UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM	10-	O
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\boxtimes	QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15	5(d) OF THE SECURITIES EXCHANGE ACT OF	
	For the quarterly period ended S	September 30, 2012	
	OR		
	TRANSITION REPORT PURSUANT TO SECTION 13 OR 1: 1934	5(d) OF THE SECURITIES EXCHANGE ACT OF	
	For the transition period from	to .	
	Commission File Number	: 000-50484	
	MEI Pharm (Exact name of registrant as spec		
	DELAWARE (State or other jurisdiction of incorporation or organization)	51-0407811 (I.R.S. Employer Identification No.)	
	11975 El Camino Real, Suite 101, S (Address of principal executive off	9 ,	
	(858) 792-6300 (Registrant's telephone number, inc		
the p	cate by check mark whether the registrant (1) has filed all reports required to be filed preceding 12 months (or for such shorter period that the registrant was required to file past 90 days. Yes 🗵 No 🗆		
subn	cate by check mark whether the registrant has submitted electronically and posted on mitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) strant was required to submit and post such files). Yes 🗵 No 🗆		be
	cate by check mark whether the registrant is a large accelerated filer, an accelerated filinition of "large accelerated filer," "accelerated filer," and "smaller reporting company		
Larg	ge accelerated filer	Non-accelerated filer	
Acce	elerated filer	Smaller reporting entity	\times
Indic	cate by check mark whether the registrant is a shell company (as defined in Rule 12b	-2 of the Exchange Act). Yes □ No ⊠	
	of November 13, 2012, the number of shares outstanding of the issuer's common stoo	ek \$0,00000002 par value was 21,673,482	

MEI PHARMA, INC.

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PART I FINANCIAL INFORMATION

Item 1: Financial Statements

MEI PHARMA, INC. (A Development Stage Company) BALANCE SHEETS

(In thousands, except share and per share data)

	September 30, 2012 (unaudited)	June 30, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,713	\$ 6,202
Prepaid expenses and other current assets	123	146
Total current assets	3,836	6,348
Property and equipment, net	23	25
Intangible assets, net	496	
Total assets	\$ 4,355	\$ 6,373
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 533	\$ 594
Accrued liabilities	1,097	1,180
Total current liabilities	1,630	1,774
Commitments and contingencies (Note 3)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 100,000 shares authorized;		
Series A: 1,000 shares issued and outstanding at September 30, 2012 and June 30, 2012	_	_
Series B: 742 shares issued and redeemed; none outstanding at September 30, 2012 and June 30, 2012	_	_
Common stock, \$0.00000002 par value; 113,000,000 shares authorized;		
21,673,482 shares and 20,498,946 shares issued and outstanding at September 30, 2012 and June 30, 2012,		
respectively	_	
Additional paid-in-capital	90,300	89,710
Deficit accumulated during the development stage	(87,575)	(85,111)
Total stockholders' equity	2,725	4,599
Total liabilities and stockholders' equity	\$ 4,355	\$ 6,373

See accompanying notes to the unaudited financial statements.

MEI PHARMA, INC.

(A Development Stage Company) STATEMENTS OF OPERATIONS

(In thousands, except share and per share data) (Unaudited)

	_	Three Mont Septemb 2012		led 2011	Dece	eriod from ember 1, 2000 Inception) through ptember 30, 2012
Operating expenses:	ø	(1.552)	¢.	(1.044)	¢	(45 (56)
Research and development	\$	(1,552)	\$	(1,044)	\$	(45,656)
License fees		_		-		(21,500)
General and administrative		(914)		(889)		(23,684)
Total operating expenses		(2,466)		(1,933)		(90,840)
Loss from operations		(2,466)		(1,933)		(90,840)
Other income (expense):						
Fair value of derivative liabilities in excess of proceeds						(508)
Adjustments to fair value of derivative liabilities		_		716		1,188
Interest and dividend income		3		3		2,902
Financing costs		_		(397)		(406)
Gain on sale of investment		_		_		100
Income tax expense		(1)		(1)		(11)
Net loss arising during development stage	\$	(2,464)	\$	(1,612)	\$	(87,575)
Net loss per share, basic and diluted	\$	(0.12)	\$	(0.17)		
Shares used to calculate net loss per share	20	,996,847	9,	,588,551		

See accompanying notes to the unaudited financial statements.

MEI PHARMA, INC. (A Development Stage Company) STATEMENTS OF CASH FLOWS (In thousands) (Unaudited)

	Three Mon Septem 2012		Dece (I	eriod from mber 1, 2000 nception) through otember 30, 2012
Cash flows from operating activities:				
Net loss arising during the development stage	\$(2,464)	\$(1,612)	\$	(87,575)
Adjustments to reconcile net loss to net cash used in operating activities:				
Share-based compensation	90	118		2,881
Fair value of derivative liabilities in excess of proceeds	_	_		508
Gain on adjustment to fair value of derivative liabilities		(716)		(1,188)
Financing costs	_	397		406
Depreciation and amortization	8	3		34
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	23	164		(123)
Accounts payable	(61)	3		533
Accrued liabilities	(83)	(87)		1,097
Net cash used in operating activities	(2,487)	(1,730)		(83,427)
Cash flows from investing activities:				
Purchases of property and equipment	(2)	_		(53)
Net cash used in investing activities	(2)			(53)
Cash flows from financing activities:				
Net proceeds from issuance of common stock	_	3,069		86,934
Net proceeds from issuance of preferred stock	_	_		665
Financing costs	_	(397)		(406)
Net cash provided by financing activities		2,672		87,193
Net increase/(decrease) in cash and cash equivalents	(2,489)	942		3,713
Cash and cash equivalents at beginning of the period	6,202	3,858		
Cash and cash equivalents at end of the period	\$ 3,713	\$ 4,800	\$	3,713
Supplemental cash flow information:				
Issuance of common stock for purchase of intellectual property	\$ 500	<u>\$</u>	\$	500

See accompanying notes to the unaudited financial statements.

MEI PHARMA, INC. (A Development Stage Company) NOTES TO FINANCIAL STATEMENTS (Unaudited)

1. Organization and Summary of Significant Accounting Policies

The Company

MEI Pharma, Inc. (formerly Marshall Edwards, Inc.), or the Company, is a development stage oncology company focused on the clinical development of novel therapies for cancer. The Company's drug development pipeline includes Pracinostat, ME-143 and ME-344. The Company's former wholly-owned subsidiary, Marshall Edwards Pty Ltd ("MEPL"), was legally dissolved in April 2012. As MEPL was the Company's only subsidiary, the financial statements are no longer consolidated. The Company was incorporated in December 2000 as a wholly-owned subsidiary of Novogen Limited ("Novogen") and commenced operations in May 2002. MEI Pharma's common stock is listed on the Nasdaq Capital Market and was previously listed under the symbol "MSHL" through June 30, 2012. On July 2, 2012, in conjunction with the change in the Company's corporate name to MEI Pharma, Inc., the Company's common stock began trading under the symbol "MEIP". As of September 30, 2012, Novogen owned 60% of the outstanding shares of the Company's common stock. On July 27, 2012, Novogen announced that, subject to shareholder approval, at a meeting to be held on November 12, 2012, it will undertake a capital reduction and *in specie* distribution to the Novogen shareholders of the shares of the Company that it owns. This distribution will allow Novogen shareholders to own their proportionate share of the Company's common stock now held by Novogen.

Basis of Presentation

The accompanying unaudited financial statements should be read in conjunction with the audited financial statements and notes thereto as of and for the year ended June 30, 2012, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on September 18, 2012. The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since these are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements reflect all adjustments (consisting of normal recurring adjustments) that are necessary for a fair statement of the financial position, results of operations and cash flows for the interim periods presented. Interim results are not necessarily indicative of results for a full year. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from those estimates. The Company has evaluated subsequent events through the date the financial statements were issued.

Capital Resources

Since inception, the Company's operations have been financed primarily through the sale of equity securities. The Company has incurred losses from operations and negative cash flows since its inception due in large part to expenditures for its research and development activities, and the Company expects to continue to incur substantial losses for the foreseeable future as it continues development of its lead drug candidates. As a result, the Company will need to obtain additional financing to fund its operations in the future. The Company intends to obtain any additional required funding through strategic relationships, public or private equity, debt financings, or other arrangements. Conditions in the financial markets and other factors could have a material adverse effect on the Company's ability to access sufficient funding on acceptable terms, or at all. If the Company cannot raise adequate additional capital, it will be required to delay, further reduce the scope of, or eliminate one or more of its research or development programs. In addition, the Company may be required to relinquish greater, or even all, rights to product candidates at earlier stages of development or on less favorable terms than it would otherwise choose.

Management believes that the Company's existing cash balances of approximately \$3.7 million as of September 30, 2012, will be sufficient to fund the Company's operations until early calendar year 2013. Changes in the Company's research and

development plans or other changes affecting its operating expenses may affect actual future use of existing cash resources. If the Company is unable to obtain additional funds, the Company may be required to cease or reduce its operations. On November 4, 2012, the Board of Directors of the Company approved, and on November 5, 2012 the Company's majority shareholder, Novogen, provided its written consent with respect to, the issuance of 55,000,000 units ("Units") to Vivo Ventures and affiliated funds, New Leaf Venture Partners and affiliated funds and other qualified investors (together the "2012 PIPE Purchasers") for an aggregate purchase price of \$27,500,000 pursuant to the Securities Purchase Agreement by and among the Company and the 2012 PIPE Purchasers dated as of November 4, 2012. Each Unit consists of one share of common stock and a warrant to acquire 0.70 shares of common stock at an exercise price of \$0.52 per share. The Units will consist of an aggregate of 55,000,000 shares of common stock and warrants exercisable for an aggregate of 38,500,000 shares of common stock (the "2012 PIPE"). The 2012 PIPE is subject to certain conditions and is expected to be completed in December 2012.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of liabilities in the normal course of business and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. While the basis of presentation remains that of a going concern, the Company has a history of recurring losses from operations and, as of September 30, 2012, the Company had no revenue sources, an accumulated deficit of \$87.6 million and available cash and cash equivalents of \$3.7 million. If the Company is unable to complete the 2012 PIPE financing or to obtain additional funds, the Company may be required to cease or reduce its operations. The factors mentioned above raise substantial doubt about the Company's ability to continue as a going concern if the 2012 PIPE is not completed.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes to the financial statements. The Company uses estimates for certain accruals including clinical and pre-clinical study fees and expenses, share-based compensation, and valuations of derivative liabilities, among others. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid investments with remaining maturities of three months or less when purchased.

Fair Value of Financial Instruments

The carrying amounts of financial instruments such as cash equivalents and current liabilities approximate the related fair values due to the short-term maturities of these instruments.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains accounts in federally insured financial institutions in excess of federally insured limits. However, management believes that the Company is not exposed to significant credit risk due to the financial positions of the depository institutions in which these deposits are held.

Property and Equipment

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets (generally three to seven years) using the straight-line method. Leasehold improvements are stated at cost and are amortized over the shorter of the estimated useful lives of the assets or the lease term. Capital improvements are stated at cost and amortized over the estimated useful lives of the underlying assets.

Intangible Assets

Our intangible assets consist of patents acquired from S*Bio in August 2012 relating to a family of heterocyclic compounds that inhibit histone deacetylases. Capitalized amounts are amortized on a straight line basis over the expected life of the intellectual property, which we estimate to be 14 years. The carrying values of our intangible assets are periodically reviewed to determine if the facts and circumstances suggest that a potential impairment may have occurred. Our results of operations for the three months ended September 30, 2012 do not reflect any write-downs associated with the potential impairment of our intangible assets.

Research and Development Costs

Research and development costs are expensed as incurred and include costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials. Clinical trial costs, including costs associated with third-party contractors, are a significant component of research and development expenses. The Company accrues research and development costs based on work performed. In determining the amount to accrue, management relies on estimates of total costs based on contract components completed, the enrollment of subjects, the completion of trials, and other events.

License Fees

Costs incurred related to the licensing of products that have not yet received regulatory approval to be marketed, or that are not commercially viable and ready for use, or have no alternative future use, are charged to expense in the period incurred. The Company was subject to license fees payable to Novogen under various license agreements through December 2010, at which time the license agreements were terminated.

Share-based Compensation

The fair value of each stock option granted is estimated on the grant date under the fair value method using a binomial valuation model. The estimated fair values of the stock options, including the effect of estimated forfeitures, are expensed over the vesting period. The Company recognized share-based compensation expenses of \$90,000 and \$118,000 during the three months ended September 30, 2012 and 2011, respectively.

Interest and Dividend Income

Interest on cash balances is recognized when earned. Dividend income is recognized when the right to receive the payment is established.

Income Taxes

The Company's income tax expense consists of current and deferred income tax expense or benefit. Current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for the future tax consequences attributable to tax credits and loss carryforwards and to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of September 30, 2012 and June 30, 2012, the Company has established a valuation allowance to fully reserve its net deferred tax assets. Tax rate changes are reflected in income during the period such changes are enacted. Changes in ownership may limit the amount of net operating loss carry-forwards that can be utilized in the future to offset taxable income.

The *Financial Accounting Standards Board Topic on Income Taxes* prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. An uncertain income tax position will not be recognized if management believes it has less than a 50% likelihood of being sustained. There were no unrecognized tax benefits as of September 30, 2012.

Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board ("FASB") issued authoritative guidance which amended existing guidance related to the presentation of comprehensive income. The adoption of this guidance did not have a material impact on the Company's financial statements.

2. Net Loss Per Share

Basic and diluted net loss per share is computed using the weighted-average number of shares of common stock outstanding during the period, less any shares subject to repurchase or forfeiture. There were no shares of common stock subject to repurchase or forfeiture for the three months ended September 30, 2012 and 2011. Because the Company is in a net loss position, it has excluded stock options, warrants, and convertible preferred stock from the calculation of diluted net loss per share because these securities are antidilutive for all periods presented. As of September 30, 2012 and 2011, the number of securities excluded from the computation of diluted net loss per share totalled approximately 11,629,766 and 8,272,335, respectively.

3. Commitments and Contingencies

The Company has contracted with various consultants and third parties to assist it in pre-clinical research and development and clinical trials work for its leading drug compounds. The contracts are terminable at any time, but obligate the Company to reimburse the providers for any time or costs incurred through the date of termination. The Company also has employment agreements with certain of its current employees that provide for severance payments and accelerated vesting for share-based awards if their employment is terminated under specified circumstances. Additionally, the Company leases office space for a monthly rental rate of \$10,734, plus other pass-through charges, under the lease term expiring in April 2013.

Asset Purchase Agreement

On August 7, 2012, the Company entered into a definitive asset purchase agreement with S*BIO Pte Ltd, a privately held biotechnology company, pursuant to which the Company agreed to acquire certain assets comprised of intellectual property and technology including rights to Pracinostat, a histone deacetylases (HDAC) inhibitor in Phase II clinical trials for hematologic cancers, from S*BIO in exchange for \$500,000 of common stock. The agreement also provides for potential success-based clinical, regulatory and sales milestone payments of up to \$75.2 million, as well as contingent earn-out payments based on net sales.

License Agreement

On September 28, 2012, the Company entered into a license agreement with CyDex Pharmaceuticals, Inc. ("CyDex"). Under the license agreement, CyDex granted to the Company an exclusive, nontransferable license to intellectual property rights relating to Captisol® for use with the Company's two lead isoflavone-based drug compounds. The Company agreed to pay to CyDex a non-refundable license issuance fee, future milestone payments, and royalties on future sales of the Company's approved drugs utilizing Captisol. Contemporaneously with the license agreement, the Company and CyDex entered into a commercial supply agreement pursuant to which the Company agreed to purchase 100% of its requirements for Captisol from CyDex. The Company may terminate both the license agreement and the supply agreement for convenience at any time upon 90 days' prior written notice.

4. Segment Information

The Company has one operating segment, the development of pharmaceutical compounds. The Company's business contained two geographic segments, the United States of America and Australia, from inception until MEPL's legal dissolution in April 2012. For the three months ended September 30, 2012 and 2011, net losses attributable to Australia were immaterial. All of the Company's assets and liabilities were located in the United States of America as of September 30, 2012 and June 30, 2012.

5. Related Party Transactions

In March 2012, the Company distributed one subscription right for each share of common stock and each Series A warrant exercisable for a share of common stock to holders of record as of March 30, 2012. Each subscription right entitled the holder to purchase one Unit, which consisted of 0.5 shares of the Company's common stock and a warrant to purchase 0.25 shares of the Company's common stock. In connection with the rights offering, in May 2012, Novogen purchased 8,988,675 units consisting of 4,494,337 shares of common stock and warrants to purchase an additional 2,247,169 shares of common stock. The warrants are exercisable for a five-year period beginning on May 11, 2012 at an exercise price of \$1.19 per share. See further discussion regarding the Rights Offering in Note 6 "Stockholders' Equity".

On September 27, 2011, the Company entered into a Securities Subscription Agreement with Novogen, pursuant to which the Company sold to Novogen 1,333,333 shares of common stock, at a purchase price of \$1.50 per share, for proceeds of \$2,000,000. The offering closed on September 29, 2011. On December 28, 2011, the Company entered into a Securities Subscription Agreement with Novogen, pursuant to which the Company sold to Novogen 1,941,747 shares of common stock, at a purchase price of \$1.03 per share, for proceeds of \$2,000,000. The offering closed on December 29, 2011.

Isoflavone Transaction

In December 2010, the Company entered into an Asset Purchase Agreement (the "Isoflavone Asset Purchase Agreement") with Novogen and Novogen Research Pty Limited, a wholly-owned subsidiary of Novogen, pursuant to which the Company agreed to purchase certain assets used in or generated under, or in connection with, the discovery, development, manufacture and marketing of intellectual property and products based on the field of isoflavonoid technology and on compounds known as isoflavones, including those related to the drug candidates Phenoxodiol, Triphendiol, ME-143 and NV-128, "Isoflavone-related Assets", in exchange for 1,000 shares of the Company's Series A Convertible Preferred Stock. The transaction closed on May 9, 2011. Under the terms of the Isoflavone Asset Purchase Agreement, the Company also assumed certain liabilities that are related to the Isoflavone-related Assets.

The Company did not record a value for the Isoflavone-related Assets acquired, since there were no historical carrying amounts recorded by Novogen and the transaction was between entities under common control.

In conjunction with signing the Isoflavone Asset Purchase Agreement, the Company and Novogen agreed to terminate, effective upon consummation of the Isoflavone Transaction, each of the following agreements, along with any other agreements relating thereto, with respect to the Isoflavone-related Assets:

- September 2003 license agreement pursuant to which Novogen's wholly-owned subsidiary, Novogen Research Pty Limited granted MEPL a worldwide, non-transferable license to conduct clinical trials and commercialize and distribute certain Phenoxodiol products. MEPL paid Novogen a total of \$16,000,000 in fiscal years 2004 through 2007 under the terms of the agreement;
- May 2006 license agreement between MEPL and Novogen Research Pty Limited pursuant to which Novogen Research Pty Limited granted MEPL a world-wide, non-transferable license to conduct clinical trials and commercialize and distribute certain products based on Triphendiol and NV-143 (now known as ME-143). MEPL paid Novogen a total of \$4,000,000 in fiscal years 2006 through 2009 under the terms of the agreement;
- August 2009 license agreement between MEPL and Novogen Research Pty Limited pursuant to which Novogen Research Pty Limited granted MEPL an exclusive, worldwide, non-transferable license to conduct clinical trials, commercialize and distribute NV-128. MEPL paid Novogen \$1,500,000 in fiscal year 2010 under the terms of the agreement.

Services Agreement

Effective December 31, 2010, the Company and Novogen terminated the September 2003 services agreement between MEPL and Novogen pursuant to which Novogen had provided services to the Company relating to the development and commercialization of Phenoxodiol and other licensed products, including Triphendiol and NV-143. Novogen had provided these services at cost plus a 10% mark-up. Novogen did not perform any services for the Company during the quarters ended September 30, 2012 or 2011.

6. Stockholders' Equity

Equity Transactions

Reverse Stock Split

On September 25, 2012, the Board of Directors of the Company approved, and on September 27, 2012, the Company's majority shareholder, Novogen, provided its written consent with respect to, a Certificate of Amendment to the Company's Restated Certificate of Incorporation to effect a reverse stock split at a ratio of 1-for-10 (the "Reverse Stock Split"). On the effective date of the Reverse Stock Split, every holder of Common Stock will receive one (1) share of Common Stock for every ten (10) shares of Common Stock held immediately prior to such effective date. Pursuant to Section 242 of the General Corporation Law of the State of Delaware, amendments to a corporation's certificate of incorporation require the approval of stockholders representing at least a majority of the corporation's outstanding capital stock entitled to vote thereon. The Company will prepare an information statement to be filed with the SEC that will provide additional important information concerning the reverse stock split and which must be mailed to stockholders at least 20 days prior to the effectiveness of the stockholder approval provided by Novogen by written consent. The Company expects the reverse stock split to become effective during the second quarter of fiscal year 2013.

Asset Purchase

On August 7, 2012, the Company entered into a definitive asset purchase agreement with S*BIO Pte Ltd ("S*Bio"), a privately held biotechnology company, pursuant to which the Company agreed to acquire certain assets comprised of intellectual property and technology including rights to Pracinostat, a histone deacetylases (HDAC) inhibitor in Phase II clinical trials for

hematologic cancers, from S*BIO in exchange for \$500,000 of common stock. The agreement also provides for potential success-based clinical, regulatory and sales milestone payments of up to \$75.2 million, as well as contingent earn-out payments based on net sales. The Company may pay up to \$500,000 of the first milestone payment in shares of common stock. On August 22, 2012, the Company completed the asset purchase and issued 1,174,536 shares of common stock to S*BIO.

Rights Offering

On March 26, 2012, the Company's registration statement on Form S-1, as previously filed with the Securities and Exchange Commission on February 21, 2012 and amended on March 20, 2012, became effective. The Form S-1 was filed in connection with the Company's rights offering ("Rights Offering") to existing stockholders and to holders of our Series A warrants issued in connection with the May 2011 private placement. Pursuant to the Rights Offering, the Company distributed one subscription right for each share of common stock and each Series A warrant exercisable for a share of common stock to holders of record as of March 30, 2012. Each subscription right entitled the holder to purchase one Unit, which consisted of 0.5 shares of our common stock and a warrant to purchase 0.25 shares of the Company's common stock. The subscription period expired on May 11, 2012. The Rights Offering also included an over-subscription privilege, which entitled stockholders to purchase additional Units that remained unsubscribed at the expiration of the Rights Offering. For every two Units purchased in the Rights Offering, stockholders received one share of common stock for a purchase price of \$0.89 per share, which represents a 10 percent discount to the volume-weighted average price of the Company's common stock for the 30 consecutive trading days ending on, and inclusive of, March 13, 2012, and warrants to purchase one-half of one share of common stock with an exercise price of \$1.19 per share, which represented a 20 percent premium to the volume-weighted average price of the Company's common stock during the same period. The warrants are exercisable for a five-year period beginning on May 11, 2012. The Company issued 5,830,202 shares of common stock and warrants to purchase 2,915,152 shares of common stock in conjunction with the Rights Offering. Net proceeds associated with the Rights Offering were \$4.8 million.

Warrants and Options to Purchase Common Stock `

As of September 30, 2012, there were outstanding warrants to purchase 2,915,152 shares of the Company's common stock at an exercise price of \$1.19 per share, which expire in May 2017, issued in conjunction with the Rights Offering; outstanding warrants to purchase 4,608 shares of the Company's common stock at an exercise price of \$21.70 per share, which expire in July 2013; and outstanding Series A warrants and warrants issued to the Company's placement agent for the May 2011 private placement to purchase up to 2,460,617 shares of common stock at \$1.00, which expire in November 2016.

As of September 30, 2012 there were options outstanding to purchase 1,422,389 shares of common stock at exercise prices ranging from \$0.46 to \$6.30 per share. The outstanding options expire at various dates in calendar years 2014 through 2016.

The fair value of each stock option granted is estimated on the grant date under the fair value method using a binomial valuation model. The estimated fair values of the stock options, including the effect of estimated forfeitures, are expensed over the vesting period. To calculate these fair values, the following assumptions were used:

	Three months ended	l September 30,
	2012	2011
Risk-free interest rate	.64%71%	.90% - 1.32%
Expected life	5 years	5 years
Expected volatility	153% - 155%	145% - 147%
Dividend yield	0%	0%
Weighted-average grant date fair value	\$ 0.46	\$ 1.66

Stock option activity for the three months ended September 30, 2012 was as follows

	Stock options outstanding	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value
Outstanding at June 30, 2012	863,560	\$ 1.94	3.5	\$ —
Options granted	558,829	\$ 0.51	4.9	\$ —
Options forfeited or expired	_	\$ —	_	\$ —
Outstanding at September 30, 2012	1,422,389	\$ 1.38	3.9	\$ —
Exercisable at September 30, 2012	331,296	\$ 2.26	3.0	\$ —

Unrecognized compensation expense related to non-vested stock options totalled \$537,000 as of September 30, 2012. Such compensation expense is expected to be recognized over a weighted-average period of 4.2 years.

Series A Convertible Preferred Stock

In connection with the closing of the Isoflavone Transaction in May 2011, the Company designated and issued 1,000 shares of Series A Convertible Preferred Stock to Novogen. Each share of the Series A Convertible Preferred Stock is convertible into 4,827 shares of Common Stock. In the event a Phase II clinical trial involving any of the isoflavone technology acquired by the Company pursuant to the Asset Purchase Agreement has achieved a statistically significant result (p=0.05 or less) or a first patient is enrolled in a Phase III clinical trial involving such technology, whichever is earlier, each share of the Series A Convertible Preferred Stock not already converted may be converted into 9,654 shares of Common Stock. In the Amendment No. 6 to Schedule 13/D filed with the SEC on October 19, 2012, Novogen indicated its intent, subject to shareholder approval, to convert all 1,000 shares of Series A Convertible Preferred Stock in connection with the distribution to Novogen shareholders of all of the Company's common stock held by Novogen.

7. Subsequent Events

Securities Purchase Agreement

As described in Note 1, on November 4, 2012, the Board of Directors of the Company approved, and on November 5, 2012 Novogen provided its written consent with respect to, the issuance of 55,000,000 Units to the 2012 PIPE Purchasers for an aggregate purchase price of \$27,500,000 pursuant to the Securities Purchase Agreement dated as of November 4, 2012.

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

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding the future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things:

- our inability to obtain required additional financing or financing available to us on acceptable terms, or at all, which may cause us to delay, scale-back or eliminate plans related to development of our drug candidates:
- we are in an early stage of clinical studies for our product candidates on which our development plans are based; clinical studies by their nature typically have a high level of risk of failure, and may not produce successful results;
- our inability to maintain or enter into, and the risks resulting from our dependence upon, contractual arrangements necessary for the clinical development, manufacture, commercialization, marketing, sales and distribution of our product candidates;
- costs and delays in the clinical development programs and/or receipt of U.S. Food and Drug Administration (the "FDA") or other required governmental approvals, or the failure to obtain such approvals, for our product candidates;
- our failure to successfully commercialize our product candidates;
- the failure of any products to gain market acceptance;
- our inability to control the costs of manufacturing our products;
- competition and competitive factors;
- our inability to protect our patents or proprietary rights and obtain necessary rights to third party patents and intellectual property to operate our business;
- our inability to operate our business without infringing the patents and proprietary rights of others;
- · costs stemming from our defense against third party intellectual property infringement claims;
- general economic conditions;
- technological changes;
- government regulation generally and the receipt of regulatory approvals;
- · changes in industry practice; and
- one-time events.

These risks are not exhaustive. Our business and financial performance could also be adversely affected by the factors that are discussed under "Risk Factors" in the Annual Report on Form 10-K for the year ended June 30, 2012, filed on September 18, 2012, as well as factors discussed elsewhere in this report and in our other filings with the Securities and Exchange Commission. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

You should not rely upon forward looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward looking statements will be achieved or occur. Although we believe that the expectations reflected in the forward looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

The following discussion is qualified in its entirety by, and should be read in conjunction with, the more detailed information set forth in the financial statements and the notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q.

Overview

MEI Pharma, Inc. (formerly Marshall Edwards Inc.) is a development-stage oncology company focused on the clinical development of novel small molecules for the treatment of cancer. We were incorporated in Delaware in 2000 as a wholly owned subsidiary of Novogen Limited ("Novogen"). Our common stock is listed on the Nasdaq Capital Market and was previously listed under the symbol "MSHL" through June 30, 2012. On July 2, 2012, in conjunction with the change of our corporate name to MEI Pharma, Inc., our common stock began trading under the symbol "MEIP". As of September 30, 2012, Novogen owned approximately

60% of the outstanding shares of our common stock, as well as all of the outstanding shares of our Series A Convertible Preferred Stock. Novogen has indicated its intent, subject to shareholder approval, to undertake a capital reduction by making a distribution to the Novogen shareholders of all of its shares of common stock of the Company, including 4,827,000 shares of common stock issuable upon conversion of the Company's Series A Convertible Preferred Stock, but excluding 2,247,168 shares of common stock issuable upon exercise of warrants. This distribution will allow Novogen shareholders to own their proportionate share of the Company's common stock now held by Novogen.

Our business purpose is the development of novel therapies for cancer. We are currently focused on the clinical development of our three lead drug candidates, Pracinostat, ME-143 and ME-344 and Pracinostat has been tested in more than 150 patients in multiple Phase I and exploratory Phase II clinical trials, including advanced hematologic malignancies such as myelodysplastic syndrome (MDS), acute myeloid leukemia and myelofibrosis. We expect to initiate a randomized Phase II clinical trial of Pracinostat in combination with azacitidine in patients with MDS by the second quarter of calendar year 2013. Results from a Phase I clinical trial of intravenous ME-143 in heavily treated patients with solid refractory tumors were presented at the American Society of Clinical Oncology Annual Meeting in June 2012. A Phase I clinical trial of intravenous ME-344 in patients with solid refractory tumors is ongoing. In May 2011, we completed the acquisition of certain assets and intellectual property, including those related to ME-143 and ME-344, from Novogen, in accordance with the terms of an Asset Purchase Agreement, dated as of December 21, 2010, between us, Novogen and Novogen Research Pty Limited. In August 2012, we completed the acquisition of certain assets and intellectual property, including those related to Pracinostat, from S*BIO Pte Ltd ("S*Bio").

As of September 30, 2012, our existing cash balances were approximately \$3.7 million. We believe that our existing cash balances, excluding expected future proceeds from the 2012 PIPE, will be sufficient to fund our operations until early calendar year 2013. Changes to our research and development plans or other changes affecting our operating expenses may affect actual future use of existing cash resources. In any event, however, we intend to pursue one or more capital raising transactions, whether through the sale of equity securities or the entry into strategic partnerships, in order to continue the development of our lead drug candidates and financing to fund our operations in the future. On November 4, 2012, the Board of Directors of the Company approved, and on November 5, 2012 Novogen provided its written consent with respect to, the issuance of 55,000,000 units to the 2012 PIPE Purchasers for an aggregate purchase price of \$27,500,000 pursuant to the Securities Purchase Agreement by and among the Company and the 2012 PIPE Purchasers dated as of November 4, 2012. Each unit will consist of one share of common stock and warrants to acquire 0.70 shares of common stock at an exercise price of \$0.52 per share. The units will consist of an aggregate of 55,000,000 shares of common stock and warrants exercisable for an aggregate of 38,500,000 shares of Common Stock. The stockholder approval provided by Novogen by written consent will become effective 20 days after we mail an information statement describing the proposed transaction to our other stockholders. In addition to the effectiveness of the stockholder approval, the transaction is subject to our entry into a registration rights agreement providing customary registration rights to the 2012 PIPE Purchasers, as well as our entry into a governance agreement with each of the 2012 PIPE Purchasers and certain other customary closing conditions. Pursuant to the governance agreement, we will agree, among other things, to increase the size of the Board of Directors of the Company from six members to seven members and to provide each of the 2012 PIPE Purchasers who beneficially owns at least 10% of our outstanding common stock the right to designate one nominee for election to the Board of Directors. In addition, we have agreed to use our best efforts to hold an annual meeting of stockholders within three months of the closing of the issuance of the units to consider, among other things, an amendment to our certificate of incorporation to eliminate our classified Board of Directors.

If the 2012 PIPE is not completed, we may be required to reduce or cease our operations.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates. We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Clinical Trials Expenses and Accruals

Estimates have been used in determining the expense and accrued liability under certain clinical trial contracts where services have been performed but not yet invoiced. Generally, the costs associated with clinical trial contracts are based on the number of patients in each trial, the service contracts associated with clinical sites, service providers and drug development contracts. The length of time before actual amounts can be determined will vary, and are therefore estimated, depending on length of the drug administration cycles and the timing of the invoices by the clinical trial partners and contractors.

Share-based Compensation

Share-based compensation expense for employees and directors is recognized in the statement of operations based on estimated amounts, including the grant date fair value and the expected service period. For stock options, we estimate the grant date fair value using a binomial valuation model, which requires the use of multiple subjective inputs including estimated future volatility, expected forfeitures and the expected term of the awards. We estimate our expected future volatility based on our stock's historical price volatility. Our stock's future volatility may differ from our estimated volatility at the grant date. Share-based compensation

recorded in our statement of operations is based on awards expected to ultimately vest and has been reduced for estimated forfeitures. Our estimated forfeiture rates may differ from actual forfeiture rates which would affect the amount of expense recognized during the period. We recognize the value of the awards on a straight-line basis over the awards' requisite service periods. The requisite service period is generally the time over which our share-based awards vest.

Results of Operations

Three Months Ended September 30, 2012 and 2011

We incurred losses of \$2,464,000 and \$1,612,000 for the three months ended September 30, 2012 and 2011, respectively.

Research and Development: Research and development expenses consist primarily of clinical trial costs (including payments to contract research organizations or CROs), pre-clinical study costs, cost to manufacture our drug candidates for pre-clinical and clinical studies and salaries and other personnel costs. Research and development expenses increased by \$508,000 to \$1,552,000 for the three months ended September 30, 2012 compared to \$1,044,000 for the three months ended September 30, 2011. The increase is primarily due to Phase I clinical trial costs and drug manufacturing costs associated with ME-344.

General and Administrative: General and administrative expenses increased by \$25,000 to \$914,000 for the three months ended September 30, 2012 compared to \$889,000 for the three months ended September 30, 2011. The increase primarily relates to legal fees and other costs associated with the issuance of common stock to S*Bio in conjunction with the purchase of Pracinostat.

Other income or expense: We received interest on cash and cash equivalents of \$3,000 for the three months ended September 30, 2011. Additionally, during the year ended June 30, 2011, we issued securities that are accounted for as derivative liabilities. As of September 30, 2011, the derivative liabilities were revalued to \$423,000, resulting in a net decrease in value of \$702,000 during the three months ended September 30, 2011, based primarily upon a change in the terms of Series A warrants and exercise of Series B warrants, which had been accounted for as derivative liabilities. The decrease in value was recorded as non-operating income for the three months ended September 30, 2011. Additionally, we recorded a reversal of a prior expense of \$14,000 in conjunction with amending the Series A Warrant terms, based on the fair value of the Amended Series A Warrants. During the three months ended September 30, 2011, we also made cash payments of \$365,000 to certain of our investors in conjunction with an agreement to modify the terms of Series A and Series B warrants and we paid \$32,000 in other expenses related to the agreement. These expenses were recorded as "Financing Costs".

Liquidity and Capital Resources

Our sources of liquidity include our cash and cash equivalents. Our existing cash balances were approximately \$3.7 million as of September 30, 2012. We believe that an existing cash balances, excluding expected future proceeds from the 2012 PIPE, will be sufficient to fund our operations until early calendar year 2013. Our current business operations are focused on continuing the clinical development of our three lead drug candidates, Pracinostat, ME-143 and ME-344. Changes to our research and development plans or other changes affecting our operating expenses may affect actual future use of existing cash resources. To date, we have obtained cash and funded our operations primarily through the sale of equity securities. We have accumulated losses of \$87.6 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. We will need additional financing to fund our operations in the future, including the continued development of our drug candidates. We intend to seek additional capital through one or more equity transactions; As described under "Overview" above, on November 4, 2012, we entered into the Securities Purchase Agreement with the 2012 PIPE Purchasers, which we expect to close in the second quarter of fiscal year 2013. However, there can be no assurances that the transactions contemplated by the Securities Purchase Agreement, or any other equity transactions that we may pursue, will be completed. If the Company is unable to obtain additional funds on favorable terms or at all, the Company may be required to cease or reduce its operations. Our independent certified public accountants have stated that at June 30, 2012, there is substantial doubt about the Company's ability to continue as a going concern.

Sources and Uses of Our Cash

Net cash used in operations for the three months ended September 30, 2012 was \$2,487,000 compared to \$1,730,000 in the three months ended September 30, 2011 due to our net loss resulting from expenses incurred for research and development and general and administrative costs.

Net cash provided by financing activities was \$2,672,000 during the three months ended September 30, 2011. There was no cash provided by financing activities during the three months ended September 30, 2011 reflected net proceeds of \$1,094,000 raised through the issuance of common stock from the exercise of Series B warrants and \$1,975,000 through the issuance of common stock to Novogen. Additionally, during the three months ended September 30, 2011 we paid \$397,000 in financing costs associated with amending the terms of securities that had been issued as part of the May 2011 private placement.

Contractual Obligations

We have contracted with various consultants and third parties to assist us in pre-clinical research and development and clinical trials work for our leading drug compounds. The contracts are terminable at any time, but obligate us to reimburse the providers for any time or costs incurred through the date of termination. Additionally, we have employment agreements with certain of our current employees that provide for severance payments and accelerated vesting for share-based awards if their employment is terminated under specified circumstances.

In July 2010, we entered into a lease arrangement to rent approximately 3,700 square feet of office space for 33 months beginning in July 2010 for monthly rental rates ranging from \$10,109 to \$10,734 over the lease term, plus other pass-through charges. We have two options to extend the lease term for one year each at the market rate in effect at the time of renewal.

License Agreement

On September 28, 2012, the Company entered into a license agreement with CyDex Pharmaceuticals, Inc. ("CyDex"). Under the license agreement, CyDex granted to the Company an exclusive, nontransferable license to intellectual property rights relating to Captisol® for use with the Company's two lead isoflavone-based drug compounds. The Company agreed to pay to CyDex a non-refundable license issuance fee, future milestone payments, and royalties on future sales. Contemporaneously with the license agreement, the Company and CyDex entered into a commercial supply agreement pursuant to which the Company agreed to purchase 100% of its requirements for Captisol from CyDex. The Company may terminate both the license agreement and the supply agreement for convenience at any time upon 90 days' prior written notice.

Corporate Developments

Nasdag

On March 27, 2012, we received notice from Nasdaq stating that, based on the closing bid price for our common stock for the last 30 consecutive business days, we no longer meet the \$1.00 per share minimum bid price requirement for continued inclusion on the Nasdaq Capital Market under Nasdaq Rule 5550(a)(2). The notification letter stated that we would be afforded a grace period of 180 calendar days, or until September 24, 2012, to regain compliance with the minimum bid price requirement in accordance with Nasdaq Rule 5810(c)(3)(A). In order to regain compliance, shares of our common stock must maintain a minimum closing bid price of at least \$1.00 per share for a minimum of ten consecutive business days during the grace period. On September 25, 2012, the Company received a determination letter from NASDAQ notifying the Company that we had not regained compliance with the Rule during the 180 calendar day period and that the Company's common stock is therefore subject to delisting from The Nasdaq Capital Market, unless the Company requests a hearing before the NASDAQ Listing Qualifications Panel (the "Panel"). On October 2, 2012, the Company timely requested a hearing before the Panel to present its plan to regain compliance with Nasdaq Rule 5550(a)(2), which request automatically stayed the delisting of the Company's securities pending at least the issuance of the Panel's decision following the hearing, which was held on November 1, 2012, where the Company requested an exception from compliance with Nasdaq Rule 5550(a)(2) through February 11, 2013 to evidence compliance with all applicable requirements for continued listing. On November 8, 2012, the Company was notified by the Panel that it granted the Company's request for continued listing subject to the condition that on or before February 11, 2013, the Company shall have evidenced a closing bid price of \$1.00 or more for a minimum of ten prior consecutive trading days. In order to fully comply with the terms of the exception from compliance with Nasdaq Rule 5550(a)(2), the Company must be able to demonstrate compliance with all requirements for continued listing on the NASDAQ Capital Market. In the event the Company is unable to do so, its common stock may be delisted from The NASDAQ Stock Market. The Company intends to effect a one-for-ten reverse stock split in order to regain compliance with the minimum closing bid price requirements set forth in the Rule, which has been approved by Novogen as our majority stockholder. The Company will prepare an information statement to be filed with the SEC that will provide additional important information concerning the reverse stock split and which must be mailed to stockholders at least 20 days prior to the effectiveness of the stockholder approval provided by Novogen. See Note 6 – "Stockholders' Equity" for additional information.

During 2010, we received deficiency notices from Nasdaq regarding non-compliance with the minimum stockholders' equity and the minimum Market Value of Publicly Held Shares in accordance with Nasdaq Listing Standards for the Nasdaq Global Market. On March 7, 2011, a Nasdaq Hearing Panel granted us until May 16, 2011 to evidence compliance with the stockholders equity and minimum Market Value of Publicly Held Shares requirement. On March 23, 2011, we received a positive response from the Nasdaq Listing Qualifications Staff indicating that our request for a transfer and continued listing on the Nasdaq Capital Market had been granted. Our common stock began trading on the Nasdaq Capital Market effective with the open of business on March 16, 2011.

Recent Accounting Pronouncements

See Item 1 of Part I, "Notes to Financial Statements- Note 1- Organization and Summary of Significant Accounting Policies".

Item 3: Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our exposure to market interest rates relates primarily to the investments of cash balances. We have cash reserves held primarily in U.S. dollars and we place funds on deposit with financial institutions and are generally at call.

We do not use derivative financial instruments to hedge our risks related to cash balances. We place our cash deposits with high credit quality financial institutions, and, by policy, limit the amount of credit exposure to any single counter-party. We are adverse to principal loss and we ensure the safety and preservation of our invested funds by limiting default risk, market risk and reinvestment risk. We seek to mitigate default risk by depositing funds with high credit quality financial institutions and by constantly positioning its portfolio to respond appropriately to a significant reduction in a credit rating of any financial institution.

We do not consider the effects of interest rate movements to be a material risk to our financial condition.

Foreign Currency Risk

We conduct our operations principally in U.S. dollars. However, we also have some exposure to foreign currencies. At September 30, 2012, we had not established a foreign currency hedging program. Net foreign exchange losses during the three months ended September 30, 2011 were \$14,000. We did not have any foreign exchange gains or losses during the three months ended September 30, 2012. We do not consider the effects of foreign currency movements to be a material risk to our financial condition.

Item 4: Controls and Procedures

Evaluation of Disclosure Controls and Procedures

At the end of the period covered by this Quarterly Report on Form 10-Q, the Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures are effective to ensure that the information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

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

PART II OTHER INFORMATION

Item 6: **Exhibits**

Exhibits

Exhibit Index

4.1	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 5, 2012 (File No. 000-50484)).
10.14	

- License Agreement, dated September 28, 2012, between Cydex Pharmaceuticals, Inc. and the Company. 10.1*
- 10.2* Supply Agreement, dated September 28, 2012, between Cydex Pharmaceuticals, Inc. and the Company.
- Securities Purchase Agreement, dated as of November 4, 2012, by and among the Company, Vivo Ventures Fund VII, L.P., Vivo Ventures VII 10.3 Affiliates Fund, L.P., and New Leaf Ventures II, L.P., and certain other accredited investors identified in Exhibit A thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 5, 2012 (File No. 000-50484)).
- Form of Governance Agreement between the Company and Vivo Ventures Fund VII, L.P., Vivo Ventures VII Affiliates Fund, L.P., and New Leaf 10.4 Ventures II, L.P. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 5, 2012 (File No. 000-50484)).
- 10.5 Form of Registration Rights Agreement between the Company and Vivo Ventures Fund VII, L.P., Vivo Ventures VII Affiliates Fund, L.P., and New Leaf Ventures II, L.P. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on November 5, 2012 (File No. 000-50484)).
- 31.1 Certification required by Rule 13a-14(a) or Rule 15d-14(a)
- 31.2 Certification required by Rule 13a-14(a) or Rule 15d-14(a)
- 32.1 Certification required by Rule 13a-14(b) or Rule 15d-14(b) and section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C 1350).
- 101.INS XBRL Instance Document.
- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document
- Portions of this exhibit have been redacted pursuant to a confidential treatment request filed with the Securities and Exchange Commission.

SIGNATURES

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

MEI Pharma, Inc.

/s/ Daniel P. Gold

Daniel Gold

President and Chief Executive Officer

Date: November 13, 2012

CONFIDENTIAL

CERTAIN MATERIAL (INDICATED BY ASTERISKS) HAS BEEN OMITTED FROM THIS DOCUMENT PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

LICENSE AGREEMENT

BETWEEN

CYDEX PHARMACEUTICALS, INC.

AND

MEI PHARMA, INC.

DATED: September 28, 2012

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LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "Agreement") is made this 28th day of September, 2012 (the "Effective Date") between:

CYDEX PHARMACEUTICALS, INc., a Delaware corporation, with offices at 11119 North Torrey Pines Road, Suite 200, La Jolla, California 92037) ("CyDex"); and

MEI PHARMA, INC., a Delaware corporation, with offices at 11975 El Camino Real, Suite 101, San Diego, California 92130 ("Company").

RECITALS

WHEREAS, CyDex is engaged in the business of developing and commercializing novel drug delivery technologies designed to enhance the solubility and effectiveness of existing and development-stage drugs;

WHEREAS, CyDex is the exclusive supplier of Captisol®, a patented drug formulation system designed to enhance the solubility and stability of drugs;

WHEREAS, Company desires to obtain an exclusive license to use the Captisol® patented drug formulation system in connection with its development and commercialization of one or more Licensed Products (defined below) and CyDex is willing to grant such an exclusive license to Company under the terms and conditions set forth herein: and

WHEREAS, CyDex desires to sell Captisol® to Company, and Company desires to purchase Captisol® from CyDex, in accordance with the terms and conditions of that certain Supply Agreement between the parties of even date herewith (the "Supply Agreement");

Now, Therefore, in consideration of the following mutual promises and other good and valuable consideration, the receipt and sufficiency of which are acknowledged, the parties, intending to be legally bound, agree as follows:

1. DEFINITIONS.

For the purposes of this Agreement, the following terms shall have the meanings as defined below:

"Adverse Event" means any undesirable medical occurrence in a patient or clinical investigation subject administered Captisol or a Licensed Product (whether or not necessarily having a causal relationship with Captisol or a Licensed Product).

"Affiliate" means, with respect to any party, any entity controlling, controlled by, or under common control with such party, during and for such time as such control exists. For these purposes, "control" shall refer to the ownership, directly or indirectly, of at least 50% of the voting securities or other ownership interest of the relevant entity.

- "Captisol" means sulfobutylether \(\beta \) cyclodextrin, sodium salt. CyDex supplies such material under the Captisol® brand.
- "Captisol Improvement" means any technology or improvement specifically related to the physical properties of Captisol, whether or not patentable, that is developed by Company or its Affiliates or Sublicensees, solely or jointly with a Third Party.
- "Captisol Related Compound" means Captisol or any derivative, homolog analog of Captisol or any isomer, salt, hydrate, solvate, amide, ester, metabolite or product of any of the foregoing, including without limitation sulfobutylether g(gamma) cyclodextrin sodium salt.
- "Captisol Data Package" means (i) all toxicology/safety and other relevant scientific safety data owned, licensed or developed by CyDex and its Affiliates relating to Captisol; (ii) all toxicology/safety and other relevant scientific data owned, licensed or developed by the licensees or sublicensees of CyDex or its Affiliates or other Third Parties (to the extent permitted in the applicable license or other agreements between CyDex and/or its Affiliates and such licensees, sublicensees or other Third Parties); and (iii) the open portion of the DMF for Captisol, in each case relating to Captisol alone (and not in conjunction with a product formulation).
 - "Claim" has the meaning specified in Section 10.1.
 - "Company Indemnitees" has the meaning specified in Section 10.1.
- "Competing Product" shall mean any product an active pharmaceutical ingredient of which is a Compound and which is not marketed and sold by or under license from Company.
- "Compound" means the proprietary Company isoflavone-based drug compound known as ME-143 (also known as NV-143) or the proprietary Company mitochondrial inhibitor drug compound known as ME-344, or any derivative, homolog, or analog of ME-143 or ME-344 or any isomer, salt, hydrate, solvate, amide, ester, metabolite, or prodrug of any of the foregoing.
 - "Confidential Information" has the meaning specified in Section 8.1.
 - "Contract Manufacturer" has the meaning specified in Section 2.4.
 - "CyDex Indemnitees" has the meaning specified in Section 10.2.
 - "Disclosing Party" has the meaning specified in Section 8.1.
- "**DMF**" means a Drug Master File (or similar dossier filed with an equivalent regulatory body in another country) for Captisol, as filed as of the Effective Date, or as hereafter updated from time to time during the Term, by CyDex with the FDA (or equivalent regulatory body in another country).
 - "FDA" means the United States Food and Drug Administration, or any successor thereto.
- "Field" means the entire field of prevention, diagnosis and treatment of all human and animal diseases and disorders with the exceptions of: (i) ocular treatment of any disease or condition with a

formulation including a hormone; (ii) topical ocular treatment of inflammatory conditions; (iii) treatment and prophylaxis of fungal infections in humans; and (iv) any ocular treatment for retinal degeneration.

"First Commercial Sale" means the first sale for use or consumption by the general public of a Licensed Product in a particular country following Marketing Approval.

"Generic Captisol" [***]

"Generic Supplier" [***]

"IND" means an Investigational New Drug application, as defined in the United States Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, or similar application filed with an equivalent regulatory body in another country.

"Indemnified Party" has the meaning specified in Section 10.4.

"Indemnifying Party" has the meaning specified in Section 10.4.

"Licensed Patents" means all patents and patent applications in the Territory which cover Captisol and which now or at any time during the Term are owned by or licensed to CyDex or any CyDex Affiliate with the right to sublicense, including any and all extensions, renewals, continuations, substitutions, continuations-in-part, divisions, patents-of-addition, reissues, reexaminations and/or supplementary protection certificates to any such patents. Set forth in *Exhibit A* attached hereto is a list of the Licensed Patents as of the Effective Date. Such *Exhibit A* shall be updated by CyDex at least annually during the Term. CyDex shall designate for each Licensed Patent specified in *Exhibit A* whether such Licensed Patent is exclusively owned by CyDex, jointly owned by CyDex, or is licensed to CyDex by a Third Party, and in each case whether CyDex has the right to grant an exclusive license to Company hereunder (*i.e.* with respect to itself and any Third Party).

"Licensed Product" means (a) a Compound combined with or formulated using Captisol for ultimate use in humans in a dosage form/formulation, or (b) a pharmaceutical composition that includes a Compound and that is developed with the assistance of or incorporates any then-confidential component of the Captisol Data Package.

"Licensed Product Family" means one or more Licensed Products which are based on the same Compound(s) (or any isomers, salts, hydrates, solvates, amides, esters, metabolites, or prodrugs of the foregoing), irrespective of whether such Licensed Products contain different dosage forms, proportions or formulations of such Compound(s), utilize different inactive ingredients and/or are marketed for different indications. Notwithstanding the foregoing, a Licensed Product based on a Compound shall be deemed to be in a distinct Licensed Product Family from a Licensed Product based on the combination of the same relevant Compound with any other active pharmaceutical

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

ingredient. As such, if Company develops one Licensed Product with ME-344 as the sole active ingredient with Captisol and also develops another Licensed Product with ME-344 in combination with another active ingredient with Captisol, then two distinct sets of milestone payments shall be potentially due under this Agreement, one for each of such two distinct Licensed Products.

"Losses" has the meaning set forth in Section 10.1.

"Major Market" means each of Japan, France, Germany, Italy, Spain, the United Kingdom and the United States of America.

"Marketing Approval" means final approval of an NDA by the FDA, or final approval of a comparable document filed with an equivalent health regulatory authority in any other country or in the European Union (using the centralized process or mutual recognition), including all required marketing, pricing or reimbursement approvals; provided, that if a First Commercial Sale has occurred in any country (or within any country within a region), it shall be conclusively deemed for purposes of this Agreement that all required marketing, pricing and reimbursement approvals in such country and in such (entire) region have been obtained.

"NDA" means a New Drug Application, as defined in the United States Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, or similar application filed with an equivalent regulatory body in another country.

"Net Sales" means the gross amount invoiced by Company (including a Company Affiliate) or any Sublicensee thereof to unrelated Third Parties, excluding any Sublicensee, for a Licensed Product, less:

- (i) Trade, quantity and cash discounts allowed;
- (ii) Discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances which effectively reduce the net selling price (other than such which have already diminished the gross amount invoiced);
- (iii) Licensed Product returns and allowances;
- (iv) Administrative fees paid to group purchasing organizations (e.g., Medicare);
- (v) [***
- (vi) Shipping, handling, freight, postage, insurance and transportation charges, but all only to the extent included as a separate line item in the gross amount invoiced; and
- (vii) Any tax imposed on the production, sale, delivery or use of the Licensed Product, including, without limitation, sales, use, excise or value added taxes and customs and duties, but all only to the extent included as a separate line item (e.g., "taxes") in the gross amount invoiced.

Such amounts shall be determined from the books and records of Company and its Affiliates and Sublicensees, maintained in accordance with U.S. GAAP or, in the case of Sublicensees, similar

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accounting principles, consistently applied. Company further agrees in determining such amounts, it shall use Company's then current standard procedures and methodology, including Company's then current standard exchange rate methodology for the translation of foreign currency sales into U.S. Dollars or, in the case of Sublicensees, such similar methodology, consistently applied.

"Notice of Termination" has the meaning specified in Section 13.3.

"Phase II Clinical Trial" means any human clinical trial of a Licensed Product conducted for purposes of preliminary determination of efficacy and/or preliminary establishment of appropriate dosage ranges for efficacy and safety in patients, as described under 21 C.F.R. §312.21(b) (as hereafter modified or amended) and any of its foreign equivalents.

"Phase III Clinical Trial" means any human clinical trial to confirm with statistical significance the efficacy and safety of a Licensed Product, as described under 21 C.F.R. §312.21(c) (as hereafter modified or amended) and any of its foreign equivalents. For avoidance of doubt: any pivotal trial shall be deemed to be a Phase III Clinical Trial.

"Pfizer" has the meaning specified in Section 8.5.

"Quality Agreement" means any document developed, approved, and updated between CyDex and Company that sets forth the quality expectations, responsibilities, rights (including, as applicable and agreed upon, audit requirements) and requirements relating to the manufacture and supply of Captisol. Such agreement may be amended from time to time by written agreement between the parties.

"Receiving Party" has the meaning specified in Section 8.1.

"Safety Agreement" has the meaning specified in Section 7.4.

"SEC" means the United States Securities and Exchange Commission.

"Study" has the meaning specified in Section 6.2.

"Sublicensees" has the meaning specified in Section 2.3.

"Term" has the meaning specified in Section 13.1.

"Territory" means the entire world.

"Third Party" means any person or entity or authority other than CyDex or Company or an Affiliate of either of them.

"Third Party Infringement" has the meaning specified in Section 12.3.

"Third Party Manufacturer" has the meaning specified in Section 2.3 of the Supply Agreement.

"Upstream Licensor has the meaning specified in Section 2.6.

"U.S. GAAP" means United States generally accepted accounting principles, consistently applied.

"Valid Claim" means a claim which, but for the license granted hereunder, would be infringed by Company's use, manufacture or sale of a Licensed Product in a country in the Territory, and which is covered by an issued and unexpired patent in such country included within the Licensed Patents which has not been held invalid or unenforceable by a decision of a court or governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid, canceled or unenforceable by the owner through re-issue, re-examination or disclaimer, opposition procedure, nullity suit, or otherwise or is not enforceable by virtue of applicable law in such country.

2. GRANT OF RIGHTS.

2.1 License Grants from CyDex to Company.

(a) Licensed Patents. Subject to the terms and conditions of this Agreement, including but not limited to payment of the amounts set forth in Section 4.1 below, CyDex hereby grants to Company an exclusive (even as against CyDex and its Affiliates), nontransferable (except with respect to the assignment provision in Section 14.15) limited license during the Term under the Licensed Patents, solely to make, have made (pursuant to Section 2.4), use, sell, offer for sale and import the Licensed Products in the Territory in and for the Field. (No license, exclusive or nonexclusive, is granted hereunder under the Licensed Patents, except to so make, have made, use, sell, offer for sale and import the Licensed Products in the Territory in and for the Field.) Notwithstanding the foregoing, to the extent that any Licensed Patents are licensed to CyDex or its Affiliates by a Third Party on a non-exclusive basis, the license granted to Company in the foregoing sentence shall be exclusive as to CyDex and its Affiliates and non-exclusive as to any Third Party. For clarity, as CyDex is unable to grant Company any rights that it does not have, in the event that CyDex obtains a non-exclusive license from a Third Party for intellectual property necessary for Company to perform its obligations hereunder, then CyDex shall pass on such rights to Company hereunder via a license that grants rights that are non-exclusive with respect to Third Parties but that is exclusive with respect to CyDex and its Affiliates. Company may not make, use, sell, offer for sale, or import the Licensed Products for any other purposes than those granted to it in this Agreement. Company may not sublicense the Licensed Patents, except as expressly set forth in Sections 2.3 and 2.4 below.

(b) Captisol Data Package. Subject to the terms and conditions of this Agreement, CyDex hereby grants to Company an exclusive (even as against CyDex and its Affiliates), nontransferable (except with respect to the assignment provision in Section 14.15) license during the Term under CyDex's rights in and to the Captisol Data Package, solely to make, have made, use, sell, offer for sale and import the Licensed Products in the Territory in and for the Field. CyDex shall make its personnel reasonably available to Company and its Contract Manufacturers to respond to informational inquiries and provide technical assistance related to the Captisol Data Package. Company may sublicense its rights in and to the Captisol Data Package, as expressly set forth in Sections 2.3 and 2.4 below

(c) Scope of Licenses. CyDex grants no licenses or rights to use other than as expressly set forth herein. Without limiting the generality of the foregoing, CyDex grants no rights

to Company to manufacture, import, sell or offer for sale bulk Captisol; provided, however; that Company may provide Captisol to bona fide collaborators in order to help Company to make, have made (pursuant to Section 2.4), use, sell, offer for sale or import the Licensed Products in the Territory in the Field. Licensee acknowledges that not all rights of CyDex related to Captisol are included within the rights licensed hereunder, given that CyDex shall supply Company's requirements of Captisol for the Licensed Products. Company shall not attempt to reverse engineer, deconstruct or in any way determine the structure or composition of Captisol except as and to the extent reasonably required to determine an optimal formulation of the Licensed Product, and such structure and composition of Captisol (as and if so determined) shall be considered Confidential Information of CyDex; [***] CyDex shall not be liable to Company for violation of Company's exclusive rights hereunder by parties which are not Affiliates or licensees of CyDex except to the extent CyDex has contributed to such violation. Company acknowledges and agrees that except as is expressly set forth in this Agreement (i) CyDex shall not be required to obtain or maintain patent rights in the Territory for the Licensed Patents, (ii) CyDex shall not be restricted in making sales of Captisol or, except as provided herein for the Licensed Products and/or Competing Products, licensing rights to other parties, and (iii) CyDex does not warrant or indemnify Licensee or its Affiliates and Sublicensees against the Licensed Products infringing Third Party rights.

- 2.2 Grant of License from Company to CyDex. Company hereby grants to CyDex a nonexclusive, transferable, perpetual, worldwide and royalty-free license, with the right to grant sublicenses (through multiple tiers of sublicenses), under Company's and its Affiliates' and Sublicensees' rights in and to Captisol Improvements to develop, make, have made, use, market, distribute, import, sell and offer for sale Captisol, any Captisol Improvement and products formulated with Captisol or any Captisol Improvement (other than the Licensed Products in the Field). If during the Term any of (a) Company, (b) Affiliates to whom Company has provided rights under the licenses granted to Company by CyDex pursuant to Section 2.1, or (c) Sublicensees pursuant to the practice of their respective sublicenses from Company under Section 2.3, file any patent application claiming any Captisol Improvement anywhere in the world, CyDex shall be deemed automatically to have a nonexclusive, transferable, perpetual, worldwide and royalty-free license, with the right to grant sublicenses (through multiple tiers of sublicensees), under the claims relating specifically to any Captisol Improvement to make, have made, use, market, distribute, import, sell, and offer for sale Captisol. Company shall provide prompt notice of any Captisol Improvement.
- 2.3 Sublicensing. Company shall have the right to grant sublicenses (through one or more tiers of sublicenses) to its Affiliates and licensees of the Licensed Products (collectively "Sublicensees") under the licenses granted to Company pursuant to Section 2.1; provided, however, Company warrants and shall procure, as a condition precedent thereto, that each such Sublicensee shall first be advised of the restrictions set forth in this Agreement with respect to the transfer of the rights sublicensed to such Sublicensee and such Sublicensee shall enter into an agreement with Company (with CyDex named as an intended third-party beneficiary) pursuant to which such Sublicensee shall acknowledge and agree to observe and be bound by the applicable restrictions set forth in this Agreement. Other than as specifically provided in this Section 2.3 and Section 2.4, Company shall not have the right to grant sublicenses to any Third Party under the licenses granted pursuant to Section 2.1. Company shall ensure that all of its Sublicensees shall comply with the
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terms and conditions of this Agreement and Company shall be and remain fully responsible for the compliance by such Sublicensees with the terms and conditions of this Agreement as if such Sublicensees were Company hereunder.

- 2.4 Contracting. Company may manufacture the Licensed Products (but not the bulk Captisol) or contract the manufacture of the Licensed Products (but not the manufacture of bulk Captisol) with Third Party manufacturers (collectively "Contract Manufacturers"). To the extent necessary to engage a Contract Manufacturer for a Licensed Product, Company shall be permitted under this Agreement to grant any such Contract Manufacturer a sublicense under the licenses granted to Company pursuant to Section 2.1 solely for such purposes; provided, however, Company warrants and shall procure, as a condition precedent thereto, that (a) any such Contract Manufacturer shall first be advised of the restrictions set forth in this Agreement with respect to the transfer of the rights licensed to Company and its Sublicensees hereunder and (b) any such Contract Manufacturer shall enter into an agreement with Company pursuant to which such Contract Manufacturer shall acknowledge and agree to observe and be bound by the applicable restrictions set forth in this Agreement. Company shall ensure that all of its Contract Manufacturers shall comply with the terms and conditions of this Agreement and shall remain fully responsible for the compliance by such Contract Manufacturers with the terms and conditions of this Agreement as if such Contract Manufacturers were Company hereunder.
- 2.5 Bankruptcy Code. All rights and licenses granted under or pursuant to this Agreement by CyDex to Company are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The parties agree that Company, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. All rights and licenses granted under or pursuant to this Agreement by Company to CyDex are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The parties agree that, as a licensee of such rights under this Agreement, CyDex shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code.
- 2.6 Compliance with Upstream Licenses. CyDex shall be solely responsible for paying directly to any and all Third Parties having rights in any of the Licensed Patents and/or Captisol Data Package (each an "Upstream Licensor") any royalties or other amounts due to such Upstream Licensors as a result of Company exercising its rights hereunder. In addition, CyDex represents and warrants that it is not in breach of any of its obligations to such Upstream Licensors and covenants that it shall maintain its rights under and shall comply with the terms of its agreements with such Upstream Licensors throughout the Term. Furthermore, CyDex represents and warrants that it shall not amend, modify or supplement the terms of, or waive any rights under any such agreements if the same would have the effect of limiting or further restricting Company's rights or expanding Company's obligations hereunder.

2.7 Negative Covenants by CyDex.

(a) During the Term (on a country-by-country basis), neither CyDex nor any of its Affiliates shall directly themselves, nor provide any Third Party any assistance whatsoever, nor grant any Third Party any right or license under any of the Licensed Patents to, research, develop,

modify, make, have made, import, export, use, promote, market, distribute, package, offer for sale, sell, or otherwise commercially exploit Licensed Products or any Competing Products.

- (b) During the Term (on a country-by-country basis), neither CyDex nor any of its Affiliates shall supply Captisol or a Captisol Related Compound to any Third Party (other than a Company designee) which it knows or should know will use it for a Licensed Product or a Competing Product. If during the Term (on a country-by-country basis), any such Third Party, or any other Third Party that acquires any Captisol Related Compound, utilizes such Captisol Related Compound in a Licensed Product or Competing Product, CyDex shall immediately cease and cause its Affiliates and any other Third Party to immediately cease supplying any Captisol Related Products to the offending Third Party for the duration of the Term or until (if sooner) assurances reasonably satisfactory to Company that the infringing use has ended and will not resume have been obtained.
- (c) During the Term, neither CyDex nor any of its Affiliates shall sue or threaten to sue, or take any similar action against, or aid, abet or enable any Third Party to sue, threaten to sue or take any similar action against, Company, or any Sublicensees, or any of their respective Affiliates, or any customers or endusers of any Licensed Products, claiming that the manufacture, use, sale, offer for sale or importation of any Licensed Product infringes any Captisol-related patents or patent applications owned, licensed, sublicensed or otherwise controlled by, now or in the future, CyDex or any of its Affiliates.

3. MANUFACTURE AND SUPPLY OF CAPTISOL.

The provisions of the Supply Agreement and any related Quality Agreement shall govern the manufacture and supply of Captisol for use in the formulation of the Licensed Products. Company acknowledges and agrees that, pursuant to the Supply Agreement, CyDex is the exclusive manufacturer of Captisol for Company and its Affiliates and Sublicensees and nothing set forth herein shall be deemed to grant Company or its Affiliates or Sublicensees the right to manufacture Captisol nor the right to contract the manufacture of Captisol to a Third Party except as provided in Section 3.8(d) of the Supply Agreement.

4. COMPENSATION.

- 4.1 Payments and Royalties for Licenses.
- (a) One-Time Fee. Company shall forthwith pay to CyDex a [***] one-time fee of [***] in partial consideration of the rights granted to Company under this Agreement which shall be due fifteen (15) days after the Effective Date. [***]
- **(b) Milestone Payments.** Within 14 days following the occurrence of each and any of the milestone events listed below, Company shall provide written notice to CyDex of the achievement of such milestone event, and within 21 days of the occurrence of such milestone event, pay to CyDex the applicable non-refundable milestone fee listed next to such event in further consideration of the rights granted Company hereunder. If for any respective Licensed Product
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Family, milestone (iv), (vi) or (viii) is achieved before any or all of milestones (i), (ii) and (iii) have been actually achieved, then any and all of milestones (i), (ii) and (iii) which were not previously actually achieved for such Licensed Product Family shall be deemed to have thereby been achieved for such Licensed Product Family, and the milestone payments for such deemed-achieved milestones shall also be payable within such 21 days.

	MILESTONE	MILESTONE PAYMENT
(i)	Upon dosing of the first patient in the first [***] Clinical Trial by Company or under	
	rights from Company for a Licensed Product in a Licensed Product Family*	[***]
(ii)	Upon dosing of the first patient in the first [***] Clinical Trial by Company or under	
	rights from Company for a Licensed Product in a Licensed Product Family*	[***]
(iii)	Upon submission of a NDA to the FDA for a Licensed Product in a Licensed Product	
	Family*	[***]
(iv)	Upon receipt of Marketing Approval from the FDA for the first indication of a Licensed	
	Product in a Licensed Product Family*	[***]
(v)	Upon receipt of Marketing Approval from the FDA for each additional indication of a	
	Licensed Product in a Licensed Product Family	[***]
(vi)	Upon receipt of Marketing Approval in the EU for the first indication of a Licensed	
	Product in a Licensed Product Family*	[***]
(vii)	Upon receipt of Marketing Approval in the EU for each additional indication of a	
	Licensed Product in a Licensed Product Family	[***]
(viii)	Upon receipt of Marketing Approval in Japan for the first indication of a Licensed	
	Product in a Licensed Product Family*	[***]
(ix)	Upon receipt of Marketing Approval in Japan for each additional indication of a	
	Licensed Product in a Licensed Product Family	[***]

^{*} such milestone shall only be payable once per Licensed Product Family.

(c) Royalties.

(i) In addition to amounts payable pursuant to Sections 4.1(a) and 4.1(b) above, Company shall make royalty payments to CyDex on a calendar quarterly basis in an amount equal to [***] of the applicable Net Sales during such quarter, as determined for each Licensed Product. Provided that for the duration of any period in the Term in which (a) [***]

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- (ii) The royalty shall be reduced with respect to Net Sales in a particular country by deducting (a) 50% of any and all royalties paid by Company, its Affiliates and/or Sublicensees to any Third Party for any additional solubility technology that is incorporated in a Licensed Product in such country, up to a maximum reduction of 50% in the aggregate of the royalty owing for Net Sales in such country; (b) 100% of any and all royalties paid for any license that the parties mutually determine in good faith would be prudent to obtain given the potential to resolve or avoid any claims that Captisol, or specifically the Captisol element of a Licensed Product infringes or misappropriates the intellectual property rights of any Third Party in such country; and (c) any final, unappealed judgment awarded against Company, its Affiliates or Sublicensees for damages for infringement of Third Party intellectual property rights with respect to making, having made, using, selling, offering for sale or importing Captisol, or specifically the Captisol element of a Licensed Product in such country. Company shall use commercially reasonable efforts to minimize any such royalties or other payments to Third Parties on account of sales of Licensed Products hereunder.
- (iii) In the event that a Licensed Product is commercialized in combination with one or more products which are themselves not Licensed Products under this Agreement for a single price, the Net Sales for such Licensed Product shall be calculated by multiplying the sales price of such combination sale by the fraction A/(A+B) where A is the fair market value of the Product and B is the fair market value of the other product(s) in the combination sale. If the fair market value for any product sold in combination with a Licensed Product cannot be reasonably determined, the price attributed to such product shall be based on the relative cost of goods for such product, as determined in accordance with U.S. GAAP.
- (iv) All royalties payable to CyDex pursuant to Section 4.1(c) shall be due and payable within [***] after the conclusion of each calendar quarter, provided that within [***] after the conclusion of each Company fiscal year Company may provide notice to CyDex of any adjustments necessary to account for any royalties which were overpaid or underpaid for such prior fiscal year's calendar quarters (as determined from Company's end of fiscal year external audit), and the parties shall promptly true-up for any such adjustments which are mutually determined to be correct.

In establishing the royalty structure hereunder, the parties recognize, and Company acknowledges, the substantial value of the various obligations being undertaken by CyDex under this Agreement, in addition to the grant of the licenses under the Captisol Data Package as well as under the Licensed Patents, to enable the rapid and effective market introduction of the Licensed Products. The parties have agreed to the payment structure set forth herein as a convenient and fair mechanism to compensate CyDex for these obligations.

- **4.2 Taxes**. All amounts due hereunder exclude all applicable withholding, sales, use, and other taxes and duties, and Company shall be responsible for payment of all such taxes (other than taxes based on CyDex's income) and duties and any related penalties and interest, arising from the payment of amounts due under this Agreement. The parties agree to cooperate with one another and use commercially reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by Company to CyDex under this Agreement. To the extent Company is required to withhold taxes on any payment to CyDex,
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Company shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to CyDex official receipts issued by the appropriate taxing authority and/or an official tax certificate, or such other evidence as CyDex may reasonably request, to establish that such taxes have been paid. CyDex shall provide Company any tax forms that may be reasonably necessary in order for Company to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. CyDex shall use commercially reasonable efforts to provide any such tax forms to Company at least 45 days before the due date for any payment for which CyDex desires that Company apply a reduced withholding rate. Each party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the party bearing such withholding tax or value added tax. CyDex shall indemnify and hold Company harmless from and against any penalties, interest or other tax liability arising from any failure by Company (at the express request of CyDex) to withholding.

4.3 Payments. Payments that are not made when due hereunder shall accrue interest, from due date until paid, at an annual interest rate equal to the prime rate, as reported in *The Wall Street Journal*, Eastern U.S. Edition, on the date such payment is due, plus an additional 200 basis points (2%). All amounts due hereunder are stated in, and shall be paid in, U.S. Dollars.

5. RECORDS; REPORTS; AUDIT.

5.1 Records. During the Term and for a period of three years thereafter, Company shall, and shall require its Affiliates and Sublicensees to, maintain accurate records relating to Net Sales of the Licensed Products and clinical study subject enrollment for Studies.

5.2 Reports.

- (a) Quarterly Financial Reports. Within 45 days following the conclusion of each calendar quarter during the Term, Company shall provide CyDex with a written report with respect to such calendar quarter that sets forth sales of the Licensed Products in the Territory during such calendar quarter. Such report shall include Net Sales and royalties due for each Licensed Product. Within 90 days after the conclusion of each Company fiscal year Company may provide notice to CyDex of any adjustments necessary to such reports and any royalties which were overpaid or underpaid for such prior fiscal year's calendar quarters (as determined from Company's end of fiscal year external audit) shall be adjusted in accordance with Section 4.1(c)(iv).
- **(b) Annual Milestone Reports.** By November 1st of each calendar year during the Term, Company shall provide CyDex with written reports that describe in reasonable detail Company's progress made toward achievement of the milestones specified in Section 4.1(b) above during such calendar year and set forth such other information regarding Captisol as mutually agreed upon by the parties. Company shall also provide quarterly updates regarding any significant changes to the expected completion of any such milestones outlined in the annual report.
- **5.3 Audit.** Upon at least 14 days advance written notice by CyDex, Company shall permit CyDex's independent, Third Party certified public accountant, reasonably acceptable to Company, to have access during normal business hours to such of the records of Company as may be reasonably necessary to verify the royalty reports under **Section 5.2(a)** in respect of any calendar

year ending not more than 36 months before the date of such request. Except as described in the next paragraph, all such audits shall be conducted at the expense of CyDex and not more than once in each calendar year and not more than once for each audited period. In the event such accountant concludes that additional payments of any kind as required by this Agreement were owed to CyDex during such period, the additional amounts shall be paid within 30 days of the date CyDex delivers to Company such accountant's written report so concluding unless Company disputes the results of such audit in accordance with Section 14.3. The fees charged by such accountant shall be paid by CyDex, unless the audit discloses that the amounts payable by Company for the audited period are more than [***] of the amounts actually paid for such period and more than [***] in which case Company shall pay the reasonable fees and expenses charged by the accountant (pending the results of any dispute initiated by either party pursuant to Section 14.3 with respect to the same). In the event such accountant concludes that there was an overpayment by Company to CyDex during such period, at Company's option, the overpayment shall be (i) credited against future amounts due from Company, or (ii) paid by CyDex to Company within 30 days of the date of the written report. The independent certified public accountant shall keep confidential any information obtained during such inspection in accordance with the provisions set forth in Section 8 hereof and shall report to CyDex and Company only the amounts of Net Sales and royalties due and payable. The parties agree that all information subject to review under this Section 5.3 or under any sublicense agreement is the Confidential Information of Company and that CyDex shall cause its accountant to retain all such information in confidence.

6. DEVELOPMENT AND COMMERCIALIZATION BY COMPANY.

- **6.1 Costs and Expenses**. Company shall be solely responsible for all costs and expenses related to its development and commercialization of the Licensed Products, including without limitation costs and expenses associated with all preclinical activities and clinical trials, and all regulatory filings and proceedings relating to the Licensed Products.
- **6.2 In Vivo Studies.** If Company wishes to conduct any in vivo study (preclinical or clinical, in animals or in humans, each a "**Study**") of a Licensed Product utilizing Captisol, the following provisions shall apply:
- (a) Dosing. Company shall not exceed the maximum allowable dosing levels of Captisol specified in CyDex's then-current clinical dosing matrix (which shall be provided by CyDex to Company from time to time) without the written consent of CyDex.
- **(b) Compliance with Laws.** Company represents and warrants that each Study shall be performed in accordance with all applicable laws, regulations and requirements. Company shall provide or cause to be provided all appropriate warnings to participants enrolled in each Study and obtain or cause to be obtained appropriate documentation of informed consent from all participants in each such Study.
- (c) Adverse Events. Company agrees to immediately inform CyDex if any adverse effects are observed and ascribed to Captisol in any Study in accordance with Section 7.3 hereof. To accurately track adverse events and preserve the validity of each Study preceding the First Commercial Launch of the applicable Licensed Product, subject to Company's additional rights under the Supply Agreement, Company shall only use Captisol supplied by CyDex for each such Study preceding the First Commercial Launch of the applicable Licensed Product conducted under
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the scope of this Agreement, and, subject to Company's additional rights under the Supply Agreement, shall not use any other cyclodextrin product supplied by a Third Party.

- (d) Reporting and Study Data. Within three months after receipt of the final Study report for a Study, Company shall provide to CyDex a summary of the data and results of each Study that pertain solely to Captisol, and subject to Section 8, Company hereby grants to CyDex a non-exclusive, royalty-free license (with the right to sublicense) to use and disclose such data solely as necessary for regulatory purposes, including without limitation to update the DMF for Captisol.
- **(e) Responsibility.** Company has the freedom to formulate and design each Study, and (as between Company and CyDex) Company is solely responsible for executing each Study; and so it is reasonable that, and the parties agree that, Company shall be solely responsible therefor and for any effects or consequences of the formulation, design and execution of each Study.
- **6.3 Right of Reference.** Company shall have the right to reference the DMF solely in connection with Company's regulatory filings (including INDs, NDAs, etc.) submitted in connection with obtaining Marketing Approval for a Licensed Product. CyDex shall use commercially reasonable efforts to keep its DMF in good standing throughout the Term.
- **6.4 Access to Company's Data.** CyDex shall have the right to reference and utilize all toxicology/safety and other relevant scientific data developed on Captisol alone (and not in conjunction with a Licensed Product) by Company, its Sublicensees or Affiliates, at no cost to CyDex. Upon request by CyDex, Company shall either provide CyDex, at CyDex's sole expense, with a copy of all such data or shall make such data accessible to CyDex at times and locations reasonably agreeable to CyDex and Company subject to the provisions of **Section 8**.

7. REGULATORY MATTERS.

- 7.1 Captisol Information Submitted for Regulatory Review. Except as otherwise set forth herein, Company shall be solely responsible for all communications with regulatory agencies in connection with the Licensed Products, provided CyDex shall reasonably cooperate with Company with respect to any interactions with regulatory authorities concerning Captisol. Company shall provide CyDex with copies of the portions of all regulatory submissions containing Captisol data alone (and not in conjunction with any Licensed Product) 14 days before submission and shall allow CyDex to review and comment upon said submissions. The contents of each such submission shall be deemed to be Confidential Information of Company, subject to the terms and provisions of Section 8 below. Company shall promptly inform CyDex of meetings with the FDA (or other regulatory agencies in the Territory) regarding Captisol. If Company submits written responses to the FDA that include data on Captisol alone, CyDex shall be permitted to review such written materials 14 days before submission. If CyDex reasonably objects to the contents of such written responses relating to Captisol, the parties agree to cooperate in working toward a reasonable and mutually agreeable response; provided, however, that Company shall be entitled to in good faith make the final determination as to the contents of any such materials.
- **7.2 Material Safety.** CyDex shall provide Company, in writing, from time to time, with (a) relevant material information currently known to it regarding handling precautions, toxicity and hazards with respect to Captisol, and (b) the then-current material safety data sheet for Captisol. Notwithstanding the foregoing or anything in this Agreement to the contrary, Company is solely

responsible for (i) use of all documentation provided by CyDex, including without limitation, use in any regulatory submission to the FDA or any other regulatory agency in the Territory, (ii) document control and retention, and (iii) determining the suitability of any documentation provided by CyDex hereunder for use in any regulatory submission.

7.3 Adverse Event Reporting. Company shall adhere, and shall require that its Affiliates, Sublicensees, co-marketers and distributors adhere, to all requirements of applicable law and regulations that relate to the reporting and investigation of any adverse event, including without limitation an unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease, whether or not considered Captisol or Licensed Product-related, which occurs or worsens following administration of Captisol or Licensed Product. Each party shall provide the other with copies of all reports it obtains (either directly or through any Sublicensee or licensee) of any adverse event which is serious (e.g., any such adverse event involving Captisol or the Licensed Product that results in death, is life-threatening, requires or prolongs inpatient hospitalization, results in disability, congenital anomaly or is medically important (i.e., may require other medical or surgical intervention to prevent other serious criteria from occurring)) which such party has reason to believe are associated with Captisol within 14 days following (i) submission of any such report to any regulatory agency, or (ii) receipt from such party's Sublicensee, licensee, comarketer or distributor of any such report to any regulatory agency. Company shall also advise CyDex regarding any proposed labeling or registration dossier changes affecting Captisol. Reports from Company shall be delivered to the attention of Chief Scientific Officer, CyDex, with a copy to Chief Executive Officer, CyDex, at the address set forth in Section 14.7. The parties shall mutually cooperate with regard to investigation of any such serious adverse event, whether experienced by Company, CyDex or any other Affiliate, Sublicensee, sublicensee, co-marketer or distributor of CyDex or Company.

7.4 Safety Agreement. Upon request by Company, CyDex shall negotiate in good faith a separate safety agreement (the "Safety Agreement"), for each proposed Licensed Product, at least 120 days before submission of an IND related to such proposed Licensed Product (or, for any proposed Licensed Products for which the IND was submitted before the Effective Date, then as soon as practicable after the Effective Date). The Safety Agreement would be anticipated to provide details related to the management of serious Adverse Events that occur during clinical trials, including safety issues rising from pre-clinical research and other safety and reporting practices and procedures, detailing obligations related to the development and commercialization of the Licensed Product in compliance with all applicable laws, rules, and regulations.

8. CONFIDENTIALITY.

8.1 Definition. Company and CyDex each recognizes that during the Term, it may be necessary for a party (the "**Disclosing Party**") to provide Confidential Information (as defined herein) to the other party (the "**Receiving Party**") that is highly valuable, the disclosure of which would be highly prejudicial to such party. The disclosure and use of Confidential Information shall be governed by the provisions of this **Section 8**. Neither Company nor CyDex nor their Affiliates shall use the other's Confidential Information except as expressly permitted in this Agreement. For purposes of this Agreement, "**Confidential Information**" means all information disclosed by the Disclosing Party to the Receiving Party and which reasonably ought to have been understood to be confidential and/or non-public information at the time disclosed to the Receiving Party, or which is designated in writing by the Disclosing Party as "Confidential" (or equivalent), or which when

disclosed orally to the Receiving Party is declared to be confidential by the Disclosing Party and is so confirmed in a writing delivered to the Receiving Party within 30 days of such oral disclosure, including but not limited to product specifications, data, know-how, formulations, product concepts, sample materials, business and technical information, financial data, batch records, trade secrets, processes, techniques, algorithms, programs, designs, drawings, and any other information related to a party's present or future products, sales, suppliers, customers, employees, investors or business. Without limiting the generality of the foregoing, CyDex's Confidential Information includes all materials provided as part of the Captisol Data Package.

- **8.2 Obligation.** CyDex and Company agree that they will disclose the other party's Confidential Information to its own (or its 100% stockholder's, or with respect to Company, its Sublicensees') officers, employees, consultants and agents only if and to the extent necessary to carry out their respective responsibilities under this Agreement or in accordance with the exercise of their rights under this Agreement, and such disclosure shall be limited to the maximum extent possible consistent with such responsibilities and rights. Except as set forth in the foregoing sentence, neither party shall disclose Confidential Information of the other to any Third Party without the other's prior written consent; *provided, however*, consent shall not be required to the extent such Confidential Information is disclosed for diligence purposes to Company's potential Sublicensees, sources of funding or acquirers of any or all of the Company's assets to which this Agreement relates. In all events, however, any and all disclosure to a Third Party shall be pursuant to the terms of a non-disclosure/nonuse agreement no less restrictive than this **Section 8**. The party which disclosed Confidential Information of the other to any Third Party or Affiliate shall be responsible and liable for any disclosure or use by such Third Party or Affiliate (or its disclosees) which would have violated this Agreement if committed by the party itself. Neither party shall use Confidential Information of the other except as expressly allowed by and for the purposes of this Agreement. Each party shall take such action to preserve the confidentiality of each other's Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information (but in no event less than a reasonable standard of care). Upon expiration or termination of this Agreement, each party, upon the other's request, shall return or destroy (at disclosing party's discretion) all the Confidential Information disclosed to the other party pur
- **8.3** Exceptions. The use and non-disclosure obligations set forth in this **Section 8** shall not apply to any Confidential Information, or portion thereof, that the Receiving Party can demonstrate by competent evidence:
 - (a) at the time of disclosure is in the public domain;
 - (b) after disclosure, becomes part of the public domain, by publication or otherwise, through no fault of the Receiving Party or its disclosees;
- (c) at the time of disclosure is already in the Receiving Party's possession, and such prior possession can be properly demonstrated by the Receiving Party, with the exception of Confidential Information exchanged between parties before the execution of this Agreement;
- (d) is made available to the Receiving Party by an independent Third Party without obligation of confidentiality; provided, however, that to the Receiving Party's knowledge,

such information was not obtained by said Third Party, directly or indirectly, from the Disclosing Party hereunder; or

(e) is independently developed by an employee of the Receiving Party not accessing or utilizing the Disclosing Party's information.

In addition, the Receiving Party may disclose information that is required to be disclosed by law, by a valid order of a court or by order or regulation of a governmental agency including but not limited to, regulations of the SEC or in the course of arbitration or litigation; *provided, however*; that in all cases the Receiving Party shall give the other party prompt notice of the pending disclosure and use commercially reasonable efforts to obtain, or to assist the Disclosing Party in obtaining, a protective order or confidential-treatment order preventing or limiting (to the greatest possible extent and for the longest possible period) the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation required, or for which the order was issued.

8.4 Injunction. Each party agrees that should it breach or threaten to breach any provisions of this **Section 8**, the Disclosing Party will suffer irreparable damages and its remedy at law will be inadequate. Upon any breach or threatened breach by the Receiving Party of this **Section 8**, the Disclosing Party shall be entitled to seek temporary, preliminary and/or permanent injunctive relief in addition to any other remedy which it may have, without need to post any bond or security, in addition to any and all other legal and equitable rights and remedies available to the Disclosing Party.

8.5 Third Party Information.

- (a) Company acknowledges that CyDex's Confidential Information and DMF include information developed by Pfizer, Inc. ("Pfizer") that is confidential to both CyDex and Pfizer. Only to the extent that confidential information of Pfizer is disclosed to Company hereunder, and only as required by CyDex's pre-existing contractual obligations to Pfizer, then Pfizer is a limited third party beneficiary of only this Section 8 of this Agreement and may seek remedies pursuant to it, but only in accordance with its terms.
- (b) Both parties agree not to disclose to the other party any Confidential Information of a Third Party which is in the possession of such party, unless the other party has given an express prior written consent (which specifies the owner of such Confidential Information) to receive such particular Confidential Information.
- **8.6 Public Announcements.** The parties shall mutually agree on any press release to be issued upon execution of this Agreement. Neither party shall make any subsequent public announcement concerning this Agreement or the terms hereof not previously made public without the prior written approval of the other party with regard to the form, content, and precise timing of such announcement, except as may be required to be made by either party in order to comply with applicable law, regulations, court orders, or tax, securities filings, financing arrangements, acquisitions, or sublicenses. Such consent shall not be unreasonably withheld or delayed by such other party. Before any such public announcement, the party wishing to make the announcement shall submit a draft of the proposed announcement to the other party in sufficient time to enable such other party to consider and comment thereon. In addition, Company shall not, without at least 14

days' prior written notice to CyDex (except to the extent such a notice period would not be allowed due to an affirmative requirement of applicable law for immediate disclosure to governmental authorities), state or suggest orally or in writing to any governmental authorities, physicians or other Third Parties that Captisol (sulfobutylether ß cyclodextrin) has any safety or efficacy issues or that any Adverse Event was due to Captisol. Upon providing such notice, Company shall not be required to provide any additional notices to CyDex for any subsequent statements (oral or written) concerning the same issue. Similarly, CyDex shall not, without at least 14 days' prior written notice to Company (except to the extent such a notice period would not be allowed due to an affirmative requirement of applicable law for immediate disclosure to governmental authorities), state or suggest orally or in writing to any governmental authorities, physicians or other Third Parties that a Compound or Licensed Product has any safety or efficacy issues or that any Adverse Event was due to a Compound or a Licensed Product. Upon providing such notice, CyDex shall not be required to provide any additional notices to Company for any subsequent statements (oral or written) concerning the same issue.

9. REPRESENTATIONS AND WARRANTIES.

- 9.1 Mutual Representations and Warranties. Each party represents and warrants to the other that, as of the Effective Date:
 - (a) it is a corporation duly organized and validly existing under the laws of the state or country of its incorporation;
 - (b) it has the full power and right to enter into this Agreement and to perform its obligations hereunder;
- (c) this Agreement has been duly authorized, executed and delivered by such party and constitutes a legal, valid and binding obligation of such party enforceable against such party in accordance with its terms except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, receivership, moratorium, fraudulent transfer, or other similar laws affecting the rights and remedies of creditors generally and by general principles of equity;
- (d) the execution, delivery and performance of this Agreement by such party do not conflict with any agreement, instrument or understanding, oral or written, to which such party is a party or by which such party may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having authority over such party;
- (e) all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such party in connection with the execution and delivery of this Agreement have been obtained;
- (f) no person or entity has or will have, as a result of the transactions contemplated by this Agreement, any right, interest or valid claim against or upon such party for any commission, fee or other compensation as a finder or broker because of any act by such party or its agents, or, with respect to Company, because of any act by its Affiliates or Sublicensees; and
 - (g) it has not entered into any agreement with any Third Party that is in conflict with the rights granted to the other party pursuant to this Agreement.

9.2 CyDex Representations and Warranties. CyDex hereby represents and warrants to Company as follows:

- (a) that it has no knowledge of any unsettled past or current, and has not received notice of any threatened, patent, trade secret or other intellectual property dispute with any Third Party that actually or is reasonably likely to have a material adverse effect on the Licensed Patents or Captisol Data Package;
- (b) the Licensed Patents are not subject to any outstanding injunction, judgment order, ruling or charge and CyDex knows of no pending or threatened claim or action which challenges the validity, legality, enforceability or use of the Licensed Patents or Captisol Data Package;
 - (c) CyDex has the full right, power and authority to grant all of the licenses granted to Company under this Agreement;
- (d) as of the Effective Date, CyDex has not granted to any Third Party any license to any of the Licensed Patents or Captisol Data Package which conflicts with the exclusive license hereunder;
- (e) through the Effective Date CyDex has filed and maintained with the appropriate regulatory authorities in the Territory all permits, licenses, regulatory filings (including the DMF) and approvals related to Captisol and the manufacture and sale thereof, necessary for CyDex to carry out its obligations and for Company to exercise its rights under this Agreement and the Supply Agreement, except where the failure to so file and maintain does not have and would not reasonably be expected to have a material adverse effect on (i) CyDex and/or its ability to supply Captisol and/or (ii) Company and/or its ability to obtain Captisol and/or exploit Licensed Products;
- (f) all information provided pursuant to Section 7.2, in Exhibit A hereof and Exhibit B of the Supply Agreement and as a part of the Captisol Data Package shall to CyDex's knowledge be complete and accurate; and
- (g) CyDex shall notify Company promptly if it becomes aware of any material facts or circumstances occurring after the Effective Date which it has reason to believe would have made the aforementioned representations and warranties untrue had they been given after the Effective Date.
- 9.3 Disclaimer. The warranties set forth in this Section 9 above are provided in lieu of, and each party hereby disclaims, all other warranties, express and implied, relating to the subject matter of this Agreement, Captisol, the Licensed Patents, the Captisol Data Package, the Compounds, the Licensed Products, the Captisol Improvements, any Study Data or Results provided hereunder and/or any toxicology and/or scientific data provided hereunder including but not limited to the implied warranties of merchantability and fitness for a particular purpose, title and non-infringement of third party rights. Each party's warranties under this Agreement are solely for the benefit of the other party and may be asserted only by the other party and not by any Affiliate, Sublicensee or any customer of the other party, its Affiliates or Sublicensees. Each party, its Affiliates and Sublicensees shall be solely responsible for all representations and warranties that it, its Affiliates or Sublicensees make to any customer of such party, its Affiliates or Sublicensees.

10. INDEMNIFICATION.

10.1 By CyDex. CyDex shall defend, indemnify and hold Company and its Affiliates and Sublicensees, and each of their respective directors, officers, agents and employees (collectively, the "Company Indemnitees"), harmless from and against any and all losses, judgments, damages, liabilities, settlements, penalties, fines, costs and expenses of attorneys and other professionals) (collectively, "Losses") incurred by the Company Indemnitees as a result of any claim, demand, action or other proceeding (each, a "Claim") by a Third Party, to the extent such Losses arise out of (i) CyDex's breach of this Agreement or the Supply Agreement, including without limitation any of its representations and warranties set forth herein or therein; (ii) the research, development, manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of Captisol by CyDex, its Affiliates, distributors, licensees or agents (for clarity, such terms shall not include Company in any event); (iii) [***] (iv) interactions and communications by CyDex, its Affiliates, manufacturers, distributors or agents with governmental authorities, physicians or other Third Parties relating to Captisol, including the Captisol Data Package; (v) use or reliance by CyDex upon the Captisol Improvements, any Study data or results provided to CyDex pursuant to Section 6.2(d) and/or any toxicology and/or scientific data provided to CyDex pursuant to Section 6.4; (vi) the supply, sale, distribution or, consumption of any defective Captisol and any recall resulting therefrom (whether or not rejected by Company under the Supply Agreement); (vii) any enforcement action by a regulatory authority relating to Captisol; or (viii) the grossly negligent or willful misconduct of CyDex or its Affiliates or any of their respective distributors, officers, directors, employees or agents; all except to the extent that such Losses are primarily caused by a Company Indemnitee's gross negligence or willful misconduct.

10.2 By Company. Company shall defend, indemnify and hold CyDex and its Affiliates, and each of their respective directors, officers, agents and employees (collectively, the "CyDex Indemnitees"), harmless from and against any and all Losses incurred by the CyDex Indemnitees as a result of any Claim by a Third Party, to the extent such Losses arise out of: (i) Company's breach of this Agreement or the Supply Agreement, including without limitation any of its representations and warranties herein or therein; (ii) any Study conducted by or on behalf of Company (whether before or after the Effective Date); (iii) the research, development, manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of Licensed Products by Company, its Affiliates, Sublicensees, Contract Manufacturers, distributors or agents (for clarity, such terms shall not include CyDex in any event); (iv) infringement of a Third Party's intellectual property rights in the making, having made (other than by CyDex or its designee), using, selling, offering for sale and importing of Licensed Products (other than intellectual property rights claiming Captisol *per se* or its manufacture or use); (v) interactions and communications by Company, its Affiliates, Sublicensees, distributors or agents with governmental authorities, physicians or other Third Parties relating to Licensed Products; or (vi) the grossly negligent or willful misconduct of Company or its Affiliates, Sublicensees, Contract Manufacturers, distributors or agents or any of their respective officers, directors, managers, employees or agents; all except to the extent that such Losses are primarily caused by a CyDex Indemnitee's gross negligence or willful misconduct.

10.3 Expenses. As the parties intend complete indemnification, all costs and expenses of enforcing any provision of this Section 10 shall also be reimbursed by the Indemnifying Party.

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

10.4 Procedure. The party intending to claim indemnification under this Section 10 (an "Indemnified Party") shall promptly notify the other party (the "Indemnifying Party") of any Claim in respect of which the Indemnified Party intends to claim such indemnification, and the Indemnifying Party shall assume the defense thereof whether or not such Claim is rightfully brought; provided, however; that an Indemnified Party shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnified Party, unless Indemnifying Party does not assume the defense, in which case the reasonable fees and expenses of counsel retained by the Indemnified Party shall be paid by the Indemnifying Party. The Indemnified Party, and its employees and agents, shall cooperate fully with the Indemnifying Party and its legal representatives in the investigations of any Claim. Indemnifying Party shall not be liable for the indemnification of any Claim settled (or resolved by consent to the entry of judgment) without the written consent of the Indemnifying Party. Also, if the Indemnifying Party shall control the defense of any such Claim, the Indemnifying Party shall have the right to settle such Claim; provided, that the Indemnifying Party shall obtain the prior written consent (which shall not be unreasonably withheld or delayed) of the Indemnified Party before entering into any settlement of (or resolving by consent to the entry of judgment upon) such Claim unless (A) there is no finding or admission of any violation of law or any violation of the rights of any Person by an Indemnified Party, no requirement that the Indemnified Party admit fault or culpability, and no adverse effect on any other claims that may be made by or against the Indemnified Party and (B) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party and such settlement does not require the Indemnified Party to take (or refrain from taking) any action.

Regardless of who controls the defense, the other party hereto shall reasonably cooperate in the defense as may be requested. Without limitation, the Indemnified Party, and its directors, officers, advisers, agents and employees, shall cooperate fully with the Indemnifying Party and its legal representatives in the investigations of any Claim.

11. LIMITATION OF LIABILITY.

EXCEPT FOR DAMAGES FOR WHICH A PARTY IS RESPONSIBLE PURSUANT TO ITS INDEMNIFICATION OBLIGATIONS SET FORTH IN SECTION 10 OR AS OTHERWISE EXPRESSLY STATED HEREIN (E.G., VIA AN EXPRESS REFERENCE TO "INCIDENTAL" COSTS), EACH PARTY SPECIFICALLY DISCLAIMS ALL LIABILITY FOR AND SHALL IN NO EVENT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES, EXPENSES, LOST PROFITS, LOST SAVINGS, INTERRUPTIONS OF BUSINESS OR OTHER DAMAGES OF ANY KIND OR CHARACTER WHATSOEVER ARISING OUT OF OR RELATED TO THIS AGREEMENT OR RESULTING FROM THE MANUFACTURE, HANDLING, MARKETING, SALE, DISTRIBUTION OR USE OF LICENSED PRODUCTS, THE LICENSED PATENTS OR CAPTISOL DATA PACKAGE, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. SUBJECT TO THE FOREGOING, EACH PARTY SHALL BE ENTITLED TO ALL REMEDIES AVAILABLE TO IT IN CONTRACT LAW OR IN EQUITY (OTHER THAN REMEDIES IN EQUITY WHICH REQUIRE THE PAYMENT OF MONEY). EXCEPT WITH RESPECT TO THE INDEMNIFICATION SPECIFICALLY PROVIDED IN SECTION 10, A PARTY'S RECALL OBLIGATIONS UNDER SECTION 3.9 OF THE SUPPLY AGREEMENT, A BREACH OF SECTION 2.7 OR CLAIMS FOR NON-PAYMENT OF MILESTONES OR ROYALTIES DUE HEREUNDER, IN NO EVENT SHALL A PARTY'S TOTAL AGGREGATE LIABILITY FOR ALL CLAIMS ARISING OUT OF OR RELATED TO THIS AGREEMENT EXCEED THE AMOUNTS PAID BY COMPANY TO CYDEX PURSUANT TO SECTION 4 OF THIS AGREEMENT DURING THE 12 MONTH PERIOD IMMEDIATELY PRECEDING THE EVENT GIVING RISE TO LIABILITY. NO ACTION, REGARDLESS OF FORM, ARISING OUT OF

OR RELATED TO THIS AGREEMENT MAY BE BROUGHT BY EITHER PARTY MORE THAN TWO YEARS AFTER SUCH PARTY HAS KNOWLEDGE OF THE OCCURRENCE THAT GAVE RISE TO THE CAUSE OF ACTION OR AFTER EXPIRATION OF THE APPLICABLE STATUTORY LIMITATIONS PERIOD, WHICHEVER IS SOONER.

12. MANAGEMENT OF INTELLECTUAL PROPERTY.

12.1 Ownership.

- (a) Existing and Acquired Rights. Each party shall maintain its ownership and other rights with respect to intellectual property owned or controlled by such party before the Effective Date. Each party shall own any intellectual property acquired by such party outside of this Agreement after the Effective Date.
- **(b)** New Rights. The ownership of discoveries, inventions, improvements and other technology, whether or not patentable, made by Company's and/or CyDex's personnel and related to the subject matter of this Agreement (but expressly excluding Company IP) ("New Rights") shall be determined in accordance with US patent law and state intellectual-property law, as applicable.
- (c) Company IP. Notwithstanding anything to the contrary in this Agreement, any technology or improvement, whether or not patentable, that claims the Compound or the Compound with Captisol (but excluding any claims to Captisol alone), shall be owned solely by Company (collectively, "Company IP"). If such Company IP was developed under the Agreement solely by or jointly with CyDex, its Affiliates, or their employees or contractors, CyDex hereby assigns and will assign and cause such Affiliates, employees or contractors to assign all rights in such Company IP to Company or its designated Affiliate.

12.2 Prosecution and Maintenance.

- (a) Existing Rights (Licensed Patents). During the Term CyDex shall use commercially reasonable efforts to prosecute and maintain, at its sole cost and expense, the Licensed Patents. CyDex shall have the sole right to control the prosecution and maintenance of patent applications and the selection of countries where patent applications are filed related to the Licensed Patents, subject to the following sentence. In the event that CyDex decides not to prosecute and maintain the Licensed Patents in a country in the Territory, CyDex shall provide not less than 30 days' prior written notice of such decision to Company, and Company shall have the right, but not the obligation, to take over such prosecution and maintenance in such country on CyDex's behalf at Company's sole and unreimbursable expense. Each party shall reasonably cooperate with the prosecuting party in connection with its prosecution and maintenance activities at the prosecuting party's request and expense, including by making scientists and scientific records reasonably available to the prosecuting party.
- **(b)** New Rights. The parties shall cooperate to take whatever, if any, action they mutually agree upon in writing and in their respective discretion to prosecute patent applications and maintain patents covering rights which are jointly owned in accordance with Section 12.1(b). Such agreement shall include actions to be taken by each party and the allocation of expenses related to such action. Neither party shall seek patent protection covering such rights without such agreement.

(c) For the avoidance of doubt, subject to Sections 12.2(a) and (b) each party shall be solely responsible for all decisions and actions pertaining to the prosecution and maintenance of patents owned solely by such party.

12.3 Infringement by Third Parties.

- (a) Each party shall promptly notify the other party in writing of any actual or threatened infringement, misappropriation or other violation by a Third Party of any Licensed Patents in the Field and in the Territory ("Third Party Infringement") of which it becomes aware.
- (b) Existing Rights. CyDex shall have the initial right (but not the obligation), at its own expense, to initiate and control any action to enforce the Licensed Patents against any Third Party Infringement and may name Company as a party plaintiff solely to the extent required to maintain standing, providing CyDex shall reimburse Company for any such costs incurred by Company therefor. If CyDex does not obtain agreement from the alleged infringer to desist or fails to initiate an infringement action within: (i) 60 days following receipt of notice of the alleged infringement (120 days if CyDex is in active negotiations with such infringer), or (ii) 30 days before the expiration date for filing such actions, whichever comes first, Company shall have the right, at its sole discretion, to initiate and control an action to enforce the Licensed Patents against such Third Party Infringement at its sole expense and may name CyDex as a party plaintiff solely to the extent required to maintain standing; provided, however, Company shall reimburse CyDex for any costs incurred by CyDex therefor, provided, further, Company shall not enforce any Licensed Patents to the extent such Third Party Infringement is unrelated to the development, filing for regulatory approval for, manufacture, offer for sale, sale, import or use of a Competing Product. Before commencing an action, the party bringing such action (the "Enforcing Party") shall consult with the other party and give consideration to the other party's recommendations regarding the proposed action. The Enforcing Party shall give the other party timely notice of any proposed settlement of any such action instituted by the Enforcing Party and shall not, without the prior written consent of the other party, enter into any settlement. Notwithstanding the foregoing, if CyDex is the Enforcing Party and such Third Party Infringement is unrelated to a Competing Product or Company is the Enforcing Party (and thus by default such Third Party Infringement is related to a Competing Product), then in either such case the Enforcing Party shall not be required to obtain the other party's prior written consent to settle an action so long as such settlement does not: (i) adversely affect the validity, enforceability or scope of any of the Licensed Patents, (ii) give rise to liability of the other party or its Affiliates, (iii) admit noninfringement of any Licensed Patents, or (iv) otherwise impair the other party's rights in any Licensed Patents or under this Agreement. Any recoveries resulting from an action relating to a claim of Third Party Infringement of the Licensed Patents (including any recoveries resulting from settlement) shall first be applied against payment of each party's costs and expenses incurred in connection therewith. If CyDex was the Enforcing Party, then any remaining recoveries shall be retained by CyDex, provided that if such Third Party Infringement is related to the development, filing for regulatory approval for, manufacture, offer for sale. sale, import or use of a Competing Product, then any remaining recoveries shall be split such that CyDex retains [***] and Company retains [***] of such remainder. If Company was the Enforcing Party, then any remaining recoveries shall be retained solely by Company but shall be treated as Net Sales for purposes of determining royalties under Section 4.1(c).
- (c) New Rights. The parties shall cooperate to take whatever, if any, action they mutually agree upon in writing and in their respective discretion against the alleged infringer of New
- *** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

Rights which are jointly owned in accordance with Section 12.1(b). Such agreement shall include actions to be taken by each party and the allocation of expenses and recoveries related to such action. Neither party shall take any such action against the alleged infringer without the written consent of the other party.

(d) For the avoidance of doubt, subject to Sections 12.3(a), (b) and (c), each party shall be solely responsible for all decisions and actions pertaining to the enforcement of patents owned solely by such party.

13. TERM AND TERMINATION.

13.1 Term. The term of this Agreement (the "Term") shall commence on the Effective Date and shall continue in effect thereafter on a country-by-country basis until the later of (i) the fifth anniversary of the First Commercial Sale of a Licensed Product in the Territory (and irrespective of whether such First Commercial Sale occurred in the applicable country or another country in the Territory) or (ii) the date that there no longer exists any Valid Claim in the applicable country.

13.2 Termination by Company for Convenience.

- (a) Company may terminate this Agreement, in its entirety, for convenience at its election, upon 90 days' prior express written notice to CyDex. If the Agreement is terminated by Company pursuant to this **Section 13.2(a)**, within 30 days after such termination, Company shall pay to CyDex all payments owing at the date of termination.
- **(b)** Company may terminate this Agreement, solely with respect to any country(ies) in the Territory in which Generic Captisol is being manufactured or sold on a commercial basis, at its election, upon [***] prior express written notice to CyDex. If the Agreement is terminated by Company with respect to any such country(ies) pursuant to this **Section 13.2(b)**, within 30 days after such termination, Company shall pay to CyDex all royalty payments owing at the date of termination with respect to prior Net Sales in such country.
- 13.3 Termination for Breach. If either party should violate or fail to perform any material term or covenant of this Agreement, then the other party may give written notice of such default to such party. If such party should fail to cure such default within 60 days (or 10 days with respect to any payment obligation) after such notice, the other party shall have the right to terminate this Agreement by a second written notice (a "Notice of Termination") to such party. If Notice of Termination is sent to such party, this Agreement shall automatically terminate on the effective date of such notice. In the event of a material breach by CyDex, if CyDex fails to cure such default within the applicable cure period under this Section 13.3 Company may elect to either (i) terminate this Agreement in accordance with the provisions set forth in this Section 13.3 or (ii) without limiting any other legal or equitable remedies that Company may have, continue this Agreement in full force and effect, but with the milestones and royalties otherwise due hereunder to be reduced by an amount to be mutually agreed upon by the parties.
- **13.4 Termination for Bankruptcy.** Either party may terminate this Agreement immediately upon written notice to the other party in the event that the other party has a petition in bankruptcy filed against it that is not dismissed within 60 days of such filing, files a petition in bankruptcy, or makes an assignment for the benefit of creditors.
- *** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

13.5 Termination of the Supply Agreement. If the Supply Agreement is terminated by CyDex pursuant to Section 13.2 thereof for Company's material breach of the Supply Agreement, then CyDex shall have the right to terminate this Agreement upon written notice to Company. If the Supply Agreement is terminated in accordance with its terms (except for by CyDex for Company's material breach), Company shall have the right to terminate this Agreement upon written notice to CyDex.

13.6 Effect of Termination.

- (a) Following the termination by Company under Section 13.2 or by CyDex for Company's breach under Section 13.3, all rights granted to Company herein shall immediately terminate and each party shall promptly return all relevant records and materials in its possession or control containing the other party's Confidential Information with respect to which the former party does not retain rights hereunder; *provided, however*; that each party may retain one archival copy of such records and materials solely to be able to monitor its obligations that survive under this Agreement.
- **(b)** Upon the natural expiration of the Term as to a country, the licenses granted in Section 2.1 shall become perpetual, fully paid-up and royalty-free as to such country.
- (c) Upon any early termination of this Agreement and until the first anniversary of such early termination, Company shall have the right to sell its remaining inventory of Licensed Products so long as Company has fully paid, and continues to fully pay when due, any and all payments owed to CyDex, and provides royalty reports as called for hereunder, and Company otherwise is not in continuing material breach of this Agreement.
- 13.7 Survival. Notwithstanding any other provisions of this Agreement, any liability or obligation of either party to the other for acts or omissions before the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement. Such termination or expiration shall not relieve either party from obligations that are expressly indicated or obviously intended to survive termination or expiration of this Agreement, nor shall any termination or expiration of this Agreement relieve Company of its obligation to pay CyDex, subject to the terms herein, (i) royalties for all Licensed Products sold by Company, its Affiliates or Sublicensees before the effective date of such expiration or termination (or pursuant to Section 13.6(c)), or (ii) sums due in respect of Captisol shipped before termination or expiration of this Agreement. Sections 2.2 (Grant of License from Company to CyDex), 4.2 (Taxes), 4.3 (Late Payments), 5 (Records; Reports; Audit), 6.2(d) (Reporting and Study Data), 6.4 (Access to Company's Data), 7.3 (Adverse Event Reporting), 8 (Confidentiality), 9.3 (Disclaimer), 10 (Indemnification), 11 (Limitation of Liability), 12 (Management of Intellectual Property), 13 (Term and Termination), and 14 (General Provisions) shall survive termination or expiration of this Agreement.

14. GENERAL PROVISIONS.

14.1 Relationship of Parties. Each of the parties hereto is an independent contractor and nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the parties. No party shall have the right to, and each party agrees not to purport to, incur any debts or make any commitments or contracts for the other. During the Term of this Agreement and for a period of one year thereafter, Company shall

not solicit, induce, encourage or attempt to induce or encourage any employee of CyDex to terminate his or her employment with CyDex or to breach any other obligation to CyDex; *provided*, that this sentence is not meant to encompass general solicitations such as may be found in newspaper advertisements and the like.

14.2 Compliance with Law. Company agrees that use of the Licensed Patents, Captisol and Captisol Data Package by it and its Affiliates and Sublicensees, and the manufacture, handling, marketing, sale, distribution and use of Licensed Products, shall comply with all applicable international, federal, state and local laws, rules and regulations, including, but not limited to, import/export restrictions, laws, rules and regulations governing use and patent, copyright and trade secret protection. CyDex agrees that its manufacture, handling, marketing, sale, distribution and use of Captisol hereunder shall comply with all applicable international, federal, state and local laws, rules and regulations, including, but not limited to, import/export restrictions, laws, rules and regulations governing use and patent, copyright and trade secret protection.

14.3 Arbitration.

- (a) Procedure. Any and all disputes or controversies arising out of or relating to this Agreement shall be exclusively and finally resolved by binding arbitration in accordance with the commercial arbitration rules of the American Arbitration Association then in effect, in San Diego, California. The arbitration shall be conducted by an arbitrator reasonably knowledgeable about the pharmaceutical industry and acceptable to CyDex and Company. If CyDex and Company cannot agree on a single arbitrator within 30 days after a demand for arbitration has been made, CyDex shall appoint an arbitrator, Company shall appoint an arbitrator, the two (2) arbitrators shall appoint a third arbitrator, and the three arbitrators shall hear and decide the issue in controversy. If either party fails to appoint an arbitrator within 45 days after service of the demand for arbitration, then the arbitrator appointed by the other party shall arbitrate any controversy in accordance with this Section 14.3(a). Except as to the selection of arbitrators, the arbitration proceedings shall be conducted promptly and in accordance with the rules of the American Arbitration Association then in effect. The expenses of any arbitration, including the reasonable attorney fees of the prevailing party, shall be borne by the party deemed to be at fault or on a pro-rata basis should the arbitration conclude in a finding of mutual fault.
- **(b) Confidentiality of Proceedings.** All arbitration proceedings hereunder shall be confidential and the arbitrator(s) shall issue appropriate protective orders to safeguard each party's Confidential Information. Except as required by law, no party shall make (or instruct the arbitrator(s) to make) any public announcement with respect to the proceedings or decision of the arbitrator(s) without prior written consent of the other party.
- (c) Interim Equitable Relief. Each party shall, in addition to all other remedies accorded by law (or in equity) and permitted by this Agreement, be entitled to equitable relief (including but not limited to interim injunctive relief) in any court having jurisdiction to protect its interests. Neither party shall commence any court proceeding or action against the other to resolve any dispute, except (i) to enforce an arbitral award rendered pursuant to this Section 14.3, or (ii) for such interim injunctive relief.
- (d) Binding Effect. The provisions of this Section 14.3 shall survive any expiration or termination of this Agreement, and shall be severable and binding on the parties hereto,

notwithstanding that any other provision of this Agreement may be held or declared to be invalid, illegal or unenforceable.

- **14.4 Costs and Expenses.** Except as otherwise expressly provided in this Agreement, each party shall bear all costs and expenses associated with the performance of such party's obligations under this Agreement.
- 14.5 Further Assurances. The parties hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.
- 14.6 Force Majeure. Neither party shall be liable for failure to perform, or delay in the performance of, its obligations under this Agreement (other than payment obligations) when such failure or delay is caused by an event of *force majeure*. For purposes of this Agreement, an event of *force majeure* means any event or circumstance beyond the reasonable control of the affected party and not reasonably preventable using industry standard practices, including but not limited to, war, insurrection, riot, fire, flood or other unusual weather condition, explosion, act of God, peril of the sea, sabotage, accident, embargo, act of governmental authority, compliance with governmental order on national defense requirements, or inability due to general industry wide shortages to obtain fuel, power, raw materials, labor or transportation facilities. If, due to any event of *force majeure*, either party shall be unable to fulfill its obligations under this Agreement (other than payment obligations), the affected party shall immediately notify the other party of such inability and of the period during which such inability is expected to continue, shall use commercially reasonable efforts to cure and remedy such non-performance and the time for performance shall be extended for a number of days equal to the duration of the *force majeure*, and the parties shall meet promptly to determine an equitable solution to the effects of such event. If any event of *force majeure* continues in effect for a period of 90 days or more, the party who is not claiming excuse from performance under such *force majeure* may terminate this Agreement by giving not less than 30 days' notice to the other party on a country-by-country basis.

14.7 Notices. Any notice, request, or communication under this Agreement shall be effective only if it is in writing and personally delivered; sent by certified mail, postage pre-paid; or sent by nationally recognized overnight courier with signature required, addressed to the parties at the addresses stated below or such other persons and/or addresses as shall be furnished in writing by any party in accordance with this Section 14.7. Unless otherwise provided, all notices shall be sent:

If to CyDex, to:

CyDex Pharmaceuticals, Inc. c/o Ligand Pharmaceuticals Incorporated 11119 North Torrey Pines Road, Suite 200 La Jolla, CA 92037 Attention: President If to Company, to:

MEI Pharma, Inc.
11975 El Camino Real, Suite 101
San Diego, CA 92130

Attention: Chief Executive Officer

With a copy to:

Ligand Pharmaceuticals Incorporated 11119 North Torrey Pines Road, Suite 200 La Jolla, CA 92037 Attention: General Counsel

If sent by overnight courier, the next business day after the date of deposit with such courier shall be deemed to be the date on which such notice, request or communication was given. If sent by certified mail, the third business day after the date of mailing shall be deemed the date on which such notice, request or communication was given.

- **14.8** Use of Name. Neither party shall have any right, express or implied, to use in any manner the name or other designation of the other party or any other trade name or trademark of the other party for any purpose, except as may be required by applicable law or regulation or with the written approval of the other party, such approval not to be unreasonably withheld.
- 14.9 Public Announcements. No party shall use the name, trademark, trade name or logo of the other party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or public disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other party, such permission not to be unreasonably withheld, except as may be required by law or required by the rules of an applicable US national securities exchange or as permitted by Section 14.8. The parties agree that a party may disclose this Agreement and its terms, and material developments or material information generated under this Agreement, in (i) securities filings with the SEC (or equivalent foreign agency), or taxing authorities, to the extent required by law after complying with the procedure set forth in this Section 14.9, or (ii) under conditions of confidentiality/nonuse in connection with investment and similar corporate transactions.
- **14.10 Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of California (without giving effect to any conflicts of law principles that require the application of the law of a different state).
- 14.11 Entire Agreement; Amendment. This Agreement and the Supply Agreement and all Exhibits attached hereto or thereto contain the entire agreement of the parties relating to the subject matter hereof and thereof and supersede any and all prior or contemporaneous agreements, written or oral, between CyDex and Company relating to the subject matter hereof and thereof, including without limitation the Limited Clinical Use Agreement between the parties dated November 11, 2010, as amended October 4, 2011. Without limiting the foregoing, CyDex hereby acknowledges and agrees that Company owes no further payments under such prior agreements and to the extent there are any invoices that have yet to be paid or issued under such prior agreements, CyDex hereby releases Company and waives its rights to any such payments or amounts owed. Subject to the foregoing, neither party shall be relieved from any liability for any past breach of any such prior written agreements, for any strict liability claims or tort claims or from any indemnification obligation thereunder. In addition, any confidential information which was disclosed under such prior agreements shall remain confidential and shall be subject to the nondisclosure and nonuse provisions set forth in Section 8 of this Agreement. This Agreement may not be amended unless agreed to in writing by both parties.

- **14.12 Binding Effect.** This Agreement shall be binding upon, and the rights and obligations hereof shall apply to CyDex and Company and any successor(s) and permitted assigns. The name of a party appearing herein shall be deemed to include the names of such party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement.
- 14.13 Waiver. The rights of either party under this Agreement may be exercised from time to time, singularly or in combination, and the exercise of one or more such rights shall not be deemed to be a waiver of any one or more of the others. No waiver of any breach of a term, provision or condition of this Agreement shall be deemed to have been made by either party unless such waiver is addressed in writing and signed by an authorized representative of that party. The failure of either party to insist upon the strict performance of any of the terms, provisions or conditions of this Agreement, or to exercise any option contained in this Agreement, shall not be construed as a waiver or relinquishment for the future of any such term, provision, condition or option or the waiver or relinquishment of any other term, provision, condition or option.
- 14.14 Severability. If any provision of this Agreement is determined by a final and binding court or arbitration judgment to be invalid, illegal or unenforceable to any extent, such provision shall not be not affected or impaired up to the limits of such invalidity, illegality or unenforceability; the validity, legality and enforceability of the remaining provisions of this Agreement shall not be affected or impaired in any way; and the parties agree to negotiate in good faith to replace such invalid, illegal and unenforceable provision (or portion of provision) with a valid, legal and enforceable provision that achieves, to the greatest lawful extent under this Agreement, the economic, business and other purposes of such invalid, illegal or unenforceable provision (or portion of provision). Subject to Section 13.1, this Agreement shall not be terminated or invalidated by any future determination that any or all of the Licensed Patents have expired or been invalidated.
- 14.15 Assignment. Neither party may assign its rights or delegate its obligations under this Agreement, in whole or in part, by operation of law or otherwise, to any Third Party without the prior written consent of the other party, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, either party may assign in whole or in part its rights and/or delegate in whole or in part its obligations under this Agreement to an Affiliate or to any Third Party successors (including with respect to Company, Third Party successors to one or more Licensed Products), whether by way of merger, sale of assets to which this Agreement relates, sale of stock or otherwise, without prior written consent. As a condition to any permitted assignment hereunder, the assignee must expressly assume (for the express benefit of the party hereto which is not the assignor) the performance of the terms and obligations of this Agreement by such assignee. Furthermore, notwithstanding anything to the contrary herein, CyDex shall not (i) assign any of the Licensed Patents to an Affiliate or Third Party without assigning this Agreement in its entirety to such Third Party and (ii) assign this Agreement to any Affiliate or Third Party without assigning the Licensed Patents. Any assignment not in accordance with this Section 14.15 shall be void.
- 14.16 Third Party Beneficiaries. Except for the rights of Indemnified Parties pursuant to Section 10 hereof, and subject to Pfizer's rights under Section 8.5 hereof, the terms and provisions of this Agreement are intended solely for the benefit of each party hereto and their respective successors or permitted assigns and it is not the intention of the parties to confer third-party beneficiary rights upon any other person, including without limitation Sublicensees. The enforcement of any obligation of CyDex under this Agreement shall only be pursued by Company or a Company Indemnitee, and not Sublicensees (unless otherwise a Company Indemnitee).

- 14.17 Remedies Cumulative; Right of Set-Off. Except as provided in Section 11, any enumeration of a party's rights and remedies in this Agreement is not intended to be exclusive, and a party's rights and remedies are intended to be cumulative to the extent permitted by law and include any rights and remedies authorized in law or in equity. Notwithstanding anything to the contrary in this Agreement, Company shall not have a right to set-off any royalties, milestones or other amount due to CyDex under this Agreement and/or the Supply Agreement against any damages incurred by Company for a breach by CyDex of this Agreement and/or the Supply Agreement.
- **14.18 Interpretation.** The language used in this Agreement is the language chosen by the parties to express their mutual intent, and no provision of this Agreement shall be interpreted for or against any party because that party or its attorney drafted the provision.
- **14.19 Headings.** The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.
- 14.20 Construction. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa, and (d) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation", "inter alia" or words of similar import.
- **14.21 Counterparts.** This Agreement may be executed in counterparts (facsimile and electronic transmission included), each of which shall constitute an original document, but both of which shall constitute one and the same instrument.

[Remainder of this page left blank intentionally]

IN WITNESS WHEREOF, the parties have executed this License Agreement as of the Effective Date.

CYDEX PHARMACEUTICALS, INC.

By: /s/ Charles Berkman

Name: Charles Berkman
Title: VP and Secretry

MEI PHARMA, INC.

By: /s/ Daniel P. Gold

Name: Daniel P. Gold

Title: President & Chief Executive Officer

EXHIBIT A LICENSED CAPTISOL PATENTS

PATENT FAMILY 2: CIP of 5,134,127 – "Derivatives of Cyclodextrins Exhibiting Enhanced Aqueous Solubility and the Use Thereof"

Country			Filing Date	Serial No.	Patent No.	Expiration Date
PCT			07/26/93	PCT/US93/06880	WO94/02518	
Australia			07/26/93	47799/93	672814	07/26/13
	EPO		07/26/93	93918302.6	620828	07/26/13
		Austria	07/26/93	93918302.6	E 217325	07/26/13
		Belgium	07/26/93	93918302.6	620828	07/26/13
		Denmark	07/26/03	93918302.6	620828	07/31/13
		Djibouti	05/08/02	93918302.6	620828	05/08/22
		France	07/26/93	93918302.6	620828	07/31/13
		Germany	07/26/93	69331900	69331900	07/31/13
		Great Britain (UK)	05/17/02	93918302.6	620828	07/26/13
		Greece	07/26/93	93918302.6	3040489	07/26/13
		Ireland	07/26/03	93918302.6	620828	07/31/13
		Italy	07/26/03	93918302.6	620828	07/26/13
		Luxembourg	07/26/03	93918302.6	620828	07/26/13
		Monaco	07/26/03	93918302.6	620828	07/26/13
		Netherlands	07/26/03	93918302.6	620828	07/26/13
		Portugal	07/26/93	93918302.6	620828	07/26/13
		Spain	07/26/93	93918302.6	620828	07/26/13
		Sweden	07/26/93	93918302.6	620828	07/26/13
		Switzerland	07/26/93	93918302.6	620828	07/26/13
Korea			03/23/94	94-700951	279111	07/26/13
Canada			07/26/93	2,119,154	2,119,154	07/26/13
Japan			07/26/93	6-504678	3393253	07/26/13
Russia			07/26/93	94028890/04	2113442	07/26/13
Georgia			03/17/95	691/01-95	1649	07/26/13
Armenia			07/26/93	96237	822	07/22/13
Kyrgyzstan			08/09/96	960481.1	333	05/10/16
Moldova			08/08/96	960306/PCT	1813	07/26/13
Tajikistan			07/26/93	96000377	275	07/26/13
Turkmenistan			08/08/96	393	430	07/26/13
Uzbekistan			09/15/94	IHAP9400808.2	5799	04/28/19

PATENT FAMILY 3: "Solid Pharmaceutical Formulations Containing A Physical Mixture of Sulfoalkyl Ether Cyclodextrin and a Therapeutic Agent"

Country	Serial No.	Filing Date	Patent No.	Expiration Date
United States	08/851,006	5/5/1997	5874418	5/5/2017
Australia	71535/98	4/20/1998	729671	4/20/2018
Austria	98918648.1	4/20/1998	980262	4/20/2018
Belgium	98918648.1	4/20/1998	980262	4/20/2018
Canada	2,289,202	4/20/1998	2289202	4/20/2018
European Union	98918648.1	4/20/1998	980262	4/20/2018
France	98918648.1	4/20/1998	980262	4/20/2018
Germany	980262	4/20/1998	69812343.3-08	4/20/2018
Greece	302627	4/20/1998	980262	4/20/2018
Italy	21811BE/2003	4/20/1998	980262	4/20/2018
Japan	548136/98	4/20/1998	3,745,382	4/20/2018
Korea	10-1999-7010182	4/20/1998	378031	4/20/2018
Luxembourg	98918648.1	4/20/1998	980262	4/20/2018
Netherlands	98918648.1	4/20/1998	980262	4/20/2018
Russian Federation	99125610	4/20/1998	2173172	4/20/2018
Spain	98918648.1	4/20/1998	980262	4/20/2018
Sweden	98918648.1	4/20/1998	980262	4/20/2018
Switzerland	98918648.1	4/20/1998	980262	4/20/2018
United Kingdom	98918648.1	4/20/1998	980262	4/20/2018

<u>Country</u>	Serial No.	Filing Date	Patent No.	Expiration Date
United States	09/229,513	1/13/1999	6046177	5/5/2017
Australia	25011/00	1/11/2000	758376	1/11/2020
Austria	903234.3	1/11/2000	1140960	1/11/2020
Belgium	903234.3	1/11/2000	1140960	1/11/2020
Canada	2,360,236	1/11/2000	2360236	1/11/2020
China	802747.1	1/11/2000	ZL 00802747.1	1/11/2020
European Union	903234.3	1/11/2000	1140960	1/11/2020
France	903234.3	1/11/2000	1140960	1/11/2020
Germany	60036534.4-08	1/11/2000	1140960	1/11/2020
Greece	903234.3	1/11/2000	1140960	1/11/2020
Hong Kong	3101970.9	3/18/2003	HK1049797	1/11/2020
India	00241/MUMNP/2005	1/11/2000	211311	1/11/2020
Israel	143900	1/11/2000	143900	1/11/2020
Italy	903234.3	1/11/2000	1140960	1/11/2020
Korea	10-2005-7015530	1/11/2000	712941	1/11/2020
Mexico	PA/a/2001/007122	1/11/2000	221504	1/11/2020
Netherlands	903234.3	1/11/2000	1140960	1/11/2020
New Zealand	512692	1/11/2000	512692	1/11/2020
Portugal	903234.3	1/11/2000	1140960	1/11/2020
Russian Federation	2001119270	1/11/2000	2233176	1/11/2020
Spain	903234.3	1/11/2000	1140960	1/11/2020
Switzerland	903234.3	1/11/2000	1140960	1/11/2020
United Kingdom	903234.3	1/11/2000	1140960	1/11/2020

PATENT FAMILY 5: "Polar Drugs or Prodrug Compositions with Extended Shelf-life Storage and a Method of Making Thereof"

	Serial No.			
Country		Filing Date	Patent No.	Expiration Date
United States	09/096,747	6/12/1998	6133248	6/12/2018
Australia	80591/98	6/12/1998	750207	6/12/2018
Austria	98928901.2	6/12/1998	E253941	6/12/2018
Belgium	98928901.2	6/12/1998	986403	6/12/2018
European Union	98928901.2	6/12/1998	986403	6/12/2018
France	98928901.2	6/12/1998	986403	6/12/2018
Germany	69819721.6-08	6/12/1998	986403	6/12/2018
Italy	98928901.2	6/12/1998	986403	6/12/2018
Japan	502895/10	6/12/1998	4439596	6/12/2018
Netherlands	98928901.2	6/12/1998	986403	6/12/2018
Portugal	98928901.2	6/12/1998	986403	6/12/2018
Spain	98928901.2	6/12/1998	986403	6/12/2018
Sweden	98928901.2	6/12/1998	986403	6/12/2018
Switzerland	98928901.2	6/12/1998	986403	6/12/2018
United Kingdom	98928901.2	6/12/1998	986403	6/12/2018

PATENT FAMILY 9: "Capsules Containing Aqueous Fill Compositions Stabilized with Derivatized Cyclodextrin"

	Serial No.			
Country		Filing Date	Patent No.	Expiration Date
United States	11/076,072	9/12/2003	7,829,114	9/12/2023
Australia	275329/03	9/12/2003	2003275329	9/12/2023
China	3825141.8	9/12/2003	Z103825141.8	9/12/2023
India	954/DELNP/2005	9/12/2003	233167	9/12/2023
Russian Federation	2005110945	9/12/2003	2359698	9/12/2023

PATENT FAMILY LICENSED FROM PFIZER: "Process for Making a Cyclodextrin" 1

Country	Serial No.	Filing Date	Patent No.	Expiration Date
United States	09/106,983	6/29/1998	6153746	06/29/2018
Austria	98304785.3	6/17/1998	E323110	06/17/2018
Belgium	98304785.3	6/17/1998	889056	06/17/2018
Brazil	P19802331-4	7/1/1998	9802331-4	07/1/2018
Canada	2241774	6/29/1998	2241774	06/29/2018
Cyprus	98304785.3	6/17/1998	CY1104797	06/17/2018
European Union	98304785.3	6/17/1998	889056	06/17/2018
Finland	98304785.3	6/17/1998	889056	06/17/2018
France	98304785.3	6/17/1998	889056	06/17/2018
Germany	98304785.3	6/17/1998	69834154.6-08	06/17/2018
Great Britain	98304785.3	6/17/1998	889056	06/17/2018
Greece	98304785.3	6/17/1998	3057304	06/17/2018
Ireland	98304785.3	6/17/1998	889056	06/17/2018
Italy	98304785.3	6/17/1998	889056	06/17/2018
Japan	178831/98	6/25/1998	3272669	06/25/2018
Luxembourg	98304785.3	6/17/1998	889056	06/17/2018
Mexico	985383	7/1/1998	213259	07/1/2018
Netherlands	98304785.3	6/17/1998	889056	06/17/2018
Portugal	98304785.3	6/17/1998	889056	06/17/2018
Spain	98304785.3	6/17/1998	889056	06/17/2018
Sweden	98304785.3	6/17/1998	889056	06/17/2018
Switzerland	98304785.3	6/17/1998	889056	06/17/2018

Sublicense to this patent family is non-exclusive

PATENT FAMILY 15: "Sulfoalkyl Ether Cyclodextrin Compositions and Methods of Preparation Thereof."

Country			Filing Date	Serial No.	Patent No.	Expiration Date
United States			4/23/2008	12/108,228	8,049,003	12/19/2026
United States			04/23/2008	12/363,719	7,629,331	10/26/2025
PCT			10/26/2005	PCT/US2005/038933		
Australia			10/26/2005	2005337613		
	EPO		10/26/2005	05856927.8	1945228	
		Belgium	05/26/2008	5856927.8-1216		
		Denmark	05/26/2008	5856927.8-1216		
		Djibouti	05/26/2008	5856927.8-1216		
		France	05/26/2008	5856927.8-1216		
		Germany	05/26/2008	5856927.8-1216		
		Great Britain (UK)	05/26/2008	5856927.8-1216		
		Greece	05/26/2008	5856927.8-1216		
		Ireland	05/26/2008	5856927.8-1216		
		Italy	05/26/2008	5856927.8-1216		
		Luxembourg	05/26/2008	5856927.8-1216		
EPO Divisional			04/05/2011	11161125.7		
Brazil			04/28/2008	PI0520654-5		
Canada			04/28/2008	2632211		
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Austria			04/29/2008	337613/05		
India			04/25/2008	3462/DELNP/2008		
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Korea			05/26/2008	10-2008-7012541		
Mexico			04/25/2008	MX/a/2008/005397		
Russian Federation			05/23/2008	2008120659		

Country			Filing Date	Serial No.	Patent No.	Expiration Date
United States			03/13/2009	12/404,174	7,635,773	03/13/2029
United States CON			11/5/2009	12/613,103		
PCT			4/28/2009	PCT/US09/02572		
Australia			4/28/2009	2009241858		
	EPO		01/20/2010	09739150.2		
		Austria	01/20/2010	application		
		Belgium	01/20/2010	application		
		France	01/20/2010	application		
		Germany	01/20/2010	application		
		Great Britain (UK)	01/20/2010	application		
		Greece	01/20/2010	application		
		Italy	01/20/2010	application		
		Luxembourg	01/20/2010	application		
		Netherlands	01/20/2010	application		
		Sweden	01/20/2010	application		
		Switzerland	01/20/2010	application		
Canada			04/13/2010	2702603		
China			07/10/2010	application		
Japan			03/16/2010	application		
Brazil			05/13/2010	application		
Mexico			05/03/2010	application		
Korea			4/28/2009	102107026534		
	Eurasia		04/01/2010	application		
		Turkmenistan	04/01/2010	application		
		Republic of Belarus	04/01/2010	application		
		Republic of Tajikistan	04/01/2010	application		
		Russia	04/01/2010	application		
		Azerbaijan Republic	04/01/2010	application		
		Republic of Kazakhstan	04/01/2010	application		
		Kyrgyzstan	04/01/2010	application		
		Republic of Armenia	04/01/2010	application		
		Republic of Moldova	04/01/2010	application		

PATENT FAMILY 13: "DPI Formulation Containing Sulfoalkyl Ether Cyclodextrin."

Country	Filing Date	Serial No.	Patent No.	Expiration Date
PCT	04/22/2005	PCT/US05/14010		
United States	10/19/2006	11/550,976		
EPC				
Designated States: Austria, Belgium, Bulgaria, Switzerland and Liechtenstein, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Hungary, Ireland, Iceland, Italy, Lithuania, Luxembourg, Monaco, Netherlands, Poland, Portugal, Romania, Sweden,				
Slovakia, and Turkey	10/17/2006	05743067.0-2112		
Australia DIV	06/16/2010	202503/10		
Brazil	10/23/2006	PI0510119-0		
China	04/22/2005	200580021269		
Israel	04/22/2005	178728		
Japan	10/20/2006	509706/07		
Korea	11/14/2006	10-2006-7023802		
Mexico	10/23/2006	PA/a/2006/012240		
New Zealand	11/23/2006	550593		

CONFIDENTIAL

CERTAIN MATERIAL (INDICATED BY ASTERISKS) HAS BEEN OMITTED FROM THIS DOCUMENT PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

SUPPLY AGREEMENT

BETWEEN

CYDEX PHARMACEUTICALS, INC.

AND

MEI PHARMA, INC.

DATED: September 28, 2012

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SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (this "Agreement") is made this 28th day of September, 2012 (the "Effective Date") between:

CYDEX PHARMACEUTICALS, INc., a Delaware corporation, with offices at 11119 North Torrey Pines Road, Suite 200, La Jolla, California 92037) ("CyDex"); and

MEI PHARMA, INC., a Delaware corporation, with offices at 11975 El Camino Real, Suite 101, San Diego, California 92130 ("Company").

RECITALS

WHEREAS, CyDex is engaged in the business of developing and commercializing novel drug delivery technologies designed to enhance the solubility and effectiveness of existing and development-stage drugs;

WHEREAS, CyDex is the exclusive supplier of Captisol®, a drug formulation system designed to enhance the solubility and stability of drugs;

WHEREAS, CyDex desires to supply and Company desires to purchase Captisol from CyDex, under the terms and conditions set forth herein; and

WHEREAS, CyDex and Company are contemporaneously entering into a License Agreement (the "License Agreement");

Now, Therefore, in consideration of the following mutual promises and other good and valuable consideration, the receipt and sufficiency of which are acknowledged, the parties, intending to be legally bound, agree as follows:

1. DEFINITIONS.

For the purposes of this Agreement, the following definitions shall apply:

"Captisol" means sulfobutylether β (beta) cyclodextrin, sodium salt. CyDex supplies such material under the Captisol® brand, manufactured in accordance with the Specifications and the applicable DMF.

"Clinical Grade Captisol" means Captisol which (i) has been manufactured under GMP conditions, (ii) is intended for use in humans, and (iii) is intended for clinical trials for the Licensed Products.

"Commercial Grade Captisol" means Captisol which (i) has been manufactured under GMP conditions, (ii) is intended for use in humans, and (iii) is intended for commercial sale of the Licensed Products.

"Commercial Grade Shortfall" shall have the meaning defined in Section 4.2.

"Defect" and "Defective" shall have the meanings defined in Section 3.6(b).

- "Detailed Forecast" shall have the meaning defined in Section 3.2.
- "First Commercial Order Date" shall have the meaning defined in Section 3.1.
- "Generic Captisol" [***]
- "Generic Supplier" [***]
- "GMP" means manufactured under conditions of current good manufacturing practices for bulk excipients as set forth in U.S. Pharmacopeia <1078> as of the Effective Date or any successor thereto.
 - "Latent Defect" shall have the meaning defined in Section 3.6(c).
- "Minimum Remaining Shelf Life" means with respect to Captisol, a remaining shelf life of not less than the longer of (i) four years or (ii) the period that is 80% of the duration of stability reasonably confirmed by CyDex in the ordinary course of its stability testing program.
 - "Notice" shall have the meaning defined in Section 4.1.
 - "Notice of Termination" shall have the meaning defined in Section 6.2.
 - "Permitted Purchaser Requirements" means the requirements during the Term of all Permitted Purchasers for Captisol for sale or use in the Territory.
- "Permitted Purchasers" means, collectively: (i) Company; (ii) Affiliates of Company; (iii) Sublicensees of Company; and (iv) all Contract Manufacturers for Company, Affiliates of Company and Sublicensees and assignees permitted in accordance with the License Agreement.
 - "Purchase Volume Limitations" shall have the meaning defined in Section 3.3.
 - "Q1", "Q2", "Q3" and "Q4" shall have the meanings defined in Section 3.2.
 - "Significant Market Event" shall have the meaning defined in Section 3.2.
 - "Specifications" means the specifications for Captisol set forth in Exhibit B hereto, as such may be amended from time to time pursuant to Section 3.10.
 - "Supply Interruption" shall have the meaning defined in Section 3.8(d).
 - "Term" shall have the meaning defined in Section 6.1.
 - "Testing Methods" shall have the meaning defined in Section 3.6(a).
- *** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

"Third-Party Manufacturer" shall have the meaning defined in Section 2.3.

In addition, any capitalized terms not separately defined herein, including "Affiliate", "Claim", "Compound", "Confidential Information", "Contract Manufacturer", "DMF", "FDA", "IND", "Licensed Product", "Major Market", "NDA", "Quality Agreement", "Sublicensee", "Territory", "Third Party" and "Valid Claim" shall have the respective meanings defined in the License Agreement.

2. PURCHASE AND SUPPLY OF CAPTISOL.

- 2.1 Purchase Commitment. Subject to the provisions of this Agreement and so long as CyDex is not in breach of any material term under this Agreement, Company agrees that Company and the other Permitted Purchasers shall purchase and CyDex shall supply 100% of the Permitted Purchaser Requirements for Captisol during the Term. Except as provided in Section 3.8(d), this Agreement and the License Agreement do not grant Company or any other Permitted Purchaser the right to manufacture (or have manufactured on their behalf) under Licensed Patents, Captisol, without CyDex's prior written consent except as otherwise set forth in this Agreement.
- 2.2 Supply Commitment. CyDex agrees that CyDex shall produce (or have produced for it as set forth in Section 2.3), sell and deliver to Company and the other Permitted Purchasers 100% of the Permitted Purchaser Requirements, subject to the provisions of this Agreement. CyDex shall only be required to sell Captisol pursuant to this Agreement. Company shall place orders for Captisol on behalf of itself and the other Permitted Purchasers, and shall guarantee payment to CyDex of all amounts payable with respect thereto.
- 2.3 Third-Party Manufacturers. Without limiting CyDex's responsibility under this Agreement, CyDex shall have the right, subject to Section 3.10 and upon written notice to Company, to satisfy its supply obligations to Company hereunder either in whole or in part through arrangements with third parties engaged by CyDex to perform services or supply facilities or goods in connection with the manufacture or testing of Captisol (each, a "Third-Party Manufacturer"). CyDex shall guarantee the performance of all Third-Party Manufacturers and shall promptly notify Company of the name and other relevant information of any Third-Party Manufacturer intended to be used by CyDex to satisfy its supply obligations of Captisol to any Permitted Purchasers hereunder. CyDex shall warrant that such Captisol shall, at a minimum, meet the Specifications as set forth in *Exhibit B* and the Minimum Remaining Shelf Life and have been manufactured in accordance with all applicable laws and regulations, including under conditions of GMP and under the same DMF and manufacturing processes referenced in Company's IND or NDA. The parties hereby agree that The Hovione Group is a Third-Party Manufacturer as of the Effective Date of this Agreement. Unless otherwise instructed by CyDex, Company shall reference The Hovione Group's manufacturing processes, and no others, in Company's INDs and NDAs in each country that the Supply Agreement has not been terminated, except (i) [***] or (ii) in the event CyDex notifies Company that it is using a different Third Party Manufacturer. If CyDex decides to change or add a Third Party Manufacturer, or if the facilities of a Third Party Manufacturer used to supply Captisol are changed, CyDex shall use commercially reasonable efforts to continue to supply Company from the original manufacturing site listed in the Company's regulatory filings until Company has obtained any required amendment or other modification of the regulatory approvals for Licensed Products.
- *** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

2.4 Restrictions. Company covenants and agrees that: (i) all Captisol supplied by CyDex pursuant to this Agreement shall be for use only in Licensed Products (except for testing, etc., required by Company, Permitted Purchasers and/or regulatory authorities, in relation to Licensed Products); (ii) Company shall obtain the written agreement of each Permitted Purchaser to not resell Captisol as a standalone product and only use Captisol in accordance with (i) above; and (iii) [***]

3. SUPPLY TERMS.

- 3.1 Long-Term Forecast. Company will use commercially reasonable efforts to provide to CyDex, at least one year before the date on which Company anticipates issuing its first purchase order to CyDex for Commercial Grade Captisol (the "First Commercial Order Date"), a non-binding forecast setting forth Company's estimate of the required quantities of Commercial Grade Captisol for each of the following two years. Such non-binding long-term forecast shall thereafter be updated by Company at least once every 12 months.
- 3.2 Binding Detailed Forecast. At least one calendar quarter before the First Commercial Order Date, Company shall provide to CyDex a detailed rolling forecast setting forth Company's requirements (inclusive of all Permitted Purchaser Requirements) and anticipated delivery schedules for Commercial Grade Captisol for each calendar quarter during a 12 month period (the "Detailed Forecast") which includes the calendar quarter in which the First Commercial Order Date occurs and the next three calendar quarters. For purposes of this Agreement, a calendar quarter means the consecutive three month period ending March 31, June 30, September 30, and December 31, respectively. The Detailed Forecast shall thereafter be updated by Company quarterly on a rolling basis, no later than the first day of each calendar quarter, so that in each calendar quarter CyDex shall have been provided with a rolling Detailed Forecast for each calendar quarter during the 12 month period commencing on the first day of the next calendar quarter following the date on which such Detailed Forecast is submitted. Following the six (6) month anniversary of the First Commercial Order Date, the Detailed Forecast shall be firm and binding on Company, subject to the permissible variances set forth in Section 3.3 below, with respect to the first, second and third calendar quarters covered by such updated Detailed Forecast ("Q1", "Q2", "Q3", respectively, and where the fourth calendar quarter shall be "Q4"). Q4 of such Detailed Forecast shall not be binding and shall be provided for the sole purpose of planning; provided, that if Company fails to provide any updated Detailed Forecast in accordance with this Section 3.2, the Detailed Forecast last provided by Company shall be deemed to be Company's binding Detailed Forecast for the next succeeding 12 month period, and with the same quantity and timing as had been forecasted (or deemed to be forecasted) for the fourth quarter of the prior Detailed Forecast being repeated as the forecasted quantity and timin

Notwithstanding the foregoing, if following the six (6) month anniversary of the First Commercial Order Date either (1) a Generic Supplier enters the market, (2) a significant Licensed Product or Captisol has any significant efficacy or safety concerns, or (3) any regulatory approvals for Captisol and/or a significant Licensed Product are suspended or revoked in a country in the Territory, and Company reasonably believes that such occurrence will have a significant effect upon its Detailed Forecasts (such occurrence, a "Significant Market Event"), then only Q1 of the Detailed Forecast provided to CyDex immediately before such Significant Market Event shall be

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firm and binding, while Q2, Q3 and Q4 shall not be binding and shall be provided for the sole purpose of planning.

- **3.3 Detailed Forecast Variances.** Following the six (6) month anniversary of the First Commercial Order Date and absent a Significant Market Event, each updated Detailed Forecast may modify the amount of Commercial Grade Captisol estimated in the previous Detailed Forecast in accordance with the following limitations (the "**Purchase Volume Limitations**"):
- (i) for the Q1 covered by such updated Detailed Forecast, no change in excess of a 25% volume increase or decrease may be made to the forecast provided for the Q2 in the immediately preceding Detailed Forecast without the prior express written consent of CyDex;
- (ii) for the Q2 covered by such updated Detailed Forecast, no change in excess of a 50% volume increase or decrease may be made to the forecast provided for the Q3 in the immediately preceding Detailed Forecast without the prior express written consent of CyDex; and
- (iii) for the Q3 covered by such updated Detailed Forecast, no change in excess of a 75% volume increase or decrease may be made to the forecast provided for the Q4 in the immediately preceding Detailed Forecast without the prior express written consent of CyDex.

3.4 Supply.

(a) Purchase Orders. Together with each Detailed Forecast provided under Section 3.2, Company shall place a firm purchase order with CyDex, for Company's order of Commercial Grade Captisol for the first calendar quarter of the Detailed Forecast for delivery consistent with the Detailed Forecast. Each purchase order, for all grades of Captisol, shall specify: (i) the grade of Captisol ordered (i.e., Commercial Grade Captisol or Clinical Grade Captisol); (ii) quantities; (iii) delivery dates; and (iv) reasonable shipping instructions and packaging requirements. Any firm purchase order for Captisol, to the extent it does not request more or less than the Purchase Volume Limitations (in the case of Commercial Grade Captisol ordered) nor request a delivery date less than 60 nor more than 100 days after the date of such purchase order (in the case of any grade of Captisol ordered), shall be deemed accepted by CyDex upon receipt by CyDex. With respect to quantities of Commercial Grade Captisol ordered pursuant to such purchase order that exceed the Purchase Volume Limitations, CyDex shall not be obligated to accept the excess portion of such purchase order but nevertheless shall use good faith efforts to fill such orders for such excess quantities from available supplies other than safety stock. If CyDex, despite the use of good faith efforts, is unable to supply such quantities that exceed the Purchase Volume Limitations for Commercial Grade Captisol, such inability to supply shall not be deemed to be a breach of this Agreement by CyDex or a failure by CyDex to supply for any purpose. CyDex shall use commercially reasonable efforts to notify Company as soon as possible, but no less than within 14 days, after its receipt of a purchase order of its ability to fill any amounts of such order that are in excess of the Purchase Volume Limitation for Commercial Grade Captisol. If any purchase order or other document submitted by Company hereunder or any other document passing between the parties contains terms or conditions in addition to or inconsistent with the terms of this Agreement, the terms of this Agreement shall control and prevail and the parties hereby agree that such additional or inconsistent terms shall simply be ignored and deemed not to exist, unless they are handwritten and expressly identified as being additional to or inconsistent with this Section 3.4 and are signed by officers of both parties next to the handwriting.

(b) **Safety Stock.** CyDex shall establish and maintain, solely for the benefit of the Permitted Purchasers, a safety stock of Captisol equivalent to the amounts forecasted by Company in Q2 of each Detailed Forecast. CyDex shall keep Company reasonably informed of the level of inventory identified as the safety stock and shall notify Company in the event any deliveries to Company deplete safety stock levels.

3.5 Delivery. [***]

3.6 Quality Control; Acceptance and Rejection.

- (a) Quality Control. The Parties shall negotiate in good faith a mutually agreeable Quality Agreement. It is anticipated that the Quality Agreement would clearly describe audit rights and procedures, which shall be consistent with this Agreement. CyDex shall conduct or have conducted quality control testing of Captisol before shipment in accordance with the Quality Agreement, Specifications, all applicable laws and regulations, including GMP and other CyDexapproved quality control testing procedures (the "Testing Methods"). CyDex shall retain or have retained accurate and complete records pertaining to such testing. Each shipment of Captisol hereunder shall be accompanied by a certificate of analysis for each lot of Captisol therein signed by the responsible quality control official of CyDex. Such certificate must include the results (whether numerical or otherwise) for each test performed that verifies that the Captisol is in compliance with the Specifications, as well as a statement that the subject lot was manufactured under conditions of GMP and in accordance with the appropriate DMF and all applicable laws and regulations.
- (b) Acceptance Testing. Company shall have a period of 30 days from the date of receipt to test or cause to be tested Captisol supplied under this Agreement. Company or its designee shall have the right to reject by notice to CyDex any shipment of Captisol that does not conform in all material respects with the Specifications, DMF, the Minimum Remaining Shelf Life, applicable laws and regulations, including GMP or is otherwise defective or not in compliance with the applicable purchase order (including any packaging instructions set forth therein) or the terms of this Agreement at the time of delivery pursuant to Section 3.5 when tested in accordance with the Testing Methods (such Captisol thereby having a "Defect" and upon proper rejection, deemed "Defective"). All shipments of Captisol shall be deemed accepted by Company unless CyDex receives written notice of rejection from Company within such 30 day period describing the reasons for the rejection in reasonable detail. Once a delivery of Captisol is accepted or deemed accepted
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hereunder, Company shall have no recourse against CyDex in the event Captisol is subsequently deemed unsuitable for use for any reason, except as provided in **Section 10.1** of the License Agreement or except in circumstances where the Defect is deemed a Latent Defect.

- (c) **Latent Defects.** As soon as either party becomes aware of any Defect in any Captisol lot which either (i) existed at the time of acceptance but was not discovered after a reasonable inspection or (ii) arose, before the first anniversary of actual or deemed acceptance, by no fault of any Permitted Purchasers (each such Defect, a "**Latent Defect**"), it will promptly notify the other party of such event (including reasonable details and the lot involved). If Captisol accepted by Company becomes non-conforming by virtue of the Latent Defect, Company may place the lot on quality assurance hold pending CyDex's investigation and a final resolution of the claimed Latent Defect. In the event that such Captisol is found to contain a Latent Defect, such Captisol will be deemed rejected as of the date of the notice, and the rights and obligations of the parties with respect to the rejected Captisol will thereafter be governed by the same process as governs acceptance testing set forth below.
- (d) **Confirmation.** After its receipt of a notice of rejection from Company pursuant to **Section 3.6(b)** or **(c)** above, CyDex shall notify Company as soon as reasonably practical whether it accepts Company's basis for rejection and Company shall cooperate with CyDex in determining whether such rejection was necessary or justified. If the parties are unable to agree as to whether a shipment of Captisol supplied by CyDex or its Third-Party Manufacturer hereunder is Defective, such question shall be submitted to an independent quality control laboratory mutually agreed upon by the parties. The findings of such independent laboratory shall be binding upon the parties. The cost of the independent quality control laboratory shall be borne by the party whose results are shown by such laboratory to have been incorrect.
- (e) **Return or Destruction of Rejected Shipments.** Company may not return or destroy any batch of Captisol until it receives written notification from CyDex that CyDex does not dispute that the batch or material portion thereof is Defective. CyDex will indicate in its notice either that Company is authorized to destroy the rejected batch of Captisol or that CyDex requires return of the rejected Captisol. Upon written authorization from CyDex to do so (which authorization shall be deemed an admission that the batch was properly rejected by Company), Company shall promptly destroy the rejected batch of Captisol and provide CyDex with written certification of such destruction, or, if the request so states, Company shall promptly return the rejected batch of Captisol to CyDex. In each case, CyDex will reimburse Company for the documented, reasonable costs associated with the destruction or return of the rejected Captisol.
- (f) **Independent Testing**. If there is a dispute as to whether any batch is Defective or has been properly rejected, then the Parties shall designate a mutually acceptable Third Party laboratory to make a determination on such matter from a sample obtained from the rejected batch. The decision of the Third Party laboratory shall be binding on all parties hereto and all expenses related to such Third Party investigation shall be borne by the party found to have been mistaken. Should such Third Party laboratory confirm Company's claim, the batch will be deemed to be Defective and properly rejected and may be returned or destroyed in accordance with CyDex's instructions.
- (g) **Refund or Replacement.** Company shall not be required to pay any invoice with respect to any shipment of Captisol properly rejected pursuant to this **Section 3.6**. Notwithstanding the foregoing, Company shall be obligated to pay in full for any rejected shipment

of Captisol that is not subsequently determined to be Defective, irrespective of whether Company has already paid CyDex for a replacement shipment. If Company pays in full for a shipment of Captisol and subsequently properly rejects such shipment in accordance with this **Section 3.6**, Company shall be entitled in addition to any other rights or remedies Company may have under this Agreement, upon confirmation that such shipment or material portion thereof is Defective, at its election, either: (i) to a refund or credit equal to the purchase price, shipping, insurance and other incidental expenses paid with respect to such rejected shipment; or (ii) to require CyDex to replace such rejected shipment with non-Defective Captisol at no additional cost to Company. Company acknowledges and agrees that, except for the indemnification obligations set forth in **Section 10.1** of the License Agreement, Company's rights to a refund or credit for or to receive replacement of properly rejected shipments of Captisol hereunder shall be Company's sole and exclusive remedy, and CyDex's sole obligation, with respect to Defective or non-conforming Captisol delivered hereunder.

- (h) Exceptions. Company's rights of rejection, return, refund and replacement set forth in this Section 3.6 shall not apply to any Captisol that is Defective due to damage (i) caused by Company, its Affiliates or Permitted Purchasers or their respective employees or agents, including but not limited to misuse, neglect, improper storage, transportation or use beyond any dating provided or (ii) that occurs after delivery of such Captisol to the carrier at the point of delivery, including but not limited to any damage caused thereafter by accident, fire or other hazard; and CyDex shall have no liability or responsibility to Company with respect thereto.
- 3.7 Facilities and Inspections. CyDex shall permit, and shall use commercially reasonable efforts to induce each Third-Party Manufacturer to permit, a reasonable and limited number of Company's authorized representatives, during normal working hours and upon reasonable prior notice to CyDex but in no event less than 30 days prior notice (subject to Third-Party Manufacturer's consent to be reasonably sought by CyDex), to confidentially inspect for a reasonable and limited number of days that portion of all CyDex facilities utilized for the manufacture, preparation, processing, storage or quality control of Captisol or such facilities of any Third-Party Manufacturer, no more frequently than once per calendar year; provided, however, if a defect in Licensed Product is attributed to Defective Captisol, there are pending Licensed Product recall decisions, or significant regulatory actions, such as warning letters, then a for-cause audit may be performed by Company upon shorter notice and as frequently as necessary. In addition, Company may, upon prior written notice which is reasonable as to timing and availability, request the ability to conduct additional not for cause audits more frequently than once per year for purposes of due diligence by Company's existing or prospective partners, Sublicensees, collaborators, acquirers or investors, provided that any such party would assume for CyDex's benefit similar obligations of confidentiality as those set forth in this Agreement. All costs and expenses associated with the conduct of such not for cause audit, to the extent occurring more frequently than once per year, would be reimbursed by Company to CyDex. Company's authorized representatives shall be accompanied by CyDex personnel at all times, shall be qualified to conduct such manufacturing audits, shall comply with all applicable rules and regulations relating to facility security, health and safety. Company shall ensure that its authorized representatives conduct each manufacturing audit in such a manner as to not

3.8 Inability to Supply.

- (a) Additional Site. CyDex may in its discretion seek to induce its current Third-Party Manufacturer to undertake and complete validation, qualification and regulatory approvals for a secondary site for the manufacture of Captisol utilizing the same DMF, Specifications and manufacturing processes as its initial site.
- (b) **Notice.** CyDex shall use commercially reasonable efforts to, within 14 days after CyDex's receipt of a purchase order from Company, notify Company if CyDex knows it will be unable to supply at the scheduled delivery time any quantity of non-Defective Captisol ordered by Company.
- (c) **Allocation.** If CyDex is unable to supply to Company and/or its Permitted Purchasers the quantity of non-Defective Captisol that CyDex is required to supply hereunder, CyDex shall (i) first utilize the safety stock it was required to maintain pursuant to **Section 3.4(b)** solely for the benefit of the Permitted Purchasers, (ii) allocate any remaining inventories of Captisol among Company and/or Permitted Purchasers and any other purchasers of Captisol with which CyDex then has an on-going contractual relationship, in proportion to the quantity of Captisol for which each of them has orders pending at such time, (iii) require its Third-Party Manufacturer to utilize the additional site discussed in **Section 3.8(a)** (if any such additional site has been established) for the supply of any shortfall amounts of Captisol and (iv) take all reasonable steps necessary to minimize supply delays.

(d) Alternate Suppliers.

(i) [***]

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

(ii) [***]

3.9 Product Recalls. If any Captisol should be alleged or proven to be Defective, Company shall notify CyDex immediately, and both parties shall cooperate fully regarding the investigation and disposition of any such matter. If (i) Company recalls any Licensed Product, or (ii) the FDA requires the recall of any Licensed Product, and in either case such recall is primarily due to any act or omission of CyDex in general or the Captisol being Defective (either at the time of delivery or due to a Latent Defect), then CyDex agrees, upon substantiation thereof, to refund the purchase price for such Captisol and the costs incurred by Company for such recall including any incidental expenses related thereto. Company shall ensure that Permitted Purchasers maintain records of all sales of Licensed Product sufficient to adequately administer any such recall consistent with applicable laws and regulations.

3.10 Regulatory Status and Specifications.

- (a) CyDex shall be solely responsible for maintaining the necessary approvals and authorizations for Captisol from applicable regulatory authorities, including updating and maintaining the DMF.
- (b) CyDex shall promptly notify Company on becoming aware of any matters that are likely to affect adversely the regulatory status of Captisol or the ability of CyDex to supply Captisol in accordance with the terms of this Agreement. CyDex shall promptly furnish to Company copies of all reports or correspondence issued by such governmental authority related to the Captisol in connection with such inquiry, notification or inspection and copies of any and all proposed responses or explanations relating to items set forth above. Before submission of any response or explanation to such governmental agency, CyDex shall discuss with Company all such proposed responses or explanations and shall reasonably consider in good faith, in the preparation of final responses or explanations, all comments made by Company that reasonably relate to Captisol.
- *** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

- (c) Except as set forth herein, CyDex may, after [***] prior written notice to Company, make reasonable, non-material changes to the Specifications and/or the DMF and/or the manufacturing process for Captisol without Company's prior written consent, provided such changes do not, in Company's reasonable opinion (i) require Company to conduct additional process validation or stability testing, (ii) require Company to comply with additional clinical study requirements from the FDA or other Major Market regulatory agencies that would be beyond that required for the Licensed Products formulated with Captisol meeting the unmodified Specifications, DMF and/or the manufacturing process, (iii) delay Company's development or regulatory approval of a Licensed Product, (iv) negatively affect the solubility, stability, shelf life, safety, or efficacy of a Licensed Product, or (v) affect in any Major Market the regulatory status of any Licensed Product or any additional regulatory approvals. In the event of any permitted change to the Specifications, the DMF or the manufacturing process for Captisol effected by CyDex under this Section 3.10(c), CyDex will nonetheless continue to provide Company with Captisol under the unmodified Specifications and manufacturing process, as applicable, for Captisol by the FDA and other applicable regulatory agencies, or the third anniversary of such permitted change to the Specifications.
- (d) In addition, CyDex may, after [***] prior written notice to Company, offer a different or improved Captisol product for use by third parties (or for use by Company if requested by Company in writing) which requires material changes (including changes not otherwise permitted in subsection (c) above) to the Specifications for Captisol, the DMF for Captisol or the manufacturing process for Captisol, provided that CyDex will nonetheless continue to manufacture and provide to Company Captisol manufactured under the unmodified Specifications, DMF and manufacturing processes for the duration of the Term or as long (but not longer than the duration of the Term) as so requested by Company.
- (e) During such [***] periods described in **Sections 3.10(c)** and **3.10(d)** above, Company shall have the opportunity to evaluate and comment upon the reasonableness of any proposed change to the Specifications or the manufacturing process for Captisol. CyDex shall use commercially reasonable efforts to cooperate with Company to, if necessary, have any change approved by the FDA and other regulatory agencies having jurisdiction.
- (f) In the event that the FDA or another applicable Major Market regulatory agency requires Company to implement any changes to the Specifications or the manufacturing process for Captisol, CyDex shall make all such changes required by the FDA or such other applicable Major Market regulatory agency; and in the event that Company desires to make any non-mandatory changes to the Specifications or the manufacturing process for Captisol and CyDex elects in its sole discretion to accommodate such desire, CyDex shall make all such changes requested by Company. CyDex shall promptly advise Company as to any lead-time changes or other terms that may result from such a change to the Specifications or the manufacturing process for Captisol. (In such a case, the lead-times specified in Section 3.10(c) shall be inapplicable.) CyDex shall reimburse Company for any Captisol purchased hereunder which is rendered unusable by any change in Specifications or the manufacturing process for Captisol required by the FDA or such other applicable Major Market regulatory agency.
- (g) The parties shall use commercially reasonable efforts to cooperate with each other in order to carry out the intent and purposes of this **Section 3.10**. In addition to the rights set forth above, before a change in any of the Specifications or the manufacturing process for Captisol
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(other than a change required by the FDA or another applicable regulatory agency having jurisdiction), Company shall have the right make a one-time bulk purchase of Captisol (in addition to any amounts previously forecast) pursuant to a separately issued purchase order and CyDex shall use commercially reasonable efforts to accommodate and deliver the same in a reasonably timely manner.

3.11 Orders of Clinical Grade Captisol. During Company's clinical development of any Licensed Product, (a) Company or a Permitted Purchaser shall provide CyDex with purchase orders from time to time as needed for Clinical Grade Captisol, and (b) CyDex shall accept and fulfill all such purchase orders for Clinical Grade Captisol, provided that such purchase order is consistent with the terms of Section **3.4(a)**. **Sections 3.4, 3.5, 3.6** and **3.8** shall apply to such order.

4. COMPENSATION.

- **4.1 Pricing.** The purchase prices for Captisol pursuant to this Agreement are as specified in *Exhibit A*. CyDex reserves the right to increase such purchase prices set forth in *Exhibit A* on each January 1 during the Term, upon not less than 30 days' prior written notice to Company, by a percentage equal to the aggregate percentage increase, if any, in the Producer Price Index, Pharmaceutical Preparation Mfg—PCU325412325412 as reported by the Bureau of Labor Statistics, U.S. Department of Labor, for the 12 month period ending October 31 of the prior year, subject to an annual cap of three percent (3%). Notwithstanding the foregoing, in the event Generic Captisol is available by a Generic Supplier for use in a country in the Territory, Company may give CyDex written notice of its desire to discuss modifying the purchase price with respect to any Captisol intended for use in Licensed Products in such country in order to make it competitive with a price being offered by a Generic Supplier ("Notice"). This notice may be provided each time such Generic Supplier lowers the price of its Generic Captisol. Within 14 days after receipt of a Notice, the parties shall agree to a mutually acceptable time to discuss, consult and negotiate with each other in good faith a revised supply price satisfactory to CyDex and Company for such quantities of Captisol in respect of such countries. If a revised purchase price satisfactory to Company is not reached within 30 days of the day a Notice is received by CyDex, Company shall have the right to terminate its obligation to purchase exclusively from CyDex any quantities of Captisol intended for Licensed Products to be sold in such country in which Generic Captisol is available.
- 4.2 Shortfall Reimbursement (Take or Pay). If Company fails to order (pursuant to and in compliance with Article 3) for the Q1 of any Detailed Forecast a quantity of Commercial Grade Captisol to be delivered during such Q1 (or within 100 days after the firm purchase order is placed) that is equal to or greater than the quantity of Commercial Grade Captisol Company is obligated to purchase pursuant to the applicable Detailed Forecast (the difference between the quantity of Commercial Grade Captisol Company is obligated to purchase in Q1 pursuant to the applicable Detailed Forecast and the amount of Commercial Grade Captisol that Company actually orders for delivery in Q1 (or within 60 days after the firm purchase order is placed), the "Commercial Grade Shortfall"), then Company shall either (a) pay CyDex 60% of the purchase price hereunder for the Commercial Grade Shortfall amount and in such case shall not be entitled to receive delivery of such Commercial Grade Shortfall amount. In either event, such payment must be made within 20 days after the end of the Q1. This Section 4.2 is based on the time stated for delivery in the original order, as opposed to the time delivery is actually made.

4.3 Payments; Taxes. All amounts due hereunder are stated in, and shall be paid in, U.S. Dollars. Payment of CyDex's invoices shall be made, except to the extent disputed in good faith, within 30 days of Company's receipt of such invoices. The purchase prices for Captisol specified in *Exhibit A* exclude all applicable sales, use, and other taxes, and Company will be responsible for payment of all such taxes (other than taxes based on CyDex's income), fees, duties, and charges, and any related penalties and interest, arising from the payment of amounts due hereunder. Unpaid and undisputed balances shall accrue interest, from due date until paid, at an annual interest rate equal to the prime rate, as reported in The Wall Street Journal, Eastern U.S. Edition, on the date such payment is due (or the last previous publication date if such date is not a publication date), plus an additional 200 basis points (2%). If any amount due hereunder and not subject to a reasonable, good-faith dispute by Company remains outstanding for more than 30 days after its due date, CyDex may, in addition to any other rights or remedies it may have, refuse to ship Captisol hereunder except upon payment by Company in advance.

5. REPRESENTATIONS AND WARRANTIES.

- **5.1 Limited Warranty.** CyDex warrants solely to Company that:
- (a) all Captisol sold to Company pursuant to this Agreement shall conform to the respective Specifications (as applicable for Clinical Grade Captisol or Commercial Grade Captisol), the DMF, the Minimum Remaining Shelf Life and all applicable laws, including GMP, at the time of delivery and shall not, before the first anniversary of actual or deemed acceptance, be subject to any Latent Defects;
- (b) CyDex, its Affiliates and its Third-Party Manufacturers are not a debarred entity and have not used and will not use in any capacity the services of any individual or entity debarred under 21 U.S.C. §335(a) or (b) of the Federal Food, Drug and Cosmetic Act in connection with its obligations hereunder;
- (c) CyDex, its Affiliates and its Third-Party Manufacturers hold, and are operating in material compliance with, all permits, licenses, franchises, authorizations and clearances of the FDA and/or any other regulatory authority required in connection with the manufacture and supply of Captisol, except where the failure to so hold or be so operating does not have and would not reasonably be expected to have a material adverse effect on (i) CyDex and/or its ability to supply Captisol and/or (ii) Company and/or its ability to obtain Captisol and/or exploit Licensed Products;
- (d) there are no actual or threatened enforcement actions relating to the manufacture and/or supply of Captisol against CyDex or its Affiliates by the FDA or any other federal, state or foreign regulatory authority. Further, CyDex does not know of any actual or threatened enforcement actions relating to the manufacture and/or supply of Captisol against any Third Party Manufacturers by the FDA or any other federal, state or foreign regulatory authority; and
- (e) CyDex shall notify Company promptly if it becomes aware of any material facts or circumstances occurring after the Effective Date which it has reason to believe would have made the aforementioned representations and warranties untrue had they been given after the Effective Date.
- **5.2 Representations, Warranties.** The provisions of **Section 9.1** (Mutual Representations and Warranties) of the License Agreement are incorporated herein by reference as if

fully set forth herein, with references therein to "this Agreement" being understood to refer to this Supply Agreement rather than to the License Agreement.

5.3 Disclaimer. The warranties set forth in this **Section 5** are provided in lieu of, and each party hereby disclaims, all other warranties, express and implied, relating to the subject matter of this agreement or Captisol, including but not limited to the implied warranties of merchantability, non-infringement and fitness for a particular purpose. CyDex's warranties under this Agreement are solely for the benefit of Company and may be asserted only by Company and not any Affiliate, Permitted Purchaser or other Third Party (other than a Company Indemnitee with respect to an indemnification claim). Company shall be solely responsible for all representations and warranties that Company or its Affiliates make to any Permitted Purchaser.

6. TERM AND TERMINATION.

- 6.1 Term. The term of this Agreement (the "Term") shall commence on the Effective Date and, unless terminated earlier as set forth herein, shall continue until the earlier of (a) termination of the License Agreement in its entirety or (b) 90 days after Company provides written notice to CyDex of its intent to terminate this Agreement for convenience. In any event, termination for convenience shall have no effect on outstanding purchase orders or Detailed Forecasts and the binding nature thereof. Notwithstanding the foregoing, Company shall have the right to terminate the Agreement with immediate effect in its entirety in the event a significant Licensed Product or Captisol has any significant efficacy or safety concerns, or to terminate the Agreement with immediate effect on a country-by-country basis if any regulatory approvals for Captisol and/or a significant Licensed Product are suspended or revoked in a country in the Territory, and Company reasonably believes that such occurrence will have a significant effect upon its Detailed Forecasts. In addition, if Company terminates the License Agreement as to any particular country pursuant to Section 13.2(b) or Section 14.6 thereof or terminates this Agreement pursuant to the foregoing sentence as to any particular country, the definition of "Territory" for purposes of this Agreement shall thereupon automatically and immediately be deemed amended to exclude such country, and CyDex shall have no further obligation to supply Captisol to Company for use or sale in such country.
- **6.2 Termination for Breach.** If either party should violate or fail to perform any term or covenant of this Agreement, then the other party may give written notice of such default to the first party. If such party should fail to cure such default within 60 days (or 10 days with respect to any payment obligation) of the date of such notice, the other party shall have the right to terminate this Agreement by a second written notice (a "**Notice of Termination**") to the first party. If Notice of Termination is sent to such first party, this Agreement shall automatically terminate on the effective date of such notice.
- **6.3 Termination for Bankruptcy.** Either party may terminate this Agreement immediately upon written notice to the other party in the event that the first party has a petition in bankruptcy filed against it that is not dismissed within 60 days of such filing, files a petition in bankruptcy or makes an assignment for the benefit of creditors.
- **6.4 Effect of Termination.** Upon the termination of this Agreement by CyDex under **Section 6.2**, (a) Company shall no longer have any rights to purchase Captisol, and (b) each party shall promptly return all relevant records and materials in its possession or control containing the other party's Confidential Information with respect to which the former party does not retain rights

hereunder; *provided*, *however*, that each party may retain one archival copy of such records and materials solely to be able to monitor its obligations that survive under this Agreement. Upon the termination of this Agreement by Company under Section 6.2, (i) a permanent Supply Interruption will be deemed to have occurred and Section 3.8(d) shall survive in perpetuity, including CyDex's obligations under such subsection and Company's right and license to manufacture and/or have manufactured Captisol.

6.5 Survival. Notwithstanding any other provisions of this Agreement, any liability or obligation of either party to the other for acts or omissions before the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement. Such termination or expiration shall not relieve either party from obligations that are expressly indicated to survive termination or expiration of this Agreement, nor shall any termination or expiration of this Agreement relieve Company of its obligation to pay CyDex sums due in respect of Captisol shipped before termination or expiration of this Agreement. Sections 2.4 (Restrictions), 3.5 (Delivery), 3.6 (Quality Control; Acceptance and Rejection), 3.7 (Facilities and Inspections), 3.8(d) (Alternate Suppliers; to the extent set forth in Section 6.4), 3.9 (Product Recalls), 4.3 (Payments; Taxes), 5.2 (Representations, Warranties), 5.3 (Disclaimer), 6.4 (Effect of Termination), 6.5 (Survival) and 7 (General Provisions) shall survive termination or expiration of this Agreement.

7. GENERAL PROVISIONS.

The following **Sections** of the License Agreement are incorporated into this Agreement by this reference as if fully set forth herein, with references therein to "this Agreement" being understood to refer to this Supply Agreement rather than to the License Agreement: **4.2** (Taxes), **7.2** (Material Safety), **7.3** (Adverse Event Reporting), **8** (Confidentiality), **10** (Indemnification), **11** (Limitation of Liability), **12** (Management of Intellectual Property), and **14** (General Provisions).

[Remainder of this page left blank intentionally]

IN WITNESS WHEREOF, the parties have executed this Supply Agreement as of the Effective Date.

CYDEX PHARMACEUTICALS, INC.

By: /s/ Charles Berkman

Name: Charles Berkman

Title: VP and Secretary

MEI PHARMA, INC.

By: /s/ Daniel P. Gold

Name: Daniel P. Gold

Title: President & Chief Executive Officer

EXHIBIT A

PURCHASE PRICES FOR CAPTISOL

[***]

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT B: SPECIFICATIONS

[***]

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

CERTIFICATION

I, Daniel Gold, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of MEI Pharma, Inc.;
- 2. 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 Quarterly 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 Quarterly 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Ouarterly Report is being prepared:
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Quarterly Report based on such evaluation; and
 - (d) Disclosed in this Quarterly 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.
- 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 the audit committee of the registrant's board of directors:
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2012

/s/ Daniel Gold

Daniel Gold President and Chief Executive Officer (Principal Executive Officer)

CERTIFICATION

I, Thomas M. Zech, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of MEI Pharma, Inc.;
- 2. 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 Quarterly 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 Quarterly 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Ouarterly Report is being prepared:
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in the Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Quarterly Report based on such evaluation; and
 - (d) Disclosed in this Quarterly 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.
- 5. The Company'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 the audit committee of the registrant's board of directors:
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2012

/s/ Thomas M. Zech

Thomas M. Zech Chief Financial Officer (Principal Financial Officer)

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Daniel P. Gold, the President and Chief Executive Officer of MEI Pharma, Inc. (the "Registrant"), and Thomas M. Zech, the Chief Financial Officer of the Registrant, each hereby certifies that, to his knowledge:

- 1. The Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2012, (the "Form 10-Q") to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2. The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition of the Registrant at the end of the period covered by the Form 10-Q and results of operations of the registrant for the period covered by the Form 10-Q.

These certifications accompanying the Form 10-Q to which they relate, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Dated: November 13, 2012

/s/ Daniel P. Gold
Daniel P. Gold
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Thomas M. Zech

Thomas M. Zech Chief Financial Officer (Principal Financial Officer)