (c) Inex may terminate all licenses granted to Enzon pursuant to this Agreement in respect of such country(ies) of the Territory, and such country(ies) shall no longer form part of the Territory.
- 11.3.2 Enzon may terminate this Agreement in its entirety at any time by:
  - (a) providing Inex ninety (90) days prior written notice of

Enzon's intention to terminate;

- (b) paying all outstanding obligations due to Inex, including Enzon's portion of all non-cancelable Development Costs incurred by Inex and its Affiliates pursuant to the Related Agreements as of the date of termination; and
- (c) paying a termination fee of two million dollars (\$2,000,000), unless such termination is effected after 12 months from the Effective Date but prior to Inex completing its NDA submission to the FDA for the Product.
- (d) All amounts due hereunder shall be paid by Enzon to Inex within ten (10) days of termination, without reduction, except as agreed in writing between the parties.

#### 11.4 Termination for Breach

Each Party shall be entitled to terminate this Agreement and the licenses granted hereunder to the other Party by written notice to the other Party in the event that the other Party shall be in material default of any of its obligations hereunder, and shall fail to remedy any such default within ninety (90) days after notice thereof by the non-breaching Party. Any such notice shall specifically state that the non-breaching Party intends to terminate this Agreement in the event that the breaching Party shall fail to remedy the default. Any such notice shall set out expressly the actions required of the breaching Party to remedy the default. If such default is not corrected, the non-breaching Party shall have the right to terminate this Agreement by giving written notice to the Party in default provided the notice of termination is given within six (6) months of the default and prior to correction of the default.

## 11.5 Termination upon Bankruptcy

- 11.5.1 This Agreement may be terminated by a Party by providing written notice to the other Party upon:
  - (a) the bankruptcy, liquidation or dissolution of the other Party;
  - (b) the filing of any voluntary petition for bankruptcy, dissolution, liquidation or winding-up of the affairs of the other Party; or
  - (c) the filing of any involuntary petition for bankruptcy, dissolution, liquidation or winding-up of the affairs of the other Party which is not dismissed within one hundred twenty (120) days after the date on which it is filed or commenced.
- 11.5.2 Notwithstanding the foregoing, either Party may seek the waiver of the operation of Section 11.5.1 in advance of any event giving rise to a right of termination under Section 11.5.1(b), and, provided that:
- \*\*\* Indicates the omission of confidential material pursuant to a request for confidential treatment made in accordance with Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The Confidential material is being filed separately with the Secretary to the Securities and Exchange Commission.

- (a) the requesting Party is in good standing and not in breach of any of the terms of the Related Agreements;
- (b) the requesting Party is in reasonable financial condition; and
- (c) the Party whose consent is sought will not be prejudiced by granting such waiver,

the Party whose consent is sought will not unreasonably withhold its consent to such waiver. Such waiver may be revocable in the event of a material adverse change in circumstances related to the requesting Party not contemplated at the time of granting the waiver.

- 11.6 Survival of Obligations; Return of Confidential Information
  - 11.6.1 Upon any termination of this Agreement pursuant to this Article 11, neither Party shall be relieved of any obligations incurred prior to such termination.
  - 11.6.2 Upon any termination of this Agreement pursuant to this Article 11, the licenses granted in Section 2.1 will forthwith terminate.
  - 11.6.3 Notwithstanding any termination of this Agreement, the obligations of the Parties under Article 1, Sections 5.9 and 5.10, Article 9, Article 10, Article 11 and Article 12, as well as under any other provisions which by their nature are intended to survive any such termination, shall survive and continue to be enforceable. 11.6.4 Upon any termination of this Agreement pursuant to this Article 11, except as contemplated hereby, each Party shall promptly return to the other Party all written Confidential Information, and all copies thereof (except for one archival copy to be retained by a person designated by such Party (who shall not make such Confidential Information generally available to employees or other representatives of such Party) for the purpose of confirming which information to hold in confidence hereunder), of the other Party which is not covered by a license surviving such termination.
- 11.7 Additional Consequences of Termination
  - 11.7.1 On or before the effective date of termination of this Agreement, except as otherwise set forth herein:
    - (a) Enzon shall promptly deliver to Inex a copy of all Data and such other information, materials (including biological materials) and documents in Enzon's possession or control arising from the development of the Product under this Agreement, including, without limitation, the Development, provided that Inex shall be responsible for any reasonable associated Out-of-Pocket Costs associated with transferring same;
    - (b) Enzon shall pay its share of the Development Costs as determined in accordance with Article 5, including all non-cancelable Development Costs reasonably committed to by Inex and its Affiliates prior to the termination of the Agreement;
- \*\*\* Indicates the omission of confidential material pursuant to a request for confidential treatment made in accordance with Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The Confidential material is being filed separately with the Secretary to the Securities and Exchange Commission.

- in the event that such termination occurs before the payment of all of the milestone payments referred to in Section Error! Reference source not found., then, concurrently with such termination, Enzon shall pay to Inex the next such payment, pro-rated so that such payment is reduced by the proportion of the year remaining prior to the date for such payment as of the effective date of such termination;
- (d) Enzon's right to use the Data pursuant to Section 10.4.2 will forthwith terminate;
- (e) all licenses and sublicenses granted pursuant to this Agreement shall forthwith terminate;

- (f) Enzon shall:
  - (i) use all reasonable endeavors to take all steps and execute all documents reasonably necessary to assign and/or transfer or permit reference to (to the extent legally permissible in the relevant country) all Regulatory Approvals and Regulatory Submissions arising from the development of the Product under this Agreement, including, without limitation, the Development, in Enzon's name or in the name of Enzon's Affiliates or Sublicensees, to Inex or its designee;
  - (ii) provide to Inex or its designee copies of or access to all correspondence, meeting minutes and any other written information exchanged between Enzon and any Regulatory Authority(ies) regarding such Regulatory Approvals and Regulatory Submissions;
  - (iii) in the event that no such assignment and/or transfer and/or reference pursuant to Section 11.7.1(f)(i) may legally be made, then Enzon shall forthwith surrender such Regulatory Approvals and Regulatory Submissions for cancellation; and
  - (iv) upon Inex's request, Enzon shall within the same period deliver to Inex or its designee any and all documents relating to Regulatory Approvals and Regulatory Submissions in its possession or control arising from the Development that are reasonably required in order to file, obtain or maintain Regulatory Approvals for the Product.

# 11.8 Termination on a Country by Country Basis

In the event of termination of this Agreement in respect of one or more country(ies) in the Territory pursuant to Section 11.3.1, then Sections 11.6 and 11.7 shall apply in respect of the country(ies) to which such termination applies.

### 11.9 Termination of Related Agreements

In the event of termination of this Agreement, the Related Agreements shall terminate with immediate effect, subject to any continuing or surviving obligations as set forth in each such Related Agreement.

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### Article 12 Miscellaneous

### 12.1 Assignment

- 12.1.1 The rights and obligations set out in this Agreement are personal to each Party and for this reason, except as expressly set out in this Agreement, this Agreement will not be assignable by either Party in whole or in part, nor will either Party subcontract any of its obligations hereunder without the prior written consent of the other Party, which consent shall not be withheld or delayed unreasonably; provided, however, that the restriction contained herein will in no way limit the rights of either Party to:
  - (a) assign or subcontract any right or obligation hereunder to any of its Affiliates; or
  - (b) appoint as its agent for any purpose of this Agreement any such Affiliate; or

- (c) assign any right or obligation hereunder to any person or entity that:
  - (i) purchases all or substantially all of its assets to which this Agreement relates or
  - (ii) purchases all or substantially all of the stock of either Party; or
  - (iii) acquires or is combined with either Party in a merger or some other form of business combination.
- 12.1.2 This Agreement will be binding upon and will enure to the benefit of the parties hereto and to any permitted assignee or successor of either party.
- 12.1.3 Subject to other provisions of this Section 12.1, if one Party validly assigns or subcontracts any or all of its obligations hereunder, such assigning or subcontracting Party agrees to remain bound by all of its responsibilities and obligations hereunder.
- 12.1.4 Any and all assignments of this Agreement or any interest herein not made in accordance with this Section 12.1 will be void ab initio.

## 12.2 Counterparts

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

### 12.3 Force Majeure

In the event that either Party is prevented from performing or is unable to perform any of its obligations under this Agreement due to any act of God; fire; casualty; flood; war; strike; lockout; failure of public utilities; injunction or any act, exercise, assertion or requirement of governmental authority; epidemic; destruction of production facilities; riots; insurrection; failure of transportation; inability to procure or use materials; or any other cause beyond the reasonable control of the Party invoking this Section 12.3 if such Party shall have used its reasonable efforts to avoid such occurrence, such Party shall give notice to the other Party in writing promptly, and thereupon the affected Party's performance shall be excused and the

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time for performance shall be extended for the period of delay or inability to perform due to such occurrence.

### 12.4 Further Assurances

Each Party hereto agrees to execute, acknowledge and deliver such further instruments and do all such further acts as may be necessary or appropriate to carry out the purposes and intent of this Agreement.

### 12.5 International Sale of Goods Act

The Parties acknowledge and agree that the International Sale of Goods Act and the United Nations Convention on Contracts for the International Sale of Goods have no application to this Agreement.

# 12.6 Modification

No waiver, alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed by the Parties by their respective officers thereunto duly authorized.

# 12.7 No Agency

Nothing herein shall be deemed to constitute either Party as the agent or Representative of the other Party, or both Parties as joint venturers or partners for any purpose. Inex shall be an independent contractor, not an employee or partner of Enzon, and the manner in which Inex renders its services under this Agreement shall be within Inex's sole discretion. Neither Party shall be responsible for the acts or omissions of the other Party, and neither Party will have authority to speak for, represent or obligate the other Party in any way without prior written authority from the other Party.

## 12.8 No Solicitation or Hiring of Employees

During the Development and for one year thereafter, neither Inex nor Enzon shall, without the prior consent of the other Party, solicit the employment of or hire any person who during the course of employment with the other Party was involved with activities under the Development Plan and who when solicited or to be hired is a current employee of the other Party.

#### 12.9 Non-Use of Names

Except as otherwise expressly set out in this Agreement, neither Party shall use the name of the other Party, nor any adaptation thereof, in any advertising, promotional or sales literature without prior written consent obtained from such other Party in each case (which consent shall not be unreasonably withheld or delayed).

#### 12.10 Notices

Any notice or other communication in connection with this Agreement must be in writing and if by mail, by registered mail, return receipt requested, and shall be effective when delivered to the addressee at the address listed below or such other address as the addressee shall have specified in a notice actually received by the addressor.

### If to Inex:

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Inex Pharmaceuticals, Inc.
c/o Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

Attention: President and CEO

With copies to:

Inex Pharmaceuticals Corporation 100-8900 Glenlyon Parkway Burnaby, British Columbia Canada V5J 5J8 Fax: 604-419-3202 Attention: Sr. V.P. Commercial Operations, and

With a copy to:

Inex Pharmaceuticals Corporation 100-8900 Glenlyon Parkway Burnaby, British Columbia Canada V5J 5J8 Fax: 604-419-3202 Attention: Business Development

and: Lang Michener 1500-1055 West Georgia Street Vancouver, British Columbia Canada V5J 5J8

Fax: 604-685-7084

Canada V6E 4N7

Attention: Leo Raffin

and:

Farris, Vaughan, Wills & Murphy 2600 - 700 West Georgia Street Vancouver, British Columbia Canada V7Y 1B3
Fax: 604-661-9349

Fax: 604-661-9349 Attention: James Hatton

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If to Enzon:

Enzon Pharmaceuticals, Inc. 685 Route 202/206 Bridgewater, New Jersey, USA 08807 Fax: 908.541.8680 Attention: V.P. Business Development

with a copy to:

Enzon Pharmaceuticals, Inc. 685 Route 202/206 Bridgewater, NJ 08807 Attention: General Counsel Fax: 908.541.8838

12.11 Publicity

Except as required by law, stock exchange or Regulatory Authority:

- 12.11.1 neither Party, nor any of its Affiliates, shall originate any publicity, news release or other public announcement, written or oral, relating to this Agreement or the existence of an arrangement between the Parties, without the prior written approval of the other Party and agreement upon the nature and text of such announcement or disclosure, which approval shall not be unreasonably withheld;
- 12.11.2 the Party desiring to make any such public announcement or other disclosure shall inform the other Party of the proposed announcement or disclosure in reasonably sufficient time prior to public release, and shall provide the other Party with a written copy thereof, in order to allow such other Party to comment upon such announcement or disclosure; and
- 12.11.3 notwithstanding the foregoing, the Parties agree that the press release set out as an Exhibit to the Product Supply Agreement shall be released by the Parties upon execution and delivery of this Agreement by both Parties.

# 12.12 No Third Party Beneficiaries

Except as expressly set out in this Agreement, nothing in this Agreement is intended to or shall confer upon any Third Part any legal or equitable right, benefit or remedy of any nature whatsoever.

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### 12.13 Waiver

The waiver by either Party of a breach or a default of any provision of this Agreement by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision, nor shall any delay or omission on the part of either Party to exercise or avail itself of any right, power or privilege that it has or may have hereunder operate as a waiver of any right, power or privilege by such Party.

### 12.14 Cross Default

A breach of or default under any of the Related Agreements other than the Co-Promotion Agreement shall constitute a breach of and default under all the Related Agreements.

IN WITNESS WHEREOF, the Parties hereto have caused this Development Agreement to be executed as a sealed instrument in their names by their properly and duly authorized officers or representatives.

Inex Pharmaceuticals, Inc.

By: /s/ David J. Main

Name: David J. Main Title: President & CEO

Enzon Pharmaceuticals, Inc.

By: /s/ Arthur J. Higgins

Name: Arthur J. Higgins Title: Chairman & CEO

\*\*\* Indicates the omission of confidential material pursuant to a request for confidential treatment made in accordance with Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The Confidential material is being filed separately with the Secretary to the Securities and Exchange Commission.

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### Exhibit 1.1.1: Adverse Drug Event

### ADVERSE DRUG EVENT FORM

An Adverse Drug Event shall mean any noxious, unintended, or untoward medical occurrence in a patient or clinical investigation subject associated with the use of a medicinal or investigational product, whether or not related to the medicinal or investigational product.

This Form must be completed and faxed to the Regulatory Authorities (with a copy provided to the other Party)::

- a) Immediately, or not later than 24 hours following receipt of any information relating to an Adverse Drug Event; and
- b) No later than two (2) business days following receipt of any information relating to a product complaint.

Complaint Date:			
Complaint received by:	Tit	cle:	
Manner complaint received in:	Oral  _  Other:	Written  _	Faxed  _
Complainant's name:	Phone:	Fax: _	
Clinic's name:	Phone:	Fax:	
Clinic's Address:			

	Lot nur	nbei	r:		_ Expiry	Date:
Product	Complaint	or	Adverse	Drug	Event:	
	Product	Product Complaint	Product Complaint or	Product Complaint or Adverse	Product Complaint or Adverse Drug	Product Complaint or Adverse Drug Event:

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Exhibit 1.1.27: \*\*\*

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Exhibit 1.1.36: \*\*\*

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Exhibit 5.2.1(c): Ongoing Phase II Clinical Trials

\*\*\*

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Exhibit 6.1: Joint Steering Committee Responsibilities

The members of the Joint Steering Committee as of the Effective Date are:

For Enzon:

Eddy Anglade, VP - Clinical

Clarke Atwell, VP - Sales & Marketing

Katherine Bishburg, VP - Regulatory

Eric Liebler, VP - Business Development

### For Inex:

Tom MacRury, Senior VP, Commercial Opoerations

Alexandra Mancini, Senior VP, Clinical and Regulatory Affairs

Jeff Charpentier, VP Finance and CFO

Linda Diano, Director, Project Management

The Joint Steering Committee shall have responsibilities including:

- review amendments to the Development Plan and submit same to the Parties for review and approval;
- 2. establish working committees to conduct work under the Development Plan;
- 3. assign responsibility for conducting all needed Development work appropriately between the Parties, including providing for subcontractors to perform certain tasks if desirable;
- 4. oversee all Development activities, including the review and approval as appropriate, of all reports on the progress of Development;
- 5. coordinate the overall strategy for Development and commercialization;
- 6. meet quarterly, circulate agendas at least one (1) week in advance of each quarterly meeting, and circulate minutes of meetings within two (2) weeks following each meeting;
- 7. verify the reports of Development Costs;
- 8. such other duties and responsibilities as may be agreed upon by the Parties; and
- be the primary contact point between the Parties regarding the transfer of information and the discussion of each Party's efforts to conduct Development.
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# PRODUCT SUPPLY AGREEMENT

## BETWEEN

# INEX PHARMACEUTICALS, INC.

AND

# ENZON PHARMACEUTICALS, INC.

## January 19, 2004

\*\*\* Indicates the omission of confidential material pursuant to a request for confidential treatment made in accordance with Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The Confidential material is being filed separately with the Secretary to the Securities and Exchange Commission.

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### PRODUCT SUPPLY AGREEMENT

This PRODUCT SUPPLY AGREEMENT dated as of the 19th day of January, 2004 between Inex Pharmaceuticals, Inc., a corporation duly incorporated pursuant to the laws of Delaware, USA, having a registered office at Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801 (hereinafter referred to as "Inex"), and Enzon Pharmaceuticals, Inc., a corporation duly incorporated pursuant to the laws of Delaware, having a principal place of business at 685 Route 202/206, Bridgewater, New Jersey 08807 (hereinafter referred to as "Enzon").

## INTRODUCTION

A. Enzon is a pharmaceutical company with operations in research and

development, import, export, manufacture and sale of pharmaceutical products;

- B. Inex is in the business of developing, manufacturing and selling certain pharmaceutical products, including Vincristine Sulfate Liposomes Injection (as further defined in this Agreement);
- C. Of even date hereof, the Parties have entered into a Development Agreement for the development of Vincristine Sulfate Liposomes Injection and for the purpose of enabling Enzon to acquire rights to develop, market, distribute and sell Inex's Vincristine Sulfate Liposomes Injection product;
- D. Subject to the terms and conditions set forth in this Agreement, Enzon wishes to have Inex supply to Enzon Vincristine Sulfate Liposomes Injection; and
- E. Inex wishes to supply same to Enzon;

NOW, THEREFORE, the Parties, intending to be legally bound, hereby agree as follows:

### Article 1 Interpretation

#### 1.1 Definitions

Unless otherwise defined in this Agreement, capitalized terms used in this Agreement shall have the meaning set out therefor in the Development Agreement and the Co-Promotion Agreement. In the event of a conflict between the definitions set out for capitalized terms in this Agreement and the capitalized terms set out in any other Related Agreement, the priority set out in Section 1.2 shall govern. For purposes of this Agreement, the following terms will have the meanings set forth below:

- 1.1.1 "Adverse Drug Event" will have the meaning set forth in Exhibit 1.1.1.
- 1.1.2 "Affiliate" means any corporation, company, partnership, joint venture or other person or entity which controls, is controlled by or is under common control with a Party. For purposes of this Section 1.1.2, "control" shall mean (a) in the case of corporate entities,
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direct or indirect ownership of at least 50% of the stock or shares (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) entitled to vote for the election of directors or otherwise having the power to vote on or direct the affairs of such Party; and (b) in the case of non-corporate entities, direct or indirect ownership of at least 50% of the equity interest or the power to direct the management and policies of such non-corporate entities.

- 1.1.3 "Agreement" means this Product Supply Agreement including all exhibits attached to this Agreement.
- "Applicable Laws" means all applicable federal, provincial, state and local laws, ordinances, rules and regulations of any kind whatsoever in the Territory, including, without limitation, pharmaceutical and environmental rules and regulations, including cGMP Requirements, GCP Requirements, GLP Requirements and the General Biological Products Standards of the FDA, and the Federal Food, Drug and Cosmetic Act, as amended, or any successor act thereto ("FDCA").
- 1.1.5 "Approved S&OP" has the meaning set out in Section 3.1.4.
- 1.1.6 "Business Day" means any day other than a day which is a Saturday, a Sunday or a statutory holiday in New York City, New York, USA.

- 1.1.7 "Calendar Quarter" means the three-month period ending on March 31, June 30, September 30 or December 31.
- 1.1.8 "CGMP Requirements" shall mean the current Good Manufacturing Practices standards required by the FDA, the Therapeutic Products Directorate Organization of Health Canada ("TPD") and the equivalent Regulatory Authority(ies) elsewhere in the Territory, and the applicable regulations, policies or guidelines of each of them in effect for the manufacture and testing of pharmaceutical materials, active ingredients, or excipients, as applicable.
- 1.1.9 "Code" or "Codes" means the Code on Interactions with Healthcare Professionals promulgated by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the American Medical Association (AMA) Guidelines on Gifts to Physicians from Industry, as either of the foregoing may be amended from time to time.
- 1.1.10 "Commercial Quarter" means a Calendar Quarter during which Net Sales are recorded.
- 1.1.11 "Commercial Year" means a period of four consecutive Calendar Quarters commencing with the Initial Commercial Quarter.
- 1.1.12 "Commercialization" means the activities customarily associated with sales of pharmaceutical products including without limitation, DDMAC Activities, price and reimbursement negotiations, pre-launch and launch activities, marketing, sales, distribution, Post-Approval Clinical Activities, the development, prosecution, registration and maintenance of trademarks, trade names and domain names, and Pharmacovigilance in each country in the Territory.
- 1.1.13 "Commercialization Costs" means the cost of Commercialization of the Product, including the Commercialization FTE Costs and Out-of-Pocket Costs utilized or incurred by a Party in fulfilling its obligations under the then-current Commercialization Plan and
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all Commercialization FTE Costs and Out of Pocket Costs incurred in excess of the Budget in the then-current Commercialization Plan, provided that any such excess costs have been approved in advance by the Joint Steering Committee. For greater certainty, "Commercialization Costs" do not include Development Costs as defined in the Development Agreement.

- 1.1.14 "Commercialization FTE" means a scientific or technical person employed by a Party or a Party's Affiliates and assigned to work on Commercialization with such time and effort to constitute one person working on Commercialization on a full time basis consistent with normal business and scientific practice (e.g., having appropriate education, training and experience and working \*\*\* hours per year of dedicated effort).
- 1.1.15 "Commercialization FTE Costs" means the price of Commercialization FTEs to be used for the purposes of determining the costs incurred with respect to personnel performing work on the Commercialization in accordance with the then-approved Commercialization Plan. The price per Commercialization FTE shall initially be \*\*\* per Commercialization FTE year or pro-rata portion thereof incurred on the Commercialization. The Commercialization FTE rate includes all the fully burdened cost of salary, employee benefits, incidental materials, travel, lodging and other expenses including support staff and direct and indirect overhead for or associated with a Commercialization FTE. On each anniversary of the Effective Date, the FTE rate shall be raised by a percentage equal to the percentage increase in the Index (defined below) for the twelve (12) month period ending with December of the calendar year

immediately preceding such anniversary date (such increase, the "CPI Increase"). For purposes of this Agreement, the term "Index" shall mean the Consumer Price Index for all Urban Consumers (CPI-U) - - U.S. City Average. All Items (1982-1984 = 100), as published by the United States Bureau of Labor Statistics, or if such index is no longer published, then the index most comparable thereto.

- 1.1.16 "Commercialization Plan" means the Commercialization Plan for Commercializing the Product, together with a corresponding budget accounting for the anticipated Commercialization Costs to be expended or incurred by each Party in conducting the Commercialization. The Parties will adopt a definitive Commercialization Plan in accordance with Section 9.9, which Commercialization Plan will form a part of this Agreement.
- 1.1.17 "Commercially Reasonable Efforts" means efforts which are not less than those efforts a Party makes with respect to other pharmaceutical products in its portfolio (but, in any event, not less than the efforts that would be exerted by a reasonably prudent and diligent pharmaceutical company similarly situated and seeking to accomplish similar objectives), taking into account the product's market potential, level of competition, number of prescribers and other relevant factors.
- 1.1.18 "Competitive Product" means any liposomal medicinal products where such liposomal medicinal products incorporate Vincristine.
- 1.1.19 "Confidential Information" means:
  - (a) all proprietary information and materials, patentable or otherwise, of a Party which is disclosed in writing by or on behalf of such Party to the other Party and marked as confidential or proprietary, including DNA sequences, vectors, cells, substances, formulations, techniques, methodology, equipment, data, reports,

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Inex Technology, preclinical and clinical trials and the results thereof, sources of supply, patent positioning, marketing plans and business plans, including any negative developments;

- (b) any other information, oral or written, designated in writing by the disclosing Party to the other Party as confidential or proprietary within ten (10) days after such disclosure, whether or not related to the making, use, importing or selling of the Product; and
- (c) the Data, the Inex Technology, the Regulatory Approvals and Regulatory Submissions, and the Licensed Patents (all of which are deemed to be Confidential Information of Inex);

provided that Confidential Information shall not include such information which:

- (d) was known or used by the receiving Party or its Affiliates prior to its date of disclosure to the receiving Party, as evidenced by the prior written records of the receiving Party or its Affiliates; or
- (e) either before or after the date of the disclosure to the receiving Party is lawfully disclosed to the receiving Party or its Affiliates by an independent, unaffiliated Third Party rightfully in possession of the Confidential Information; or

- (f) either before or after the date of the disclosure to the receiving Party becomes published or generally known to the public through no fault or omission on the part of the receiving Party or its Affiliates; or
- (g) the receiving Party can verify, by written documentation, results from research and development by the receiving Party or any of its Affiliates independent of disclosure by the other Party thereof.
- 1.1.20 "Co-Promotion" has the meaning set out in the Co-Promotion Agreement.
- 1.1.21 "Co-Promotion Agreement" means the Co-Promotion Agreement between Inex and Enzon of even date herewith.
- 1.1.22 "DDMAC Activities" mean all jointly agreed-to activities performed or to be performed by one or both Parties in accordance with the requirements of the Division of Drug Marketing, Advertising and Communications, Center for Drug Evaluation and Research of the FDA, and the Office of the Inspector General of the Department of Health and Human Services of the United States.
- 1.1.23 "Deferred Sales Price" and "Deferred Sales Payment" shall have the meaning set forth in Exhibit 2.1.1(b).
- 1.1.24 "Development Agreement" shall mean the Development Agreement between Inex and Enzon entered into as of the Effective Date.
- 1.1.26 "Dollar" and "\$" means United States Dollars.

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- 1.1.27 "Effective Date" means the date shown on page one of this  $$\operatorname{Agreement.}$$
- 1.1.28 "FDA" means the United States Food and Drug Administration or any successor agency thereto.
- 1.1.29 "First Commercial Sale" means (a) with respect to a country in the Territory, the first sale by Enzon, its sublicensees or its Affiliates for use, consumption or resale of the Product in such country (excluding any sales for clinical trials, compassionate uses or other non-commercial purposes) and (b) with respect to the Territory, the First Commercial Sale in any country within the Territory. A sale to a sublicensee or an Affiliate shall not constitute a First Commercial Sale unless the sublicensee or Affiliate is the end user of the Product.
- 1.1.30 "Forecast" shall have the meaning set out in Section 3.1.2.
- 1.1.31 "GCP Requirements" or "Good Clinical Practices" means the then current standards for clinical trials for pharmaceuticals as required by the FDA, the TPD and the equivalent Regulatory Authority(ies) elsewhere in the Territory, and as applicable, the policies and guidelines of the International Conference on Harmonization in effect for the clinical testing of pharmaceutical materials.
- 1.1.32 "GLP Requirements" or "Good Laboratory Practices" means the current Good Laboratory Practices standards required by the FDA and the TPD and the equivalent Regulatory Authority(ies) elsewhere in the Territory in effect for the testing of pharmaceutical materials as applied to raw materials and finished products.

- 1.1.33 "include" and "including" (and the like) means "including, without limitation".
- 1.1.34 "Indemnitee" shall have the meaning set out in Section 14.3.
- 1.1.35 "Indemnitor" shall have the meaning set out in Section 14.3.
- 1.1.36 "Inex Technology" means all technical information and know-how owned or controlled by Inex which relates to the Product and is necessary or useful for the development and commercialization of the Product and shall include:
  - (a) as of the Effective Date, all biological, chemical, pharmacological, toxicological, clinical, assay, control and manufacturing data and any other information owned or controlled by Inex and necessary or useful for the development and commercialization of the Product;
  - (b) any Data referred to in Section 10.3 of the Development Agreement; and
  - (c) any Data referred to in Section 12.3.
- 1.1.37 "Intellectual Property Rights" means any rights to any Patents and copyright rights and registrations and applications for registration of the foregoing rights, and trade secrets and moral rights. "Intellectual Property Rights" do not include trademark, domain name or trade name rights.
- 1.1.38 "Initial Commercial Quarter" means the Calendar Quarter during which the First Commercial Sale is recorded.
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- 1.1.39 "Joint Steering Committee" or "JSC" means the committee formed pursuant to Section 10.1 and having the duties and responsibilities set forth in Exhibit 10.1. The Joint Steering Committee formed under this Agreement shall be the same as the Joint Steering Committee formed under the Development Agreement.
- 1.1.40 "Licensed Patents" means the Patents owned or controlled by Inex relating to VSLI and necessary or useful for the development and commercialization of the Product, and shall include:
  - (a) as of the Effective Date, the Inex Patents, the \*\*\*;
  - (b) any Patents on inventions referred to in Section 10.3 of the Development Agreement;
  - (c) any Patents on inventions referred to in Section 12.3;
  - (d) any Patents to which Inex acquires a right to grant a sublicense to Enzon pursuant to Section 2.5.2 or 14.2.
- 1.1.41 "Losses" has the meaning set out in Section 14.1.1.
- 1.1.42 "Manufacture" shall mean the performance of all activities or a portion thereof for the manufacture of Product and Product Components, including the shipping, receipt, handling, testing, and storage of starting materials, the bulk manufacture, filling, packaging, labelling, testing, storage, shipping or receiving of the Product and Product Components, and all associated activities, including quality control and quality assurance. "Manufacturing", and "Manufactured" shall have comparable meanings.

- 1.1.44 "Manufacturing FTE" means a person employed by Inex or its Affiliates and assigned to work, at least as a portion of his or her responsibilities, on Manufacturing with such time and effort to constitute one person working on Manufacturing on a full time basis consistent with normal business and pharmaceutical practice (e.g., having appropriate education, training and experience and working 1800 hours per year of dedicated effort).
- 1.1.45 "Manufacturing FTE Cost" means the price of Manufacturing FTEs to be used for the purposes of determining the costs incurred with respect to personnel performing work on the Manufacturing. The price per Manufacturing FTE shall be \*\*\* per Manufacturing FTE year or pro-rata portion thereof incurred on the Manufacturing. The Manufacturing FTE rate includes all the fully burdened cost of salary, employee benefits, incidental materials, travel, lodging and other expenses including support staff and direct and indirect overhead for or associated with a Manufacturing FTE. On each anniversary of the Effective Date, the Manufacturing FTE rate shall be raised by a percentage equal to the percentage increase in the Index (defined below) for the twelve (12) month period ending with December of the calendar year immediately preceding such anniversary date (such increase, the "CPI Increase"). For purposes of this Agreement, the term "Index" shall mean the Consumer Price Index for all Urban Consumers (CPI-U) - - U.S. City Average. All Items (1982-1984 = 100), as published by the United States Bureau of Labor Statistics, or if such index is no longer published, then the index most comparable thereto.

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- 1.1.46 "Master Production Record" shall mean Inex's complete detailed manufacturing and control instructions and specifications for the manufacture of the Product, as defined by Regulatory Requirements, as amended from time to time by mutual agreement of the Parties.

  The current Master Production Record is identified as set out in Exhibit 1.1.44.
- 1.1.47 "NDA" means a New Drug Application in accordance with the rules and regulations of the FDA.
- 1.1.48 "Net Sales" means the aggregate United States dollar equivalent of gross revenues invoiced by Enzon and its Affiliates and its Sublicensees from or on account of the sale of the Product to Third Parties, less deductions allowed to customers by Enzon, its Affiliates or Sublicensees as the case may be, to sell the Product using generally accepted accounting principles and reasonable practices with respect to sales of all Enzon's products, consistently applied, for the following:

\* \* \*

(collectively, the "Permitted Deductions"). No deduction shall be made for any item of cost incurred by Enzon, its Affiliates or Sublicensees in preparing, shipping or selling the Product except as permitted pursuant to Sections 1.1.48Error! Reference source not found. through 1.1.48(g) inclusive. Net Sales shall not include any transfer between any of Enzon and any of its Affiliates or Sublicensees for resale, but Net Sales shall include the subsequent final sales to Third Parties by such Affiliates or Sublicensees. Fair market value shall be assigned to any and all non-cash consideration such as but not limited to any credit, barter, benefit, advantage or concession received by Enzon or its Affiliates or Sublicensees in payment for sale of the Product. As used in this definition, a "sale" shall have occurred on the earlier of when the Products are invoiced or shipped. Notwithstanding anything herein to the contrary, the following shall not be considered a sale of a Product under this Agreement:

- (i) the transfer of a Product to a Third Party without consideration to Enzon in connection with the development or testing of a Product; or (ii) the transfer of a Product to a Third Party without consideration in connection with the marketing or promotion of the Product (e.g., pharmaceutical samples). Notwithstanding the foregoing, in calculating Net Sales, no deductions from gross revenues that are not permitted by U.S. GAAP from being deducted for the purposes of such calculation shall be deducted.
- 1.1.49 "not to be unreasonably withheld" and the like means not to be unreasonably withheld or delayed.
- 1.1.50 "Notice of Rejection" shall have the meaning set out in Section 5.5.1.
- 1.1.51 "Out-of-Pocket Cost" means an out-of-pocket payment made by a
  Party to a Third Party but only to the extent such payment relates
  to costs which are incurred by such Party with respect to
  fulfilling its obligations with respect to Commercialization,
  Manufacturing, or Co-Promotion.
- 1.1.52 "Party" means Inex or Enzon and "Parties" means Inex and Enzon.
- 1.1.53 "Person" means and includes any individual, corporation, partnership, firm, joint venture, syndicate, association, trust, government body, and any other form of entity or organization.
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- 1.1.54 "Pharmacovigilance" means all the activities associated with maintaining an effective drug safety monitoring system and adverse events reporting system in compliance with the requirements of Regulatory Authorities.
- 1.1.55 "Prime Rate" means the prime or equivalent rate quoted by Citibank, N.A. from time to time.
- 1.1.56 "Product" means VSLI.
- 1.1.57 "Product Components" means all components of Products, including Sodium Phosphate Injection, Sphingomyelin Cholesterol Liposome Injection, and Vincristine Sulfate Injection.
- 1.1.58 "Purchase Order" means a purchase order from Enzon to Inex for the Product issued in accordance with the provisions herein.
- 1.1.59 "Purchase Price" shall have the meaning set forth in Section 2.1.
- 1.1.60 "QA" means Quality Assurance, being that part of each management system, within Inex and Enzon separately, having responsibility for assuring the quality of the Product in respect of compliance with Regulatory Requirements.
- 1.1.61 "Quality/Technical Agreement" shall have the meaning set forth in Section 4.6.
- 1.1.62 "Reference Price" has the meaning given it in Section 2.2.1.
- 1.1.63 "Regulatory Approvals" means all necessary and appropriate regulatory approvals which must be obtained before placing the Product on the market in the Field in any country in the Territory in which such approval is required, including without limitation, INDs, NDAs, and any other comparable terms as applicable with regard to any such approvals in any other country in the Territory.
- 1.1.64 "Regulatory Authority" or "Regulatory Authorities" means:

- (a) the FDA, the TPD and the equivalent Regulatory Authority(ies) elsewhere in the Territory, whether federal, provincial, state or municipal, regulating the importation, distribution, marketing and/or sale of therapeutic substances in the Territory; and
- (b) the corresponding governmental authorities, whether federal, provincial, state or municipal, of each other applicable jurisdiction outside the Territory in which the Product will be developed, used or sold.
- 1.1.65 "Regulatory Requirements" means:
  - (a) Applicable Laws, rules, regulations, guidances, and the Codes and Standards in respect of all activities of the Parties and their permitted Representatives under the Related Agreements, including guidances in respect of quality control and QA procedures and processes, manufacturing and production batch records (including the Master Production Record), packaging, handling, storage, delivery and retention of raw material and Product samples and associated support data, and all licenses, certificates, authorizations or requirements from Regulatory Authorities; and
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- (b) the corresponding laws, rules, regulations and guidances of each other applicable jurisdiction outside the Territory in which such activities take place.
- 1.1.66 "Regulatory Submissions" means all submissions and filings made in furtherance of obtaining and maintaining any Regulatory Approvals.
- 1.1.67 "Related Agreements" means, collectively, this Agreement, the Quality/Technical Agreement, the Development Agreement and the Co-Promotion Agreement.
- 1.1.68 "Representatives" means, in respect of a Party, that Party's
  Affiliates and their respective directors, officers, employees,
  consultants, subcontractors, sublicensees, agents, representatives
  and other persons acting under their authority.
- 1.1.69 "S&OP" has the meaning set out in Section 3.1.1.
- 1.1.70 "SOP" means the duly authorized and documented standard operating procedure practised by each of Enzon and Inex in the performance of a specified process.
- 1.1.71 "Specifications" means the specifications for Manufacturing the Product and the related methods and stability protocols and procedures as set forth in the approved NDA and any supplements and amendments thereto, together with the specifications for raw materials, packaging, sampling, shipping and storage of Product. The Specifications are set forth at Exhibit 1.1.71 attached hereto.
- 1.1.72 "Standards" means the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of Continuing Medical Education, as they may be amended from time to time.
- 1.1.73 "Sublicensee" means a Third Party which is not an Affiliate of Enzon and to whom Enzon has granted a sublicense for the purpose of developing, using, selling, having sold, distributing or importing the Product in one or more countries of the Territory.
- 1.1.74 "Term" shall have the meaning set out in Section 17.1.

- 1.1.75 "Territory" means Mexico, Canada and the USA.
- 1.1.76 "Third Party" means any Person other than a Party or an Affiliate of a Party.
- 1.1.77 "Trademarks" means trademarks, trade names, and domain names identified in Exhibit 1.1.77 and all alternate trademarks adopted and used by Enzon for the Product and all applications and registrations therefor in the Territory.
- 1.1.78 "USA" means the United States of America, including its territories, possessions and the Commonwealth of Puerto Rico.
- 1.1.79 "Vincristine" means the chemical compound known as vincristine sulfate.
- 1.1.80 "Vincristine Sulfate Liposomes Injection" or "VSLI" means
  Vincristine encapsulated in sphingomyelin/cholesterol liposomes or
  a kit for production of same.

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#### 1.2 Entire Agreement; Conflicts

This Agreement, together with the other Related Agreements, constitutes the entire agreement between the Parties concerning the subject matter hereof. In the event of a conflict between the terms and conditions set out in any of the Related Agreements, the following agreement shall govern in the following priority:

- 1.2.1 this Agreement; then
- 1.2.2 the Quality/Technical Agreement; then
- 1.2.3 the Development Agreement; and then
- 1.2.4 the Co-Promotion Agreement.

#### 1.3 Governing Law

This Agreement shall be governed by and construed in accordance with the laws of Delaware in force therein without regard to its conflict of law rules.

## 1.4 Headings

The headings contained in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. References to Articles are references to Articles of this Agreement and the Sections contained therein, and references to Sections are references to Sections of this Agreement.

#### 1.5 Severability

If a court or other tribunal of competent jurisdiction should hold any term or provision of this agreement to be excessive, invalid, void or unenforceable, the offending term or provision shall be deemed inoperative to the extent it conflicts with such holding and shall be deemed to be modified to the extent necessary to conform with such statute or rule of law, while still preserving, to the extent practicable, the legitimate aims of the Parties, provided that the remaining portions hereof shall remain in full force and effect. In the event that the terms and conditions of this Agreement are materially altered as a result of the above, the Parties will renegotiate the terms and conditions of this Agreement to resolve any inequities.

## Article 2 Purchasing and Price

#### 2.1 Purchase Price of Product

- 2.1.1 Subject to the terms of this Agreement, Enzon will purchase Product from Inex for commercial resale at the Purchase Price comprised of the sums set forth in this Section 2.1.1 ("Purchase Price") below:
  - (a) Manufacturing Cost for the units delivered as set forth in Exhibit 2.1.1(a) plus five percent (5%)
  - (b) Deferred Sales Payments as set forth in Exhibit 2.1.1(b); and
  - (c) Sales Threshold Bonuses ("Sales Threshold Bonuses") as follows:
    - (i) Ten Million Dollars (\$10,000,000) payable when cumulative Net Sales first exceeds One Hundred Twenty-five Million Dollars (\$125,000,000) in any rolling four (4) Commercial Quarter period; and

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- (ii) Fifteen Million Dollars (\$15,000,000) payable when cumulative Net Sales first exceeds Two Hundred Fifty Million Dollars (\$250,000,000) in any rolling four (4) Commercial Quarter period.
- 2.1.2 Subject to the terms of this Agreement, Enzon will purchase Product from Inex for use in Post-Approval Clinical Activities at a purchase price equal to the Manufacturing Cost.
- 2.1.3 The Parties shall cooperate in good faith to establish a mechanism to share on a 50/50 basis the per unit financial benefit associated with any reduction in the Manufacturing Cost derived from the Technical and Manufacturing Support Activities described in Section 5.6.2 of the Development Agreement and/or the transfer of Manufacturing to Enzon (if any) pursuant to Section 4.4. If the Parties cannot agree, either Party may refer the matter to resolution pursuant to Article 16.
- 2.2 Terms of Payment for Manufacturing Cost Plus

With respect to payments pursuant to Section 2.1:

- On or before Enzon issues its first pre-launch Purchase Order pursuant to Section 3.2.1, but in any event on or before the earlier of: 45 days of the Effective Date; and the date of the first Purchase Order, the Parties will agree on their best estimate of the Manufacturing Cost for a unit of Product for 2004 plus five percent (the "Reference Price"). If the Parties are unable to agree on such price, either Party may refer the matter for resolution pursuant to Article 16.
- 2.2.2 Upon shipment of Product and complete QA documentation related thereto, including Certificate(s) of Analysis, to Enzon, Inex shall deliver an invoice to Enzon for the Product included in such shipment, which invoice shall be based on the Reference Price for the units of Product shipped. Provided the Product has not been rejected pursuant to Section 5.5.1, Enzon agrees to pay each such invoice within thirty (30) days after its receipt of the shipment, complete QA documentation for such shipment and the applicable invoice.
- 2.2.3 Within twelve (12) Business Days after the end of each Calendar Quarter, Inex shall calculate the actual Manufacturing Cost for the units of Product shipped to Enzon during such Calendar Quarter and deliver a report setting forth such actual Manufacturing Cost (with amounts broken out for the line items reflected in Exhibit 2.1.1(a)). Any Manufacturing Cost for the units of Product shipped

to Enzon during any Calendar Quarter and not captured in the calculation delivered in the report referred to in this Section shall be captured in subsequent reports.

- 2.2.4 If the aggregate actual Manufacturing Cost for all the units of Product shipped to Enzon (and for which Enzon owed or owes payment to Inex pursuant to Section 2.2.2) during such Calendar Quarter exceeds the aggregate Reference Price paid or payable by Enzon pursuant to Section 2.2.2 for the units of Product so shipped, then Inex will deliver an invoice to Enzon (contemporaneous with the report described in Section 2.2.3) for the amount of such excess. Enzon shall pay such invoice within thirty (30) days from the receipt of such invoice.
- 2.2.5 If the aggregate actual Manufacturing Cost for all the units of Product shipped to Enzon (and for which Enzon owed or owes payment to Inex pursuant to Section 2.2.2) during such Calendar Quarter is less than the aggregate Reference Price paid or payable by

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Enzon pursuant to Section 2.2.2 for the units of Product so shipped, then Inex will deliver a credit statement to Enzon (contemporaneous with the report described in Section 2.2.3) for the amount of such deficiency. The amount of the deficiency shall be credited against future amounts owed by Enzon to Inex under Section 2.2.2.

- 2.2.6 At least once annually, or as more frequently as the Parties may agree, the Parties will agree on their best estimate of a revised Reference Price, and thereafter use the revised Reference Price for the purposes of invoices issued pursuant to Section 2.2.2. If the Parties are unable to agree on such price, either Party may refer the matter for resolution pursuant to Article 16.
- 2.3 Terms of Payment for Deferred Sales Payments

With respect to the Deferred Sales Payment as set forth in Section 2.1.1(b), on a quarterly basis, Enzon shall make a Deferred Sales Payment in accordance with Exhibit 2.1.1(b) on each unit of Product in every country in the Territory until the expiry of the Term in such country.

2.4 Remuneration respecting Sublicensees

In the event Enzon grants sublicenses to others to sell the Product, such sublicenses shall include an obligation for the Sublicensee to account for and report its sales of the Product on the same basis as if such sales were sales of Enzon, and Inex shall receive compensation in the same amounts as if the sales of the Sublicensee were sales of Enzon.

- 2.5 Third Party Payments
  - 2.5.1 Inex shall pay all royalties or other remuneration owing to Third Parties pursuant to agreements between Inex and such Third Parties in effect as of the Effective Date which result from the exercise by Enzon of the rights granted in Section 2.1 of the Development Agreement.
  - 2.5.2 If, during the term of this Agreement, Enzon and Inex mutually agree that it is necessary to seek a license from any Third Party in the Territory in order to avoid infringement during the exercise of the rights herein granted or if a court of competent jurisdiction determines that such a license is required, or if an independent, mutually acceptable Third Party patent attorney determines that such a license is required (in accordance with the procedure outlined in this Section 2.5.2), \*\*\*. In the event that the Parties are unable to agree on whether any such license is needed or on the terms of such license, the Parties shall submit

such dispute to an independent, mutually acceptable Third Party patent attorney for a final and binding determination of such dispute, and the Parties shall equally share the cost of engaging such patent attorney.

- 2.5.3 Notwithstanding the provisions of Section 2.5.2, if the license from the Third Party or the royalty or other fee payable to such Third Party gives rise to an indemnification obligation under the Related Agreements in favour of Enzon on the part of Inex, then such royalty or other fee shall be paid by Inex as Losses in accordance therewith.
- 2.6 Commercial Sales of Development Stock

Any Product produced for Development which, by agreement of the Parties, is converted to commercial stock for resale, will be sold by Inex to Enzon for commercial sale pursuant to this Agreement, and any

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contribution of Development Costs already paid by Enzon in respect of such stock will be credited against Enzon's purchase of such stock.

## 2.7 Reports and Payment

Enzon shall deliver to Inex within thirty (30) days after the end of each Commercial Quarter a written report showing its computation of Deferred Sales Payments and Sales Threshold Bonuses, if any, due under this Agreement in respect of such Commercial Quarter, and setting out:

- 2.7.1 Net Sales segmented in each such report according to sales by Enzon, each Affiliate and each Sublicensee, as well as on a country-by-country and month-by-month basis.
- 2.7.2 Deductions from gross revenues by the categories for same set out in the definition of Net Sales.
- 2.7.3 The rates of exchange used to convert such Deferred Sales Payments to United States dollars from the currency in which such sales were made. For purposes hereof, such conversion calculations are to be made on a monthly basis and the rate of exchange to be used for converting Deferred Sales Price payments hereunder from a foreign currency to United States dollars in any month shall be equal to the average of: (i) the daily foreign mid-range rate as published in the Wall Street Journal (or any rate replaced thereby) in respect of the first Business Day of the relevant month; and (ii) the same rate in respect of the last Business Day of the relevant month.

Enzon, simultaneously with the delivery of each such report, shall tender payment in United States dollars all Deferred Sales Payments and Sales Threshold Bonuses, if any, shown to be due thereon.

## 2.8 Withholding Taxes

The Parties contemplate that there will be no payment or withholding by Enzon of taxes on any payments made by Enzon to Inex pursuant to this Agreement. In the event that either Party takes any action, or if the circumstances applicable to either Party change with the result that taxes must be paid or withheld on the payments due pursuant to this Agreement, then such taxes shall be borne by such Party. Without limiting the generality of the foregoing:

2.8.1 if Enzon assigns or sublicenses its rights hereunder, undergoes a reorganization or otherwise changes its structure, or changes its domicile, and thereafter taxes must be paid or withheld on the payments hereunder, such payments shall be grossed up so that Inex receives the actual amounts set out in this Agreement; and

- 2.8.2 if Inex assigns or sublicenses its rights hereunder, undergoes a reorganization or otherwise changes its structure, or changes its domicile, and thereafter taxes must be paid or withheld on the payments hereunder, then such tax or withholding payments shall be deducted from the amounts set forth herein, and Enzon shall assist Inex as may be reasonably required, including providing proof of such payment of such tax payment, in order to allow Inex to claim the benefit of, exemption from or repayment such tax payment, as may be applicable; and
- 2.8.3 in the event that payment or withholding by Enzon of taxes becomes necessary on any payments made by Enzon to Inex pursuant to this Agreement when neither Section 2.8.1 nor Section 2.8.2 applies, then such tax or withholding payments shall be deducted from the amounts set forth herein, and Enzon shall assist Inex as may be reasonably required,

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including providing proof of such payment of such tax payment, in order to allow Inex to claim the benefit of, exemption from or repayment such tax payment, as may be applicable.

Notwithstanding the foregoing, if Inex is able to credit the grossed up portion of any payment made by Enzon pursuant to Section 2.8.1 against taxes payable by Inex, or gain exemption from or repayment of such tax payment, Inex will promptly pay the equivalent of the benefit received by Inex to Enzon.

## 2.9 Foreign Payments

Where payments are due Inex hereunder for sales of the Product in a country in the Territory where, by reason of currency regulations or taxes of any kind, it is impossible or illegal for Enzon, any Affiliate or Sublicensee to transfer such payments to Inex, such payments shall be deposited in whatever currency is allowable by the Person not able to make the transfer for the benefit or credit of Inex in an accredited bank in that country in the Territory that is reasonably acceptable to Inex.

#### 2.10 Method of Payment

Enzon shall make all payments due under this Agreement in U.S. Dollars by wire transfer of funds via the Federal Reserve Wire Transfer System to Inex's account as designated in writing by Inex to Enzon.

## 2.11 Late Payments

Any payment by Enzon or Inex that is not paid on or before the date such payment is due under this Agreement shall bear interest at a rate equal to the lesser of:

- 2.11.1 Prime Rate plus \*\*\* per year, or
- 2.11.2 the maximum rate permitted by law;

calculated based on the number of days that payment is delinquent.

# 2.12 Records

Both Parties shall keep full, true and accurate books of accounts and other records containing all information and data which may be necessary to ascertain and verify:

- 2.12.1 the Commercialization Costs incurred by each Party and their respective Representatives hereunder for a period of three (3) years after the completion of the Commercialization; and
- 2.12.2 any other amount payable hereunder for a period of three (3) years after the completion of the Term.

During the Term and for a period of three years thereafter, each Party shall have the right from time to time (not to exceed once during each calendar year) to have either its internal financial audit personnel or an independent firm of accountants (i.e., a certified public accountant or like person reasonably acceptable to the Party being audited) inspect the books, records and supporting data of the other Party referred to in Section 2.12. Such independent firm of accountants shall perform these audits at the requesting Party's expense upon reasonable prior notice and during the other Party's regular business hours, and shall agree as a condition to such audit to maintain the confidentiality of all information disclosed or observed in connection

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with such audit and to disclose to the requesting Party only whether the other Party has complied with its obligations under this Agreement with respect to the calculation and payment of Commercialization Costs and any other money owing pursuant to this Agreement. If the result of such audit demonstrates an overpayment or underpayment, there shall be a prompt (but in no event more than 60 days after completion of the audit) accounting between the parties to reconcile such overpayment or underpayment. If the results of such audit demonstrates a discrepancy and the discrepancy represents \*\*\* or more of the actual value, then the party that has to pay to settle the discrepancy shall pay the reasonable costs of the audit.

# Article 3 Forecasting and Purchase Orders

- 3.1 Sales and Operations Plan
  - The Parties will confer monthly as contemplated by this Section to review and update a rolling eighteen (18) month Sales and Operation Plan (the "S&OP") to govern activities related to forecasting, production capacity, inventory management, risk management and other activities related to the timely and efficient management of the supply and distribution of the Product.
  - 3.1.2 Initially, within 30 days after the Effective Date, and on or before the last Business Day of each month thereafter, Enzon will provide Inex by electronic mail a rolling, eighteen (18) month forecast ("Forecast") estimating Enzon's requirements for Product for the following eighteen (18) months. The Forecast will be made in good faith to assist Inex in developing the S&OP and, except as otherwise set forth in this Agreement, shall be non-binding. Each Forecast will contain:
    - (a) in respect of Forecasts provided by Enzon subsequent to Inex's first shipment to Enzon, an inventory status of Products on hand; and
    - (b) in respect of the first nine (9) months of each Forecast, the quantities of Product to be purchased broken down both by:
      - (i) the use for the Product, designated as either for clinical use or commercial use; and
      - (ii) the jurisdiction in which the Product will be used.
  - 3.1.3 Promptly (but in any event within two (2) Business Days after becoming aware of same) Inex will notify Enzon of any difficulties that are likely to cause a delay in meeting or a failure to meet Enzon's requirements during the Forecast period. Inex shall present detailed descriptions of such difficulties for discussion during the monthly S&OP planning meeting or teleconference.

3.1.4 Within one week of Inex's receipt of Enzon's Forecast for each Forecast period, Inex will provide Enzon a draft S&OP setting out the quantity of Product scheduled to be Manufactured during the Forecast period, and the Parties will jointly review and make reasonable efforts to agree upon such changes as may be required to develop an S&OP approved by both Parties (the "Approved S&OP"). In the absence of express agreement of the Parties to the contrary, if the Parties fail to agree on any Approved S&OP, Inex will continue to operate using the most recently Approved S&OP. In the absence of express agreement of the Parties to the contrary, in no event will the total and monthly quantities of Product set out in the Approved S&OP exceed the capacity of Inex's Representatives.

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- 3.1.5 Inex's commitment to Manufacture, and Enzon's commitment to Purchase such quantities of Product as set forth in the first nine (9) months of each Approved S&OP shall be binding upon the parties.
- 3.1.6 The parties acknowledge and confirm that Inex shall rely upon the Forecasts provided by Enzon in determining its Manufacturing schedules and acquiring the necessary raw materials in advance thereof, and notwithstanding the non-binding nature of the remaining nine (9) months of the Approved S&OP, Enzon shall use Commercially Reasonable Efforts to project accurately its requirements.
- 3.2 Purchase Orders Issued Before First FDA Approval
  - 3.2.1 Prior to the FDA's grant of Regulatory Approval for the Product, and pursuant to each Approved S&OP, Enzon will provide Inex binding Purchase Orders by facsimile or electronic mail at least nine (9) months prior to each proposed delivery date, specifying
    - (a) delivery date specified as "the week of;"
    - (b) delivery location; and
    - (c) mode of delivery (default transportation will be by surface in the USA);

and shall pay to Inex within five Business Days of issuing each such Purchase Order, a pre-payment of \*\*\* of the Reference Price of the quantity of Product specified in each Purchase Order, creditable against Enzon's future payment of the Purchase Price of the Product.

- 3.2.2 Inex or its designee will respond by facsimile or electronic mail within three (3) Business Days of receipt of Enzon's Purchase Orders with a confirmed delivery date that is within two (2) weeks of that specified in the Purchase Order.
- 3.2.3 Notwithstanding anything else herein to the contrary, except for the payment of \*\*\* of the Reference Price under Section 3.2.1, Enzon shall not be obligated to purchase any shipment of Product for commercial use prior to Regulatory Approval of the Product by the FDA.
- 3.2.4 Provided the batch or batches of Product Manufactured pursuant to Enzon's Purchase Orders under Section 3.2.1 meets the minimum shelf life set forth in Section 5.2.2 or such other shelf life as agreed between the Parties acting reasonably and provided Enzon shall not have rejected the Product pursuant to Section 5.5.1, Enzon shall purchase such batch or batches of Product at the Purchase Price less the pre-payment already made in respect of

such batch or batches of Product as set out in Section 3.2.1. Inex's right to receive payment hereunder is in addition to and not in lieu of Inex's right to quarterly reconciliations of payment pursuant to Article 2.

- 3.2.5 If any batch of Product Manufactured pursuant to Enzon's Purchase Orders under Section 3.2.1 does not meet the minimum shelf life set forth in Section 5.2.2 or such other shelf life as agreed between the Parties acting reasonably, Enzon shall not be required to purchase such batch of Product, but shall not be entitled to a refund of any prepayment made in respect of such batch of Product pursuant to Section 3.2.1.
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- 3.3 Purchase Orders Issued After First FDA Approval
  - 3.3.1 In accordance with the most recently Approved S&OP, Enzon will provide Inex a binding Purchase Order at least nine (9) months prior to each proposed delivery date, specifying:
    - (a) quantity of Product to be purchased as provided in the Approved S&OP, broken down both by:
      - (i) the use for the Product, designated as either for clinical use or commercial use; and
      - (ii) the jurisdiction in which the Product will be used:
    - (b) delivery date specified as "the week of" as provided in the Approved S&OP;
    - (c) delivery location; and
    - (d)  $\operatorname{mode}$  of delivery (default transportation will be by  $\operatorname{surface}$  in the USA).
  - 3.3.2 Enzon will send all Purchase Orders to Inex by facsimile or electronic mail.
  - 3.3.3 Inex or its designee will respond by facsimile or electronic mail within three (3) Business Days of receipt of Enzon's Purchase Order with a confirmed delivery date that is within two (2) weeks of that specified in the Purchase Order.

Article 4 Manufacturing

4.1 Technical Activities to Support Manufacturing

Subject to Section 4.4 and unless otherwise agreed between the Parties, Inex will oversee all Manufacturing activities required to:

- 4.1.1 obtain and maintain Regulatory Approvals; and
- 4.1.2 provide Product for Clinical Activities and commercial sale.
- 4.2 Manufacturing in Compliance

Inex shall Manufacture the Product in compliance with the Regulatory Requirements, the Specifications and the Master Production Record.

4.3 Subcontractors

Except for contracts executed prior to the Effective Date, Inex may not subcontract to any Third Party the Manufacture of the Product without the consent of Enzon, which consent shall not be withheld unreasonably. Inex shall be responsible to Enzon for the performance of and all activities undertaken by

Inex's subcontractors.

## 4.4 Technical Transfer to and Manufacture by Enzon

If the Parties' mutually agree that Inex will subcontract some or all of the Manufacture of Product to Enzon, upon completion by Inex of manufacturing due diligence with Enzon to Inex's satisfaction:

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- 4.4.1 the Parties will amend the Commercialization Plan to establish the respective responsibilities of the Parties in respect of such subcontracting;
- 4.4.2 Enzon will effect such transfer and ensure validation of Enzon's processes and facility by no later than a date to be mutually agreed upon by the Parties;
- 4.4.3 Enzon will fund \*\*\* and Inex will fund \*\*\* of all costs of such transfer, including FTE Costs and Out of Pocket Costs;
- 4.4.4 the Manufacture of Product by Enzon will cover clinical and commercial requirements both inside and outside the Territory;
- 4.4.5 for Product supplied by Enzon to Inex for commercial purposes outside the Territory, Product will be supplied at the cost of goods per unit of Product \*\*\*;
- 4.4.6 for Product supplied by Enzon to Inex for clinical development, Product will be supplied at Manufacturing Cost; and
- 4.4.7 the Parties will amend this Agreement or enter into a new Product Supply Agreement to provide for such transfer.

The matters set forth in this Section 4.4 constitute merely an expression of the desire of the Parties to negotiate with each other regarding the terms of an agreement regarding the subject matter of this Section 4.4, and nothing in this Section 4.4 will have any legal or binding effect unless set out in writing in a separate agreement and signed by the duly authorized representatives of the Parties.

# 4.5 Material Change to Financial Terms

Unless otherwise agreed in writing by the Parties, in the event of:

- 4.5.1 any material amendment to any of the Related Agreements;
- 4.5.2 any termination of any of the Related Agreements that does not result in termination of all of the Related Agreements;

the Parties will review and renegotiate financial terms under the amended or remaining Related Agreements so that the financial compensation received by Inex as a result of the amended or remaining Related Agreements is no less favourable to Inex than the financial terms of the Related Agreements would have been without such amendment or termination. If the Parties are unable to agree to such terms, either Party may refer the matter for resolution pursuant to Article 16.

# 4.6 Quality/Technical Agreement

Upon execution of this Agreement, the Parties will commence good faith negotiations of a Quality/Technical Agreement setting forth in greater detail the regulatory and quality assurance responsibilities of the Parties with regard to the Manufacture of Product and further providing for compliance with Regulatory Requirements. Each of the Parties will exercise Commercially Reasonable Efforts to finalize and execute such agreement within 90 days after the Effective Date.

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## Article 5 Supply and Shipment

## 5.1 Shipping Notification

- 5.1.1 No later than five (5) Business Days prior to Product shipment, Inex will provide Enzon with shipping details that include lot number, quantity, shipping date, transport mode, and destination.
- 5.1.2 Inex will send all shipping notices to Enzon by facsimile or electronic mail.

# 5.2 Shipment of Product

- 5.2.1 In respect of each shipment of Product, Inex shall:
  - (a) ensure the Product is properly stored in validated transport containers;
  - (b) prepare and ship Product in accordance with approved shipping SOPs;
  - (c) provide tracking information to Enzon upon shipment from Inex's or Inex's subcontractors' facilities at the time of shipment.
- 5.2.2 All Product shipped by Inex or its designees shall have a expiry date no less than eight (8) months from the date of shipment, provided that Enzon purchases the entire batch or batches of Product Manufactured for shipment, except as mutually agreed upon between the Parties, acting reasonably. The Parties will use Commercially Reasonable Efforts to increase the Product shelf life to at least twelve (12) months.
- 5.2.3 Unless otherwise agreed between the Parties, Inex shall not ship any Product to Enzon except pursuant to a Purchase Order.

## 5.3 Shipment of Released Product

Inex will ship Product to Enzon or Enzon's designees only after Product has been released by Inex's QA representatives. Enzon shall not be responsible for QA release of the Product.

5.4 Risk of Loss and Shipping Expenses

The Product will be shipped F.A.S. Enzon's designated location.

- 5.5 Rejection of Delivered Product
  - 5.5.1 After receipt by Enzon of the Product or of the sample of the Product and complete QA documentation corresponding thereto, including Certificate(s) of Analysis, if Enzon rejects the Product delivered to it by reason of any shortage in quantity of the shipment, damage to the Product or packaging, including the shipping container, or any obvious defect detectable by the naked eye, Enzon will notify Inex within 10 Business Days.
  - 5.5.2 Product not rejected in accordance with these terms within such period will be deemed accepted.
  - 5.5.3 Inex will use Commercially Reasonable Efforts to make up any shortage of Product.
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#### 5.6 Obsolescence and Returns

If Enzon has not rejected the Product in accordance with Section 5.5, Inex will not accept return of any Product from Enzon or its Representatives regardless of the reason(s) therefor.

## 5.7 Disposal and Destruction

Unless otherwise agreed in writing between the Parties, unsold Product in Enzon's possession or control will be destroyed or disposed by Enzon in accordance with Regulatory Requirements at Enzon's sole expense.

Article 6 Product Receipt and Distribution

## 6.1 Receipt

Unless otherwise agreed upon in advance between the Parties, Enzon shall practice receipt procedures in accordance with agreed SOPs or written instructions agreed between the Parties.

#### 6.2 Storage and Handling

If Enzon or its Representatives' receipt, storage or handling of Product is not done in accordance with the Specifications or Regulatory Requirements and the whole or part of a shipment of Product is rendered unsuitable for its purpose, Enzon shall remain liable for the Purchase Price of any compromised Product and for any shipping costs associated with such purchase.

#### 6.3 Distribution

In respect of each shipment of Product from Enzon to its Representatives or any Third Parties, Enzon shall, and shall cause its Representatives to:

- 6.3.1 ensure the Product is properly stored in validated transport containers; and
- 6.3.2 prepare and ship Product in accordance with approved shipping SOPs.

## 6.4 Records for Traceability

Enzon shall maintain and shall require its Representatives who receive, handle, store, ship, or distribute Product to maintain a record retention policy consistent with cGMP and Regulatory Requirements, and to maintain records with sufficient detail to facilitate traceability in the event of recalls or voluntary withdrawals of Product.

Article 7 Shipments for Launch

## 7.1 Consequence of Launch Supply Failure

7.1.1 If Inex fails to deliver to Enzon at least \*\*\* of the quantity of Product (that satisfies all material, applicable requirements of this Agreement) ordered by Enzon in its initial pre-Regulatory Approval Purchase Order (as contemplated in Section 3.2) (such \*\*\* the "Minimum Launch Quantity") within six months after the: the delivery date specified in such Purchase Order; and the date of Regulatory Approval; whichever is later, and such failure has not been caused by any act or omission of Enzon (such failure to deliver within six months shall be a "Launch Supply Failure"), Inex shall, within 10 Business Days after the Launch Supply Failure, make a cash payment to Enzon in the amount set out in Section 7.1.2 to compensate Enzon for the loss in value associated with a delayed

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launch. For greater clarity, in the event of a Launch Supply Failure, the date of the Launch Supply Failure will be the date six months from the later of: the delivery date specified in such Purchase Order; and the date of Regulatory Approval.

- 7.1.2 The amount to compensate for the loss in value shall be:
  - (a) if the Launch Supply Failure is before April 15, 2006, then the amount shall be \*\*\*; and
  - (b) if the Launch Supply Failure is on or after April 15, 2006 and before April 15, 2007, then the amount shall be \*\*\*; and
  - (c) if the Launch Supply Failure is on or after April 15, 2007, then the amount shall be \*\*\*.
- 7.2 Enzon's First Option to Terminate
  - 7.2.1 Upon the occurrence of a Launch Supply Failure, Enzon shall have the right, which right must be exercised within ten Business Days after the date of occurrence of the Launch Supply Failure, to terminate this Agreement immediately upon notice to Inex.

    Termination by Enzon under this Section 7.2 shall not relieve Inex of its liability under Section 7.1.
  - 7.2.2 If Enzon fails to exercise its termination right pursuant to Section 7.2.1, then it may not terminate this Agreement for a period of six months after the date of occurrence of the Launch Supply Failure, provided Inex does not commit any non-supply related material breach of this Agreement that would otherwise provide a basis for termination by Enzon.
- 7.3 Enzon's Second Option to Terminate

If Enzon elects not to exercise its termination right pursuant to Section 7.2.1, but Inex fails to deliver the Minimum Launch Quantity within six months after the Launch Supply Failure, Enzon shall be entitled to terminate this Agreement immediately upon notice to Inex, which right must be exercised within ten Business Days after the expiry of six months after the Launch Supply Failure. Any such termination by Enzon shall be deemed to be pursuant to Section 17.3.

## 7.4 Cure by Inex

If a Launch Supply Failure occurs and Enzon has not exercised its termination right pursuant to Section 7.2.1 or 7.3, and Inex delivers the Minimum Launch Quantity, then Enzon shall, within 10 Business Days after such delivery (provided such shipment is not rejected under Section 5.5.1) make a cash payment to Inex in an amount determined by the following formula:

\*\*\*

where X is equal to the amount of the payment to be made by Enzon, A is equal to the amount paid by Inex to Enzon pursuant to Section 7.1.2, Y is equal to the number of full months elapsed between the date of occurrence of the Launch Supply Failure and the date of the delivery of the Minimum Launch Quantity and Z is equal to a fraction that expresses the pro rata portion of the last month elapsed prior to the delivery.

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- 8.1.1 In respect of changes to the Specifications, Master Production Records, procedures, processes, materials, facilities, equipment or any matter contained or referenced in the NDA or DMFs pertaining to the Product, Inex shall notify Enzon and/or seek Enzon's prior approval in accordance with the Quality/Technical Agreement.
- 8.1.2 The Quality/Technical Agreement will provide that Inex will:
  - (a) inform Enzon of all notices received by Inex in respect of changes described in Section 8.1.1 provided to Inex by its Representatives; and
  - (b) cooperate with Enzon to resolve all requests for changes described in Section 8.1.1;

so that all notice and consent obligations between Inex and Enzon take into consideration those now in effect between Inex and its Representatives.

## 8.2 New Regulatory Requirements

Inex and Enzon will use Commercially Reasonable Efforts to make such changes as reasonably necessary to the Master Production Record, the Specifications or procedures, processes, materials, facilities, equipment or any matter utilized by Inex under this Agreement or contained or referenced in Inex's NDA or DMF controlled by Inex to meet new Regulatory Requirements and guidelines in the Territory. Upon agreement by the Parties to proceed with such changes, Enzon shall be responsible for \*\*\*, and Inex \*\*\*, of all costs incurred by the Parties, including Development FTE costs, in respect of any changes made by either Party pursuant to this Section 8.2.

## 8.3 Reservation

Except as set out in this Article 8, as between Inex and Enzon, Inex retains the sole right and authority to make all decisions with respect to the Manufacture of the Product and Inex's performance under this Agreement.

## Article 9 Commercialization

#### 9.1 Regulatory Compliance

- 9.1.1 Each of the Parties, directly and through its permitted Representatives, shall perform the Commercialization activities in compliance with Regulatory Requirements.
- 9.1.2 Each Party shall ensure none of its Representatives who participate in any Commercialization and/or Co-Promotion:
  - (a) is or has been suspended, debarred or disqualified by the FDA;
  - (b) has been convicted of any offence that would form the basis for any debarment; or
  - (c) is or has been subject to any proceedings for the suspension, disqualification or debarment of such Party or any Representative of such Party.
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## 9.2 Assignment of Trademarks

Inex shall assign to Enzon the Trademarks identified in Exhibit 1.1.77 in the Territory as soon as reasonably possible after such Trademark(s) may be legally transferred. Inex shall own and have the right to use all Trademarks outside the Territory.

#### 9.3 Use of Inex Trademarks in Labelling

- 9.3.1 The parties agree that Enzon shall affix to the outer packaging of and shall include on the package insert for the Product, and in addition to its own trademarks and names, one or more labels displaying with equal prominence to the Enzon trademarks or names, the Inex name and corporate logo, or such other trademark or statement as Inex shall reasonably request. Inex shall also have the right to review and approve all claims relating to the intended use of Product contained in package inserts and other promotional materials, which approval shall not be unreasonably delayed or withheld.
- 9.3.2 Inex hereby grants to Enzon a non-exclusive license, sublicensable in accordance with the terms of this Agreement, to use such name(s) or trademark(s) accordingly and in substantially the same manner as used by its owner; provided, however, that each such use of such trademark(s) be accompanied by a printed notice identifying Inex as the owner thereof. In the event that any Products do not meet the specifications or quality standards required under this Agreement, Inex may cause Enzon to remove all trademarks of Inex from such Product and shall have the right to cancel the foregoing grant of license to use such trademarks, unless Enzon promptly meets such specifications or quality standards. Inex shall have the right to receive and approve the use of its marks in any proposed product literature, advertising material or material for publication.

## 9.4 Patent Marking

Enzon shall mark all Product made, used or sold under the terms of the Related Agreements, or their containers in compliance with the applicable patent marking laws. Inex shall have the right to review and approve all patent marking, such approval not to be unreasonably withheld.

## 9.5 Commercialization Efforts

Subject to the terms of the Co-Promotion Agreement, in each country in the Territory in which the Product has received Regulatory Approval, Enzon, directly and through its permitted Representatives, shall use Commercially Reasonable Efforts to Commercialize the Product. Enzon's Commercially Reasonable Efforts to Commercialize the Product shall include the obligation to Manufacture the Product only if the Manufacture of same is transferred to Enzon pursuant to Section 4.4.

9.6 Commercial Diligence in accordance with Commercialization Plan

Subject to the terms of the Co-Promotion Agreement, without limiting Enzon's obligations set out in Section 9.5:

- 9.6.1 Enzon will undertake the Commercialization as set out in the Commercialization Plan and as amended from time to time by the Parties in accordance with this Article 9.
- 9.6.2 Enzon shall:
  - (a) conduct pre-launch marketing activities in respect of the Product;

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- (b) market and launch the Product and sell the Product in each country in the Territory where Regulatory Approval have been granted;
- (c) pay \*\*\* of the costs of Commercializing the Product, including the costs referred to in this Section;

- (d) Enzon will maintain a minimum effort of an aggregate of \*\*\* Sales Representatives and Medical Science Liaisons to Promote the Product in the Territory; and
- (e) diligently prosecute and maintain the Trademarks and use the Trademarks for the Product.

#### 9.7 Overview of Commercialization

The Parties intend to work cooperatively to pursue the Commercialization in accordance with the terms of this Agreement and the Co-Promotion Agreement. Unless otherwise agreed by the Joint Steering Committee or otherwise set out in this Agreement, Enzon will conduct the Commercialization monitored by the Joint Steering Committee and under the oversight of the Parties in conformance with the Commercialization Plan.

#### 9.8 Subcontractors

Either Party may subcontract to any of its Representatives any of its obligations in respect of the Commercialization with the consent of the other Party, such consent not to be unreasonably withheld or delayed; provided however, that the subcontracting Party shall be responsible for the performance of its Representatives and shall remain fully responsible and obligated to the other Party for all activities undertaken by its Representatives.

#### 9.9 Commercialization Plans

- 9.9.1 Within ninety (90) days after the Effective Date, Enzon shall prepare, review and submit to the Parties for approval a detailed Commercialization Plan for the Commercialization of the Product and the Parties shall reasonably promptly thereafter agree on a reasonable, detailed Commercialization Plan. The Commercialization Plan shall reflect Enzon's covenant set forth in Section 9.5.
- 9.9.2 Commercialization of the Product shall be conducted by Enzon in conformance with the Commercialization Plan.
- 9.9.3 The Commercialization Plan may be updated by Enzon for review and approval by the Parties as provided herein.
- 9.9.4 At a minimum, the Commercialization Plan as amended from time to time shall describe the specific activities to be performed for a twelve (12) month period, with a summary of Commercialization Activities to be performed thereafter. The Commercialization Plan will be reviewed on at least a semi-annual basis by the Joint Steering Committee to update the specific activities to be performed for the rolling twelve (12) month period, as well as to reflect the revised Commercialization Plan as the Joint Steering Committee reasonably determines to be necessary or useful. Notwithstanding the above, no amendment to any Commercialization Plan shall be construed to be final unless it has been made in accordance with the provisions of this Article 9.
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9.9.5 The JSC shall review progress against the Commercialization Plan on a quarterly basis.

# 9.10 Funding of Commercialization Costs

From and after the Effective Date until the definitive Commercialization Plan is approved by the Parties, Enzon shall fund 100% of the cost of Commercialization activities and shall pay Inex for any Commercialization Costs incurred by Inex in accordance with the interim budget set out as Exhibit 9.10 (the "Interim Budget"). After the Effective Date, in the absence of a definitive Commercialization Plan agreed upon by the Parties, no commitment not in effect as of the Effective date with a price exceeding \$5,000 in Commercialization Costs will be incurred without the agreement of the Parties. If the Parties fail

to agree on the terms of the definitive Commercialization Plan within 90 days of the Effective Date, until the terms of the definitive Commercialization Plan are determined, Enzon shall fund 100% of Commercialization Costs incurred by the Parties acting reasonably, in pursuit of Commercialization of the Product during this transition period. After the definitive Commercialization Plan is approved by the Parties, Enzon shall fund 100% of the cost of Commercialization activities and shall pay Inex for any Commercialization Costs incurred by Inex in its performance of activities in accordance with the Commercialization Plan as amended from time to time, without deduction or set off, except as otherwise expressly set forth in this Agreement. On a quarterly basis, Inex shall send Enzon invoices accompanied by the appropriate documentation, including a listing of expenditures in reasonably specific detail within twelve (12) Business Days after the end of each Calendar Quarter. Enzon shall pay such invoices within thirty (30) days after receipt of same. Any Commercialization Costs arising in any Calendar Quarter and not captured in the calculation delivered in the report referred to in this Section shall be captured in subsequent reports. The costs incurred by Inex in pursuing Co-Promotion activities under the Co-Promotion Agreement shall not be included in the Commercialization Costs referenced above in this Section 9.10 or reimbursed by Enzon. The Co-Promotion Agreement describes the manner in which Enzon will make payments to Inex in respect of such Co-Promotion activities.

#### 9.11 Consequence of No Sales

In addition to the terms of Section 9.6, Enzon shall be deemed to have breached its obligation to use Commercially Reasonable Efforts in conducting marketing of a Product in any country in the Territory if, for a continuous period of \*\*\* at any time following launch of commercial sales of the Product in any such country, no sales of the Product are made in the ordinary course of business in such country by Enzon, an Affiliate or a Sublicensee, unless Enzon is prevented, restricted, interfered with or delayed in making such sales by reason of a cause beyond Enzon's reasonable control and can demonstrate same to Inex, in which event such period shall be extended by the period of Enzon's inability, provided that Enzon uses Commercially Reasonable Efforts to avoid or remove the cause of such inability.

#### 9.12 Reports

Enzon shall report to Inex on the status and progress of Enzon's efforts under this Article 9 as follows:

9.12.1 Enzon shall deliver to Inex within thirty (30) days after the end of each Calendar Quarter reports setting forth in general terms, reasonably sufficient for evaluation of the diligence obligations contained herein, the efforts Enzon made to commercialize the Product during the such year, including the achievement of any Sales Threshold Bonuses, any significant adverse developments, and any plans for or occurrences of any commercial sales of the Product in any jurisdiction and a summary of the efforts it intends to make in the upcoming year(s) on these matters. Enzon agrees to appropriately consider any Inex input and comments related to Enzon's plan for the upcoming year(s), provided that it is understood that Enzon shall have final decision making responsibility for such plans.

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9.12.2 To the extent that such could not be appropriately communicated to Inex in accordance with Section 9.12.1, Enzon shall keep Inex informed in a timely manner of significant developments in Enzon's (and its Affiliates and Sublicensees where relevant) progress of its efforts to Commercialize the Product, including without limitation, the achievement of any Sales Threshold Bonuses, any significant adverse developments, and any plans for or occurrences of any commercial sales of the Product in any jurisdiction.

Enzon hereby agrees that in the event Enzon or its Affiliates, either alone or in partnership, in collaboration or in conjunction with any Person other than Inex or Inex's Affiliate(s), whether as principal, agent, employee, director, officer, shareholder, licensor or in any capacity or manner whatsoever, whether directly or indirectly, develops, manufactures or commercializes any Competitive Product during the Term in the Territory, this Agreement shall terminate and Enzon's rights hereunder shall revert to Inex. No termination pursuant to this Section shall terminate this Agreement with respect to any other country in the Territory. Notwithstanding the foregoing, if Enzon or an Affiliate acquires an entity or all or substantially all of the assets of an entity during such period of time and such entity distributes or such assets include a Competitive Product, Enzon, or its Affiliate(s), shall have two hundred seventy (270) days in which to either (a) divest itself of such Competitive Product or to otherwise cease distribution of such Competitive Product, and Enzon shall not be in violation of this Section 9.13 if it so divests or ceases distribution within such two hundred seventy (270) day period, or (b) terminate this Agreement and Related Agreements. The Parties mutually agree that Enzon's (or Affiliates') commercialization, as described above, of any Competitive Product shall not be deemed a breach of this Agreement, and Inex's sole recourse for such an event shall be that as described in this Section 9.13 only.

## Article 10 Joint Steering Committee

#### 10.1 Joint Steering Committee

- 10.1.1 As of the Effective Date of this Agreement, the Joint Steering Committee shall be formed and shall be constituted of four representatives from each Party. The members of the Joint Steering Committee as of the Effective Date are as set forth on Exhibit 10.1. The Chairperson of the Joint Steering Committee at the first meeting of the Joint Steering Committee shall be an Enzon member of the Joint Steering Committee, and thereafter, the Chairperson will alternate at each meeting between a representative of Inex and a representative of Enzon. The Chairperson shall be responsible for issuing an agenda for the meeting, conducting and chairing the meeting and preparing the minutes for the meeting, and such other tasks as assigned by the committee. The Joint Steering Committee shall meet regularly:
  - (a) at least quarterly during the period when Commercialization is occurring, or more frequently if necessary; and
  - (b) at such periods to be determined by the Joint Steering Committee.  $\ensuremath{\mathsf{Committee}}$
- 10.1.2 Each Party shall bear its own expenses associated with its participation in the Joint Steering Committee and its administration and oversight of the activities contemplated by this Agreement. Such expenses shall not be included in Commercialization Costs.
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## 10.2 Meetings of the Joint Steering Committee

10.2.1 The Joint Steering Committee should meet at least once per year at the location of Inex or an Affiliate of Inex, and once per year at a location of Enzon or an Affiliate of Enzon. All other meetings of the Joint Steering Committee may occur by telephone, video conference or other acceptable means if requested by a Party. The Joint Steering Committee shall oversee all Commercialization activities of the Parties under this Agreement, including coordinating the overall strategy for Commercialization. The Joint Steering Committee shall have the responsibilities as set forth generally in Exhibit 10.1. Each Party may appoint its representatives to the Joint Steering Committee and other members of its project team at its discretion. The Joint Steering

Committee shall act only as a body making recommendations to the Parties, and neither Party is bound by any recommendation of the Joint Steering Committee. The members of the Joint Steering Committee shall attempt, in good faith, to reach consensus on all matters before the committee and make a consensus recommendation to the Parties. In the event that the Joint Steering Committee cannot make a consensus recommendation to the Parties which is acceptable to the Parties, either Party may refer the matter for resolution in accordance with the terms of Article 16.

10.2.2 The Joint Steering Committee shall cause there to be recorded reasonably detailed minutes of its meetings. The Party providing the chairperson of each meeting shall be responsible for preparing draft minutes of such meeting and distributing same to the other members of the committee within five Business Days after such meeting. If the other Party desires to revise the draft minutes it will provide comments on such minutes within ten Business Days after receiving the minutes. If such comments are provided, members of the Joint Steering Committee designated by each Party shall confer promptly and in good faith to resolve such comments and finalize the minutes. If the members of the Joint Steering Committee are unable to finalize the minutes within 30 days after the date of the meeting, either Party may refer the matter for resolution in accordance with the terms of Article 16.

#### 10.3 Working Committees

The Joint Steering Committee may establish working committees to oversee the Commercialization. Such working committees will conduct at a minimum quarterly planning and review meetings as well as ad hoc meetings as necessary. The primary method of meeting will be teleconference. Responsibilities of the working committees may include overseeing the planning and monitoring of the manufacturing and supply issues arising under this Agreement.

Article 11 Pharmacovigilance, DDMAC and Recalls

#### 11.1 Regulatory Responsibilities

Inex will be responsible for maintaining and fulfilling all Regulatory Requirements with respect to the Product that are imposed upon Inex as the manufacturer and holder of the Regulatory Approvals. Subject to the other express terms of the Related Agreements, Enzon and its designees will have sole responsibility for the advertising and other promotion of the Product and for maintaining and fulfilling all Regulatory Requirements with respect to the Product that are imposed upon Enzon as the advertiser, marketer and distributor thereof.

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## 11.2 Pharmacovigilance Agent

11.2.1 Unless the Parties agree to establish the agency referred to in Section 11.2.2 on an accelerated basis, Inex shall be responsible for performing Pharmacovigilance in respect of all pre-Regulatory Approval Clinical Activities (in addition to all other Regulatory Activities for which Inex is responsible). Until this agency is established, if Enzon receives any information of any type whatsoever that may constitute a complaint regarding the Product or indicates that the Product in any way relates to an Adverse Drug Event, then it will record the information set forth on Exhibit 1.1.1 and transmit the completed form to Inex as soon as possible, and in any event at least in time to allow Inex to meet its reporting obligations under Regulatory Requirements. Inex will then report the Adverse Drug Event in accordance with Regulatory Requirements, and provide Enzon with a copy(ies) of all documentation provided to Regulatory Authorities in respect of such complaint or Adverse Drug Event. Further, until this agency is established, if Inex receives any information of any type

whatsoever that may constitute a complaint regarding the Product or indicates that the Product in any way relates to an Adverse Drug Event, then it will record the information set forth on Exhibit 1.1.1, provide a copy of the completed form to Enzon (if possible, prior to submitting it to Regulatory Authorities) and report the Adverse Drug Event in accordance with Regulatory Requirements.

- 11.2.2 After Regulatory Approval of the Products by a Regulatory Authority (or sooner if and to the extent agreed to by the Parties), Enzon shall be appointed by Inex as Inex's agent with respect to the regulatory dossier for the Product in the Field in the Territory for the sole purpose of conducting Pharmacovigilance. After this agency has been established, Enzon shall manage and carry out on behalf of Inex all relevant communications and relations with Regulatory Authorities to the extent related to Pharmacovigilance with respect to the Product. Inex shall be entitled to participate in all negotiations and discussions between Enzon and Regulatory Authorities relating to Pharmacovigilance with respect to the Product. Without limiting the generality of the foregoing, after this agency has been established, if Inex receives any information of any type whatsoever that may constitute a complaint regarding the Product or indicates that the Product in any way relates to an Adverse Drug Event, then it will record the information set forth on Exhibit 1.1.1 and transmit the completed form to Enzon as soon as possible, and in any event at least in time to allow Enzon to meet its reporting obligations under Regulatory Requirements. Enzon will then report the Adverse Drug Event in accordance with Regulatory Requirements, and provide Inex with a copy(ies) of all documentation provided to Regulatory Authorities in respect of such complaint or Adverse Drug Event. Further, after this agency has been established, if Enzon receives any information of any type whatsoever that may constitute a complaint regarding the Product or indicates that the Product in any way relates to an Adverse Drug Event, then it will record the information set forth on Exhibit 1.1.1, provide a copy of the completed form to Inex (if possible, prior to submitting it to Regulatory Authorities) and report the Adverse Drug Event in accordance with Regulatory Requirements.
- 11.3 Agency for DDMAC Activities and the Like
  - 11.3.1 Inex hereby appoints Enzon as its agent for the Product in the Field in the Territory for the sole purpose of conducting all DDMAC Activities in the USA and the foreign equivalents in the remainder of the Territory.
  - 11.3.2 Enzon shall perform the DDMAC Activities in the USA and the foreign equivalents in the remainder of the Territory in compliance with Regulatory Requirements.
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- 11.3.3 Enzon will perform all DDMAC Activities in the USA and the foreign equivalents in the remainder of the Territory and subject to Section 11.2, be responsible for all post-approval Pharmacovigilance activities, and assume all the costs associated therewith.
- 11.3.4 In each country for which Inex is the holder of the Regulatory Approval, Enzon shall regularly inform Inex of Enzon's DDMAC Activities and foreign equivalents and obtain Inex's prior consent to Enzon's DDMAC Activities and foreign equivalents and plans respecting any of them. In the event Enzon informs Inex of its DDMAC Activities, foreign equivalents and plans, and does not receive a written objection from Inex within 10 Business Days, Inex shall be deemed to have consented to such activities and

plans.

- 11.4 Agent for Regulatory Authorities Generally
  - 11.4.1 Nothing in Sections 11.2, 11.3 or this Section 11.4 precludes Inex from appointing an agent for Regulatory Authorities for products other than the Product, or for territories outside the Territory.
  - 11.4.2 All activities, communications and relations as well as Enzon's role as agent for Regulatory Authorities shall be performed by Enzon in close coordination with Inex, as holder of the Regulatory Approvals.
  - 11.4.3 In respect of all of the foregoing under Sections 11.2, 11.3 or this Section 11.4, except as required by Regulatory Requirements and except for those reporting requirements which have timeliness requirements that make it impossible to seek and obtain Inex's consent prior to making such report, any communications with Regulatory Authorities by Enzon under Sections 11.2, 11.3 or this Section 11.4 are subject to the consent of the Inex, such consent not to be unreasonably withheld.
- 11.5 Recalls and Withdrawals of Product
  - 11.5.1 If Inex or Enzon will be required or requested by any Regulatory Authority to recall any Product for any reason, or should Enzon decide voluntarily to withdraw any Product:
    - (a) Enzon will be responsible for co-ordinating such recall or withdrawal;
    - (b) Enzon shall pay the costs and expenses of such recall or withdrawal, subject to recovery of some or all of same in accordance with the terms of Section 11.5.2;
    - (c) unless Inex is liable for such costs and expenses in accordance with the terms of Section 11.5.2, Enzon will remain responsible to Inex for the Purchase Price for such Product and will reimburse Inex for all of the reasonable costs and expenses actually incurred by Inex in connection with such recall or withdrawal including, but not limited to, administration of the recall or withdrawal and such other reasonable costs as may be reasonably related to the recall or withdrawal; and
    - (d) both Parties will cooperate fully with one another in connection with any such recall or withdrawal.
  - 11.5.2 If a recall or withdrawal is due to Inex's negligence, wilful misconduct or breach of this Agreement or Inex's failure to Manufacture the Product in conformity with the Specifications or the provisions of this Agreement or the Quality/Technical Agreement referred to in Section 4.6, Inex will reimburse Enzon for all of Enzon's reasonable costs
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and expenses actually incurred by Enzon in connection with the recall or withdrawal, including the Purchase Price for the recalled or withdrawn Product, costs of retrieving Product already delivered to customers, costs and expenses Enzon is required to pay for notification, shipping and handling charges, destruction or return of the defective Product or Product and such other reasonable costs as may be reasonably related to the recall or withdrawal.

11.5.3 If the Parties are unable to agree on whether or not a recall or withdrawal is due to Inex's negligence, wilful misconduct or

breach of this Agreement, either Party may refer the matter for resolution pursuant to Article 16.

#### 11.6 Replacement Shipments

In the event of a recall or withdrawal of Product, and upon Enzon's request, Inex shall use Commercially Reasonable Efforts to deliver replacement Product as soon as reasonably possible.

Article 12 Restrictive Covenants; Title

#### 12.1 Injunctive Relief

Each Party acknowledges the competitive and technical value and the sensitive and confidential nature of the Confidential Information and agrees that monetary damages alone will be inadequate to protect the other Party's interests against any actual or threatened material breach of this Agreement. Accordingly, each Party consents to the granting of specific performance and injunctive or other equitable relief to the other Party in respect of any actual or threatened breach of this Agreement, without proof of actual damages.

12.2 Ownership of Pre-Existing Intellectual Property Rights

Any Intellectual Property Rights or trademark rights owned by either Party prior to the Effective Date shall remain solely owned by such Party.

- 12.3 Ownership of Intellectual Property Rights in the Product
- All Intellectual Property Rights arising from and during the course of the Commercialization or Co-Promotion, including all Intellectual Property Rights:
  - 12.3.1 to all inventions arising from and during the course of the Commercialization or Co-Promotion;
  - 12.3.2 to all data, information, know-how and results and the like created as part of the Commercialization or Co-Promotion (the "Data"); and
  - 12.3.3 relating to the Product or improvements thereto or the process for manufacturing the Product;

shall be solely owned by Inex or its designee, regardless of:

- 12.3.4 which Party(ies) created or invented the same; and
- 12.3.5 whether or not such Intellectual Property Rights are required to
   obtain and maintain Regulatory Approvals;
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and shall be licensed to Enzon hereunder as Licensed Patents and Inex Technology without additional consideration or formality during the Term. Without limiting the generality of the foregoing, any Elan Improvements made by Enzon, or its Representatives, regardless of whether or not arising from and during the course of the Commercialization or Co-Promotion, shall be solely owned by Elan and sublicensed (within the Field and within the Territory) without additional consideration to Enzon through Inex on the terms set out in this Section. Enzon shall cooperate, and shall cause its Representatives to cooperate, with Inex and Elan, at Inex's expense, in perfecting Elan's ownership and other proprietary rights in respect of any Elan Improvements and shall execute and deliver, and cause its Representatives to execute and deliver, to Elan any documents that Elan may reasonably require with respect thereto. If at any time Elan does not exercise its rights under this Section, such rights may be exercised by Inex as if Inex were Elan under this Section.

12.4 Ownership of Regulatory Approvals and Regulatory Submissions

Notwithstanding the terms of Section 12.3:

- 12.4.1 Inex or an Affiliate of Inex will own all Regulatory Approvals and Regulatory Submissions made as part of the Commercialization or Co-Promotion in respect of the Product in the Territory and all Intellectual Property Rights in same; and
- 12.4.2 Inex may use all Data and Regulatory Approvals and Regulatory Submissions without further consideration, in Inex's efforts to register and commercialize the Product outside the Territory and inside the Territory but outside the Field.
- 12.5 Ownership of Intellectual Property Rights Outside the Commercialization and  $Co\mbox{-Promotion}$

Except as otherwise provided in Sections 12.3 and 12.4, and subject to provisions of the Development Agreement, each Party shall have and retain sole and exclusive title to all inventions, discoveries and know-how which are made, conceived, reduced to practice or generated by its Representatives. For greater certainty, Intellectual Property Rights or inventions or creations generated outside the Commercialization and Co-Promotion and without access to the other Party's Confidential Information shall not be licensed hereunder as or included in the Licensed Patents or Inex Technology.

## 12.6 Co-operation

Enzon shall make available to Inex or Inex's authorized attorneys any Enzon Representatives whom Inex in its reasonable judgment deems necessary in order to assist it in obtaining patent protection of the Licensed Patents and any applications therefor. Enzon shall execute all legal documents reasonably necessary to support the filing, prosecution and maintenance of said Patents. Enzon shall, at the request of Inex, enter into such further agreements and execute any and all documents as may reasonably be required to ensure that ownership of the Licensed Patents remains with Inex.

- 12.7 Prosecution and Maintenance of Licensed Patents
  - 12.7.1 Inex shall be responsible for and pay all future costs of prosecuting and maintaining the Licensed Patents.
  - 12.7.2 Subject to Inex's obligations to its licensors, if Inex decides to abandon prosecution or maintenance of a particular Licensed Patent whose claims relate directly to the Field, Inex will notify Enzon of such decision as soon as reasonably possible, and in any event no less than 30 days prior to the effective abandonment date. As for patent applications, upon receiving such notice, Enzon may request that Enzon have the right to continue such prosecution of such patent application, which request Inex will reasonably consider,
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but Inex need not grant such request in any event if Inex has a strategic reason, with respect to its prosecution strategy for its Patents, for abandoning such patent applications. As for issued patents, upon receiving such notice, Enzon will have the right at its sole discretion, to direct Inex to continue payment of maintenance fees of any such issued patents, at Enzon's expense.

## 12.8 Notice of Inventions

Each Party will report promptly any inventions or anything giving rise to Intellectual Property Rights arising in the course of and in connection with the Development, Commercialization or Co-Promotion to the other Party. Without limiting the generality of the foregoing, Enzon shall promptly notify Inex of any Elan Improvements, and Inex will notify Elan of such Elan Improvements.

#### 12.10 Elan a Third Party Beneficiary

The Parties agree that Elan is a third party beneficiary under this Agreement and shall have the right (at its option) to directly enforce any obligations for the benefit of Elan contained in this Agreement.

## Article 13 Allocation of Risk

## 13.1 Limits

Except as expressly set out in the Related Agreements, nothing in the Related Agreements shall be construed as:

- 13.1.1 a warranty or representation by Inex as to title to the Licensed Patents and Inex Technology or that anything made, used, sold or otherwise disposed of under the license granted in the Related Agreements is or will be free from infringement of patents, copyrights, trade-marks, industrial design or other intellectual property rights;
- 13.1.3 an obligation by Inex to bring or prosecute or defend actions or suits against Third Parties for infringement of patents, copyrights, trade-marks, industrial designs or other intellectual property or contractual rights;
- 13.1.4 the conferring by Inex of the right to use in advertising or publicity the name of Inex or its trade marks;
- 13.1.5 a warranty or representation by Enzon that anything made, used, sold or otherwise disposed of under the license granted in the Related Agreements is or will be free from infringement of patents, copyrights, trade-marks, industrial design or other intellectual property rights; or
- 13.1.6 the conferring by Enzon of the right to use in advertising or publicity the name of Enzon or its trade marks.
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13.2 \*\*\*

13.3 \*\*\*

13.4 Co-operation with Other Licensees

Enzon acknowledges that Inex or its Affiliates have granted rights:

- 13.4.1 in the Territory in respect of fields outside the Field, and
- 13.4.2 outside the Territory,

and may grant to other sublicensees rights:

- 13.4.3 in the Territory in respect of fields outside of the Field, or
- 13.4.4 outside the Territory,

similar to those granted to Enzon under Sections 13.2, 13.3 and this Section 13.4. In the event of any litigation of the kind described in Sections 13.2 and 13.3:

13.4.5 inside the Territory in fields outside of the Field, or outside the Territory, that may reasonably affect Enzon's use in the Territory of the Licensed Patents or Inex Technology in the Field or the use or sale of the Product; or 13.4.6 in respect of the Field that may reasonably affect Inex or one or more of Inex's or its Affiliates' sublicensee's use of the Licensed Patents or Inex Technology outside the Field or outside the Territory or the manufacture, use or sale of products outside the Field or outside the Territory by Inex, its Affiliates, or one or more other such sublicensee(s);

then Inex, Enzon and such other sublicensees will use good faith efforts to consult with each other and consider the interests of the other parties in determining the course of action, if any, necessary or appropriate to prosecute or defend the litigation. Inex will use Commercially Reasonable Efforts to include in its sublicense agreements, provisions that allow the participation of Enzon as contemplated herein.

Article 14 Indemnification and Liability Limitations

## 14.1 Indemnification by Enzon

- 14.1.1 Enzon hereby agrees that it shall be responsible for, indemnify, hold harmless and defend Inex and its Affiliates, and their respective shareholders, partners, Representatives, and their respective heirs, successors and assigns (collectively, the "Inex Indemnitees") from and against any and all claims, demands, losses, liabilities, damages, Development Costs and expenses (including reasonable legal fees) (collectively, "Losses") suffered or incurred by any Inex Indemnitee arising out of, relating to, resulting from or in connection with:
  - (a) any claim by Enzon's employees arising out of the employment by Enzon of such employees and related to the employment relationship or termination thereof; or
  - (b) any Third Party claims arising out of or relating to:
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- (i) the breach of any representation or warranty made by Enzon in any of the Related Agreements;
- (ii) the default by Enzon in the performance or observance of any of its obligations to be performed or observed under any of the Related Agreements;
- (iii) the breach by Enzon, its Affiliates or Sublicensees of any Regulatory Requirements in connection with the Product or in the performance or observance of any of its obligations to be performed or observed under any Related Agreement;
- (iv) the negligence or wilful misconduct of Enzon or its Representatives.
- 14.1.2 The foregoing shall not apply to the extent that such Losses are due to:
  - (a) the breach of any representation or warranty made by Inex in the Related Agreements;
  - (b) the default by Inex in the performance or observance of any of its obligations to be performed or observed under the Related Agreements;
  - (c) the breach by Inex of any Regulatory Requirements in connection with the Product or in the performance or observance of any of its obligations to be performed or

observed under the Related Agreements; or

(d) the negligence or wilful misconduct of Inex or its Representatives.

# 14.2 Indemnification by Inex

- 14.2.1 Inex hereby agrees that it shall be responsible for, indemnify, hold harmless and defend Enzon and Enzon's Affiliates and Sublicensees, and their respective shareholders, partners, Representatives, and their respective heirs, successors and assigns (collectively, the "Enzon Indemnitees"), from and against any and all Losses suffered or incurred by any Enzon Indemnitee arising out of, relating to, resulting from or in connection with:
  - (a) any claim by Inex's employees arising out of the employment by Inex of such employees and related to the employment relationship or termination thereof; or
  - (b) any Third Party claims arising out of or relating to:
    - (i) the breach of any representation or warranty made by Inex in any Related Agreement;
    - (ii) Inex's failure to convey to Enzon Intellectual Property Rights under the Regents' Patents at least co-extensive (within the Field and within the Territory as defined in the Related Agreements) with the scope of the Intellectual Property Rights under the Regents' Patents purported to be granted by Elan to IE pursuant to the Elan License;
    - (iii) the default by Inex in the performance or observance of any of its obligations to be performed or observed under any Related Agreement;

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- (iv) the breach by Inex of any Regulatory Requirements in connection with the Product or in the performance or observance of any of its obligations to be performed or observed under any Related Agreement; or
- (v) the negligence or wilful misconduct of Inex or its Representatives.
- 14.2.2 The foregoing shall not apply to the extent that such Losses are due to:
  - (a) the breach of any representation or warranty made by Enzon in the Related Agreements;
  - (b) the default by Enzon in the performance or observance of any of its obligations to be performed or observed under the Related Agreements;
  - (c) the breach by Enzon, its Affiliates or Sublicensees of any Regulatory Requirements in connection with the Product or in the performance or observance of any of its obligations to be performed or observed under the Related Agreements; or
  - (d) the negligence or wilful misconduct of Enzon or its Representatives.

In the event that a claim is made pursuant to Section 14.1 or 14.2 above against any person or entity which seeks indemnification hereunder (the "Indemnitee"), the Indemnitee shall give the indemnifying Party (the "Indemnitor") prompt notice of any claim or lawsuit or other action for which it seeks to be indemnified under this Agreement and agrees that the Indemnitor shall not have any obligation under the relevant Section unless:

- 14.3.1 the Indemnitor is granted, subject to the provisions of this Section 14.3 and the relevant provisions of Article 13, full authority and control over the defense, including settlement, against such claim or law suit or other action, and
- 14.3.2 the Indemnitee cooperates fully with the Indemnitor and its agents in defense of the claims or law suit or other action.

The Indemnitee shall have the right to participate in the defense of any such claim, complaint, suit, proceeding or cause of action referred to in this Section utilizing attorneys of its choice, at its own expense, provided however, that the Indemnitor shall, subject to the provisions of this Section 14.3 and the relevant provisions of Article 13, have full authority and control to handle any such claim, complaint, suit proceeding, or cause of action, including any settlement or other disposition thereof, for which the Indemnitee seeks indemnification under this Section, provided however, subject to the following sentence, that no settlement or consent judgment or other voluntary final disposition may be entered into without the consent of the Indemnitee if such settlement would require the Indemnitee to be subject to an injunction or to make a monetary payment or would restrict the claims in or admit any invalidity of any Licensed Patent(s) or significantly adversely affect the rights of the Indemnitee.

#### 14.4 Consequential Losses

NO PARTY WILL BE LIABLE FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY NATURE ARISING FROM SUCH PARTY'S ACTIVITIES UNDER THE RELATED AGREEMENTS; PROVIDED, HOWEVER, THAT THIS LIMITATION SHALL NOT LIMIT THE INDEMNIFICATION

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OBLIGATION OF SUCH PARTY UNDER SECTIONS 14.1 OR 14.2 FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES RECOVERED BY A THIRD PARTY.

## 14.5 Actions Between the Parties

For the avoidance of doubt, in connection with actions brought by one Party hereto against the other (whether for breach of any provisions hereof, any representation or warranty made herein or otherwise), each Party expressly reserves all of its rights and remedies under Applicable Law, including, without limitation, the right to sue for breach of contract.

## 14.6 Insurance

Except as provided for below, for the term of this Agreement and for a period of five years after the expiration of this Agreement or the earlier termination thereof, each of the Parties shall obtain and maintain, and shall cause their respective Affiliates and any Sublicensees to obtain and maintain, at their respective sole cost and expense, comprehensive general liability insurance, including product liability insurance on the Products, in amounts, which are reasonable and customary in the USA pharmaceutical industry for companies of comparable size and activities, but in no event less than \*\*\*. To the extent reasonably practicable, this insurance shall include the other Party and their respective Representatives as additional insureds. Each Party shall provide written proof of the existence of such insurance to the other Party upon request. If a Party maintains clinical trial insurance separate from its product liability insurance, which clinical trial insurance is in an amount that is reasonable and customary in the US pharmaceutical industry for companies of comparable size and activities, then the product liability insurance need not commence until FDA approval.

#### 15.1 Treatment of Confidential Information

Each Party hereto shall maintain the Confidential Information of the other Party in confidence, and shall not disclose, divulge or otherwise communicate such Confidential Information to others, or use it for any purpose, except pursuant to, and in order to carry out, the terms and objectives of the Related Agreements, and hereby agrees to exercise every reasonable precaution to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its Representatives.

#### 15.2 Permitted Disclosures

- 15.2.1 Either Party may disclose the Confidential Information of the other Party to its permitted Representatives to facilitate or carry out the activities under the Related Agreements, provided that such Third Parties enter into an agreement with such Party which contains confidentiality provisions substantially the same as those set forth herein, and such Party remains liable to the other Party for the breach of such terms by such Party's Representatives.
- 15.2.2 Either Party may disclose the Confidential Information of the other Party to its attorneys, accountants or other advisors, or actual or potential lenders, investors or purchasers, each of whom is subject to confidentiality restrictions similar to those set forth herein and such Party remains liable to the other Party for the breach of such terms by such persons.
- 15.2.3 Either Party may disclose the Confidential Information of the other Party to the extent such disclosure is required to be disclosed by the receiving Party to comply with Applicable Laws, to defend or prosecute litigation or to comply with governmental
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regulations, provided that the receiving Party provides prior written notice of such disclosure to the other Party and takes reasonable and lawful actions to avoid and/or minimize the degree of such disclosure, and provided further that disclosure of such Confidential Information pursuant to this Section shall not relieve the receiving Party of continued adherence to Section 15.1 with respect to such Confidential Information.

# 15.3 Publications Generally

The following restrictions shall apply with respect to the disclosure in scientific journals or publications or speeches by any Party or any employee or consultant of any Party relating to the inventions contained in the Licensed Patents and the Inex Technology or to the activities or results of the Development, Manufacture or Commercialization:

- 15.3.1 a Party (the "Publishing Party") shall provide the other Party with an advance copy of any proposed publication and such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to preserve Intellectual Property Rights or Confidential Information belonging in whole or in part to Inex or Enzon, and the incorporation of such recommended changes shall not be unreasonably refused; and
- 15.3.2 if such other Party informs the Publishing Party, within fifteen (15) Business Days after receipt of an advance copy of a proposed publication, that such publication in its reasonable judgment could be expected to have a material adverse effect on any Intellectual Property Rights or Confidential Information belonging in whole or in part to Inex or Enzon, the Publishing Party shall

delay or prevent such publication as proposed. In the case of inventions, the delay shall be sufficiently long to permit the timely preparation and filing of a patent application(s) or application(s) for a certificate of invention on the information involved but not less than ninety (90) days or more than 120 days.

Nothing in this Section 15.3 shall apply to Promotional Materials approved for use in accordance with the Co-Promotion Agreement.

## 15.4 No Limitation on Regulatory Compliance

Nothing in the Related Agreements shall be construed as preventing or in any way inhibiting either Party from complying with Regulatory Requirements governing the development, manufacture, use and sale or other distribution of Product in the Territory in any manner which it reasonably deems appropriate, including, for example, by disclosing to Regulatory Authorities confidential or other information received from the other Party.

#### Article 16 Dispute Resolution

#### 16.1 Negotiation

Subject to Section 12.1 of this Agreement:

- 16.1.1 If a dispute or controversy regarding any right or obligation under the Related Agreements arises between the Parties and cannot be resolved within fifteen (15) days of the dispute or controversy, or within such other period as may be agreed by the Parties, the Parties will seek to resolve such dispute or controversy or failure to agree by good
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faith negotiation between senior management representatives of the Parties, to be commenced promptly after such dispute or controversy or failure to agree arises.

16.1.2 If such dispute or controversy or failure to agree is not resolved by such negotiation within thirty (30) days after written notice by one Party to the other, and at least one Party requires such resolution, then the Parties shall proceed as follows: any unresolved dispute, controversy, action, claim or proceeding initiated by either Party (other than a Third Party action, claim or other proceeding in a bona fide action, claim or other proceeding initiated by a Third Party against a Party) relating to, arising out of or resulting from any Related Agreement, or the performance by either Party of its obligations under any Related Agreement, or any alleged breach, termination or invalidity of any Related Agreement, whether before or after termination or expiration of any Related Agreement, shall be finally resolved by binding arbitration pursuant to Section 16.2.

## 16.2 Arbitration

Subject to Section 12.1 of this Agreement, in the event of any unresolvable dispute, difference, or question arising between the Parties in connection with the Related Agreements or any clause or the construction thereof, or the rights, duties or liabilities of either Party, or the scope or validity of any patent licensed hereunder, the matter shall be submitted for arbitration in accordance with the rules of the American Arbitration Association. Such arbitration shall take place in Chicago, Illinois or as otherwise agreed by the Parties. A single arbitrator shall be appointed by agreement of the Parties to resolve all such disputes, differences or questions. The arbitrator shall be guided by the contents of the Related Agreements in arriving at a decision to resolve the dispute, but may rely on extrinsic evidence where appropriate and/or necessary. The arbitrator's resolution must be pursuant to and consistent with the laws of Delaware. The Parties shall share the cost of the arbitration unless, in the arbitrator's opinion, the position advanced by one of the Parties, or the nature

or manner of presenting it, is such that it would be unfair to so apportion such expenses, in which case the arbitrator may apportion such expenses differently.

#### 16.3 Consent to Jurisdiction

Subject to Section 12.1 of this Agreement, the parties hereto irrevocably consent to the non-exclusive personal jurisdiction of any state or federal court in the Northern District of Illinois for the enforcement of any arbitration award arising under the Related Agreements.

#### Article 17 Termination

## 17.1 Term of Agreement

This Agreement shall become effective on the Effective Date and, unless earlier terminated as provided for herein, shall expire, on a country-by-country basis, upon the later of:

- 17.1.1 expiration of the last to expire of the Licensed Patents containing Valid Claims covering the Product in such country in the Territory; and
- 17.1.2 fifteen years from the date of the First Commercial Sale in that country;

and such period shall be the "Term" under this Agreement.

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#### 17.2 Renewal

On or before six months before the expiration of this Agreement in accordance with its terms in any country in the Territory, Enzon may notify Inex in writing that Enzon wishes to renew this Agreement. In the event that Enzon so notifies Inex, the Parties will negotiate in good faith for the extension of the Term. If the Parties have not reached agreement in writing to extend the Term on or before the expiry of the Term in such country, this Section 17.2 shall be of no further force or effect.

#### 17.3 Termination for Breach

Each Party shall be entitled to terminate this Agreement by written notice to the other Party in the event that the other Party shall be in material default of any of its obligations hereunder, and shall fail to remedy any such default within ninety (90) days after notice thereof by the non-breaching Party. Any such notice shall specifically state that the non-breaching Party intends to terminate this Agreement in the event that the breaching Party shall fail to remedy the default. Any such notice shall set out expressly the actions required of the breaching Party to remedy the default. If such default is not corrected, the non-breaching Party shall have the right to terminate this Agreement by giving written notice to the Party in default provided the notice of termination is given within six (6) months of the default and prior to correction of the default.

## 17.4 Termination upon Bankruptcy

- 17.4.1 This Agreement may be terminated by a Party by providing written notice to the other Party upon:
  - (a) the bankruptcy, liquidation or dissolution of the other Party;
  - (b) the filing of any voluntary petition for bankruptcy, dissolution, liquidation or winding-up of the affairs of the other Party; or
  - (c) the filing of any involuntary petition for bankruptcy, dissolution, liquidation or winding-up of the affairs of

the other Party which is not dismissed within one hundred twenty (120) days after the date on which it is filed or commenced.

- 17.4.2 Notwithstanding the foregoing, either Party may seek the waiver of the operation of Section 17.4.1 in advance of any event giving rise to a right of termination under Section 17.4.1(b), and, provided that:
  - (a) the requesting Party is in good standing and not in breach of any of the terms of the Related Agreements;
  - (b) the requesting Party is in reasonable financial condition; and
  - (c) the Party whose consent is sought will not be prejudiced by granting such waiver,

the Party whose consent is sought will not unreasonably withhold its consent to such waiver. Such waiver may be revocable in the event of a material adverse change in circumstances related to the requesting Party not contemplated at the time of granting the waiver.

## 17.5 Termination of Related Agreements

In the event of termination of this Agreement, the Related Agreements shall terminate with immediate effect, subject to any continuing or surviving obligations as set forth in each such Related Agreement.

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## 17.6 Effect of Termination

The termination of this Agreement for any reason will be without prejudice to:

- 17.6.1 at Enzon's option and request, and subject to the terms of this Agreement, Inex shall continue to perform its obligations hereunder in respect of any Purchase Orders delivered to Inex prior to the effective date of such termination, and Enzon will pay Inex for any such Product received in accordance with such Purchase Order(s);
- 17.6.2 Inex's right to receive all payments accrued from Enzon as of the effective date of such termination including, but not limited to, payment for all Product for which a Purchase Order has been received as of the effective date of such termination and for which Enzon has elected to have Inex perform its obligations hereunder pursuant to Section 17.6.1;
- 17.6.3 Inex's right to receive reimbursement for all costs and liabilities incurred by Inex as of the date of Inex's receipt of Enzon's notice of termination, which cost and liabilities Inex has properly and reasonably incurred in exercising good supply chain management practices in response to Enzon's Forecast. For greater certainty, such costs and liabilities shall include all reasonable and necessary non-cancellable obligations entered into prior to Inex's receipt of Enzon's notice of termination, but arising after Inex's receipt of Enzon's notice of termination; and
- 17.6.4 any other legal, equitable or administrative remedies as to which either Party may then or thereafter become entitled.

## 17.7 Consequences of Termination in Certain Circumstances

## 17.7.1 In the event of:

(a) the termination of this Agreement by Enzon pursuant to

Sections 17.3 or 17.4:

- (i) Inex hereby provides Enzon permission to provide the FDA and any foreign equivalent of the FDA in the Territory with reference access to Inex's NDA filed or to be filed in the United States, Canada and elsewhere and such other Regulatory Submissions as Enzon may request. In countries in the Territory where required by Regulatory Requirements, Enzon may incorporate Inex's NDA and Regulatory Submissions into Enzon's own submissions;
- (ii) Inex will use Commercially Reasonable Efforts, at Enzon's expense, to transfer the Inex Technology then in the possession of Inex to the extent necessary to permit Enzon or its designee to Manufacture the Product. Where the Manufacturing is performed by Third Parties, Inex shall use Commercially Reasonable Efforts to assist Enzon, at Enzon's expense, in dealing with such Third Parties; and
- (iii) Enzon will buy Inex's raw materials, work in progress and inventory of Product at Inex's cost of same; and
- (iv) For up to three years after the effective date of such termination, Inex shall use Commercially Reasonable Efforts to ensure that Enzon has a continuous and uninterrupted supply of Product, on commercially

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reasonable terms to the extent under Inex's reasonable control, until Enzon has a reasonably secure alternative source of supply for the Product, provided that Enzon is using Commercially Reasonable Efforts to obtain such an alternative source of supply.

- (b) termination of this Agreement by Inex pursuant to Sections 17.3 or 17.4, Inex may, on notice in writing to Enzon, do any or all of the following:
  - (i) cause Enzon to buy Inex's raw materials, work in progress and inventory of Product at Inex's cost of same;
  - (ii) cause Enzon to assign to Inex any Trademarks and all registrations and applications therefor without additional consideration; and
  - (iii) terminate the license to certain Inex Trademarks set out in Section 9.3.
- 17.7.2 Enzon shall within thirty (30) days after the effective date of a termination pursuant to this Article 17, notify Inex in writing of the amount of the Product which Enzon, its Affiliates and Sublicensees then have on hand, the sale of which would, but for the termination, be subject to payments to Inex in accordance with this Agreement, and Enzon, its Affiliates and Sublicensees shall thereupon be permitted during the six (6) month period following such termination to sell that amount of the Product, provided that Enzon shall pay the aggregate sums owed to Inex pursuant to this Agreement thereon at the conclusion of the earlier of the last such sale or such period.

## 17.8 Additional Consequences of Termination

- 17.8.1 On or before the effective date of termination of this Agreement, Enzon shall promptly deliver to Inex a copy of all Data and such other information, materials (including biological materials) and documents in Enzon's possession or control arising from the development of the Product under this Agreement, including, without limitation, the Development, provided that Inex shall be responsible for any reasonable associated Out-of-Pocket Costs associated with transferring same;
- 17.8.2 In the event that termination occurs before the payment of all Manufacturing Costs referred to in Article 2, then, concurrently with such termination, Enzon shall pay to Inex such payment on the effective date of such termination.
- 17.9 Survival of Obligations; Return of Confidential Information
  - 17.9.1 Upon any termination of this Agreement pursuant to this Article 17, neither Party shall be relieved of any obligations incurred prior to such termination.
  - 17.9.2 Notwithstanding any termination of this Agreement, the obligations of the Parties under Article 1, Sections 2.8, 2.9, 2.11, 2.12, 2.13, 5.6, 5.7, 6.2, 6.3, 6.4, 9.12 and 11.5, Article 12, Article 13, Article 14, Article 15, Article 16, Article 17 and Article 18, as well as under any other provisions which by their nature are intended to survive any such termination, shall survive and continue to be enforceable.
  - 17.9.3 Upon any termination of this Agreement pursuant to Article 17, except as contemplated hereby, each Party shall promptly return to the other Party all Manufactured materials, written Confidential Information, and all copies thereof (except for one archival copy to
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be retained by a person designated by such Party (who shall not make such Confidential Information generally available to employees or other representatives of such Party) for the purpose of confirming which information to hold in confidence hereunder), of the other Party which is not covered by a license surviving such termination.

# Article 18 Miscellaneous

## 18.1 Assignment

- 18.1.1 The rights and obligations set out in this Agreement are personal to each Party and for this reason, except as expressly set out in this Agreement, this Agreement will not be assignable by either Party in whole or in part, nor will either Party subcontract any of its obligations hereunder without the prior written consent of the other Party, which consent shall not be withheld or delayed unreasonably; provided, however, that the restriction contained herein will in no way limit the rights of either Party to:
  - (a) assign or subcontract any right or obligation hereunder to any of its Affiliates; or
  - (b) appoint as its agent for any purpose of this Agreement any such Affiliate; or
  - (c) assign any right or obligation hereunder to any person or entity that:

- (i) purchases all or substantially all of its assets to which this Agreement relates or
- (ii) purchases all or substantially all of the stock of either Party; or
- (iii) acquires or is combined with either Party in a merger or some other form of business combination.
- 18.1.2 This Agreement will be binding upon and will enure to the benefit of the parties hereto and to any permitted assignee or successor of either party.
- 18.1.3 Subject to other provisions of this Section 18.1, if one Party validly assigns or subcontracts any or all of its obligations hereunder, such assigning or subcontracting Party agrees to remain bound by all of its responsibilities and obligations hereunder.
- 18.1.4 Any and all assignments of this Agreement or any interest herein not made in accordance with this Section 18.1 will be void ab initio.

#### 18.2 Counterparts

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

#### 18.3 Exhibits and Appendices

Each exhibit hereto is incorporated by reference and made a part of this Agreement.

#### 18.4 Force Majeure

In the event that either Party is prevented from performing or is unable to perform any of its obligations under this Agreement due to any act of God; fire; casualty; flood; war; strike; lockout; failure of public

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utilities; injunction or any act, exercise, assertion or requirement of governmental authority; epidemic; destruction of production facilities; riots; insurrection; failure of transportation; inability to procure or use materials, or any other cause beyond the reasonable control of the Party invoking this Section 18.4 if such Party shall have used its reasonable efforts to avoid such occurrence, such Party shall give notice to the other Party in writing promptly, and thereupon the affected Party's performance shall be excused and the time for performance shall be extended for the period of delay or inability to perform due to such occurrence.

#### 18.5 Further Assurances

Each Party hereto agrees to execute, acknowledge and deliver such further instruments and do all such further acts as may be necessary or appropriate to carry out the purposes and intent of this Agreement.

# 18.6 International Sale of Goods Act

The Parties acknowledge and agree that the International Sale of Goods Act and the United Nations Convention on Contracts for the International Sale of Goods have no application to this Agreement.

## 18.7 Modification

No waiver, alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed by the Parties by their respective officers thereunto duly authorized.

## 18.8 No Agency

Except as explicitly set forth herein, nothing herein shall be deemed to constitute either Party as the agent or representative of the other Party, or both Parties as joint venturers or partners for any purpose. Inex shall be an independent contractor, not an employee of Enzon, and the manner in which Inex renders its services under this Agreement shall be within Inex's sole discretion. Neither Party shall be responsible for the acts or omissions of the other Party, and neither Party will have authority to speak for, represent or obligate the other Party in any way without prior written authority from the other Party.

## 18.9 No Solicitation or Hiring of Employees

During the Term and for one year thereafter, neither Inex nor Enzon shall, without the prior consent of the other Party, solicit the employment of or hire any person who during the course of employment with the other Party was involved with activities under the Commercialization Plan and who when solicited or to be hired is a current employee of the other Party.

#### 18.10 Non-Use of Names

Except as otherwise expressly set out in this Agreement, neither Party shall use the name of the other Party, nor any adaptation thereof, in any advertising, promotional or sales literature without prior written consent obtained from such other Party in each case (which consent shall not be unreasonably withheld or delayed).

#### 18.11 Notices

Any notice or other communication in connection with this Agreement must be in writing and if by mail, by registered mail, return receipt requested, and shall be effective when delivered to the addressee at the address listed below or such other address as the addressee shall have specified in a notice actually received by the addressor.

#### If to Inex:

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Inex Pharmaceuticals, Inc.
c/o Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

Attention: President and CEO

With copies to:

Inex Pharmaceuticals Corporation
100-8900 Glenlyon Parkway
Burnaby, British Columbia
Canada V5J 5J8
Fax: 604-419-3202
Attention: Sr. V.P. Commercial Operations;

With a copy to:

Inex Pharmaceuticals Corporation 100-8900 Glenlyon Parkway Burnaby, British Columbia Canada V5J 5J8 Fax: 604-419-3202 Attention: Business Development

and:

Lang Michener 1500-1055 West Georgia Street Vancouver, British Columbia Canada V6E 4N7 Fax: 604-685-7084

and:

Farris, Vaughan, Wills & Murphy 2600 - 700 West Georgia Street Vancouver, British Columbia Canada V7Y 1B3

Fax: 604-661-9349
Attention: James Hatton

Attention: Leo Raffin

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If to Enzon:

ENZON PHARMACEUTICALS, INC. 685 Route 202/206
Bridgewater, New Jersey 08807

Fax: 908.541.8680

Attention: Vice President, Business Development

with a copy to:

Enzon Pharmaceuticals, Inc. 685 Route 202/206
Bridgewater, NJ 08807
Fax: 908.541.8838

Attention: General Counsel

# 18.12 Parallel Imports

Enzon and Inex shall each use its Commercially Reasonable Efforts to provide that each Party's sublicensees, distributors or dealers to whom each Party or its Affiliates or sublicensees sells the Products for resale shall not sell any Product to any customer located outside any country or region of the Territory where each Party may exercise its rights.

# 18.13 Publicity

Except as required by law, stock exchange or Regulatory Authority:

- 18.13.1 neither Party, nor any of its Affiliates, shall originate any publicity, news release or other public announcement, written or oral, relating to this Agreement or the existence of an arrangement between the Parties, without the prior written approval of the other Party and agreement upon the nature and text of such announcement or disclosure, which approval shall not be unreasonably withheld;
- 18.13.2 the Party desiring to make any such public announcement or other disclosure shall inform the other Party of the proposed announcement or disclosure in reasonably sufficient time prior to public release, and shall provide the other Party with a written copy thereof, in order to allow such other Party to comment upon such announcement or disclosure; and
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18.13.3 notwithstanding the foregoing, the Parties agree that the press release set out in Exhibit 18.13.3 shall be released by the Parties upon execution and delivery of this Agreement by both Parties.

## 18.14 No Third Party Beneficiaries

Except as expressly set out in this Agreement, nothing in this Agreement is intended to or shall confer upon any Third Part any legal or equitable right, benefit or remedy of any nature whatsoever.

#### 18.15 Waiver

The waiver by either Party of a breach or a default of any provision of this Agreement by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision, nor shall any delay or omission on the part of either Party to exercise or avail itself of any right, power or privilege that it has or may have hereunder operate as a waiver of any right, power or privilege by such Party.

## 18.16 Cross Default

A breach of or default under any of the Related Agreements other than the Co-Promotion Agreement shall constitute a breach of and default under all the Related Agreements.

IN WITNESS WHEREOF, the Parties have executed this Product Supply Agreement as of the date first above written.

Inex Pharmaceuticals, Inc.

By: /s/ David J. Main

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Name: David J. Main Title: President & CEO

Enzon Pharmaceuticals, Inc.

By: /s/ Arthur J. Higgins

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Name: Arthur J. Higgins Title: Chairman & CEO

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## Exhibit 1.1.1: Adverse Drug Event

#### ADVERSE DRUG EVENT FORM

An Adverse Drug Event shall mean any noxious, unintended, or untoward medical occurrence in a patient or clinical investigation subject associated with the use of a medicinal or investigational product, whether or not related to the medicinal or investigational product.

This Form must be completed and faxed to the Regulatory Authorities (with a copy provided to the other Party):

- a) Immediately, or not later than 24 hours following receipt of any information relating to an Adverse Drug Event; and
- b) No later than two (2) business days following receipt of any information relating to a product complaint.

Complaint Date:				
	Camalaint	Data		

Complaint received by:		Title:
Manner complaint recei	ved in: Oral  _  W	Written     Faxed
	Other:	
Complainant's name:	Phone:	Fax:
Clinic's name:	Phone:	Fax:
Clinic's Address:		
Product Name:	Lot number:	Expiry Date:
Description of Product	Complaint or Adverse Dr	rug Event:

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## Exhibit 1.1.44: Master Production Record

Inex SOP 1202.28-RO Manufacturing of Vincristine Sulfate Liposomes Injection (14.2 mg/mL) (incorporated by reference)

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## Exhibit 1.1.71: Specifications

Specifications as set forth in the approved NDA will be inserted upon FDA approval

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## Exhibit 1.1.77: Trademarks in the Territory

The trademark which the FDA approves for use in association with the Product in the USA and its Canadian counterpart.

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confidential treatment made in accordance with Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The Confidential material is being filed separately with the Secretary to the Securities and Exchange Commission.

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Exhibit 2.1.1(a): Manufacturing Cost

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Exhibit 2.1.1(b): Deferred Sales Price and Deferred Sales Payments

In partial consideration for the purchase of Product, Enzon shall pay Inex Deferred Sales Payments based on all Net Sales in the Territory of the Product by Enzon, its Affiliates and Sublicensees at the following rates, calculated in the manner set out below and in Article 2:

\_\_\_\_\_\_

Deferred Sales Price

Annual Net Sales of Product in Territory (\$)

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Exhibit 9.10: Interim Budget

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Exhibit10.1: Joint Steering Committee Responsibilities and Initial Constituency

The members of the Joint Steering Committee as of the Effective Date are:

For Enzon:

Eddy Anglade, VP - Clinical

Clarke Atwell, VP - Sales & Marketing

Katherine Bishburg, VP - Regulatory

Eric Liebler, VP - Business Development

For Inex:

Tom MacRury, Senior VP, Commercial Operations

Alexandra Mancini, Senior VP, Clinical and Regulatory Affairs

Jeff Charpentier, VP Finance and CFO

Linda Diano, Director, Project Management

The Joint Steering Committee shall have the following responsibilities:

- review amendments to the Commercialization Plan and submit same to the Parties for review and approval;
- establish working committees to conduct work under the Commercialization Plan;
- 3. assign responsibility for conducting all needed Commercialization work appropriately between the Parties, including providing for subcontractors to perform certain tasks if desirable;
- 4. oversee all Commercialization activities;
- 5. coordinate between the Parties with respect to the overall strategy for Commercialization;
- 6. review the reports of Commercialization Costs;
- 7. review the reports of Net Sales against sales targets;
- 8. be the primary contact point between the Parties regarding the transfer of information and the discussion of each Party's efforts to conduct Commercialization;
- 9. such other duties and responsibilities as may be agreed upon by the Parties; and
- 10. be the primary contact point between the Parties regarding the transfer of information and the discussion of each Party's efforts to conduct Commercialization.
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#### Exhibit 18.13.3: Press Release

ENZON AND INEX SIGN COMMERCIALIZATION PARTNERSHIP FOR ONCOLOGY DRUG ONCO TCS

Bridgewater, NJ, and Vancouver, Canada - January XX, 2004 - Enzon Pharmaceuticals, Inc. ("Enzon"; NASDAQ: ENZN) and Inex Pharmaceuticals Corporation ("INEX"; TSX: IEX) today announced a strategic partnership to develop and commercialize INEX's proprietary oncology product Onco TCS.

Under the terms of the agreement, Enzon receives the exclusive North American commercialization rights for Onco TCS for all indications. The lead indication is relapsed aggressive non-Hodgkin's lymphoma (NHL) for which INEX is in the process of submitting a "rolling" New Drug Application (NDA) to the United States Food and Drug Administration (FDA), which is expected to be completed during the first quarter of calendar year 2004. The product is also in numerous phase II clinical trials for several other cancer indications, including first-line NHL.

INEX receives a US\$12 million up-front payment and will receive up to a US\$20 million payment upon Onco TCS receiving approval from the FDA. Additional development milestones and sales based bonus payments could total US\$43.75 million, of which US\$10 million is payable upon annual sales first reaching US\$125 million and US\$15 million is payable upon annual sales first reaching US\$250 million. INEX will also receive a percentage of commercial sales of Onco TCS and this percentage will increase as sales reach certain predetermined thresholds.

INEX has the option of complementing Enzon's sales efforts by co-promoting Onco TCS through the formation of a dedicated North American sales and medical

science liaison force. The costs of building INEX's co-promotion force would be shared equally by both companies and Enzon will record all sales in the licensed territories.

Arthur Higgins, Enzon's chairman and chief executive officer, said, "This transaction is highly complementary to our R&D and manufacturing infrastructure, is an excellent fit with the therapeutic focus of our field force and most importantly, offers the potential to significantly increase Enzon's product revenues beginning as soon as fiscal 2005."

David Main, INEX's president and chief executive officer, said the agreement meets INEX's objectives for a commercialization partnership. "It rewards our company for successfully taking Onco TCS through clinical trials and through to an NDA, it gives us a strong partner dedicated to oncology with which to share costs of commercializing Onco TCS and expanding its potential uses. It also lets us benefit from future sales with a formula for capturing an increasing share of commercial sales."

"Enzon has expertise in the development, manufacturing and marketing of liposomal drugs and has the motivation to make Onco TCS sales an important part of its future," Main said. "This deal also provides a cost-effective means for us to build our own commercial infrastructure to work alongside Enzon's, which is important for our future growth strategy and pipeline activities."

Enzon and INEX will share equally the future development costs designed to obtain and maintain marketing approvals in North America for Onco TCS, while Enzon will pay all sales and marketing costs and certain other post-approval clinical development costs typically associated with commercialization activities. Enzon plans to market Onco TCS through its entire North American

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sales force of approximately 60 people, which currently markets ABELCET(R), ONCASPAR(R), and DEPOCYT(R) to the oncology market.

INEX retains manufacturing rights and will initially manufacture and supply the drug and be reimbursed by Enzon. INEX and Enzon are discussing the potential of transferring manufacturing to Enzon's sterile injectable manufacturing facility in Indianapolis, Indiana where Enzon manufacturers its commercial drug ABELCET(R) (Amphotericin B Lipid Complex Injection) and where MYOCETTM (liposome encapsulated doxorubicin citrate complex) is manufactured for Elan Corporation, plc.

The companies will also explore the acquisition and joint development of other cancer drugs.

About Onco TCS

Onco TCS is a proprietary drug comprised of the widely used off-patent cancer drug vincristine encapsulated in INEX's TCS (liposomal) drug delivery technology. The TCS technology provides prolonged blood circulation, tumor accumulation and extended drug release at the cancer site. These characteristics are designed to increase the effectiveness and reduce the side effects of the encapsulated drug.

INEX has completed a pivotal phase II/III clinical trial treating relapsed aggressive NHL with Onco TCS. Currently, there is no effective treatment for patients with aggressive NHL that have relapsed following first-line and second-line treatment.

INEX's multi-center pivotal phase II/III trial treated 119 NHL patients who had not responded to their previous therapy or had responded and subsequently relapsed. After treatment with Onco TCS, an overall response rate of 25% was attained. The results of this pivotal trial were released in June 2003 and presented in December 2003 at the American Society of Hematology annual conference along with interim results from two ongoing phase II trials in relapsed Hodgkin's disease and relapsed B-cell lymphoma.

INEX has submitted two major sections of its "rolling" NDA to the FDA seeking marketing approval for Onco TCS as a treatment for relapsed aggressive NHL. The first section was submitted September 30, 2003 and included nonclinical, safety and pharmacology data. The second section was submitted December 3, 2003 and included data on manufacturing process, stability of the drug, composition of the drug and other chemistry and related information. INEX expects the third and final section, containing data from clinical trials, to be submitted during the first quarter of calendar year 2004.

A "rolling" NDA is a process used by the FDA to expedite the review of a drug intended for the treatment of a serious or life threatening condition and that demonstrates the potential to address an unmet medical need. This allows the FDA to begin to review sections of the NDA as they are submitted, as opposed to the normal approval process, which requires the entire NDA to be submitted at one time. In order to be eligible to submit a rolling NDA, a company will usually have been granted Fast Track designation by the FDA, which INEX received in August 2000.

Subject to acceptance of the full NDA for review, INEX expects to have a response from the FDA within six months. If approved, it is anticipated that Onco TCS could be introduced to the marketplace before the end of calendar year 2004 or early in 2005.

Although INEX has chosen to file an NDA for relapsed aggressive NHL as the first route to approval for Onco TCS, Enzon and INEX intend to develop Onco TCS for use as a stand-alone  $\frac{1}{2}$ 

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drug and/or in combination therapy for several cancers in which vincristine is now used. Onco TCS is being evaluated in several phase II clinical trials as a treatment for first-line NHL, relapsed small cell lung cancer, relapsed Hodgkin's disease, relapsed acute lymphoblastic leukemia, relapsed pediatric malignancies, relapsed NHL in combination with the approved cancer drug Rituxan(R) (rituximab), and relapsed NHL in combination with the approved cancer drug etoposide.

About Non-Hodgkin's Lymphoma (NHL)

NHL is the fifth-leading cause of cancer deaths in the United States (23,400 estimated in 2003) and the sixth-leading cause of cancer deaths in Canada (2,800 estimated in 2003), according to estimates of the American Cancer Society and the Canadian Cancer Society. Approximately 53,400 and 6,400 new cases were diagnosed in the U.S. and Canada respectively in 2003.

Enzon Conference Call

Company management of Enzon will be hosting a conference call on Wednesday, January 14, 2004 at 7:30 AM EST regarding the agreement. All interested parties can access the call using the following information:

Domestic dial-in number 888-423-3274

International dial-in number 612-332-0345

Access Code 717232

Enzon's conference call will also be webcast in a "listen only" mode via the internet at http://www.vcall.com. Additionally, for those parties unable to listen at the time of Enzon's conference call, a rebroadcast will be available following the call from Wednesday, January 14, 2004 at approximately 11:00 AM. This rebroadcast will end on Wednesday, January 21, 2004 at 11:59PM. The rebroadcast may be accessed using the following information:

Domestic Dial-In Number: 800-475-6701

International Dial-In Number: 320-365-3844

Access Code: 717232

#### INEX Conference Call

Company management of INEX will be hosting a conference call on Wednesday, January 14, 2004 at 8:30 AM EST regarding the formation of the partnership. All interested parties can access the call using the following information:

Dial-In Number: 416-405-9328

North American toll free access: 800-387-6216

INEX's conference call will also be webcast via the internet at www.inexpharm.com.

Additionally, for those parties unable to listen at the time of INEX's conference call, a replay will be available shortly following the completion of the call. This rebroadcast will end on January 20, 2004 at 11:59 PM. The rebroadcast may be accessed using the following information:

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Dial-In Number: 416-695-5800

North American toll free access: 800-408-3053

Access Code: 1520395

### About INEX

INEX is a Canadian biopharmaceutical company developing and commercializing proprietary drugs and drug delivery systems to improve the treatment of cancer.

INEX entered into the partnership with Enzon through agreements entered into by its wholly owned U.S. subsidiary, Inex Pharmaceuticals, Inc.

### About Enzon

Enzon Pharmaceuticals is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics to treat life-threatening diseases. The company has developed or acquired a number of marketed products, including PEG-INTRON(R), marketed by Schering-Plough, and ABELCET(R), ONCASPAR(R), ADAGEN(R), and DEPOCYT(R), which are all marketed in North America by Enzon's hospital and oncology sales forces. Enzon's science-focused strategy includes an extensive drug development program that leverages the Company's macromolecular engineering technology platforms, including PEG modification and single-chain antibody (SCA(R)) technologies Internal research and development efforts are complemented by strategic transactions that provide access to additional products, projects, and technologies. Enzon has several drug candidates in various stages of development, independently and with partners.

There are forward-looking statements contained herein that are not based on historical fact, including without limitation statements containing the words "believes," "may," "plans," "will," "estimate," "continue," "anticipates," "intends," "expects," and similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, events or developments to be materially different from actual future results, events or developments. Such factors include the risk that Onco-TCS may not receive regulatory approval from the FDA, as well as those described in Enzon's Form 10-K and Forms 10-Q on file with the SEC and INEX's publicly filed periodic reports and others, such as, (i) as to Enzon, Enzon's ability to successfully launch and market Onco-TCS, Enzon's ability to sustain profitability, and positive cash flow; risks in obtaining and maintaining regulatory approval for indications and expanded indications for Enzon's products; market acceptance of and continuing demand for Enzon's products; timing and results of clinical trials and the impact of competitive products and pricing and (ii) as to INEX, INEX's stage of

development, lack of product revenues, additional capital requirements, risks associated with the completion of clinical trials and obtaining regulatory approval to market INEX's products, risks associated with the failure to secure all necessary intellectual property from third parties, the ability to protect its intellectual property and dependence on collaborative partners. These factors should be considered carefully and readers are cautioned not to place undue reliance on such forward-looking statements. All information in this press release is as of January , 2004, and Enzon and INEX undertake no duty to update this information.

This release is also available at http://www.enzon.com and http://www.inexpharm.com

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Contacts for Enzon Pharmaceuticals, Inc.

Contacts for Inex Pharmaceuticals

Corporation

Investors

Investors

Susan M. Mesco

Ian Mortimer

Director, Investor Relations

Senior Director, Investor Relations

Phone: 908-541-8678

Phone: 604-419-3200

Media

Media

Euro RSCG Life NRP Mark Vincent

James Hoggan & Associates Inc.

Karen Cook Boas

Phone : 212-845-4239

Phone: 604-739-7500

Enzon's common shares are traded on NASDAQ under the trading symbol "ENZN".

INEX's common shares are traded on the Toronto Stock Exchange under the trading symbol "IEX".

## CO-PROMOTION AGREEMENT

## BETWEEN

## INEX PHARMACEUTICALS, INC.

AND

## ENZON PHARMACEUTICALS, INC.

# January 19, 2004

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#### CO-PROMOTION AGREEMENT

This CO-PROMOTION AGREEMENT dated as of the 19th day of January, 2004 between Inex Pharmaceuticals, Inc., a corporation duly incorporated pursuant to the laws of Delaware, USA, having a registered office at Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801 (hereinafter referred to as "Inex"), and Enzon Pharmaceuticals, Inc., a corporation duly incorporated pursuant to the laws of Delaware, having a principal place of business at 685 Route 202/206, Bridgewater, New Jersey 08807 (hereinafter referred to as "Enzon").

#### INTRODUCTION

- A. Enzon is a pharmaceutical company with operations in research and development, import, manufacture and sale of pharmaceutical products;
- B. Inex is in the business of developing, manufacturing and selling certain pharmaceutical products, including Vincristine Sulfate Liposomes Injection (as further defined in this Agreement);
- C. Of even date hereof, the Parties have entered into a Product Supply Agreement pursuant to which Inex will supply to Enzon Vincristine Sulfate Liposomes Injection (the "Product Supply Agreement");
- D. Of even date hereof, the Parties also have entered into a Development Agreement for the development of Vincristine Sulfate Liposomes Injection and for the purpose of providing for the Regulatory Approval of, and conveying certain rights to Enzon with respect to, Inex's Vincristine Sulfate Liposomes Injection product in the Territory (the "Development Agreement"); and
- E. Subject to the terms and conditions set forth in this Agreement, the Parties wish to set out certain co-promotion rights for Inex and Enzon in the Territory.
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NOW, THEREFORE, the Parties, intending to be legally bound, hereby agree as follows:

Unless otherwise defined in this Agreement, capitalized terms used in this Agreement shall have the meaning set out therefor in the Product Supply Agreement or the Development Agreement (in the event of a conflict, the Product Supply Agreement shall prevail). For purposes of this Agreement, the following terms will have the meanings set forth below:

- 1.1.1 "Code" or "Codes" means the Code on Interactions with Healthcare Professionals promulgated by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the American Medical Association (AMA) Guidelines on Gifts to Physicians from Industry, as either of the foregoing may be amended from time to time.
- 1.1.2 "Commercialization" means the activities customarily associated with sales of pharmaceutical products including without limitation, Manufacturing, DDMAC Activities, price and reimbursement negotiations, pre-launch and launch activities, marketing, sales, distribution, Co-Promotion, Post-Approval Clinical Activities, the development, prosecution, registration and maintenance of trademarks, trade names and domain names, and pharmaco-vigilance in each country in the Territory.
- 1.1.3 "Co-Promotion" or "Promotion" means:
  - (a) Detailing and/or other related activities, including the provision of medical information services or medical liaison support, and
  - (b) market research, journal advertising, direct mail programs, participation in trade shows, symposia, congresses and other medical meetings; and
  - (c) MSL Activities;

undertaken by Enzon, or by Inex in concert with Enzon's marketing personnel and sales force to augment Enzon's marketing and sale of VSLI. When used as a verb, "Co-Promote" or "Promote" means to engage in such activities.

- 1.1.4 "Co-Promotion Costs" means, with respect to Co-Promotion of the Product by Inex or its Representatives, Inex's personnel cost of Sales Representatives and Medical Science Liaisons including \*\*\*. For greater certainty, "Co-Promotion Costs" are not included in Commercialization Costs as defined in the Product Supply Agreement.
- 1.1.5 "Detail" means a face-to-face meeting (including live video presentation) with a physician; other medical professional with prescribing authority; or office nurse or medical paraprofessional with influence over pharmaceutical

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prescribing or treatment regimes for patients in the Territory during which scientific and/or medical information about the Product is discussed. When used as a verb, the term "Detailing" means to engage in the activity of a Detail.

- 1.1.6 "Medical Science Liaison" means an individual employed by either Party to perform MSL Activities.
- 1.1.7 "MSL Activities" means through the use of Medical Science Liaisons the maintenance of effective relationships with clinical investigators with respect to the Product in the Territory. MSL Activities would also include responding to physicians' requests for medical information with respect to the Field.
- 1.1.8 "Pharmacovigilance" means all the activities associated with

maintaining an effective drug safety monitoring system and adverse events reporting system in compliance with the requirements of Regulatory Authorities.

## 1.1.9 "Product Labeling" means:

- (a) the full prescribing information for the Product, including any required patient information, as approved by Regulatory Authorities; and
- (b) all labels and other written, printed, or graphic matter upon any container, wrapper, or any package insert, utilized with or for the Product.
- 1.1.10 "Promotional Materials" means all written, printed, graphic, electronic, audio or video matter, including journal advertisements, sales visual aids, direct mail, direct-to-consumer advertising, web pages, web links, Internet postings, broadcast advertisements, sales reminder aids (e.g., scratch pads, pens and other such items) and reprints intended for use or used by the Parties in connection with any Promotion, except the Product Labeling.
- 1.1.11 "Sales Representative" means an individual employed by either Party or whose services are contracted for by either Party and who engages in Co-Promotion.
- 1.1.12 "Standards" means the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of Continuing Medical Education, as they may be amended from time to time.
- 1.1.13 "Term" shall have the meaning set out in Section 7.1.

#### Article 2 Co-Promotion

#### 2.1 Co-Promotion Rights

Inex shall have the right to engage in Co-Promotion activities with respect to VSLI in the Territory pursuant to and in accordance with the provisions of this Agreement.

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## 2.2 Use by Inex of Representatives

To the extent Inex does engage in Co-Promotion activities, it will do so through its own employees or, subject to the approval of Enzon, not to be unreasonably withheld, through its Representatives, such Representatives to include a contract sales force.

## 2.3 Enzon's Back Office Responsibilities

Notwithstanding any Co-Promotion activities engaged in by the Parties, Enzon shall remain responsible to book all sales of VSLI, conduct reimbursement negotiations, conduct Pharmacovigilance, handle returns/recalls and order processing, invoicing and collection, distribution, warehousing, inventory and receivables, collection of sales data from hospitals and other end users and all other customer service related functions and the like.

## Article 3 Coordination

## 3.1 Coordination of Activities

Enzon and Inex shall cooperate on the determination of activities to be undertaken by Inex employees and its Representatives engaged in Co-Promotion on both a geographic and physician base basis. Due consideration will be given to ensure that Inex employees and its Representatives have no lesser economic opportunity than Enzon employees for their respective geographic and physician

## 3.2 Reporting Relationships

To the extent they are engaged in Co-Promotion, Inex employees and its Representatives shall be subject to the control and direction of Enzon. For the purposes of conducting Co-Promotion, such Inex employees and Representatives shall have reporting responsibilities and be subordinate to the Enzon managers to whom their peer level Enzon employees report and are subordinate. Enzon managers will work cooperatively with their peer level Inex employees and Inex's Vice President, Sales & Marketing or such other executive officer as Inex designates in the management of such Inex employees and Representatives. To the extent the same Inex employees and its Representatives are engaged in promotional activities related to products other than VSLI, they shall not be subject to the control and direction of Enzon.

#### 3.3 Supervision and Management of Personnel

Inex shall cooperate with Enzon promptly and reasonably with respect to the supervision and management of its employees and its Representatives engaged in Co-Promotion. Subject to Section 3.1, Inex shall consider in good faith and give due weight to and, to the extent practicable, accommodate the recommendations of Enzon with respect to the management of Inex's employees and its Representatives engaged in Co-Promotion, including such matters as territorial assignments, performance improvement and disciplinary actions, promotions, demotions, terminations, etc. In addition, to the extent practical, the Parties will employ similar compensation systems to foster strategic alignment and to foster positive relations between each Party's personnel engaged in Co-Promotion.

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## 3.4 Training

Inex shall have the opportunity to review all training materials prior to their use. Inex employees and its Representatives engaged in Co-Promotion shall be subject to the same training, knowledge and performance requirements to which their peer level Enzon employees are subject. They shall attend the same training sessions and the same sales and other meetings that Enzon employees are required to attend. Enzon shall bear all costs of organizing and conducting any training sessions, except for travel and out-of-pocket costs incurred by Inex personnel which shall be shared by Inex and Enzon pursuant to Section 6.1.

## 3.5 Communication

Each Party shall have the right to arrange for its employees and Representatives directly involved in Co-Promotion of the Product to visit the other Party at the other Party's offices, and to discuss related activities with the technical and business personnel and consultants of such Party, provided that such visits shall be upon reasonable prior notice and during normal business hours and shall not unreasonably interrupt the operations of such Party.

#### 3.6 Marketing Subcommittee

The Joint Steering Committee shall create a subcommittee, to be called the Marketing Subcommittee, which will be constituted of such persons and engage in such activities regarding Co-Promotion as shall be determined by the Joint Steering Committee.

## Article 4 Promotional Material

## 4.1 Approved Promotional Materials

In its Co-Promotion, Inex shall use only the Promotional Materials approved by Enzon in writing and the trademarks, tradenames and domain names maintained by Enzon and Inex for VSLI. Enzon shall bear all costs related to the preparation and production of promotional materials for use by Inex employees and its Representatives.

#### 4.2 Provision of Enzon's Promotional Materials

Enzon shall provide Inex with sufficient final copies of all Promotional Materials concurrently with Enzon's finalization of the form of same, and in any event, prior to any public dissemination of same.

## 4.3 Approval of Inex's Promotional Material

Enzon shall have absolute discretion to approve all Promotional Materials prepared by Inex prior to their use by Inex in Co-Promoting the Product. Enzon shall designate an employee contact to whom Inex shall send for approval all Promotional Materials.

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#### 4.4 Use of Promotional Materials

- 4.4.1 Each Party shall own all Intellectual Property Rights in any Promotional Materials created or developed by such Party.
- 4.4.2 Inex will provide to Enzon prior to their use Promotional Materials that Inex creates for use outside the Territory. Inex will consider in good faith any comments or suggestions made by Enzon concerning such Promotional Materials.
- 4.4.3 Inex reserves the right to use outside the Territory all Promotional Material created by Inex and approved by Enzon for use inside the Territory.
- 4.4.4 Inex shall have the opportunity to review Promotional Materials created by Enzon.
- 4.4.5 Enzon and Inex will cooperate in good faith with Inex's Representatives, and Inex will use Commercially Reasonable Efforts to cause its Representatives to cooperate in good faith with Enzon and Inex, with respect to the preparation of Promotional Materials for, and the use of such materials in, different geographic markets on a global basis.

#### 4.5 Corporate Logos

All training materials and Promotional Materials shall bear both Parties' corporate logos in equal prominence. During the Term, each Party grants to the other, the non-exclusive right to use its corporate logo in the Territory solely for the purpose of the Promotion of the Product in accordance with the terms of this Agreement. Each Party will use commercially reasonable efforts to protect the other Party's corporate name, logo and symbol. Each Party acknowledges that the other Party owns all right, title and interest in such other Party's corporate name, logo and symbols and all good will associated therewith and that any and all use of corporate name, logo or symbols under the Related Agreements, and any good will associated with such use, shall inure exclusively to the benefit of the owner of such name, logo or symbol.

## 4.6 Website

On any website relating solely to the Product that is owned or controlled by, or operated on behalf of, Enzon to promote the Product (the "Websites"), Enzon shall place (or cause to have placed) the Inex logo and accompanying text provided by Inex, or such other Inex logo and accompanying text as Inex may designate from time to time in writing to Enzon, subject to review and approval of any such text by Enzon. Any such logo and accompanying text shall be given appropriate placement on such websites and shall link to a uniform resource locator ("URL") address designated by Inex, which URL address may be changed by Inex from time to time upon reasonable notice to Enzon; provided, however, that before providing any such link to a URL address, Enzon shall have the right to review and approve the contents thereof. Inex grants Enzon the right to establish a link to the Websites or other websites designated by Enzon and approved by Inex from specific websites relating solely to the Product owed or

controlled by, or operated on behalf of, Inex. Enzon also grants Inex the right to place (or cause to have

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placed) the Enzon logo and accompanying text provided by Enzon, or such other Enzon logo and accompanying text as Enzon may designate from time to time in writing to Inex, on such Inex websites, subject to review and approval of any such text by Inex. The content of the websites owned or controlled by Inex relating solely to the Product and accessible in the Territory, and the portions of other websites owned or controlled by Inex that relate to the Product and are directed at Commercializing the Product shall be subject to the review and approval of Enzon, which approval shall not be unreasonably withheld.

## Article 5 Compliance

#### 5.1 Consistent Statements

In connection with each Party's Promotion and Detailing of the Product, neither Party shall make, nor permit its Sales Representatives to make, any statement, representation or warranty, oral or written, to any person that is inconsistent with the Product Labeling or the Promotional Materials. Each Party shall promptly notify the other Party of and provide the other Party with a copy of any correspondence or other reports or complaints received by a Party from any Regulatory Authority, or any third party claiming that any Promotional Materials are inconsistent with the Product Labeling or are otherwise in violation of Regulatory Requirements.

#### 5.2 Medical Science Liaisons

Each Party shall conduct MSL Activities using only Medical Science Liaisons who have sufficient technical training and experience to perform such activities in a manner consistent with the practice by leading pharmaceutical and biotechnology companies of such activities within the Field. Each Party shall require each Medical Science Liaison to attend training before such Medical Science Liaison is permitted to conduct MSL Activities.

5.3 Communications to Sales Representatives and Medical Science Liaisons

Enzon shall provide Inex with copies of general communications (including communications sent electronically or by voice mail) disseminated by Enzon to the Sales Representatives and Medical Science Liaisons and relating to strategies for the Promotion or Detailing of the Product or the conduct of MSL Activities, as applicable.

## 5.4 Standards

In addition to its obligations to comply with Regulatory Requirements, each Party shall:

- 5.4.1 Promote the Product in conformity with the practices and procedures relating to the education of the medical community set forth in the Standards; and
- 5.4.2 promptly notify the other Party of and provide the other Party with a copy of any correspondence or other reports with respect to the Promotion of the Product or the conduct of the MSL Activities that a Party receives from:
  - (a) the Accreditation Council for Continuing Medical Education (ACCME) relating to either Party's compliance with the Standards;

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- (b) the PhRMA and the AMA relating to either Party's compliance with the Codes; and
- (c) the Division of Drug Marketing, Advertising and Communications (DDMAC), of the FDA in relation to either Party's compliance with Applicable Laws.

#### Article 6 Payments by Enzon

## 6.1 Reporting and Payment of Co-Promotion Costs

Enzon shall reimburse Inex for 50% of the Co-Promotion Costs of Inex's Co-Promotion to augment Enzon's efforts up to a maximum of 30 sales persons and medical science liaisons in accordance with the following:

- 6.1.1 after launch of the Product and until Enzon has achieved Net Sales of the Product of at least \$\*\*\* in any rolling four Commercial Quarter period, the number of Sales Representatives and Medical Science Liaisons shall not exceed \*\*\*;
- 6.1.2 after Enzon has achieved Net Sales of the Product of at least \$\*\*\* in any rolling four Commercial Quarter period, but before it has achieved annual Net Sales of the Product of at least \$\*\*\* in any rolling four Commercial Quarter period, the number of Sales Representatives and Medical Science Liaisons shall not exceed \*\*\*; and
- 6.1.3 after Enzon has achieved Net Sales of the Product of at least \$\*\*\* in any rolling four Commercial Quarter period:, the number of Sales Representatives and Medical Science Liaisons may increase to \*\*\* or such number of Sales Representatives and Medical Science Liaisons above \*\*\* as mutually agreed to by the Parties in writing (and in accordance with such agreement).

#### 6.2 Additional Sales Representatives and Medical Science Liaisons

Notwithstanding the foregoing, Inex may at any time utilize Sales Representatives and Medical Science Liaisons in excess of the numbers set out in Sections 6.1.1, 6.1.2 and 6.1.3 at Inex's expense, provided that such Sales Representatives and Medical Science Liaisons comply with the terms of this Agreement and Inex bears any incremental costs of Enzon associated with such Sales Representatives and Medical Science Liaisons.

# 6.3 Payment of Co-Promotion Costs

On a quarterly basis, within 12 Business Days after the end of each Calendar Quarter, Inex shall send Enzon invoices for 50% of its Co-Promotion Costs accompanied by the appropriate documentation, including a listing of expenditures in reasonably specific detail. Enzon shall pay such invoices within thirty (30) days after receipt of same. Any Co-Promotion Costs incurred by Inex or its Representatives in a particular quarter and not reflected in the invoice delivered pursuant to the foregoing sentence shall be captured in subsequent invoice(s).

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## 6.4 Notice of Other Promotional Activities

If any Inex employee or Representative engaged in Co-Promotion is to commence promotional activities with respect to any other product, Inex will provide written notice thereof to Enzon at least 60 days prior to the commencement of such other promotional activities. Enzon shall not be obligated to reimburse Inex with respect to any promotional activities related to other products. For purposes of determining Enzon's reimbursement obligations, the Commercialization Costs for any employee engaged in such other promotional efforts shall be

allocated between VSLI and the other products on an equitable basis.

#### 6.5 Taxes; Indemnification

The Inex employees and Representatives engaged in the Co-Promotion shall not be deemed to be employees of Enzon. Inex shall be responsible for all income tax withholding and similar obligations to all relevant taxing and other authorities associated with all personnel engaged in Co-Promotion. Enzon's sole financial obligations shall be to make the reimbursement payments directly to Inex as set forth in this Agreement. Inex hereby does indemnify and shall defend Enzon against and hold it harmless from any and all claims and/or liabilities that may arise out of any characterization of, or attempt to characterize, any person engaged in the Co-Promotion as an employee of Enzon.

#### Article 7 Termination

#### 7.1 Term of Agreement

This Agreement shall become effective on the Effective Date and, unless earlier terminated as provided for herein, shall expire, on a country-by-country basis, upon the expiration of any of the Related Agreements and such period shall be the "Term" under this Agreement.

#### 7.2 Termination for Breach

Each Party shall be entitled to terminate this Agreement by written notice to the other Party in the event that the other Party shall be in material default of any of its obligations hereunder, and shall fail to remedy any such default within sixty (60) days after notice thereof by the non-breaching Party. Any such notice shall specifically state that the non-breaching Party intends to terminate this Agreement in the event that the breaching Party shall fail to remedy the default. Any such notice shall set out expressly the actions required of the breaching Party to remedy the default. If such default is not corrected, the non-breaching Party shall have the right to terminate this Agreement by giving written notice to the Party in default provided the notice of termination is given within six (6) months of the default and prior to correction of the default.

## 7.3 Termination upon Bankruptcy

7.3.1 This Agreement may be terminated by a Party by providing written notice to the other Party upon:

\*\*\* Indicates the omission of confidential material pursuant to a request for confidential treatment made in accordance with Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The Confidential material is being filed separately with the Secretary to the Securities and Exchange Commission.

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- (a) the bankruptcy, liquidation or dissolution of the other Party;
- (b) the filing of any voluntary petition for bankruptcy, dissolution, liquidation or winding-up of the affairs of the other Party; or
- (c) the filing of any involuntary petition for bankruptcy, dissolution, liquidation or winding-up of the affairs of the other Party which is not dismissed within one hundred twenty (120) days after the date on which it is filed or commenced.
- 7.3.2 Notwithstanding the foregoing, either Party may seek the waiver of the operation of Section 7.3.1 in advance of any event giving rise to a right of termination under Section 7.3.1(b), and, provided that:
  - (a) the requesting Party is in good standing and not in breach of any of the terms of the Related Agreements;
  - (b) the requesting Party is in reasonable financial condition; and

(c) the Party whose consent is sought will not be prejudiced by granting such waiver,

the Party whose consent is sought will not unreasonably withhold its consent to such waiver. Such waiver may be revocable in the event of a material adverse change in circumstances related to the requesting Party not contemplated at the time of granting the waiver.

#### 7.4 Effect of Termination

The termination of this Agreement for any reason will be without prejudice to:

- 7.4.1 Inex's right to receive all payments accrued from Enzon as of the effective date of such termination;
- 7.4.2 Inex's right to receive reimbursement for all costs and liabilities incurred by Inex as of the date of Inex's receipt of Enzon's notice of termination, which cost and liabilities Inex has properly and reasonably incurred in its obligations hereunder. For greater certainty, such costs and liabilities shall include all reasonable and necessary non-cancellable obligations entered into prior to Inex's receipt of Enzon's notice of termination, but arising after Inex's receipt of Enzon's notice of termination; and
- 7.4.3 any other legal, equitable or administrative remedies as to which either Party may then or thereafter become entitled.
- \*\*\* Indicates the omission of confidential material pursuant to a request for confidential treatment made in accordance with Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The Confidential material is being filed separately with the Secretary to the Securities and Exchange Commission.

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- 7.5 Survival of Obligations; Return of Confidential Information
  - 7.5.1 The provisions of Article 1, Sections 4.4.1, 4.4.3, 4.4.5, Article 5, Section 6.5, Article 7 and Article 8 will survive any expiration or termination of this Agreement in accordance with their terms.
  - 7.5.2 Upon any termination of this Agreement pursuant to Article 7, except as contemplated hereby, each Party shall promptly return to the other Party all written Confidential Information, and all copies thereof (except for one archival copy to be retained by a person designated by such Party (who shall not make such Confidential Information generally available to employees or other representatives of such Party) for the purpose of confirming which information to hold in confidence hereunder), of the other Party which is not covered by a license surviving such termination.

## Article 8 Miscellaneous

## 8.1 Assignment

- 8.1.1 The rights and obligations set out in this Agreement are personal to each Party and for this reason, except as expressly set out in this Agreement, this Agreement will not be assignable by either Party in whole or in part, nor will either Party subcontract any of its obligations hereunder without the prior written consent of the other Party, which consent shall not be withheld or delayed unreasonably; provided, however, that the restriction contained herein will in no way limit the rights of either Party to:
  - (a) assign or subcontract any right or obligation hereunder to any of its Affiliates; or
  - (b) appoint as its agent for any purpose of this Agreement any such Affiliate; or
  - (c) assign any right or obligation hereunder to any person

or entity that:

- (i) purchases all or substantially all of its assets to which this Agreement relates or
- (ii) purchases all or substantially all of the stock of either Party; or
- (iii) acquires or is combined with either Party in a  $$\operatorname{\mathsf{merger}}$  or some other form of business combination.
- 8.1.2 This Agreement will be binding upon and will enure to the benefit of the parties hereto and to any permitted assignee or successor of either party.
- 8.1.3 Subject to other provisions of this Section 8.1, if one Party validly assigns or subcontracts any or all of its obligations hereunder, such assigning or

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subcontracting Party agrees to remain bound by all of its responsibilities and obligations hereunder.

8.1.4 Any and all assignments of this Agreement or any interest herein not made in accordance with this Section 8.1 will be void ab initio.

#### 8.2 Counterparts

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

### 8.3 Exhibits and Appendices

Each exhibit hereto is incorporated by reference and made a part of this Aqreement.

## 8.4 Force Majeure

In the event that either Party is prevented from performing or is unable to perform any of its obligations under this Agreement due to any act of God; fire; casualty; flood; war; strike; lockout; failure of public utilities; injunction or any act, exercise, assertion or requirement of governmental authority; epidemic; destruction of production facilities; riots; insurrection; failure of transportation; inability to procure or use materials, or any other cause beyond the reasonable control of the Party invoking this Section 8.4 if such Party shall have used its reasonable efforts to avoid such occurrence, such Party shall give notice to the other Party in writing promptly, and thereupon the affected Party's performance shall be excused and the time for performance shall be extended for the period of delay or inability to perform due to such occurrence.

### 8.5 Further Assurances

Each Party hereto agrees to execute, acknowledge and deliver such further instruments and do all such further acts as may be necessary or appropriate to carry out the purposes and intent of this Agreement.

#### 8.6 Modification

No waiver, alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed by the Parties by their respective officers thereunto duly authorized.

## 8.7 No Agency

Except as explicitly set forth herein, nothing herein shall be deemed to constitute either Party as the agent or representative of the other Party, or both Parties as joint venturers or partners for any purpose. Inex shall be an independent contractor, not an employee of Enzon, and the manner in which Inex renders its services under this Agreement shall be within Inex's sole

discretion. Neither Party shall be responsible for the acts or omissions of the other Party, and neither Party will have authority to speak for, represent or obligate the other Party in any way without prior written authority from the other Party.

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## 8.8 No Solicitation or Hiring of Employees

During the Term and for one year thereafter, neither Inex nor Enzon shall, without the prior consent of the other Party, solicit the employment of or hire any person who during the course of employment with the other Party was involved with activities under the Commercialization Plan and who when solicited or to be hired is a current employee of the other Party.

#### 8.9 Non-Use of Names

Except as otherwise expressly set out in this Agreement, neither Party shall use the name of the other Party, nor any adaptation thereof, in any advertising, promotional or sales literature without prior written consent obtained from such other Party in each case (which consent shall not be unreasonably withheld or delayed).

## 8.10 Notices

Any notice or other communication in connection with this Agreement must be in writing and if by mail, by registered mail, return receipt requested, and shall be effective when delivered to the addressee at the address listed below or such other address as the addressee shall have specified in a notice actually received by the addressor.

## If to Inex:

Inex Pharmaceuticals, Inc.
c/o Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

Attention: President and CEO

With copies to:

Inex Pharmaceuticals Corporation 100-8900 Glenlyon Parkway Burnaby, British Columbia Canada V5J 5J8 Fax: 604-419-3202 Attention: Sr. V.P. Commercial Operations;

With a copy to:

Inex Pharmaceuticals Corporation 100-8900 Glenlyon Parkway Burnaby, British Columbia Canada V5J 5J8 Fax: 604-419-3202 Attention: Business Development

and:

\*\*\* Indicates the omission of confidential material pursuant to a request for confidential treatment made in accordance with Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The Confidential material is being filed separately with the Secretary to the Securities and Exchange Commission.

Lang Michener 1500-1055 West Georgia Street Vancouver, British Columbia Canada V6E 4N7 Fax: 604-685-7084 Attention: Leo Raffin

and:

Farris, Vaughan, Wills & Murphy 2600 - 700 West Georgia Street Vancouver, British Columbia Canada V7Y 1B3
Fax: 604-661-9349
Attention: James Hatton

If to Enzon:

ENZON PHARMACEUTICALS, INC.
685 Route 202/206
Bridgewater, New Jersey
08807
Fax: 908.541.8680
Attention: Vice President, Business Development

with a copy to:

Enzon Pharmaceuticals, Inc. 685 Route 202/206 Bridgewater, NJ 08807 Fax: 908.541.8838 Attention: General Counsel

8.11 Publicity

Except as required by law, stock exchange or Regulatory Authority:

- 8.11.1 neither Party, nor any of its Affiliates, shall originate any publicity, news release or other public announcement, written or oral, relating to this Agreement or the existence of an arrangement between the Parties, without the prior written approval of the other Party and agreement upon the nature and text of such announcement or disclosure, which approval shall not be unreasonably withheld;
- 8.11.2 the Party desiring to make any such public announcement or other disclosure shall inform the other Party of the proposed announcement or disclosure in reasonably sufficient time prior to public release, and shall provide the other Party with a written copy thereof, in order to allow such other Party to comment upon such announcement or disclosure; and
- \*\*\* Indicates the omission of confidential material pursuant to a request for confidential treatment made in accordance with Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The Confidential material is being filed separately with the Secretary to the Securities and Exchange Commission.

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- 8.11.3 notwithstanding the foregoing, the Parties agree that the press release set out as an Exhibit to the Product Supply Agreement shall be released by the Parties upon execution and delivery of this Agreement by both Parties.
- 8.12 No Third Party Beneficiaries

Except as expressly set out in this Agreement, nothing in this Agreement is intended to or shall confer upon any Third Part any legal or equitable right, benefit or remedy of any nature whatsoever.

8.13 Waiver

The waiver by either Party of a breach or a default of any provision of this Agreement by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision, nor shall any delay or omission on the part of either Party to exercise or avail itself of any right, power or privilege that it has or may have hereunder operate as a waiver of any right, power or privilege by such Party.

IN WITNESS WHEREOF, the Parties have executed this Co-Promotion Agreement as of the date first above written.

Inex Pharmaceuticals, Inc.

By: /s/ David J. Main

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Name: David J. Main Title: President & CEO

Enzon Pharmaceuticals, Inc.

By: /s/ Arthur J. Higgins

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Name: Arthur J. Higgins Title: Chairman & CEO

\*\*\* Indicates the omission of confidential material pursuant to a request for confidential treatment made in accordance with Rule 24b-2 under the Securities Exchange Act of 1934, as amended. The Confidential material is being filed separately with the Secretary to the Securities and Exchange Commission.

# CERTIFICATION PURSUANT TO SECTION 302 of THE SARBANES-OXLEY ACT OF 2002

## I, Arthur J. Higgins, certify that:

- I have reviewed this quarterly report on Form 10-Q of Enzon Pharmaceuticals, Inc. ("Enzon");
- Based on my knowledge, this quarterly 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 quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we 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 quarterly report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure and procedures, as of the end of the period covered by this report based on such evaluation;
  - 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and to the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonable 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.

May 10, 2004

By: /s/ Arthur J. Higgins

Arthur J. Higgins Chief Executive Officer (Principal Executive Officer)

# CERTIFICATION PURSUANT TO SECTION 302 of THE SARBANES-OXLEY ACT OF 2002

## I, Kenneth J. Zuerblis, certify that:

- I have reviewed this quarterly report on Form 10-Q of Enzon Pharmaceuticals, Inc. ("Enzon");
- Based on my knowledge, this quarterly 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 quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we 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 quarterly report is being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure and procedures, as of the end of the period covered by this report based on such evaluation;
  - 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and to the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonable 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.

May 10, 2004

By: /s/ Kenneth J. Zuerblis

Kenneth J. Zuerblis Vice President Finance, Chief Financial Officer Corporate Secretary (Principal Financial and

# CERTIFICATION PURSUANT TO SECTION 906, OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Enzon Pharmaceuticals, Inc. and Subsidiaries (the "Company") on Form 10-Q for the period ended March 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Arthur Higgins, Chairman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of section 13 (a) or 15 (d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

By: /s/ Arthur J. Higgins

Arthur J. Higgins Chief Executive Officer (Principal Executive Officer)

May 10, 2004

A signed original of this written statement required by section 906 has been provided to Enzon Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

# CERTIFICATION PURSUANT TO SECTION 906, OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Enzon Pharmaceuticals, Inc. and Subsidiaries (the "Company") on Form 10-Q for the period ended March 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kenneth J. Zuerblis, Vice President Finance, Chief Financial Officer and Corporate Secretary of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of section 13 (a) or 15 (d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

By: /s/ Kenneth J. Zuerblis

Kenneth J. Zuerblis Vice President Finance, Chief Financial Officer (Principal Financial and Accounting Officer) and Corporate Secretary

May 10, 2004

A signed original of this written statement required by section 906 has been provided to Enzon Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.