

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

FORM 10-Q

Mark One

Quarterly Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934

For the quarterly period ended June 30, 2011

or

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Transition Period From \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number: 001-33093

**LIGAND PHARMACEUTICALS INCORPORATED**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

77-0160744  
(I.R.S. Employer  
Identification No.)

11085 North Torrey Pines Road  
La Jolla, CA  
(Address of principal executive offices)

92037  
(Zip Code)

Registrant's Telephone Number, Including Area Code: (858) 550-7500

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

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

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

Large Accelerated Filer  Accelerated Filer  Non-Accelerated Filer  Smaller Reporting Company   
(Do not check if a smaller reporting company)

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

As of August 1, 2011, the registrant had 19,673,100 shares of common stock outstanding.

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LIGAND PHARMACEUTICALS INCORPORATED  
QUARTERLY REPORT

FORM 10-Q

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\* No information provided due to inapplicability of item.

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**LIGAND PHARMACEUTICALS INCORPORATED**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(Unaudited)**  
**(in thousands, except share data)**

	June 30, 2011	December 31, 2010
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 3,441	\$ 3,346
Short-term investments	10,000	19,351
Accounts receivable, net	1,038	993
Inventory	2,594	0
Other current assets	1,868	720
Deferred income taxes	1,169	0
Income tax receivable	0	4,575
Current portion of co-promote termination payments receivable	8,029	8,034
Total current assets	28,139	37,019
Restricted cash and investments	1,341	1,341
Property and equipment, net	679	559
Goodwill and other identifiable intangible assets	75,157	12,951
Long-term portion of co-promote termination payments receivable	21,346	22,851
Other assets	773	838
Total assets	\$ 127,435	\$ 75,559
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 10,628	\$ 8,597
Accrued liabilities	6,814	8,859
Accrued litigation settlement costs	0	1,000
Current portion of liability for contingent value rights	5,955	0
Current portion of deferred gain	851	1,702
Current portion of co-promote termination liability	8,029	8,034
Current portion of lease termination payments	0	5,296
Bank line of credit	10,000	0
Current portion of deferred revenue	38	0
Total current liabilities	42,315	33,488
Long-term portion of note payable	20,114	0
Long-term portion of co-promote termination liability	21,346	22,851
Long-term portion of deferred revenue, net	1,291	2,546
Long-term portion of lease exit obligations	9,861	11,118
Deferred income taxes	3,137	372
Liability for contingent value rights	15,006	700
Other long-term liabilities	694	989
Total liabilities	113,764	72,064
Commitments and contingencies		
Common stock subject to conditional redemption; 112,371 shares issued and outstanding at June 30, 2011 and December 31, 2010, respectively	8,344	8,344
Stockholders' equity (deficit):		
Convertible preferred stock, \$0.001 par value; 833,333 shares authorized; none issued	0	0
Common stock, \$0.001 par value; 33,333,333 shares authorized; 20,676,547 and 20,620,917 shares issued at June 30, 2011 and December 31, 2010, respectively	21	21
Additional paid-in capital	730,966	729,271
Accumulated other comprehensive income	0	31
Accumulated deficit	(683,380)	(691,947)
Treasury stock, at cost; 1,118,222 and 1,111,999 shares at June 30, 2011 and December 31, 2010, respectively	(42,280)	(42,225)
Total stockholders' equity (deficit)	5,327	(4,849)
	\$ 127,435	\$ 75,559

*See accompanying notes.*

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**LIGAND PHARMACEUTICALS INCORPORATED**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**  
**(in thousands, except share data)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
<b>Revenues:</b>				
Royalties	\$ 2,172	\$ 1,601	\$ 4,165	\$ 3,563
Material sales	2,984	0	4,034	0
Collaborative research and development and other revenues	2,307	4,237	3,160	8,233
<b>Total revenues</b>	<b>7,463</b>	<b>5,838</b>	<b>11,359</b>	<b>11,796</b>
<b>Operating costs and expenses:</b>				
Cost of sales	1,623	0	2,148	0
Research and development	3,237	6,602	5,223	13,963
General and administrative	3,855	3,290	8,034	6,338
Lease exit and termination costs	(16)	0	(168)	0
<b>Total operating costs and expenses</b>	<b>8,699</b>	<b>9,892</b>	<b>15,237</b>	<b>20,301</b>
Accretion of deferred gain on sale leaseback	426	426	851	851
<b>Loss from operations</b>	<b>(810)</b>	<b>(3,628)</b>	<b>(3,027)</b>	<b>(7,654)</b>
<b>Other income (expense):</b>				
Interest income	0	118	30	328
Interest expense	(674)	(13)	(1,093)	(31)
Decrease (increase) in liability for contingent value rights	679	3,690	(1,057)	4,242
Other, net	32	168	82	734
<b>Total other income (expense), net</b>	<b>37</b>	<b>3,963</b>	<b>(2,038)</b>	<b>5,273</b>
Income (loss) before income taxes	(773)	335	(5,065)	(2,381)
Income tax expense (benefit)	141	625	(13,637)	899
<b>Income (loss) from continuing operations</b>	<b>(914)</b>	<b>(290)</b>	<b>8,572</b>	<b>(3,280)</b>
<b>Discontinued operations:</b>				
Gain on sale of AVINZA Product Line	0	3	0	13
Gain on sale of Oncology Product Line	0	4	4	233
<b>Discontinued operations</b>	<b>0</b>	<b>7</b>	<b>4</b>	<b>246</b>
<b>Net income (loss):</b>	<b>\$ (914)</b>	<b>\$ (283)</b>	<b>\$ 8,576</b>	<b>\$ (3,034)</b>
<b>Basic and diluted per share amounts:</b>				
Income (loss) from continuing operations	\$ (0.05)	\$ (0.01)	\$ 0.44	\$ (0.16)
Discontinued operations	0.00	0.00	0.00	0.01
<b>Net income (loss)</b>	<b>\$ (0.05)</b>	<b>\$ (0.01)</b>	<b>\$ 0.44</b>	<b>\$ (0.15)</b>
Weighted average number of common shares - basic	19,650,260	19,608,685	19,623,249	19,595,784
Weighted average number of common shares - diluted	19,650,260	19,608,685	19,637,983	19,595,784

*See accompanying notes.*

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**LIGAND PHARMACEUTICALS INCORPORATED**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(Unaudited)**  
**(in thousands)**

	<u>For the six months ended June 30,</u>	
	<u>2011</u>	<u>2010</u>
<b>Operating activities</b>		
Net income (loss)	\$ 8,576	\$ (3,034)
Less: gain from discontinued operations	<u>4</u>	<u>246</u>
Income (loss) from continuing operations	8,572	(3,280)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Accretion of deferred gain on sale leaseback	(851)	(851)
Change in estimated fair value of contingent value rights	1,057	(4,242)
Depreciation and amortization	1,349	1,448
Non-cash lease costs	(135)	(64)
Gain on asset write-offs	1	(64)
Realized gain on investment	6	(564)
Stock-based compensation	1,696	1,457
Deferred income taxes	(13,783)	0
Other	102	27
Changes in operating assets and liabilities, net of acquisition:		
Accounts receivable, net	1,157	618
Inventory	(179)	0
Other current assets	4,340	(66)
Other long term assets	570	(413)
Accounts payable and accrued liabilities	(8,183)	(8,032)
Other liabilities	(1,636)	(1,055)
Deferred revenue	<u>(1,217)</u>	<u>(3,275)</u>
Net cash used in operating activities of continuing operations	(7,134)	(18,356)
Net cash provided by operating activities of discontinued operations	<u>0</u>	<u>263</u>
Net cash used in operating activities	(7,134)	(18,093)
<b>Investing activities</b>		
Purchases of property and equipment	(5)	(65)
Acquisition of CyDex, net of cash acquired	(32,024)	0
Acquisition of Metabasis, net of cash acquired	0	(2,834)
Acquisition of intellectual property	0	(1,375)
Purchases of short-term investments	(10,000)	(31,861)
Proceeds from sale of short-term investments	19,346	40,667
Proceeds from sale of property and equipment and building	0	205
Other, net	<u>(33)</u>	<u>499</u>
Net cash provide by (used in) investing activities of continuing operations	(22,716)	5,236
Net cash provided by investing activities of discontinued operations	<u>0</u>	<u>0</u>
Net cash provided by (used in) investing activities	(22,716)	5,236
<b>Financing activities</b>		
Proceeds from issuance of debt	30,000	0
Share repurchases	(55)	0
Principal payments on equipment financing obligations	0	(52)
Net proceeds from issuance of common stock	<u>0</u>	<u>112</u>
Net cash provided by financing activities	29,945	60
Net increase (decrease) in cash and cash equivalents	95	(12,797)
Cash and cash equivalents at beginning of period	<u>3,346</u>	<u>16,032</u>
Cash and cash equivalents at end of period	<u>\$ 3,441</u>	<u>\$ 3,235</u>

*See accompanying notes.*

**LIGAND PHARMACEUTICALS INCORPORATED**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**1. Basis of Presentation**

Ligand Pharmaceuticals Incorporated, a Delaware corporation (the “Company” or “Ligand”), is a biotechnology company that focuses on drug discovery and development of pharmaceuticals that address critical unmet medical needs or that are more effective and/or safer than existing therapies, more convenient to administer and are cost effective. The Company’s principle market is the United States. The Company sold its Oncology Product Line (“Oncology”) and AVINZA Product Line (“AVINZA”) on October 25, 2006 and February 26, 2007, respectively. The operating results for Oncology and AVINZA have been presented in the accompanying consolidated financial statements as “Discontinued Operations”.

The Company has incurred significant losses since its inception. At June 30, 2011, the Company’s accumulated deficit was \$683.4 million and the Company had negative working capital of \$14.2 million. Based on management’s plans, including increases in CAPTISOL® sales and royalty revenues, as well as anticipated new license revenue and expense reductions, if necessary, the Company believes its currently available cash, cash equivalents, and short-term investments as well as its current and future royalty, license and milestone revenues will be sufficient to satisfy its anticipated operating and capital requirements, including the \$4.3 million payment due to CyDex shareholders in January 2012, through at least the next twelve months. The Company’s future operating and capital requirements will depend on many factors, including, but not limited to: the pace of scientific progress in its research and development programs; the potential success of these programs; the scope and results of preclinical testing and clinical trials; the time and costs involved in obtaining regulatory approvals; the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims; competing technological and market developments; the amount of royalties on sales of the commercial products of its partners; the efforts of its collaborative partners; obligations under its operating lease agreements; and the capital requirements of any companies the Company acquires, including Pharmacoepia, Inc. (“Pharmacoepia”), Neurogen Corporation (“Neurogen”), Metabasis Therapeutics, Inc. (“Metabasis”) and CyDex Pharmaceuticals, Inc. (“CyDex”). Management believes that the actions presently being taken to generate sufficient operating cash flow provide the opportunity for the Company to continue as a going concern. While the Company believes in the viability of its strategy to generate sufficient operating cash flow and in its ability to raise additional funds, there can be no assurances to that effect. The ability of the Company to achieve its operational targets is dependent upon the Company’s ability to further implement its business plan and generate sufficient operating cash flow.

*Principles of Consolidation*

The condensed consolidated financial statements include the Company’s wholly owned subsidiaries, Seragen, Inc. (“Seragen”), Nexus Equity VI LLC (“Nexus”), Pharmacoepia, Neurogen, Metabasis and CyDex. All significant intercompany accounts and transactions have been eliminated in consolidation.

*Basis of Presentation*

Our accompanying unaudited consolidated condensed financial statements as of June 30, 2011 and for the three and six months ended June 30, 2011 and 2010 have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for annual financial statements. Our consolidated condensed balance sheet at December 31, 2010 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the financial position and results of operations of Ligand Pharmaceuticals Incorporated, and our subsidiaries (the Company) have been included. Operating results for the three and six months ended June 30, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011. These financial statements should be read in conjunction with the consolidated financial statements and notes therein included in our annual report on Form 10-K for the year ended December 31, 2010.

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### *Use of Estimates*

The preparation of consolidated financial statements in conformity with generally accepted accounting principles requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosure of contingent assets and liabilities, at the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. The Company's critical accounting policies are those that are both most important to the Company's financial condition and results of operations and require the most difficult, subjective or complex judgments on the part of management in their application, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Because of the uncertainty of factors surrounding the estimates or judgments used in the preparation of the consolidated financial statements, actual results may materially vary from these estimates.

### *Income (Loss) Per Share*

Basic earnings per share is calculated by dividing net income or loss by the weighted average number of common shares and vested restricted stock units outstanding. Diluted earnings per share is computed by dividing net income or loss by the weighted average number of common shares and vested restricted stock units outstanding and the weighted average number of dilutive common stock equivalents, including stock options and non-vested restricted stock units. Common stock equivalents are only included in the diluted earnings per share calculation when their effect is dilutive. For the three months ended June 30, 2011 and 2010 and the six months ended June 30, 2010, no potential common shares are included in the computation of any diluted per share amounts, including income (loss) per share from discontinued operations and net loss per share, as the Company reported a loss from continuing operations. Potential common shares, the shares that would be issued upon the exercise of outstanding stock options and warrants and the vesting of restricted shares that would be excluded from the computation of diluted loss per share, were 1.6 million and 1.2 million at June 30, 2011 and 2010, respectively.

The following table sets forth the computation of basic and diluted net income (loss) per share for the periods indicated (in thousands, except per share amounts):

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2011	2010	2011	2010
Net income (loss) from continuing operations	\$ (914)	\$ (290)	\$ 8,572	\$ (10,906)
Discontinued operations	0	7	4	5,922
Net income (loss)	\$ (914)	\$ (283)	\$ 8,576	\$ (4,984)
Shares used to compute basic income (loss) per share	19,650,260	19,608,685	19,623,249	19,595,784
Dilutive potential common shares:				
Restricted stock	0	0	14,734	0
Shares used to compute diluted income (loss) per share	19,650,260	19,608,685	19,637,983	19,595,784
Basic and diluted per share amounts:				
Income (loss) from continuing operations	\$ (0.05)	\$ (0.01)	\$ 0.44	\$ (0.16)
Discontinued operations	0.00	0.00	0.00	0.01
Net income (loss)	\$ (0.05)	\$ (0.01)	\$ 0.44	\$ (0.15)

### *Revenue Recognition*

Royalties on sales of products commercialized by the Company's partners are recognized in the quarter reported by the respective partner.

Material sales revenue is recognized upon transfer of title, which normally passes to the buyer upon shipment to the customer. The Company's credit and exchange policy includes provisions for the return of product between 30 to 90 days, depending on the specific terms of the individual agreement, when that product (1) does not meet

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specifications, (2) is damaged in shipment (in limited circumstances where title does not transfer until delivery), or (3) is exchanged for an alternative grade of CAPTISOL.

Revenue from research funding under the Company's collaboration agreements is earned and recognized on a percentage-of-completion basis as research hours are incurred in accordance with the provisions of each agreement.

Nonrefundable, up-front license fees and milestone payments with standalone value that are not dependent on any future performance by the Company under the Company's collaboration agreements are recognized as revenue upon the earlier of when payments are received or collection is assured, but are deferred if the Company has continuing performance obligations. Amounts received under multiple-element arrangements requiring ongoing services or performance by the Company are recognized over the period of such services or performance.

Revenue from milestones is recognized when earned, as evidenced by written acknowledgement from the collaborator, provided that (i) the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, and the Company has no further performance obligations relating to that event, and (ii) collectability is reasonably assured. If these criteria are not met, the milestone payment is recognized over the remaining period of the Company's performance obligations under the arrangement.

### *Income Taxes*

The Company recognizes liabilities or assets for the deferred tax consequences of temporary differences between the tax bases of assets or liabilities and their reported amounts in the financial statements. These temporary differences will result in taxable or deductible amounts in future years when the reported amounts of the assets or liabilities are recovered or settled. A valuation allowance is established when management determines that it is more likely than not that all or a portion of a deferred tax asset will not be realized. Management evaluates the realizability of its net deferred tax assets on a quarterly basis and valuation allowances are provided, as necessary. During this evaluation, management reviews its forecasts of income in conjunction with other positive and negative evidence surrounding the realizability of its deferred tax assets to determine if a valuation allowance is required. Adjustments to the valuation allowance will increase or decrease the Company's income tax provision or benefit. Management also applies the relevant guidance to determine the amount of income tax expense or benefit to be allocated among continuing operations, discontinued operations, and items charged or credited directly to stockholders' equity. The Company recorded income tax expense of \$0.1 million for the three months ended June 30, 2011 and an income tax benefit of \$13.6 million for the six months ended June 30, 2011. The Company also recorded income tax expense of \$0.6 million and \$0.9 million for the three and six months ended June 30, 2010, respectively. The income tax benefit for the six months ended June 30, 2011 relates to the Company's acquisition of CyDex in January 2011. For financial statement purposes, the Company recorded the acquired Cydex intangible assets of approximately \$64 million. For tax purposes, the Company is required to carry over the historic tax basis of the assets and liabilities of Cydex. In accordance with ASC Topic 805, the Company established net deferred tax assets and liabilities of approximately \$15 million. As a result of the ability to recognize deferred tax assets for these deferred tax liabilities, the Company released valuation allowances against its deferred tax assets resulting in an income tax benefit of \$13.6 million for the six months ended June 30, 2011.

A tax position must meet a minimum probability threshold before a financial statement benefit is recognized. The minimum threshold is a tax position that is more likely than not to be sustained upon examination by the applicable taxing authority, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense.

### *Accounting for Stock-Based Compensation*

Stock-based compensation expense for awards to employees and non-employee directors is recognized on a straight-line basis over the vesting period until the last tranche vests. Compensation cost for consultant awards is recognized over each separate tranche's vesting period. The Company recognized compensation expense of \$1.2 million and \$0.8 million for the three months ended June 30, 2011 and 2010, respectively. The compensation



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expense related to share-based compensation arrangements is recorded as components of research and development expenses (\$0.4 million and \$0.5 million) and general and administrative expenses (\$0.8 million and \$0.3 million) for the three months ended June 30, 2011 and 2010, respectively. The Company recognized compensation expense of \$1.7 million and \$1.5 million for the six months ended June 30, 2011 and 2010, respectively. The compensation expense related to share-based compensation arrangements is recorded as components of research and development expenses (\$0.5 million and \$0.9 million) and general and administrative expenses (\$1.2 million and \$0.6 million) for the six months ended June 30, 2011 and 2010, respectively.

The fair-value for options that were awarded to employees and directors was estimated at the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Risk-free interest rate	2.4%	2.6%	2.5%	2.7%
Dividend yield	0	0	0	0
Expected volatility	68%	72%	69%	73%
Expected term	6.1 years	3.5 years	6.1 years	5.8 years

The expected term of the employee and non-employee director options is the estimated weighted-average period until exercise or cancellation of vested options (forfeited unvested options are not considered) based on historical experience. The expected term for consultant awards is the remaining period to contractual expiration.

Volatility is a measure of the expected amount of variability in the stock price over the expected life of an option expressed as a standard deviation. In selecting this assumption, management used the historical volatility of the Company's stock price over a period approximating the expected term.

### *Cash, Cash Equivalents and Short-term Investments*

Cash and cash equivalents consist of cash and highly liquid securities with maturities at the date of acquisition of three months or less. The following table summarizes the various investment categories at June 30, 2011 and December 31, 2010 (in thousands):

	Cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
<b>June 30, 2011</b>				
Certificates of deposit	\$10,000	\$ 0	\$ 0	\$10,000
Corporate obligations	0	0	0	0
	10,000			10,000
Certificates of deposit—restricted	1,341	0	0	1,341
	<u>\$11,341</u>	<u>\$ 0</u>	<u>\$ 0</u>	<u>\$11,341</u>
<b>December 31, 2010</b>				
U.S. government securities	\$ 2,031	\$ 9	\$ (3)	\$ 2,037
Certificates of deposit	5,062	98	0	5,160
Corporate obligations	12,164	104	(114)	12,154
	19,257	211	(117)	19,351
Certificates of deposit—restricted	1,341	0	0	1,341
	<u>\$20,598</u>	<u>\$ 211</u>	<u>\$ (117)</u>	<u>\$20,692</u>

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### *Concentrations of Credit Risk*

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash equivalents and investments and accounts receivable.

The Company invests its excess cash principally in United States government debt securities, investment grade corporate debt securities and certificates of deposit. The Company has established guidelines relative to diversification and maturities that maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates. Except as described above, the Company has not experienced any significant losses on its cash equivalents, short-term investments or restricted investments.

As of June 30, 2011 and December 31, 2010, cash deposits held at financial institutions in excess of FDIC insured amounts of \$250,000 were approximately \$12.4 million and \$5.1 million, respectively.

Accounts receivable from one customer was 85% and 100% of total accounts receivable at June 30, 2011 and December 31, 2010, respectively.

The Company obtains CAPTISOL® from a sole-source supplier. If this supplier were not able to supply the requested amounts of CAPTISOL, the Company would be unable to continue to derive revenues from the sale of CAPTISOL until it obtained an alternative source, which might take a considerable length of time.

### *Allowance for Doubtful Accounts*

The Company maintains an allowance for doubtful accounts based on the best estimate of the amount of probable losses in the Company's existing accounts receivable. Accounts receivable that are outstanding longer than their contractual payment terms, ranging from 30 to 90 days, are considered past due. When determining the allowance for doubtful accounts, several factors are taken into consideration, including historical write-off experience and review of specific customer accounts for collectibility. Account balances are charged off against the allowance after collection efforts have been exhausted and the potential for recovery is considered remote. There was no allowance for doubtful accounts included in the balance sheets at June 30, 2011 and December 31, 2010.

### *Inventory*

Inventory is stated at the lower of cost or market. The Company determines cost using the first-in, first-out method. The Company analyzes its inventory levels periodically and writes down inventory to its net realizable value if it has become obsolete, has a cost basis in excess of its expected net realizable value or is in excess of expected requirements.

### *Other Current Assets*

Other current assets consist of the following (in thousands):

	<u>June 30, 2011</u>	<u>December 31, 2010</u>
Prepaid expenses	\$ 598	\$ 578
Advanced manufacturing payments	493	0
Other receivables	777	142
	<u>\$1,868</u>	<u>\$ 720</u>

### *Property and Equipment*

Property and equipment is stated at cost and consists of the following (in thousands):

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	June 30, 2011	December 31, 2010
Lab and office equipment	\$ 5,956	\$ 5,676
Computer equipment and software	4,050	3,996
Leasehold improvements	62	55
	<u>10,068</u>	<u>9,727</u>
Less accumulated depreciation and amortization	<u>(9,389)</u>	<u>(9,168)</u>
	<u>\$ 679</u>	<u>\$ 559</u>

Depreciation of equipment is computed using the straight-line method over the estimated useful lives of the assets, which range from three to ten years. Leasehold improvements are amortized using the straight-line method over their estimated useful lives or their related lease term, whichever is shorter.

### *Goodwill and Other Identifiable Intangible Assets*

Goodwill and other identifiable intangible assets consist of the following (in thousands):

	June 30, 2011	December 31, 2010
Acquired in-process research and development	\$15,579	\$ 12,379
Complete technology	14,643	0
Trade name	2,537	0
Customer relationships	29,400	0
Goodwill	<u>14,250</u>	<u>700</u>
	\$76,409	\$ 13,079
Accumulated amortization	<u>(1,252)</u>	<u>(128)</u>
	<u>\$75,157</u>	<u>\$ 12,951</u>

As discussed in Note 2, on January 24, 2011, the Company completed its acquisition of CyDex Pharmaceuticals, Inc. As a result of the transaction, the Company recorded \$46.6 million of intangible assets with definite lives. The weighted-average amortization period for the identified intangible assets with definite lives is 20 years. In addition, the Company recorded \$3.2 million of acquired In-Process Research and Development (IPR&D) and \$13.6 million of goodwill.

Intangible assets related to IPR&D are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. During the period the assets are considered to be indefinite-lived, they will not be amortized but will be tested for impairment on an annual basis and between annual tests if the Company becomes aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time.

### *Impairment of Long-Lived Assets*

Management reviews long-lived assets for impairment annually or whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Fair value for the Company's long-lived assets is determined using the expected cash flows discounted at a rate commensurate with the risk involved. As of June 30, 2011, management does not believe there have been any events or circumstances indicating that the carrying amount of its long-lived assets may not be recoverable.

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### *Accrued Liabilities*

Accrued liabilities consist of the following (in thousands):

	June 30, 2011	December 31, 2010
Compensation	\$ 643	\$ 2,201
Legal	181	330
Lease exit obligations	1,942	2,076
Other	4,048	4,252
	<u>\$6,814</u>	<u>\$ 8,859</u>

### *Other Long-Term Liabilities*

Other long-term liabilities consist of the following (in thousands):

	June 30, 2011	December 31, 2010
Deferred rent	\$ 306	\$ 601
Deposits	388	388
	<u>\$ 694</u>	<u>\$ 989</u>

### *Sale of Royalty Rights*

The Company previously sold to third parties the rights to future royalties of certain of its products. As part of the underlying royalty agreements, the partners have the right to offset a portion of any future royalty payments owed to the Company to the extent of previous milestone payments. Accordingly, the Company deferred a portion of the revenue associated with each tranche of royalty right sold, equal to the pro-rata share of the potential royalty offset. Such amounts associated with the offset rights against future royalty payments will be recognized as revenue upon receipt of future royalties from the respective partners. During the quarter ended June 30, 2011, one of the Company's partners abandoned its product and thereby ceased the right to offset of future royalty payments. As a result, the Company recognized \$1.2 million in collaborative research and development and other revenue for the quarter ended June 30, 2011. As of June 30, 2011 and December 31, 2010, the Company had deferred \$1.3 million and \$2.5 million, respectively, of revenue, which is included in long-term portion of deferred revenue.

### *Comprehensive Income (loss)*

Comprehensive income (loss) represents net income (loss) adjusted for the change during the periods presented in unrealized gains and losses on available-for-sale securities less reclassification adjustments for realized gains or losses included in net income (loss). Comprehensive loss is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Net income (loss) as reported	\$ (914)	\$ (283)	\$8,576	\$(3,034)
Unrealized net gain (loss) on available-for-sale securities	(5)	(136)	(31)	372
Comprehensive loss	<u>\$ (919)</u>	<u>\$ (419)</u>	<u>\$8,545</u>	<u>\$(2,662)</u>

### *Recently Adopted Accounting Pronouncements*

In October 2009, the FASB issued Accounting Standards Update ("ASU") No. 2009-13, "Multiple-Deliverable Revenue Arrangements," or ASU 2009-13, which amends existing revenue recognition accounting pronouncements that are currently within the scope of ASC 605. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon

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management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. ASU 2009-13 is effective for the Company prospectively for revenue arrangements entered into or materially modified beginning January 1, 2011. The Company's adoption of this amendment had no impact on its consolidated financial position, results of operations or cash flows.

In January 2010, the FASB issued ASU No. 2010-06, *Improving Disclosures about Fair Value Measurements*, which, among other things, amends *Accounting Standards Topic 820 Fair Value Measurements and Disclosures (ASC 820)* to require entities to separately present purchases, sales, issuances, and settlements in their reconciliation of Level 3 fair value measurements (i.e., to present such items on a gross basis rather than on a net basis), and which clarifies existing disclosure requirements provided by ASC 820 regarding the level of disaggregation and the inputs and valuation techniques used to measure fair value for measurements that fall within either Level 2 or Level 3 of the fair value hierarchy. ASU No. 2010-06 is effective for interim and annual periods beginning after December 15, 2009, except for the disclosures about purchases, sales, issuances, and settlements in the roll forward of activity in Level 3 fair value measurements which are effective for fiscal years beginning after December 15, 2010 and for interim periods within those fiscal years. The Company's adoption of this standard had no impact on its consolidated financial position, results of operations or cash flows.

## **2. Acquisition of CyDex**

On January 24, 2011, the Company acquired CyDex Pharmaceuticals, Inc. ("CyDex"), a specialty pharmaceutical company developing products and licensing its CAPTISOL technology. CAPTISOL is currently incorporated in five FDA-approved medications and marketed by three of CyDex's licensees: Pfizer, Bristol-Myers Squibb and Baxter (formerly Prism Pharmaceuticals). In addition, CyDex is supporting drug development efforts with more than 40 companies worldwide.

Under the terms of the agreement, the Company paid \$31.6 million, net of a working capital adjustment of \$0.5 million, to the CyDex shareholders and issued a series of Contingent Value Rights. The Company is obligated to pay \$4.3 million in January 2012 and may be required to pay up to an additional \$7.25 million upon achievement of certain milestones. In addition, the Company will pay CyDex shareholders, for each respective year from 2011 through 2016, 20% of all CyDex-related revenue, but only to the extent that and beginning only when CyDex-related revenue for such year exceeds \$15.0 million; plus an additional 10% of all CyDex-related revenue recognized during such year, but only to the extent that and beginning only when aggregate CyDex-related revenue for such year exceeds \$35.0 million.

The CyDex CVR Agreement requires the Company to, in the event of a Default, deliver to an escrow agent the future cash payments described above, and such amounts would then be delivered by the escrow agent to the CyDex shareholders if, as and when they would have by the CyDex CVR Agreement been required to be delivered to the CyDex shareholders by the Company. "Default" includes the following, subject to certain cure rights: (a) the Company fails to pay to the Shareholders' Account any amount as and when required under the CyDex CVR Agreement, (b) at any time the Company is obligated for more than \$35.0 million of financial indebtedness (other than financial indebtedness which is expressly subordinated to all obligations of Ligand under the CyDex CVR Agreement pursuant to a written subordination agreement signed by and reasonably acceptable to the Shareholders' Representative), (c) at any time after March 15, 2011 the Company's cash, cash equivalents and short-term investments is less than \$10.0 million, or (d) the Company commits any material breach of the CyDex CVR Agreement.

Ligand is required by the CyDex CVR Agreement to dedicate at least five experienced full-time employee equivalents per year to the acquired business and to invest at least \$1.5 million per year, inclusive of such employee expenses, in the acquired business, through 2015.

At the closing of the acquisition, the Company recorded a \$14.9 million contingent liability for amounts potentially due to holders of the CyDex CVRs. The initial fair value of the liability was determined using a discounted cash flow analysis incorporating the estimated future cash flows from potential milestones and revenue sharing. These cash flows were then discounted to present value using a discount rate of 21.6%. The liability will be periodically assessed based on events and circumstances related to the underlying milestones, and the change in fair value will be recorded in the Company's consolidated statements of operations. The carrying amount of the

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liability may fluctuate significantly and actual amounts paid under the CVR agreements may be materially different than the carrying amount of the liability. The fair value of the liability at June 30, 2011 was \$19.2 million.

The components of the purchase price allocation for CyDex are as follows (in thousands):

<b>Purchase Consideration:</b>	
Cash paid to CyDex shareholders	\$ 31,572
Estimated fair value of contingent consideration	14,905
Cash payable to CyDex shareholders	4,300
Total purchase consideration	<u>\$ 50,777</u>

<b>Allocation of Purchase Price:</b>	
Accounts receivable	\$ 1,202
Inventory	2,414
In-process research and development	3,200
Intangible assets with definite lives	46,580
Goodwill	13,290
Other assets	6,135
Liabilities assumed	(22,044)
	<u>\$ 50,777</u>

The acquired identified intangible assets with definite lives from the acquisition with CyDex are as follows:

<b>Acquired Intangible Assets (in thousands)</b>	
Complete technology	\$ 14,643
Trademark and trade name	2,537
Customer relationships	29,400
	<u>\$ 46,580</u>

The weighted-average amortization period for the identified intangible assets with definite lives is 20 years.

The Company has allocated \$3.2 million of the purchase price of CyDex to acquired In-Process Research and Development (IPR&D). This amount represents the estimated fair value of CyDex's two main proprietary products that have not yet reached technological feasibility and do not have future alternative use as of the date of the merger. The valuation was based on a probability-weighted present value of the expected upfront and milestone payments based on a recently signed letter of intent and term sheet. The probability of success takes into account the stages of completion and the risks surrounding successful development and commercialization of the underlying product candidates. These cash flows were then discounted to present value using a discount rate of 21.5%.

The valuation of the complete technology, or CyDex's CAPTISOL technology, was based on a derivative of the discounted cash flow method that estimated the present value of a hypothetical royalty stream derived via the licensing of similar technology. These projected cash flows were then discounted to present value using a discount rate of 20.5%. The valuation of the trademark and trade name was based on the Relief from Royalty method using royalty rates paid in third-party licensing agreements involving similar trade names. These projected cash flows were then discounted to present value using a discount rate of 20.5%. The valuation of the customer relationships was based on a discounted cash flow analysis incorporating the estimated future cash flows from these relationships during their assumed life of 20 years. These cash flows were then discounted to present value using a discount rate of 21.5%.

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**3. Financial Instruments**

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including available-for-sale fixed income and equity securities and other equity securities. The following table provides a summary of the assets and liabilities that are measured at fair value on a recurring basis as of June 30, 2011 (in thousands):

	Fair Value Measurements at Reporting Date Using			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Fixed income available-for-sale securities	\$10,000	\$ 10,000	\$ 0	\$ 0
<b>Liabilities:</b>				
Current portion of liability for contingent value rights -				
CyDex	\$ 5,955	\$ 0	\$ 0	\$ 5,955
Liability for contingent value rights - Metabasis	1,603	\$ 1,603	\$ 0	\$ 0
Liability for contingent value rights - Neurogen	700	0	0	700
Liability for contingent value rights - CyDex	14,905	0	0	14,905
Total liabilities	\$23,163	\$ 1,603	\$ 0	\$ 21,560

The following table provides a summary of the assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2010 (in thousands):

	Fair Value Measurements at Reporting Date Using			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Fixed income available-for-sale securities	\$19,351	\$ 19,351	\$ 0	\$ 0
<b>Liabilities:</b>				
Liability for contingent value rights - Metabasis	\$ 0	\$ 0	\$ 0	\$ 0
Liability for contingent value rights - Neurogen	700	0	0	700
	\$ 700	\$ 0	\$ 0	\$ 700

The Company's short-term investments are fixed income available-for-sale securities and include Corporate Notes, Corporate Discount Commercial Paper and certificates of deposit. The fair value of the Company's short-term investments and liability for contingent value rights- Metabasis are determined using quoted market prices in active markets.

**4. AVINZA Co-Promotion**

In February 2003, Ligand and Organon Pharmaceuticals USA Inc. (Organon) announced that they had entered into an agreement for the co-promotion of AVINZA. Subsequently in January 2006, Ligand signed an agreement with Organon that terminated the AVINZA co-promotion agreement between the two companies and returned AVINZA co-promotion rights to Ligand. In consideration of the early termination, Ligand agreed to make quarterly royalty payments to Organon equal to 6.5% of AVINZA net sales through December 31, 2012 and thereafter 6.0% through patent expiration, currently anticipated to be November of 2017.

In February 2007, Ligand and King Pharmaceuticals, Inc., or King, executed an agreement pursuant to which King acquired all of the Company's rights in and to AVINZA. King also assumed the Company's co-promote termination obligation to make royalty payments to Organon based on net sales of AVINZA. For the fourth quarter of 2006 and through the closing of the AVINZA sale transaction, amounts owed by Ligand to Organon on net reported sales of AVINZA did not result in current period expense, but instead were charged against the co-promote termination liability. The liability was adjusted at each reporting period to fair value and was recognized, utilizing

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the interest method, as additional co-promote termination charges for that period at a rate of 15%, the discount rate used to initially value this component of the termination liability.

In connection with King's assumption of this obligation, Organon did not consent to the legal assignment of the co-promote termination obligation to King. Accordingly, Ligand remains liable to Organon in the event of King's default of the obligation. Therefore, Ligand recorded an asset as of February 26, 2007 to recognize King's assumption of the obligation, while continuing to carry the co-promote termination liability in the Company's consolidated financial statements to recognize Ligand's legal obligation as primary obligor to Organon. This asset represents a non-interest bearing receivable for future payments to be made by King and is recorded at its fair value. The receivable and liability will remain equal and adjusted each quarter for changes in the fair value of the obligation including for any changes in the estimate of future net AVINZA product sales. This receivable will be assessed on a quarterly basis for impairment (e.g. in the event King defaults on the assumed obligation to pay Organon).

On an annual basis, management reviews the carrying value of the co-promote termination liability. Due to assumptions and judgments inherent in determining the estimates of future net AVINZA sales through November 2017, the actual amount of net AVINZA sales used to determine the current fair value of the Company's co-promote termination asset and liability may be materially different from current estimates.

A summary of the co-promote termination liability as of June 30, 2011 is as follows (in thousands):

Net present value of payments based on estimated future net AVINZA product sales as of December 31, 2010	\$30,885
Assumed payments made by King or assignee	(2,165)
Fair value adjustments due to passage of time	655
Total co-promote termination liability as of June 30, 2011	29,375
Less: current portion of co-promote termination liability as of June 30, 2011	(8,029)
Long-term portion of co-promote termination liability as of June 30, 2011	<u>\$21,346</u>

## 5. Property Leases

In August 2009, the Company entered into a lease termination agreement for its 82,500 square foot office and laboratory facility in San Diego, California, which had a lease term through November 2021. Under the terms of the termination agreement, the Company paid a termination fee of \$14.3 million as follows: \$4.5 million was paid upon signing, \$4.5 million was paid in July 2010 and \$5.3 million was paid in April 2011. In addition, the Company entered into a new lease for a period of 27 months commencing October 2009, for premises consisting of approximately 30,000 square feet of office and lab space located in San Diego to serve as its new corporate headquarters. Under the terms of the new lease, the Company pays a basic annual rent of \$1.2 million (subject to an annual fixed percentage increase, as set forth in the agreement), plus other normal and necessary expenses associated with the lease.

The Company also leases an office and research facility in San Diego, California under an operating lease arrangement through July 2015. The Company fully vacated this facility in February 2008. The lease agreement provides for increases in annual rents based on changes in the Consumer Price Index or fixed percentage increases ranging from 3% to 7%. Commencing January 2008, the Company sublet this facility through July 2015. The sublease agreement provides for a 3% increase in annual rents. As of June 30, 2011 and December 31, 2010, the lease exit obligation related to this lease was \$3.2 million and \$3.6 million, respectively.

The Company leases approximately 99,000 square feet in three facilities in Cranbury, New Jersey under leases that expire in 2016. The leases for the New Jersey facilities provide generally for scheduled rent increases, options to extend the leases with certain changes to the terms of the lease agreement, and refurbishment allowances.



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Commencing September 2009, the Company sublet 5,100 square feet of space through August 2014. As of June 30, 2011, the Company expects to receive \$0.3 million in aggregate future lease payments over the duration of the sublease agreement.

In September 2010, the Company ceased use of its facility located in New Jersey. As a result, during the quarter ended September 30, 2010, the Company recorded lease exit costs of \$9.7 million for costs related to the difference between the remaining lease obligations of the abandoned operating leases, which run through August 2016, and management's estimate of potential future sublease income, discounted to present value. As of June 30, 2011 and December 31, 2010, the lease exit obligation related to this lease was \$8.5 million and \$9.4 million, respectively.

## 6. Segment Reporting

Under Accounting Standards Codification No. 280, "Segment Reporting", or ASC 280, operating segments are defined as components of an enterprise about which separate financial information is available that is regularly evaluated by the entity's chief operating decision maker, in deciding how to allocate resources and in assessing performance. The Company has evaluated this Codification and has identified two reportable segments: the development and commercialization of drugs using CAPTISOL technology by the recently acquired CyDex Pharmaceuticals, Inc. and the traditional biotech operations including drug discovery and development of Ligand Pharmaceuticals, Inc. We evaluate performance based on the operating profit (loss) of the respective business segments. The segment results may not represent actual results that would be expected if they were independent, stand-alone businesses. Segment information was as follows for the three and six months ended June 30, 2011:

	<u>Ligand</u>	<u>CyDex</u>	<u>Total</u>
<b>For the Three Months Ending June 30, 2011:</b>			
Net revenues from external customers	\$ 3,056	\$ 4,407	\$ 7,463
Operating profit (loss)	(1,346)	536	(810)
Depreciation and amortization expense	168	617	785
Income tax expense (benefit)	141	0	141
Assets	91,524	35,911	127,435
<b>For the Six Months Ending June 30, 2011:</b>			
Net revenues from external customers	\$ 5,404	\$ 5,955	\$ 11,359
Operating profit (loss)	(3,861)	834	(3,027)
Depreciation and amortization expense	266	1,083	1,349
Income tax expense (benefit)	(13,637)	0	(13,637)
Assets	91,524	35,911	127,435

## 7. Debt

In January 2011, in connection with the acquisition of CyDex, the Company entered into a \$20 million Loan and Security Agreement (the "Oxford Loan") with Oxford Finance Corporation ("Oxford"). Under the terms of the Oxford Loan agreement, the Company will make interest only payments for one year at a fixed rate of 8.64%, with an option to extend the interest only payments for an additional year, which the Company intends to exercise. Subsequent to the interest only payments, the note will amortize with principal and interest payments due through the remaining term of the loan. The loan term, including interest only payments, is 42 months.

If the Company prepays the Oxford Loan, (i) on or before January 24, 2012, the Company must pay Oxford an additional amount equal to 2.0% of the principal amount of the term loan prepaid, and (ii) after January 24, 2012, the Company must pay Oxford an additional amount equal to 1.0% of the principal amount of the term loan prepaid.

Upon final repayment of the Oxford Loan on the maturity date, by prepayment, or upon acceleration of the Oxford Loan, the Company also must make an additional final payment of \$1.2 million, which is being accreted over the term of the loan. To secure the Company's repayment obligations under the Oxford Loan, Oxford obtained a first priority security interest in all of the Company's assets, excluding intellectual property.

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Additionally, in March 2011, the Company entered into a Loan and Security Agreement (the “Square 1 Loan”) with Square 1 Bank (“Square 1”). The Square 1 Loan established a cash-collateralized revolving line of credit facility under which Square 1 agreed to loan up to \$5.0 million to the Company. The Company immediately borrowed the full \$5.0 million. All outstanding amounts under the Agreement bear interest at a floating rate equal to 200 basis points above the prime rate and may become immediately due and payable if the Company fails to maintain a cash balance at Square 1 of at least \$5.0 million. Interest is payable on a monthly basis. The maturity date of the revolving line of credit facility is March 29, 2012.

In April 2011, the Company entered into an amended Loan and Security Agreement (the “Square 1 Amended Loan”) with Square 1. The Square 1 Amended Loan increased a cash-collateralized revolving line of credit facility by \$5.0 million under which Square 1 agreed to loan up to \$10.0 million to the Company. The Company immediately borrowed the additional \$5.0 million. All outstanding amounts under the Agreement bear interest at a floating rate equal to 200 basis points above the prime rate. Interest is payable on a monthly basis. The maturity date of the revolving line of credit facility is March 29, 2012.

## **8. Stockholders’ Equity**

On November 8, 2010, following approval from the Company’s stockholders at a special meeting of stockholders on September 9, 2010, the Company announced a 1-for-6 reverse stock split of its common stock. Accordingly, all share, warrant, option and per share information for all periods presented has been restated to account for the effect of the reverse stock split.

### Stock Option Activity

The following is a summary of the Company’s stock option plan activity and related information:

	<u>Shares</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted-Average Remaining Contractual Term in Years</u>	<u>Aggregate Intrinsic Value (in thousands)</u>
Balance at December 31, 2010	641,261	\$ 21.36		
Granted	633,330	9.96		
Exercised	(3,312)	9.98		
Forfeited	(18,873)	15.52		
Cancelled	(70,859)	31.73		
Balance at June 30, 2011	<u>1,181,547</u>	\$ 14.73	8.59	\$ 1,629
Exercisable at June 30, 2011	362,148	\$ 23.87	6.87	\$ 155
Options expected to vest as of June 30, 2011	1,036,721	\$ 15.23	8.51	\$ 1,383

The weighted-average grant-date fair value of all stock options granted during the six months ended June 30, 2011 was \$6.31 per share. The total intrinsic value of all options exercised during the six months ended June 30, 2011 was approximately \$2,500. There were no options exercised during the six months ended June 30, 2010. As of June 30, 2011, there was \$5.1 million of total unrecognized compensation cost related to nonvested stock options. That cost is expected to be recognized over a weighted-average period of 2.5 years.

As of June 30, 2011, 0.7 million shares were available for future option grants or direct issuance under the Company’s 2002 Stock Incentive Plan, as amended.

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### Restricted Stock Activity

Restricted stock activity for the six months ended June 30, 2011 is as follows:

	Shares	Weighted-Average Grant Date Stock Price
Nonvested at December 31, 2010	62,146	\$ 13.60
Granted	119,126	10.05
Vested	(59,141)	12.51
Forfeited	(3,271)	13.15
Nonvested at June 30, 2011	<u>118,860</u>	<u>\$ 10.60</u>

The weighted-average grant-date fair value of restricted stock granted during the six months ended June 30, 2011 was \$10.05 per share. As of June 30, 2011, there was \$1.0 million of total unrecognized compensation cost related to nonvested restricted stock. That cost is expected to be recognized over a weighted-average period of 2.0 years.

### Employee Stock Purchase Plan

The Company's Employee Stock Purchase Plan, as amended and restated (the "Amended ESPP") allows participants to purchase up to 1,250 shares of Ligand common stock during each offering period, but in no event may a participant purchase more than 1,250 shares of common stock during any calendar year. The length of each offering period is six months, and employees are eligible to participate in the first offering period beginning after their hire date.

The Amended ESPP allows employees to purchase Ligand common stock at the end of each six month period at a price equal to 85% of the lesser of fair market value on either the start date of the period or the last trading day of the period (the "Lookback Provision"). The 15% discount and the Lookback Provision make the Amended ESPP compensatory. There were 2,404 and 81,844 shares of common stock issued and \$18,000 and \$0.1 million of proceeds received under the Amended ESPP during the six months ended June 30, 2011 and 2010, respectively. The Company recorded compensation expense of \$700 and \$44,000 for the six months ended June 30, 2011 and 2010, respectively. As of June 30, 2011, 102,498 shares were available for future purchases under the Amended ESPP.

### Warrants

As of June 30, 2011, warrants to purchase 144,606 shares of the Company's common stock were outstanding with an exercise price of \$51.54 per share and an expiration date of April 2012. The warrants were assumed in the acquisition of Pharmacoepia, Inc.

As of June 30, 2011, 163,568 warrants with an exercise price of \$179.40 per warrant and an expiration date of April 2013 were outstanding to purchase an aggregate of 129,360 shares of the Company's common stock. If exercised, these warrants are also entitled to receive \$0.1 million in cash and 981,411 of each of the Company's four contingent value rights issued to Neurogen shareholders in December 2009. The series of warrants was assumed in the acquisition of Neurogen Corporation.

### Share Repurchases

On June 15, 2010, the Company announced that its Board of Directors has authorized the Company to repurchase up to \$10.0 million of its common stock from time to time in privately negotiated and open market transactions for a period of up to two years, subject to the Company's evaluation of market conditions, applicable legal requirements and other factors. The Company is not obligated to acquire common stock under this program and the program may be suspended at any time. Through June 30, 2011, the Company repurchased 16,905 shares of its common stock totaling \$0.1 million.

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**9. Litigation**

From time to time the Company is subject to various lawsuits and claims with respect to matters arising out of the normal course of its business. If, based on the Company's assessment, it is probable that a liability has been incurred and can be reasonably estimated, then such loss is accrued and charged to operations. Management believes all costs that can be reasonably estimated will not exceed the related existing accruals.

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### **ITEM 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations**

***Caution:** This discussion and analysis may contain predictions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed in Part II, Item 1A “Risk Factors.” This outlook represents our current judgment on the future direction of our business. These statements include those related to our royalty revenues, product returns, and product development. Actual events or results may differ materially from our expectations. For example, there can be no assurance that our revenues or expenses will meet any expectations or follow any trend(s), that we will be able to retain our key employees or that we will be able to enter into any strategic partnerships or other transactions. We cannot assure you that we will receive expected royalties to support our ongoing business or that our internal or partnered pipeline products will progress in their development, gain marketing approval or achieve success in the market. In addition, ongoing or future arbitration, or litigation or disputes with third parties may have a material adverse effect on us. Such risks and uncertainties, and others, could cause actual results to differ materially from any future performance suggested. We undertake no obligation to release publicly the results of any revisions to these forward-looking statements to reflect events or circumstances arising after the date of this quarterly report. This caution is made under the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended.*

*Our trademarks, trade names and service marks referenced herein include Ligand. Each other trademark, trade name or service mark appearing in this quarterly report belongs to its owner.*

References to Ligand Pharmaceuticals Incorporated (“Ligand,” the “Company,” “we” or “our”) include our wholly owned subsidiaries—Seragen, Inc. (“Seragen”); Nexus Equity VI LLC (“Nexus”); Pharmacoepia, LLC; Neurogen Corporation; Metabasis Therapeutics, Inc.; and CyDex Pharmaceuticals, Inc.

#### **Overview**

We are a biotechnology company that operates with a business model focused on developing or acquiring revenue generating assets and coupling them to a lean corporate cost structure. Our goal is to create a sustainably profitable business and generate meaningful value for our stockholders. Since our business model is based on the goal of partnering with other pharmaceutical companies to commercialize and market our assets, the revenue that supports our business is based largely on payments made to us by partners for royalties, milestones, license fees, and material sales of CAPTISOL. We expect to receive revenue from eight partner-marketed products in 2011 and have a portfolio of over fifty additional programs that are in various stages of development with the potential to become future revenue generating assets. This portfolio of assets is highly diversified across numerous technology types, therapeutic areas, drug targets, and industry partners, offering investors a unique and, we believe, lower risk portfolio opportunity in which to invest in the increasingly complicated and unpredictable pharmaceutical industry. These programs address the unmet medical needs of patients for a broad spectrum of diseases including hepatitis, muscle wasting, Alzheimer’s disease, dyslipidemia, diabetes, anemia, COPD, asthma, rheumatoid arthritis, oncology and osteoporosis. We have established multiple alliances with the world’s leading pharmaceutical companies including GlaxoSmithKline, Merck, Pfizer, Bristol-Myers Squibb, Onyx, Baxter and AstraZeneca.

On September 7, 2006, we announced the sale of ONTAK, Targretin capsules, Targretin gel, and Panretin gel to Eisai, Inc., or Eisai, and the sale of AVINZA to King Pharmaceuticals, Inc., or King. The Eisai sales transaction subsequently closed on October 25, 2006. The AVINZA sale transaction subsequently closed on February 26, 2007. Accordingly, the results for the Oncology and AVINZA Product Lines have been presented in our consolidated statements of operations as “Discontinued Operations.”

On December 23, 2008, we acquired all of the outstanding common shares of Pharmacoepia, Inc., or Pharmacoepia, a clinical development stage biopharmaceutical company dedicated to discovering and developing novel small molecule therapeutics to address significant medical needs.

On December 23, 2009, we acquired all of the outstanding common shares of Neurogen Corporation, or Neurogen, a drug development company historically focusing on small-molecule drugs to improve the lives of patients suffering from psychiatric and neurological disorders with significant unmet medical needs.

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On January 27, 2010, we completed the acquisition of Metabasis Therapeutics, Inc., or Metabasis, following approval of the transaction by Metabasis stockholders. As a result, we gained additional pipeline assets and drug discovery technologies and resources.

On January 26, 2011, we completed the acquisition of CyDex Pharmaceuticals, Inc., or CyDex, following approval of the transaction by CyDex stockholders. As a result, we gained revenue from four currently marketed products, a large portfolio of partnered drug development programs, an internal pipeline of proprietary drugs, and the CAPTISOL drug formulation platform technology.

In June 2011, we licensed exclusive worldwide rights to The Medicines Company for our Captisol(R)-enabled intravenous formulation of clopidogrel. Clopidogrel is the active ingredient in PLAVIX(R), the world's leading anti-platelet medication which is currently only available in an oral formulation. The Captisol-enabled clopidogrel formulation is designed to provide an intravenous option in situations where the administration of oral platelet inhibitors is not feasible or desirable. We received an upfront payment of \$1.8 million plus we are eligible to receive up to \$22 million in milestones and up to double digit royalties on annual worldwide net sales. In addition, we will also supply clinical and commercial materials of Captisol for this program, and if the intravenous formulation is approved for commercialization, we will be the exclusive supplier of the product. Under the terms of our CyDex contingent value rights agreement, \$0.9 million of the upfront payment was paid to CyDex shareholders.

On July 15, 2011, we executed a patent license agreement for the exclusive license, under the Licensed Patents, to make, have made, import, use, sell or offer for sale the compound associated with Fablyn. The licenses and rights granted are free of any ongoing obligations to Pfizer, Inc. Previously, on May 13, 2011, Pfizer Inc. announced in a Form 10-Q filed with the SEC that it is in the process of withdrawing its NDAs with the FDA relating to Fablyn (lasofoxifene tartrate). Fablyn is a selective estrogen receptor modulator product candidate that resulted from a collaboration between Pfizer and us formed to develop therapies for osteoporosis. Pfizer submitted an NDA to the FDA and a marketing authorization application to the European Medicines Agency for Fablyn for the treatment of osteoporosis in December 2007 and January 2008, respectively, and in February 2009, Pfizer received approval from the European Commission for Fablyn tablets.

On July 26, 2011, we announced that GlaxoSmithKline (NYSE: GSK) has announced that it received positive data from ENABLE-1, the first of two Phase III studies examining Promacta (eltrombopag) in patients with hepatitis C-related thrombocytopenia, and that full data will be released at an upcoming scientific conference.

### **Metabasis Contingent Value Rights**

In January 2010, we completed our acquisition of Metabasis. In addition to cash consideration, we issued four tradable Contingent Value Rights ("CVRs"), one CVR from each of four respective series of CVRs, for each Metabasis share. The CVRs will entitle the holder to cash payments as frequently as every six months as cash is received by us from the sale or partnering of any of the Metabasis drug development programs, among other triggering events. We have also committed to spend at least \$8 million in new research and development funding on the Metabasis programs within 42 months following the closing of the transaction. Through June 30, 2011, we estimate that we have spent approximately \$4.2 million of the committed amount.

In January 2011, we entered into a strategic relationship with Chiva Pharmaceuticals, Inc. to develop multiple assets and technology in China and potentially worldwide. Chiva was granted licenses to begin immediate development in China of two clinical-stage HepDirect programs, Pradefovir for hepatitis B and MB01733 for hepatocellular carcinoma. Additionally, we granted Chiva a non-exclusive HepDirect technology license for the discovery, development and worldwide commercialization of new compounds in hepatitis B (HepB), hepatitis C (HepC) and hepatocellular carcinoma (HCC). Under the terms of the agreement, we are entitled to milestones and royalties on potential sales. In addition, we will also receive a portion of any sublicensing revenue generated from sublicensing of collaboration compounds to third parties in a major world market. We received a \$0.5 million license payment in March 2011, of which \$0.1 million was remitted to CVR holders, and we are entitled to receive an additional \$0.5 million license payment in December 2011.

### **Results of Operations**

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### *Six Months Ended June 30, 2011 and 2010*

Total revenues for the three and six months ended June 30, 2011 were \$7.5 million and \$11.4 million compared to \$5.8 million and \$11.8 million for the same period in 2010. We reported a loss from continuing operations of \$0.9 million for the three months ending June 30, 2011 and income from continuing operations of \$8.6 million for the six months ended June 30, 2011, compared to losses from continuing operations of \$0.3 million and \$3.3 million for the three and six months ended June 30, 2010.

### *Royalty Revenue*

Royalty revenues were \$2.2 million and \$4.2 million for the three and six months ended June 30, 2011, compared to \$1.6 million and \$3.6 million for the same period in 2010. The increase in royalty revenue is primarily due to an increase in PROMACTA royalties and royalties on CyDex licensed products offset by a decrease in AVINZA royalties.

### *Material Sales*

We recorded material sales of \$3.0 million and \$4.0 million for the three and six months ended June 30, 2011 as a result of our acquisition of CyDex in January 2011.

### *Collaborative Research and Development and Other Revenues*

We recorded collaborative research and development and other revenues of \$2.3 million and \$3.2 million for the three and six months ended June 30, 2011, compared to \$4.2 million and \$8.2 million for the same 2010 periods. The decrease of \$1.9 million and \$5.0 million, respectively for the three and six months ended June 30, 2011, compared to the same period in 2010, is primarily due to the termination of our remaining research obligations under collaboration agreements, partially offset by the recognition of \$1.2 million of deferred revenue related to the previous sale of royalty rights.

### *Research and Development Expenses*

The major components of research and development expenses are as follows (in thousands):

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
Internal research programs	\$2,336	\$ 2,985	\$4,155	\$ 6,017
Collaborative research	0	2,782	0	6,464
Development	901	835	1,068	1,482
Total research and development	<u>\$3,237</u>	<u>\$ 6,602</u>	<u>\$5,223</u>	<u>\$13,963</u>

Research and development expenses were \$3.2 million and \$5.2 million for the three and six months ended June 30, 2011, respectively, compared to \$6.6 million and \$14.0 million for the same 2010 periods. The decrease of \$3.4 million for the three months ended June 30, 2011, compared to the same period in 2010, is primarily due to \$2.8 million of costs associated with collaboration agreements that were terminated, \$0.8 million of reduced costs as a result of staff reductions at the end of 2010 and \$1.1 million of reduced costs associated with internal programs. Partially offsetting, are costs associated with CyDex operations of \$1.2 million. The decrease of \$8.8 million for the six months ended June 30, 2011, compared to the same period in 2010, is primarily due to \$6.5 million of costs associated with collaboration agreements that were terminated, \$1.7 million of reduced costs as a result of staff reductions at the end of 2010, and \$2.1 million related to reduced costs associated with internal programs. Partially offsetting, were costs associated with CyDex operations of \$2.0 million.

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As summarized in the table below, we are developing several proprietary products for a variety of indications. These programs represent our future licensing opportunities to expand our partnered asset portfolio.

<u>Program</u>	<u>Disease/Indication</u>	<u>Development Phase</u>
Selective Androgen Receptor Modulators (SARMs) (agonists)	Muscle wasting and frailty	Phase I
CAPTISOL-Enabled Melphalan I	Oncology	Phase II
CAPTISOL-Enabled Topiramate IV	Epilepsy/Seizures	Preclinical
Glucagon receptor antagonists	Diabetes	Preclinical
IRAK4 inhibitor	Inflammation/Oncology	Research

We do not provide forward-looking estimates of costs and time to complete our ongoing research and development projects, as such estimates would involve a high degree of uncertainty. Uncertainties include our inability to predict the outcome of complex research, our inability to predict the results of clinical studies, regulatory requirements placed upon us by regulatory authorities such as the FDA and EMEA, our inability to predict the decisions of our collaborative partners, our ability to fund research and development programs, competition from other entities of which we may become aware in future periods, predictions of market potential from products that may be derived from our research and development efforts, and our ability to recruit and retain personnel or third-party research organizations with the necessary knowledge and skills to perform certain research. Refer to "Item 1A. Risk Factors" for additional discussion of the uncertainties surrounding our research and development initiatives.

### *General and Administrative Expenses*

General and administrative expenses were \$3.9 million and \$8.0 million for the three and six months ended June 30, 2011, respectively, compared to \$3.3 million and \$6.3 million for the same period in 2010. The increase of \$0.6 million for the three months ended June 30, 2011, compared to the same period in 2010, is primarily due to transactions costs associated with the acquisition of CyDex as well as the additional costs to operate the CyDex business. The increase of \$1.7 million for the six months ended June 30, 2011, compared to the same period in 2010, is primarily due to transactions costs associated with the acquisition of CyDex as well as the additional costs to operate the CyDex business.

### *Lease Exit and Termination Costs*

In September 2010, we ceased use of our facility located in Cranbury, New Jersey. As a result, during the quarter ended September 30, 2010, we recorded lease exit costs of \$9.7 million for costs related to the difference between the remaining lease obligations of the abandoned operating leases, which run through August 2016, and management's estimate of potential future sublease income, discounted to present value. Actual future sublease income may differ materially from our estimate, which would result in us recording additional expense or reductions in expense. In addition, we wrote-off approximately \$5.4 million of property and equipment related to the facility closure and recorded approximately \$0.8 million of severance related costs. During the three and six ended June 30, 2011, we sold certain property and equipment for \$16,000 and \$0.2 million, respectively, from our former facility, which was recorded as a reduction of lease termination and exit costs.

### *Accretion of Deferred Gain on Sale Leaseback*

On November 9, 2006, we sold real property located in San Diego, California for a sale price of \$47.6 million. This property included our corporate headquarter building totaling approximately 82,500 square feet, the land on



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which the building was situated, and two adjacent vacant lots. As part of the sale transaction, we agreed to leaseback the building for a period of 15 years. We recognized an immediate pre-tax gain on the sale transaction of \$3.1 million and deferred a gain of \$29.5 million on the sale of the building. The deferred gain was being recognized on a straight-line basis over the 15 year term of the lease at a rate of approximately \$2.0 million per year. In August 2009, we entered into a lease termination agreement for this building. As a result, we recognized \$20.4 million of accretion of deferred gain during the quarter ended September 30, 2009, and will recognize the remaining balance of the deferred gain through the term of our new building lease, which expires in December 2011. The amount of the deferred gain recognized for the three and six months ended June 30, 2011 was \$0.4 million and \$0.9 million, compared to \$0.4 million and \$0.9 million for the same period in 2010.

### *Interest Income, net*

Interest income was \$0 and \$30,000 for the three and six months ended June 30, 2011, respectively, compared to \$0.1 million and \$0.3 million for the same period in 2010. The decrease in interest income in 2011 was due to lower cash and investment balances.

### *Interest Expense*

Interest expense was \$0.7 million and \$1.1 million, for the three and six months ended June 30, 2011, respectively, compared to \$13,000 and \$31,000 for the same period in 2010. The increase in interest expense of \$0.7 million and \$1.1 million, respectively was due to the \$20 million loan obtained to acquire CyDex in January 2011 and \$10 million drawn on the line of credit in March and April 2011.

### *Liability for Contingent Value Rights*

We recorded a decrease in liability for CVRs of \$0.7 million and an increase \$1.0 million for the three and six months ended June 30, 2011, respectively, compared to a decrease in liability for CVRs of \$3.7 million and \$4.2 million for the three and six months ended June 30, 2010, respectively. The change relates to our liability for amounts potentially due to holders of CVRs associated with our Metabasis and CyDex acquisitions. The Metabasis CVR liability is marked-to-market at each reporting period based upon the quoted market prices of the underlying CVR. The CyDex CVR liability is marked-to-market at each reporting period based upon a discounted cash flow analysis. The change in fair value is recorded in our consolidated statements of operations. The carrying amount of the liability may fluctuate significantly based upon quoted market prices and actual amounts paid under the CVR agreements may be materially different than the carrying amount of the liability.

### *Income Taxes*

We recorded income tax expense of \$0.1 million for the three months ended June 30, 2011 and an income tax benefit of \$13.6 million for the six months ended June 30, 2011. We recorded income tax expense of \$0.6 million and \$0.9 million for the three and six months ended June 30, 2010, respectively. The income tax benefit for the six months ended June 30, 2011 relates to the release of a portion of our valuation allowance against deferred tax assets which can be used to offset deferred tax liabilities recorded in connection with our acquisition of CyDex in January 2011. The income tax expense for the three and six months ended June 30, 2010 related to estimated interest on a proposed underpayment of tax as a result of an audit of our 2007 fiscal year. In January 2011, we were notified by the IRS that they had completed their examination resulting in no changes to the taxes for our 2007 tax year.

### *Discontinued Operations*

#### *Oncology Product Line*

On September 7, 2006, we and Eisai Inc., a Delaware corporation, and Eisai Co., Ltd., a Japanese company (which we collectively refer to as Eisai), entered into a purchase agreement, or the Oncology Purchase Agreement, pursuant to which Eisai agreed to acquire all of our worldwide rights in and to our oncology products, including, among other things, all related inventory, equipment, records and intellectual property, and assume certain liabilities as set forth in the Oncology Purchase Agreement. The Oncology product line included our four marketed oncology drugs: ONTAK, TARGRETIN capsules, TARGRETIN gel and PANRETIN gel.

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Pursuant to the terms of the Oncology Purchase Agreement, we retained the liability for returns of product from wholesalers that had been sold by us prior to the close of the transaction. Accordingly, as part of the accounting for the gain on the sale of the Oncology product line, we recorded a reserve for Oncology product returns.

During the three and six months ended June 30, 2011, we recognized \$0 and \$4,000, respectively, of pre-tax gains due to subsequent changes in certain estimates and liabilities recorded as of the sale date. During the three and six months ended June 30, 2010, we recognized a \$4,000 and a \$0.2 million pre-tax gain, respectively, due to subsequent changes in certain estimates and liabilities recorded as of the sale date.

### *AVINZA Product Line*

On September 6, 2006, we entered into a purchase agreement with King, or the AVINZA Purchase Agreement, pursuant to which King agreed to acquire all of our rights in and to AVINZA in the United States, its territories and Canada, including, among other things, all AVINZA inventory, records and related intellectual property, and assume certain liabilities as set forth in the AVINZA Purchase Agreement, which we collectively refer to as the Transaction.

Pursuant to the terms of the AVINZA Purchase Agreement, we retained the liability for returns of product from wholesalers that had been sold by us prior to the close of the Transaction. Accordingly, as part of the accounting for the gain on the sale of AVINZA, we recorded a reserve for AVINZA product returns.

During the three and six months ended June 30, 2010, we recognized a \$3,000 and a \$13,000 pre-tax gain, respectively, due to subsequent changes in certain estimates and liabilities recorded as of the sale date. We recognized no pre-tax gain during the three and six months ended June 30, 2011.

### *Income Taxes*

We recorded no provision for income taxes related to discontinued operations for the three and six months ended June 30, 2011 and 2010 as we did not realize any taxable income from either discontinued or continuing operations.

## **Liquidity and Capital Resources**

We have financed our operations through offerings of our equity securities, borrowings from long-term debt, issuance of convertible notes, product sales and the subsequent sales of our commercial assets, royalties, collaborative research and development and other revenues, capital and operating lease transactions.

We had a working capital deficit of \$14.2 million at June 30, 2011 compared to working capital of \$3.5 million at December 31, 2010. Available cash, cash equivalents and short-term investments totaled \$13.4 million as of June 30, 2011 compared to \$22.7 million as of December 31, 2010. We primarily invest our cash in certificates of deposit and United States government and investment grade corporate debt securities.

In August 2009, we entered into a lease termination agreement for our corporate facility in San Diego. Under the terms of the agreement, we paid a termination fee of \$14.3 million as follows: \$4.5 million was paid upon signing, \$4.5 million was paid in July 2010 and \$5.3 million was paid in April 2011. In addition, we entered into a new lease for a period of 27 months commencing October 2009, for premises consisting of office and lab space located in San Diego to serve as our new corporate headquarters.

In January 2011, we used \$12.0 million of our existing cash, cash equivalents and short-term investments for the acquisition of CyDex. In connection with the acquisition, we entered into a \$20 million Loan and Security Agreement, or the Loan Agreement, with a lender. Under the terms of the Loan Agreement, we will make interest only payments for one year at a fixed rate of 8.64%, with an option to extend the interest only payments for an additional year, which we intend to exercise. Subsequent to the interest only payments, the note will amortize with principal and interest payments due through the remaining term of the loan. The loan term, including interest only payments, is 42 months.

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Additionally, in March 2011, we entered into a Loan and Security Agreement, or the Commercial Loan, with our commercial bank, Square 1 Bank, or Square 1. The Commercial Loan established a cash-collateralized revolving line of credit facility under which Square 1 agreed to loan up to \$5.0 million to us. We immediately borrowed the full \$5.0 million.

In April 2011, the Company entered into an amended Loan and Security Agreement (the "Square 1 Amended Loan") with Square 1. The Square 1 Amended Loan increased a cash-collateralized revolving line of credit facility by \$5.0 million under which Square 1 agreed to loan up to \$10.0 million to the Company. The Company immediately borrowed the additional \$5.0 million. All outstanding amounts under the Agreement bear interest at a floating rate equal to 200 basis points above the prime rate. Interest is payable on a monthly basis. The maturity date of the revolving line of credit facility is March 29, 2012.

In connection with the acquisition of CyDex Pharmaceuticals, Inc. on January 24, 2011, we issued a series of Contingent Value Rights. We are obligated to pay \$4.3 million in January 2012 and may be required to pay up to an additional \$6.4 million upon achievement of certain milestones. In June 2011, \$0.9 million was paid to the CyDex Shareholders upon completion of a licensing agreement with The Medicines Company for the Captisol enabled Intravenous formulation of Clopidogrel. In addition, we will pay CyDex shareholders, for each respective year from 2011 through 2016, 20% of all CyDex-related revenue, but only to the extent that and beginning only when CyDex-related revenue for such year exceed \$15.0 million; plus an additional 10% of all CyDex-related revenue recognized during such year, but only to the extent that and beginning only when aggregate CyDex-related revenue for such year exceeds \$35.0 million.

The CyDex CVR Agreement requires us to, in the event of a Default, deliver to an escrow agent the future cash payments described above, and such amounts would then be delivered by the escrow agent to the CyDex shareholders if, as and when they would have by the CVR Agreement been required to be delivered by the Company. "Default" includes the following, subject to certain cure rights: (a) we fail to pay to the Shareholders' Account any amount as and when required under the CVR Agreement, (b) at any time we are obligated for more than \$35.0 million of financial indebtedness (other than financial indebtedness which is expressly subordinated to all obligations of Ligand under the CVR Agreement pursuant to a written subordination agreement signed by and reasonably acceptable to the Shareholders' Representative), (c) at any time after March 15, 2011 our cash, cash equivalents and short-term investments is less than \$10.0 million, or (d) we commit any material breach of the CVR Agreement.

We are also required by the CyDex CVR Agreement to dedicate at least five experienced full-time employee equivalents per year to the acquired business and to invest at least \$1.5 million per year, inclusive of such employee expenses, in the acquired business, through 2015. Through June 30, 2011, we estimate that we have exceeded our committed amount.

Based on management's plans, including increases in CAPTISOL® sales and royalty revenues, as well as anticipated new license revenue and expense reductions, if necessary, we believe our currently available cash, cash equivalents, and short-term investments as well as our current and future royalty, license and milestone revenues will be sufficient to satisfy our anticipated operating and capital requirements, including the \$4.3 million payment due to CyDex shareholders in January 2012, through at least the next twelve months. Our future operating and capital requirements will depend on many factors, including, but not limited to: the pace of scientific progress in our research and development programs; the magnitude of these programs; the scope and results of preclinical testing and clinical trials; the time and costs involved in obtaining regulatory approvals; the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims; competing technological and market developments; the amount of royalties on sales of our partners' commercial products; the efforts of our collaborative partners; obligations under our operating lease agreements and lease termination agreement; and the capital requirements of any companies we may acquire, including Neurogen, Metabasis and Cydex. We believe that the actions presently being taken to generate sufficient operating cash flow provide the opportunity for us to continue as a going concern. While we believe in the viability of our strategy to generate sufficient operating cash flow and in our ability to raise additional funds, there can be no assurances to that effect. Our ability to achieve our operational targets is dependent upon our ability to further implement our business plan and generate sufficient operating cash flow.

### *Operating Activities*

Operating activities used cash of \$7.1 million for the six months ended June 30, 2011, compared to \$18.4 million of cash used in operating activities for the same period in 2010.

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The cash generated for the six months ended June 30, 2011 reflects net income of \$8.5 million, adjusted by \$4,000 of gain from discontinued operations and \$10.6 million of non-cash items to reconcile the net income to net cash used in operations. These reconciling items primarily reflect the change in deferred income taxes of \$13.8 million, accretion of deferred gain on the sale leaseback of the building of \$0.9 million and non-cash lease costs of \$0.1 million partially offset by the change in estimated fair value of contingent value rights of \$1.1 million, depreciation and amortization of \$1.3 million and stock-based compensation of \$1.7 million. The cash generated during the six months ended June 30, 2011 is further impacted by changes in operating assets and liabilities due primarily to a decrease in other liabilities of \$1.6 million, an increase in inventory of \$0.2 million, a decrease in deferred revenue of \$1.2 million and a decrease in accounts payable and accrued liabilities of \$8.2 million, partially offset by increases in other current assets of \$4.3 million, accounts receivable of \$1.2 million and other long term assets of \$0.6 million. None of the cash used in operating activities for the six months ended June 30, 2011 related to discontinued operations.

The use of cash for the six months ended June 30, 2010 reflects a net loss of \$3.0 million, adjusted by \$0.2 million of gain from discontinued operations and \$2.9 million of non-cash items to reconcile the net income to net cash used in operations. These reconciling items primarily reflect the change in estimated fair value of CVRs of \$4.2 million, accretion of deferred gain on the sale leaseback of the building of \$0.9 million and realized gain on investment of \$0.6 million, partially offset by depreciation of assets of \$1.4 million and the recognition of \$1.5 million of stock-based compensation expense. The use of cash during the six months ended June 30, 2010 is further impacted by changes in operating assets and liabilities due primarily to decreases in accounts payable and accrued liabilities of \$8.0 million, an increase in other long term assets of \$0.4 million, a decrease in other liabilities of \$1.1 million and a decrease in deferred revenue of \$3.3 million, partially offset by a decrease in accounts receivable, net of \$0.6 million. Net cash provided by operating activities of discontinued operations was \$0.3 million for the six months ended June 30, 2010.

### *Investing Activities*

Investing activities used cash of \$22.7 million for the six months ended June 30, 2011, compared to \$5.2 million of cash provided by investing activities for the same 2010 period.

Cash used by investing activities during the six months ended June 30, 2011 primarily reflects \$32.0 million of cash paid for the acquisition of CyDex and \$10.0 million for purchases of short-term investments, partially offset by \$19.3 million of proceeds from the sale of short-term investments. None of the cash provided by investing activities for the six months ended June 30, 2011 related to discontinued operations.

Cash provided by investing activities during the six months ended June 30, 2010 primarily reflects the net proceeds from the sale of short-term investments of \$8.8 million and the proceeds from the sale of property, equipment and buildings of \$0.2 million, partially offset by \$2.8 million paid for the acquisition of Metabasis and \$1.4 million for the acquisition of intellectual property. None of the cash provided by investing activities for the six months ended June 30, 2010 related to discontinued operations.

### *Financing Activities*

Financing activities provided cash of \$30.0 million for the six months ended June 30, 2011, compared to \$0.1 million for the same 2010 period.

Cash provided by financing activities for the six months ended June 30, 2011 primarily reflects \$30.0 million of proceeds from the issuance of debt, partially offset by share repurchases of \$0.1 million.

Cash provided by financing activities for the six months ended June 30, 2010 primarily reflects \$0.1 million of proceeds from the issuance of common stock upon the exercise of stock options, partially offset by payments under equipment financing obligations of \$0.1 million.

None of the cash used in financing activities for the six months ended June 30, 2011 and 2010 relates to discontinued operations.

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### *Other*

As part of certain of our strategic alliances with our research partners, we have received up-front cash payments and licenses to certain product candidates. In connection with these agreements, we were obligated to perform significant research and development activities over multiple years. As of June 30, 2011, we have no remaining obligations to perform research and development activities under these agreements.

In connection with the acquisition of Pharmacoepia on December 23, 2008, Pharmacoepia security holders received a contingent value right that entitles them to an aggregate cash payment of \$15.0 million under certain circumstances. At June 30, 2011 and December 31, 2010, our management deemed, based on available information, that the likelihood of payment was not determinable beyond a reasonable doubt and, therefore, no liability has been recorded.

In connection with the acquisition of Neurogen on December 23, 2009, Neurogen security holders received CVRs under four CVR agreements. The CVRs entitle Neurogen shareholders to cash payments upon the sale or licensing of certain assets and upon the achievement of a specified clinical milestone. At June 30, 2011 and December 31, 2010, the aggregate fair values of the Aplindore, VR1 and H3 CVR's were \$0.7 million, and included in other long-term liabilities in the accompanying balance sheets as management is unable to estimate the timing of potential future payments.

In connection with the acquisition of Metabasis Therapeutics on January 27, 2010, Metabasis security holders received CVRs under four CVR agreements. The CVRs entitle the holders to cash payments upon the sale or licensing of certain assets and upon the achievement of specified milestones. The fair value of the liability at June 30, 2011 and December 31, 2010 was \$1.6 million and \$0, respectively.

### *Leases*

We lease our office and research facilities under operating lease arrangements with varying terms through November 2021. The agreements provide for increases in annual rents based on changes in the Consumer Price Index or fixed percentage increases ranging from 3% to 7%. We also sublease two of our facilities through their respective lease terms of July 2015 and August 2016. The sublease agreements provide for a 3% increase in annual rents.

### *Off-Balance Sheet Arrangements*

We had no off-balance sheet arrangements at June 30, 2011 and December 31, 2010.

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### *Contractual Obligations*

As of June 30, 2011, future minimum payments due under our contractual obligations are as follows (in thousands):

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations (1)	\$23,692	\$ 5,560	\$9,783	\$7,896	\$ 453
Consulting agreements	167	167	0	0	0
Total contractual obligations	\$23,858	\$ 5,727	\$9,783	\$7,896	\$ 453

- (1) We currently sublease two of our facilities through their respective lease terms of July 2015 and August 2016. As of June 30, 2011, we expect to receive aggregate future minimum lease payments totaling \$6.4 million (nondiscounted) over the duration of the sublease agreements as follows: less than one year, \$1.4 million; one to three years, \$2.9 million; three to five years, \$1.9 million; and after five years, \$0.2 million.

As of June 30, 2011, we have net open purchase orders (defined as total open purchase orders less any accruals or invoices charged to or amounts paid against such purchase orders) totaling approximately \$6.1 million. We currently do not have any significant capital expenditures planned for the remainder of 2011. In addition, under the terms of our merger with Metabasis, we are committed to spend at least \$8.0 million in new research and development funding on the Metabasis programs within 42 months following the closing of the transaction. Through June 30, 2011, we estimate that we have spent approximately \$4.2 million of the committed amount. We are also required under our CyDex CVR Agreement to invest at least \$1.5 million per year, inclusive of employee expenses, in the acquired business, through 2015. Through June 30, 2011, we estimate that we have exceeded our committed amount.

In September 2010, we ceased use of our facility in Cranbury, New Jersey. As a result, during the quarter ended September 30, 2010, we recorded lease exit costs of \$9.7 million for costs related to the difference between the remaining lease obligations of the abandoned operating leases, which run through August 2016, and management's estimate of potential future sublease income, discounted to present value.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

At June 30, 2011, our investment portfolio included fixed-income securities of \$10 million. These securities are subject to interest rate risk and will decline in value if interest rates increase. However, due to the short duration of our investment portfolio, an immediate 10% change in interest rates is not expected to have a material impact on our financial condition, results of operations or cash flows. Declines in interest rates over time will, however, reduce our interest income, while increases in interest rates over time will increase our interest expense.

We do not have a significant level of transactions denominated in currencies other than U.S. dollars and as a result we have limited foreign currency exchange rate risk. The effect of an immediate 10% change in foreign exchange rates would have no material impact on our financial condition, results of operations or cash flows.

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**ITEM 4. CONTROLS AND PROCEDURES**

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of the end of the period covered by this report, June 30, 2011, which we refer to as the Evaluation Date. Based on this evaluation, our principal executive officer and principal financial officer concluded as of the Evaluation Date that our disclosure controls and procedures were effective such that the information relating to us, including our consolidated subsidiaries, required to be disclosed in our SEC reports (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and (ii) is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our most recently completed fiscal quarter. Based on that evaluation, our principal executive officer and principal financial officer concluded that there has not been any change in our internal control over financial reporting during that quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



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**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

From time to time we are subject to various lawsuits and claims with respect to matters arising out of the normal course of our business. Due to the uncertainty of the ultimate outcome of these matters, the impact on future financial results is not subject to reasonable estimates.

In January 2011, we were notified by the IRS that they had completed their examination resulting in no changes to the taxes for our 2007 tax year.

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### ITEM 1A. RISK FACTORS

*The following is a summary description of some of the many risks we face in our business including any risk factors as to which there may have been a material change from those set forth in our Annual Report on Form 10-K for the year ended December 31, 2010. You should carefully review these risks in evaluating our business, including the businesses of our subsidiaries. You should also consider the other information described in this report.*

*We have marked with an asterisk (\*) those risk factors that reflect substantive changes from the risk factors included in our previously filed Annual Report on Form 10-K for the year ended December 31, 2010.*

#### **Risks Related To Us and Our Business.**

***Our business has recently undergone a significant change, and we may not be successful in integrating the CAPTISOL technology and CyDex's other development product candidates into our existing operations or in realizing the planned results from our recently expanded product portfolio and pipeline.***

In January 2011, we completed our merger with CyDex, in which we obtained the CAPTISOL technology, in addition to other product candidates. We will need to overcome significant challenges in order to realize the benefits from this acquisition. These challenges will include the timely, efficient and successful execution of a number of tasks, including the following:

- integrating CyDex into our existing operations;
- integrating CyDex's developmental product candidates and successfully managing the development and regulatory processes; and
- coordinating with CyDex's and our collaborative partners concerning the development, manufacturing, regulatory and intellectual property protection strategies for CAPTISOL and new development product candidates.

In addition, we rely on our collaborative partners for many aspects of our developmental and commercialization activities, and we are subject to risks related to their financial stability and solvency. We may not succeed in addressing these risks or any other problems encountered in connection with the acquisition of CyDex.

Furthermore, all of CyDex's products and product candidates, as well as the technology that it outlicenses, are based on CAPTISOL. In addition, CyDex or its partners are attempting to develop some product candidates that may contain significantly higher levels of CAPTISOL than in any currently-approved product and at levels at the FDA has challenged developers to demonstrate acceptable renal safety. If products or product candidates incorporating CAPTISOL technology were to cause any unexpected adverse events, whether in preclinical studies, clinical trials or as commercialized products, whether as a result of CAPTISOL or otherwise, the perception of CAPTISOL safety could be seriously harmed. If this were to occur, we may not be able to market these products unless and until we are able to demonstrate that the adverse event was unrelated to CAPTISOL, which we may not be able to do. Further, whether or not the adverse event was a result of CAPTISOL, we could be required by the FDA to submit to additional regulatory reviews or approvals, including extensive safety testing or clinical testing of products using CAPTISOL, which would be expensive and, even if we were to demonstrate that the adverse event was unrelated to CAPTISOL, would delay our marketing of CAPTISOL-enabled products and receipt of revenue related to those products.

***Royalties based on sales of AVINZA and PROMACTA represent a substantial portion of our revenues.***

King is obligated to pay us royalties based on its sales of AVINZA and GSK is obligated to pay us royalties on its sales of PROMACTA. These royalties are expected to be a substantial portion of our ongoing revenues for some time. As a result, any setback that may occur with respect to AVINZA or PROMACTA could significantly impair our operating results and/or reduce the market price of our stock. Setbacks for AVINZA and PROMACTA could include problems with shipping, distribution, manufacturing, product safety, marketing, government regulation,

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licenses and approvals, intellectual property rights, competition with existing or new products and physician or patient acceptance of the products, as well as higher than expected total rebates, returns or discounts.

AVINZA or PROMACTA could also face regulatory action and product safety issues. For example, the FDA previously requested expanded warnings on the AVINZA label to alert doctors and patients to the dangers of using AVINZA with alcohol. Changes were subsequently made to the label. The FDA also requested clinical studies to investigate the risks associated with taking AVINZA with alcohol. Any additional warnings, studies and any further regulatory action could have significant adverse effects on AVINZA sales.

King, King Pharmaceuticals Research and Development, Inc., Elan Corporation, plc and Elan Pharma International Ltd. jointly filed suit in federal district court in New Jersey on October 18, 2007 against Actavis, Inc. and Actavis Elizabeth LLC for patent infringement under U.S Patent No. 6,066,339. On July 13, 2011 the lawsuit was dismissed.

On July 21, 2009, King, King Pharmaceuticals Research and Development, Inc., Elan Corporation, plc and Elan Pharma International Ltd. jointly filed suit in federal district court in New Jersey against Sandoz Inc., or Sandoz, for patent infringement under U.S patent 6,066,339. By order dated May 12, 2011, all proceedings have been stayed for a period of six months, ending on November 2, 2011.

### ***Our product candidates face significant development and regulatory hurdles prior to marketing which could delay or prevent sales and/or milestone revenue.***

Before we or our partners obtain the approvals necessary to sell any of our potential products, we must show through preclinical studies and human testing that each product is safe and effective. We and our partners have a number of products moving toward or currently awaiting regulatory action, including bazedoxifene and lasofoxifene. Failure to show any product's safety and effectiveness could delay or prevent regulatory approval of a product and could adversely affect our business. The clinical trials process is complex and uncertain. For example, the results of preclinical studies and initial clinical trials may not necessarily predict the results from later large-scale clinical trials. In addition, clinical trials may not demonstrate a product's safety and effectiveness to the satisfaction of the regulatory authorities. Recently, a number of companies have suffered significant setbacks in advanced clinical trials or in seeking regulatory approvals, despite promising results in earlier trials. The FDA may also require additional clinical trials after regulatory approvals are received. Such additional trials may be expensive and time-consuming, and failure to successfully conduct those trials could jeopardize continued commercialization of a product.

The rates at which we complete our clinical trials depends on many factors, including, but are not limited to, our ability to obtain adequate supplies of the products to be tested and patient enrollment. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites and the eligibility criteria for the trial. Delays in patient enrollment for our trials may result in increased costs and longer

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development times. For example, the trial entitled “Eltrombopag To Reduce The Need For Platelet Transfusion In Subjects With Chronic Liver Disease And Thrombocytopenia Undergoing Elective Invasive Procedures (ELEVATE)” was suspended in October 2009 in accordance with an IDMC Recommendation. GSK terminated the ELEVATE study and the program is under review. In addition, our collaborative partners have rights to control product development and clinical programs for products developed under the collaborations. As a result, these collaborative partners may conduct these programs more slowly or in a different manner than expected. Moreover, even if clinical trials are completed, we or our collaborative partners still may not apply for FDA approval in a timely manner or the FDA still may not grant approval.

***We rely heavily on collaborative relationships, and any disputes or litigation with our collaborative partners or termination or breach of any of the related agreements could reduce the financial resources available to us, including milestone payments and future royalty revenues.***

Our strategy for developing and commercializing many of our potential products, including products aimed at larger markets, includes entering into collaborations with corporate partners and others. These collaborations have provided us with funding and research and development resources for potential products for the treatment of a variety of diseases. However, the funding provided to us by our existing collaborative partners for ongoing research and development under our existing collaborative agreements has ceased. These agreements also give our collaborative partners significant discretion when deciding whether or not to pursue any development program. Our existing collaborations may not continue or be successful, and we may be unable to enter into future collaborative arrangements to develop and commercialize our product candidates.

In addition, our collaborators may develop drugs, either alone or with others that compete with the types of drugs they are developing with us. This would result in increased competition for our programs. If products are approved for marketing under our collaborative programs, revenues we receive will depend on the manufacturing, marketing and sales efforts of our collaborative partners, who generally retain commercialization rights under the collaborative agreements. Generally, our current collaborative partners also have the right to terminate their collaborations under specified circumstances. If any of our collaborative partners breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully, our product development under these agreements will be delayed or terminated. Disputes or litigation may also arise with our collaborators, including disputes or litigation over ownership rights to intellectual property, know-how or technologies developed with our collaborators. Such disputes or litigation could adversely affect our rights to one or more of our product candidates. Any such dispute or litigation could delay, interrupt or terminate the collaborative research, development and commercialization of certain potential products, create uncertainty as to ownership rights of intellectual property, or could result in litigation or arbitration. The occurrence of any of these problems could be time-consuming and expensive and could adversely affect our business.

***We obtain CAPTISOL from a sole source supplier, and if this supplier were to cease to be able to supply CAPTISOL to us, or decline to supply CAPTISOL to us, we would be unable to continue to derive revenue or continue to develop our product candidates until we obtained an alternative source, which could take a considerable length of time.***

We currently have one supplier of CAPTISOL, Hovione FarmaCiencia SA, or Hovione, through its agent Hovione LLC. Hovione is a major supplier of APIs and API intermediates located in Lisbon, Portugal. Hovione has other production sites in Cork, Ireland and Macau, China, but those sites are not yet qualified to make CAPTISOL. If a major disaster were to happen at Hovione or Hovione were to suffer major production problems or were to fail to deliver CAPTISOL to us for any other reason, there could be a significant interruption of our CAPTISOL supply. While we carry a significant inventory of CAPTISOL for this type of occurrence, which should permit us to satisfy our existing supply obligations through 2011 under current and anticipated demand conditions, an unusually large order or two could rapidly deplete that inventory and cause significant problems with our licensees and disrupt our business. In addition, if we fail to supply CAPTISOL under our supply agreements, our customers could obtain the right to have CAPTISOL manufactured by other suppliers, which would significantly harm our business.

***We rely on contract manufacturers for the manufacture of CAPTISOL and product candidates, and if these contract manufacturers fail to perform as we expect, we will incur delays in our ability to generate revenue and substantial additional expenses in obtaining new contract manufacturers.***

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We do not manufacture products or product candidates, but rather contract with contract manufacturers for the manufacture of products and product candidates. With respect to any specific product or product candidate, we only contract with one contract manufacturer due to the high cost of compliance with good manufacturing practices prior to the contract manufacturer being permitted to manufacture the product or product candidate for use in humans. If a contract manufacturer is unable or unwilling to continue to manufacture for us in the future, we would be required to contract with a new contract manufacturer for the specific product or product candidate. In the case of products, this would cause us to lose revenue during the qualification process, and in the case of product candidates, this could cause a delay in the commercialization of the product candidate. In addition, in either case we would incur substantial additional expenses as a result of the new contract manufacturer becoming qualified. Further, if a contract manufacturer were to experience a delay in producing products or product candidates due to a failure to meet strict FDA manufacturing requirements or otherwise, we would also experience a delay in development and commercialization of the product candidate or, in the case of products, sales of the product. This risk is exacerbated in the case of manufacture of injectables, which require heightened sterility and other conditions as well as specialized facilities for preparation.

***If we consume cash more quickly than expected, and if we are unable to raise additional capital, we may be forced to curtail operations.***

Our operations have consumed substantial amounts of cash since inception. As of June 30, 2011, we had a negative working capital of \$14.2 million. Clinical and preclinical development of drug candidates is a long, expensive and uncertain process. Also, we may acquire companies, businesses or products and the consummation of such acquisitions may consume additional cash. For example, as part of the consideration for our recent acquisition of CyDex, we distributed approximately \$12.0 million of our cash to CyDex stockholders. The Contingent Value Rights Agreement (“CVR Agreement”) that was part of the CyDex acquisition obligates us to pay \$4.3 million in January 2012 to the CyDex stockholders. In addition, in the event of a Default (as defined in the CVR Agreement), we would be obligated to deliver to an escrow agent the future cash payments called for under the CVR Agreement. There can be no assurances that in the event of a Default that we would be able to deliver the lump sum payment to the escrow agent.

In September 2010, we ceased use of our facility in Cranbury, New Jersey. As a result, during the quarter ended September 30, 2010, we recorded lease exit costs of \$9.7 million for costs related to the difference between the remaining lease obligations of the abandoned operating leases, which run through August 2016, and management’s estimate of potential future sublease income, discounted to present value.

Additionally, in March 2011, we borrowed \$5.0 million from Square 1 Bank and April 2011 we borrowed an additional \$5.0 million from Square 1. All outstanding amounts under the loan bear interest at a floating rate equal to 200 basis points above the prime rate and may become immediately due and payable if we fail to maintain a cash balance at Square 1 of at least \$5.0 million. The maturity date of the revolving line of credit facility is March 29, 2012.

We believe that our capital resources, including our currently available cash, cash equivalents, and short-term investments as well as our current and future royalty revenues, will be adequate to fund our operations at their current levels at least for the next twelve months. However, changes may occur that would cause us to consume available capital resources before that time. Examples of relevant potential changes that could impact our capital resources include:

- the costs associated with our drug research and development activities, and additional costs we may incur if our development programs are delayed or are more expensive to implement than we currently anticipate;
- changes in collaborative relationships, including the funding we receive in connection with those relationships;
- the progress of our milestone and royalty producing activities;
- acquisitions of other businesses or technologies;

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- the termination of our lease agreements;
- the costs of the closure of our operations at our Cranbury, New Jersey facility;
- the purchase of additional capital equipment;
- cash payments, including CVR payments, or refunds we may be required to make pursuant to certain agreements with third parties;
- competing technological and market developments; and
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights, and the outcome of related litigation.

Additional capital may not be available on favorable terms, or at all. If additional capital is not available, we may be required to curtail operations significantly, including but not limited to reducing our current headcount, or to obtain funds by entering into arrangements with partners or other third parties that may require us to relinquish rights to certain of our technologies, products or potential markets that we would not otherwise relinquish.

***Our collaborative partners may change their strategy or the focus of their development and commercialization efforts with respect to our alliance products, the success of our alliance products could be adversely affected.***

If our collaborative partners terminate their collaborations with us or do not commit sufficient resources to the development, manufacture, marketing or distribution of our alliance products, we could be required to devote additional resources to our alliance products, seek new collaborative partners or abandon such alliance products, all of which could have an adverse effect on our business.

In March 2011, Pfizer completed its acquisition of King, which had purchased the AVINZA product line from us. There can be no assurance of the impact that this acquisition will have on our relationship with Pfizer.

On September 7, 2010, we received notice from GSK that it was exercising its right to terminate the Product Development and Commercialization Agreement, dated as of March 24, 2006 and as amended, among SmithKlineBeecham Corporation, doing business as GlaxoSmithKline, Glaxo Group Limited and Pharmacoepia, LLC, as successor to Pharmacoepia Drug Discovery, Inc. The termination became effective on October 7, 2010. Absent the termination by GSK, the research term under this agreement would have terminated on March 24, 2011. Following termination, we retained rights to the current programs under this agreement and may continue to develop the programs and commercialize any products resulting from the programs, or we may elect to cease progressing the programs and/or seek other partners for further development and commercialization.

On May 13, 2011, Pfizer Inc. announced in a Form 10-Q filed with the SEC that it is in the process of withdrawing its NDAs with the FDA relating to Fablyn (lasofoxifene tartrate). As previously disclosed, Fablyn is a selective estrogen receptor modulator product candidate that resulted from a collaboration between Pfizer and us formed to develop therapies for osteoporosis. Pfizer submitted an NDA to the FDA and a marketing authorization application to the European Medicines Agency for Fablyn for the treatment of osteoporosis in December 2007 and January 2008, respectively, and in February 2009, Pfizer received approval from the European Commission for Fablyn tablets. On July 15, 2011, we executed a patent license agreement for the exclusive license, under the Licensed Patents, to make, have made, import, use, sell or offer for sale the compound associated with Fablyn. The licenses and rights granted are free of any ongoing obligations to Pfizer, Inc.

***We are currently dependent upon outlicensing business and we may not be successful in entering into additional out-license agreements on favorable terms, which may adversely affect our liquidity or require us to alter development plans on our products.***

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We have entered into several out-licensing agreements for the development and commercialization of our products. We currently depend on our arrangements with our outlicensees to sell products using our CAPTISOL technology. These agreements generally provide that outlicensees may terminate the agreements at will. If our outlicensees discontinue sales of products using our CAPTISOL technology, fail to obtain regulatory approval for their products using our CAPTISOL technology, fail to satisfy their obligations under their agreements with us, or otherwise choose to utilize a generic form of CAPTISOL should it become available, or if we are unable to establish new licensing and marketing relationships, our financial results and growth prospects would be materially affected. Further, under most of our CAPTISOL outlicenses, the amount of royalties we receive will be reduced or will cease when the relevant patent expires. While we have other more recent patents relating to CAPTISOL with later expiration dates (for example, our high purity patent, U.S. Patent No. 7,635,773 is not expected to expire until 2029 and our morphology patent, U.S. Patent No. 7,629,331 is not expected to expire until 2025), the initially filed patents relating to CAPTISOL expire in 2010 in the U.S. and are expected to expire between 2011 and 2016 outside the U.S. If our other intellectual property rights are not sufficient to prevent a generic form of CAPTISOL from coming to market and if in such case our outlicensees choose to terminate their agreements with us, the source of the vast majority of our CAPTISOL revenue may cease to exist.

Although we expend considerable resources on internal research and development for our proprietary programs, we may not be successful in entering into additional out-licensing agreements under favorable terms due to several factors including:

- the difficulty in creating valuable product candidates that target large market opportunities;
- research and spending priorities of potential licensing partners;
- willingness of and the resources available to pharmaceutical and biotechnology companies to in-license product candidates for their clinical pipelines; or
- differences of opinion with potential partners on the valuation of products we are seeking to out-license.

The inability to enter into out-licensing agreements under favorable terms and to earn milestone payments, license fees and/or upfront fees may adversely affect our liquidity and may force us to curtail or delay development of some or all of our proprietary programs, which in turn may harm our business and the value of our stock.

***Third party intellectual property may prevent us or our partners from developing our potential products and we may owe a portion of any payments we receive from our collaborative partners to one or more third parties.***

Our success will depend on our ability and the ability of our collaborative partners to avoid infringing the proprietary rights of others, both in the United States and in foreign countries. In addition, disputes with licensors under our license agreements may arise which could result in additional financial liability or loss of important technology and potential products and related revenue, if any. Further, the manufacture, use or sale of our potential products or our collaborative partners' products or potential products may infringe the patent rights of others. This could impact AVINZA, PROMACTA, VIVIAN and CONBRIZA (bazedoxifene), lasofoxifene, LGD-4665, and any other products or potential products.

Several drug companies and research and academic institutions have developed technologies, filed patent applications or received patents for technologies that may be related to our business. Others have filed patent applications and received patents that conflict with patents or patent applications we have licensed for our use, either by claiming the same methods or compounds or by claiming methods or compounds that could dominate those licensed to us. In addition, we may not be aware of all patents or patent applications that may impact our ability to make, use or sell any of our potential products. For example, US patent applications may be kept confidential while pending in the United States Patent and Trademark Office and patent applications filed in foreign countries are often first published six months or more after filing.

Disagreements or litigation with our collaborative partners could delay our ability and the ability of our collaborative partners to achieve milestones or our receipt of other payments. In addition, other possible disagreements or litigation could delay, interrupt or terminate the research, development and commercialization of certain potential products being developed by either our collaborative partners or by us. The occurrence of any of the foregoing problems could be time-consuming and expensive and could adversely affect our business.

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Third parties have not directly threatened an action or claim against us, although we do periodically receive other communications or have other conversations with the owners of other patents or other intellectual property. If others obtain patents with conflicting claims, we may be required to obtain licenses to those patents or to develop or obtain alternative technology. We may not be able to obtain any such licenses on acceptable terms, or at all. Any failure to obtain such licenses could delay or prevent us from pursuing the development or commercialization of our potential products.

In general, litigation claims can be expensive and time consuming to bring or defend against and could result in settlements or damages that could significantly impact our results of operations and financial condition. We cannot predict or determine the outcome of these matters or reasonably estimate the amount or range of amounts of any fines or penalties that might result from a settlement or an adverse outcome. However, a settlement or an adverse outcome could have a material adverse effect on our financial position, liquidity and results of operations.

### ***Expirations of, challenges to or failure to secure patents and other proprietary rights may significantly hurt our business.***

The initially filed patents relating to CAPTISOL expired in 2010 in the U.S. and are expected to expire between 2011 and 2013 outside the U.S. We have also obtained patent protection in the U.S. through 2025 on Agglomerated form and through 2029 on High Purity form of CAPTISOL. We have obtained patent protection on a number of combinations of APIs and CAPTISOL through three combination patents in the U.S., and we have applied for six additional combination patents in the U.S. relating to the combination of CAPTISOL with specific APIs. Our U.S. combination patent relating to Fosphenytoin expires June 12, 2018 and our U.S. combination patent relating to Amiodarone expires May 4, 2022. Our U.S. combination patent relating to one of our early-stage product candidates expires March 19, 2022. There is no guarantee that these patents will be sufficient to prevent competitors from creating a generic form of CAPTISOL after 2010 and competing against us, or from developing combination patents for products that will prevent us from developing products using those APIs. In addition, most of the agreements in our CAPTISOL outlicensing business, including our agreements with Pfizer relating to Geodon IM, Vfend IV and Cerenia, provide that once the relevant patent expires, the amount of royalties we receive will be reduced or eliminated.

Generally, our success will depend on our ability and the ability of our licensors to obtain and maintain patents and proprietary rights for our potential products both in the United States and in foreign countries. Patents may not be issued from any of these applications currently on file, or, if issued, may not provide sufficient protection. Our patent position, like that of many biotechnology and pharmaceutical companies, is uncertain and involves complex legal and technical questions for which important legal principles are unresolved. We may not develop or obtain rights to products or processes that are patentable. Even if we do obtain patents, such patents may not adequately protect the technology we own or have licensed. In addition, others may challenge, seek to invalidate, infringe or circumvent any patents we own or license and rights we receive under those patents may not provide competitive advantages to us.

Any conflicts resulting from the patent rights of others could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection. We have had and will continue to have discussions with our current and potential collaborative partners regarding the scope and validity of our patents and other proprietary rights. If a collaborative partner or other party successfully establishes that our patent rights are invalid, we may not be able to continue our existing collaborations beyond their expiration. Any determination that our patent rights are invalid also could encourage our collaborative partners to seek early termination of our agreements. Such invalidation could adversely affect our ability to enter into new collaborations.

We may also need to initiate litigation, which could be time-consuming and expensive, to enforce our proprietary rights or to determine the scope and validity of others' rights. If litigation occurs, a court may find our patents or those of our licensors invalid or may find that we have infringed on a competitor's rights. In addition, if any of our competitors have filed patent applications in the United States which claim technology we also have invented, the United States Patent and Trademark Office may require us to participate in expensive interference proceedings to determine who has the right to a patent for the technology.



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We also rely on unpatented trade secrets and know-how to protect and maintain our competitive position. We require our employees, consultants, collaborative partners and others to sign confidentiality agreements when they begin their relationship with us. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our competitors may independently discover our trade secrets.

***Our product development involves a number of uncertainties, and we may never generate sufficient collaborative payments and royalties from the development of products to become profitable.\****

We were founded in 1987. We have incurred significant losses since our inception. As of June 30, 2011, our accumulated deficit was \$683.4 million.

Most of our products in development will require extensive additional development, including preclinical testing and human studies, as well as regulatory approvals, before they can be marketed. We cannot predict if or when any of the products we are developing or those being developed with our partners will be approved for marketing. There are many reasons why we or our collaborative partners may fail in our efforts to develop our potential products, including the possibility that: preclinical testing or human studies may show that our potential products are ineffective or cause harmful side effects; the products may fail to receive necessary regulatory approvals from the FDA or foreign authorities in a timely manner, or at all; the products, if approved, may not be produced in commercial quantities or at reasonable costs; the products, if approved, may not achieve commercial acceptance; regulatory or governmental authorities may apply restrictions to our products, which could adversely affect their commercial success; or the proprietary rights of other parties may prevent us or our partners from marketing the products.

Any product development failures for these or other reasons, whether with our products or our partners' products, may reduce our expected revenues, profits, and stock price.

***We may not be able to hire and/or retain key employees.***

If we are unable to hire and/or retain key employees, we may not have sufficient resources to successfully manage our assets or our business, and we may not be able to perform our obligations under various contracts and commitments. Furthermore, there can be no assurance that we will be able to retain all of our key management and scientific personnel. If we fail to retain such key employees, we may not realize the anticipated benefits of our mergers. Either of these could have substantial negative impacts on our business and our stock price.

***If plaintiffs bring product liability lawsuits against us or our partners, we or our partners may incur substantial liabilities and may be required to limit commercialization of our approved products and product candidates, and we may be subject to other liabilities related to the sale of our prior commercial product lines.\****

We and our partners face an inherent risk of product liability as a result of the clinical testing of our product candidates in clinical trials and face an even greater risk for commercialized products. Although we are not currently a party to product liability litigation, if we are sued, we may be held liable if any product or product candidate we develop causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, liability claims may result in decreased demand for any product candidates or products that we may develop, injury to our reputation, discontinuation of clinical trials, costs to defend litigation, substantial monetary awards to clinical trial participants or patients, loss of revenue and the inability to commercialize any products that we develop. We have product liability insurance that covers our clinical trials up to a \$5.0 million annual limit. We intend to expand product liability insurance coverage to include the sale of commercial products if we obtain marketing approval for any products that we may develop. However, this insurance may be prohibitively expensive, or may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or delay the commercialization of our product candidates. If we are sued for any injury caused by our product candidates or any future products, our liability could exceed our total assets.

In addition, we agreed to indemnify Eisai and King under certain circumstances pursuant to the asset purchase agreements we entered into with Eisai and King in connection with the sale of our prior commercial product lines. Some of our indemnification obligations still remain and our potential liability in certain circumstances is not

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limited to specific dollar amounts. We cannot predict the liabilities that may arise as a result of these matters. Any claims related to our indemnification obligations to King or Eisai could materially and adversely affect our financial condition.

In addition, King assumed our obligation to make payments to Organon based on net sales of AVINZA (the fair value of which was \$29.4 million as of June 30, 2011). We remain liable to Organon in the event King defaults on this obligation. Any requirement to pay a material amount to Organon, could adversely affect our business and the price of our securities.

The sale of our prior commercial product lines does not relieve us of exposure to product liability risks on products we sold prior to divesting these product lines. A successful product liability claim or series of claims brought against us may not be insured and could result in payment of significant amounts of money and divert management's attention from running our business.

***If our partners do not reach the market with our alliance products before our competitors offer products for the same or similar uses, or if our partners are not effective in marketing our alliance products, our revenues from product sales, if any, will be reduced.***

We face intense competition in our development activities. Our competitors might succeed in obtaining regulatory approval for competitive products more rapidly than our partners can for our products. In addition, competitors might develop technologies and products that are less expensive and perceived to be safer or more effective than those being developed by us or our partners, which could impair our product development and render our technology obsolete.

***We use hazardous materials, which may expose us to significant liability.***

In connection with our research and development activities, we handle hazardous materials, chemicals and various radioactive compounds. To properly dispose of these hazardous materials in compliance with environmental regulations, we are required to contract with third parties. We believe that we carry reasonably adequate insurance for toxic tort claims. However, we cannot eliminate the risk or predict the exposure of accidental contamination or injury from the handling and disposing of hazardous materials, whether by us or our third-party contractors. Any accident in the handling and disposing of hazardous materials may expose us to significant liability.

***Our shareholder rights plan and charter documents may hinder or prevent change of control transactions.***

Our shareholder rights plan and provisions contained in our certificate of incorporation and bylaws may discourage transactions involving an actual or potential change in our ownership. In addition, our Board of Directors may issue shares of preferred stock without any further action by the stockholders. Such restrictions and issuances may have the effect of delaying or preventing a change in our ownership. If changes in our ownership are discouraged, delayed or prevented, it would be more difficult for our current Board of Directors to be removed and replaced, even if you or our other stockholders believe that such actions are in the best interests of us and our stockholders.

***We may lose some or all of the value of some of our short-term investments.***

We engage one or more third parties to manage some of our cash consistent with an investment policy that allows a range of investments and maturities. The investments are intended to maintain safety of principal while providing liquidity adequate to meet projected cash requirements. Risks of principal loss are to be minimized through diversified short and medium term investments of high quality, but the investments are not in every case guaranteed or fully insured. As a result of changes in the credit market, one of our short-term investments in commercial paper was in default. As a result, we were unable to recoup all of our investment in the commercial paper. In addition, from time to time we may suffer other losses on our short-term investment portfolio.

***We may require additional funds to run our business and may be required to raise these funds on terms which are not favorable to us or which reduce our stock price.***

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We may need to complete additional equity or debt financings to fund our operations. Our inability to obtain additional financing could adversely affect our business. Financings may not be available at all or on terms favorable to us. In addition, these financings, if completed, may not meet our capital needs and could result in substantial dilution to our stockholders.

If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or drug development programs. We may also be required to liquidate our business or file for bankruptcy protection. Alternatively, we may be forced to attempt to continue development by entering into arrangements with collaborative partners or others that require us to relinquish some or all of our rights to technologies or drug candidates that we would not otherwise relinquish.

***Our drug development programs will require substantial additional future funding which could hurt our operational and financial condition.***

Our drug development programs require substantial additional capital to successfully complete them, arising from costs to: conduct research, preclinical testing and human studies; establish pilot scale and commercial scale manufacturing processes and facilities; and establish and develop quality control, regulatory, marketing, sales and administrative capabilities to support these programs.

Our future operating and capital needs will depend on many factors, including: the pace of scientific progress in our research and development programs and the magnitude of these programs; the scope and results of preclinical testing and human studies; the time and costs involved in obtaining regulatory approvals; the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims; competing technological and market developments; our ability to establish additional collaborations; changes in our existing collaborations; the cost of manufacturing scale-up; and the effectiveness of our commercialization activities.

We expect our research and development expenditures over the next three years to continue to be significant. However, we base our outlook regarding the need for funds on many uncertain variables. Such uncertainties include regulatory approvals, the timing of events outside our direct control such as product launches by partners and the success of such product launches, negotiations with potential strategic partners, possible sale of assets or other transactions and other factors. Any of these uncertain events can significantly change our cash requirements.

While we expect to fund our research and development activities from cash generated from royalties and milestones from our partners in various past and future collaborations to the extent possible, if we are unable to do so, we may need to complete additional equity or debt financings or seek other external means of financing. These financings could depress our stock price. If additional funds are required to support our operations and we are unable to obtain them on terms favorable to us, we may be required to cease or reduce further development or commercialization of our products, to sell some or all of our technology or assets or to merge with another entity.

***Significant returns of products we sold prior to selling our prior commercial businesses could harm our operating results.***

Under our agreements to sell our prior commercial businesses, we remain financially responsible for returns of our products sold before those businesses were transferred to their respective buyers. Consequently, if returns of those products are higher than expected, we could incur substantial expenses for processing and issuing refunds for those returns which, in turn, could negatively impact our financial results. The amount of returns could be affected by a number of factors including, but not limited to, ongoing product demand, product rotation at distributors and wholesalers, and product stability issues.

***Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.***

Our results of operations could be materially negatively affected by economic conditions generally, both in the U.S. and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining residential real estate market in the U.S.

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have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline.

Our investment securities consist primarily of money market funds, corporate debt obligations and U.S. government agency securities. We do not have any auction rate securities. Recently, there has been concern in the credit markets regarding the value of a variety of mortgage-backed securities and the resultant effects on various securities markets. We cannot provide assurance that our investments are not subject to adverse changes in market value. If our investments experience adverse changes in market value, we may have less capital to fund our operations.

### ***We may be unable to successfully integrate Metabasis and realize the anticipated benefits of the acquisition.***

In January 2010, we completed our merger with Metabasis. The integration of an independent company is a complex, costly and time-consuming process. It is possible that the integration processes could result in the loss of key employees, diversion of management's attention, the disruption or interruption of, or the loss of momentum in, our ongoing business or inconsistencies in standards, controls, procedures and policies, any of which could adversely affect our ability to maintain relationships with licensors, collaborators, partners, suppliers and employees or our ability to achieve the anticipated benefits of the merger, or could reduce our earnings or otherwise adversely affect the business and financial results of the combined company and, as a result, adversely affect the market price of our common stock.

During the integration process for our Metabasis acquisition, we have become aware that the electronic data we received as part of the acquisition is incomplete due to the data retention and backup policies in place at Metabasis prior to the time of the acquisition. The missing electronic data could impact our ability to partner affected compounds and may lead to increased costs and development time for affected programs, which could impact our ability to achieve the anticipated benefits of the acquisition and lead to unanticipated development costs.

We expect to incur significant costs and commit significant management time integrating Metabasis' business operations, technology, development programs, products and personnel with those of ours. If we do not successfully integrate the business of Metabasis, the expenditure of these costs will reduce our cash position.

### ***Our stock price has been volatile and could experience a sudden decline in value.***

Our common stock has experienced significant price and volume fluctuations and may continue to experience volatility in the future. As a result, you may not be able to sell your shares quickly or at the latest market price if trading in our stock is not active or the volume is low. On November 19, 2010, we effected a 1-for-6 reverse stock split. We believe the reverse stock split will have the effect of increasing the per share trading price of our common stock. Many factors may have a significant impact on the market price of our common stock, including, but not limited to, the following factors: results of or delays in our preclinical studies and clinical trials; the success of our collaboration agreements; publicity regarding actual or potential medical results relating to products under development by us or others; announcements of technological innovations or new commercial products by us or others; developments in patent or other proprietary rights by us or others; comments or opinions by securities analysts or major stockholders; future sales of our common stock by existing stockholders; regulatory developments or changes in regulatory guidance; litigation or threats of litigation; economic and other external factors or other disaster or crises; the departure of any of our officers, directors or key employees; period-to-period fluctuations in financial results; and limited daily trading volume.

The Financial Industry Regulatory Authority, or FINRA, (formerly the National Association of Securities Dealers, Inc.) and the Securities and Exchange Commission, or SEC, have adopted certain new rules. If we were unable to continue to comply with the new rules, we could be delisted from trading on the NASDAQ Global Market,

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or Nasdaq, and thereafter trading in our common stock, if any, would be conducted through the over-the-counter market or on the Electronic Bulletin Board of FINRA. As a consequence of such delisting, an investor would likely find it more difficult to dispose of, or to obtain quotations as to the price of, our common stock. Delisting of our common stock could also result in lower prices per share of our common stock than would otherwise prevail.

***Any future material weaknesses or deficiencies in our internal control over financial reporting could harm stockholder and business confidence on our financial reporting, our ability to obtain financing and other aspects of our business.***

While no material weaknesses were identified as of June 30, 2011, we cannot assure you that material weaknesses will not be identified in future periods. The existence of one or more material weakness or significant deficiency could result in errors in our consolidated financial statements. Substantial costs and resources may be required to rectify any internal control deficiencies. If we fail to achieve and maintain the adequacy of our internal controls in accordance with applicable standards, we may be unable to conclude on an ongoing basis that we have effective internal controls over financial reporting. If we cannot produce reliable financial reports, our business and financial condition could be harmed, investors could lose confidence in our reported financial information, or the market price of our stock could decline significantly. In addition, our ability to obtain additional financing to operate and expand our business, or obtain additional financing on favorable terms, could be materially and adversely affected, which, in turn, could materially and adversely affect our business, our financial condition and the market value of our securities. Moreover, our reputation with customers, lenders, investors, securities analysts and others may be adversely affected.

***Impairment charges pertaining to goodwill, identifiable intangible assets or other long-lived assets from our mergers could have an adverse impact on our results of operations and the market value of our common stock.***

The total purchase price pertaining to our mergers with Pharmacoepia, Neurogen, Metabasis and CyDex have been allocated to net tangible assets, identifiable intangible assets, in process research and development and goodwill. To the extent the value of goodwill or identifiable intangible assets or other long-lived assets become impaired, we will be required to incur material charges relating to the impairment. Any impairment charges could have a material adverse impact on our results of operations and the market value of our common stock.

***We may undertake strategic acquisitions in the future and any difficulties from integrating such acquisitions could adversely affect our stock price, operating results and results of operations.***

We may acquire companies, businesses and products that complement or augment our existing business. We may not be able to integrate any acquired business successfully or operate any acquired business profitably. Integrating any newly acquired business could be expensive and time-consuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than we predict. The diversion of our management's attention and any delay or difficulties encountered in connection with any future acquisitions we may consummate could result in the disruption of our on-going business or inconsistencies in standards and controls that could negatively affect our ability to maintain third-party relationships. Moreover, we may need to raise additional funds through public or private debt or equity financing, or issue additional shares, to acquire any businesses or products, which may result in dilution for stockholders or the incurrence of indebtedness.

As part of our efforts to acquire companies, business or product candidates or to enter into other significant transactions, we conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. If we fail to realize the expected benefits from acquisitions we may consummate in the future, whether as a result of unidentified risks, integration difficulties, regulatory setbacks and other events, our business, results of operations and financial condition could be adversely affected. If we acquire product candidates, we will also need to make certain assumptions about, among other things, development costs, the likelihood of receiving regulatory approval and the

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market for such product candidates. Our assumptions may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of these transactions.

In addition, we will likely experience significant charges to earnings in connection with our efforts, if any, to consummate acquisitions. For transactions that are ultimately not consummated, these charges may include fees and expenses for investment bankers, attorneys, accountants and other advisors in connection with our efforts. Even if our efforts are successful, we may incur, as part of a transaction, substantial charges for closure costs associated with elimination of duplicate operations and facilities and acquired IPR&D charges. In either case, the incurrence of these charges could adversely affect our results of operations for particular quarterly or annual periods.

***Our CyDex facilities are located in a tornado zone, and the occurrence of a tornado or other catastrophic disaster could damage our facilities and equipment, which could cause us to curtail or cease local operations.***

Our CyDex facilities are located outside of Kansas City, Kansas, which is in a tornado zone. We are therefore vulnerable to damage from tornados. We are also vulnerable to damage from other types of disasters, such as power loss, fire, floods and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. We are insured against up to \$2.6 million in damages resulting from natural disasters, including tornados. We currently may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business, financial condition and prospects.

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**ITEM 6. EXHIBITS**

The Index to Exhibits on page 49 is incorporated herein by reference as the list of exhibits required as part of this Quarterly Report.

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**LIGAND PHARMACEUTICALS INCORPORATED**  
**SIGNATURE**

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

Date: August 8, 2011

By: /s/ John P. Sharp

John P. Sharp

Vice President, Finance and Chief Financial Officer



**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
2.1(1)	Agreement and Plan of Merger, by and among the Company, Pharmacoepia, Inc., Margaux Acquisition Corp. and Latour Acquisition, LLC, dated as of September 24, 2008 (Filed as Exhibit 2.1).
2.2(2)	Agreement and Plan of Merger, by and among the Company, Neurogen Corporation and Neon Signal, LLC, dated as of August 23, 2009 (Filed as Exhibit 10.1).
2.3(3)	Amendment to Agreement and Plan of Merger, by and among the Company, Neurogen Corporation, and Neon Signal, LLC, dated September 18, 2009 (Filed as Exhibit 10.1).
2.4(3)	Amendment No. 2 to Agreement and Plan of Merger, by and among the Company, Neurogen Corporation, and Neon Signal, LLC, dated November 2, 2009 (Filed as Exhibit 10.2).
2.5(4)	Amendment No. 3 to Agreement and Plan of Merger, by and among the Company, Neurogen Corporation, and Neon Signal, LLC, dated December 17, 2009 (Filed as Exhibit 10.1).
2.6(5)	Certificate of Merger for acquisition of Neurogen Corporation (Filed as Exhibit 2.1).
2.7(6)	Agreement and Plan of Merger, dated as of October 26, 2009, by and among the Company, Metabasis Therapeutics, Inc., and Moonstone Acquisition, Inc (Filed as Exhibit 10.1).
2.8(7)	Amendment to Agreement and Plan of Merger, by and among the Company, Metabasis Therapeutics, Inc., Moonstone Acquisition, Inc., and David F. Hale as Stockholders' Representative, dated November 25, 2009 (Filed as Exhibit 10.1).
2.9(8)	Certificate of Merger for acquisition of Metabasis Therapeutics, Inc. dated January 27, 2010 (Filed as Exhibit 2.1).
2.10(9)	Certificate of Merger, dated and filed January 24, 2011 (Filed as Exhibit 2.1).
2.11(9)	Agreement and Plan of Merger, by and among the Company, CyDex Pharmaceuticals, Inc., and Caymus Acquisition, Inc., dated January 14, 2011 (Filed as Exhibit 10.1).
3.1(10)	Amended and Restated Certificate of Incorporation of the Company (Filed as Exhibit 3.1).
3.2(10)	Bylaws of the Company, as amended (Filed as Exhibit 3.3).
3.3(11)	Amended Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock of the Company (Filed as Exhibit 3.3).
3.4(12)	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Company dated June 14, 2000 (Filed as Exhibit 3.5).
3.5(13)	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Company dated September 30, 2004 (Filed as Exhibit 3.6).
3.6(14)	Amendment of the Bylaws of the Company dated November 8, 2005 (Filed as Exhibit 3.1).
3.7(15)	Amendment of Bylaws of the Company dated December 4, 2007 (Filed as Exhibit 3.1).
4.1(16)	Specimen stock certificate for shares of Common Stock of the Company.
4.4(17)	2006 Preferred Shares Rights Agreement, by and between the Company and Mellon Investor Services LLC, dated as of October 13, 2006 (Filed as Exhibit 4.1).
10.1(18)	Amendment of "General" Contingent Value Rights Agreement, dated January 26, 2011 (filed as Exhibit 10.1).

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<u>Exhibit Number</u>	<u>Description</u>
10.2(9)	Contingent Value Rights Agreement, by and among the Company, CyDex Pharmaceuticals, Inc., and Allen K. Roberson and David Poltack, acting jointly as Shareholders' Representative, dated January 14, 2011 (Filed as Exhibit 10.2).
10.3(19) †	CAPTISOL Supply Agreement, dated December 20, 2002, between CyDex and Hovione LLC, Hovione FarmaCiencia S.A., Hovione Pharmascience Limited, and Hovione International Limited (Filed as Exhibit 10.100).
10.4(19) †	1st Amendment to CAPTISOL Supply Agreement, dated July 29, 2005, between CyDex and Hovione LLC, Hovione FarmaCiencia S.A., Hovione Pharmascience Limited, and Hovione International Limited (Filed as Exhibit 10.101).
10.5(19)	2nd Amendment to CAPTISOL Supply Agreement dated March 1, 2007, between CyDex and Hovione LLC, Hovione FarmaCiencia S.A., Hovione Pharmascience Limited, and Hovione International Limited (Filed as Exhibit 10.102).
10.6(19) †	3rd Amendment to CAPTISOL Supply Agreement dated January 28, 2008, between CyDex and Hovione LLC, Hovione FarmaCiencia S.A., Hovione Pharmascience Limited, and Hovione International Limited (Filed as Exhibit 10.103).
10.7(19) †	4th Amendment to CAPTISOL Supply Agreement dated September 23, 2009 between CyDex and Hovione LLC, Hovione FarmaCiencia S.A., Hovione Pharmascience Limited, and Hovione International Limited (Filed as Exhibit 10.104).
10.8(19) †	License Agreement, dated September 3, 1993, between CyDex and The University of Kansas (Filed as Exhibit 10.105).
10.9(19) †	First Amendment to License Agreement, dated February 24, 1998, between CyDex and The University of Kansas (Filed as Exhibit 10.106).
10.10(19) †	Second Amendment to License Agreement, dated August 4, 2004, between CyDex and The University of Kansas (Filed as Exhibit 10.107).
10.11(19) †	Exclusive License Agreement, dated June 4, 1996, between Pfizer, Inc. and CyDex (Filed as Exhibit 10.108).
10.12(19) †	Nonexclusive License Agreement, dated June 4, 1996, between Pfizer, Inc. and CyDex (Filed as Exhibit 10.109).
10.13(19) †	Addendum to Nonexclusive License Agreement, dated December 11, 2001, between CyDex and Pfizer, Inc. (Filed as Exhibit 10.110).
10.14(19) †	Acknowledgement Agreement, dated March 3, 2008, between CyDex and The University of Kansas (Filed as Exhibit 10.111).
10.15(19) †	License Agreement, dated January 4, 2006, between CyDex and Prism Pharmaceuticals (Filed as Exhibit 10.112).
10.16(19) †	Amendment to License Agreement, dated May 12, 2006 between CyDex and Prism Pharmaceuticals (Filed as Exhibit 10.113).
10.17(19) †	Supply Agreement, dated March 5, 2007, between CyDex and Prism Pharmaceuticals (Filed as Exhibit 10.114).
10.18(19) †	License and Supply Agreement, dated October 12, 2005 between CyDex and Proteolix, Inc. (Filed as Exhibit 10.115).
10.19(9)	Loan and Security Agreement, by and among the Company, its subsidiaries and Oxford Finance Corporation, dated January 24, 2011 (Filed as Exhibit 10.3).
10.20(20)	First Amendment to Loan and Security Agreement, by and between Ligand Pharmaceuticals Incorporated and Oxford Finance LLC, dated April 29, 2011 (Filed as Exhibit 10.2).
10.21(21)	Loan and Security Agreement, by and between Ligand Pharmaceuticals Incorporated and

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<u>Exhibit Number</u>	<u>Description</u>
	Square 1 Bank, dated March 31, 2011 (Filed as Exhibit 10.1).
10.22(20)	First Amendment to Loan and Security Agreement, by and between Ligand Pharmaceuticals Incorporated and Square 1 Bank, dated April 29, 2011 (Filed as Exhibit 10.1).
10.23 †(22)	License Agreement dated March 24, 2011 by and between the Company and Chiva Pharmaceuticals, Inc.
10.24	Director Compensation and Stock Ownership Policy, dated June 1, 2011
10.25†	License Agreement dated June 1, 2011 by and between CyDex and The Medicines Company
10.26†	Supply Agreement dated June 1, 2011 by and between CyDex and The Medicines Company
10.27†	Supply Agreement dated June 13, 2011 by and between CyDex and Merck
31.1	Certification by Principal Executive Officer, Pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification by Principal Financial Officer, Pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification by Principal Executive Officer, Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification by Principal Financial Officer, Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.1**	The following financial information from the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2011, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to Condensed Consolidated Financial Statements, tagged as blocks of text.
†	Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from this quarterly report and submitted separately to the Securities and Exchange Commission
(1)	This exhibit was previously filed as part of, and is hereby incorporated by reference to the numbered exhibit filed with the Company's Current Report on Form 8-K filed on September 26, 2008.
(2)	This exhibit was previously filed as part of, and is hereby incorporated by reference to the numbered exhibit filed with the Company's Current Report on Form 8-K filed on August 24, 2009.
(3)	This exhibit was previously filed as part of, and is hereby incorporated by reference to the numbered exhibit filed with the Company's Current Report on Form 8-K filed on November 6, 2009
(4)	This exhibit was previously filed as part of, and is being incorporated by reference to the numbered exhibit filed with the Company's Current Report on Form 8-K filed on December 17, 2009.
(5)	This exhibit was previously filed as part of, and is hereby incorporated by reference to the numbered exhibit filed with the Company's Current Report on Form 8-K filed on December 24, 2009.
(6)	This exhibit was previously filed as part of, and is being incorporated by reference to the numbered exhibit filed with the Company's Current Report on Form 8-K filed on October 28, 2009.
(7)	This exhibit was previously filed as part of, and is being incorporated by reference to the numbered exhibit filed with the Company's Current Report on Form 8-K filed on December 1, 2009.
(8)	This exhibit was previously filed as part of, and is hereby incorporated by reference to the numbered exhibit filed with the Company's Current Report on Form 8-K filed on January 28, 2010.
(9)	This exhibit was previously filed as part of, and is hereby incorporated by reference to the numbered exhibit filed with the Company's Current Report on Form 8-K filed on January 26, 2011.

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- (10) This exhibit was previously filed as part of, and is hereby incorporated by reference to the numbered exhibit filed with the Company's Registration Statement on Form S-4 (No. 333-58823) filed on July 9, 1998.
  - (11) This exhibit was previously filed as part of and is hereby incorporated by reference to same numbered exhibit filed with the Company's Quarterly Report on Form 10-Q for the period ended March 31, 1999.
  - (12) This exhibit was previously filed as part of, and are hereby incorporated by reference to the numbered exhibit filed with the Company's Annual Report on Form 10-K for the year ended December 31, 2000.
  - (13) This exhibit was previously filed as part of, and is hereby incorporated by reference to the numbered exhibit filed with the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2004.
  - (14) This exhibit was previously filed as part of, and is being incorporated by reference to the numbered exhibit filed with the Company's Current Report on Form 8-K filed on November 14, 2005.
  - (15) This exhibit was previously filed as part of, and is hereby incorporated by reference to the numbered exhibit filed with the Company's Current Report on Form 8-K filed on December 6, 2007.
  - (16) This exhibit was previously filed as part of, and is hereby incorporated by reference to the same numbered exhibit filed with the Company's Registration Statement on Form S-1 (No. 33-47257) filed on April 16, 1992 as amended.
  - (17) This exhibit was previously filed as part of, and is being incorporated by reference to the numbered exhibit filed with the Company's Current Report on Form 8-K filed on October 17, 2006.
  - (18) This exhibit was previously filed as part of, and is hereby incorporated by reference to the numbered exhibit filed with the Company's Current Report on Form 8-K filed on January 31, 2011.
  - (19) This exhibit was previously filed as part of, and are hereby incorporated by reference to the same numbered exhibit filed with the Company's Annual Report on Form 10-K for the year ended December 31, 2010.
  - (20) This exhibit was previously filed as part of, and is being incorporated by reference to the numbered exhibit filed with the Company's Current Report on Form 8-K filed on April 29, 2011.
  - (21) This exhibit was previously filed as part of, and is being incorporated by reference to the numbered exhibit filed with the Company's Current Report on Form 8-K filed on April 4, 2011.
  - (22) This exhibit was previously filed as part of, and is being incorporated by reference to the numbered exhibit filed with the Company's Quarterly Report on Form 10-Q filed on May 10, 2011.
- \* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of Ligand Pharmaceuticals, Incorporated, whether made before or after the date hereof, regardless of any general incorporation language in such filing. Signed originals of these certifications have been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
- \*\* Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

**LIGAND PHARMACEUTICALS INCORPORATED**  
**DIRECTOR COMPENSATION AND STOCK OWNERSHIP POLICY**  
**(Amended and Restated Effective June 1, 2011)**

**I. DIRECTOR COMPENSATION**

Non-employee members of the board of directors (the “*Board*”) of Ligand Pharmaceuticals Incorporated (the “*Company*”) shall be eligible to receive cash and equity compensation effective as of June 1, 2011, as set forth in this Director Compensation Policy. The cash compensation and stock awards described in this Director Compensation Policy shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, an “*Independent Director*”) who may be eligible to receive such cash compensation or stock awards, unless such Independent Director declines the receipt of such cash compensation or stock awards by written notice to the Chairman of the Board. This Director Compensation Policy shall remain in effect until it is revised or rescinded by further action of the Board. The terms and conditions of this Director Compensation Policy shall supersede any prior cash or equity compensation arrangements between the Company and its directors.

1. Cash Compensation.

(a) Annual Retainer. Each Independent Director shall be eligible to receive an annual retainer of \$45,000 for service on the Board. In addition, an Independent Director serving as:

(i) chairman of the Board shall be eligible to receive an additional annual retainer of \$20,000 for such service;

(ii) chairman of the Audit Committee shall be eligible to receive an additional annual retainer of \$20,000 for such service;

(iii) members (other than the chairman) of the Audit Committee shall be eligible to receive an additional annual retainer of \$10,000 for such service;

(iv) chairman of the Compensation Committee shall be eligible to receive an additional annual retainer of \$12,000 for such service;

(v) members (other than the chairman) of the Compensation Committee shall be eligible to receive an additional annual retainer of \$6,000 for such service;

(vi) chairman of the Nominating and Corporate Governance Committee shall be eligible to receive an additional annual retainer of \$8,000 for such service; and

(vii) members (other than the chairman) of the Nominating and Corporate Governance Committee shall be eligible to receive an additional annual retainer of \$4,000 for such service.

(b) Payment of Cash Compensation. Annual retainer fees shall be paid after each annual meeting of the Company’s stockholders in advance for the upcoming year of service and shall be prorated for the period of the year served for Independent Directors who are elected or appointed to the Board at a time other than the date of the annual meeting of the Company’s stockholders; provided,

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however, that an Independent Director may elect in writing prior to the date of an annual meeting to receive all or a portion of his annual retainer fee in the form of such number of fully vested shares of the Company's common stock as is equal to (i) the amount of the annual retainer the Independent Director has elected to receive in the form of shares of the Company's common stock, divided by (ii) the closing price per share of the Company's common stock on the Nasdaq Global Market (or such other established stock exchange or national quotation system on which the stock is quoted) on the date of the annual meeting; provided, however, that for the two year period commencing June 1, 2011, at least fifty percent (50%) of each Independent Director's annual retainer fees shall be paid in the form of fully vested shares of the Company's common stock, subject to any greater election by such Independent Director. Such shares shall be issued automatically on the date of the annual meeting pursuant to the Company's 2002 Stock Incentive Plan (the "**2002 Plan**"). Committee retainer fees shall also be paid annually after each annual meeting of the Company's stockholders in advance for the upcoming year of service and shall be prorated for any partial quarters served for Independent Directors who serve on a committee for the period of the year served for Independent Directors who are elected or appointed to a committee at a time other than the date of the annual meeting of the Company's stockholders.

2. Equity Compensation. The Independent Directors shall be granted the following stock awards. The stock awards described below shall be granted under and shall be subject to the terms and provisions of the 2002 Plan and shall be granted subject to the execution and delivery of award agreements, including attached exhibits, in substantially the same forms previously approved by the Board.

(a) Initial Stock Awards. A person who was initially elected or appointed to the Board on or after April 16, 2009, and who was or is an Independent Director at the time of such initial election or appointment, shall be eligible to receive the following stock awards on the date of such initial election or appointment (each, an "**Initial Stock Award**"):

- (i) a restricted stock grant of 1,666 shares of common stock (subject to adjustment as provided in the 2002 Plan); and
- (ii) a stock option to purchase 5,000 shares of common stock (subject to adjustment as provided in the 2002 Plan).

(b) Subsequent Stock Awards. A person who is an Independent Director automatically shall be eligible to receive the following stock awards on the date of each annual meeting of the Company's stockholders on or after June 1, 2011 (each, a "**Subsequent Stock Award**"):

- (i) an award of 2,925 restricted stock units (subject to adjustment as provided in the 2002 Plan); and
- (ii) a stock option to purchase 7,335 shares of common stock (subject to adjustment as provided in the 2002 Plan).

An Independent Director elected for the first time to the Board at an annual meeting of stockholders shall only receive an Initial Restricted Stock grant in connection with such election, and shall not receive a Subsequent Restricted Stock grant on the date of such meeting as well. The stock awards described in this clause shall be referred to as "**Subsequent Stock Awards**."

(c) Termination of Employment of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their employment with the Company and any parent or subsidiary of the Company and remain on the

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Board will not receive any Initial Stock Awards pursuant to clause 2(a) above, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from employment with the Company and any parent or subsidiary of the Company, Subsequent Stock Awards as described in clause 2(b) above.

(d) Vesting of Stock Awards Granted to Independent Directors.

(i) Initial Stock Awards granted hereunder shall vest in three (3) equal annual installments on each of the first three (3) anniversaries following the date of grant, subject to the director's continuing service on the Board through each such vesting date.

(ii) Subsequent Stock Awards granted hereunder shall vest on the first anniversary of the date of grant, subject to the director's continuing service on the Board through each such vesting date.

(iii) Any stock awards granted hereunder shall vest in full in the event of a Change in Control or a Hostile Take-Over (each as defined in the 2002 Plan) to the extent the director is serving on the Board at the time of such transaction or in the event a director ceases to serve on the Board by reason of death or Permanent Disability as defined in the 2002 Plan.

(iv) Any unvested stock awards will be forfeited to the Company in the event a director ceases to serve on the Board prior to the vesting of such shares.

(e) Effect of Termination of Board Service on Stock Options. A director shall be able to exercise his or her stock options that were vested at the time of his or her cessation of Board service until the first to occur of (A) the third anniversary of the date of his or her cessation of Board service, or (B) the original expiration date of the term of such stock options.

(f) Term of Stock Options. Each stock option granted hereunder shall have a term of ten (10) years measured from the date of grant.

(g) Exercise Price of Stock Options. The exercise price per share of any stock options granted hereunder shall be equal to one hundred percent (100%) of the Fair Market Value (as defined in the 2002 Plan) of the common stock on the date of grant.

## II. DIRECTOR STOCK OWNERSHIP GUIDELINES

Independent Directors are expected to own and hold shares of the Company's common stock with a value equal to three times the annual cash retainer for service as an Independent Director (without regard to any retainers paid for committee service or service as chairman of the Board). The stock ownership level should be achieved by each Independent Director on or before April 30, 2014 or, if later, within three years after the Independent Director's first appointment to the Board.

Stock that counts toward satisfaction of these guidelines include: shares of common stock owned outright by the Independent Director and his or her immediate family members who share the same household, whether held individually or jointly; restricted stock where the restrictions have lapsed; shares acquired upon stock option exercise; shares purchased in the open market; and shares held in trust for the benefit of the Independent Director or his or her family. Restricted stock units, which represent the right to receive shares, do not count towards satisfaction of these guidelines. Shares held in trust may be included. Due to the complexities of trust accounts, requests to include shares held in trust should be

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submitted to the Secretary of the Company and the Chairman of the Board will make the final decision as to whether to include those shares.

An Independent Director will be deemed to be in compliance with these guidelines if the Fair Market Value (as defined in the 2002 Plan) of the shares of the Company's common stock held by such Independent Director on any date prior to the deadline for his or her compliance equals or exceeds the required multiple of his or her annual cash retainer. After meeting the requirements set forth in these guidelines, any subsequent decreases in the market value of the Company's common stock shall not be considered, so long as the Independent Director continues to hold at least the same number of shares of the Company's common stock as he or she did when the guidelines were first met or exceeded by such Independent Director.

The guidelines may be waived for Independent Directors, at the discretion of the Board, if compliance would create hardship or prevent an Independent Director from complying with a court order, as in the case of a divorce settlement.



CERTAIN MATERIAL (INDICATED BY AN ASTERISK) 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

**THIS LICENSE AGREEMENT** (this “**Agreement**”) is made this 1<sup>st</sup> day of June, 2011 (the “**Effective Date**”) between:

**CYDEX PHARMACEUTICALS, INC.**, a Delaware corporation with offices at 10513 W. 84<sup>th</sup> Terrace, Lenexa, Kansas 66214 (“**CyDex**”); and

**THE MEDICINES COMPANY**, a Delaware corporation with offices at 8 Sylvan Way, Parsippany, New Jersey 07054 (“**MDCO**”).

### **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 worldwide licensee of Captisol®, a patented drug formulation system designed to enhance the solubility and stability of drugs;

**WHEREAS**, CyDex has developed or obtained certain rights related to the Compound (defined below);

**WHEREAS**, MDCO desires to obtain a license to use such patented drug formulation system for Captisol and such rights to the Compound for the development and commercialization of the Licensed Product (defined below) and CyDex is willing to grant such license to MDCO under the terms and conditions set forth herein; and

**WHEREAS**, CyDex desires to sell Captisol® to MDCO or its Contract Manufacturers (defined below), and MDCO desires to obtain supplies of Captisol® from CyDex, for use in the Licensed Product, 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 is acknowledged, the parties, intending to be legally bound, agree as follows:

#### **1. DEFINITIONS.**

For the purposes of this Agreement, the following terms whether used in singular or plural form shall have the meanings as defined below:

“**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 [\*\*\*] of the voting securities or other ownership interest of the relevant entity.

\*\*\* 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.

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“**Captisol**” means Captisol®, also known scientifically as [\*\*\*].

“**Captisol Data Package**” means (a) all toxicology/safety and other relevant scientific safety data owned, licensed or developed by CyDex and its Affiliates; and (b) all toxicology/safety and other relevant scientific safety 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), in each case on Captisol alone (and not in conjunction with a product formulation).

[\*\*\*].

“**Captisol Patents**” means all patents and patent applications in the Territory which pertain to Captisol, other than the Licensed Product Patents, 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. For avoidance of doubt, all intellectual property pertaining to the Licensed Product generated by MDCO or its Affiliates or their Sublicensees during the Term of this Agreement shall be solely owned by MDCO and shall not be part of the Captisol Patents. Set forth in *Exhibit A* attached hereto include, without limitation, a list of the Captisol Patents as of the Effective Date. Such *Exhibit A* may be updated by CyDex from time to time during the Term.

“**Claim**” has the meaning specified in **Section 10.1**.

“**Clinical Grade Captisol**” means [\*\*\*].

“**Commercial Grade Captisol**” means [\*\*\*].

“**Commercial Launch Date**” means, in any particular country, the first commercial sale by MDCO, its Affiliates or Sublicensees of the Licensed Product to a Third Party (as defined below) in a given regulatory jurisdiction after Marketing Approval has been obtained in such jurisdiction. For avoidance of doubt, any transfer of the Licensed Product to a Third Party for preclinical, clinical or regulatory purposes shall not be deemed as commercial launch.

“**Commercially Reasonable Efforts**” means those efforts consistent with the exercise of prudent scientific and business judgment as applied by a party to the development and commercialization of its own pharmaceutical products at a similar stage of development and with similar market potential.

“**Compound**” means that certain pharmaceutical compound known as [\*\*\*].

“**Confidential Information**” has the meaning specified in **Section 8.1**.

“**Contract Manufacturer**” has the meaning specified in **Section 2.4**.

“**Cover**” (including variations thereof such as “Covered,” “Coverage,” or “Covering”) means that the manufacture, use, importation or sale of the Licensed Product which such term is

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being applied would infringe a Valid Claim of a patent in the absence of a grant of rights under such patent. The determination of whether an item or process is Covered by a Valid Claim shall be made on a country-by-country basis.

“**Disclosing Party**” has the meaning specified in **Section 8.1** hereof.

“**DMF**” means a Drug Master File 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.

“**EMA**” means the European Medicines Agency or any successor thereto.

“**Expenditure**” means the act of paying out funds to a Third Party for development of the Licensed Product. For the avoidance of doubt, Expenditure shall not include any credit for internal MDCO expenses, such as MDCO personnel expenses.

“**FDA**” means the United States Food and Drug Administration, or any successor thereto.

“**Field**” means all indications, including without limitation, all dosages, formulations, uses, and routes of administration for the Licensed Product.

“**Generic Competing Product**” has the meaning specified in **Section 4.1(c)(ii)** hereof.

“**Indemnitee**” has the meaning specified in **Section 10.4**.

“**Indemnitor**” has the meaning specified in **Section 10.4**.

“**Licensed Patents**” means, collectively, the Captisol Patents and the Licensed Product Patents.

“**Licensed Product**” means a pharmaceutical composition comprising the Compound [\*\*\*]. For clarity, the Licensed Product shall not include any product which is a combination product incorporating the Compound with any other active pharmaceutical ingredient.

“**Licensed Product Patents**” means all patents and patent applications in the Territory which Cover the use of Captisol with the Compound, other than the Captisol Patents, 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. Licensed Product Patents further include all other patents and patent applications, other than the Captisol Patents, which are owned or licensed by CyDex before the Effective Date or at any time during the Term of this Agreement, and which are necessary to develop, manufacture, and commercialize the Licensed Product or which are necessary for MDCO to exercise its license under this Agreement. Set forth in **Exhibit B** attached hereto is a list of the Licensed Products Patents as of the Effective Date. Such **Exhibit B** may be updated by CyDex from time to time during the Term.

“**Losses**” has the meaning set forth in **Section 10.1**.

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“**Marketing Approval**” means final approval of an NDA by the FDA for the United States, 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.

“**MDCO Know-How**” means information or data owned, licensed or generated by MDCO and its Affiliates, before and during the Term of this Agreement. For clarity, MDCO Know-How shall not include Product Know-How licensed under this Agreement.

“**MDCO Patents**” means all patents and patent applications owned now, licensed or developed during the Term of this Agreement by MDCO and its Affiliates, 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. For clarity, MDCO Patents shall not include Licensed Patents under this Agreement.

“**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.

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“**Product Know-How**” means information or data related to the Licensed Product owned, licensed or developed by CyDex and its Affiliates, which is not included within the Licensed Product Patents.

“**Receiving Party**” has the meaning specified in **Section 8.1**.

“**Regulatory Approval**” means, with respect to the Licensed Product in any country or jurisdiction, all approvals (including, where required, pricing and reimbursement approvals), registrations, licenses or authorizations from the relevant regulatory authority in a country or jurisdiction that is specific to the Licensed Product and necessary to market and sell such Licensed Product in such country or jurisdiction.

“**Royalty Obligation Term**” means, for each country within the Territory on a country-by-country basis, the time period commencing on the first Commercial Launch Date of the

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Licensed Product in such country and ending on the date that is the later of (i) the date that a Valid Claim no longer exists under the Licensed Patents in such country, or [\*\*\*].

“**SEC**” has the meaning specified in **Section 8.3**.

“**Specifications**” means the specifications for Captisol set forth in *Exhibit C* hereto, as such may be amended from time to time.

“**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 other than CyDex or MDCO or an Affiliate of either of them.

“**Valid Claim**” means a claim in any unexpired, issued patent which has not been irrevocably abandoned or held to be invalid or unenforceable by a non-appealed or unappealable decision of a court or other authority of competent jurisdiction, which is not admitted to be invalid through disclaimer or dedication to the public, and which Covers the Licensed Product.

## **2. GRANT OF RIGHTS.**

### **2.1 License Grants from CyDex to MDCO.**

**(a) Licensed Patents.** Subject to the terms and conditions of this Agreement, CyDex hereby grants to MDCO an exclusive, nontransferable (except with respect to the assignment provision in **Section 14.15** and even with respect to CyDex and its Affiliates regarding exclusivity) license during the Term under the Licensed Patents, solely to research, develop, make, have made, import, use, offer for sale and sell the Licensed Product in the Territory in 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 MDCO in the foregoing sentence shall be exclusive as to CyDex and non-exclusive as to any Third Party. MDCO may not sublicense the Licensed Patents, except as expressly set forth in **Section 2.3** below.

**(b) Know-How License.** Subject to the terms and conditions of this Agreement, CyDex hereby grants to MDCO an exclusive, nontransferable (except with respect to the assignment provision in **Section 14.15** and even with respect to CyDex and its Affiliates) license during the Term under CyDex’s rights in and to the Captisol Data Package and Product Know-How, solely to research, develop, make, have made, import, use, offer for sale and sell the Licensed Product in the Territory in the Field. Notwithstanding the foregoing, to the extent that any Captisol Data Package and Product Know-How are licensed to CyDex or its Affiliates by a Third Party on a non-exclusive basis, the license granted to MDCO in the foregoing sentence shall be exclusive as to CyDex and non-exclusive as to any Third Party. MDCO may not sublicense its rights to the Captisol Data Package or Product Know-How, except as expressly set forth in **Section 2.3** below.

\*\*\* 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.

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**(c) Scope of Licenses.** Unless otherwise provided in this Agreement, CyDex grants no rights to MDCO to manufacture, import, sell or offer for sale bulk Captisol.

**2.2 Grant of License from MDCO to CyDex.** MDCO hereby grants to CyDex a nonexclusive, transferable, perpetual, worldwide and royalty-free license, with the right to grant sublicenses (through multiple tiers of sublicensees), under MDCO's and its Affiliates' rights in and to Captisol Improvements to develop, make, have made, use, market, distribute, import, sell and offer for sale Captisol.

**2.3 Sublicensing.** MDCO shall have the right to grant sublicenses to any Third Party (collectively "**Sublicensees**") under the licenses granted to MDCO pursuant to **Section 2.1**; [\*\*\*]

**2.4 Contracting.** MDCO may manufacture the Licensed Product or contract the manufacture of the Licensed Product with reputable FDA-inspected third party manufacturers (each a "**Contract Manufacturer**"). To the extent necessary to engage a Contract Manufacturer for manufacturing the Licensed Product, MDCO shall be permitted under this Agreement to grant any such Contract Manufacturer a sublicense under the licenses granted to MDCO pursuant to **Section 2.1** solely for such purposes. MDCO shall ensure that all of its Contract Manufacturers will 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 MDCO hereunder.

**2.5 Technology Transfer.** Within [\*\*\*] after the Effective Date, CyDex shall provide MDCO with a technology transfer package, which shall include the Product Know-How and the Captisol Data Package, related to the formulation, filling and packaging of the Licensed Product. CyDex shall also, for a period of [\*\*\*] after the Effective Date, make its personnel available to MDCO and its Contract Manufacturers to respond to informational inquiries and provide technical assistance related to the Product Know-How and the Captisol Data Package. Beginning on the earlier of (i) [\*\*\*] after the first contact by MDCO relating to the technology transfer or (ii) [\*\*\*] after the Effective Date, MDCO shall compensate CyDex at the rate of [\*\*\*] for the time of CyDex personnel incurred to provide such services. Such technology transfer shall not include information related to the manufacture of bulk Captisol.

**2.6 Negative Covenant.** During the Term of this Agreement, CyDex and its Affiliates shall not develop or commercialize any pharmaceutical composition comprising the Compound, and shall not in any way assist any Third Party in developing or commercializing any pharmaceutical composition comprising the Compound.

### **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 Product.

\*\*\* 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.

4. COMPENSATION.

4.1 Payments and Royalties for Licenses.

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4.2 [\*\*\*]

**4.3 Currency.** All amounts due hereunder are stated in, and shall be paid in, U.S. dollars. Net Sales based on foreign revenue [\*\*\*]. MDCO shall provide CyDex, together with each royalty payment owed pursuant to **Section 4.1(c)** above, a schedule detailing the calculation of Net Sales resulting from the conversion of foreign revenue to U.S. dollars as set forth herein.

**4.4 Taxes.**

**(a) Taxes on Income.** Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement or the Supply Agreement.

**(b) Tax Cooperation.** The parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by MDCO to CyDex under this Agreement or the Supply Agreement. To the extent MDCO is required to deduct and withhold taxes on any payment to CyDex, MDCO shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to CyDex an official tax certificate or other evidence of such withholding sufficient to enable CyDex to claim such payment of taxes. CyDex shall provide MDCO any tax forms that may be reasonably necessary in order for MDCO to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. CyDex shall use reasonable efforts to provide any such tax forms to MDCO at least [\*\*\*] prior to the due date for any payment for which CyDex desires that MDCO 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.

**4.5 Late Payments.** Payment of CyDex's invoices shall be made within [\*\*\*] of MDCO's receipt of such invoices. Unpaid balances shall accrue interest, from due date until paid, at a rate equal to the prime rate, [\*\*\*], unless such unpaid balance is subject to a reasonable, good faith dispute by MDCO.

**5. RECORDS; REPORTS; AUDIT.**

**5.1 Records.** During the Term and for a period of [\*\*\*] thereafter, MDCO shall, and shall require its Affiliates and Sublicensees to maintain accurate records relating to Net Sales of the Licensed Product.

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**5.2 Reports.** MDCO shall update CyDex annually regarding development and commercial activities with respect to the Licensed Product.

**5.3 Audit.** Upon reasonable prior notice, such records shall be available during regular business hours for a period [\*\*\*], and not more often than [\*\*\*], by an independent certified public accountant selected by CyDex and reasonably acceptable to MDCO, for the sole purpose of verifying the accuracy of the financial reports furnished by MDCO pursuant to this Agreement. Any such auditor shall not disclose MDCO's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by MDCO or the amount of payments due by MDCO under this Agreement. Any amounts shown to be owed but unpaid shall be paid within [\*\*\*] from the accountant's report from the original due date, plus interest accrued thereon (from the applicable original due date) at the rate set forth in **Section 4.4** above. Any amounts shown to have been overpaid shall be refunded within [\*\*\*]. CyDex shall bear the full cost of such audit unless such audit discloses an underpayment by MDCO of more than [\*\*\*] of the amount due, in which case MDCO shall bear the full cost of such audit.

**6. DEVELOPMENT AND COMMERCIALIZATION BY MDCO.**

**6.1 Diligence.** MDCO shall (i) use at least Commercially Reasonable Efforts, and shall further require its Affiliates and Sublicensees to use at least Commercially Reasonable Efforts, to develop the Licensed Product, and to commercialize the Licensed Product following Regulatory Approval of the Licensed Product [\*\*\*].

**6.2 Costs and Expenses.** Other than those specified in this Agreement, MDCO shall be solely responsible for all costs and expenses related to its development and commercialization of the Licensed Product, including without limitation, costs and expenses associated with all preclinical activities and clinical trials, and all regulatory filings and proceedings relating to the Licensed Product.

**6.3 Right of Reference.** MDCO shall have the right to reference the DMF solely in connection MDCO's regulatory filings submitted in connection with obtaining Regulatory Approval for the Licensed Product.

**6.4 Access to MDCO'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 product formulation) by MDCO, its Sublicensees or Affiliates in connection with CyDex's development and commercialization of Captisol or for fulfilling its obligations under this Agreement, at no cost to CyDex. Upon request by CyDex, MDCO shall either provide CyDex with a copy of all such data or shall make such data accessible to CyDex at such times and locations mutually agreed upon by the parties.

**7. REGULATORY MATTERS.**

**7.1 Captisol Information Submitted for Regulatory Review.** Except as otherwise set forth herein, MDCO shall be solely responsible for all communications with regulatory agencies in connection with the Licensed Product. Notwithstanding the foregoing, MDCO shall

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provide CyDex with copies of the portions of all regulatory submissions containing Captisol data alone (and not in conjunction with any product formulation) [\*\*\*] prior to submission.

**7.2 Material Safety.** CyDex shall provide MDCO, in writing, from time to time, with (a) relevant 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, MDCO 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.** Either party 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. In the event that either party becomes aware of any adverse event relating to either the Licensed Product or Captisol, the party shall timely inform the other party of any such adverse event.

## **8. CONFIDENTIALITY.**

**8.1 Definition.** MDCO 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 will be governed by the provisions of this **Section 8**. Neither MDCO nor CyDex 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 designated in writing by the Disclosing Party as “Confidential” (or equivalent), and all material disclosed orally which is declared to be confidential by the Disclosing Party and confirmed in a writing delivered to the Receiving Party within [\*\*\*] of such 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 and Product Know-How. MDCO’s Confidential Information includes MDCO Patents and MDCO Know-How.

**8.2 Obligation.** CyDex and MDCO agree that they will disclose the other’s Confidential Information to its own 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. Neither party shall disclose Confidential Information of the other to any Third Party without the other’s prior written consent, and any such disclosure to a third party shall be pursuant to the terms of a non-disclosure agreement no less restrictive than this **Section 8**. Each party shall take such action to preserve the confidentiality of each other’s Confidential Information as it would

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customarily take to preserve the confidentiality of its own Confidential Information (but in no event less than a reasonable standard of care). Unless otherwise specified in this Agreement and subject to terms and conditions in this Agreement, each party, upon the other's request, will return all the Confidential Information disclosed to the other party pursuant to this Agreement, including all copies and extracts of documents, within [\*\*\*] of the request, and in any event, promptly following the termination of this Agreement, except that the receiving party may retain [\*\*\*] for archival purposes and (ii) [\*\*\*].

**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 appropriate documentation:

(i) at the time of disclosure is in the public domain;

(ii) after disclosure, becomes part of the public domain, by publication or otherwise, through no fault of the Receiving Party;

(iii) 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 prior to the execution of this Agreement; or

(iv) is made available to the Receiving Party by an independent third party, 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.

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 United States Securities and Exchange Commission (the "SEC"), or in the course of litigation, *provided* that in all cases the Receiving Party shall give the other party prompt notice of the pending disclosure and make a reasonable effort to obtain, or to assist the Disclosing Party in obtaining, a protective order preventing or limiting 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. MDCO may further disclose CyDex's Confidential Information to extent that such disclosure is necessary to develop, file for Regulatory Approval, or commercialize the Licensed Product, or to seek, prosecute and maintain intellectual property protection for the Licensed Product.

**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 injunctive relief in addition to any other remedy which it may have, without need to post any bond or security.

**8.5 Third Party Information.** MDCO acknowledges that CyDex's Confidential Information includes information developed by [\*\*\*] that is confidential to both CyDex and [\*\*\*]. In so far as Confidential Information of [\*\*\*] is disclosed, [\*\*\*] is a third-party

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beneficiary of this **Section 8** of this Agreement and may enforce it or seek remedies pursuant to it in accordance with its terms.

**8.6 Public Announcements.** The Parties will mutually agree on a press release to be issued upon execution of this Agreement or reasonably soon thereafter. 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. Prior to any such public announcement, the Party wishing to make the announcement will submit a draft of the proposed announcement to the other Party in sufficient time to enable such other Party to consider and comment thereon.

**9. REPRESENTATIONS AND WARRANTIES.**

**9.1 Mutual Representations and Warranties.** Each party represents and warrants to the other as follows:

(i) it is a corporation duly organized and validly existing under the laws of the state or country of its incorporation;

(ii) it has the complete and unrestricted power and right to enter into this Agreement and to perform its obligations hereunder;

(iii) 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;

(iv) 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;

(v) 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;

(vi) 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; and

(vii) 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.

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**9.2 Additional Representations and Warranties of CyDex.** CyDex represents and warrants to MDCO that, as of the Effective Date:

(a) it (directly or through its Affiliates) is the owner or licensee of the Licensed Patents and has the right to grant the licenses to MDCO for the Captisol Data Package, Product Know-How, and the Licensed Patents pursuant to this Agreement, and it has not and will not grant such license to any Third Party;

(b) to CyDex's knowledge, it (directly or through its Affiliates) is the owner of all the intellectual property rights necessary to develop, manufacture, and commercialize the Licensed Product, and all such rights have been licensed to MDCO pursuant to this Agreement;

(c) to CyDex's knowledge, other than the intellectual property licensed to MDCO pursuant to this Agreement, no other intellectual property right and interests are required or necessary to develop, manufacture, and commercialize the Licensed Product;

(d) after the Effective Date, it (directly or through its Affiliates) shall provide to MDCO pursuant to **Section 2.5** above, all material Confidential Information of CyDex pertaining to the development, manufacture, or commercialization of the Licensed Product;

(e) as of the Effective Date, CyDex or any of its Affiliates has not received any notice from any Third Party asserting or alleging that any research or development of the Licensed Product prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party;

(f) to CyDex's knowledge, there are no actual, pending, alleged or threatened adverse actions, suits, claims, interferences or formal governmental investigations pertaining to the Licensed Product, the Licensed Patents and the Product Know How by or against CyDex or any of its Affiliates in or before any court, governmental or regulatory authority; and

(g) CyDex covenants and agrees that it will not enter into any agreement or other arrangement with any Third Party following the Effective Date that would limit MDCO's right and ability to exploit the rights and licenses granted by CyDex to MDCO under this Agreement.

**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 OR THE CAPTISOL DATA PACKAGE, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, TITLE AND NON-INFRINGEMENT OF THIRD PARTY RIGHTS.

**10. INDEMNIFICATION.**

**10.1 By CyDex.** CyDex shall defend, indemnify and hold MDCO and its Affiliates and Sublicensees, and each of their respective directors, officers and employees, harmless from and against any and all losses, damages, liabilities, costs and expenses (including the reasonable costs and expenses of attorneys and other professionals) (collectively "**Losses**") incurred by

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MDCO 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: (a) the manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of Capitsol by CyDex and its Affiliates; or (b) CyDex’s breach of this Agreement, including without limitation any of its representations and warranties set forth in **Sections 9.1** and **9.2**, and to the extent that such Losses are not due to MDCO’s negligence or misconduct.

**10.2 By MDCO.** MDCO shall defend, indemnify and hold CyDex and its Affiliates, and each of their respective directors, officers and employees, harmless from and against any and all Losses incurred by CyDex as a result of any Claim by a Third Party, to the extent such Losses arise out of: (a) the manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of the Licensed Product by MDCO, its Affiliates and Sublicensees; or (b) MDCO’s breach of this Agreement, including without limitation any of its representations and warranties set forth in **Section 9.1** and to the extent that such Losses are not due to CyDex’s negligence or 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 Indemnitor.

**10.4 Procedure.** The party intending to claim indemnification under this **Section 10** (an “**Indemnitee**”) shall promptly notify the other party (the “**Indemnitor**”) of any Claim in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall assume the defense thereof whether or not such Claim is rightfully brought; *provided, however*, that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitor, unless Indemnitor does not assume the defense, in which case the reasonable fees and expenses of counsel retained by the Indemnitee shall be paid by the Indemnitor. The Indemnitee, and its employees and agents, shall cooperate fully with the Indemnitor and its legal representatives in the investigations of any Claim. The Indemnitor shall not be liable for the indemnification of any Claim settled or compromised by the Indemnitee without the written consent of the Indemnitor.

## **11. LIMITATION OF LIABILITY.**

**11.1 Limitation of Remedies.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES OR LOSS OF PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS **SECTION 11** IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 10, OR DAMAGES AVAILABLE FOR A PARTY’S BREACH OF CONFIDENTIALITY OBLIGATIONS IN **SECTION 8**.

### **11.2 [\*\*\*]**

\*\*\* 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.

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**12. MANAGEMENT OF LICENSED PATENTS.**

**12.1 Prosecution and Maintenance.**

(a) **CyDex Patents.** CyDex shall maintain or abandon, [\*\*\*].

(b) **Licensed Product Patents.** MDCO shall maintain [\*\*\*], *provided* that (i) CyDex shall be provided with the right and opportunity to give comments and recommendations as to the overall strategy regarding the filing, prosecution and maintenance of the Licensed Product Patents, and (ii) MDCO shall seek to prosecute, obtain and maintain the Licensed Product Patents in [\*\*\*] (the “**Major Markets**”). MDCO agrees that, during the Term, it will use best efforts to prosecute, obtain and maintain the Licensed Product Patents in the Major Markets. In the event that MDCO decides not to prosecute and maintain the Licensed Product Patents in a country or countries outside of the Major Markets, MDCO shall provide not less than [\*\*\*] prior written notice of such decision, and CyDex shall have the option to take over the prosecution and maintenance in such country or countries. For clarity, in the event that MDCO fails to meet such requirements for any Major Market country, CyDex shall have the right to terminate this Agreement pursuant to **Section 13.2** hereof with respect to such country (but not other countries within the Territory).

(c) **MDCO Patents and MDCO Know-How.** MDCO shall be the sole and exclusive owner of MDCO Patents and MDCO Know How. [\*\*\*].

**12.2 Infringement of Captisol Patents by Third Parties.** If MDCO becomes aware that a third party may be infringing a Captisol Patent, it will promptly notify CyDex in writing, providing all information available to MDCO regarding the potential infringement. CyDex shall take whatever, if any, action it deems appropriate, in its sole discretion, against the alleged infringer. If CyDex elects to take action, MDCO shall, at CyDex’s request and expense, cooperate and shall cause its employees to cooperate with CyDex in taking any such action, including but not limited to, cooperating with the prosecution of any infringement suit by CyDex related to a Captisol Patent. MDCO shall not take any such action against the alleged infringer related to a Captisol Patent without the written consent of CyDex. If either party recovers monetary damages from any Third Party in a suit or action brought for infringement of a Captisol Patent, such recovery shall be allocated [\*\*\*]. For clarity, this **Section 12.2** shall not apply in the event of Product Infringement as defined below in **Section 12.3(a)**. MDCO shall have the right to consent to any settlement concluded by CyDex that would provide the alleged infringer any right to use the Captisol Patents for a product containing the Compound.

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### 12.3 Infringement of Licensed Product Patents by Third Parties.

**(a) Notification.** Each party shall promptly notify the other party in writing of any existing or threatened infringement of the Licensed Product Patents through the development or commercialization of a product comprising the Compound as an active ingredient by a Third Party, of which such Party becomes aware, including any “patent certification” filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions and of any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability or non-infringement of any of the Licensed Product Patents (collectively “**Product Infringement**”).

**(b) Product Infringement.**

**(i)** For any Product Infringement, MDCO shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity engaged in such Product Infringement. If MDCO fails to institute and prosecute an action or proceeding to abate the Product Infringement within a period of [\*\*\*] after the first notice under this section to elect to enforce the Licensed Product Patent or otherwise having knowledge of the Product Infringement, then CyDex shall have the right, but not the obligation, to commence a suit or take action to enforce the applicable Licensed Product Patent against such third Party perpetrating such Product Infringement at its own cost and expense. In this case, MDCO shall take appropriate actions in order to enable CyDex to commence a suit or take the actions set forth in the preceding sentence.

**(ii)** Each party shall provide to the party enforcing any such rights under this **Section 12.2** reasonable assistance in such enforcement, at such enforcing party’s request and expense, including joining such action as a party plaintiff if required by applicable law to pursue such action. The enforcing party shall keep the other party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other party’s comments on any such efforts.

**(iii)** Each party [\*\*\*].

**(iv)** The party not bringing an action with respect to Product Infringement under this **Section 12.2** shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such party shall at all times cooperate fully with the party bringing such action.

**(c) Allocation of Proceeds.** If either party recovers monetary damages from any Third Party in a suit or action brought for a Product Infringement, such recovery shall be [\*\*\*].

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### 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 expiration of MDCO’s obligations to pay royalties under **Section 4.1(c)**, unless terminated earlier as set forth herein.

#### 13.2 Termination for Breach.

**(a) Notice.** If either party believes that the other is in material breach of this Agreement, then the party holding such belief (the “**Non-breaching Party**”) may deliver notice of such breach to the other party (the “**Notified Party**”). The Notified Party shall have thirty (30) days to cure such breach to the extent involving non-payment of amounts due hereunder, and one hundred twenty (120) days to either cure such breach for all other material breaches, or, if cure of such breach other than non-payment cannot reasonably be effected within such one hundred twenty (120) day period, to deliver to the Non-breaching Party a plan reasonably calculated to cure such breach within a timeframe that is reasonably prompt in light of the circumstances then prevailing but in no event in excess of an additional ninety (90) day period. Following delivery of such a plan, the Notified Party shall diligently carry out the plan and cure the breach and the cure period shall be extended by the time period provided in such plan but in no event to exceed two hundred ten (210) days from the date of any initial breach notice delivered under this **Section 13.2**.

**(b) Failure to Cure.** If the Notified Party fails to cure a material breach of this Agreement as provided for in **Section 13.2**, then the Non-Breaching Party may terminate this Agreement upon written notice to the Notified Party.

**(c) Other Termination Rights.** CyDex shall additionally have the right to terminate this Agreement either in the United States or Europe, as applicable, in accordance with **Section 4.2(d)**.

**(d) Disputes.** If a party gives notice of termination under this **Section 13.2** and the other Party disputes whether such termination is proper under this **Section 13.2**, then the issue of whether this Agreement may properly be terminated upon expiration of the notice period (unless such breach is cured as provided in **Section 13.2**) shall be resolved in accordance with **Section 14.4**. If as a result of such dispute resolution process it is determined that the notice of termination was proper, then such termination shall be deemed to have been effective [\*\*\*] following the date of the notice of termination (or such other time period applicable pursuant to **Section 13.2**). If as a result of such dispute resolution process it is determined that the notice of termination was improper, then no termination shall have occurred and this Agreement shall remain in effect.

**13.3 Termination by MDCO for Convenience.** MDCO shall have the right to terminate this Agreement in its entirety without cause by providing CyDex with [\*\*\*] prior written notice.

**13.4 CyDex Rights upon Termination (Other Than for CyDex Breach).** In event that MDCO terminates the Agreement without cause pursuant to **Section 13.3** or that CyDex

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terminates this Agreement pursuant to **Section 13.2**, the following shall apply (in addition to any other rights and obligations otherwise under this Agreement with respect to such termination):

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

**13.5 CyDex Rights upon Termination (If for CyDex Breach).** In event that MDCO terminates the Agreement due to CyDex's breach pursuant to **Section 13.2**, the following shall apply (in addition to any other rights and obligations otherwise under this Agreement with respect to such termination):

**(a) Termination of Licenses.** All rights granted to MDCO or all rights granted to CyDex herein shall immediately terminate, *provided*, that, in the event that the termination is for one or more countries, the rights granted to MDCO herein and the rights granted to CyDex shall terminate in the country or countries where this Agreement has been terminated.

**(b) Regulatory Filings.** MDCO shall retain all regulatory filings and data generated by MDCO, its Affiliates and Sublicensees during the Term of this Agreement, including any existing Market Approval for the Licensed Product, and CyDex shall not have rights to use any such regulatory filings, data or Market Approval. In the event that the termination is for one or more countries, this section shall only apply to the country or countries where this Agreement has been terminated.

**(c) Return of Records.** 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 [\*\*\*], and (ii) in the event that the termination is for one or more countries, the records to be returned shall be for the country or countries where this Agreement has been terminated.

**13.6 MDCO Rights Upon Expiration.** On a country-by-country basis, upon the expiration of MDCO's obligations to pay royalties under **Section 4.1(c)**, the license granted to

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MDCO under this Agreement shall become a fully-paid, royalty-free, and perpetual license for the Licensed Product in the Field.

**13.7 Termination of the Supply Agreement.** For clarity, this Agreement shall terminate if the Supply Agreement is terminated by MDCO without cause, or terminated by CyDex because of any material breach by MDCO.

**13.8 Survival.** Notwithstanding any other provisions of this Agreement, any liability or obligation of either party to the other for acts or omissions prior to 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 MDCO of its obligation to pay CyDex royalties for all Licensed Product sold by MDCO, its Affiliates or Sublicensees prior to the effective date of such expiration or termination. Sections 2.2 (Grant of License from MDCO to CyDex), 4.1 (Payments and Royalties for Licenses), 4.3 (Currency), 4.4 (Taxes), 4.5 (Late Payments), 5 (Records; Reports; Audits), 6.4 (Access to MDCO's Data), 7.3 (Adverse Event Reporting), 8 (Confidentiality), 9.3 (Disclaimer), 10 (Indemnification), 11 (Limitation of Liability), 13.4 (CyDex Rights Upon Termination (Other Than for CyDex Breach)), 13.5 (CyDex Rights Upon Termination (If for CyDex Breach)), 13.6 (MDCO's Rights Upon Expiration), 13.8 (Survival), and 14 (General Provisions) shall survive termination or expiration of this Agreement.

#### **14. GENERAL PROVISIONS.**

**14.1 Non-Solicitation.** During the Term and for a period of [\*\*\*] thereafter, neither party shall solicit, induce, encourage or attempt to induce or encourage any employee of the other party to terminate his or her employment with such other party or to breach any other obligation to such other party. This section is not meant to encompass general solicitations such as may be found in newspaper advertisements and the like.

**14.2 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 incur any debts or make any commitments for the other.

**14.3 Compliance with Law.** Each of the parties will 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.

#### **14.4 Arbitration.**

**(a) Procedure.** Except as otherwise expressly set forth in **Section 14.4(b)** below, 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 Chicago, Illinois. The arbitration shall be conducted by an arbitrator reasonably knowledgeable about the pharmaceutical industry and acceptable to CyDex and MDCO. If CyDex and MDCO cannot

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agree on a single arbitrator within [\*\*\*] after a demand for arbitration has been made, CyDex shall appoint an arbitrator, MDCO shall appoint an arbitrator, the two (2) arbitrators shall appoint a third arbitrator, and the three (3) arbitrators shall hear and decide the issue in controversy. If either party fails to appoint an arbitrator within [\*\*\*] after service of the demand for arbitration, then the arbitrator appointed by the other party shall arbitrate any controversy in accordance with this **Section 14.4(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, [\*\*\*].

**(b) Short-Form Arbitration.** Any dispute subject to short-form arbitration as provided in 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 Chicago, Illinois by a single arbitrator reasonably knowledgeable about the pharmaceutical industry and appointed in accordance with such rules. Such arbitrator shall make his or her determination on the basis of “baseball arbitration” principles. THE FOREGOING REMEDY SHALL BE EACH PARTY’S SOLE AND EXCLUSIVE REMEDY WITH RESPECT TO ANY SUCH DISPUTE. The expenses of any arbitration, including the reasonable attorney fees of the prevailing party, [\*\*\*]. In each case, the parties and arbitrator shall use all diligent efforts to complete such arbitration within [\*\*\*] of appointment of the arbitrator.

**(c) 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.

**(d) Interim Equitable Relief.** Each party shall, in addition to all other remedies accorded by law 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 14.4**, or (ii) for such interim injunctive relief.

**(e) Binding Effect.** The provisions of this **Section 14.4** 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.

**14.5 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.

**14.6 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, including but not limited to, war, insurrection, riot, fire, flood or other unusual

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weather condition, explosion, act of God, peril of the sea, strike, lockout or other industrial disturbance, sabotage, accident, embargo, breakage of machinery or apparatus, injunction, act of governmental authority, compliance with governmental order on national defense requirements, or inability 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.

**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; facsimile with receipt confirmed; or 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.  
10513 W. 84<sup>th</sup> Terrace  
Lenexa, KS 66214  
Attention: President  
Fax: (913) 685-8856

*With a copy to:* General Counsel  
Ligand Pharmaceuticals  
11085 North Torrey Pines Road  
Suite 300  
La Jolla, CA 92037  
Fax: 858-550-7272

*If to MDCO, to:* The Medicines Company  
8 Sylvan Way  
Parsippany, NJ 07054  
Attention: [\*\*\*]  
Fax: 862-207-6013

*With a copy to:* [\*\*\*]  
The Medicines Company  
8 Sylvan Way  
Parsippany, NJ 07054  
Fax: 862-207-6062

If sent by facsimile transmission [\*\*\*] shall be deemed to be the date on which such notice, request or communication was given. If sent by overnight courier, the [\*\*\*] 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 [\*\*\*] 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.** 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

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release or public disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other party, except as may be required by law. 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 Securities Exchange Commission (“SEC”) (or equivalent foreign agency) to the extent required by law after complying with the procedure set forth in this **Section 14.8**, or (ii) under conditions of confidentiality in connection with investment and similar corporate transactions. In the event of a required public announcement, the party making such announcement shall provide the other party with a copy of the proposed text prior to such announcement sufficiently in advance of the scheduled release of such announcement to afford such other party a reasonable opportunity to review and comment upon the proposed text and the timing of such disclosure.

**14.9 Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of New Jersey (without giving effect to any conflicts of law principles that require the application of the law of a different state).

**14.10 Entire Agreement; Amendment.** This Agreement and all Exhibits attached hereto or thereto contain the entire agreement of the parties relating to the subject matter hereof and supersede any and all prior agreements, written or oral, between CyDex and MDCO relating to the subject matter of this Agreement. This Agreement may not be amended unless agreed to in writing by both parties.

**14.11 Binding Effect.** This Agreement shall be binding upon, and the rights and obligations hereof shall apply to the CyDex and MDCO 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.

**14.12 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.

**14.13 Severability.** If a final judicial determination is made that any provision of this Agreement is unenforceable, this Agreement shall be rendered void only to the extent that such judicial determination finds such provisions unenforceable, and such unenforceable provisions shall be automatically reconstituted and become a part of this Agreement, effective as of the date first written above, to the maximum extent they are lawfully enforceable.

**14.14 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.

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Notwithstanding the foregoing, either party may assign its rights and delegate its obligations under this Agreement to an Affiliate or to a third party successor, whether by way of merger, sale of all or substantially all of its assets, sale of stock or otherwise, without the other party's prior written consent. As a condition to any permitted assignment hereunder, the assignor must guarantee the performance of any assignee to the terms and obligations of this Agreement. Any assignment not in accordance with this **Section 14.14** shall be void.

**14.15 Third Party Beneficiaries.** Except for the rights of Indemnitees pursuant to **Section 10** hereof, and subject to **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 MDCO or such Indemnitees, and not Sublicensees.

**14.16 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.

**14.17 Counterparts.** This Agreement may be executed in two counterparts, 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]*

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

**CYDEX PHARMACEUTICALS, INC.**

By: /s/ Matt Foehr

Name: Matt Foehr

Title: Executive Vice President, Chief Operating Officer

**THE MEDICINES COMPANY**

By: /s/ Clive A. Meanwell

Name: Clive A. Meanwell

Title: Chairman and CEO



EXHIBIT A: CAPTISOL PATENTS

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\*\*\* 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.

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LICENSE AGREEMENT

EXHIBIT A-3

\*\*\* 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.



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**EXHIBIT B: LICENSED PRODUCT PATENTS**

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\*\*\* 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.

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**EXHIBIT C: SPECIFICATIONS**

[\*\*\*]

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*LICENSE AGREEMENT*

*EXHIBIT C-1*

\*\*\* 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.

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*LICENSE AGREEMENT*

*EXHIBIT D-1*

\*\*\* 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.

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**EXHIBIT E: LIMITATION OF DAMAGES**

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*LICENSE AGREEMENT*

*EXHIBIT E-1*

\*\*\* 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.



CERTAIN MATERIAL (INDICATED BY AN ASTERISK) 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

**THIS SUPPLY AGREEMENT** (this “**Agreement**”) is made this 1<sup>st</sup> day of June, 2011 (the “**Effective Date**”) between:

**CYDEX PHARMACEUTICALS, INC.**, a Delaware corporation with offices at 10513 W. 84<sup>th</sup> Terrace, Lenexa, Kansas 66214 (“**CyDex**”); and

**THE MEDICINES COMPANY**, a Delaware corporation with offices at 8 Sylvan Way, Parsippany, New Jersey 07054 (“**MDCO**”).

### **RECITALS**

**WHEREAS**, CyDex and MDCO are also parties to that certain License Agreement of even date herewith (the “**License Agreement**”); and

**WHEREAS**, CyDex desires to sell Captisol® to MDCO or its Contract Manufacturers (defined below), and MDCO desires to obtain supplies of Captisol® from CyDex, for use in the Licensed Product, in accordance with the terms and conditions contained herein;

**NOW, THEREFORE**, in consideration of the following mutual promises and other good and valuable consideration, the receipt and sufficiency of which is acknowledged, the parties, intending to be legally bound, agree as follows:

#### **1. DEFINITIONS.**

For the purposes of this Agreement, defined terms shall have the meanings defined in the License Agreement or as defined elsewhere in this Agreement. For reference purposes, “**Affiliate**”, “**Captisol**”, “**Claim**”, “**Clinical Grade Captisol**”, “**Commercial Grade Captisol**”, “**Commercial Launch Date**”, “**Compound**”, “**Contract Manufacturer**”, “**FDA**”, “**Licensed Product**”, “**NDA**” “**Specifications**” and “**Sublicensee**” are defined in the License Agreement.

#### **2. PURCHASE AND SUPPLY OF CAPTISOL.**

**2.1 Clinical Quantities.** MDCO shall have the right to purchase Clinical Grade Captisol from CyDex, at the purchase prices specified in *Exhibit A* hereto; such purchase prices [\*\*\*] CyDex’s production point or storage facilities.

**2.2 Purchase Commitment.** Subject to the provisions of this Agreement and during the Term of this Agreement, MDCO agrees that MDCO and its Affiliates and Sublicensees and their Contract Manufacturers shall purchase [\*\*\*] of their requirements for Captisol for use in the formulation of Licensed Product exclusively from CyDex. This Agreement and the License Agreement do not grant MDCO, its Affiliates or Sublicensees or their Contract Manufacturers the right to manufacture (or have manufactured on their behalf) Captisol without CyDex’s prior written consent.

\*\*\* 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.

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**2.3 Supply Commitment.** CyDex agrees that CyDex shall produce (or have produced for it) and sell to MDCO and its Affiliates and Sublicensees and their Contract Manufacturers [\*\*\*] of MDCO's and its Affiliates' and Sublicensees' and their Contract Manufacturers' requirements for Captisol for use in the formulation of Licensed Product, during the Term and subject to the provisions of this Agreement; and *provided* that, and notwithstanding anything to the contrary in this Agreement, in no event shall CyDex be obligated to supply to MDCO or its Affiliates or Sublicensees or their Contract Manufacturers more than an aggregate quantity of [\*\*\*] (the "**Volume Threshold**").

**2.4 Third-Party Manufacturers.** Without limiting CyDex's responsibility under this Agreement, CyDex shall [\*\*\*].

### 3. SUPPLY TERMS.

**3.1 Long-Term Forecast.** No later than [\*\*\*] to the anticipated Commercial Launch Date by MDCO or its Affiliates or Sublicensees of a Licensed Product in any particular country, MDCO shall provide CyDex with a non-binding forecast setting forth MDCO's estimate of the required quantities of Commercial Grade Captisol for each of the following [\*\*\*]. Such long-term forecast shall thereafter be updated by MDCO at least [\*\*\*].

**3.2 Binding Detailed Forecast.** At least [\*\*\*] to the date on which MDCO will issue its first purchase order to CyDex for Commercial Grade Captisol (the "**First Commercial Order Date**"), MDCO shall provide to CyDex a detailed rolling forecast setting forth MDCO's requirements and anticipated delivery schedules for Commercial Grade Captisol for each [\*\*\*] during a [\*\*\*] period (the "**Detailed Forecast**") which includes the [\*\*\*] in which the First Commercial Order Date occurs and the next [\*\*\*]. For purposes of this Agreement, a [\*\*\*] means the [\*\*\*]. The Detailed Forecast shall thereafter be updated by MDCO 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 [\*\*\*] during the [\*\*\*] commencing on the first day of the next [\*\*\*] following the date on which such Detailed Forecast is submitted. The Detailed Forecast shall be firm and binding on MDCO, subject to the permissible variances set forth in **Section 3.3** below, with respect to the [\*\*\*] covered by such updated Detailed Forecast ("**Q1**", "**Q2**", "**Q3**", respectively, and where the fourth [\*\*\*] shall be "**Q4**"). If MDCO fails to provide any updated Detailed Forecast in accordance with this **Section 3.2**, the Detailed Forecast last provided by MDCO shall be deemed to be MDCO's binding Detailed Forecast for the next succeeding [\*\*\*]. For clarification purposes, the Detailed Forecast shall not include orders placed by MDCO for quantities of Commercial Grade Captisol to be used for validation purposes.

**3.3 Detailed Forecast Variances.** 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 [\*\*\*] covered by such updated Detailed Forecast, no change may be made to the forecast provided for the [\*\*\*] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex;

\*\*\* 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.

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(ii) for the [\*\*\*] covered by such updated Detailed Forecast, no change in excess of a [\*\*\*] volume increase or decrease may be made to the forecast provided for the [\*\*\*] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex; and

(iii) for the [\*\*\*] covered by such updated Detailed Forecast, no change in excess of a [\*\*\*] volume increase or decrease may be made to the forecast provided for the [\*\*\*] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex.

**3.4 Modified Specifications.** CyDex shall have the right to change the Specifications from time to time during the Term, provided however that any such change shall not materially affect commercial viability of License Product or regulatory status of Licensed Product. In the event that CyDex modifies Specifications, CyDex shall give MDCO at least [\*\*\*] notice of such change. MDCO shall cooperate with CyDex to have such change approved by all regulatory agencies having jurisdiction at CyDex's own costs, including replacing Captisol already purchased by MDCO with Captisol under the new modified Specifications and reimbursing MDCO all costs associated with the finished product if it is no longer suitable for human use. In the event that any regulatory agency having jurisdiction requires CyDex to implement any changes to the Specifications for Captisol generally (and not for the Licensed Product specifically), CyDex shall use all reasonable efforts to make such changes and shall, within [\*\*\*] of learning of required changes to the Specifications, advise MDCO as to any lead-time changes or other terms that may result from a change to the Specifications at CyDex's own costs, including replacing Captisol already purchased by MDCO with Captisol under the new modified Specifications and reimbursing MDCO all costs associated with the finished product if it is no longer suitable for human use. In the event that any modification to Specifications for Captisol generally (and not for the Licensed Product specifically) by CyDex leads to delay or withdrawal of Licensed Product or makes Licensed Product no longer commercially viable, Section 3.5 of this Agreement shall apply.

### **3.5 Inability to Supply.**

**(a) Notice.** CyDex shall notify MDCO if CyDex is unable to supply the quantity of (i) Commercial Grade Captisol ordered by MDCO in accordance with the Purchase Volume Limitations set forth in **Section 3.3** or (ii) Clinical Grade Captisol ordered by MDCO as set forth in **Section 2.1** above: (1) within [\*\*\*] after CyDex's receipt of a purchase order from MDCO; or (2) immediately upon becoming aware of an event of *force majeure* or any other event including, but not limited to CyDex's failure to pass any regulatory inspections or as a result of modified Specifications that would render CyDex unable to supply to MDCO the quantity of Captisol that CyDex is required to supply hereunder.

**(b) Allocation.** If CyDex is unable to supply to MDCO the quantity of Captisol that CyDex is required to supply hereunder, CyDex (i) shall allocate its available Captisol among MDCO 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 and (ii) shall take all reasonable steps necessary to minimize supply delays. The supply allocation provided in this **Section 3.5(b)** and the alternate suppliers

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provisions of **Section 3.5(c)** shall be CyDex's sole obligation and MDCO's sole and exclusive remedy for any supply shortage.

**(c) Alternate Suppliers.** If CyDex fails to supply to MDCO, or if CyDex will be unable to supply MDCO with [\*\*\*] of the quantity of Captisol properly forecasted and ordered by MDCO (and provided such order was within the Purchase Volume Limitations) in accordance with this Agreement, for a period of [\*\*\*] or longer ("**Supply Interruption**") then CyDex shall immediately provide written notice to MDCO of the Supply Interruption. In the event of a Supply Interruption:

(i) [\*\*\*]

(ii) [\*\*\*]

If CyDex is unable to resolve such Supply Interruption within [\*\*\*] after the first day of the Supply Interruption or has not taken steps within such time period likely to resolve such Supply Interruption pursuant to clauses **3.5(c)(i) or (ii)**, then MDCO shall additionally have the non-exclusive right and license, notwithstanding **Section 2.1(c)** of the License Agreement, to make (by MDCO or its Affiliates) or have made (by a contract manufacturer via sublicense, other than the Third Party Manufacturer) quantities of sulfobutylether (beta) cyclodextrin, sodium salt necessary to replace quantities of Captisol not provided by CyDex due to the Supply Interruption, for use in the Licensed Product. After CyDex resumes manufacture and supply of Captisol, MDCO shall use its best efforts to terminate the supply arrangement with any such third party and continue to purchase Captisol from CyDex. Any transfer of CyDex's Captisol manufacturing technology (which shall not include technology which is proprietary to the Third Party Manufacturer or Pfizer) to MDCO or its contract manufacturer shall be subject to contractual covenants reasonably satisfactory to CyDex regarding confidentiality, limitations on use and non-competition. In the event of a dispute between the parties as to whether or not a Supply Interruption has occurred, such dispute shall be finally resolved by short-form arbitration in accordance with **Section 14.4(b)** of the License Agreement.

**3.6 Delivery.** Unless otherwise agreed in writing by the parties, Captisol shall be delivered [\*\*\*] CyDex's production point or storage facilities.

**3.7 Product Recalls.** If any Captisol should be alleged or proven not to meet the Specifications, MDCO shall notify CyDex immediately, and both parties shall cooperate fully regarding the investigation and disposition of any such matter. In the event of a dispute arises between the parties as to whether or not Captisol purchased by MDCO meets the Specifications, such dispute shall be immediately resolved by short-form arbitration in accordance with **Section 14.4(b)** of the License Agreement. If (i) MDCO and CyDex agree in writing that it is appropriate to recall any Licensed Product, or (ii) the FDA requires the recall of any Licensed Product, and in either case such recall is solely due to issues relating to Captisol, then CyDex agrees, upon substantiation thereof, [\*\*\*]. For clarity, if such recall is not solely due to issues relating to Captisol, or is due in part to MDCO's breach of this Agreement, negligence or willful misconduct, then MDCO shall pay for such recalls. MDCO shall maintain records of all sales of Licensed Product and customers sufficient to adequately administer any such recall, for a period of [\*\*\*] after expiration or termination of this Agreement.

\*\*\* 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.

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**4. COMPENSATION.**

**4.1 Pricing.**

**(a) Captisol Purchase Prices.** The purchase prices for Captisol pursuant to this Agreement are as specified in *Exhibit A* attached hereto. CyDex reserves the right to increase such purchase prices set forth in *Exhibit A* on each January 1 during the Term, by written notice no less than [\*\*\*] to MDCO, by a percentage equal to the lesser of (i) the [\*\*\*].

**(b) Shortfall Reimbursement.** If MDCO fails to order for any [\*\*\*] a quantity of Commercial Grade Captisol to be delivered during such [\*\*\*] that is equal to or greater than the quantity of Commercial Grade Captisol MDCO is obligated to purchase pursuant to the applicable Detailed Forecast (the difference between the quantity of Commercial Grade Captisol MDCO is obligated to purchase in [\*\*\*] pursuant to the applicable Detailed Forecast and the amount of Commercial Grade Captisol that MDCO actually orders in [\*\*\*], the "Shortfall"), then MDCO agrees to reimburse CyDex for [\*\*\*] of the purchase price of the Shortfall quantities.

**(c) Compound Supplies.** For clarity, MDCO or its Contract Manufacturers shall at their cost arrange for supplies of the Compound.

**4.2 Payments.** All amounts due hereunder are stated in, and shall be paid in, U.S. dollars. Payment of CyDex's invoices shall be made within [\*\*\*] days of MDCO's receipt of such invoices. Unpaid balances shall accrue interest, from due date until paid, at a rate equal to [\*\*\*].

**5. REPRESENTATIONS AND WARRANTIES.**

[\*\*\*]

**5.2 Mutual Representations and 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.

**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 AND FITNESS FOR A PARTICULAR PURPOSE, TITLE AND NON-INFRINGEMENT OF THIRD PARTY RIGHTS.

**6. INDEMNIFICATION.**

**6.1 By CyDex.** CyDex shall defend, indemnify and hold MDCO and its Affiliates and Sublicensees, and each of their respective directors, officers and employees, harmless from and against any and all losses, damages, liabilities, costs and expenses (including the reasonable

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costs and expenses of attorneys and other professionals) (collectively “**Losses**”) incurred by MDCO 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: (a) the manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of Capitsol by CyDex and its Affiliates; or (b) CyDex’s breach of this Agreement, including without limitation any of its representations and warranties set forth in **Sections 5.1** and **5.2**, and to the extent that such Losses are not due to MDCO’s negligence or misconduct.

**6.2 By MDCO.** MDCO shall defend, indemnify and hold CyDex and its Affiliates, and each of their respective directors, officers and employees, harmless from and against any and all Losses incurred by CyDex as a result of any Claim by a Third Party, to the extent such Losses arise out of: (a) the manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of the Licensed Product by MDCO, its Affiliates and Sublicensees; or (b) MDCO’s breach of this Agreement, including without limitation any of its representations and warranties set forth in **Section 5.2** and to the extent that such Losses are not due to CyDex’s negligence or misconduct.

**6.3 Expenses.** As the parties intend complete indemnification, all costs and expenses of enforcing any provision of this **Section 6** shall also be reimbursed by the Indemnitor.

**6.4 Procedure.** The party intending to claim indemnification under this **Section 6** (an “**Indemnitee**”) shall promptly notify the other party (the “**Indemnitor**”) of any Claim in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall assume the defense thereof whether or not such Claim is rightfully brought; *provided, however*, that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee, unless Indemnitor does not assume the defense, in which case the reasonable fees and expenses of counsel retained by the Indemnitee shall be paid by the Indemnitor. The Indemnitee, and its employees and agents, shall cooperate fully with the Indemnitor and its legal representatives in the investigations of any Claim. The Indemnitor shall not be liable for the indemnification of any Claim settled or compromised by the Indemnitee without the written consent of the Indemnitor.

## **7. LIMITATION OF LIABILITY.**

**7.1 Limitation of Remedies.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES OR LOSS OF PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS **SECTION 7** IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER **SECTION 6**, OR DAMAGES AVAILABLE FOR A PARTY’S BREACH OF CONFIDENTIALITY OBLIGATIONS IN **SECTION 8** OF THE LICENSE AGREEMENT.

[\*\*\*]

\*\*\* 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.

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## 8. TERM AND TERMINATION.

**8.1 Term.** The term of this Agreement (the “**Term**”) shall commence on the Effective Date and shall continue in effect, on a country-by-country basis, until the expiration or termination of the License Agreement, for any reason, unless terminated earlier as set forth herein. The parties agree that [\*\*\*] to expiration of this Agreement, they shall meet and discuss renewal of this Agreement for an additional term, but neither party shall be obligated to renew the Agreement.

### 8.2 Termination for Breach.

**(a) Notice.** If either party believes that the other is in material breach of this Agreement, then the party holding such belief (the “**Non-breaching Party**”) may deliver notice of such breach to the other party (the “**Notified Party**”). The Notified Party shall have [\*\*\*] to cure such breach to the extent involving non-payment of amounts due hereunder, and [\*\*\*] to either cure such breach for all other material breaches, or, if cure of such breach other than non-payment cannot reasonably be effected within such [\*\*\*] day period, to deliver to the Non-breaching Party a plan reasonably calculated to cure such breach within a timeframe that is reasonably prompt in light of the circumstances then prevailing but in no event in excess of an additional [\*\*\*] period. Following delivery of such a plan, the Notified Party shall diligently carry out the plan and cure the breach and the cure period shall be extended by the time period provided in such plan but in no event to exceed [\*\*\*] from the date of any initial breach notice delivered under this **Section 8.2**.

**(b) Failure to Cure.** If the Notified Party fails to cure a material breach of this Agreement as provided for in **Section 8.2**, then the Non-Breaching Party may terminate this Agreement upon written notice to the Notified Party.

**(a) Disputes.** If a party gives notice of termination under this **Section 8.2** and the other Party disputes whether such termination is proper under this **Section 8.2**, then the issue of whether this Agreement may properly be terminated upon expiration of the notice period (unless such breach is cured as provided in **Section 8.2**) shall be resolved in accordance with **Section 14.4** of the License Agreement. If as a result of such dispute resolution process it is determined that the notice of termination was proper, then such termination shall be deemed to have been effective [\*\*\*] following the date of the notice of termination (or such other time period applicable pursuant to **Section 8.2**). If as a result of such dispute resolution process it is determined that the notice of termination was improper, then no termination shall have occurred and this Agreement shall remain in effect.

**8.3 Termination with License Agreement.** Unless otherwise agreed upon by the parties, this Agreement shall automatically terminate upon the expiration or termination, for whatever reason, of the License Agreement.

**8.4 Survival.** Notwithstanding any other provisions of this Agreement, any liability or obligation of either party to the other for acts or omissions prior to 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. Sections 3.7 (Product Recalls),

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4.2 (Payments), 5.3 (Disclaimer), 6 (Indemnification), 7 (Limitation of Liability), 8.4 (Survival), and 9 (General Provisions) shall survive termination or expiration of this Agreement.

**9. GENERAL PROVISIONS.**

The following Sections of the License Agreement are incorporated into this Agreement by this reference as if fully set forth herein: 7.2 (Material Safety), 7.3 (Adverse Event Reporting), 8 (Confidentiality) and 14 (General Provisions). In the event that there is any conflict between this Agreement and the License Agreement, the License Agreement shall govern.

*[Remainder of this page left blank intentionally]*



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

**CYDEX PHARMACEUTICALS, INC.**

By: /s/ Matt Foehr

Name: Matt Foehr

Title: Executive Vice President, Chief Operating Officer

**THE MEDICINES COMPANY**

By: /s/ Clive A. Meanwell

Name: Clive A. Meanwell

Title: Chairman and CEO

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**EXHIBIT A: PURCHASE PRICES FOR CAPTISOL**

[\*\*\*]

[\*\*\*]

[\*\*\*]  
[\*\*\*]  
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*SUPPLY AGREEMENT*

*EXHIBIT A - 1*

\*\*\* 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.

CERTAIN MATERIAL (INDICATED BY AN ASTERISK) 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**

**THIS SUPPLY AGREEMENT** (this “**Agreement**”) is made this 13th day of June, 2011 (the “**Effective Date**”) between:

**CYDEX PHARMACEUTICALS, INC.**, a Delaware corporation with offices at 10513 W. 84<sup>th</sup> Terrace, Lenexa, Kansas 66214 (“**CyDex**”); and

**MERCK SHARP & DOHME CORPORATION**, a New Jersey corporation with offices at One Merck Drive, Whitehouse Station, NJ 08889-0100 (“**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 worldwide licensee of Captisol (defined below), a [\*\*\*] which is protected by certain patents and designed to enhance the solubility and stability of drugs;

**WHEREAS**, Company desires to obtain a comprehensive license to use Captisol in connection with its development and commercialization of the Compound (defined below) and CyDex is willing to grant such 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 for use in the Licensed Product (defined below), in accordance with the terms and conditions contained herein;

**NOW, THEREFORE**, in consideration of the following mutual promises and other good and valuable consideration, the receipt and sufficiency of which is 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:

“**Affiliate**” means any entity directly or indirectly controlling, controlled by or under common control with a party, control being the direct or indirect ownership of at [\*\*\*] of the stock or other equity interest entitled to vote upon election of directors or persons performing similar functions.

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“**cGMPs**” means current good manufacturing practices for the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, packing and holding of pharmaceutical excipients, all as set forth from time to time by the U.S. Pharmacopoeia General Chapter <1078> Good Manufacturing Practices For Bulk Pharmaceutical Excipients and International Pharmaceutical Excipients Council’s IPEC/PQG GMP Guide For Pharmaceutical Excipients, and any successors thereto.

“**Captisol**” means a [\*\*\*] as specified in *Exhibit B* hereto.

“**Captisol Data Package**” means (a) all toxicology/safety and other relevant scientific safety data owned, licensed or developed by CyDex and its Affiliates; and (b) 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), in each case on Captisol alone (and not in conjunction with a product formulation).

“**Captisol Improvement**” means any technology or improvement related to Captisol, whether or not patentable, that is developed during the Term by Company or its Affiliates or Sublicensees, solely or jointly with a third party through use of Captisol supplied hereunder. Captisol Improvement shall not include any Captisol Information. For the avoidance of doubt, Captisol Improvement shall not include any technology or improvement related to Captisol, whether or not patentable, that was developed before the Term by CyDex or its Affiliates, solely or jointly with Company, its Affiliates or a third party.

“**Captisol Information**” means any information solely related to Captisol that is developed during the Term by Company or its Affiliates or Sublicensees, solely or jointly with a third party, that would enhance a drug master file for Captisol if incorporated therein.

“**Captisol Patents**” means the patents and patent applications (until such time as such applications or any of them are denied, abandoned or issued into patents), and any foreign cognates, divisional, continuation, continuation-in-part, reissue, re-examination, extension, renewal, substitution, patent of addition, provisional applications, confirmation patent, registration patent, pipeline protection or supplementary protection certificate related thereto, that include at least one claim relating to the composition, use in the relevant Product or manufacture of a cyclodextrin, which at any time during the Term are owned by CyDex or under which CyDex is licensed with the right to sublicense, *excluding, however*, the Restricted Patent Rights.

“**Claim**” has the meaning specified in **Section 10.1**.

“**Clinical Grade Captisol**” means [\*\*\*]. For clarity, Clinical Grade Captisol shall meet the specifications set forth in *Exhibit B*.

“**Commercial Grade Captisol**” means [\*\*\*]. For clarity, Commercial Grade Captisol shall meet the specifications set forth in *Exhibit B*.

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“**Commercial Launch Date**” means, in any particular country, the first sale by Company, its Affiliates or Sublicensees of the Licensed Product.

“**Compound**” means that certain pharmaceutical compound known as [\*\*\*].

“**Confidential Information**” has the meaning specified in **Section 8.1**.

“**Detailed Forecast**” has the meaning specified in **Section 3.2(b)**.

“**Disclosing Party**” has the meaning specified in **Section 8.1** hereof.

“**DMF**” means a Drug Master File 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.

“**FDA**” means the United States Food and Drug Administration, or any successor thereto.

“**Generic Competition**” has the meaning specified in **Section 4.1(c)(ii)** hereof.

“**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.

“**Indemnitee**” has the meaning specified in **Section 10.4**.

“**Indemnitor**” has the meaning specified in **Section 10.4**.

“**LCUA**” means that certain Limited Clinical Use Agreement between CyDex and Schering Corporation effective April 17, 2008, as amended.

“**Laws**” means all applicable federal, state, local or foreign statute or law and shall be deemed also to include all rules and regulations promulgated thereunder by any regulatory authorities in the Territory, unless context requires otherwise. With respect to cGMPs, Laws shall also include guidance documents formally promulgated by the governmental agency with jurisdiction over the manufacture of Captisol. Any reference to a particular law or regulation will be interpreted to include any revision of or successor to such statute, law, rule or regulation regardless of how it is numbered or classified.

“**Licensed Product**” means a human drug product which is formulated as a combination of the active pharmaceutical ingredient [\*\*\*] and Captisol. For clarity, the Licensed Product shall not include any product which is a combination product incorporating the Compound with any other active pharmaceutical ingredient.

“**Losses**” has the meaning set forth in **Section 10.1**.

“**Marketing Approval**” means final approval of an NDA by the FDA for the United States, 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.

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“**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.

“**Notice of Default**” has the meaning specified in **Section 13.2**.

“**Notice of Termination**” has the meaning specified in **Section 13.2**.

[\*\*\*]

“**Purchase Volume Limitations**” has the meaning specified in **Section 3.2(c)**.

“**Receiving Party**” has the meaning specified in **Section 8.1**.

“**Restricted Patent Rights**” shall mean the [\*\*\*], as set forth in *Exhibit D*.

“**Q1**”, “**Q2**”, “**Q3**”, and “**Q4**” have the meanings specified in **Section 3.2(b)**.

“**Research Grade Captisol**” means [\*\*\*], but which meets CyDex’s specifications for Research Grade Captisol.

“**SEC**” has the meaning specified in **Section 8.3**.

“**Specifications**” means the specifications for Captisol set forth in *Exhibit B* hereto, as such may be amended from time to time pursuant to **Section 3.4**.

“**Study**” has the meaning specified in **Section 6.3**.

“**Sublicensees**” means parties to whom Company and/or its Affiliates has sublicensed rights granted to Company and/or its Affiliates under this Agreement, as permitted under this Agreement.

“**Term**” has the meaning specified in **Section 13.1**.

“**Testing Methods**” has the meaning specified in **Section 3.5(a)**.

“**Third-Party Manufacturer**” has the meaning specified in **Section 3.6**.

“**Territory**” means the entire world, *excluding, however*, any country during such time that a Restricted Patent Right is valid and enforceable in such country, as follows: [\*\*\*].

“**Volume Threshold**” has the meaning specified in **Section 3.1**.

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**2. GRANT OF RIGHTS.**

**2.1 License Grants from CyDex to Company.**

**(a) Licenses.** Subject to the terms and conditions of this Agreement, during the Term, CyDex hereby grants to Company and its Affiliates:

- (i) an exclusive license in the Territory, even with respect to CyDex, under the Captisol Patents, with right to sublicense (subject to **Sections 2.3** and **2.4**), to make, use, sell, offer to sell, promote, market, distribute, package, import, export, develop, test, study and otherwise commercially exploit any Licensed Product and otherwise engage in activities relating to the regulatory approval of any Licensed Product; and
- (ii) a non-exclusive, worldwide license under CyDex's right in and to:
  - (A) all Captisol related toxicology/safety and other relevant scientific safety data owned, licensed or developed by CyDex and its Affiliates;
  - (B) all Captisol related 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
  - (C) any drug master file related to Captisol;

to engage in any activity related to regulatory approval of any Licensed Product. CyDex shall deliver to Company, or provide Company access to, the information and files described in (A), (B) and (C) above at Company's request, which Company may use within the scope of the license.

**(b) Scope of Licenses.** For the avoidance of doubt, Company shall have no license to the Captisol Patents outside of the Territory and, except for activities deemed non-infringing of patents under national law, Company hereby agrees not to otherwise make, use, sell, offer to sell, promote, market, distribute, package, import, export, develop, test, study and otherwise commercially exploit any Licensed Product or Captisol in [\*\*\*]. Without limiting the generality of the foregoing, CyDex grants no rights to Company to manufacture, import (except in association with supply of Captisol under this Agreement), sell or offer for sale bulk Captisol. CyDex represents and warrants to Company that the licenses granted under Section 2.1 confer the only rights enforceable by CyDex that are required by CyDex for Company to exploit Captisol purchased under this Agreement within the Territory. Such licenses pursuant to this **Section 2.1** shall be nontransferable (except with respect to the sublicense provisions of **Sections 2.3** and **2.4** and the assignment provision in **Section 14.15**); Company may not sublicense any rights hereunder except as expressly set forth in **Sections 2.3** and **2.4** below. To the extent that any patent rights are licensed to CyDex or its Affiliates by a third party on a non-exclusive basis, any exclusive license granted to Company shall be exclusive as to CyDex and non-exclusive as to any third party. Other than for investigations relating to quality issues, Company shall not

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analyze Captisol in an attempt to reverse engineer, deconstruct or in any way determine the structure or composition of Captisol supplied under this Agreement, nor shall the Company develop, test, study or research Captisol supplied under this Agreement other than in combination with the active pharmaceutical ingredient [\*\*\*] for the purpose of making, using, selling, offering to sell, promoting, marketing, distributing, packaging, importing, exporting, and otherwise commercially exploiting any Licensed Product. CyDex shall not be liable to Company for violation of Company's exclusive rights hereunder by parties which are not Affiliates of CyDex except where CyDex or any Affiliate has granted any license or supplied any material in conflict with Company's exclusive rights and/or CyDex's obligations of exclusivity hereunder. Company acknowledges and agrees that (i) CyDex shall not be required to obtain patent rights in the Territory within the scope of the Captisol Patents, (ii) subject to **Section 2.5(a)** hereof, CyDex shall not be restricted in making sales of Captisol or licensing rights to other parties to the extent that such sales and licenses do not conflict with the exclusive license grants and supply exclusivity obligations hereunder.

**2.2 Grant of Licenses and Option from Company to CyDex.** Company hereby grants to CyDex:

- (i) *License for Captisol Information.* A nonexclusive, transferable, perpetual, worldwide and royalty-free license, with the right to grant sublicenses (through multiple tiers of sublicensees), under Company's and its Affiliates' and Sublicensees' rights in and to Captisol Information, to use Captisol Information for the sole purpose of incorporation of Captisol Information into any drug master file for Captisol;
- (ii) *Option to Negotiate.* An option, exercisable by written notice to Company within [\*\*\*] after notice of the development of any Captisol Improvement is provided by Company to CyDex pursuant to this Section 2.2, to negotiate with Company for a period of [\*\*\*] after Company's receipt of the option exercise notice, for a nonexclusive, transferable, perpetual, worldwide and royalty-free license, with the right to grant sublicenses (through multiple tiers of sublicensees), under Company's and its Affiliates' and Sublicensees' rights in and to such Captisol Improvement, to develop, make, have made, use, market, distribute, import, sell and offer for sale Captisol and products formulated with Captisol other than products comprising Company proprietary materials (for clarity, Company is under no obligation to grant any license to CyDex under this Section 2.2(ii)); and

Company shall provide prompt notice (within [\*\*\*]) of the development of any Captisol Information or Captisol Improvement. Information relating to Captisol Improvements shall be deemed Confidential Information of Company.

**2.3 Sublicensing.** Company shall have the right to grant sublicenses to its Affiliates and licensees of the Licensed Product (such non-Affiliate sublicensees which hold a Marketing Approval for the Licensed Product are collectively referred to herein as "**Sublicensees**") under the licenses granted to Company pursuant to **Section 2.1**; *provided* that Sublicensees shall first enter into an agreement reasonably satisfactory to CyDex (such agreement naming CyDex as an intended third-party beneficiary) with Company pursuant to which such Sublicensee shall acknowledge and agree to observe and be bound by the applicable restrictions set forth in this

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Agreement. Other than as specifically provided in and 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**, *provided, however*, that Company may grant to any party in the Licensed Product supply chain (beginning from Company's receipt of Captisol to the end user of the Licensed Product) a sublicense under the licenses granted pursuant to **Section 2.1** to use, sell, offer to sell, promote, market, distribute, package, import or export any Licensed Product.

**2.4 Contracting.** Company and its Affiliates may manufacture the Licensed Product (but not the bulk Captisol), or contract the manufacture of the Licensed Product (but not the manufacture of bulk Captisol) with non-Affiliate third party manufacturers upon notification to CyDex in writing of Company's or any of its Affiliate's intent to do so (such notice to include the identity and location of the proposed third party manufacturers). To the extent Company or its Affiliates engage a third party manufacturer for the Licensed Product, Company or any of its Affiliates shall be permitted under this Agreement to grant any such third party manufacturer a sublicense under the licenses granted to Company pursuant to **Section 2.1** solely for such purposes; *provided* that any such third party manufacturer shall enter into an agreement reasonably satisfactory to CyDex (such agreement naming CyDex as an intended third-party beneficiary) with Company pursuant to which such third party manufacturer shall acknowledge and agree to observe and be bound by the applicable restrictions set forth in this Agreement for the production of Licensed Product.

**2.5 Exclusivity.**

**(a) CyDex Commitment.** During the Term, CyDex agrees (i) to supply all of Company's and its Affiliates' requirements of Captisol for the Licensed Product on the terms set forth herein, and (ii) that neither CyDex nor its Affiliates shall sell or otherwise transfer, nor facilitate the sale or other transfer of, any [\*\*\*] to [\*\*\*] for [\*\*\*], *provided, however*, that CyDex may sell [\*\*\*].

**(b) Company Commitment.** During the Term, Company agrees that Company and its Affiliates shall not, directly or indirectly, [\*\*\*].

**3. MANUFACTURE AND SUPPLY OF CAPTISOL.**

**3.1 Purchase of Captisol.**

**(a) Purchase and Supply of Requirements.** Company agrees that, during the Term, Company and its Affiliates and Sublicensees shall purchase one hundred percent (100%) of Company's and its Affiliates' and Sublicensees' requirements for Captisol for use in the formulation of Licensed Product for commercial sale exclusively from CyDex. This Agreement does not grant Company, its Affiliates or Sublicensees the right under the rights licensed hereunder, to manufacture (or have manufactured on their behalf) Captisol. CyDex agrees that CyDex shall produce (or have produced for it) and sell to Company one hundred percent (100%) of Company's and its Affiliates' and Sublicensees' requirements for Captisol for use in the formulation of Licensed Product for commercial sale, during the Term and subject to the provisions of this Agreement and *provided that*, and notwithstanding anything to the contrary in this Agreement, in no event shall CyDex be obligated to supply to Company or its Affiliates or Sublicensees more than an aggregate quantity of [\*\*\*] of Captisol per year (the "**Volume**

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**Threshold**”). Purchases of Captisol may include Research Grade Captisol, Clinical Grade Captisol and/or Commercial Grade Captisol. Company may place orders for Captisol on behalf of its Affiliates and Sublicensees; *provided, however* that: (a) Company shall instruct CyDex as to the location for the shipment thereof; (b) Company shall guarantee payment to CyDex of all amounts payable with respect thereto; and (c) if Company requests that CyDex deliver such orders to Company for re-delivery thereof by Company to its Affiliates or Sublicensees, Company shall comply with all applicable laws, rules and regulations applicable to the transportation of Captisol from Company to its Affiliates and Sublicensees.

(b) [\*\*\*]. Except for the obligations associated with the Detailed Forecasts that may be issued at Company’s sole discretion, the parties acknowledge and agree that Company and its Affiliates are [\*\*\*].

### 3.2 Supply Terms.

(a) **Long-term Forecast.** No later than [\*\*\*] prior to the anticipated Commercial Launch Date by Company or its Affiliates or Sublicensees of a Licensed Product in any particular country, Company shall provide CyDex with a forecast setting forth Company’s estimate of the required quantities of Captisol for each of the following [\*\*\*]. Such long-term forecast shall thereafter be updated by Company at least once every [\*\*\*]. It is understood and agreed that such long term forecasts shall not constitute commitments to take delivery of Captisol.

(b) **Binding Detailed Forecast.** At least [\*\*\*] prior to the first purchase order submitted by Company for Captisol for formulation of a Licensed Product intended for commercial sale, Company shall deliver to CyDex a detailed rolling forecast setting forth Company’s requirements and anticipated delivery schedules for Captisol for each [\*\*\*] during the [\*\*\*] period commencing on the first day of the [\*\*\*] during which the first requested delivery date of Captisol is specified in such purchase order (the “**Detailed Forecast**”). For purposes of this Agreement, a [\*\*\*] means the [\*\*\*]. The Detailed Forecast shall thereafter be updated by Company quarterly on a rolling basis, no later than the last day of each [\*\*\*], so that each [\*\*\*] CyDex shall have been provided with a rolling Detailed Forecast for each [\*\*\*] during the [\*\*\*] period commencing on the first day of the next [\*\*\*] following the date on which such Detailed Forecast is submitted. The Detailed Forecast shall be firm and binding on Company, subject to permissible variances set forth in **Section 3.2(c)** below. If Company fails to provide any updated Detailed Forecast in accordance with this **Section 3.2(b)**, the Detailed Forecast last provided by Company shall be deemed to be Company’s binding Detailed Forecast for the next succeeding [\*\*\*].

#### (c) Detailed Forecast Variances.

(i) **For the First Year.** During the first [\*\*\*] in which Company orders Captisol for use in Licensed Products intended for commercial sale, each Detailed Forecast may modify the amount of Captisol estimated in the previous Detailed Forecast in accordance with the following limitations (the “**Purchase Volume Limitations**”):

(A) for the [\*\*\*] covered by such updated Detailed Forecast, and regardless of the quantity of Captisol forecasted in the Detailed Forecast, no change

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in excess of a [\*\*\*] volume increase or decrease may be made to the forecast provided for the [\*\*\*] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex;

(B) for the [\*\*\*] covered by such updated Detailed Forecast, and regardless of the quantity of Captisol forecasted in the Detailed Forecast, no change in excess of a [\*\*\*] volume increase or decrease may be made to the forecast provided for the [\*\*\*] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex; and

(C) for the [\*\*\*] covered by such updated Detailed Forecast, and regardless of the quantity of Captisol forecasted in the Detailed Forecast, no change in excess of a [\*\*\*] volume increase or decrease may be made to the forecast provided for the [\*\*\*] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex.

**(ii) For Subsequent Years.** After the first [\*\*\*] in which Company orders Captisol for use in a Licensed Product intended for commercial sale, the Purchase Volume Limitations shall be determined in accordance with the following:

(A) for the [\*\*\*] covered by such updated Detailed Forecast, and regardless of the quantity of Captisol forecasted in the Detailed Forecast, no change in excess of a [\*\*\*] volume increase or decrease may be made to the forecast provided for the [\*\*\*] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex;

(B) for the [\*\*\*] covered by such updated Detailed Forecast:

- (1) if the quantity of Captisol forecasted in the [\*\*\*] of the immediately preceding Detailed Forecast is less than [\*\*\*], then no change in excess of a [\*\*\*] volume increase or decrease may be made to the forecast provided for the [\*\*\*] of the in the immediately preceding Detailed Forecast without the prior express written consent of CyDex; and
- (2) if the quantity of Captisol forecasted in the [\*\*\*] of the immediately preceding Detailed Forecast is equal to or greater than [\*\*\*], then no change in excess of a [\*\*\*] volume increase or decrease may be made to the forecast provided for the [\*\*\*] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex.

(C) for the [\*\*\*] covered by such updated Detailed Forecast:

- (1) if the quantity of Captisol forecasted in the [\*\*\*] of the immediately preceding Detailed Forecast is less than [\*\*\*], then no change in excess of a [\*\*\*] volume increase or decrease may be made to the forecast provided for the [\*\*\*] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex; and

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- (2) if the quantity of Captisol forecasted in the [\*\*\*] of the immediately preceding Detailed Forecast is equal to or greater than [\*\*\*], then no change in excess of a [\*\*\*] volume increase or decrease may be made to the forecast provided for the [\*\*\*] in the immediately preceding Detailed Forecast without the prior express written consent of CyDex.

In each case where CyDex's consent is required for a change, CyDex's consent may be conditioned on such payment or other terms as CyDex may require.

**(d) Purchase Orders.** Together with each Detailed Forecast provided under **Section 3.2(b)**, Company shall issue a purchase order to CyDex for Commercial Grade Captisol to be delivered to Company during the next [\*\*\*] following the date on which such Detailed Forecast is submitted (for [\*\*\*] delivery to Company consistent with the Detailed Forecast). Notwithstanding any other provision of the Agreement, CyDex shall not be required to deliver Captisol on a date less than [\*\*\*] from the date that the relevant purchase order is submitted. Each purchase order, for all grades of Captisol, shall specify: (i) the grade of Captisol ordered (*i.e.*, Commercial Grade Captisol, Clinical Grade Captisol or Research Grade Captisol); (ii) quantities of Captisol to be delivered; (iii) delivery dates; and (iv) shipping instructions. CyDex shall use all commercially reasonable efforts to accommodate the quantities and delivery dates requested in the purchase order; *provided, however*, that (i) the purchase order is received by CyDex at least [\*\*\*] prior to the requested delivery date for Captisol, and (ii) the quantities are within the Purchase Volume Limitations. No purchase order shall be binding upon CyDex until accepted by CyDex in writing; *provided that* CyDex shall accept or reject Company's purchase order in writing within [\*\*\*] after CyDex's actual receipt of each purchase order. A failure to reject Company's purchase order within such [\*\*\*] of actual receipt of the purchase order will be deemed an acceptance by CyDex of the purchase order. Acceptance of the purchase order shall obligate CyDex to comply with the delivery specifications set forth therein, including Captisol quantities, delivery locations and delivery dates. If CyDex rejects a purchase order issued by Company or its Affiliates that (i) is received by CyDex at least [\*\*\*] prior to the requested delivery date, and (ii) requests quantities of Captisol within the Purchase Volume Limitations, then Company shall bear no responsibility nor liability for any resulting failure to meet Company's obligations associated with the Detailed Forecasts. 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 such additional or inconsistent terms are hereby expressly rejected.

**3.3 Delivery.** CyDex shall deliver to Company or Company's designee each order of Captisol, packed for shipment in accordance with CyDex's customary practices and the Specifications, FCA (Incoterms 2000) CyDex's production point or storage facilities. Title and risk of loss and/or damage to Captisol shall pass to Company upon delivery of Captisol to Company or Company's designee at CyDex's production point or storage facilities. CyDex will use commercially reasonable efforts to include, in the next shipment of Captisol to Company, any quantities ordered pursuant to an accepted purchase order but not delivered at Company's discretion.

**3.4 Modified Specifications.** CyDex shall have the right to change the Specifications from time to time during the Term. In such event, CyDex shall provide to Company at least

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[\*\*\*] written notice of such change, which shall include information detailing the purpose for and elements of such change. Company shall cooperate with CyDex to have such change approved by all regulatory agencies having jurisdiction in the Territory at CyDex's expense. In addition, if any regulatory agency having jurisdiction requires CyDex to implement any changes to the Specifications, CyDex shall use all reasonable efforts to make such changes. If any change in the Specifications required by a regulatory agency necessitates changes to the terms of this Agreement, the parties shall negotiate such changes in good faith. All direct costs associated with a Specification change shall be borne by CyDex, *provided, however*, if a regulatory agency requires a change to the Specifications where such change is specific to Captisol as implemented in the Licensed Product, then Company shall be responsible for the costs incurred to generate such unique, modified Specifications. At Company's request, and if the change in Specification is discretionary for CyDex and not required by a regulatory agency, CyDex shall continue to supply Captisol meeting the pre-change Specification for up to [\*\*\*] after Company's receipt of written notice of such change.

**3.5 Change Control Notifications.** CyDex shall comply with the notification obligations set forth in the External Supplier Process Change Agreement Form and associated instructions attached hereto as *Exhibit E*.

**3.6 Quality Control; Acceptance and Rejection.**

**(a) Quality Control.** CyDex shall conduct or have conducted quality control testing of Captisol prior to shipment in accordance with the Specifications and other CyDex-approved quality control testing procedures (the "**Testing Methods**"). CyDex shall retain or have retained accurate and complete records pertaining to such testing, as well as samples (at least twice the quantity required to perform the full suite of Testing Methods) from each lot of Captisol shipped to Company, for at least through the expiration date of such Captisol [\*\*\*] or longer if required by Law. Each shipment of Captisol hereunder shall be accompanied by a certificate of analysis for each lot of Captisol therein.

**(b) Acceptance Testing.** Company shall have a period of [\*\*\*] from the date of receipt to test or cause to be tested Captisol supplied under this Agreement ("**Acceptance Testing Period**"). The Acceptance Testing Period may be extended for an additional [\*\*\*], for a total of [\*\*\*] from the date of Company's receipt of the Captisol, so long as Company does not subject such Captisol to improper storage conditions that cause material degradation of the Captisol. Company or its designee shall have the right to reject any shipment of Captisol that does not conform with the Specifications at the time of delivery pursuant to **Section 3.3** hereof when tested in accordance with the Testing Methods. All shipments of Captisol shall be deemed accepted by Company unless CyDex receives written notice of rejection from Company within such Acceptance Testing Period describing the reasons for the rejection. Once a delivery of Captisol is accepted or deemed accepted hereunder, Company shall have no recourse against CyDex in the event Captisol is subsequently deemed unsuitable for use for any reason, except (i) as provided in **Section 10** below, or (ii) in the case of Captisol that is not fit for use in humans after the Acceptance Testing Period due to a latent defect in such Captisol caused by CyDex, its employees or agents.

**(c) Confirmation.** After its receipt of a notice of rejection from Company pursuant to **Section 3.6(b)** above, CyDex shall notify Company as soon as reasonably practical

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(but no later than [\*\*\*] after receipt of Company's rejection notice) whether it accepts Company's basis for rejection and CyDex may perform its own testing at its own cost to evaluate 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 meets the Specifications, 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.

**(d) 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 fails to meet the Specifications. 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, Company shall promptly destroy the rejected batch of Captisol and provide CyDex with written certification of such destruction. Upon receipt of CyDex's request for return, 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.

**(e) 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 3.5**. Notwithstanding the foregoing, Company shall be obligated to pay in full for any rejected shipment of Captisol that is subsequently determined to meet the Specifications in all material respects, irrespective of whether Company has already paid CyDex for a replacement shipment. CyDex shall, upon acceptance of Company's basis of rejection or other confirmation that such shipment failed to meet the Specifications, at Company's sole discretion and direction either: (i) issue a refund or credit equal to the purchase price paid, taxes paid and shipping costs with respect to such rejected shipment within [\*\*\*] of Company's request; or (ii) replace such rejected shipment at no additional cost (beyond the total cost, including delivery, for the rejected shipment paid or owed by Company to CyDex) to Company, with such replacement to be shipped to Company in accordance with Company's instructions and schedule (or, if CyDex in good faith cannot meet Company's schedule, as soon as reasonably practical). Company acknowledges and agrees that, except for the warranty provisions set forth in Section 9.2 below and the indemnification obligations set forth in Section 10 below, 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 non-conforming Captisol delivered hereunder which has not been used in the manufacture of the Licensed Product.

**(f) 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 non-conforming due to damage caused by (i) Company, its Affiliates or Sublicensees or their respective employees or agents, including but not limited to, misuse, neglect, improper storage, transportation or use beyond any dating provided or (ii) events subsequent to delivery of such Captisol to the carrier at the point of origin, including but not limited to any damage caused

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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.** Without limiting CyDex's responsibility under this Agreement, CyDex shall have the right at any time to satisfy its supply obligations to Company hereunder either in whole or in part through arrangements with third parties engaged to perform services or supply facilities or goods in connection with the manufacture or testing of Captisol (each, a "**Third-Party Manufacturer**"). CyDex shall give Company prior written notice of any such arrangement. The parties hereby agree that [\*\*\*] is a Third-Party Manufacturer as of the Effective Date of this Agreement. CyDex shall permit no more than [\*\*\*] of Company's authorized representatives, during normal working hours and upon reasonable prior notice to CyDex but in no event less than [\*\*\*] prior notice, to inspect 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 [\*\*\*] per calendar year. If such inspection is of the facilities of a Third-Party Manufacturer, Company shall pay [\*\*\*]. 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, and shall execute a written confidentiality agreement with terms at least as restrictive as those set forth in **Section 8** hereof. In no event shall any such manufacturing audit exceed [\*\*\*] in duration. Company shall ensure that its authorized representatives conduct each manufacturing audit in such a manner as to not interfere with the normal and ordinary operations of CyDex or its Third-Party Manufacturer. Except as expressly set forth in this **Section 3.6**, neither Company nor its Affiliates, Sublicensees or their respective employees or representatives shall have access to CyDex's facilities or the facilities of any Third-Party Manufacturer.

**3.8 Inability to Supply.**

**(a) Notice.** CyDex shall notify Company if CyDex is unable to supply the quantity of (i) Commercial Grade Captisol ordered by Company in accordance with the Purchase Volume Limitations set forth in **Section 3.2(c)** or (ii) Research Grade Captisol or Clinical Grade Captisol ordered by Company as set forth in **Section 3.2(d)** above: (1) within [\*\*\*] after CyDex's receipt of a purchase order from Company as provided in **Section 3.2(d)**; or (2) immediately upon becoming aware of an event of *force majeure* or any other event that would render CyDex unable to supply to Company the quantity of Captisol that CyDex is required to supply hereunder.

**(b) Allocation.** If CyDex is unable to supply to Company the quantity of Captisol that CyDex is required to supply hereunder, CyDex (i) shall allocate its available Captisol among Company 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 and (ii) shall use commercially reasonable efforts to alleviate supply delays. The supply allocation provided in this **Section 3.8(b)** and the alternative supplier provisions of **Sections 3.8(c)** and **(d)** below shall be CyDex's sole obligation and Company's sole and exclusive remedy for any supply shortage.

**(c) Supply Shortfall and Risk Management.** If CyDex believes that it will be unable to supply to Company with the quantity of Captisol respectively specified below,

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properly forecasted and ordered by Company (and provided such order was within the Purchase Volume Limitations) in accordance with this Agreement, for the continuous period respectively specified below (a “**Supply Shortfall**”):

<u>Period of Time</u>	<u>Quantity that can be Supplied by CyDex</u>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

then CyDex shall immediately provide written notice to Company of the Supply Shortfall. In the event of a Supply Shortfall:

- (i) [\*\*\*]
- (ii) [\*\*\*]
- (iii) [\*\*\*]

CyDex will use commercially reasonable efforts to develop, update and implement a full risk mitigation plan, including full disaster recovery plan. This plan will be made available to Company, conditional upon subcontractor permitting Company access to risk mitigation plans.

**(d) Direct Supply from Third Party Manufacturer.** In the event that the supply shortfall is caused by the bankruptcy or other financial distress experienced by CyDex, the parties agree that Company may purchase its requirements of Captisol for the Licensed Product directly from The Hovione Group or other Third Party Manufacturer until the expiration of the Term for use in accordance with the terms of this Agreement.

**4. COMPENSATION.**

**4.1 Payments and Royalties for Licenses.**

(a) [\*\*\*]

[\*\*\*]

[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]

[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]

[\*\*\*]

[\*\*\*]

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#### 4.2 Pricing for Captisol.

**(a) Pricing.** The purchase prices for Captisol are as specified in *Exhibit C* attached hereto. CyDex reserves the right to increase the purchase prices set forth in *Exhibit C* on [\*\*\*], and every [\*\*\*] hereafter during the Term, by written notice to Company, by a percentage equal to the [\*\*\*]. The minimum order for Commercial Grade Captisol shall be in [\*\*\*] increments. Notwithstanding the foregoing, if Company fails to order for any [\*\*\*] a quantity of Commercial Grade Captisol to be delivered during such [\*\*\*] 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 [\*\*\*] pursuant to the applicable Detailed Forecast and the amount of Commercial Grade Captisol that Company actually orders in [\*\*\*], the “**Shortfall**”), then provided that CyDex has used commercially reasonable efforts to mitigate, Company agrees to reimburse CyDex for the cost of any raw materials and supplies acquired or used in anticipation of supplying Company with such Shortfall to the extent that such raw materials and supplies cannot be redeployed to other projects and any resulting Commercial Grade Captisol cannot be resold to other customers.

**(b) Invoicing; Payment.** CyDex shall invoice Company upon shipment of each order of Captisol. All invoices shall be sent to the address specified in the applicable purchase order, and each invoice shall state the purchase price for Captisol in such shipment, plus any insurance, taxes, shipping costs or other costs incidental to such purchase or shipment initially paid by CyDex but to be borne by Company hereunder; *provided, however*, that if such insurance, taxes, shipping costs or other costs incidental to such purchase or shipment initially paid by CyDex but to be borne by Company are not known at the time CyDex invoices Company for the purchase price for the Captisol ordered by Company, CyDex may invoice such costs at a later date. Payment of such invoices shall be made within [\*\*\*] after the date of Company’s receipt of an undisputed invoice at the address specified in the applicable purchase order, except in the event of a good faith rejection of a delivery under **Article 3.5** above, in which case payment shall be made within [\*\*\*] after such order is confirmed to be in compliance with the Specifications in accordance with **Section 3.5(c)** above.

**4.3 Currency.** All amounts due hereunder are stated in, and shall be paid in, U.S. dollars.

**4.4 Taxes.** All amounts due hereunder 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), arising from the payment of amounts due hereunder.

**4.5 Late Payments.** Unpaid balances shall accrue interest, from due date until paid, at a rate equal to the lesser of (i) [\*\*\*], or (ii) the maximum rate permitted under applicable law. If any amount properly invoiced and due hereunder and not subject to a reasonable, good-faith dispute by Company remains outstanding for more than [\*\*\*] 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.

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## 5. REPORTS.

Annually, by December 1st of each calendar year during the Term, Company shall provide CyDex with written reports that: (i) describe in reasonable detail Company's progress made toward achievement of the milestones specified in **Section 4.1(b)** above during such calendar year; (ii) summarize Company's communications and meetings involving the FDA related to Captisol during such calendar year; (iii) summarize Company's anticipated preclinical and clinical use of Captisol for the next calendar year; and (iv) set forth such other information regarding Captisol as mutually agreed upon by the parties.

## 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 Product, including without limitation costs and expenses associated with all preclinical activities and clinical trials, and all regulatory filings and proceedings relating to the Licensed Product.

### 6.2 [Reserved]

**6.3 Right of Reference.** Company shall have the right to reference the DMF solely in connection Company's regulatory filings submitted in connection with obtaining Marketing Approval for the Licensed Product.

**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 product formulation) by Company, its Sublicensees or Affiliates in connection with CyDex's development and commercialization of Captisol or compounds, at no cost to CyDex. Upon request by CyDex, Company shall either provide CyDex with a copy of all such data or shall make such data accessible to CyDex at such times and locations mutually agreed upon by the parties.

## 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 Product. Notwithstanding the foregoing, CyDex agrees to provide proprietary technical information relating to Captisol directly to global health authorities as reasonably requested by Company during development and/or new product registration. Company shall provide CyDex with copies of the portions of all regulatory submissions containing Captisol data alone (and not in conjunction with any product formulation) [\*\*\*] prior to submission and shall allow CyDex to review and comment upon said submissions. If CyDex reasonably determines that any such submission would materially adversely affect another product utilizing Captisol, CyDex shall notify Company within [\*\*\*] of receipt of such submission, and the parties shall discuss and resolve the matter in good faith. Company shall inform CyDex of meetings with the FDA (or other regulatory agencies in the Territory) regarding the Licensed Product [\*\*\*] prior to such event and shall allow CyDex to participate in any FDA (or other regulatory agency) review that might reasonably include inquiries regarding Captisol. If Company submits written responses to the FDA that include data

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on Captisol alone, CyDex shall be permitted to review such written materials prior to 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.

**7.2 Material Safety.** CyDex shall provide Company, in writing, promptly as it becomes available, with (a) relevant 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 (for clarity, CyDex is responsible for the accuracy of the information contained in such documentation), (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. Company and/or its Affiliates or Sublicensees shall provide CyDex with copies of all reports of any such adverse event which is serious (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 Company and/or its Affiliates or Sublicensees has reason to believe are associated with Captisol within [\*\*\*] days promptly following (i) Company's submission of any such report to any regulatory agency, or (ii) receipt from Company's Sublicensee, co-marketer 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 Vice President, Chief Operating Officer, CyDex, with a copy to Vice President, Assistant Secretary, CyDex, at the addresses set forth in **Section 14.6**. By no later than [\*\*\*] following the Effective Date and not later than the initiation of any clinical studies involving the Licensed Product, the parties shall enter into a formal safety agreement for the mutual exchange of adverse event reports and safety information associated with Captisol. Details of the operating procedure respecting such adverse event reports and safety information exchange shall be the subject of a mutually-agreed pharmacovigilance agreement between the parties. Company shall be solely responsible for reporting to the regulatory agencies and health authorities, adverse events relating to the Licensed Product and for maintaining the global safety database of such adverse events. The parties shall mutually cooperate with regard to investigation of any such serious adverse event believed to be associated with Captisol supplied under this Agreement, whether experienced by Company, CyDex or any other Affiliate, Sublicensee, co-marketer or distributor of CyDex or Company.

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**7.4 Product Recalls.** In the event that a Licensed Product is recalled or withdrawn, CyDex shall fully cooperate with Company in connection with such recall or withdrawal. If such recall is caused by a breach of any warranty or other obligation of CyDex under this Agreement, CyDex will reimburse Company for [\*\*\*]. CyDex agrees to abide by all decisions of Company to recall or withdraw Licensed Product.

**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 will be governed by the provisions of this **Section 8**. Neither Company nor CyDex shall use the other’s Confidential Information except as expressly permitted in this Agreement. For purposes of this Agreement, “**Confidential Information**” means all scientific, clinical, regulatory, marketing, business, operational, financial or commercial information disclosed by the Disclosing Party to the Receiving Party, 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; nevertheless, Company’s and/or its Affiliates disclosure and use of the Captisol Data Package in connection with any activity related to regulatory approval of any Licensed Product shall not constitute a breach of any non-disclosure and/or limited use obligations owed by Company and/or its Affiliates to CyDex or [\*\*\*].

**8.2 Obligation.** CyDex and Company agree that they will disclose the other’s Confidential Information to its own officers, employees, consultants, Affiliates 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. Neither party shall disclose Confidential Information of the other to any third party without the other’s prior written consent, and any such disclosure to a third party shall be pursuant to the terms of a non-disclosure agreement no less restrictive than this **Section 8**. 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). Each party, upon the other’s request, will return all the Confidential Information disclosed to the other party pursuant to this Agreement, including all copies and extracts of documents, within sixty (60) days of the request, except that the receiving party may retain (i) one (1) copy for archival purposes and (ii) such electronic copies that exist as part of the party’s computer systems, network storage systems and electronic backup systems.

**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 appropriate documentation:

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(i) at the time of disclosure is in the public domain;

(ii) after disclosure, becomes part of the public domain, by publication or otherwise, through no fault of the Receiving Party;

(iii) 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 prior to the execution of this Agreement which is subject to an ongoing obligation of confidentiality;

(iv) is made available to the Receiving Party by an independent third party, 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

(v) is developed by or on behalf of the Receiving Party or its Affiliates without the aid, application or use of the Disclosing Party's Confidential 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 United States Securities and Exchange Commission (the "SEC"), or in the course of litigation, *provided* that in all cases the Receiving Party shall give the other party prompt notice of the pending disclosure and shall assist the Disclosing Party (at Disclosing Party's request and expense) in obtaining, a protective order preventing or limiting 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 may suffer irreparable damages and its remedy at law may be inadequate. Upon any breach or threatened breach by the Receiving Party of this **Section 8**, the Disclosing Party shall be entitled to seek injunctive relief in addition to any other remedy which it may have.

## 9. REPRESENTATIONS AND WARRANTIES.

**9.1 Mutual Representations and Warranties.** Each party represents and warrants to the other as follows:

(i) it is a corporation duly organized and validly existing under the laws of the state or country of its incorporation;

(ii) it has the power and authority to enter into this Agreement and to perform its obligations hereunder;

(iii) 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

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equity as applied by courts of competent jurisdiction or dispute resolution authorities authorized by the parties;

(iv) 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;

(v) 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;

(vi) 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

(vii) 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 Limited Warranty.** CyDex warrants solely to Company and its Affiliates that all Captisol sold to Company shall:

(i) conform to the respective Specifications (as applicable for Research Grade Captisol, Clinical Grade Captisol or Commercial Grade Captisol) in all material respects at the time of delivery;

(ii) have been manufactured, stored, packaged and (to the extent CyDex is responsible for shipping) shipped in accordance with cGMPs (Research Grade Captisol excluded) and all other Laws in the country of manufacture and CyDex's site of delivery;

(iii) be delivered to Company (or Company's designated carrier if Company is responsible for shipping) with good and marketable title, free and clear of any liability, pledge, lien, restriction, claim, charge, security interest or other encumbrance; and

(iv) have not less than [\*\*\*] of remaining shelf life (until re-testing is required) on the date of delivery.

CyDex's sole obligation, and Company's sole and exclusive remedy, for any breach of such warranty shall be as set forth in **Sections 3.5(e)** (Refund or Replacement) and **10.1** (Indemnification by CyDex) hereof.

**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 CAPTISOL PATENTS OR THE CAPTISOL DATA PACKAGE, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. CYDEX'S WARRANTIES UNDER THIS

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AGREEMENT ARE SOLELY FOR THE BENEFIT OF COMPANY AND ITS AFFILIATES AND MAY BE ASSERTED ONLY BY COMPANY AND/OR ITS AFFILIATES AND NOT BY ANY SUBLICENSEE OR ANY CUSTOMER OF COMPANY. COMPANY, ITS AFFILIATES AND SUBLICENSEES SHALL BE SOLELY RESPONSIBLE TO ITS CUSTOMERS FOR ALL REPRESENTATIONS AND WARRANTIES THAT COMPANY, ITS AFFILIATES OR SUBLICENSEES MAKE TO ANY CUSTOMER OF COMPANY, ITS AFFILIATES OR SUBLICENSEES. NOTHING IN THIS SECTION 9.3 SHALL BE DEEMED TO LIMIT OR OTHERWISE ALTER CYDEX'S OBLIGATIONS UNDER ARTICLE 10 (INDEMNIFICATION AND INSURANCE).

## **10. INDEMNIFICATION AND INSURANCE.**

**10.1 By CyDex.** CyDex shall defend, indemnify and hold Company and its Affiliates and Sublicensees, and each of their respective directors, officers and employees, harmless from and against any and all losses, damages, liabilities, costs and expenses (including the reasonable costs and expenses of attorneys and other professionals) (collectively "**Losses**") incurred by Company 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, including without limitation any of its representations and warranties set forth in **Sections 9.1 and 9.2**, (ii) any infringement or alleged infringement of the intellectual property rights of a third party by Captisol alone, but not where the combination of Captisol and any other material is a required element of the alleged or actual infringement, or (iii) CyDex's or CyDex's employees', officers', directors' and agents' negligence or willful misconduct in connection with performance under this Agreement. Notwithstanding the foregoing, CyDex shall have no obligation under this **Section 10.1** to the extent that a third party Claim arises from (i) Company's breach of this Agreement, including without limitation any of its representations and warranties set forth in **Section 9.1**, or (ii) Company's or Company's employees', officers', directors' and agents' negligence or willful misconduct in connection with performance under this Agreement.

**10.2 By Company.** Company shall defend, indemnify and hold CyDex and its Affiliates, and each of their respective directors, officers and employees, harmless from and against any and all Losses incurred by CyDex as a result of any Claim by a third party, to the extent such Losses arise out of: (a) the use or sale of the Licensed Product by Company, its Affiliates, Sublicensees, distributors, agents or other parties; (b) the manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of Licensed Products; (c) interactions and communications with governmental authorities, physicians or other third parties; (d) Company's breach of this Agreement, including without limitation any of its representations and warranties set forth in **Section 9.1**, or (e) Company's or Company's employees', officers', directors' and agents' negligence or willful misconduct in connection with performance under this Agreement. Notwithstanding the foregoing, Company shall have no obligation under this **Section 10.2** to the extent that a third party Claim arises from (i) CyDex's breach of this Agreement, including without limitation any of its representations and warranties set forth in **Sections 9.1 and 9.2**, (ii) any infringement or alleged infringement of the intellectual property rights of a third party by Captisol where a combination of Captisol with a material other than Captisol is a required element of the infringement or alleged infringement, or (iii) CyDex's or CyDex's employees', officers', directors' and agents' negligence or willful misconduct in connection with performance under this Agreement.

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**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 Indemnitor.

**10.4 Procedure.** The party intending to claim indemnification under this **Section 10** (an “**Indemnitee**”) shall promptly notify the other party (the “**Indemnitor**”) of any Claim in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall assume the defense thereof whether or not such Claim is rightfully brought; *provided, however*, that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee, unless Indemnitor does not assume the defense, in which case the reasonable fees and expenses of counsel retained by the Indemnitee shall be paid by the Indemnitor. The Indemnitee, and its employees and agents, shall cooperate fully with the Indemnitor and its legal representatives in the investigations of any Claim. The Indemnitor shall not be liable for the indemnification of any Claim settled or compromised by the Indemnitee without the written consent of the Indemnitor.

**10.5 Insurance.** Each party agrees to maintain, during the Term and for [\*\*\*] thereafter, through policies of insurance or programs of self-insurance, commercial general liability insurance, products liability and products completed operations coverages, with a minimum limitation of [\*\*\*] per occurrence and [\*\*\*] annual aggregate upon execution of this Agreement. Each party shall deliver to the other party, prior to the execution of this Agreement and prior to commencing work hereunder, an insurer or insurer’s agent signed certificates of insurance, as evidence that policies providing such coverage and limits of insurance are in full force and effect and with insurers, having an AM Best (A-) or higher rating, or similar metric as deemed reasonably acceptable to the other party, or evidence of such self insurance. Thereafter, the certificates of insurance (if applicable) shall be provided annually. These certificates (if applicable) shall provide that not less than [\*\*\*] advance notice will be given in writing to the other party of any cancellation, termination, or material alteration of said insurance policies to the extent that such provisions are reasonably available. Each party shall name the other party as an additional insured under its policies of commercial general liability insurance. All deductibles or self-insured retentions are the responsibility of CyDex or Company, as applicable, under the foregoing policies maintained by CyDex or Company, as applicable.

#### **11. LIMITATION OF LIABILITY.**

EXCEPT FOR DAMAGES FOR WHICH A PARTY IS RESPONSIBLE PURSUANT TO ITS CONFIDENTIALITY OBLIGATIONS SET FORTH IN **SECTION 8** AND INDEMNIFICATION OBLIGATIONS SET FORTH IN **SECTION 10** ABOVE, THE PARTIES SPECIFICALLY DISCLAIM 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 PRODUCT OR USE OF THE CAPTISOL PATENTS AND CAPTISOL DATA PACKAGE, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF A PARTY WERE ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. EXCEPT WITH RESPECT TO PAYMENTS DUE TO CYDEX PURSUANT TO **SECTION 4** OF THIS AGREEMENT AND THE INDEMNIFICATION SPECIFICALLY PROVIDED IN **SECTION 10** ABOVE, IN NO EVENT SHALL EITHER 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

\*\*\* 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.



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THIS AGREEMENT DURING THE [\*\*\*] 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 [\*\*\*] AFTER SUCH PARTY HAS KNOWLEDGE OF THE OCCURRENCE THAT GAVE RISE TO THE CAUSE OF SUCH ACTION.

## 12. MANAGEMENT OF CAPTISOL PATENTS.

**12.1 Prosecution and Maintenance.** CyDex shall maintain, at its sole cost and expense and using reasonable discretion, the Captisol Patents set forth on *Exhibit A*. 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 Captisol Patents.

**12.2 Infringement by Third Parties.** If Company becomes aware that a third party may be infringing a Licensed Patent, it will promptly notify CyDex. CyDex shall take whatever, if any, action it deems appropriate, in its sole discretion, against the alleged infringer. If CyDex elects to take action, Company shall, at CyDex's request and expense, cooperate and shall cause its employees to cooperate with CyDex in taking any such action, including but not limited to, cooperating with the prosecution of any infringement suit by CyDex. Company shall not take any such action against the alleged infringer without the written consent of CyDex.

## 13. TERM AND TERMINATION.

**13.1 Term.** The term of the Agreement (the "**Term**") shall commence upon the Effective Date and shall continue in effect thereafter until December 31, 2015, unless extended or earlier terminated by (i) one of the parties as expressly provided herein, or (ii) written agreement of the parties. The Term may be extended one time, at Company's sole discretion, for an additional period of five (5) years, expiring on December 31, 2020, by Company providing written notice to CyDex on or before December 31, 2014.

**13.2 Termination by CyDex.** If Company should violate or fail to perform any material term or covenant of this Agreement, then CyDex may give written notice of such default (a "**Notice of Default**") to Company. If Company should fail to cure such default within ninety (90) days of the date of such notice is received by Company or prior to the natural expiration date of this Agreement, whichever is shorter in duration, CyDex shall have the right to terminate this Agreement by a second written notice (a "**Notice of Termination**") to Company. If Notice of Termination is sent to Company, this Agreement shall automatically terminate on the date such notice is received by Company. In addition, CyDex may terminate this Agreement immediately upon written notice to Company in the event Company makes an assignment for the benefit of creditors or has a petition in bankruptcy filed for or against it that is not dismissed within ninety (90) days of such filing.

\*\*\* 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.

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**13.3 Termination by Company.** Company shall have the right at any time to terminate this Agreement in whole by giving CyDex at least [\*\*\*] prior written notice.

**13.4 Effect of Termination.** Following the termination or expiration of this Agreement for any reason:

(a) All rights granted to Company herein shall immediately terminate. For clarity, the termination of rights means that, except to as provided otherwise in separate agreements, (i) Company and its Affiliates shall not have the right to operate within the scope of any valid and enforceable claim contained in an issued patent within the Captisol Patents or the Restricted Patent Rights in any jurisdiction where such valid and enforceable claim exists; (ii) and Company and its Affiliates shall cease use of non-public Captisol-related toxicology/safety and other relevant non-public scientific safety data provided by CyDex to Company under this Agreement. Company acknowledges that reformulation of and new regulatory approvals for the Product may be required as a result of this provision.

(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.

**13.5 Survival.** Notwithstanding any other provisions of this Agreement, any liability or obligation of either party to the other for acts or omissions prior to 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 ordered by Company and shipped prior to termination or expiration of this Agreement, and subsequently received by Company in good condition meeting all specifications applicable at the time of order. Sections 2.2 (Grant of Licenses and Option from Company to CyDex), 3.6 (Quality Control; Acceptance and Rejection), 4.1 (Payments and Royalties for Licenses), 4.3 (Currency), 4.4 (Taxes), 4.5 (Late Payments), 7.3 (Adverse Event Reporting), 7.4 (Product Recalls), 8 (Confidentiality), 9.3 (Disclaimer), 10 (Indemnification and Insurance), 11 (Limitation of Liability), 13.4 (Effect of Termination), 13.5 (Survival), and 14 (General Provisions) shall survive termination or expiration of this Agreement.

\*\*\* 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.

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#### 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 incur any debts or make any commitments for the other.

**14.2 Compliance with Law.** Company agrees that use of the Captisol Patents and Captisol Data Package by Company and its Affiliates and Sublicensees, and the manufacture, handling, marketing, sale, distribution and use of Licensed Product, will comply with all Laws.

#### 14.3 Arbitration.

**(a) Procedure.** Any controversy or claim 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 Chicago, Illinois. The arbitration shall be conducted by an arbitrator(s) reasonably knowledgeable about the pharmaceutical industry and acceptable to CyDex and Company. If CyDex and Company cannot agree on a single arbitrator within [\*\*\*] after a written 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 (3) arbitrators shall hear and decide the issue in controversy. If either party fails to appoint an arbitrator within [\*\*\*] 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 Commercial Arbitration Rules of the American Arbitration Association in effect at the time the arbitration demand is made. The costs and fees of any arbitration shall be paid by [\*\*\*]. For purposes of this Agreement, "costs and fees" shall mean all reasonable pre-award expenses of the arbitration, including the fees of the arbitrator(s), administrative fees, travel expenses, out-of-pocket expenses such as copying and telephone, witness fees, and attorney's fees.

**(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, neither a party nor an arbitrator may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of both parties.

**(c) Interim Equitable Relief.** Either party may apply to the arbitrator(s) seeking injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either party may, without waiving any right or remedy under this Agreement, seek from any court having jurisdiction any interim or provisional relief (including but not limited to interim injunctive relief) that is necessary to protect the rights or property of that party, pending the establishment of an arbitration tribunal or pending the arbitration tribunal's determination of the merits of the controversy. Neither party shall commence any court proceeding or action against the other to resolve any dispute arising out of relating to this Agreement, or the breach thereof, except (i) to enforce an arbitral award rendered pursuant to this **Section 14.3**, or (ii) under the circumstances set forth in this Section 14.4(c).

\*\*\* 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.

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**(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 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, including but not limited to, war, insurrection, riot, fire, flood or other unusual weather condition, explosion, act of God, peril of the sea, strike, lockout or other industrial disturbance, sabotage, accident, embargo, breakage of machinery or apparatus, injunction, act of governmental authority, compliance with governmental order on national defense requirements, or inability 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.

**14.6 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; facsimile with receipt confirmed; or 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 14.6**. Unless otherwise provided, all notices shall be sent:

*If to CyDex, to:*

CyDex Pharmaceuticals, Inc.  
10513 W. 84<sup>th</sup> Terrace  
Lenexa, KS 66214  
Attention: General Manager  
Fax: (913) 685-8856

with a copy to:

Ligand Pharmaceuticals Incorporated  
11085 North Torrey Pines Road, Suite 300  
La Jolla, CA 92037  
Attn: General Counsel  
Fax : (858) 550-7272

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*If to Company, to:*

Schering-Plough Brinny Company  
Brinny  
Innishannon  
County Cork  
Ireland  
Attention: Plant Manager

with a copy to:

Merck Sharp & Dohme Corporation  
One Merck Drive  
Whitehouse Station, NJ 08889-0100  
Attention: VP & Assistant General Counsel, MMD  
Fax: (908) 423-4892

If sent by facsimile transmission, [\*\*\*] shall be deemed to be the date on which such notice, request or communication was given. If sent by overnight courier, [\*\*\*] 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 [\*\*\*] after the date of mailing shall be deemed the date on which such notice, request or communication was given.

**14.7 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 (i) as may be required by applicable law or regulation, or (ii) as approved in writing by the other party.

**14.8 Public Announcements.** Upon execution of this Agreement, CyDex or its Affiliate Ligand Pharmaceuticals Incorporated (Ligand) shall have the right to issue a press release so long as such press release has been reviewed and approved in writing by Company prior to issuance (such approval not to be unreasonably withheld) and file a Form 8-K with the SEC summarizing the Agreement. Thereafter, except for such disclosure as is deemed necessary, in the reasonable judgment of a party, to comply with applicable laws or regulations, securities filings or the rules of the NYSE or NASDAQ, no announcement, news release, public statement, publication, or presentation relating to the existence of this Agreement, or the terms hereof, will be made without the other party's prior written approval; such prior written approval not to be unreasonably withheld. In the event of a required public announcement, the party making such announcement shall provide the other party with a copy of the proposed text prior to such announcement sufficiently in advance of the scheduled release of such announcement to afford such other party a reasonable opportunity to review and comment upon the proposed text and the timing of such disclosure. In the event that Ligand files a copy of the Agreement with the SEC, CyDex shall afford Company a reasonable opportunity to review and comment upon the proposed redactions, if any.

\*\*\* 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.

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**14.9 Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of New York (without giving effect to any conflicts of law principles that require the application of the law of a different state).

**14.10 Entire Agreement; Amendment.** This Agreement and all Exhibits attached hereto or thereto contain the entire agreement of the parties relating to the subject matter hereof and supersede any and all prior agreements, written or oral, between CyDex and Company relating to the subject matter of this Agreement. This Agreement may not be amended unless agreed to in writing by both parties.

**14.11 Binding Effect.** This Agreement shall be binding upon, and the rights and obligations hereof shall apply to the 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.

**14.12 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.

**14.13 Severability.** If a final judicial determination is made that any provision of this Agreement is unenforceable, this Agreement shall be rendered void only to the extent that such judicial determination finds such provisions unenforceable, and such unenforceable provisions shall be automatically reconstituted and become a part of this Agreement, effective as of the date first written above, to the maximum extent they are lawfully enforceable.

**14.14 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 its rights and delegate its obligations under this Agreement to an Affiliate or to a third party successor, whether by way of merger, sale of all or substantially all of its assets of the business to which this Agreement pertains, sale of stock or otherwise, without the other party's prior written consent. As a condition to any permitted assignment hereunder, the assignor hereby guarantees the performance of any assignee to the terms and obligations of this Agreement. Any assignment not in accordance with this **Section 14.14** shall be void.

**14.15 Third Party Beneficiaries.** Except for the rights of Indemnitees pursuant to **Section 10** hereof, and subject to Section 8.5 hereof, the terms and provisions of this Agreement are intended solely for the benefit of each party hereto and their respective Affiliates, successors or permitted assigns and it is not the intention of the parties to confer third-party beneficiary

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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, its Affiliates or such Indemnitees, and not Sublicensees.

**14.16 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.

**14.17 Counterparts.** This Agreement may be executed in two counterparts, 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]*

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

**CYDEX PHARMACEUTICALS, INC.**

By: /s/ Matt Foehr

Name: Matt Foehr

Title: Executive Vice President, Chief Operating Officer

**MERCK SHARP & DOHME CORPORATION**

By: /s/ J.P. Hanthold

Name: J.P. Hanthold

Title: Director of Global Procurement



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**EXHIBIT A**

**CAPTISOL PATENTS**

***				
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***	***	***	***	***
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\*\*\* 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.

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*LICENSE AND SUPPLY AGREEMENT*

*EXHIBIT A-2*

\*\*\* 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.

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**EXHIBIT B**  
**SPECIFICATIONS**

[\*\*\*]

[\*\*\*]

\* \* \* \* \*

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*LICENSE AND SUPPLY AGREEMENT*

*EXHIBIT B-1*

\*\*\* 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.

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[\*\*\*]

\* \* \* \* \*

\*\*\* 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.

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**EXHIBIT C**

**PURCHASE PRICE FOR CAPTISOL**

[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]

[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]

\* \* \* \* \*

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*LICENSE AND SUPPLY AGREEMENT*

*EXHIBIT C-1*

\*\*\* 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.

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**EXHIBIT D**

**RESTRICTED PATENT RIGHTS**

[***]				
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

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*LICENSE AND SUPPLY AGREEMENT*

*EXHIBIT D-1*

\*\*\* 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.

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**EXHIBIT E**

**EXTERNAL SUPPLIER PROCESS CHANGE AGREEMENT FORM**

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. ("Merck"), is committed to achieving the highest standards of quality and is dedicated to continuous improvement in compliance and quality through our business processes and practices with our suppliers. That said, suppliers are responsible for manufacturing their products in conformance with all laws and regulations that pertain to their specific operations. Suppliers are also responsible for assuring that they have qualified personnel with adequate training to control their own manufacturing processes and ensure consistent quality. Such controls extend to your firm properly evaluating any change in the materials; equipment or processes to ensure your products conform to original specifications.

Sometimes, a change in materials, equipment or process by a supplier may have an unintended impact on the product produced by the supplier and subsequently have an unintended impact on a product being produced by the customer. Merck requires notification of certain changes in materials, equipment or process so as to be able to evaluate whether such change may have an unintended impact on our use of your product. Our requiring this information does not alter your own responsibility in evaluating any and all changes undertaken by your firm.

This agreement will be relevant for any and all products Merck or any of its affiliates, including without limitation Schering Corporation, receives from any of your approved facilities.

Examples of changes that require prior notification and approval by Merck are described in the attached agreement. In the event of uncertainty as to whether or not notification is required, please contact your local Merck procurement office.

**Does Require Notification**

[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
  
[\*\*\*]  
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[\*\*\*]

**Does Not Require Notification**

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\*\*\* 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.

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CyDex agrees to notify local Merck Procurement contact using the External Supplier Process Change Notification Form (next page), or other written notification containing equivalent information, prior to implementing changes in accordance with this Exhibit.

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**External Supplier Change Notification Form**

**1. GENERAL INFORMATION:**

Company:	_____	Product Supplied	_____
Address	_____	Date:	_____
	_____	Phone:	_____
	_____	Fax:	_____

**2. Target Date for Full Scale Implementation**

**3. Will Sample Be Available?**       Yes       No      If Yes, Date sample available \_\_\_\_\_

**4. CHANGE DESCRIPTION: (Attach more info as required)**

**Current:**

**Proposed:**

**5. TECHNICAL INFO – Describe relevant technical information. (Attach more info as required)**

**6. SUMMARY CHECKLIST: Impact to supplier**

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Cleaning Validation Impact? (if yes, technical info must describe cleaning validation plan)
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Equipment Qualification Impact? (if yes, technical info must describe equipment validation plan)
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Process Validation Impact? (if yes, technical info must describe process validation plan)
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Labeling or Artwork Impact? (if yes, technical info must describe labeling/artwork impact)
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Packaging or Shipping Impact? (if yes, technical info must describe packaging/shipping impact)
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Regulatory Impact? (if yes, technical info must describe regulatory impact)
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Change in Quality? (E.g. chemical composition, impurity profile, shelf life)?

Supplier Signature: \_\_\_\_\_ Title: \_\_\_\_\_ Date: \_\_\_\_\_

Printed Name \_\_\_\_\_

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a)  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John L. Higgins, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ligand Pharmaceuticals Incorporated;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer 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 report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2011

/s/ John L. Higgins

John L. Higgins

President, Chief Executive Officer and Director

(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a)  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John P. Sharp, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ligand Pharmaceuticals Incorporated;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer 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 report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2011

/s/ John P. Sharp

John P. Sharp

Vice President, Finance and Chief Financial Officer  
(Principal Financial Officer)

**CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the accompanying Quarterly Report on Form 10-Q of Ligand Pharmaceuticals Incorporated (the "Company") for the quarter ended June 30, 2011, I, John L. Higgins, President, Chief Executive Officer and Director of the Company, hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge and belief, that:

(1) such Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in such Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, fairly presents, in all material respects, the financial condition and results of operations of the Company.

The foregoing certification is being furnished solely to accompany such Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Date: August 8, 2011

/s/ John L. Higgins

John L. Higgins

*President, Chief Executive Officer and Director*

*(Principal Executive Officer)*

**CERTIFICATION BY PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the accompanying Quarterly Report on Form 10-Q of Ligand Pharmaceuticals Incorporated (the "Company") for the quarter ended June 30, 2011, I, John P. Sharp, Vice President, Finance and Chief Financial Officer of the Company, hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge and belief, that:

(1) such Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in such Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, fairly presents, in all material respects, the financial condition and results of operations of the Company.

The foregoing certification is being furnished solely to accompany such Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Date: August 8, 2011

/s/ John P. Sharp

John P. Sharp

*Vice President, Finance and Chief Financial Officer  
(Principal Financial Officer)*