

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

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**FORM 10-Q**

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

**For the quarterly period ended September 30, 2013**

or

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

**For the Transition Period From \_\_\_\_\_ to \_\_\_\_\_. Commission File Number: 001-33093**

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**LIGAND PHARMACEUTICALS INCORPORATED**

**(Exact name of registrant as specified in its charter)**

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**Delaware**

**(State or other jurisdiction of  
incorporation or organization)**

**11119 North Torrey Pines Road, Suite 200**

**La Jolla, CA**

**(Address of principal executive offices)**

**77-0160744**

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

**92037**

**(Zip Code)**

**(858) 550-7500**

**(Registrant's Telephone Number, Including Area Code)**

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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

Non-Accelerated Filer  (Do not check if a smaller reporting company)

Accelerated Filer

Smaller Reporting Company

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

As of October 29, 2013, the registrant had 20,410,247 shares of common stock outstanding.

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LIGAND PHARMACEUTICALS INCORPORATED  
QUARTERLY REPORT

FORM 10-Q

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### PART I. FINANCIAL INFORMATION

#### ITEM 1. FINANCIAL STATEMENTS

### LIGAND PHARMACEUTICALS INCORPORATED CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(in thousands, except share data)

	September 30, 2013	December 31, 2012
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 3,271	\$ 12,381
Accounts receivable	5,507	4,589
Inventory	1,838	1,697
Other current assets	1,512	829
Current portion of co-promote termination payments receivable	4,507	4,327
Total current assets	16,635	23,823
Restricted cash and investments	4,968	2,767
Property and equipment, net	834	788
Deferred income taxes	8	8
Intangible assets, net	53,692	55,912
Goodwill	12,238	12,238
Commercial license rights	4,571	—
Long-term portion of co-promote termination payments receivable	8,387	8,207
Other assets	344	517
Total assets	\$ 101,677	\$ 104,260
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,304	\$ 5,854
Accrued liabilities	4,619	4,961
Current portion of contingent liabilities	1,879	356
Current portion of deferred income taxes	1,581	1,581
Current portion of note payable	12,375	14,835
Current portion of co-promote termination liability	4,507	4,327
Current portion of lease exit obligations	2,860	3,039
Current portion of deferred revenue	336	486
Total current liabilities	32,461	35,439
Long-term portion of note payable	—	13,443
Long-term portion of co-promote termination liability	8,387	8,207
Long-term portion of deferred revenue, net	2,085	2,369
Long-term portion of lease exit obligations	3,725	5,963
Deferred income taxes	962	725
Long-term portion of contingent liabilities	8,552	10,543
Other long-term liabilities	690	1,086
Total liabilities	56,862	77,775
Commitments and Contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 33,333,333 shares authorized; 21,528,284 and 21,278,606 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	22	21
Additional paid-in capital	758,080	751,503
Accumulated other comprehensive income	2,201	—
Accumulated deficit	(673,208)	(682,759)
Treasury stock, at cost; 1,118,222 shares at September 30, 2013 and December 31, 2012, respectively	(42,280)	(42,280)
Total stockholders' equity	44,815	26,485
Total liabilities and stockholders' equity	\$ 101,677	\$ 104,260

See accompanying notes.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	2012	2013	2012
<b>Revenues:</b>				
Royalties	\$ 5,724	\$ 3,213	\$ 16,466	\$ 9,256
Material sales	6,728	1,818	12,260	4,150
Collaborative research and development and other revenues	553	1,344	5,511	4,347
Total revenues	<u>13,005</u>	<u>6,375</u>	<u>34,237</u>	<u>17,753</u>
<b>Operating costs and expenses:</b>				
Cost of sales	2,538	683	4,416	1,273
Research and development	2,414	2,647	6,900	8,315
General and administrative	4,756	4,306	13,564	11,579
Lease exit and termination costs	227	164	359	666
Write-off of in-process research and development	—	—	480	—
Total operating costs and expenses	<u>9,935</u>	<u>7,800</u>	<u>25,719</u>	<u>21,833</u>
Income (loss) from operations	<u>3,070</u>	<u>(1,425)</u>	<u>8,518</u>	<u>(4,080)</u>
<b>Other (expense) income:</b>				
Interest expense, net	(394)	(735)	(1,755)	(2,198)
(Increase) decrease in contingent liabilities	(532)	2,093	368	1,191
Other, net	(119)	15	69	272
Total other (expense) income, net	<u>(1,045)</u>	<u>1,373</u>	<u>(1,318)</u>	<u>(735)</u>
Income (loss) before income taxes	2,025	(52)	7,200	(4,815)
Income tax expense	(60)	(142)	(237)	(445)
Income (loss) from continuing operations	<u>1,965</u>	<u>(194)</u>	<u>6,963</u>	<u>(5,260)</u>
<b>Discontinued operations:</b>				
Gain on sale of Avinza Product Line before income taxes	—	—	2,588	3,656
Income tax benefit on discontinued operations	—	—	—	14
Income from discontinued operations	<u>—</u>	<u>—</u>	<u>2,588</u>	<u>3,670</u>
Net income (loss):	<u>\$ 1,965</u>	<u>\$ (194)</u>	<u>\$ 9,551</u>	<u>\$ (1,590)</u>
<b>Basic per share amounts:</b>				
Income (loss) from continuing operations	\$ 0.10	\$ (0.01)	\$ 0.34	\$ (0.27)
Income from discontinued operations	—	—	0.13	0.19
Net income (loss)	<u>\$ 0.10</u>	<u>\$ (0.01)</u>	<u>\$ 0.47</u>	<u>\$ (0.08)</u>
<b>Diluted per share amounts:</b>				
Income (loss) from continuing operations	\$ 0.09	\$ (0.01)	\$ 0.33	\$ (0.27)
Income from discontinued operations	—	—	0.13	0.19
Net income (loss)	<u>\$ 0.09</u>	<u>\$ (0.01)</u>	<u>\$ 0.46</u>	<u>\$ (0.08)</u>
Weighted average number of common shares-basic	<u>20,357,558</u>	<u>19,917,676</u>	<u>20,268,261</u>	<u>19,791,793</u>
Weighted average number of common shares-diluted	<u>20,843,742</u>	<u>19,917,676</u>	<u>20,562,622</u>	<u>19,791,793</u>

*See accompanying notes.*

**LIGAND PHARMACEUTICALS INCORPORATED**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**  
**(Unaudited)**  
**(in thousands)**

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Net income (loss)	\$ 1,965	\$ (194)	\$ 9,551	\$ (1,590)
Unrealized net gain on available-for-sale securities, net of tax of \$0	806	—	2,201	—
Comprehensive income (loss)	<u>\$ 2,771</u>	<u>\$ (194)</u>	<u>\$ 11,752</u>	<u>\$ (1,590)</u>

*See accompanying notes.*

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

	Nine Months Ended	
	September 30,	
	2013	2012
<b>Operating activities</b>		
Net income (loss)	\$ 9,551	\$ (1,590)
Less: gain from discontinued operations	2,588	3,670
Income (loss) from continuing operations	6,963	(5,260)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Non-cash change in estimated fair value of contingent liabilities	(368)	(1,191)
Write-off of in-process research and development	480	—
Depreciation and amortization	2,007	1,978
Share-based compensation	4,149	3,116
Deferred income taxes	237	446
Accretion of note payable	321	362
Other	(13)	(14)
Changes in operating assets and liabilities:		
Accounts receivable	(918)	3,953
Inventory	86	(798)
Other current assets	(683)	329
Other long-term assets	173	322
Accounts payable and accrued liabilities	(2,306)	(3,009)
Other liabilities	(396)	15
Deferred revenue	(434)	(1,710)
Net cash provided by (used in) operating activities of continuing operations	9,298	(1,461)
Net cash used in operating activities of discontinued operations	(642)	(550)
Net cash provided by (used in) operating activities	8,656	(2,011)
<b>Investing activities</b>		
Purchase of commercial license rights	(3,571)	—
Payments to CVR holders and former license holders	(100)	(8,049)
Purchases of property and equipment	(263)	(633)
Proceeds from sale of property and equipment	3	17
Proceeds from sale of short-term investments	—	10,000
Other	(40)	—
Net cash (used in) provided by investing activities	(3,971)	1,335
<b>Financing activities</b>		
Proceeds from issuance of debt	—	7,500
Repayment of debt	(16,224)	(10,000)
Net proceeds from issuance of common stock	—	2,647
Net proceeds from employee stock purchase plan	84	68
Net proceeds from stock option exercises	2,345	466
Net cash (used in) provided by financing activities	(13,795)	681
Net (decrease) increase in cash and cash equivalents	(9,110)	5
Cash and cash equivalents at beginning of period	12,381	7,041
Cash and cash equivalents at end of period	\$ 3,271	\$ 7,046
<b>Supplemental Disclosure of cash flow information</b>		
Interest paid	\$ 1,566	\$ 1,854
Taxes paid	5	15
<b>Supplemental schedule of non-cash activity</b>		
Liability for commercial license rights	\$ 1,000	\$ —
Accrued inventory purchases	227	449
Unrealized gain on AFS investments	2,201	—
<i>See accompanying notes.</i>		

**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 biopharmaceutical company with a business model that is based upon the concept of developing or acquiring revenue generating assets and coupling them to a lean corporate cost structure. By diversifying the portfolio of assets across numerous technology types, therapeutic areas, drug targets, and industry partners, the Company offers investors an opportunity to invest in the increasingly complicated and unpredictable pharmaceutical industry. These therapies address the unmet medical needs of patients for a broad spectrum of diseases including hepatitis, multiple myeloma, muscle wasting, Alzheimer's disease, dyslipidemia, diabetes, anemia, asthma, FSGS and osteoporosis. Ligand has established multiple alliances with the world's leading pharmaceutical companies including GlaxoSmithKline, Onyx Pharmaceuticals (recently acquired by Amgen), Merck, Pfizer, Baxter International, Bristol-Myers Squibb, Lundbeck Inc., and Spectrum Pharmaceuticals, Inc. The Company's principal 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. As of September 30, 2013, the Company's accumulated deficit was approximately \$673.2 million and the Company had negative working capital of approximately \$15.8 million. Management believes that cash flows from operations will improve due to Captisol® sales, an increase in revenues driven primarily from continued increases in Promacta® and Kyprolis® sales, and also from anticipated new license and milestone revenues. In the event revenues and operating cash flows are not meeting expectations, management plans to reduce discretionary expenses. However, it is possible that the Company may be required to seek additional financing. There can be no assurance that additional financing will be available on terms acceptable to management, or at all. Management believes its currently available cash and cash equivalents as well as its current and future royalty, license and milestone revenues will be sufficient to satisfy its anticipated operating and capital requirements through at least the next 12 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; costs associated with future acquisitions and the capital requirements of any companies the Company may acquire in the future. 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 accompanying consolidated financial statements include Ligand and its wholly owned subsidiaries, Ligand JVR, Allergan Ligand Retinoid Therapeutics, Seragen, Inc. ("Seragen"), Pharmacopeia, Inc. ("Pharmacopeia"), Neurogen Corporation ("Neurogen"), Metabasis Therapeutics, Inc. ("Metabasis"), CyDex Pharmaceuticals, Inc. ("CyDex") and Nexus VI LLC ("Nexus"). All significant intercompany accounts and transactions have been eliminated in consolidation.

*Basis of Presentation*

The Company's accompanying unaudited condensed consolidated financial statements as of September 30, 2013 and for the three and nine months ended September 30, 2013 and 2012 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. The Company's condensed consolidated balance sheet at December 31, 2012 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 the Company, and its subsidiaries have been included. Operating results for the three and nine months ended September 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013. These financial statements should be read in conjunction with the consolidated financial statements and notes therein included in the Company's annual report on Form 10-K for the year ended December 31, 2012.

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### Use of Estimates

The preparation of condensed 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 condensed 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.

### Reclassifications

Certain reclassifications have been made to the previously issued statement of operations for the three and nine months ended September 30, 2012 for comparability purposes. These reclassifications had no effect on the reported net income, stockholders' equity, and operating cash flows as previously reported.

### Earnings (Loss) Per Share

Basic earnings (loss) 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. The total number of potential common shares excluded from the computation of diluted loss per share because their inclusion would have been anti-dilutive was 0.9 million and 1.3 million, at September 30, 2013 and 2012, 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		Nine months ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Net income (loss) from continuing operations	\$ 1,965	\$ (194)	\$ 6,963	\$ (5,260)
Net income from discontinued operations	—	—	2,588	3,670
Net income (loss)	<u>\$ 1,965</u>	<u>\$ (194)</u>	<u>\$ 9,551</u>	<u>\$ (1,590)</u>
Shares used to compute basic income (loss) per share	20,357,558	19,917,676	20,268,261	19,791,793
Dilutive potential common shares:				
Restricted stock	77,609	—	62,051	—
Stock options	408,575	—	232,310	—
Shares used to compute diluted income (loss) per share	<u>20,843,742</u>	<u>19,917,676</u>	<u>20,562,622</u>	<u>19,791,793</u>
Basic per share amounts:				
Income (loss) from continuing operations	\$ 0.10	\$ (0.01)	\$ 0.34	\$ (0.27)
Income from discontinued operations	—	—	0.13	0.19
Net income (loss)	<u>\$ 0.10</u>	<u>\$ (0.01)</u>	<u>\$ 0.47</u>	<u>\$ (0.08)</u>
Diluted per share amounts:				
Income (loss) from continuing operations	\$ 0.09	\$ (0.01)	\$ 0.33	\$ (0.27)
Income from discontinued operations	—	—	0.13	0.19
Net income (loss)	<u>\$ 0.09</u>	<u>\$ (0.01)</u>	<u>\$ 0.46</u>	<u>\$ (0.08)</u>

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### *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. Non-restricted equity and debt securities with a maturity of more than three months are considered short-term investments.

### *Restricted Cash and Investments*

Restricted cash and investments consist of certificates of deposit held with a financial institution as collateral under a facility lease including third-party service provider arrangements and available-for-sale securities received by the Company as a result of milestone payments from a licensee. The fair value of the Company's available-for-sale securities are determined using quoted market prices in active markets and are discounted based on trading restrictions.

The following table summarizes the various investment categories at September 30, 2013 and December 31, 2012 (in thousands):

	Cost	Gross unrealized gains	Gross unrealized losses	Estimated fair value
<b>September 30, 2013</b>				
Available-for-sale securities	\$ 1,426	\$ 2,201	\$ —	\$ 3,627
Certificates of deposit - restricted	1,341	—	—	1,341
	<u>\$ 2,767</u>	<u>\$ 2,201</u>	<u>\$ —</u>	<u>\$ 4,968</u>
<b>December 31, 2012</b>				
Available-for-sale securities	\$ 1,426	\$ —	\$ —	\$ 1,426
Certificates of deposit-restricted	1,341	—	—	1,341
	<u>\$ 2,767</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,767</u>

### *Concentrations of Credit Risk*

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash equivalents, 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. The Company has not experienced any significant losses on its cash equivalents, short-term investments or restricted investments for the periods ending September 30, 2013 and December 31, 2012.

As of September 30, 2013 and December 31, 2012, cash deposits held at financial institutions in excess of FDIC insured amounts of \$250,000 were approximately \$2.8 million and \$11.9 million, respectively.

Accounts receivable from two customers was 48% and 39% of total accounts receivable at September 30, 2013. Accounts receivable from two customers was 53% and 35% of total accounts receivable at December 31, 2012.

The Company currently obtains Captisol from a sole-source supplier. If this supplier was 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.

### *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.

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### Property and Equipment

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

	September 30, 2013	December 31, 2012
Lab and office equipment	\$ 4,541	\$ 4,374
Leasehold improvements	213	145
Computer equipment and software	1,025	1,150
	5,779	5,669
Less accumulated depreciation and amortization	(4,945)	(4,881)
	\$ 834	\$ 788

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. Depreciation expense of \$0.1 million and \$0.2 million was recognized for the three and nine months ended September 30, 2013 and 2012, respectively.

### Other Current Assets

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

	September 30, 2013	December 31, 2012
Prepaid expenses	\$ 1,393	\$ 801
Other receivables	119	28
	\$ 1,512	\$ 829

### Goodwill and Other Identifiable Intangible Assets

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

	September 30, 2013	December 31, 2012
Indefinite lived intangible assets		
Acquired in-process research and development	\$ 12,556	\$ 13,036
Goodwill	12,238	12,238
Definite lived intangible assets		
Complete technology	15,267	15,227
Trade name	2,642	2,642
Customer relationships	29,600	29,600
	47,509	47,469
Accumulated amortization	(6,373)	(4,593)
Total goodwill and other identifiable intangible assets, net	\$ 65,930	\$ 68,150

The Company accounts for goodwill and other intangible assets in accordance with Accounting Standards Codification Topic 350-Intangibles-Goodwill and Other ("ASC 350") which, among other things, establishes standards for goodwill acquired in a business combination, eliminates the amortization of goodwill and requires the carrying value of goodwill and certain non-amortizing intangibles to be evaluated for impairment on an annual basis. The Company considers its market capitalization and

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the carrying value of its assets and liabilities, including goodwill, when performing its goodwill impairment test. If the carrying value of the assets and liabilities, including goodwill, were to exceed the Company's estimation of the fair value, the Company would record an impairment charge in an amount equal to the excess of the carrying value of goodwill over the implied fair value of the goodwill. The Company performs an evaluation of goodwill and other intangibles as of December 31 of each year, absent any indicators of earlier impairment, to ensure that impairment charges, if applicable, are reflected in our financial results before December 31 of each year. When it is determined that impairment has occurred, a charge to operations is recorded. Goodwill and other intangible asset balances are included in the identifiable assets of the business segment to which they have been assigned. Any goodwill impairment, as well as the amortization of other purchased intangible assets, is charged against the respective business segments' operating income.

Amortization of definite lived intangible assets is computed using the straight-line method over the estimated useful life of the asset of 20 years. Amortization expense of \$0.6 million and \$1.8 million was recognized for the three and nine months ended September 30, 2013 and 2012, respectively. Estimated amortization expense for the year ending December 31, 2013 through 2017 is \$2.4 million per year.

### *Acquired In-Process Research and Development*

Intangible assets related to acquired in-process research and development (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. For the nine months ended September 30, 2013, the Company recorded a non-cash impairment charge of \$0.5 million for the write-off of IPR&D for Captisol-enabled IV Clopidogrel. The asset was impaired upon notification from the Medicines Company that they intended to terminate the license agreement and return the rights of the compound to the Company. Captisol-enabled IV Clopidogrel is an intravenous option of the anti-platelet medication designed for situations where the administration of oral platelet inhibitors is not feasible or desirable. For the three months ended September 30, 2013 and the three and nine months ended September 30, 2012, there was no impairment of IPR&D.

### *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 September 30, 2013, 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.

### *Commercial license rights*

Commercial license rights represent a portfolio of future milestone and royalty payment rights acquired in accordance with the Royalty Stream and Milestone Payments Purchase Agreement entered into with Selexis SA ("Selexis") in April 2013. The portfolio consists of over 15 Selexis commercial license agreement programs with various pharmaceutical-company counterparties. The purchase price was \$4.6 million, inclusive of acquisition costs. The Company paid \$3.6 million upon closing and will pay \$1 million in April 2014. Individual commercial license rights acquired under the agreement are carried at allocated cost and approximate fair value. The carrying value of the license rights will be reduced on a pro-rata basis as revenue is realized over the term of the agreement. Declines in the fair value of individual license rights below their carrying value that are deemed to be other than temporary are reflected in earnings in the period such determination is made.

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### Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2013	December 31, 2012
Compensation	\$ 1,734	\$ 1,807
Professional fees	280	199
Other	2,605	2,955
	<u>\$ 4,619</u>	<u>\$ 4,961</u>

### Other Long-Term Liabilities

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

	September 30, 2013	December 31, 2012
Deposits	\$ 336	\$ 538
Deferred rent	354	334
Other	—	214
	<u>\$ 690</u>	<u>\$ 1,086</u>

### Contingent Liabilities

In connection with the Company's acquisition of CyDex in January 2011, the Company recorded a \$17.6 million contingent liability, inclusive of the \$4.3 million payment made in January 2012, for amounts potentially due to holders of the CyDex contingent value rights ("CVRs") and former license holders. The liability is periodically assessed based on events and circumstances related to the underlying milestones, and the change in fair value is recorded in the Company's consolidated statements of operations. The carrying amount of the 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 September 30, 2013 and December 31, 2012 was \$8.7 million and \$10.9 million, respectively. The Company recorded a fair value adjustment to increase the liability for CyDex related contingent liabilities of \$1.2 million for the three months ended September 30, 2013 and an adjustment to decrease the liability of \$2.1 million for the nine months ended September 30, 2013. The Company recorded fair value adjustments to increase the liability for CyDex related contingent liabilities of \$0.1 million for the three months ended September 30, 2012 and adjustments to decrease the liability \$2.1 million for the nine months ended September 30, 2012. Additionally, the Company recorded cash payments of \$0.1 million for the Topiramate orphan drug designation milestone for the three and nine months ended September 30, 2013. The Company recorded a cash payment of \$3.5 million for the FDA approval milestone of Kyprolis for the three months ended September 30, 2012. The Company recorded cash payments of \$4.3 million for the January 2012 guaranteed payment, \$0.2 million for the 2011 revenue sharing payment, and \$3.5 million for the FDA approval milestone of Kyprolis for the nine months ended September 30, 2012. There was no revenue sharing payment made for the three and nine months ended September 30, 2013.

In connection with the Company's acquisition of Metabasis in January 2010, the Company issued Metabasis stockholders four tradable CVRs, one CVR from each of four respective series of CVR, for each Metabasis share. The CVRs will entitle Metabasis stockholders to cash payments as frequently as every six months as cash is received by the Company from proceeds from Metabasis' partnership with Roche (which has been terminated) or the sale or partnering of any of the Metabasis drug development programs, among other triggering events. The fair values of the CVRs are remeasured at each reporting date through the term of the related agreement. Changes in the fair values are reported in the statement of operations as income (decreases) or expense (increases). The carrying amount of the liability may fluctuate significantly based upon quoted market prices and actual amounts paid under the agreements may be materially different than the carrying amount of the liability. The fair value of the liability was estimated to be \$1.7 million and \$0 as of September 30, 2013 and December 31, 2012, respectively. The Company recorded decrease in the liability for Metabasis related CVRs of \$0.7 million for the three months ended September 30, 2013 and an increase of \$1.7 million for the nine months ended September 30, 2013. The

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Company recorded no change in the liability for CVRs during the three months ended September 30, 2012 and a decrease in the liability for CVRs of \$1.1 million during the nine months ended September 30, 2012.

In connection with the Company's acquisition of Neurogen in December 2009, the Company issued to Neurogen stockholders four CVRs; real estate, Aplindore, VR1 and H3, that entitle them to cash and/or shares of third-party stock under certain circumstances. The Company recorded the acquisition-date fair value of the CVRs as part of the purchase price. In February 2010, the Company completed the sale of the real estate and subsequently distributed the proceeds to the holders of the real estate CVR. As a result and after final settlement of all related expenses, the real estate CVR was terminated in August 2010. In 2012, the Company received a notice from a collaboration partner that it was terminating its agreement related to VR1 for convenience and subsequently the Company recorded a decrease in the fair value of the liability for the related CVR of \$0.2 million. Additionally, per the CVR agreement, no payment event date for the H3 program can occur after December 23, 2012 and the Company recorded a decrease in the fair value of the liability for the related CVR of \$0.5 million. There are no remaining CVR obligations under the agreement with the former Neurogen shareholders.

### *Revenue Recognition*

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

Revenue from material sales is recognized upon transfer of title, which normally passes 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 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.

Nonrefundable, up-front license fees and milestone payments with standalone value that are not dependent on any future performance by us under our 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. The Company occasionally has sub-license obligations related to arrangements for which it receives license fees, milestones and royalties. The Company evaluates the determination of gross versus net reporting based on each individual agreement.

The Company analyzes its revenue arrangements and other agreements to determine whether there are multiple elements that should be separated and accounted for individually or as a single unit of accounting. For multiple element contracts, arrangement consideration is allocated at the inception of the arrangement to all deliverables on the basis of relative selling price, using a hierarchy to determine selling price. Management first considers vendor-specific objective evidence ("VSOE"), then third-party evidence ("TPE") and if neither VSOE nor TPE exist, the Company uses its best estimate of selling price.

Many of the Company's revenue arrangements involve the bundling of a license with the option to purchase manufactured product. Licenses are granted to pharmaceutical companies for the use of Captisol in the development of pharmaceutical compounds. The licenses may be granted for the use of the Captisol product for all phases of clinical trials and through commercial availability of the host drug or may be limited to certain phases of the clinical trial process. The Company believes that its licenses have stand-alone value at the outset of an arrangement because the customer obtains the right to use Captisol in its formulations without any additional input by the Company and the customer is able to procure inventory from another manufacturer in the absence of contractual provisions for exclusive supply by the Company.

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.

### *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

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for collectability. 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 September 30, 2013 and December 31, 2012.

### Accounting for Share-Based Compensation

Share-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 following table summarizes share-based compensation expense recorded as components of research and development expenses and general and administrative expenses for the periods indicated (in thousands):

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Share-based compensation expense as a component of:				
Research and development expenses	\$ 438	\$ 263	\$ 1,272	\$ 1,211
General and administrative expenses	1,095	750	2,877	1,905
	<u>\$ 1,533</u>	<u>\$ 1,013</u>	<u>\$ 4,149</u>	<u>\$ 3,116</u>

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		Nine months ended	
	September 30,		September 30,	
	2013	2012	2013	2012
Risk-free interest rate	1.8%	0.8%	1.4%	1.0%
Dividend yield	—	—	—	—
Expected volatility	70%	69%	70%	69%
Expected term	6.3	6.2	6.3	6.3
Forfeiture rate	8.8%	8.2%	8.4%-9.8%	8.0%-11.2%

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.

### Preclinical Study and Clinical Trial Accruals

Substantial portions of the Company's preclinical studies and all of the Company's clinical trials have been performed by third-party laboratories, contract research organizations, or other vendors (collectively "CROs"). Some CROs bill monthly for services performed, while others bill based upon milestone achievement. The Company accrues for each of the agreements it has with CROs on a monthly basis. For preclinical studies, accruals are estimated based upon the percentage of work completed and the contract milestones achieved. For clinical studies, accruals are estimated based upon a percentage of work completed, the number of patients enrolled and the duration of the study. The Company monitors patient enrollment, the progress of clinical studies and related activities to the extent possible through internal reviews of data reported to it by the CROs, correspondence with the CROs and clinical site visits. The Company's estimates are dependent upon the timelines and accuracy of the data provided by its CROs regarding the status of each program and total program spending. The Company periodically evaluates its estimates to determine if adjustments are necessary or appropriate based on information it receives concerning changing circumstances, and conditions or events that may affect such estimates. No material adjustments to preclinical study and clinical trial accrued expenses have been recognized to date.

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### *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. As of September 30, 2013 and December 31, 2012, the Company had deferred \$0.3 million and \$0.8 million, respectively, of revenue related to the sale of royalty rights. As of September 30, 2013, \$0.3 million is included in current portion of deferred revenue and there is no long-term portion of deferred revenue related to the sale of royalty rights. As of December 31, 2012, \$0.5 million is included in current portion of deferred revenue and \$0.3 million is included in long-term portion of deferred revenue related to the sale of royalty rights.

### *Product Returns*

In connection with the sale of the Avinza and Oncology product lines, the Company retained the obligation for returns of product that were shipped to wholesalers prior to the close of the transactions. The accruals for product returns, which were recorded as part of the accounting for the sales transactions, are based on historical experience. Any subsequent changes to the Company's estimate of product returns are accounted for as a component of discontinued operations.

### *Costs and Expenses*

Collaborative research and development expense consists of labor, material, equipment and allocated facility cost of the Company's scientific staff who are working pursuant to the Company's collaborative agreements. From time to time, collaborative research and development expense includes costs related to research efforts in excess of those required under certain collaborative agreements. Management has the discretion to set the scope of such excess efforts and may increase or decrease the level of such efforts depending on the Company's strategic priorities.

Proprietary research and development expense consists of intellectual property in-licensing costs, labor, materials, contracted services, and allocated facility costs that are incurred in connection with internally funded drug discovery and development programs.

### *Income Taxes*

Income taxes are accounted for under the liability method. This approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of differences between the tax basis of assets or liabilities and their carrying amounts in the consolidated financial statements. A valuation allowance is provided for deferred tax assets if it is more likely than not that these items will either expire before we are able to realize their benefit or if future deductibility is uncertain. As of September 30, 2013, we have provided a full valuation allowance against our deferred tax assets as recoverability was uncertain. Developing the provision for income taxes requires significant judgment and expertise in federal and state income tax laws, regulations and strategies, including the determination of deferred tax assets and liabilities and, if necessary, any valuation allowances that may be required for deferred tax assets. Our judgments and tax strategies are subject to audit by various taxing authorities. While we believe we have provided adequately for our income tax liabilities in our consolidated financial statements, adverse determinations by these taxing authorities could have a material adverse effect on our consolidated financial condition and results of operations.

Our ending deferred tax liability represents a future tax obligation for current tax amortization claimed on acquired IPR&D. As we cannot estimate when the IPR&D assets will be amortizable for financial reporting purposes, the deferred tax liability associated with the IPR&D assets cannot be used to support the realization of our deferred tax assets. As a result, we are required to increase our valuation allowance and record a charge to deferred taxes.

### *Discontinued Operations-Oncology Product Line*

On September 7, 2006, the Company 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 its 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

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Purchase Agreement. The Oncology product line included our four marketed oncology drugs: Ontak, Targretin capsules, Targretin gel and Panretin gel.

### *Discontinued Operations-Avinza Product Line*

On September 6, 2006, the Company and King entered into a purchase agreement, or the Avinza Purchase Agreement, pursuant to which King agreed to acquire all of the 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.

Pursuant to the terms of the Avinza Purchase Agreement, the Company 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, the Company recorded a reserve for Avinza product returns.

During the three months ended September 30, 2013 the Company did not recognize any gain or loss on the sale of the Avinza product line. During the nine months ended September 30, 2013 the Company recognized a pre-tax gain of \$2.6 million, as a result of subsequent changes in certain estimates and liabilities recorded as of the sale date. During the three months ended September 30, 2012 the Company did not recognize any gain or loss on the sale of the Avinza product line. The Company recognized a pre-tax gain of \$3.7 million for the nine months ended September 30, 2012, due to subsequent changes in certain estimates and liabilities recorded as of the sale date.

### *Segment Reporting*

Under ASC 280, Segment Reporting, ("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 CyDex and the biopharmaceutical company with a business model that is based upon the concept of developing or acquiring royalty revenue generating assets and coupling them to a lean corporate cost structure.

### *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). The unrealized gains or losses are reported on the Consolidated Statements of Comprehensive Income.

### *New Accounting Pronouncements*

In July 2012, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update ("ASU") 2012-02, *Intangibles – Goodwill and Other: Testing Indefinite-Lived Intangible Assets for Impairment* in ASU 2012-02. ASU 2012-02 allows a company the option to first assess qualitative factors to determine whether it is necessary to perform a quantitative impairment test. Under that option, a company would no longer be required to calculate the fair value of an indefinite-lived intangible asset unless the company determines, based on that qualitative assessment, that it is more likely than not that the fair value of the indefinite-lived intangible asset is less than its carrying amount. The amendments in this ASU are effective for annual and interim indefinite-lived intangible asset impairment tests performed for periods beginning after September 15, 2012. We adopted this standard for the year ended December 31, 2012. The adoption of ASU 2012-02 did not have a material impact on the Company's financial position or results of operations.

In February 2013, the FASB issued ASU No. 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*. Under ASU 2013-02, an entity is required to provide information about the amounts reclassified out of Accumulated Other Comprehensive Income ("AOCI") by component. In addition, an entity is required to present, either on the face of the financial statements or in the notes, significant amounts reclassified out of AOCI by the respective line items of net income, but only if the amount reclassified is required to be reclassified in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. Implementing ASU 2013-02 did not change the current requirements for reporting net income or other comprehensive income in the financial statements. The amendments in this ASU are effective for us for fiscal years, and interim periods within those years, beginning after January 1, 2014.

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In July, 2013, the FASB issued Accounting Standards Update No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists*. ASU 2013-11 requires the netting of unrecognized tax benefits (UTBs) against a deferred tax asset for a loss or other carryforward that would apply in settlement of the uncertain tax positions. UTBs are required to be netted against all available same-jurisdiction loss or other tax carryforwards that would be utilized, rather than only against carryforwards that are created by the UTBs. ASU 2013-11 is effective for us for interim and annual periods beginning after December 15, 2013. We are currently evaluating the effect, if any, the adoption of this standard will have on our financial statements.

## 2. Financial Instruments

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including available-for-sale fixed income, equity securities, co-promote termination payments receivable and the related liability, derivatives, and contingent liabilities.

Fair value is defined as the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement that should be determined using assumptions that market participants would use in pricing an asset or liability. The Company establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels are described in the below with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 - Observable inputs such as quoted prices in active markets

Level 2 - Inputs other than the quoted prices in active markets that are observable either directly or indirectly

Level 3 - Unobservable inputs in which there is little or no market data, which require us to develop our own assumptions

### *Equity Investments and related liability to former license holders*

The fair value of the Company's long-term investments and related liability to former license holders are determined using quoted market prices in active markets and are discounted based on trading restrictions on the resale of the shares. The fair value of the liability to former license holders is based on 15% of the equity investment. This liability is classified as a derivative in accordance with ASC 815, Derivatives and Hedging ("ASC 815"), and is included in accrued liabilities. The discount rate used to value the available-for-sale securities as of September 30, 2013 and December 31, 2012 was 10% and 28%, respectively.

### *Contingent Liabilities*

The Company issued contingent value rights and also assumed certain contingent liabilities associated with the acquisitions of Metabasis, Neurogen and CyDex. The liability for CVRs for Metabasis are determined using quoted market prices in active markets. The fair value of the liabilities for the Neurogen and CyDex contingent liabilities are determined based on the income approach. The discount rate used to value the CyDex contingent liabilities for the period ended September 30, 2013 was in the range of 1% to 5%. There are no remaining contingent value right obligations under the agreement with the former Neurogen shareholders. Under the CVR agreement with the former CyDex shareholders, the Company may be required to make payments upon achievement of certain clinical and regulatory milestones. In addition, the Company will pay CyDex shareholders, for each year 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. Additionally, the Company assumed certain contractual obligations for milestone and royalty payments potentially due in connection with Captisol-enabled intravenous formulation of Clopidogrel and Captisol-enabled intravenous formulation of Topiramate.

### *Avinza Co-Promotion*

The co-promote termination payments receivable represents a non-interest bearing receivable for future payments to be made by Pfizer 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 any changes in the estimate of future net Avinza product sales.

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The following table provides a summary of the assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2013 (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>				
Current portion of co-promote termination payments receivable	\$ 4,507	\$ —	\$ —	\$ 4,507
Available-for-sale securities	3,627	—	—	3,627
Long-term portion of co-promote termination payments receivable	8,387	—	—	8,387
<b>Total assets</b>	<b>\$ 16,521</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 16,521</b>
<b>Liabilities:</b>				
Current portion of contingent liabilities - CyDex	\$ 1,879	\$ —	\$ —	\$ 1,879
Current portion of co-promote termination liability	4,507	—	—	4,507
Long-term portion of contingent liabilities-Metabasis	1,736	1,736	—	—
Long-term portion of contingent liabilities - CyDex	6,816	—	—	6,816
Liability for restricted investments owed to former licensees	544	—	—	544
Long-term portion of co-promote termination liability	8,387	—	—	8,387
<b>Total liabilities</b>	<b>\$ 23,869</b>	<b>\$ 1,736</b>	<b>\$ —</b>	<b>\$ 22,133</b>

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, 2012 (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>				
Current portion of co-promote termination payments receivable	\$ 4,327	\$ —	\$ —	\$ 4,327
Available-for-sale securities	1,426	—	—	1,426
Long-term portion of co-promote termination payments receivable	8,207	—	—	8,207
<b>Total assets</b>	<b>\$ 13,960</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 13,960</b>
<b>Liabilities:</b>				
Current portion of contingent liabilities - CyDex	\$ 356	\$ —	\$ —	\$ 356
Current portion of co-promote termination liability	4,327	—	—	4,327
Long-term portion of contingent liabilities - CyDex	10,543	—	—	10,543
Liability for restricted investments owed to former licensees	214	—	—	214
Long-term portion of co-promote termination liability	8,207	—	—	8,207
<b>Total liabilities</b>	<b>\$ 23,647</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 23,647</b>

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A reconciliation of the level 3 financial instruments as of September 30, 2013 is as follows (in thousands):

### Assets:

Fair value of level 3 financial instrument assets as of December 31, 2012	\$	13,960
Assumed payments made by Pfizer or assignee		(2,450)
Fair value adjustments recorded as unrealized gain on available-for-sale securities		2,201
Fair value adjustments to co-promote termination liability		2,810
Fair value of level 3 financial instrument assets as of September 30, 2013	\$	<u>16,521</u>

### Liabilities

Fair value of level 3 financial instrument liabilities as of December 31, 2012	\$	23,647
Assumed payments made by Pfizer or assignee		(2,450)
Fair value adjustments for amounts owed related to restricted investments and recorded as other expense		330
Payments to CVR and other former license holders		(100)
Fair value adjustments to contingent liabilities		(2,104)
Fair value adjustments to co-promote termination liability		2,810
Fair value of level 3 financial instrument liabilities as of September 30, 2013	\$	<u>22,133</u>

### 3. 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 ("King"), now a subsidiary of Pfizer, executed an agreement pursuant to which Pfizer acquired all of the Company's rights in and to Avinza. Pfizer also assumed the Company's co-promote termination obligation to make royalty payments to Organon based on net sales of Avinza. In connection with Pfizer's assumption of this obligation, Organon did not consent to the legal assignment of the co-promote termination obligation to Pfizer. Accordingly, Ligand remains liable to Organon in the event of Pfizer's default of the obligation. Therefore, Ligand recorded an asset as of February 26, 2007 to recognize Pfizer'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 Pfizer 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 Pfizer defaults on the assumed obligation to pay Organon).

On a quarterly 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 September 30, 2013 is as follows (in thousands):

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Net present value of payments based on estimated future net Avinza product sales as of December 31, 2012	\$ 12,534
Assumed payments made by Pfizer or assignee	(2,450)
Fair value adjustments	2,810
Total co-promote termination liability as of September 30, 2013	12,894
Less: current portion of co-promote termination liability as of September 30, 2013	4,507
Long-term portion of co-promote termination liability as of September 30, 2013	\$ 8,387

### 4. Lease obligations

The Company leases office and laboratory facilities in California, Kansas, and New Jersey. These leases expire between 2014 and 2019, some of which are subject to annual increases which range from 3.0% and 3.5%. The Company currently subleases office and laboratory space in California and New Jersey. The following table provides a summary of operating lease obligations and payments expected to be received from sublease agreements as of September 30, 2013 (in thousands):

Operating lease obligations:	Lease Termination Date	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Corporate headquarters-San Diego, CA	July 2019	\$ 660	\$ 1,372	\$ 1,446	\$ 560	\$ 4,038
Bioscience and Technology Business Center-Lawrence, KS	December 2014	57	14	—	—	71
Vacated office and research facility-San Diego, CA	July 2015	2,223	1,902	—	—	4,125
Vacated office and research facility-Cranbury, NJ	August 2016	2,563	4,973	—	—	7,536
<b>Total operating lease obligations</b>		<b>\$ 5,503</b>	<b>\$ 8,261</b>	<b>\$ 1,446</b>	<b>\$ 560</b>	<b>\$ 15,770</b>

  

Sublease payments expected to be received:		Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Office and research facility-San Diego, CA	July 2015	\$ 899	\$ 771	\$ —	\$ —	\$ 1,670
Office and research facility-Cranbury, NJ	August 2014 and 2016	340	661	—	—	1,001
<b>Net operating lease obligations</b>		<b>\$ 4,264</b>	<b>\$ 6,829</b>	<b>\$ 1,446</b>	<b>\$ 560</b>	<b>\$ 13,099</b>

In 2010, the Company ceased use of its facility located in New Jersey. As a result, 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. In addition, the Company wrote-off property and equipment with a net book value of approximately \$5.4 million related to the facility closure.

As of September 30, 2013 and December 31, 2012, the Company had lease exit obligations of \$6.6 million and \$9.0 million, respectively. For the three and nine months ended September 30, 2013, the Company made cash payments, net of sublease payments received of \$0.9 million and \$2.8 million, respectively. The Company recognized adjustments for accretion and changes in leasing assumptions of \$0.2 million and \$0.4 million for the three and nine months ended September 30, 2013, respectively. For the three and nine months ended September 30, 2012, the Company made cash payments, net of sublease payments received of \$1.0 million and \$2.6 million, respectively. The Company recognized adjustments for accretion and changes in leasing assumptions of \$0.2 million and \$0.7 million for the three and nine months ended September 30, 2012, respectively.

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As part of the lease for the corporate headquarters, the Company received a tenant improvement allowance of \$3.2 million. The tenant improvements were used to build out the suite for general lab and office purposes. For the year ended December 31, 2012, the Company recorded a sale leaseback transaction whereby it removed all property from its balance sheet as of the completion date of the buildout. There was no gain on the sale-leaseback.

Total rent expense under all office leases for the three and nine months ended September 30, 2013 was \$0.2 million and \$0.5 million, respectively. Rent expense for the three and nine months ended September 30, 2012 was \$0.3 million and \$0.6 million, respectively. The Company recognizes rent expense on a straight-line basis. Deferred rent at September 30, 2013 and December 31, 2012 was \$0.4 million and \$0.3 million, respectively, and is included in other long-term liabilities.

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### 5. Segment Reporting

The Company evaluates 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 is as follows:

#### Balance Sheet Data:

	As of September 30, 2013		
	Ligand	CyDex	Total
Total assets	\$ 38,270	\$ 63,407	\$ 101,677

  

	As of December 31, 2012		
	Ligand	CyDex	Total
Total assets	\$ 28,731	\$ 75,529	\$ 104,260

#### Operating Data:

	For the three months ended September 30, 2013		
	Ligand	CyDex	Total
Net revenues from external customers	\$ 4,731	\$ 8,274	\$ 13,005
Depreciation and amortization expense	62	606	668
Operating (loss) income	(1,142)	4,212	3,070
Interest expense, net	394	—	394
Income tax expense (benefit) from continuing operations	70	(10)	60

	For the nine months ended September 30, 2013		
	Ligand	CyDex	Total
Net revenues from external customers	\$ 14,789	\$ 19,448	\$ 34,237
Depreciation and amortization expense	179	1,828	2,007
Write-off of in-process research and development	—	480	480
Operating income	(944)	9,462	8,518
Interest expense, net	1,755	—	1,755
Income tax expense (benefit) from continuing operations	301	(64)	237
Gain on sale of Avinza Product Line before income taxes	2,588	—	2,588

	For the three months ended September 30, 2012		
	Ligand	CyDex	Total
Net revenues from external customers	\$ 3,708	\$ 2,667	\$ 6,375
Depreciation and amortization expense	34	604	638
Operating (loss) income	(1,601)	176	(1,425)
Interest expense, net	735	—	735
Income tax expense (benefit) from continuing operations	173	(31)	142

	For the nine months ended September 30, 2012		
	Ligand	CyDex	Total
Net revenues from external customers	\$ 11,728	\$ 6,025	\$ 17,753
Depreciation and amortization expense	162	1,816	1,978
Operating loss	(3,560)	(520)	(4,080)
Interest expense, net	2,198	—	2,198
Income tax expense (benefit) from continuing operations	543	(98)	445
Gain on sale of Avinza Product Line before income taxes	3,656	—	3,656
Income tax benefit from discontinued operations	14	—	14

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### 6. Financing Arrangements

The Company has a secured term loan credit facility ("secured debt"). Under the terms of the secured debt, the Company made interest only payments through February 2013. Subsequent to the interest only payments, the note will amortize with principal and interest payments through the remaining term of the loan. Additionally, the Company must also make an additional final payment equal to 6% of the total amount borrowed which is due at maturity and is being accreted over the life of the loan.

In March 2013, the Company prepaid \$7 million of the secured term loan credit facility. Additionally, the Company paid a prepayment fee of 1% of the prepayment amount, or \$0.1 million and a prorated final-payment fee of 6% of the final payment or \$0.4 million.

The carrying values and the fixed contractual coupon rates of our financing arrangements are as follows (dollars in millions):

	September 30, 2013	December 31, 2012
Current portion notes payable, 8.64%, due August 1, 2014	\$ 9,025	\$ 10,792
Current portion notes payable, 8.9012%, due August 1, 2014	3,350	4,043
<b>Total current portion of notes payable</b>	<b>\$ 12,375</b>	<b>\$ 14,835</b>
Long-term portion notes payable, 8.64%, due August 1, 2014	\$ —	\$ 9,837
Long-term portion notes payable, 8.9012%, due August 1, 2014	—	3,606
<b>Total long-term portion of notes payable</b>	<b>\$ —</b>	<b>\$ 13,443</b>

### 7. Stockholders' Equity

On May 31, 2012, the Company's stockholders approved the amendment and restatement of the Company's 2002 Stock Incentive Plan to increase the number of shares available for issuance by 1.8 million shares.

#### Stock Option Activity

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

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value (In thousands)
Balance as of December 31, 2012	1,626,606	\$ 14.90	7.8	\$ 11,358
Granted	439,929	23.61		
Exercised	(158,889)	14.76		
Forfeited	(73,978)	16.72		
Cancelled	(27,780)	28.32		
Balance as of September 30, 2013	1,805,888	16.74	7.71	48,322
Exercisable as of September 30, 2013	943,027	15.66	6.82	26,419
Options vested and expected to vest as of September 30, 2013	1,805,888	16.74	7.71	48,322

The weighted-average grant date fair value of all stock options granted during the nine months ended September 30, 2013 was \$14.28 per share. The total intrinsic value of all options exercised during the nine months ended September 30, 2013 and 2012 was approximately \$3.6 million and \$0.3 million, respectively. As of September 30, 2013, there was \$8.1 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.

Cash received from options exercised during the nine months ended September 30, 2013 and 2012 was approximately \$3.0 million and \$0.5 million, respectively. There is no current tax benefit related to options exercised because of Net Operating Losses (NOLs) for which a full valuation allowance has been established.

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As of September 30, 2013, 1.5 million shares were available for future option grants or direct issuance under the Company's 2002 Stock Incentive Plan, as amended.

### Restricted Stock Activity

Restricted stock activity for the nine months ended September 30, 2013 is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Nonvested at December 31, 2012	141,561	\$ 12.52
Granted	84,547	27.71
Vested	(77,070)	15.77
Cancelled	(33,375)	12.53
Nonvested at September 30, 2013	115,663	\$ 21.45

As of September 30, 2013, there was \$1.7 million of total unrecognized compensation cost related to nonvested restricted stock. That cost is expected to be recognized over a weighted-average period of 1.4 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 5,016 and 7,374 shares of common stock issued under the amended ESPP during the nine months ended September 30, 2013 and 2012, respectively. The Company recorded compensation expense related to the ESPP of \$37,000 and \$29,000 for the nine months ended September 30, 2013 and 2012, respectively. As of September 30, 2013, 81,512 shares were available for future purchases under the Amended ESPP.

### Public Offering

In October 2011, the Company filed a Registration Statement on Form S-3 with the Securities and Exchange Commission ("SEC") for the issuance and sale of up to \$30 million of equity or other securities, proceeds from which will be used for general corporate purposes. The Form S-3 provides additional financial flexibility for us to sell shares or other securities as needed at any time. In 2012, the Company commenced its "at the market" equity offering program ("ATM") in which it may from time to time offer and sell shares of its common stock having an aggregate proceeds of up to \$30 million. As of September 30, 2013, 302,750 common shares have been issued under this registration statement, for total net proceeds of approximately \$5.5 million. In October, 2013, the Company filed a universal automatic shelf registration statement that was automatically declared effective and achieved well-known seasoned issuer ("WKSI") status. The Company intends to maintain both the \$30 million shelf registration statement and the WKSI universal automatic shelf registration statement.

During the three and nine months ended September 30, 2013, the Company did not issue any common shares pursuant to its at-the-market equity issuance plan. During the three and nine months ended September 30, 2012, the Company issued 150,000 common shares at a weighted average price of \$18.19 per share. Total net proceeds to the Company after underwriting discounts and expenses were approximately \$2.6 million.

### Corporate Share Repurchase

The Company may repurchase up to \$5.0 million of stock in privately negotiated and open market transactions for a period of up to one year, 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 September 30, 2013, the Company did not repurchase any common shares pursuant to the repurchase plan.

## 8. Litigation

The Company records an estimate of a loss when the loss is considered probable and estimable. Where a liability is probable and there is a range of estimated loss and no amount in the range is more likely than any other number in the range, the Company records the minimum estimated liability related to the claim in accordance with ASC Topic 450 Contingencies. As additional information becomes available, the Company assesses the potential liability related to its pending litigation and revises its estimates. Revisions in the Company's estimates of potential liability could materially impact our results of operations.

## 9. Common Stock Subject to Conditional Redemption - Pfizer Settlement Agreement

In April 1996, the Company and Pfizer entered into a settlement agreement with respect to a lawsuit filed in December 1994 by the Company against Pfizer. In connection with a collaborative research agreement the Company entered into with Pfizer in 1991, Pfizer purchased shares of the Company's common stock. Under the terms of the settlement agreement, at the option of either the Company or Pfizer, milestone and royalty payments owed to the Company can be satisfied by Pfizer by transferring to the Company shares of the Company's common stock at an exchange ratio of \$74.25 per share, for revenue related to lasofoxifene and drolofoxifene. The remaining common stock issued and outstanding to Pfizer following the settlement was reclassified as common stock subject to conditional redemption (between liabilities and equity) since Pfizer has the option to settle milestone and royalties payments owed to the Company with the Company's shares, and such option is not within the Company's control. The remaining shares of the Company's common stock that could be redeemed totaled 112,371 and are reflected at the exchange ratio price of \$74.25. Pfizer notified Ligand that the development of the two compounds covered under the 1996 settlement agreement were terminated and thus the Company reclassified the shares and the current carrying amount of \$8.3 million to permanent equity in the first quarter of 2012.

## 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—Ligand JVR, Allergan Ligand Retinoid Therapeutics, Seragen, Inc., or Seragen; Pharmacoopia, LLC; Neurogen Corporation, CyDex Pharmaceuticals, Inc., Metabasis Therapeutics, and Nexus Equity VI LLC, or Nexus.

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### 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 a portion of our business model is based on the goal of partnering with other pharmaceutical companies to commercialize and market our assets, a significant amount of our revenue is based largely on payments made to us by partners for royalties, milestones and license fees. We recognized the important role of the drug reformulation segment in the pharmaceutical industry and in 2011 added Captisol® to our technology portfolio. Captisol is a powerful formulation technology that has enabled six FDA approved products, including Onyx's Kyprolis® and Baxter International's Nexterone® and is currently being developed in a number of clinical-stage partner programs. In comparison to our peers, we believe we have assembled one of the largest and most diversified asset portfolios in the industry with the potential to generate significant revenue in the future. The therapies in our development portfolio address the unmet medical needs of patients for a broad spectrum of diseases including hepatitis, muscle wasting, multiple myeloma, Alzheimer's disease, dyslipidemia, diabetes, anemia, epilepsy, FSGS and osteoporosis. We have established multiple alliances with the world's leading pharmaceutical companies including GlaxoSmithKline, Onyx Pharmaceuticals (recently acquired by Amgen), Merck, Pfizer, Baxter International, Bristol-Myers Squibb, Celgene, Lundbeck Inc., Eli Lilly and Co., and Spectrum Pharmaceuticals, Inc.

In December 2012, we received a milestone payment of 620,000 shares of common stock in partner Retrophin, Inc. The milestone arose under the previously executed license agreement for the development and commercialization of Retrophin's lead clinical candidate RE-021 and was triggered by the completion of Retrophin's merger with Desert Gateway, Inc. and its transition to a publicly traded company. We recorded milestone revenue equal to the estimated fair value of the shares received, net of amounts owed to a third party, which was determined by an independent valuation firm.

In early 2013 we received a \$1.4 million milestone payment from Retrophin, Inc. and remitted \$0.2 million to former license holders under the terms of a previous license agreement for RE-021.

In March 2013, we entered into a License Agreement with Spectrum Pharmaceuticals, Inc. ("Spectrum"). Under the License Agreement, we granted to Spectrum an exclusive, nontransferable, worldwide license to such intellectual property rights that will enable Spectrum to develop and potentially commercialize Captisol-enabled® propylene glycol-free melphalan. Contemporaneously with the entry into the license agreement, we entered into a supply agreement to provide Captisol to Spectrum. Under the Supply Agreement, Spectrum agreed to purchase its Captisol requirements for the development of the compound contemplated by the license agreement, as well as any Captisol required for any product that is successfully commercialized. We received a non-refundable license issuance fee of \$3 million. Additionally, we are entitled to milestone payments and royalties on future net sales of the Captisol-enabled melphalan product. This program is currently enrolling patients in a pivotal clinical trial.

In April 2013, we entered into a Royalty Stream and Milestone Payments Purchase Agreement with Selexis SA ("Selexis"), to acquire a portfolio of possible future royalty and milestone payment rights based on over 15 Selexis commercial license agreement programs with various pharmaceutical-company counterparties. In return, we paid Selexis an upfront payment of \$3.5 million, and expect to make an additional \$1 million cash payment on the first anniversary of the closing.

In April 2012, we entered into a Research License and Option Agreement with ARES Trading SA (a unit of Merck KGaA), under which we licensed certain rights to an undisclosed anti-inflammatory discovery research program to ARES Trading SA. In May 2013, by virtue of ARES Trading SA not having exercised by that date its option to obtain a further related license from us, the Research License and Option Agreement terminated in the ordinary course in accordance with its terms, and the rights to the program reverted to us.

In May 2013, our partner Melinta Therapeutics, Inc. (formerly Rib-X) announced the initiation of a Phase 3 clinical trial of Captisol-enabled intravenous (IV) formulation of delafloxacin for the first-line treatment of acute bacterial skin and skin structure infections (ABSSSI), including infections caused by MRSA. Under the terms of a license and supply agreement, we earned a \$0.5 million milestone payment.

In July 2013, we entered into a global license agreement with Azure Biotech for the development of a novel formulation of lasofoxifene. Under the terms of the agreement, we are entitled to receive \$2.7 million in potential development and regulatory milestones and a 5% royalty on future net sales. Also under this agreement, we retain the rights to the oral formulation originally developed by Pfizer. Additionally, in July 2013, we entered into a license agreement with Ethicor Pharma Ltd. for the manufacture and distribution of the oral formulation of lasofoxifene in the European Economic Area,

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Switzerland and the Indian Subcontinent. Under the terms of the agreement, we are entitled to receive potential sales milestones and a double digit royalty on future net sales.

In July 2013, the FDA granted orphan-drug designation for our proprietary Captisol-enabled Topiramate Injection for the treatment of partial onset or primary generalized tonic-clonic seizures in hospitalized epilepsy patients who are unable to take oral topiramate. In August 2013, we entered a global license agreement with CURx Pharmaceuticals, Inc. for the development and commercialization of Topiramate.

In July 2013, we and The Medicines Company (MedCo) mutually terminated the License Agreement dated June 1, 2011 and the related Supply Agreement dated June 1, 2011. These agreements were with our subsidiary CyDex and related to the development of Captisol-enabled IV clopidogrel. Upon termination, the licensed rights relating to the compound were returned to us. MedCo recently conducted a pharmacokinetic and pharmacodynamic study of oral clopidogrel and Captisol-enabled IV clopidogrel in healthy volunteers. The study indicated a potential difference in metabolism between the oral and IV routes of administration for clopidogrel, and MedCo elected not to proceed with further development.

In July 2013, Merck notified us that it has discontinued clinical development of dinaciclib for Chronic Lymphocytic Leukemia.

In August 2013, we entered a Commercial License Agreement with Sage Therapeutics Inc. This agreement is with our subsidiary CyDex and replaces a prior agreement between the parties. In October 2011, Sage originally obtained an exclusive right to use Captisol® in SAGE's development and commercialization of therapeutic drugs formulating certain allosteric receptor modulators with Captisol against identified central nervous system disorders. Sage exercised certain product commercialization options in December 2012 and then replaced that agreement with the Commercial License Agreement in August 2013. Upon commercialization, we could potentially receive milestone payments for Captisol-enabled programs, plus tiered royalties on net sales for products that use the Captisol technology. Additionally, we could receive commercial revenue from the shipment of Captisol to Sage for clinical and commercial activities.

In October 2013, our partner, Pfizer received approval from the FDA for Duavee™, for the treatment of moderate-to-severe vasomotor symptoms (VMS) associated with menopause and the prevention of postmenopausal osteoporosis. We earned a \$0.4 million milestone payment for the approval.

In October 2013, the FDA accepted our Investigational New Drug (IND) application for Ligand's proprietary Glucagon receptor antagonist product (LGD-6972) candidate for the treatment of diabetes. LGD-6972 was acquired in connection with our acquisition of Metabasis and we may be required to remit payment to the CVR holders upon the sale or partnering of the asset. We plan to initiate Phase I clinical testing in the fourth quarter of 2013.

## Results of Operations

### *Three and nine months ended September 30, 2013 and 2012*

Total revenues for the three and nine months ended September 30, 2013 were \$13.0 million and \$34.2 million, respectively, compared to \$6.4 million and \$17.8 million, respectively, for the same periods in 2012. We reported income from continuing operations of \$2.0 million and \$7.0 million, respectively, for the three and nine months ended September 30, 2013. We reported a loss from continuing operations of \$0.2 million and \$5.3 million, respectively, for the three and nine months ended September 30, 2012.

### *Royalty Revenue*

Royalty revenues were \$5.7 million and \$16.5 million, respectively, for the three and nine months ended September 30, 2013, compared to \$3.2 million and \$9.3 million, respectively, for the same periods in 2012. The increase in royalty revenue is primarily due to an increase in Promacta and Kyprolis royalties.

### *Material Sales*

We recorded material sales of \$6.7 million and \$12.3 million, respectively, for the three and nine months ended September 30, 2013, compared to \$1.8 million and \$4.2 million, respectively, for the same periods in 2012. The increase in material sales for the three and nine months ended September 30, 2013 is primarily due to timing of customer purchases of Captisol.

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

We recorded collaborative research and development and other revenues of \$0.6 million and \$5.5 million, respectively, for the three and nine months ended September 30, 2013, compared to \$1.3 million and \$4.3 million, respectively, for the same periods in 2012. The decrease of \$0.7 million is primarily due to a \$0.2 million milestone and \$0.3 million licensing fee earned for the three months ended September 30, 2013 compared to milestones earned of \$1.1 million and license fees of \$0.2 million earned for the three months ended September 30, 2012. The increase of \$1.2 million for the nine months ended September 30, 2013, compared to the same period in 2012, is primarily due to the licensing of Captisol-enabled Melphalan to Spectrum in March 2013.

### *Cost of Sales*

Cost of sales were \$2.5 million and \$4.4 million, respectively, for the three and nine months ended September 30, 2013, compared to \$0.7 million and \$1.3 million, respectively, for the same periods in 2012. The increase of \$1.8 million and \$3.1 million, respectively, for the three and nine months ended September 30, 2013, compared to the same periods in 2012, is primarily due to an increase in material sales.

### *Research and Development Expenses*

Research and development expenses were \$2.4 million and \$6.9 million, respectively, for the three and nine months ended September 30, 2013, compared to \$2.6 million and \$8.3 million, respectively, for the same periods in 2012. The decrease of \$0.2 million and \$1.4 million, respectively, for the three and nine months ended September 30, 2013, compared to the same periods in 2012, is primarily due to timing of costs associated with internal programs.

As summarized in the table below, we are developing several proprietary products for a variety of indications. Our programs are not limited to the following, but are representative of a range of future licensing opportunities to expand our partnered asset portfolio.

<u>Program</u>	<u>Disease/Indication</u>	<u>Development Phase</u>
Selective Androgen Receptor Modulator	Various	Phase II-ready
Glucagon Receptor Antagonist	Diabetes	Phase I-ready
HepDirect™	Liver Diseases	Preclinical
Oral Human Granulocyte Colony Stimulating Factor	Neutropenia	Preclinical
Oral Erythropoietin	Anemia	Preclinical

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 EMA, 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 \$4.8 million and \$13.6 million, respectively, for the three and nine months ended September 30, 2013, compared to \$4.3 million and \$11.6 million, respectively, for the same periods in 2012. The increase of \$0.5 million and \$2 million, respectively, for the three and nine months ended September 30, 2013, compared to the same periods in 2012, is primarily due to an increase in general legal expenses and patent fees, share-based compensation expense and other headcount related expenses.

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### *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 \$1.8 million of severance related costs. Lease exit and termination costs were \$0.2 million and \$0.4 million, respectively, for the three and nine months ended September 30, 2013, compared to \$0.2 million and \$0.7 million, respectively, for the same periods in 2012. The decrease for the nine months ended September 30, 2013, compared to the same period in 2012, is primarily due to changes in subleasing assumptions.

### *Write-off of In-process research and development*

For the nine months ended September 30, 2013, we recorded a non-cash impairment charge of \$0.5 million for the write-off of in-process research and development for Captisol-enabled IV Clopidogrel. Captisol-enabled IV Clopidogrel is an intravenous option of the anti-platelet medication designed for situations where the administration of oral platelet inhibitors is not feasible or desirable. For the three months ended September 30, 2013 and the three and nine months ended September 30, 2012, there was no impairment of in-process research and development.

### *Interest Expense, net*

Interest expense was \$0.4 million and \$1.8 million, respectively, for the three and nine months ended September 30, 2013, compared to \$0.7 million and \$2.2 million, respectively, for the same periods in 2012. The decrease in interest expense of \$0.3 million and \$0.4 million, respectively, for the three and nine months ended September 30, 2013 is due to a lower principal balance due to the \$7 million payoff in March 2013 as well as principal amortization from March through September 2013.

### *(Increase) Decrease in Contingent Liabilities*

We recorded an increase in contingent liabilities of \$0.5 million and an decrease in contingent liabilities of \$0.4 million, respectively, for the three and nine months ended September 30, 2013, respectively, compared to a decrease of \$2.1 million and \$1.2 million, respectively, for the same periods in 2012. The increase for the three months ended September 30, 2013 relates to an increase in the liability for amounts potentially due to holders of CVRs and former license holders associated with our CyDex acquisition of \$1.2 million and is partially offset by a decrease in amounts potentially due to holders of CVRs associated with our Metabasis acquisition of \$0.7 million. The decrease for the nine months ended September 30, 2013 is primarily due to a decrease in amounts potentially due to CyDex CVR holders and former license holders of \$2.1 million related to Captisol-enabled Clopidogrel, and is partially offset by an increase in Metabasis CVRs of \$1.7 million.

The decrease for the three months ended September 30, 2012 relates to a decrease in the liability for amounts potentially due to holders of CVRs and former license holders associated with our CyDex acquisition. The decrease for the nine months ended September 30, 2012 is due to a decrease in Metabasis CVRs of \$1.1 million. Additionally, amounts potentially due to Neurogen CVR holders decreased \$0.2 million. Partially offsetting, amounts potentially due to CyDex CVR holders and former license holders increased \$0.1 million.

### *Income Tax Expense*

We recorded income tax expense from continuing operations of \$0.1 million and \$0.2 million, respectively, for the three and nine months ended September 30, 2013. We recorded income tax expense from continuing operations of \$0.1 million and \$0.4 million, respectively, for the three and nine months ended September 30, 2012. Our estimated annual effective rate of 3.3% is primarily attributable to deferred taxes associated with the amortization of acquired IPR&D assets for tax purposes. In 2012, our estimated annual effective rate was negative 6.4%. The negative effective rate in 2012 was also due to deferred taxes associated with the amortization of our acquired IPR&D for tax purposes.

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### *Discontinued Operations*

#### *Avinza Product Line*

On September 6, 2006, we and King entered into a purchase agreement, 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 months ended September 30, 2013 we did not recognize a gain or loss on the sale of the Avinza product line. During the nine months ended September 30, 2013 we recognized a pre-tax gain of \$2.6 million, as a result of subsequent changes in certain estimates and liabilities recorded as of the sale date. During the three months ended September 30, 2012 we did not recognize a gain or loss on the sale of the Avinza product line. We recognized a pre-tax gain of \$3.7 million, for the nine months ended September 30, 2012, due to subsequent changes in certain estimates and liabilities recorded as of the sale date.

#### *Income Tax Benefit from Discontinued Operations*

We did not record any provision for income taxes related to discontinued operations for the three and nine months ended September 30, 2013 and the three months ended September 30, 2012. We recorded an income tax benefit related to discontinued operations of \$14,000, for the nine months ended September 30, 2012.

### **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 have incurred significant losses since inception. At September 30, 2013, our accumulated deficit was \$673.2 million and we had negative working capital of \$15.8 million. We believe that cash flows from operations will improve due to Captisol® sales, an increase in royalty revenues driven primarily from continued increases in Promacta and Kyprolis sales, recent product approvals and regulatory developments, as well as anticipated new license and milestone revenues. In the event revenues and operating cash flows do not meet expectations, management plans to reduce discretionary expenses. However, it is possible that we may be required to seek additional financing. There can be no assurance that additional financing will be available on terms acceptable to management, or at all. We believe our 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, 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 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 our partners; the efforts of our collaborative partners; obligations under our operating lease agreements; and the capital requirements of any companies we acquire.

In January 2011, we entered into a \$20 million secured term loan credit facility ("secured debt") with Oxford Financial Group ("Oxford"). The loan was amended in January 2012 to increase the secured credit facility to \$27.5 million. The original \$20 million borrowed under the facility bears interest at a fixed rate of 8.6%. The additional \$7.5 million bears interest at a fixed rate of 8.9%. Under the terms of the secured debt, we made interest only payments through February 2013. Subsequent to the interest only payments, the note amortizes with principal and interest payments through the remaining term of the loan. Additionally, we must also make an additional final payment equal to 6% of the total amount borrowed which is due at maturity and is being accreted over the life of the loan. The maturity date of the term loan is August 1, 2014.

In March 2013, the Company prepaid \$7 million of the secured term loan credit facility. Additionally, we paid a prepayment fee of 1% of the prepayment amount, or \$0.1 million and a prorated final-payment fee of 6% of the final payment or \$0.4 million.

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In October 2011, we filed a Registration Statement on Form S-3 with the SEC for the issuance and sale of up to \$30 million of equity or other securities, proceeds from which will be used for general corporate purposes. The Form S-3 provides additional financial flexibility for us to sell shares or other securities as needed at any time. In October 2013, the Company filed a universal automatic shelf registration statement that was automatically declared effective and achieved well-known seasoned issuer ("WKSI") status. The Company intends to maintain both the \$30 million shelf registration statement and the WKSI universal automatic shelf registration statement.

As of September 30, 2013, 302,750 common shares have been issued under this registration statement for total net proceeds of approximately \$5.5 million. During the three and nine months ended September 30, 2013, we did not issue any common shares pursuant to its at-the-market equity issuance plan. During the three and nine months ended September 30, 2012, we issued 150,000 common shares at a weighted average price of \$18.19 per share. Total net proceeds to us after underwriting discounts and expenses were approximately \$2.6 million.

### *Operating Activities*

Operating activities generated cash of \$8.7 million for the nine months ended September 30, 2013, compared to \$2.0 million of cash used in operating activities for the same period in 2012.

The cash generated for the nine months ended September 30, 2013 reflects net income of \$9.6 million, adjusted by \$2.6 million of gain from discontinued operations and \$6.8 million of non-cash items to reconcile the net income to net cash generated in operations. These reconciling items primarily reflect depreciation and amortization of \$2.0 million, share-based compensation of \$4.1 million, the change in deferred income taxes of \$0.2 million, write-off of IPR&D of \$0.5 million, and accretion of note payable of \$0.3 million, partially offset by the decrease in the estimated fair value of contingent liabilities of \$0.4 million. The cash generated during the nine months ended September 30, 2013 is further impacted by changes in operating assets and liabilities due primarily to an increase in accounts receivable of \$0.9 million, increase in other current assets of \$0.7 million, decrease in accounts payable and accrued liabilities of \$2.3 million, decrease in other liabilities of \$0.4 million, and a decrease in deferred revenue of \$0.4 million, partially offset by a decrease in cash paid for inventory of \$0.1 million and a decrease in other long term assets of \$0.2 million. Cash used in operating activities of discontinued operations was \$0.6 million for the nine months ended September 30, 2013.

The cash used for the nine months ended September 30, 2012 reflects a net loss of \$1.6 million, adjusted by \$3.7 million of gain from discontinued operations and \$4.7 million of non-cash items to reconcile the net loss to net cash used in operations. These reconciling items primarily reflect depreciation and amortization of \$2.0 million, share-based compensation of \$3.1 million, and the change in deferred income taxes of \$0.4 million, partially offset by the non-cash change in the estimated fair value of contingent liabilities of \$1.2 million. The cash used during the nine months ended September 30, 2012 is further impacted by changes in operating assets and liabilities due primarily to an increase in inventory of \$0.8 million, a decrease in deferred revenue of \$1.7 million, and a decrease in accounts payable and accrued liabilities of \$3.0 million, partially offset by decreases in accounts receivable of \$4.0 million, other current assets of \$0.3 million, and other long term assets of \$0.3 million. Cash used in operating activities of discontinued operations was \$0.6 million for the nine months ended September 30, 2012.

### *Investing Activities*

Investing activities used cash of \$4.0 million for the nine months ended September 30, 2013, compared to \$1.3 million of cash provided by investing activities for the same 2012 period.

Cash used by investing activities during the nine months ended September 30, 2013 primarily reflects the purchase of commercial license rights of \$3.6 million.

Cash provided by investing activities during the nine months ended September 30, 2012 primarily reflects \$10 million of proceeds from the sale of short-term investments, partially offset by payment to CVR holders of \$8.0 million and purchases of property, equipment and building of \$0.6 million.

### *Financing Activities*

Financing activities used cash of \$13.8 million for the nine months ended September 30, 2013, compared to cash provided by financing activities of \$0.7 million for the same 2012 period.

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Cash used by financing activities for the nine months ended September 30, 2013 primarily reflects \$16.2 million of repayment of debt, partially offset by proceeds from stock option exercises and the employee stock purchase plan of \$2.4 million.

Cash provided by financing activities for the nine months ended September 30, 2012 primarily reflects \$10.0 million of repayment of debt, partially offset by proceeds from the issuance of debt of \$7.5 million and proceeds from the issuance of common stock of \$3.2 million.

### Other

In connection with the acquisition of Metabasis 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 September 30, 2013 was \$1.7 million and as of December 31, 2012 was zero.

In connection with the acquisition of CyDex on January 24, 2011, we issued a series of CVRs and also assumed certain contingent liabilities. In 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. An additional \$2.0 million was paid to the CyDex Shareholders upon acceptance by the FDA of Onyx's NDA, \$4.3 million was paid in January 2012, as contractually obligated, and an additional \$3.5 million was paid upon approval by the FDA of Kyprolis for the potential treatment of patients with relapsed and refractory multiple myeloma. We recorded a cash payment of \$0.1 million for the Topiramate orphan drug designation milestone to former license holders. We may be required to make additional payments upon achievement of certain clinical and regulatory milestones to the CyDex shareholders and former license holders. In addition, we will pay CyDex shareholders, for each respective year from 2013 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. We paid \$0.2 million to the CyDex shareholders in March 2012 related to 2011 CyDex-related revenue. There was no revenue sharing payment for the three and nine months ended September 30, 2013. The estimated fair value of the contingent liabilities recorded as part of the CyDex acquisition at September 30, 2013 was \$8.7 million.

### Leases And Off-Balance Sheet Arrangements

We lease our office and research facilities under operating lease arrangements with varying terms through November 2021. A portion of our agreements provide for increases in annual rents based on changes in the Consumer Price Index or fixed percentage increases ranging from 3.0% to 3.5%. Commencing in January 2008, we also sublease a portion of our facilities through August 2016. The sublease agreement provides for a 3% increase in annual rents. We had no off-balance sheet arrangements at September 30, 2013 and December 31, 2012.

### Contractual Obligations

As of September 30, 2013, future minimum payments due under our contractual obligations are as follows (in thousands):

	Payments Due by Period				
	Total	Less than 1 year	2-3 years	4-5 years	More than 5 years
Operating lease obligations (1)	\$ 15,770	\$ 5,503	\$ 8,261	\$ 1,446	\$ 560

- (1) We currently sublease a portion of our facilities through their respective lease terms of July 2015, August 2014 and August 2016. As of September 30, 2013, we expect to receive aggregate future minimum lease payments totaling \$2.6 million (nondiscounted) over the duration of the sublease agreements as follows: less than one year, \$1.2 million and two to three years, \$1.4 million.

We outsource the production of Captisol to Hovione, LLC. Under the terms of the supply agreement with Hovione, the Company has ongoing minimum annual purchase commitments and is required to purchase a total of \$15 million of Captisol over the term of the supply agreement which expires in December 2019. Through September 30, 2013 we have exceeded that

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commitment. Either party may terminate the Agreement for the uncured material breach or bankruptcy of the other party or an extended force majeure event. The Company may also terminate the supply agreement for extended supply interruption, regulatory action related to Captisol or other specified events.

Under the terms of our merger with Metabasis, we were committed to spend at least \$7 million within 30 months following the close of the transaction and \$8.0 million within 42 months in new research and development funding on the Metabasis programs. We fulfilled all spending requirements under the terms of our merger with Metabasis.

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 the year ended 2015. As of September 30, 2013, we estimate we will exceed that amount for the year ended December 31, 2013.

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

We do not have a significant level of transactions denominated in currencies other than U.S. dollars and as a result we have very limited foreign currency exchange rate risk. We purchase Captisol from Hovione, located in Lisbon, Portugal. Payments to Hovione are denominated and paid in U.S. dollars, however the unit price of Captisol contains an adjustment factor which is based on the sharing of foreign currency risk between the two parties. 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.

We are exposed to market risk involving rising interest rates. To the extent interest rates rise, our interest costs could increase. An increase in interest costs of 10% would have no material impact on our financial condition, results of operations or cash flows.

**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, which we refer to as the Evaluation Date.

As a result of material weaknesses in our internal control over financial reporting relating to the accounting for non-routine transactions and the controls over the determination of fair value of contingent liabilities, management has reassessed the effectiveness of our disclosure controls and procedures and have determined that our disclosure controls and procedures were not effective as of September 30, 2013. Despite the material weaknesses in our internal control, management believes no material inaccuracies or omissions of fact exist in this quarterly report.

*Remediation Plan.* As a result of the material weaknesses associated with non-routine transactions, we have added a corporate controller to our finance and accounting staff. While we had processes to identify and intelligently apply accounting standards to complex transactions, we did not have adequate numbers of highly skilled accountants to provide for a detailed analysis, documentation and review of such transactions. Additionally, we plan to enhance our controls over the determination of the fair value of contingent liabilities by including a formal review of mathematical calculations and completeness of such calculations. These material weaknesses prevented us from properly reporting the financial information for previous interim and annual periods, and we have filed restated 10-Q and 10-K reports for the applicable periods. Management will continue to review and make necessary changes to the overall design of its internal control environment, as well as to policies and procedures to improve the overall effectiveness of internal control over financial reporting.

The material weaknesses will not be remediated until the applicable remedial procedures are tested and management has concluded that the procedures and controls are operating effectively.

*Changes in Internal Controls.* Except as described above, there have been no changes during the last fiscal quarter in our internal control over financial reporting that have materially affected, or are 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.

#### ***Securities Litigation***

On June 8, 2012, a federal securities class action and shareholder derivative lawsuit was filed in the Eastern District of Pennsylvania against Genaera Corporation and its officers, directors, major shareholders and trustee ("Genaera Defendants") for allegedly breaching their fiduciary duties to Genaera shareholders. The lawsuit also names the Company and its CEO John Higgins as additional defendants for allegedly aiding and abetting the Genaera Defendants' various breaches of fiduciary duties based on the Company's purchase of a licensing interest in a development-stage pharmaceutical drug program from the Genaera Liquidating Trust in May 2010 and its subsequent sale of half of its interest in the transaction to Biotechnology Value Fund, Inc.

Following an amendment to the complaint and a round of motions to dismiss, the Court dismissed the amended complaint with prejudice on August 12, 2013. On September 10, 2013, plaintiff filed a notice of appeal. The Company intends to continue to vigorously defend against the claims against it and Mr. Higgins in the lawsuit. Due to the complex nature of the legal and factual issues involved, however, the outcome of this matter is not presently determinable.

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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. 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.*

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

***Revenues based on Promacta and Kyprolis represent a substantial portion of our overall current and/or expected future revenues.***

GSK is obligated to pay us royalties on its sales of Promacta and we receive revenue from Onyx based on both sales of Kyprolis and purchases of Captisol material for clinical and commercial uses. These payments 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 Promacta or Kyprolis could significantly impair our operating results and/or reduce the market price of our stock. Setbacks for Promacta and Kyprolis could include problems with shipping, distribution, manufacturing, product safety, marketing, government regulation or reimbursement, licenses and approvals, intellectual property rights, competition with existing or new products and physician or patient acceptance of the product, as well as higher than expected total rebates, returns or discounts.

***Revenue from sales of Captisol material to our collaborative partners represents a significant portion of our current revenue and our continued development and supply of Captisol is subject to a number of risks.***

In January 2011, we completed our merger with CyDex. All of CyDex's products and product candidates, as well as the technology that it outlicenses, are based on Captisol. As a result, any setback that may occur with respect to Captisol could significantly impair our operating results and/or reduce the market price of our stock. Setbacks for Captisol could include problems with shipping, distribution, manufacturing, product safety, marketing, government regulation or reimbursement, licenses and approvals, intellectual property rights, competition with existing or new products and physician or patient acceptance of the products using Captisol, as well as higher than expected total rebates, returns or discounts for such products.

If products or product candidates incorporating Captisol technology were to cause any unexpected adverse events, the perception of Captisol safety could be seriously harmed. If this were to occur, we may not be able to market Captisol 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, which could significantly impair our operating results and/or reduce the market price of our stock.

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. Our supplier of Captisol is Hovione FarmaCiencia SA, or Hovione, through its agent Hovione, LLC. 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. A series of unusually large orders could rapidly deplete our inventory and cause significant problems with our licensees and disrupt our business. In addition, if we fail to meet certain of our obligations under our supply agreements, our customers could obtain the right to have Captisol manufactured by other suppliers, which would significantly harm our business.

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. Our high purity patents, U.S. Patent Nos. 7,635,773 and 8,410,077 and foreign equivalents, are not expected to expire until 2029 and our morphology patents, U.S. Patent Nos. 7,629,331 and 8,049,003 and foreign equivalents, are not expected to expire until 2025, but the initially filed patents relating to Captisol

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expired starting in 2010 in the U.S. and will expire by 2016 in most countries 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.

***Aggregate revenues based on sales of our other products represent a significant portion of our overall current and/or expected future revenues.***

Revenues based on sales of Avinza, Duavee, Conbriza and Nexterone 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 these products could significantly impair our operating results and/or reduce the market price of our stock. Setbacks for these products could include problems with shipping, distribution, manufacturing, product safety, marketing, government regulation or reimbursement, licenses and approvals, intellectual property rights, competition with existing or new products and physician or patient acceptance of the product, as well as higher than expected total rebates, returns or discounts. These products also are or may become subject to generic competition). Any such setback could reduce our revenue.

***The product candidates of our partners and us face significant development and regulatory hurdles prior to partnering and/or marketing which could delay or prevent licensing, sales and/or milestone revenue.***

Before we or our partners obtain the approvals necessary to sell any of our unpartnered assets or partnered programs, we must show through preclinical studies and human testing that each potential product is safe and effective. We and/or our partners have a number of partnered programs and unpartnered assets moving toward or currently awaiting regulatory action. 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 drug development and 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 scientific studies and 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, the eligibility criteria for the trial and other potential drug candidates being studied. Delays in patient enrollment for our trials may result in increased costs and longer development times. In addition, our collaborative partners have rights to control product development and clinical programs for products developed under our 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.

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***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 collaboration agreements with corporate partners and others. These agreements 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 unpartnered assets.

In addition, our collaborators may develop drugs, either alone or with others that compete with the types of drugs they are developing with us (or that we are developing on our own). This would result in increased competition for our or our partners' 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 at will or 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 (for example, by not making required payments when due, or at all), our product development under these agreements will be delayed or terminated. Disputes or litigation may also arise with our collaborators (with us and/or with one or more third parties), 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.

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

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.

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.

Generally, our success will depend on our ability and the ability of us and 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. For example, our European patent related to Agglomerated forms of Captisol is currently being opposed and observations have been filed against our European patent application related to High Purity Captisol.

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We have obtained patent protection in the U.S. through 2025 on one or more Agglomerated forms of Captisol and through 2029 on one or more High Purity forms of Captisol. The initially filed patents relating to Captisol expired starting in 2010 in the United States and will expire by 2016 in most countries outside the U.S. There is no guarantee that our patents will be sufficient to prevent competitors from creating a generic form of Captisol 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, provide that once the relevant patent expires, the amount of royalties we receive will be reduced or eliminated.

***Our collaborative partners may change their strategy or the focus of their development and commercialization efforts with respect to our partnered programs; the success of our partnered programs 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 partnered programs, we could be required to devote additional resources to our partnered programs, seek new collaborative partners or abandon such partnered programs, all of which could have an adverse effect on our business.

***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 Captisol, Promacta, Kyprolis, Avinza, Duavee, Viviant and Conbriza, Nexterone, and 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.

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.

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***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.***

As described in Item 4, we identified material weaknesses as a result of improper accounting for non-routine transactions and the controls over the determination of fair value of contingent liabilities. Our audit committee, after consultation with management has determined that the material weaknesses were a result of inadequate staffing and review processes. As a result of the material weaknesses associated with non-routine transactions, we have added a corporate controller to our finance and accounting staff. While we had processes to identify and apply accounting standards to complex transactions, we enhanced these processes with the addition of a resource with the ability to research and understand the nuances of complex accounting standards. Additionally, we plan to enhance our controls over the determination of the fair value of contingent liabilities by including a formal review of mathematical calculations and completeness of such calculations. Given the material weaknesses, our audit committee, after consultation with management determined that we did not maintain effective internal control over financial reporting. The existence of one or more material weaknesses or significant deficiencies 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.

***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 or have consummated in the past, whether as a result of unidentified risks, integration difficulties, regulatory setbacks, litigation with current or former employees 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 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.

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***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. 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 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 \$12.9 million as of September 30, 2013). 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 partnered programs before our competitors offer products for the same or similar uses, or if our partners are not effective in marketing our partnered programs, 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 partnered programs. 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.

***If our business does not perform according to our expectations, we may not be able to pay off our existing debt or have sufficient resources to operate our business as currently contemplated.***

Our operations have consumed substantial amounts of cash since inception. As of September 30, 2013, we had negative working capital of \$15.8 million. In connection with our 2011 acquisition of CyDex, we entered into a \$20 million Loan and Security Agreement, or the Loan Agreement, with a lender. The loan was amended in January 2012 to increase the secured credit facility to \$27.5 million. The original \$20 million borrowed under the facility bears interest at a fixed rate of 8.6%. The additional \$7.5 million bears interest at a fixed rate of 8.9%. Under the terms of the secured debt, we made interest only payments through February 2013. Subsequent to the interest only payments, the note will amortize with principal and interest payments through the remaining term of the loan. Additionally, we must also make an additional final payment equal to 6% of the total amount borrowed which is due at maturity and is being accreted over the life of the loan. The maturity date of the term loan is August 1, 2014. In March 2013, the Company prepaid \$7 million of the secured term loan credit facility. Additionally, the Company paid a prepayment fee of 1% of the prepayment amount, or \$0.1 million and a prorated final-payment fee of 6% of the final payment or \$0.4 million. As of September 30, 2013, the remaining principal balance of the note was \$12.4 million.

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In October 2011, we filed a Registration Statement on Form S-3 with the SEC for the issuance and sale of up to \$30 million of equity or other securities, proceeds from which will be used for general corporate purposes. As of September 30, 2013, 302,750 common shares have been issued under this registration statement for total net proceeds of approximately \$5.5 million. During the three and nine months ended September 30, 2013 the Company did not issue any common shares pursuant to its at-the-market equity issuance plan. In October 2013, the Company filed a universal automatic shelf registration statement that was automatically declared effective and achieved well-known seasoned issuer ("WKSI") status. The Company intends to maintain both the \$30 million shelf registration statement and the WKSI universal automatic shelf registration statement. These registration statements provide additional financial flexibility for us to sell shares or other securities as needed at any time.

Our cash and cash equivalents as of September 30, 2013 was \$3.3 million. 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 12 months. However, changes may occur that would cause us to consume available capital resources before that time and 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 ability to use our net operating losses to offset taxes that would otherwise be due could be limited or lost entirely.***

Our ability to use our NOLs to offset taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs, and we cannot predict with certainty whether we will be able to generate future taxable income. In addition, even if we generate taxable income, realization of our NOLs to offset taxes that would otherwise be due could be restricted by annual limitations on use of NOLs triggered by a past or future "ownership change" under Section 382 of the Internal Revenue Code and similar state provisions. An "ownership change" may occur when there is a 50% or greater change in total ownership of our company by one or more 5% shareholders within a three-year period. The loss of some or all of our NOLs could materially and adversely affect our business, financial condition and results of operations. In addition, California and certain states have suspended use of NOLs for certain taxable years, and other states may consider similar measures. As a result, we may incur higher state income tax expense in the future. Depending on our future tax position, continued suspension of our ability to use NOLs in states in which we are subject to income tax could have an adverse impact on our operating results and financial condition. The calculation of the amount of our net operating loss carryforwards may be changed as a result of a challenge by the IRS or other governmental authority or our learning of new information about the ownership of, and transactions in, our securities.

### ***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.

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### ***Our shareholder rights plan, concentration of ownership 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. Our directors and Biotechnology Value Fund (BVF) have over 25% ownership as of September 30, 2013 and BVF can increase their ownership level up to 24.99% and has agreed to vote 15% ownership in accordance with the Board's recommendations in the event that BVF exceeds a 19.99% ownership level. Such restrictions, circumstances 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.

### ***Funding of our drug development programs may not result in future revenues.***

Our drug development programs may 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. 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.

### ***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, and the U.S. financial markets 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. 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.

### ***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. 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.

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***Impairment charges pertaining to goodwill, identifiable intangible assets or other long-lived assets from our mergers and acquisitions 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 acquisitions of 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.

***The occurrence of a catastrophic disaster could damage our facilities beyond insurance limits or we could lose key data which could cause us to curtail or cease operations.***

We are vulnerable to damage and/or loss of vital data from natural disasters, such as earthquakes, tornadoes, power loss, fire, floods and similar events, as well as from accidental loss or destruction. If any disaster were to occur, our ability to operate our business could be seriously impaired. We have property, liability, and business interruption insurance which may not be adequate 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

Not applicable.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable

**ITEM 5. OTHER INFORMATION**

Not applicable.

**ITEM 6. EXHIBITS**

The Index to Exhibits on page 47 is incorporated herein by reference as the list of exhibits required as part of this Quarterly Report.

**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: November 8, 2013

By: /s/ John P. Sharp

John P. Sharp

Vice President, Finance and Chief Financial Officer

Duly Authorized Officer and Principal Financial Officer

INDEX TO EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
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).
3.8 (16)	Second Amended and Restated Bylaws of the Company (Filed as Exhibit 3.1).
4.1 (17)	Specimen stock certificate for shares of Common Stock of the Company.
4.4 (18)	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).
4.5 (19)	First Amendment to 2006 Preferred Shares Rights Agreement dated June 19, 2013 (Filed as Exhibit 4.1).
10.1 †	License Agreement dated July 17, 2013 between the Company and Azure Biotech, Inc. (Filed as Exhibit 10.1).
10.2 †	Exclusive License and Distribution Agreement dated July 23, 2013 between the Company and Ethicor Pharmaceuticals, Ltd. (Filed as Exhibit 10.2).
10.3 †	License Agreement dated August 12, 2013 between CyDex Pharmaceuticals, Inc. and CURx Pharmaceuticals, Inc. (Filed as Exhibit 10.3).
10.4 †	Supply Agreement dated August 12, 2013 between CyDex Pharmaceuticals, Inc. and CURx Pharmaceuticals, Inc. (Filed as Exhibit 10.4).
24.1 (20)	Power of Attorney (Filed as Exhibit 24.1).
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.

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<b><u>Exhibit Number</u></b>	<b><u>Description</u></b>
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 September 30, 2013, 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 detailed footnotes.
(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.
(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 Current Report on Form 8-K filed on April 9, 2013.
(17)	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.
(18)	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.
(19)	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 June 19, 2013.
(20)	This exhibit was previously filed as part of, and is being incorporated by reference to the numbered exhibit filed with the Company's Annual Report on Form 10-K for the year ended December 31, 2012.

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- † Confidential treatment has been requested for portions of this exhibit. These portions have been omitted and submitted separately to the Securities and Exchange Commission.
- \* 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.

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.

Exhibit 10.1

## LICENSE AGREEMENT

This LICENSE AGREEMENT (the “**Agreement**”) is executed as of July 17, 2013 (the “**Effective Date**”) by and between **Ligand Pharmaceuticals Incorporated**, a corporation organized under the laws of Delaware and having a place of business at 11119 North Torrey Pines Road, Suite 200, La Jolla, CA, 92037 (“**Ligand**”) and **Azure Biotech, Inc.**, a corporation organized under the laws of Delaware and having a place of business at 500 East 85<sup>th</sup> Street, 19D, New York, NY, 10028 (“**Licensee**”). Ligand and Licensee are each referred to herein by name or, individually, as a “**Party**” or, collectively, as “**Parties**.”

### BACKGROUND

**WHEREAS**, Ligand owns or has rights under certain patent rights and know-how, which relate to Lasofoxifene (as defined below);

**WHEREAS**, Licensee desires to obtain an exclusive worldwide license under such patent rights and know-how for the development and commercialization of Lasofoxifene as set forth herein; and

**WHEREAS**, Ligand desires to grant such license to Licensee, all in accordance with the terms and conditions herein.

**NOW, THEREFORE**, in consideration of the mutual covenants and agreements provided herein below and other consideration, the receipt and sufficiency of which is hereby acknowledged, Ligand and Licensee hereby agree as follows:

### ARTICLE 1 DEFINITIONS

As used in this Agreement, capitalized terms shall have the meanings indicated in this Article 1 or as specified elsewhere in this Agreement:

**1.1** “**Affiliate**” means, with respect to a Person, any Person that is controlled by, controls, or is under common control with such first Person, as the case may be. For purposes of this **Section 1.1**, the term “control” means (a) direct or indirect ownership of [\*\*\*] or more of the voting interest in the entity in question, or [\*\*\*] or more interest in the income of the entity in question; *provided, however*, that if local Law requires a minimum percentage of local ownership of greater than [\*\*\*], control will be established by direct or indirect beneficial ownership of [\*\*\*] of the maximum ownership percentage that may, under such local Law, be owned by foreign interests, or (b) possession, directly or indirectly, of the power to direct or cause the direction of management or policies of the entity in question (whether through ownership of securities or other ownership interests, by contract or otherwise).

**1.2** “Challenge” means if Licensee, its Affiliates or any Sublicensee: (a) institutes, or causes its counsel to institute, any interference, opposition, re-examination or similar proceeding with respect to any Licensed Patent with the U.S. Patent and Trademark Office or any foreign patent office; or (b) makes any filing or institutes any legal proceeding, or causes its counsel to make any filing or institute any legal proceeding, with a court or other governmental body (including, the U.S. Patent and Trademark Office or any foreign patent office) in which one or more claims or allegations challenges the validity or enforceability of any Licensed Patent.

**1.3** “Claim Notice” has the meaning set forth in **Section 8.3**.

**1.4** “Clinical Trial” means an investigation in human subjects and/or patients intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of Product, and/or to identify any adverse reactions to Product, and/or to study absorption, distribution, metabolism, and/or excretion of Product with the objective of ascertaining its safety, activity and/or efficacy.

**1.5** “Confidential Information” means any information of a confidential and proprietary nature, including know-how, information, invention disclosures, patent applications, proprietary materials and/or technologies, economic information, business or research strategies, trade secrets, and material embodiments thereof, disclosed by a Party to the other Party and characterized to the receiving Party as confidential.

**1.6** “Control” or “Controlled” means, with respect to any information, material or intellectual property right, that a Party owns or has a license to such information, material or intellectual property right, as applicable, and has the ability to grant to the other Party access to, or a license or sublicense under, such information, material or intellectual property right as provided under the terms of this Agreement.

**1.7** “Develop” or “Development” means pre-clinical and clinical research and development activities, including toxicology and other pre-clinical development efforts, stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical pharmacology, clinical studies (including Clinical Trials), regulatory affairs, and Regulatory Approval and clinical study regulatory activities.

**1.8** “Dispute” has the meaning set forth in **Section 11.11**.

**1.9** “Executive” shall mean for Ligand, the Chief Executive Officer of Ligand (or such individual’s designee), and, for Licensee, the Chief Executive Officer of Licensee (or such individual’s designee). If either position is vacant or either position does not exist, then the person having the most nearly equivalent position (or such individual’s designee) shall be deemed to be the Executive of the relevant Party.

**1.10** “FD&C Act” means the U.S. Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301, et seq.), including any amendments or supplements thereto.

**1.11** “FDA” means the U.S. Food and Drug Administration, or any successor agency thereto.

**1.12** “Field” means the treatment or prevention of human diseases.

**1.13** “First Commercial Sale” means the first sale of Product by Licensee or its Affiliates or Sublicensees to a Third Party for which payment (cash or non-cash) has been received in any country in the Territory.

**1.14** “Governmental Entity” means any regional, central, federal, state, provincial or local court, commission or governmental, regulatory or administrative body, board, bureau, agency, instrumentality, authority or tribunal or any subdivision thereof.

**1.15** “Improvement” means any discovery, invention, contribution, method, finding, or improvement, whether or not patentable, and all intellectual property therein, that is conceived, reduced to practice, or otherwise developed by or on behalf of a Party, during the Term, that is a modification, improvement or enhancement to the Licensed Patents and is dominated by the claims of one or more of the patent rights described in **Section 1.22**.

**1.16** “IND” means an Investigational New Drug application, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct Clinical Trials filed with or submitted to a Regulatory Authority in the applicable jurisdiction in conformance with the requirements of such Regulatory Authority.

**1.17** “Intellectual Property Rights” means Patents, copyrights, database rights, Know-How and similar rights of any type (excluding trademarks) under the laws of any Governmental Entity, including all applications, registrations, extensions and renewals relating to any of the foregoing.

**1.18** “Know-How” means all technical information and other technical subject matter, proprietary methods, ideas, concepts, formulations, discoveries, inventions, devices, technology, trade secrets, compositions, designs, formulae, know-how, show-how, specifications, drawings, techniques, results, data, processes, methods, procedures, designs and regulatory correspondence and information (including pharmacological, toxicological, pre-clinical, clinical and manufacturing test data, manufacturing protocols, analytical methods and data, quality control data and process validation) whether or not patentable.

**1.19** “Lasofexifene” means that compound known as [\*\*\*] as identified in **Exhibit A**.

**1.20** “Law” means, individually and collectively, any and all laws, ordinances, orders, rules, rulings, directives and regulations of any kind whatsoever of any Governmental Entity or Regulatory Authority within the applicable jurisdiction.

**1.21** “Licensed Know-How” means all Know-How Controlled by Ligand or any of its Affiliates as of the Effective Date that is (a) necessary or useful in connection with developing, making, using, selling, offering to sell, exporting and importing Product in the Territory and (b) not included in the Licensed Patents.

**1.22** “Licensed Patents” means those Patents Controlled by Ligand or any of its Affiliates listed in **Schedule 1.22** attached hereto.

**1.23** “Licensed Technology” means the Licensed Know-How and the Licensed Patents.

**1.24** “Licensee Indemnities” has the meaning set forth in **Section 8.2**.

**1.25** “Ligand Indemnities” has the meaning set forth in **Section 8.1**.

**1.26** “NDA” means a “New Drug Application,” as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA and all amendments and supplements thereto filed with the FDA, or the equivalent application filed with any Regulatory Authority, including all documents, data, and other information concerning Product, which are necessary for gaining Regulatory Approval to market and sell Product in the relevant jurisdiction.

**1.27** “Net Sales” means gross amounts invoiced by or on behalf of Licensee and any of its Affiliates or Sublicensees for Product sold to Third Parties who are not Affiliates or Sublicensees, unless such Affiliate or Sublicensee is the end user of Product, in which case the amount billed therefor shall be deemed to be the amount that would be billed to a Third Party end user in bona fide, arms-length transactions, less the following deductions, as determined in accordance with Licensee’s usual and customary accounting methods, which are in accordance with United States GAAP (as generally and consistently applied throughout Licensee’s organization) to the extent included in the gross invoiced sales price of Product or otherwise directly paid or incurred by Licensee, its Affiliates or Sublicensees with respect to the sale of Product: [\*\*\*]. Each of the deductions set forth above shall be determined on [\*\*\*] in accordance with GAAP.

In the event a Product is sold in a package or formulated in combination with one or more other active ingredients that are not Products (as used in this definition of Net Sales, a “Combination Product”), then for each calendar quarter payment period and on a country-by-country basis for the remainder of this paragraph, the gross amount invoiced for that Product shall be calculated by [\*\*\*]. In the event that the other active ingredient is not sold separately, then the gross amount invoiced for that Product shall be calculated by [\*\*\*]. In the event that a particular Combination Product is not addressed by the foregoing, Net Sales for royalty determination shall be determined [\*\*\*].

**1.28** “Patents” means all: (a) United States and foreign patents, re-examinations, reissues, renewals, extensions and term restorations, inventors’ certificates and counterparts thereof; and (b) pending applications for United States and foreign patents, including, provisional applications, continuations, continued prosecution, divisional and substitute applications, and counterparts thereof.

**1.29** “Phase 1a Trial” means a Clinical Trial that would satisfy the requirements of 21 C.F.R. Part 312.21(a) (as amended from time to time) or other comparable regulation imposed by an applicable Regulatory Authority in any country other than the United States, the principal purposes of which are to generate sufficient data on safety in humans to commence a Phase 2 Trial. For purposes of this Agreement, ‘initiation’ of a Phase 1a Trial means the first dosing of Product in a human subject in a Phase 1a Trial.

**1.30** “Phase 2 Trial” means a Clinical Trial that would satisfy the requirements of 21 C.F.R. Part 312.21(b) (as amended from time to time) or other comparable regulation imposed by an applicable Regulatory Authority in any country other than the United States, the principal purposes of which are to make a preliminary determination that a Product is safe for its intended use and to obtain sufficient information about such Product’s efficacy to permit the design of further clinical trials. For purposes of this Agreement, ‘initiation’ of a Phase 2 Trial means the first dosing of Product in a human subject in a Phase 2 Trial.

**1.31** “Phase 3 Trial” means a Clinical Trial on sufficient numbers of patients that is designed to establish that a Product is safe and efficacious for its intended use, and to define warnings, precautions and adverse reactions that are associated with such Product in the dosage range to be prescribed, and to support Regulatory Approval of such Product or label expansion of such Product.

For purposes of this Agreement, ‘initiation’ of a Phase 3 Trial means the first dosing of Product in a human subject in a Phase 3 Trial.

**1.32** “Person” means any individual, corporation, partnership, association, joint-stock company, trust, unincorporated organization or government or political subdivision thereof.

**1.33** “Product” means all preparations, compositions and formulations intended for topical use in the Field that contain Lasofoxifene, whether alone or in combination with other active pharmaceutical ingredients. For clarity, Product shall not include any preparations, compositions or formulations of Lasofoxifene [\*\*\*].

**1.34** “Prosecute” or “Prosecution” means, with respect to Patents, the filing for, prosecuting, responding to oppositions, nullity actions, re-examinations, revocation actions and similar proceedings (including conducting or participating in interference and oppositions) filed by Third Parties against, and maintaining, Patents.

**1.35** “Regulatory Approval” means, with respect to a country or jurisdiction within the Territory, (a) any approvals, licenses, registrations or authorizations necessary for the manufacture, marketing and sale of a Product in such country or jurisdiction, and (b) where relevant, pricing approvals necessary to obtain reimbursement from a Governmental Entity with respect to a Product in such country or jurisdiction.

**1.36** “Regulatory Authority” means any national (e.g., the FDA), supranational (e.g., the EMA), regional, state or local regulatory agency, department bureau, commission, council or other Governmental Entity in any jurisdiction of the world involved in the granting of Regulatory Approval for pharmaceutical products.

**1.37** “Regulatory Documentation” means all submissions to Regulatory Authorities and other Governmental Entities, including for Clinical Trials, preclinical trials, tests, and biostudies, relating to a Product, including all INDs, NDAs and Regulatory Approvals, as well as all correspondence with Governmental Entities (registration and licenses, pricing and reimbursement correspondence, regulatory drug lists, advertising and promotion documents), adverse event files, complaint files, manufacturing records and inspection reports.

**1.38** “Research Plan” has the meaning set forth in **Section 4.2(a)**.

**1.39** “Retained Field” means all preparations, compositions and formulations of product containing Lasofoxifene other than topical use in the Field, including oral and intravenous use.

**1.40** “Royalty Term” has the meaning set forth in **Section 3.3(d)**.

**1.41** “Sublicense Agreement” has the meaning set forth in **Section 2.3**.

**1.42** “Sublicense Revenues” means amounts (including, any licensing fees, or license maintenance fees, or milestone payments) [\*\*\*], provided that Sublicense Revenues will not include amounts [\*\*\*] the Licensee that are reasonably and fairly attributable to any of the following to the extent that each is bona fide: [\*\*\*].

**1.43** “Sublicensee” means a Third Party to whom Licensee grants a sublicense hereunder to sell, offer for sale or import a Product, but excluding wholesalers and other physical distributors. For the avoidance of doubt, if Licensee sells to a wholesaler and/or other physical distributor, such

sale to such wholesaler and/or distributor shall be deemed a sale for purposes of calculating Net Sales hereunder.

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

**1.45** “Territory” means all of the countries in the world, and their territories and possessions.

**1.46** “Third Party” means any Person other than Ligand, Licensee or any Affiliate of either Ligand or Licensee.

**1.47** “Valid Claim” means (a) any claim of an issued and unexpired patent within the Licensed Patents that has not been held unenforceable or invalid by a court or other governmental agency of competent jurisdiction in a decision that is not appealed or is unappealable, and which patent has not been disclaimed or admitted to be invalid or unenforceable through reissue or otherwise, or (b) a pending claim in a pending patent application within the Licensed Patents that has not been abandoned, finally rejected, or expired without the possibility of appeal or refiling.

**1.48** Unless the context of this Agreement otherwise requires: (a) words of any gender include each other gender; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the terms “hereof,” “herein,” “hereby” and derivative or similar words refer to this entire Agreement; (d) the terms “Article,” “Section” or “Exhibit” refer to the specified Article, Section or Exhibit of this Agreement; and (e) the term “including” means “including without limitation.” Whenever this Agreement refers to a number of days, such number shall refer to calendar days.

## **ARTICLE 2 LICENSES AND TECHNOLOGY TRANSFER**

**2.1 Exclusive License for the Products.** During the Term, subject to the terms and conditions of this Agreement, Ligand hereby grants to Licensee an exclusive, royalty-bearing right and license under the Licensed Technology to develop, make, have made, use, sell, have sold, import and export Products in the Field in the Territory. For clarity, in the foregoing sentence, “exclusive” means that Ligand shall not for its own account, and shall not grant to any Third Party the right and license under the Licensed Technology to, develop, make, have made, use, sell, have sold, import and export Products in the Field in the Territory.

**2.2 Rights to Improvements.** Licensee and its permitted Sublicensees shall have a right to make Improvements to the Licensed Technology, and to utilize such Improvements to develop, make, have made, use, sell, have sold, import and export Products in the Field in the Territory.

### **2.3 Sublicensees.**

(a) The rights and licenses granted pursuant to **Section 2.1**, include the right to grant sublicenses pursuant to a written sublicense agreement (each a “Sublicense Agreement”); *provided, however*, that (i) any such Sublicense Agreement shall be consistent with and subject to the terms and conditions of this Agreement; (ii) Licensee shall remain fully responsible to Ligand for the performance of its Sublicensee(s); (iii) Licensee shall reserve the right under each Sublicense Agreement to conduct an audit of its Sublicensee in a comparable manner to **Section 3.10** of this Agreement; and (iv) Licensee shall provide a [\*\*\*] copy of any Sublicense Agreement [\*\*\*] *provided*, that commercially sensitive information may be redacted from such copies, to the extent

such information is not necessary to verify compliance hereunder and the terms, conditions and existence of such Sublicense Agreement shall be deemed the Confidential Information of Licensee.

(b) [\*\*\*].

(c) Licensee shall remain obligated to make all payments due to Ligand under the terms of this Agreement with respect to the activities of its Sublicensees.

**2.4 Technology Transfer.** Within [\*\*\*] after the Effective Date, Ligand shall disclose and provide to Licensee all tangible embodiments of the Licensed Technology and Regulatory Documentation in existence as of the Effective Date critical to, necessary or useful for developing, making, using or selling Products, including the Licensed Technology and Regulatory Documentation listed on **Schedule 2.4** attached hereto. Following such [\*\*\*] period, at Licensee's request, Ligand shall use commercially reasonable efforts to disclose and provide to Licensee any additional Licensed Technology and Regulatory Documentation in Ligand's (or an Affiliates') Control that is critical to, necessary or useful for developing, making, using or selling Products.

**2.5 [\*\*\*].**

**2.6 No Other Rights.** Ligand and Licensee each acknowledges and agrees that, except as expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted whether by implication, estoppel, reliance, or otherwise, by either Party to the other Party. All rights with respect to technology, Patents or other Intellectual Property Rights that are not specifically granted herein are reserved.

**2.7 Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement, including amendments hereto, are, for all purposes of 11 U.S.C. § 365(n), licenses of rights to intellectual property as defined in the United States Bankruptcy Code, and any comparable Law of a relevant jurisdiction. Each Party may elect to retain and may fully exercise all of its rights and elections under 11 U.S.C. § 365(n). [\*\*\*].

### **ARTICLE 3 COMPENSATION**

**3.1 License Issuance Fee.** In partial consideration of the rights and licenses granted by Ligand hereunder, Licensee shall pay a one-time, non-refundable and non-creditable license issuance fee as follows: (a) [\*\*\*] within [\*\*\*] of the Effective Date; or (b) provided Licensee has provided written notice to Ligand within [\*\*\*] of the Effective Date of its election to make the license issuance fee payment pursuant to this subsection (b), [\*\*\*].

**3.2 Milestone Payments.** In further consideration of the rights and licenses granted by Ligand hereunder, Licensee shall pay to Ligand the non-refundable and non-creditable milestone payments set forth below within [\*\*\*] of the achievement by Licensee or its Affiliates or Sublicensees of each of the corresponding events:

<u>Milestone</u>	<u>Payment</u>
Initiation of a Phase 3 Trial	[***]
Receipt of Regulatory Approval in the United States	[***]
Receipt of Regulatory Approval in a Major European Country (which, for purposes of this clause shall include France, Germany, Italy, Spain and the United Kingdom)	[***]
Receipt of Regulatory Approval in Japan	[***]

For clarity, it is expressly agreed that the milestone payments set forth above will be payable once only regardless of the number of Products to achieve the event.

### 3.3 Payment of Royalties

(a) Royalty Rates. In further consideration of the rights and licenses granted by Ligand hereunder, Licensee shall pay to Ligand five percent (5%) of aggregate Net Sales.

(b) Sublicensing. In the event Licensee grants a sublicense under **Section 2.3** to a Sublicensee to develop, make, use, sell, offer to sell, import or export a Product, the applicable Sublicense Agreement shall require the Sublicensee to account for and report its net sales of Product on substantially the same basis as if such sales were Net Sales, and Licensee shall pay royalties on such sales as if the net sales of the Sublicensees were Net Sales of Licensee.

(c) Payment of Royalties. Licensee shall pay on a calendar quarterly basis all royalties due and payable on Net Sales in each calendar quarter pursuant to this **Section 3.3** within [\*\*\*] days after the last day of each calendar quarter in which the applicable Net Sales underlying such royalties were billed or invoiced by Licensee, its Affiliate or its Sublicensee; [\*\*\*].

(d) Royalty Term. The obligation of Licensee to pay royalties to Ligand under this **Section 3.3** shall commence on the date of the First Commercial Sale of a Product and continue, on a country-by-country basis and on a Product-by-Product basis, until the later of (i) expiration or other termination of all Licensed Patents containing one or more Valid Claims that would be infringed by the manufacture, sale, offer for sale, use or importation of such Product in such country, or (ii) [\*\*\*] (the "Royalty Term"). Thereafter, Licensee shall have a paid up, royalty-free, exclusive license with respect to such Product in the applicable country.

(e) Third Party Payments on Products. Licensee shall be responsible for paying any amounts due to Third Parties in connection with the making, using, selling, importing or exporting Product throughout the Territory.

**3.4 Sublicense Revenues**. In addition to any payments due under **Sections 3.2** or **3.3** as a result of a Sublicensee's activities, the Licensee will pay to Ligand a percentage of all Sublicense Revenues, as follows:

- (a) [\*\*\*] of all Sublicense Revenues due and payable prior to [\*\*\*];
- (b) [\*\*\*] of all Sublicense Revenues due and payable on or after [\*\*\*]; and

(c) [\*\*\*] after [\*\*\*].

**3.5 Payment Method.** All payments made by Licensee under this Agreement shall be made in U.S. Dollars, and such payments shall be made by check or wire transfer to one or more bank accounts to be designated in writing by Ligand.

**3.6 Currency Conversion.** In the event that Products are sold in currencies other than U.S. Dollars, Net Sales shall be calculated by Licensee in accordance with U.S. generally accepted accounting principles, consistently applied. Net Sales in currencies other than U.S. Dollars shall be converted into U.S. Dollars using the average official rate of exchange for such currencies published in *The Wall Street Journal*, Eastern Edition, [\*\*\*].

**3.7 Late Payment Interest.** Any payment due and payable to Ligand under the terms and conditions of this Agreement, including any royalty payment, made by Licensee after the date such payment is due and payable shall bear interest as of the day after the date such payment was due and payable and shall continue to accrue such interest until such payment is made at a rate equal to the lesser of either [\*\*\*].

**3.8 Records and Reports.** All payments made to Ligand hereunder shall be accompanied by a written statement setting forth in reasonable detail the calculation thereof, including, for example, in the case of royalty payments, the gross amount billed or invoiced by Licensee, its Affiliate or Sublicensee for sale or other disposition of Product on a country-by-country basis in the local currency, itemized deductions against such gross amount in accordance with **Section 1.27**, Net Sales on a country-by-country basis, and, if applicable, the exchange rate utilized to convert a local currency to U.S. Dollars. Licensee shall maintain complete and accurate records sufficient to enable accurate calculation of royalties and other payments due Ligand hereunder. Such records and books of account shall be preserved by Licensee for a period of [\*\*\*] after the end of the period covered by such records and books of account, which obligation shall survive expiration or termination of this Agreement. Licensee must ensure that its Sublicensees provide reports and keep records in a manner consistent with this **Section 3.8**. Licensee shall provide reports received from Sublicensees to Ligand with the applicable payment.

**3.9 Taxes.** Licensee may withhold from payment made to Ligand under this Agreement any income tax required to be withheld by Licensee under the laws of the country or jurisdiction where Licensee has commercially sold Products. If any tax is withheld by Licensee, Licensee shall provide Ligand receipts or other evidence of such withholding and payment to the appropriate tax authorities on a timely basis following that tax payment. Each Party agrees to cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect. The Parties shall discuss applicable mechanisms for minimizing such taxes to the extent possible in compliance with applicable Law. In addition, the Parties shall cooperate in accordance with applicable Law to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) in connection with this Agreement.

**3.10 Audit Rights.** Licensee shall permit an independent public accountant designated by Ligand and reasonably acceptable to Licensee, to have access, no more than [\*\*\*] in each calendar year during the Term and no more than [\*\*\*] during the [\*\*\*] following the expiration or termination of this Agreement, during regular business hours and upon at least [\*\*\*] written notice, to Licensee's records and books to the extent necessary to determine the accuracy of Net Sales reported, and payments made, by Licensee to Ligand within the [\*\*\*] period immediately preceding such an audit. The independent public accountant shall disclose to Ligand only (a) the accuracy of Net Sales

reported and the basis for royalty and other payments made to Ligand under this Agreement and (b) the difference, if any, such reported and paid amounts vary from amounts determined as a result of the audit. If such examination results in a determination that Net Sales or payments have been misstated, over or under paid amounts due shall be paid promptly to the appropriate Party. If Net Sales are understated by greater than [\*\*\*], the fees and expenses of such accountant shall be paid by Licensee; otherwise the fees and expenses of such accountant shall be paid by Ligand. All matters reviewed by such independent public accountant shall be deemed Confidential Information of Licensee subject to **ARTICLE 6**.

## **ARTICLE 4 PRODUCT ACTIVITIES**

### **4.1 Diligence.**

(d) Licensee shall diligently Develop, manufacture and sell Products, and shall use commercially reasonable efforts to develop markets for Products, in both cases either directly or through a Sublicensee. Licensee, either directly or through a Sublicensee, shall obtain all necessary Regulatory Approvals in each country where Products are made, used, sold, imported, or offered for sale.

(e) In addition, and without limiting Licensee's obligations under **Section 4.1(a)**, Licensee will complete the following diligence milestones (each, a "Diligence Milestone") by the applicable date:

- (1) [\*\*\*];
- (2) [\*\*\*];
- (3) [\*\*\*];
- (4) [\*\*\*]; and
- (5) [\*\*\*].

(f) Ligand recognizes that there are uncertainties associated with the development of therapeutic products and the regulatory process required by Regulatory Authorities, and [\*\*\*].

(1) Accordingly, Licensee shall have the right to [\*\*\*], provided that Licensee provides written notification with supporting documents at least [\*\*\*]. Ligand shall review such supporting documents and provide Licensee with its determination on whether [\*\*\*] should fall under this **Section 4.1(c)(1)** or under **Section 4.1(c)(2)**. If the Parties disagree on whether [\*\*\*] falls under this **Section 4.1(c)(1)** or under **Section 4.1(c)(2)**, either Party may invoke the dispute resolution procedures set forth in **Section 11.11**.

(2) In addition, Licensee shall have the right to elect [\*\*\*]. For clarity, [\*\*\*] to extend a milestone under this **Section 4.1(c)** will extend all remaining milestones in **Section 4.1(b)(2)** through **4.1(b)(5)** by the applicable time period.

### **4.2 Research Plan; Progress Reports.**

(f) Licensee shall develop a research plan detailing the work it will perform and associated timelines to Develop Products and to obtain Regulatory Approval and sell Products throughout the Territory (the “Research Plan”). Licensee will provide a copy of the Research Plan to Ligand within [\*\*\*] of the Effective Date and any updates on an annual basis.

(g) By March 1, June 1, September 1 and December 1 of each year, Licensee shall submit a written report to Ligand covering the preceding three (3) month period. Each report will describe: Licensee’s progress in accordance with the Research Plan and toward commercialization of Products, including work completed, key scientific discoveries, summary of work-in-progress, current schedules or anticipated events or milestones, market plans for introduction of Product, and significant corporate transaction(s) involving Product. Licensee shall also provide to Ligand copies of any similar progress reports received from its Sublicensees, within thirty (30) days of receipt. In addition, upon the reasonable request of Ligand but no more frequently than two times in each year, Licensee and Ligand shall meet in-person at a mutually agreeable location to discuss the topics described in the progress reports, and such other topics related to Products as Ligand may reasonably request.”

**4.3 Development.** Licensee shall be solely responsible for the Development of all Products in the Field in the Territory. Licensee shall bear one hundred percent (100%) of all costs and expenses associated with the Development of Products.

**4.4 Regulatory Responsibilities.**

(a) Licensee shall bear one hundred percent (100%) of all costs and expenses associated with regulatory activities related to the Products in the Field in the Territory.

(b) Ligand has the right to request copies of Regulatory Documentation Controlled by Licensee and significant correspondence to and from all Regulatory Authorities related to Products in the Territory solely for Ligand’s use in connection with the development, use and sale of Lasofoxifene in the Retained Field; *provided*, that Ligand agrees, and causes any Third Party licensee with rights in the Retained Field to agree, to provide Licensee with reciprocal rights to copies of Regulatory Documentation Controlled by Ligand, its Affiliates and such Third Parties solely for Licensee’s use in connection with the development, use and sale of Product hereunder. Each Party shall provide the other Party with reasonable cooperation and assistance in connection with regulatory activities for Lasofoxifene, including responding to reasonable requests by the other Party for additional Regulatory Documentation (and information and clinical data contained therein) related to Lasofoxifene.

(c) Licensee shall be responsible for ensuring, at its sole expense, that the Development and commercialization of all Products in the applicable jurisdiction within the Territory are in compliance with applicable Laws in all material respects, including all rules and regulations promulgated by applicable Regulatory Authorities. Specifically and without limiting the foregoing, Licensee shall file all compliance filings, certificates and safety reporting for the Products at its sole expense in the Territory.

**4.5 Commercialization.** Licensee shall be solely responsible for the commercialization of all Products in the Field in the Territory. Licensee shall bear one hundred percent (100%) of all costs and expenses associated with commercialization of all Products in the Field in the Territory.

**ARTICLE 5  
INTELLECTUAL PROPERTY**

**5.1 Patent Maintenance and Prosecution.**

(h) Ligand shall, in its sole discretion, Prosecute the Licensed Patents; *provided, however*, Ligand shall make available to Licensee copies of material correspondence with any patent office regarding the Licensed Patents. Licensee shall have the right to comment upon the Prosecution of the Licensed Patents, and Ligand shall reasonably consider any such comments. [\*\*\*]. In the event that Ligand decides to cease activities relating to Prosecuting any Licensed Patents, Ligand shall provide written notice thereof to Licensee and, prior to taking action that would result in the abandonment of any such Licensed Patent, Ligand shall engage in good faith discussions with Licensee, such discussions to occur at least [\*\*\*] prior to the date when government rights would be lost as a consequence of abandonment of such Licensed Patent. Thereafter, Licensee may, but is not required to, undertake, at its sole expense and in its sole discretion, the Prosecution of such Licensed Patent, and Ligand shall cooperate. In addition, if Licensee no longer desires a license to one or more Licensed Patents, Licensee shall provide written notice thereof to Licensee and effective [\*\*\*] following such notice, such Patent(s) shall no longer be deemed Licensed Patent(s) and Licensee shall no longer have an obligation to reimburse Ligand for the costs to Prosecute such Patent(s).

(i) Licensee shall, at Licensee's sole cost and expense, and in its sole discretion, Prosecute any Patents covering Improvements.

**5.2 Licensed Patents and Licensed Know-How Enforcement and Defense.**

(d) Notification. Each Party shall notify the other Party of any infringement of any of the Licensed Patents or misappropriation of any of the Licensed Know-How by a Third Party in the Field that becomes known to such Party, and of any claim by a Third Party that the activities of a Party infringe patent rights or misappropriate other Intellectual Property Rights of such Third Party.

(e) Licensed Patents. As between the Parties, Ligand shall have the first right, but not an obligation, to initiate, maintain and control, [\*\*\*], legal action against any infringement of the Licensed Patents by a Third Party in the Field. In the event that Ligand initiates legal action against infringement of the Licensed Patents by a Third Party, Ligand shall notify Licensee in writing. Thereafter, Licensee shall have a right, in Licensee's sole discretion and, notwithstanding **Section 5.3**, [\*\*\*], to join or otherwise participate or not to join or otherwise participate in such legal action with legal counsel selected by Licensee. If Ligand does not take steps to defend or enforce the Licensed Patents, Licensee shall have the right, but not an obligation, to initiate, maintain and control, at its expense, legal action against any infringement of the Licensed Patents by a Third Party in the Field. Any recovery received by a Party from legal action initiated pursuant to this **Section 5.2**, whether by judgment, award, decree or settlement, shall be [\*\*\*]. The remainder of any recovery or distribution received by a Party under this **Section 5.2**, after [\*\*\*].

**5.3 Cooperation**. In any suit, proceeding or dispute involving the infringement of any of the Licensed Patents in the Field or misappropriation of any of the Licensed Know-How in the Field, the Parties shall provide each other with reasonable cooperation, and, upon the request and at the expense of the Party bringing suit, the other Party shall make available to the Party bringing suit, at reasonable times and under appropriate conditions, all relevant personnel, records, papers, information, samples, specimens, and the like in its possession. Notwithstanding any other provision

of this **ARTICLE 5**, neither Party shall make any settlements of any suit, proceeding or action relating to an infringement of the Licensed Patents in the Field or misappropriation of any of the Licensed Know-How in the Field under **Section 5.2** that would adversely affect the other Party or materially affect the rights and licenses granted hereunder without first obtaining such other Party's prior written consent, such consent not to be unreasonably withheld or delayed.

## **ARTICLE 6 CONFIDENTIALITY**

**6.1 Confidentiality Obligations.** Each Party agrees that, during the Term and for [\*\*\*] thereafter, all Confidential Information of the other Party shall be maintained in strict confidence, and shall not be used for any purpose other than the purposes expressly permitted by this Agreement, and, subject to **Section 6.2**, shall not be disclosed to any Third Party. The foregoing obligations will not apply to any portion of Confidential Information to the extent that it can be established by competent proof that such portion:

(f) was already known to the recipient as evidenced by its written records, other than under an obligation of confidentiality, at the time of disclosure;

(g) was generally available to the public or was otherwise part of the public domain at the time of its disclosure to the recipient;

(h) became generally available to the public or otherwise becomes part of the public domain after its disclosure and other than through any act or omission of the recipient in breach of this Agreement; or

(i) was subsequently lawfully disclosed to the recipient by a Third Party other than in contravention of a confidentiality obligation of such Third Party to the disclosing party.

**6.2 Permitted Usage.** Each Party may use and disclose Confidential Information of the other Party, in accordance with this Agreement, as follows: (a) under appropriate confidentiality provisions no less restrictive than those in this Agreement, in connection with the performance of its obligations or exercise of rights granted to or retained by such Party; (b) in connection with the Prosecution or enforcement of Licensed Patents or Improvements, in accordance with this Agreement; or (c) in connection with prosecuting or defending litigation, complying with applicable governmental regulations, filing for, obtaining and maintaining Regulatory Approvals, or as otherwise required by Law, but provided that if a Party is required by Law to make any disclosure of the other Party's Confidential Information, it will give reasonable advance notice to the other Party of such disclosure requirement, it will disclose only for the sole purpose of and solely to the extent required by such Law, and it will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed.

**6.3 Terms of Agreement.** The terms of this Agreement shall be Confidential Information of both Parties, and subject to the terms of this **ARTICLE 6**. Notwithstanding the foregoing, either Party may make a disclosure of terms of this Agreement (i) to any financial advisors, accountants, potential Sublicensees, investors, or potential acquirers, (ii) if required by applicable Law, or (iii) as otherwise permitted pursuant to **Section 6.4**. Except as otherwise permitted for disclosures pursuant to this **ARTICLE 6**, the disclosing Party shall use all commercially reasonable efforts to preserve the confidentiality of this Agreement and the terms thereof notwithstanding any required disclosure. A Party will give the other Party written notice of any required disclosure under (ii) above, which notice shall, to the extent reasonably practicable, be given a reasonable period of time

in advance of such required disclosure. In the event either Party is required to file this Agreement with the U.S. Securities and Exchange Commission or any comparable non-U.S. Governmental Entity, such Party shall apply for confidential treatment of this Agreement to the fullest extent permitted by applicable Law, shall provide the other Party a copy of the confidential treatment request far enough in advance of its filing to give the other Party a meaningful opportunity to comment thereon, and shall incorporate in such confidential treatment request any reasonable comments of the other Party.

**6.4 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 consent of the other Party, such consent not to be unreasonably withheld or delayed by such 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, or acquisitions. 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.

## **ARTICLE 7 REPRESENTATIONS, WARRANTIES AND COVENANTS**

**7.1 General.** Each Party represents and warrants to the other that:

(d) it is duly organized and validly existing under the Law of the jurisdiction of its incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(e) it is qualified to do business and is in good standing in each jurisdiction in which it conducts business;

(f) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the individual executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action;

(g) this Agreement is legally binding upon it and enforceable in accordance with its terms and the execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material Law; and

(h) it is not aware of any action, suit or inquiry or investigation instituted by any Person which questions or threatens the validity of this Agreement.

**7.2 Representations and Covenants of Licensee.**

(a) Licensee has not, directly or indirectly, offered, promised, paid, authorized or given, and will not in the future, offer, promise, pay, authorize or give, money or anything of value, directly or indirectly, to any Government Official (as defined below) or Other Covered Party (as defined below) for the purpose of: (i) influencing any act or decision of the Government Official or Other Covered Party; (ii) inducing the Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (iii) securing any improper advantage; or (iv) inducing the Government Official or Other Covered Party to influence the act or decision of a government or government instrumentality, in order to obtain or retain business, or direct business to, any person or entity, in any way related to this Agreement.

For purposes of this Agreement: (i) "Government Official" means any official, officer, employee or representative of: (A) any federal, state, provincial, county or municipal government or any department or agency thereof; (B) any public international organization or any department or agency thereof; or (C) any company or other entity owned or controlled by any government; and (ii) "Other Covered Party" means any political party or party official, or any candidate for political office.

(b) Anti-Corruption Compliance.

(3) In performing under this Agreement, Licensee and its Affiliates agree to comply with all applicable anti-corruption laws, including the Foreign Corrupt Practices Act of 1977, as amended ("FCPA") and all laws enacted to implement the OECD Convention on Combating Bribery of Foreign Officials in International Business Transactions.

(4) Licensee is not aware of any Government Official or Other Covered Party having any financial interest in the subject matter of this Agreement or in any way personally benefiting, directly or indirectly, from this Agreement.

(5) No political contributions or charitable donations shall be given, offered, promised or paid at the request of any Government Official or Other Covered Party that is in any way related to this Agreement or any related activity, without Ligand's prior written approval.

(6) In the event that Licensee violates the FCPA or any applicable anti-corruption law or breaches any provision in this Section, Ligand shall have the right to unilaterally terminate this Agreement. In addition, Licensee shall defend, indemnify and hold harmless Ligand from and against any and all costs, damages, losses, liabilities, expenses, judgments, fines, settlements and any other amounts of any nature, including reasonable attorneys' fees arising from any improper payment made in violation of the FCPA, any applicable anti-corruption laws or this Section, directly or indirectly, by, on behalf of or with the knowledge of the Licensee, in relation to this Agreement.

### **7.3 Representations of Ligand.**

(a) There are no adverse actions, suits, or claims pending or to the knowledge of Ligand, threatened against Ligand in any court or by or before any Governmental Entity with respect to Lasofoxifene or the Licensed Technology and, to the actual knowledge of Ligand, there are no Third Party Patents that would reasonably be expected to give rise to such actions, suits or claims. No Third Party has challenged the ownership, scope, duration, validity enforceability, priority or right to use the Licensed Technology.

(b) Ligand has not initiated or been involved in any proceedings or claims in which it alleges that any Third Party is or was infringing or misappropriating the Licensed Technology, nor have any proceedings been threatened by Ligand, nor to the knowledge of Ligand is there any valid basis for any such proceeding.

(c) Ligand Controls the Licensed Patents and Regulatory Documentation and Licensed Technology listed on **Schedule 2.4** and has sufficient right to grant the licenses and rights granted to Licensee hereunder.

(d) Ligand has provided Licensee with copies of all licenses and other agreements, whether written or oral, pursuant to which Ligand obtained ownership or licensed the Licensed Technology and Regulatory Documentation.

#### **7.4 Covenants of Ligand.**

(a) Ligand covenants that it will not, during the Term, undertake any obligation, or grant any right, license, interest or lien, that conflicts with its obligations, or the rights and licenses granted to Licensee, under the terms of this Agreement, or impairs the rights granted by Ligand to Licensee under the terms of this Agreement.

(b) Ligand has not, directly or indirectly, offered, promised, paid, authorized or given, and will not in the future, offer, promise, pay, authorize or give, money or anything of value, directly or indirectly, to any Government Official or Other Covered Party for the purpose of: (i) influencing any act or decision of the Government Official or Other Covered Party; (ii) inducing the Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (iii) securing any improper advantage; or (iv) inducing the Government Official or Other Covered Party to influence the act or decision of a government or government instrumentality, in order to obtain or retain business, or direct business to, any person or entity, in any way related to this Agreement.

#### **(c) Anti-Corruption Compliance.**

(1) In performing under this Agreement, Ligand and its Affiliates agree to comply with all applicable anti-corruption laws, including the FCPA and all laws enacted to implement the OECD Convention on Combating Bribery of Foreign Officials in International Business Transactions.

(2) Ligand is not aware of any Government Official or Other Covered Party having any financial interest in the subject matter of this Agreement or in any way personally benefiting, directly or indirectly, from this Agreement.

(3) No political contributions or charitable donations shall be given, offered, promised or paid at the request of any Government Official or Other Covered Party that is in any way related to this Agreement or any related activity, without Licensee's prior written approval.

(4) In the event that Ligand violates the FCPA or any applicable anti-corruption law or breaches any provision in this Section, Licensee shall have the right to unilaterally terminate this Agreement. In addition, Ligand shall defend, indemnify and hold harmless Licensee from and against any and all costs, damages, losses, liabilities, expenses, judgments, fines, settlements and any other amounts of any nature, including reasonable attorneys' fees arising from any improper payment made in violation of the FCPA, any applicable anti-corruption laws or this

Section, directly or indirectly, by, on behalf of or with the knowledge of the Ligand, in relation to this Agreement.

**7.5 Disclaimer.** EXCEPT AS PROVIDED IN THIS **ARTICLE 7**, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY (EXPRESS, IMPLIED, STATUTORY OR OTHERWISE) WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED WARRANTIES OR CONDITIONS OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND ALL WARRANTIES AND CONDITIONS OF THE VALIDITY OF THE LICENSED PATENTS OR NONINFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS. THIS **SECTION 7.5** SHALL NOT BE CONSTRUED TO LIMIT EITHER PARTY'S OBLIGATIONS UNDER **ARTICLE 8**.

## **ARTICLE 8 INDEMNIFICATION; INSURANCE**

**8.1 Indemnification by Licensee.** Licensee shall indemnify, defend and hold Ligand and its Affiliates, agents, employees, officers, and directors (the "Ligand Indemnitees") harmless from and against any and all liability, damage, loss, cost, or expense (including reasonable attorneys' fees) arising out of Third Party claims or suits related to: (a) breach by Licensee of any of its representations, warranties, or covenants under this Agreement; (b) the negligence or willful misconduct of Licensee or its Affiliates or Sublicensees, and its or their directors, officers, agents, employees, or consultants; and (c) any exploitation by, or under the authority of, Licensee of the licenses granted under **Section 2.1** (including by any Affiliate or Sublicensee); *provided, however*, that Licensee's obligations pursuant to this **Section 8.1** will not apply to the extent such claims or suits result from the negligence or willful misconduct of any of the Ligand Indemnitees or breach by Ligand of its representations, warranties, or covenants set forth in this Agreement, or to the extent that Ligand has indemnification obligations with respect to such claims or suits under **Section 8.2**.

**8.2 Indemnification by Ligand.** Ligand shall indemnify, defend, and hold Licensee and its Affiliates, Sublicensees, agents, employees, officers, and directors (the "Licensee Indemnitees") harmless from and against any and all liability, damage, loss, cost, or expense (including reasonable attorneys' fees) arising out of Third Party claims or suits related to: (a) breach by Ligand of any of its representations, warranties, or covenants under this Agreement; and (b) the negligence or willful misconduct of Ligand or its Affiliates, and its or their directors, officers, agents, employees, or consultants; *provided, however*, that Ligand's obligations pursuant to this **Section 8.2** will not apply to the extent such claims or suits result from the negligence or willful misconduct of any of the Licensee Indemnitees or breach by Licensee of its representations, warranties, or covenants set forth in this Agreement, or to the extent that Licensee has indemnification obligations with respect to such claims or suits under **Section 8.1**.

**8.3 Procedure.** As a condition to a Party's right to receive indemnification under **Section 8.1** or **Section 8.2**, it shall: (a) promptly deliver notice in writing (a "Claim Notice") to the other Party as soon as it becomes aware of a claim or suit for which indemnification may be sought pursuant to **Section 8.1** or **Section 8.2** (provided that the failure to give a Claim Notice promptly shall not prejudice the rights of an indemnified Party except to the extent that the failure to give prompt notice materially adversely affects the ability of the indemnifying Party to defend the claim or suit); (b) cooperate with the indemnifying Party in the defense of such claim or suit, at the expense of the indemnifying Party; and (c) if the indemnifying Party confirms in writing to the indemnified Party its intention to defend such claim or suit within [\*\*\*] after receipt of the Claim Notice, permit the indemnifying Party to control the defense of such claim or suit, including the right to select

defense counsel; *provided, however*, if the indemnifying Party fails to (i) provide such confirmation in writing within such [\*\*\*] period or (ii) after providing such confirmation, diligently and reasonably defend such suit or claim at any time, the indemnifying Party's right to defend the claim or suit shall terminate immediately in the case of (i) and otherwise upon [\*\*\*] written notice by the indemnified Party to the indemnifying Party, and the indemnified Party may assume the defense of such claim or suit at the sole expense of the indemnifying Party but may not settle or compromise such claim or suit without the consent of the indemnifying Party, not to be unreasonably withheld or delayed. In no event, however, may the indemnifying Party compromise or settle any claim or suit in a manner which admits fault or negligence on the part of any indemnified Party or that otherwise materially affects such indemnified Party's rights under this Agreement or requires any payment by an indemnified Party without the prior written consent of such indemnified Party. Except as expressly provided above, the indemnifying Party will have no liability under this **ARTICLE 8** with respect to claims or suits settled or compromised without its prior written consent.

#### **8.4 Insurance.**

(a) Licensee shall use commercially reasonable efforts to name and cause Ligand and the Ligand Indemnitees to be named as "additional insureds" on any commercial general liability and product liability insurance policies maintained by Licensee, its Affiliates and Sublicensees applicable to the Products.

(b) Licensee (or an Affiliate or Sublicensee, as applicable) shall, at its sole expense, procure and maintain commercial general liability insurance with reputable insurers in usual and customary amounts based on the stage of development for the Products. If Licensee elects to self-insure all or part of the limits described above, such self-insurance program must be acceptable to Ligand in its reasonable discretion. The maintenance of such insurance policies shall not in any way limit Licensee's liability with respect to indemnification under this Agreement.

(c) Licensee (or an Affiliate or Sublicensee, as applicable) shall maintain such commercial general liability insurance beyond the expiration or termination of this Agreement during (a) the period that any Product is being commercially distributed or sold by or on behalf of Licensee, its Affiliates or a Sublicensee; and (b) a reasonable period after the period referred to in sub-clause (a) above, which in no event shall be less than six (6) years.

### **ARTICLE 9 LIMITATION OF LIABILITY**

**9.1** EXCEPT FOR ANY LIABILITY THAT IS THE CONSEQUENCE OF WILLFUL MISCONDUCT OF A PARTY, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, EXEMPLARY OR INCIDENTAL DAMAGES (INCLUDING LOST OR ANTICIPATED REVENUES OR PROFITS RELATING TO THE SAME), HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY ARISING OUT OF THIS AGREEMENT, WHETHER SUCH CLAIM IS BASED ON CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE. THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY PROVIDED HEREIN. THIS **ARTICLE 9** SHALL NOT BE CONSTRUED TO LIMIT EITHER PARTY'S OBLIGATIONS UNDER **ARTICLE 8**.

### **ARTICLE 10 TERM AND TERMINATION**

**10.1 Term.** Unless terminated earlier pursuant to **Section 10.2**, the term of this Agreement shall commence on the Effective Date and will expire on the date on which Licensee has no additional payment obligations to Ligand under this Agreement (the “Term”).

**10.2 Termination.**

(d) **For Convenience.** Any provision herein notwithstanding, Licensee shall have the right to terminate this Agreement in its entirety at will upon [\*\*\*] prior written notice to Ligand.

(e) **For Material Breach.** If either Party shall at any time breach any material term, condition or agreement herein, and shall fail to have initiated and actively pursued remedy of any such default or breach within [\*\*\*] (or [\*\*\*] if such default or breach is the non-payment of any amounts due hereunder) after receipt of written notice thereof by the other Party, that other Party may, at its option, terminate this Agreement and revoke any rights and licenses herein. Any termination of this Agreement under this **Section 10.2(b)** shall not, however, prejudice the right of the Party who terminates this Agreement to recover any payment due at the time of such cancellation.

(f) **For Challenge.** If Licensee, its Affiliates or a Sublicensee institutes a Challenge, Ligand may, at its option, terminate this Agreement and revoke any rights and licenses herein with [\*\*\*] prior written notice.

**10.3 Effect of Termination/Expiration .**

(a) **Rights and Obligations Upon Expiration.** Upon expiration (but not earlier termination) of this Agreement, all rights and licenses granted by Ligand to Licensee hereunder that were in effect immediately prior to the effective date of such expiration shall become irrevocable, perpetual and fully-paid.

(b) **Rights and Obligations Upon Termination.** As of the effective date of a termination (but not expiration) of this Agreement for any reason, this Agreement and all rights and licenses granted to Licensee under **Section 2.1** shall terminate and all rights in the Licensed Technology shall revert to Ligand; (ii) Licensee shall return to Ligand the Licensed Know-How and shall transfer to Ligand all then-existing Regulatory Documentation provided by Ligand or its Affiliates; and (iii) each Party shall return to the other Party and cease using all Confidential Information of the other; *provided, however*, each Party may retain one (1) copy of such Confidential Information for archival purposes.

(c) **Accrued Rights.** Termination or expiration of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration will not relieve a Party from accrued payment obligations or from obligations which are expressly indicated to survive termination or expiration of this Agreement.

(d) **Survival.** All rights and obligations of the Parties which by intent or meaning have validity beyond or by their nature apply or are to be performed or exercised after the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement for the period so specified, if any, or for perpetuity.

**ARTICLE 11**  
**GENERAL PROVISIONS**

**11.1 Entire Agreement.** The Parties acknowledge that this Agreement, together with the exhibits and schedules attached hereto, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof, and supersedes all prior and contemporaneous discussions, agreements and writings in respect hereto.

**11.2 Modification; Waiver.** No waiver, modification, amendment or alteration of any provision of this Agreement will be valid or effective unless made in writing and signed by each of the Parties. The failure of a Party to enforce any rights or provisions of the Agreement shall not be construed to be a waiver of such rights or provisions, or a waiver by such Party to thereafter enforce such rights or provisions or any other rights or provisions hereunder.

**11.3 Further Assurances.** Each Party agrees to execute, acknowledge, and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the express provisions of this Agreement.

**11.4 Force Majeure.** Neither Party shall be held responsible for any delay or failure in performance hereunder caused by strikes, embargoes, unexpected government requirements, civil or military authorities, acts of God, earthquake, or by the public enemy or other causes reasonably beyond such Party's control and without such Party's fault or negligence; *provided* that the affected Party notifies the unaffected Party as soon as reasonably possible, and resumes performance hereunder as soon as reasonably possible following cessation of such force majeure event.

**11.5 Assignments.** Neither this Agreement nor any interest hereunder may be assigned, nor any other obligation delegated, by a Party without the prior written consent of the other Party; *provided, however*, that a Party shall have the right to assign this Agreement without consent of the other Party to an Affiliate of the assigning Party or to any successor in interest to the assigning Party by operation of law, merger, consolidation, or other business reorganization or the sale of all or substantially all of its assets relating to the subject matter of this Agreement in a manner such that the assigning Party will remain liable and responsible for the performance and observance of all of its duties and obligations hereunder. This Agreement shall be binding upon successors and permitted assigns of the Parties. Any assignment not in accordance with this **Section 11.5** will be null and void.

**11.6 Performance by Affiliates.** The Parties recognize that each may perform some or all of its obligations under this Agreement through its Affiliates or may exercise some or all of its rights under this Agreement through its Affiliates; *provided, however*, that each Party shall remain responsible and be the guarantor of the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. In particular and without limitation, all Affiliates of a Party that receive Confidential Information of the other Party pursuant to this Agreement shall be governed and bound by all obligations set forth in **ARTICLE 6**. Each Party will prohibit all of its Affiliates from taking any action that such Party is prohibited from taking under this Agreement as if such Affiliates were parties to this Agreement.

**11.7 Relationship of the Parties.** The Parties shall perform their obligations under this Agreement as independent contractors and nothing in this Agreement is intended or will be deemed to constitute a partnership, agency or employer-employee relationship between the Parties. Neither Party will have any right, power or authority to assume, create, or incur any expense, liability, or obligation, express or implied, on behalf of the other.

**11.8 No Use of Names.** Except as otherwise required under applicable Law, or as otherwise permitted under **Section 6.4**, neither Party will use the name of the other Party in its advertising, press releases or promotional materials without the prior written consent of such other Party.

**11.9 Notices.** Any notice, request, delivery, approval or consent required or permitted to be given under this Agreement will be in writing and will be deemed to have been sufficiently given if delivered in person (in which case, it will be effective upon delivery), transmitted by facsimile, if facsimile number is provided below (receipt verified; in which case, it will be effective upon delivery) or by express courier service (signature required; in which case, it will be effective two business days after being deposited with such courier service), to the Party to which it is directed at its address or facsimile number shown below or such other address or facsimile number as such Party will have last given by notice to the other Party.

If to Ligand: Ligand Pharmaceuticals Incorporated  
11119 North Torrey Pines Road, Suite 200  
La Jolla, CA, 92037  
Attention: General Counsel  
Fax: [\*\*\*]

With a copy to (which shall not constitute notice hereunder):

Latham & Watkins LLP  
12636 High Bluff Drive, Suite 400  
San Diego, CA, 92130  
Attention: Faye H. Russell, Esq.  
Fax: (858) 523-5450

If to Licensee: Azure Biotech, Inc.  
500 East 85<sup>th</sup> Street, 19D  
New York, NY, 10028  
Attention: Valerie Ceva

With a copy to (which shall not constitute notice hereunder):

Wiggin and Dana LLP  
Two Stamford Plaza  
281 Tresser Boulevard  
Stamford, CT 06901  
Attention: Patricia Melick, Esq.  
Fax: 203/363-7676

**11.10 Governing Law.** The rights and obligations of the Parties under this Agreement shall be governed, and shall be interpreted, construed, and enforced, in all respects by the Law of the State of New York, without giving effect to any conflict of Law rule that would result in the application of the Law of any jurisdiction other than the internal Law of the State of New York to the rights and duties of the Parties.

**11.11 Dispute Resolution.** The Parties agree that the procedures set forth in this **Section 11.11** shall be the exclusive mechanism for resolving any bona fide disputes, controversies or claims

(collectively, “Disputes”) between the Parties that arise from time to time pursuant to this Agreement relating to any Party’s rights and/or obligations hereunder that cannot be resolved through good faith negotiation between the Parties.

(a) **Executive Mediation.** Any Dispute shall first be referred to an Executive from each Party for attempted resolution by good faith negotiations. Any such Dispute shall be submitted to such Executives no later than [\*\*\*] following such request by either Party. Such Executives shall attempt in good faith to resolve any such Dispute within [\*\*\*] after submission of the Dispute. In the event the Executives are unable to resolve the Dispute, the Parties shall otherwise negotiate in good faith and use reasonable efforts to settle.

(b) **Arbitration.** If the Parties are not able to fully settle a Dispute pursuant to **Section 11.11(a)** above, and a Party wishes to pursue the matter, each such Dispute that is not an Excluded Claim shall be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association (“AAA”), and judgment on the arbitration award may be entered in any court having jurisdiction thereof.

(1) The arbitration shall be conducted by a panel of three persons experienced in the pharmaceutical business. Within [\*\*\*] after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within [\*\*\*] of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the AAA. The place of arbitration shall be San Diego, California and all proceedings and communications shall be in English.

(2) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party’s compensatory damages. Each Party shall bear its own costs and expenses and attorneys’ fees and an equal share of the arbitrators’ fees and any administrative fees of arbitration.

(3) Except to the extent necessary to confirm an award or as may be required by Law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.

(c) As used in this Section, the term “Excluded Claim” shall mean a Dispute that concerns (a) the validity or infringement of a patent, trademark or copyright; or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

**11.12 Board Observer Rights.** Licensee agrees that a representative of Ligand (“Representative”) may attend meetings of Licensee’s Board of Directors”, whether in person, via telephone, or otherwise, in a non-voting capacity from and after the Effective Date until the expiration (or earlier termination) of this Agreement. During such period, Licensee shall provide prior written notice to Ligand of all meetings of Licensee’s Board of Directors (and any committees thereof) and shall also deliver to Ligand copies of all notices, minutes, documents and other materials that it provides to its directors, concurrently with such directors and in the same manner, except for attorney-client communications. Licensee reserves the right to exclude such Representative from

access to any Board of Directors' meeting or portion thereof or materials relating thereto if Licensee determines in good faith that such exclusion is reasonably necessary to preserve the attorney-client privilege or to protect highly confidential proprietary information. Ligand acknowledges that the materials delivered to Ligand and its Representative under this **Section 11.12** shall be the Confidential Information of Licensee, subject to the terms and conditions of **ARTICLE 6**.

**11.13 Headings.** The article, section and subsection headings contained herein are for the purposes of convenience only and are not intended to define or limit the contents of the articles, sections or subsections to which such headings apply.

**11.14 Severability.** When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under Law, but, if any provision of this Agreement is held to be prohibited by or invalid under Law, such provision will be ineffective but only to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or of this Agreement. The Parties will make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.

**11.15 Counterparts.** This Agreement may be executed in counterparts (including by facsimile or electronic signature), each of which shall be deemed an original and all of which together shall constitute one instrument.

*[Signature Page Follows]*

IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their duly authorized representatives as of the Effective Date.

**LIGAND PHARMACEUTICALS    AZURE BIOTECH, INC.  
INCORPORATED**

**(“Ligand”) (“Licensee”)**

By: /s/ John L. Higgins    By: /s/ Valerie Ceva

Name: John L. Higgins    Name: Valerie Ceva

Title: Chief Executive Officer    Title: Director

*[Signature Page of License Agreement]*

**EXHIBIT A**

**Lasofoxifene**

[\*\*\*]

**Schedule 1.22**

**Licensed Patents**

**[\*\*\*] 9.5 PAGES REDACTED**

**Schedule 2.4**

**Technology Transfer**

**[\*\*\*] 42 PAGES REDACTED**

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.

**Exhibit 10.2**

**THIS EXCLUSIVE LICENSE AND DISTRIBUTION AGREEMENT (hereinafter, this ‘Agreement’)** is made effective as of the 23rd day of July, 2013.

**BETWEEN**

- (1) **LIGAND PHARMACEUTICALS INCORPORATED**, a company incorporated in the State of Delaware whose registered office is at 11119 North Torrey Pines Road, Suite 200, La Jolla, CA 92037, USA (the ‘**Licensor**’); and
- (2) **ETHICOR PHARMACEUTICALS LTD**, a company registered in England with number 7984924, whose registered office is at 1<sup>st</sup> Floor, 24/25 New Bond Street, Mayfair, London, W1S 2RR, United Kingdom (‘**Ethicor**’),

(each a ‘**Party**’ and together the ‘**Parties**’).

**RECITALS:**

**WHEREAS**, Ethicor is engaged in the manufacture, sale, marketing and distribution of unapproved medicinal products in the Territory;

**WHEREAS**, the Licensor is a pharmaceutical company engaged in the development, manufacture, sale, marketing and distribution of pharmaceutical products globally;

**WHEREAS**, the Licensor has developed the API (as hereinafter defined) for the treatment of osteoporosis and other diseases in humans;

**WHEREAS**, Ethicor is willing to procure the Product(s) (as hereinafter defined) and distribute them, in accordance with Applicable Laws (as hereinafter defined), as an unapproved medicine in the Territory (as hereinafter defined) and the Licensor is willing to grant Ethicor an exclusive License (as hereinafter defined) in the Territory as set forth herein; and

**WHEREAS**, the Parties now wish to enter into this Agreement to set out the terms under which the Licensor will grant the License to Ethicor to commercialize the Product(s) in the Territory.

**NOW, THEREFORE**, in consideration of the various promises and undertakings set forth herein, and other good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

**TERMS AND CONDITIONS**

1. **DEFINITIONS AND INTERPRETATION**

1.1 In this Agreement the following words shall have the following meanings:

1.1.1 **'Affiliate'** means, with respect to a Person, any Person that is controlled by, controls, or is under common control with such first Person, as the case may be. For purposes of this Section 1.1.1, the term "control" means (a) direct or indirect ownership of fifty percent (50%) or more of the voting interest in the entity in question, or fifty percent (50%) or more interest in the income of the entity in question; provided, however, that if local law requires a minimum percentage of local ownership of greater than fifty percent (50%), control will be established by direct or indirect beneficial ownership of one hundred percent (100%) of the maximum ownership percentage that may, under such local law, be owned by foreign interests, or (b) possession, directly or indirectly, of the power to direct or cause the direction of management or policies of the entity in question (whether through ownership of securities or other ownership interests, by contract or otherwise);

1.1.2 **'Applicable Laws'** means all legislation, laws, codes and guidance notes directly or indirectly applicable to the performance of the Agreement including, but not limited to, the commercialization and/or distribution of the Products in the Territory, as in effect from time to time;

1.1.3 **'Active Pharmaceutical Ingredient'** or **'API'** means the active pharmaceutical ingredient [\*\*\*] or combination thereof.

1.1.4 **'Calendar Quarter'** means each period of three months beginning on the first day of January, April, July and October in each calendar year;

1.1.5 **'Commencement Date'** means the date of this Agreement;

1.1.6 **'Commercially Reasonable Efforts'** means efforts which, consistent with the exercise of prudent scientific and business judgment:

- (a) are normally used by a similarly situated [pharmaceutical] company in the Territory in connection with the manufacture, use or sale of those products which it owns or has exclusive rights to and which are at a similar stage of development and have similar commercial potential in the Territory to the Product; and
- (b) conform with the requirements of the Relevant Regulatory Authority and the Applicable Laws;

1.1.7 **'Control'** or **'Controlled'** means, with respect to any information, material or Intellectual Property right, that a Party owns or has a license to such information, material or Intellectual Property right, as applicable, and has the ability to grant to the other Party access to, or a license or sublicense under, such information, material or Intellectual Property right as provided under the terms of this Agreement;

1.1.8 **'Ethicor's Facsimile Number'** means [\*\*\*] or such other number as Ethicor may notify to the Licensor pursuant to clause 19;

1.1.9 **'Field'** means the treatment of human diseases.

1.1.10 **'Intellectual Property'** means all inventions, patents (and related patent applications), utility models, design rights (registered or unregistered), database rights, copyright and trade marks (both registered and unregistered), data, know-how, technology and other proprietary rights, together with

all rights to the grant of and applications for the same and including all similar or analogous rights and all other rights in the nature of intellectual and industrial property throughout the world;

1.1.11 **'Interest Rate'** means the rate of[\*\*\*];

1.1.12 **'License'** means an exclusive (even as to Licensor), transferable (to the extent provided in clause 16) license during the term of this Agreement under the Licensor Intellectual Property, with the right to grant sublicenses (subject to clause 2.14), to develop, formulate, make, have made, use, Market and otherwise commercialize and exploit the Products for use in the Field in the Territory;

1.1.13 **'Licensor's Facsimile Number'** means [\*\*\*] or such other number as the Licensor may notify to Ethicor pursuant to clause 19;

1.1.14 **'Licensor Intellectual Property'** means any Intellectual Property necessary or useful to make, have made, use, sell or have sold the Products in the Territory that at any time during the Term is Controlled by Licensor or any of its Affiliates (including, without limitation, the Product Data);

1.1.15 **'Market'** means to promote, distribute, market and sell Products in the Territory;

1.1.16 **'Marketing Authorisation'** in relation to a country or region in the Territory means the grant of registration approval or license provided by the Relevant Regulatory Authority in such country or region for the manufacture of Products or Marketing in such country or region;

1.1.17 **'Net Sales'** means the gross amounts invoiced by or on behalf of Ethicor[\*\*\*] for sales of Products[\*\*\*], less [\*\*\*];

(a) [\*\*\*];

(b) [\*\*\*];

(c) [\*\*\*];  
and

(d) [\*\*\*].

1.1.18 **'Person'** means any individual, corporation, partnership, association, joint-stock company, trust, unincorporated organization or government or political subdivision thereof.

1.1.19 **'Product Data'** has the meaning set forth in clause 3.2;

1.1.20 **'Post Termination Sales Period'** means a period of[\*\*\*] following expiration or termination of this Agreement;

1.1.21 **'Product(s)'** means all oral preparations, compositions and formulations that contain the API, whether alone or in combination with other active pharmaceutical ingredients. For the avoidance of doubt, the Product does not include any topical formulations containing the API;

1.1.22 **'Relevant Regulatory Authority'** in relation to a country or region in the Territory, means the government authority, whether Federal, State or municipal, regulating the manufacture or Marketing of therapeutic substances in such country or region;

1.1.23 **'Sublicense Fees'** means all cash and non-cash consideration (including upfront payments, license fees, and development milestone payments) received by Ethicor or its Affiliates from a third

party in consideration for a grant to or exercise by such third party of a license or grant of other rights to develop or commercialize any Product in the Territory. Notwithstanding the foregoing, [\*\*\*];

1.1.24 'Term' means the period during which this Agreement is in force;

1.1.25 'Territory' means the countries specified in **Schedule 1** (as the same may be amended pursuant to clause 9.3);

1.1.26 'Year' means [\*\*\*] each consecutive period of twelve (12) months thereafter (or portion thereof) during the Term.

1.2 References to clauses and schedules are to the clauses of and schedules to this Agreement and all of the schedules shall form part of and shall be deemed to be incorporated in this Agreement.

1.3 Headings are for convenience only and shall be ignored in interpreting this Agreement.

## **2. ETHICOR'S UNDERTAKINGS**

Ethicor undertakes:

2.1 subject to all Applicable Laws, to use its Commercially Reasonable Efforts to Market the Product in the Territory;

2.2 to (i) enter into contracts to produce, test and validate directly or indirectly (through a third-party contract manufacturer) the API within [\*\*\*] of the Commencement Date and (ii) enter into contracts with third-party contract manufacturers who will undertake to manufacture the final Product in tablet formation within [\*\*\*] of the commencement of API production ([\*\*\*]);

2.3 to submit to Licensor written documentation [\*\*\*] within [\*\*\*] of the completion of the manufacture of the first batch of each of the API and finished Product;

2.4 once the testing and validation activities described in clause 2.2(i) are completed, to be responsible for obtaining its own supply of API and finished Product for the Territory, [\*\*\*];

2.5 to initiate a program of seminars, symposiums or similar forums with key opinion leaders in the field of osteoporosis within [\*\*\*] of the availability of API in the Territory (and Licensor will have the opportunity to attend such seminars, symposiums or similar forums following written notification of the intended date and location); [\*\*\*];

2.6 to refrain from actively seeking end-users for the Products in any country which is outside the Territory;

2.7 to pay or ensure payment to the Licensor of all sums due to the Licensor in respect of sales of the Product in accordance with the terms of this Agreement;

2.8 not to represent itself as an agent of the Licensor for any purpose nor pledge the Licensor's credit or give any condition or warranty or make any representation on the Licensor's behalf or commit the Licensor to any contracts without the Licensor's prior written consent;

2.9 to keep reasonable books of account and records with respect to sales transactions relating to the Products (and to require any sublicensee to do likewise);

- 2.10 to allow the authorized representatives of the Licensor, no more than once every six months, to have access to the premises of Ethicor during normal business hours on reasonable notice for the purpose of inspecting the aforesaid books and records with respect to sales made during the Term and during the Post Termination Sales Period (and to permit a similar right for Licensor under any Sublicense Agreement (as hereinafter defined)) to the extent provided in clause 4.9 and clause 5.4;
- 2.11 to use the Licensor Intellectual Property only for the purposes of exercising its rights and performing its obligations under this Agreement and not to represent itself as the owner of such Intellectual Property;
- 2.12 to immediately bring to the attention of the Licensor any improper or wrongful use in the Territory of the Licensor Intellectual Property which comes to its notice and at the request and cost of the Licensor assist the Licensor in taking all steps to defend the Licensor Intellectual Property ;
- 2.13 to set up a pharmacovigilance (PV) program to share data recorded in that program with the Licensor on terms to be mutually agreed with Licensor;
- 2.14 in connection with the sublicense of the License rights granted under this Agreement, to (a) obtain the prior written consent of Licensor to any such sublicense (such written consent not to be unreasonably withheld), (b) ensure that any such sublicense of the License rights shall be made pursuant to a written sublicense agreement (each a ‘**Sublicense Agreement**’), (c) ensure that any such Sublicense Agreement shall be consistent with and subject to the terms and conditions of this Agreement, (d) ensure that any such Sublicense Agreement shall terminate no later than the expiration or termination of this Agreement (unless otherwise agreed by the Parties), (e) remain fully responsible to Licensor for the performance of its sublicensees and remain obligated to make all payments due to Licensor under the terms of this Agreement with respect to the activities of its sublicensees, and (f) provide a complete, executed copy of any Sublicense Agreement within [\*\*\*] of execution thereof;
- 2.15 to provide to Licensor copies of any filings with the Relevant Regulatory Authority made by or on behalf of Ethicor related to the Products in the Territory promptly after filing and to provide copies to Licensor of any significant correspondence to and from any Relevant Regulatory Authority related to Products in the Territory promptly after receipt or sending, solely for Licensor’s, its Affiliates’ or its sublicensees’ use in connection with the development, use and sale outside the Territory of pharmaceutical products containing the API (including Products); [\*\*\*]; and
- 2.16 to fund all development and regulatory costs associated with the development and/or commercialization of the Products in the Field in the Territory incurred by Ethicor following the Commencement Date.

### 3. LICENSOR’S UNDERTAKINGS

The Licensor undertakes:

- 3.1 to grant (and Licensor hereby grants) Ethicor the License;
- 3.2 to provide Ethicor with any and all data and information in the English language that is in Licensor’s Control and that is necessary or useful to exercise the License (collectively, the “**Product Data**”) (Licensor will provide Ethicor with all Product Data existing as of the Commencement Date promptly after the Commencement Date, and will provide Ethicor with any Product Data generated or obtained

after the Commencement Date as soon as reasonably practicable after such Product Data is generated or obtained and in Licensor's Control);

- 3.3 to provide such information and support as may reasonably be requested by Ethicor to enable it to properly and efficiently to discharge its duties under this Agreement;
- 3.4 not to provide the formulation, specifications or other information related to the Product to any third party in the Territory without the express written consent of Ethicor nor to grant any rights to the Product to any third party in the Territory;
- 3.5 not to knowingly supply the Product to any third party outside the Territory for sale inside the Territory;
- 3.6 to notify Ethicor as soon as reasonably practicable of any matters which are reasonably likely to be of interest, use or benefit to Ethicor in the Marketing of the Products; and
- 3.7 in the event that the Licensor and Ethicor agree that it is in their mutual interests for Ethicor to seek Marketing Authorisation for any Product, to provide such information and support as may reasonably be requested by Ethicor to enable Ethicor properly and efficiently to discharge its duties under this Agreement (including information under Licensor's Control to enable Ethicor to ensure that any and each Marketing Authorisation in the Territory remains accurate and up to date) and comply with the requirements of the Relevant Regulatory Authority and the Applicable Laws, having regard to the fact that Ethicor will be the holder of the Marketing Authorisations.

#### 4. FINANCIAL TERMS

- 4.1 Ethicor shall book all sales of the Products in the Territory and shall have discretion over all pricing and other terms of sale of the Products in the Territory.
- 4.2 Ethicor shall pay to the Licensor royalties equal to [\*\*\*] of Net Sales during the period that begins on the Commencement Date and ends ten (10) Years thereafter (the "**Royalty Term**"). After the Royalty Term, the License [\*\*\*] under this Agreement. Ethicor shall pay such royalties to Licensor on a Calendar Quarter basis, within [\*\*\*] after the end of the Calendar Quarter in which the applicable Net Sales are invoiced.
- 4.3 Ethicor shall pay to the Licensor the following one-time, non-refundable sales milestone payments (each payable only one time regardless of the number of times achieved), [\*\*\*] after the end of the calendar year in which the applicable sales milestone is achieved:
  - (a) USD \$2,000,000, upon reaching Net Sales of USD \$20,000,000 in the Territory in a calendar year;
  - (b) USD \$4,000,000 upon reaching Net Sales of USD \$40,000,000 in the Territory in a calendar year;  
and
  - (c) USD \$10,000,000 upon reaching Net Sales of \$100,000,000 in the Territory in a calendar year.
- 4.4 Ethicor shall pay to the Licensor [\*\*\*] of any Sublicense Fees, within [\*\*\*] after receipt of any such Sublicense Fees.

4.5 All amounts payable hereunder shall be paid in U.S. Dollars. In calculating the amounts due Licensor hereunder, any currency conversions necessary in applying the above principles shall be made using the average official rate of exchange for such currencies published in The Financial Times of London, over the Calendar Quarter period in which such Net Sales were invoiced or such Sublicense Fees were received.

4.6 Any payment due and payable to Licensor under this Agreement, including any royalty payment, made by Ethicor after the date such payment is due and payable shall bear interest as of the day after the date such payment was due and payable and shall continue to accrue such interest until such payment is made at a rate equal to [\*\*\*].

4.7 All payments made to Licensor hereunder shall be accompanied by a written statement setting forth in reasonable detail the calculation thereof, including, for example, in the case of royalty payments, the gross amount invoiced by Ethicor, its Affiliate or sublicensee for sale or other disposition of Product on a country-by-country basis in the local currency, itemized deductions against such gross amount in accordance with clause 1.1.17, Net Sales on a country-by-country basis, and, if applicable, the exchange rate utilized to convert a local currency to U.S. Dollars.

4.8 [\*\*\*]. Each Party agrees to cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect.

4.9 Ethicor shall permit an independent public accountant designated by Licensor and reasonably acceptable to Ethicor, to have access, no more than [\*\*\*] during the Term and no more than [\*\*\*] following the expiration or termination of this Agreement, during regular business hours and upon at least [\*\*\*] written notice, to Ethicor's records and books to the extent necessary to determine the accuracy of Net Sales reported, and payments made, by Ethicor to Licensor within the [\*\*\*] period immediately preceding such an audit. The independent public accountant shall disclose to Licensor only [\*\*\*]. If such examination results in a determination that Net Sales or payments have been misstated, over or under paid amounts due shall be paid promptly to the appropriate Party. All matters reviewed by such independent public accountant shall be deemed Confidential Information of Ethicor and shall subject to clause 12.

## **5. REPRESENTATIONS, WARRANTIES AND COVENANTS.**

5.1 Each Party hereby represents and warrants to the other Party as of the Commencement Date, as follows:

- 5.1.1 such Party (i) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and (ii) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement;
- 5.1.2 this Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity;
- 5.1.3 such Party is not aware of any pending or threatened litigation (and has not received any communication relating to any pending or threatened litigation) that alleges that such Party's

activities related to this Agreement have violated, or that by conducting the activities as contemplated in this Agreement such Party would violate, any of the Intellectual Property rights of any Person (after giving effect to the license grants in this Agreement);

5.1.4 all necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations under this Agreement have been obtained (other than such consents, approvals and authorizations that such Party will obtain in the course of performing its obligations under this Agreement); and

5.1.5 the execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate in any material way any requirement of Applicable Law, (ii) do not conflict with or violate any provision of the articles of incorporation, bylaws, limited partnership agreement or any similar instrument of such Party, and (iii) do not conflict with, violate, or breach or constitute a default or require any consent under, any material contractual obligation or court or administrative order by which such Party is bound.

5.2 Ethicor has not, directly or indirectly, offered, promised, paid, authorized or given, and will not in the future, offer, promise, pay, authorize or give, money or anything of value, directly or indirectly, to any Government Official (as hereinafter defined) or Other Covered Party (as hereinafter defined) for the purpose of: (i) influencing any act or decision of the Government Official or Other Covered Party; (ii) inducing the Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (iii) securing any improper advantage; or (iv) inducing the Government Official or Other Covered Party to influence the act or decision of a government or government instrumentality, in order to obtain or retain business, or direct business to, any Person, in any way related to this Agreement.

For purposes of this Agreement: (i) "**Government Official**" means any official, officer, employee or representative of: (A) any federal, state, provincial, county or municipal government or any department or agency thereof; (B) any public international organization or any department or agency thereof; or (C) any company or other entity owned or controlled by any government; and (ii) "**Other Covered Party**" means any political party or party official, or any candidate for political office.

5.3 Ethicor maintains a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain accountability for assets, including records of payments to any third parties, Government Officials and Other Covered Parties; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

5.4 Ethicor shall permit Licensor, at Licensor's expense, to visit and inspect Ethicor's properties, to examine its books of account and records and to discuss Ethicor's affairs, finances and accounts with its officers, all at such reasonable times as may be requested by Licensor; provided, however, Ethicor may exclude information (a) if in the opinion of counsel to Ethicor, such exclusion is reasonably necessary to preserve attorney-client privilege with respect to a material matter or (b) if there exists,

as to Licensor, an actual or potential conflict of interest between Licensor and Ethicor. Such visits shall be limited to once per year.

- 5.5 In performing under this Agreement, Ethicor and its Affiliates agree to comply with all applicable anti-corruption laws, including, without limitation: Foreign Corrupt Practices Act of 1977, as amended ("**FCPA**"); the anti-corruption laws of the Territory; and all laws enacted to implement the OECD Convention on Combating Bribery of Foreign Officials in International Business Transactions.
- 5.6 Any third party who represents Ethicor or its Affiliates in connection with, or who will be involved in performing, this Agreement or any related activity, shall certify to compliance with all applicable anti-corruption laws and the obligations set forth in clauses 5.2 through 5.9 prior to any involvement in this Agreement or any related activity.
- 5.7 Ethicor is not aware of any Government Official or Other Covered Party having any financial interest in the subject matter of this Agreement or in any way personally benefiting, directly or indirectly, from this Agreement.
- 5.8 No political contributions or charitable donations shall be given, offered, promised or paid at the request of any Government Official or Other Covered Party that is in any way related to this Agreement or any related activity, without Licensor's prior written approval.
- 5.9 In the event that Ethicor violates the FCPA, the anti-corruption laws of the Territory or any other applicable anti-corruption law or breaches any provision in clauses 5.2 through 5.9, Licensor shall have the right to unilaterally terminate this Agreement. In addition, Ethicor shall defend, indemnify and hold harmless Ligand from and against any and all costs, damages, losses, liabilities, expenses, judgments, fines, settlements and any other amounts of any nature, including reasonable attorneys' fees arising from any improper payment made in violation of the FCPA, any applicable anti-corruption laws or clauses 5.2 through 5.9, directly or indirectly, by, on behalf of or with the knowledge of Ethicor, in relation to this Agreement."
- 5.10 EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY (AND THEIR RESPECTIVE AFFILIATES) HEREBY DISCLAIMS ANY AND ALL WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING WITH RESPECT TO ANY TECHNOLOGY LICENSED UNDER THIS AGREEMENT, INCLUDING ANY WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE. FOR THE AVOIDANCE OF DOUBT, NOTHING CONTAINED IN THIS CLAUSE 5.10 SHALL OPERATE TO LIMIT OR INVALIDATE ANY EXPRESS WARRANTY CONTAINED HEREIN.

## 6. INDEMNITY

- 6.1 Licensor will defend, indemnify and hold harmless Ethicor and its Affiliates and its and their respective officers, directors, employees and agents (collectively, the "**Ethicor Indemnified Parties**") from and against any and all claims, actions, lawsuits and investigations brought by a third party ("**Third Party Claims**") and will pay any settlements, awards, fines and reasonable attorney's fees and expenses and court costs associated with such Third Party Claims (collectively, "**Losses**"), in each case to the extent arising from or relating to: (a) any breach by Licensor of any of its representations, warranties or undertakings under this Agreement or (b) any allegation that any Product in the Field in the Territory infringes the Intellectual Property of any third party.

6.2 Ethicor will defend, indemnify and hold harmless Licensor and its Affiliates and its and their respective officers, directors, employees and agents (collectively, the “**Licensor Indemnified Parties**”) from and against any and all Third Party Claims and will pay any Losses, in each case to the extent arising from or relating to (a) any breach by Ethicor of any of its representations, warranties or undertakings under this Agreement or (b) the exploitation by or under the authority of Ethicor of the License (except for any allegation that any Product in the Field in the Territory infringes the Intellectual Property of any third party).

6.3 A Party will give the other Party written notice of any Third Party Claim for which the first Party seeks indemnification under clause 6.1 or clause 6.2 (as applicable) promptly; provided, however, that the failure to give timely notice hereunder will not affect rights to indemnification hereunder, except to the extent that the indemnifying Party demonstrates actual damage caused by such failure. The indemnifying Party may elect to direct the defense or settlement of any Third Party Claim by giving written notice to the indemnified Party, which election will be effective immediately upon receipt by the indemnified Party of such written notice of election. The indemnifying Party will have the right to employ counsel reasonably acceptable to the indemnified Party to defend any such Third Party Claim, or to compromise, settle or otherwise dispose of the same, if the indemnifying Party deems it advisable to do so, all at the expense of the indemnifying Party; provided, however, that the indemnifying Party will not settle, or consent to any entry of judgment in, any such Third Party Claim without obtaining either: (i) an unconditional release of all of the Ethicor Indemnified Parties or Licensor Indemnified Parties, as the case may be, from all liability with respect to all claims underlying such Third Party Claim or (ii) the prior, written consent of the indemnified Party, not to be unreasonably withheld or delayed. The Parties will reasonably cooperate with each other in any such Third Party Claim and will make available to each other any books or records reasonably useful for the defense of any such Third Party Claim.

6.4 Notwithstanding anything to the contrary, the indemnification set forth in clause 6.1 and clause 6.2 will not apply to the extent that acts or omissions of an indemnified Party (or its indemnitees) constitute fraud, negligence or willful misconduct of such Party or its indemnitees.

## 7. LIABILITY

7.1 NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (\*\*\* ) ARISING OUT OF OR RELATING TO THIS AGREEMENT, SUCH PARTY’S PERFORMANCE HEREUNDER, OR ANY PRODUCTS, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND REGARDLESS OF THE CAUSE OF ACTION (WHETHER IN CONTRACT, TORT, BREACH OF WARRANTY OR OTHERWISE).

7.2 EACH PARTY’S MAXIMUM CUMULATIVE LIABILITY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR SUCH PARTY’S PERFORMANCE HEREUNDER, OR ANY PRODUCTS, REGARDLESS OF THE CAUSE OF ACTION (WHETHER IN CONTRACT, TORT, BREACH OF WARRANTY OR OTHERWISE), WILL NOT EXCEED [\*\*\*] IN THE AGGREGATE.

7.3 Notwithstanding anything to the contrary, the exclusions and limitations of liability set forth in clause 7.1 and clause 7.2 will not apply: (i) to the extent that acts or omissions of a Party constitute fraud, negligence or willful misconduct, (ii) to indemnity obligations under clause 6.1 or clause 6.2 with respect to Third Party Claims or (iii) to any liability which cannot be excluded by applicable law.

## 8. DURATION AND TERMINATION

- 8.1 This Agreement shall come into effect on the Commencement Date and shall continue in force for ten (10) Years from the Commencement Date (the '**Initial Term**'). At the end of the Initial Term, or any subsequent term pursuant to a renewal under this clause ('**Renewed Term**'), this Agreement will automatically renew for consecutive periods of five (5) Years each, unless either Party provides the other Party with written notice of non-renewal not less than six (6) months prior to the expiry of the Initial Term or the Renewed Term. The Initial Term and each Renewed Term shall be subject to earlier termination in accordance with this clause 8.
- 8.2 Without prejudice to any other rights to which it may be entitled, either Party may give notice in writing to the other terminating this Agreement with immediate effect if the other Party is in breach of any material term hereof and (if such breach is remediable) fails to remedy such breach within [\*\*\*] of that Party being notified of such breach. In addition, the unaffected Party may terminate this Agreement as to any affected country or jurisdiction within the Territory, on a country-by-country or jurisdiction-by-jurisdiction basis, pursuant to clause 13.2.
- 8.3 Ethicor may terminate this Agreement for convenience at any time upon six (6) months prior, written notice to Licensor.
- 8.4 In addition to the other termination rights under this Agreement, Licensor may terminate this Agreement on a country-by-country basis upon written notice to Ethicor if [\*\*\*].

## 9. EFFECTS OF EXPIRATION OR TERMINATION

- 9.1 Expiration or termination of this Agreement howsoever caused shall be without prejudice to any rights or liabilities accrued at the date which this Agreement expires or terminates.
- 9.2 Upon any expiration or termination of this Agreement in its entirety:
- 9.2.1 the Licensor must, if requested to do so by Ethicor, allow Ethicor to fulfil all binding purchase orders for Products in place as of the effective date of such expiration or termination;
  - 9.2.2 Ethicor shall be permitted for the Post Termination Sales Period to sell and distribute any stocks of the Products as it may at the time have in store or under its control; and
  - 9.2.3 subject to this clause 9.2 all other rights and Licenses hereunder shall terminate on the date when this Agreement expires or terminates.
- 9.3 Upon any termination of this Agreement as to a country or jurisdiction within the Territory:
- 9.3.1 the Licensor must, if requested to do so by Ethicor, allow Ethicor to fulfil all binding purchase orders for Products in place as of the effective date of such termination in the affected country or jurisdiction;
  - 9.3.2 **Schedule 1** shall be amended to reflect the deletion of the affected country or jurisdiction; and

9.3.3 subject to this clause 9.3, all other rights and Licenses hereunder in the affected country or jurisdiction shall terminate on the effective date of termination.

9.4 The following provisions will survive any expiration or termination of this Agreement: Clause 1 (“Definitions and Interpretation”), Clause 4 (“Financial Terms”), clause 5.4, clause 5.10, Clause 6 (“Indemnity”), Clause 7 (“Liability”), this Clause 9 (“Effects of Expiration or Termination”), Clause 10 (“Intellectual Property”), Clause 11 (“Relationship”), Clause 12 (“Confidential Information”), Clause 13 (“Force Majeure”), Clause 14 (“Entire Agreement”), Clause 15 (“Amendments”), Clause 16 (“Assignment”), Clause 17 (“Waiver”), Clause 18 (“Counterparts”), Clause 19 (“Notices”), Clause 20 (“Rights of Third Parties”) and Clause 21 (“Governing Law and Dispute Resolution”).

## **10. INTELLECTUAL PROPERTY**

10.1 It is expressly recognised that each Party’s Intellectual Property is the exclusive property of that Party and the Parties acknowledge that this Agreement does not operate to vest in either Party any right, title or interest in any such Intellectual Property, other than the License granted to Ethicor to use the Licensor Intellectual Property in accordance with this Agreement.

10.2 Licensor shall, in its sole discretion and at its sole expense, file for, prosecute and maintain any patent applications or patents in the Territory which are included in the Licensor Intellectual Property and which have claims covering the Products (‘Licensor Patents’). Licensor shall make available to Ethicor copies of material correspondence with any patent office in the Territory regarding the Licensor Patents to the extent they relate to Products. Ethicor shall have the right to comment upon the prosecution of the Licensor Patents, and Licensor shall reasonably consider any such comments. In the event that Licensor decides to cease activities relating to prosecuting or maintaining any Licensor Patents, Licensor shall provide written notice thereof to Ethicor and, prior to taking action that would result in the abandonment of any such Licensor Patent, Licensor shall engage in good faith discussions with Ethicor, such discussions to occur [\*\*\*] prior to the date when government rights would be lost as a consequence of abandonment of such Licensor Patent.

## **11. RELATIONSHIP**

Nothing in this Agreement shall constitute or shall be deemed to constitute a partnership between the Parties hereto or constitute or be deemed to constitute Ethicor as agent of the Licensor for any purpose whatsoever and Ethicor shall have no authority or power to bind the Licensor or to contract in the name of or create a liability against the Licensor in any way or for any purpose. Ethicor hereby undertakes that it will in all correspondence and other dealings relating directly or indirectly to the sale, distribution or other disposal of the Products clearly indicate that it is acting solely on its own behalf and not as an agent for the Licensor.

## **12. CONFIDENTIAL INFORMATION**

12.1 Any proprietary or confidential information or data relating to a Party’s business, technologies or finances disclosed to the other Party under this Agreement collectively constitutes the “Confidential Information” of the disclosing Party. Neither Party will use the Confidential Information of the other Party for any purpose unrelated to the exercise of its rights or fulfillment of its obligations under this Agreement, and will hold such Confidential Information in confidence during the Term and for a period of [\*\*\*] after the termination or expiration of this Agreement (except that Confidential Information identified by a Party as a trade secret shall be held in confidence for as

long as such information remains a trade secret). Each Party shall exercise with respect to the Confidential Information of the other Party the same degree of care as the Party exercises with respect to its own confidential or proprietary information of a similar nature, but in no event less than reasonable care, and shall not disclose it or permit its disclosure to any third party, other than: (i) to its Affiliates, and those of its and its Affiliates' respective employees, sublicensees, consultants, contractors, accountants, attorneys, advisors and agents, as well as to any potential acquirers, investors or lenders and their respective advisors, in each of the foregoing cases who are bound by a substantially similar obligation of confidentiality of this Agreement and (ii) by or on behalf of Ethicor to any Relevant Regulatory Authority in connection with any regulatory matters with respect to any Product. However, the foregoing undertakings of confidentiality shall not apply to any information or data which:

- (a) the receiving Party receives without obligation of confidentiality at any time from a third party lawfully in possession of same and having the right to disclose same;
- (b) is, as of the Commencement Date, in the public domain, or subsequently enters the public domain through no fault of the receiving Party;
- (c) is independently developed by the receiving Party as demonstrated by written evidence without reference to or benefit of information disclosed to the receiving Party by the disclosing Party; or
- (d) is publically disclosed pursuant to the prior, written approval of the disclosing Party.

If a Party is required to disclose any Confidential Information of the other Party pursuant to applicable law or legal process, the first Party shall (i) give prior, written notice of such required disclosure to the other Party, to the extent reasonably practicable, (ii) give reasonable assistance to the other Party, if requested thereby, seeking confidential or protective treatment thereof, and (iii) only disclose such Confidential Information to the extent required by such applicable law or legal process; provided, however, that the foregoing requirement shall not apply with respect to any disclosures by Ethicor to any Relevant Regulatory Authority.

12.2 The terms of this Agreement shall be Confidential Information of both Parties, and subject to the terms of this clause 12. Notwithstanding the foregoing, either Party may make a disclosure of terms of this Agreement (i) to any financial advisors, accountants, potential sublicensees, investors, or potential acquirers, (ii) if required by applicable law, or (iii) as otherwise permitted pursuant to clause 12.3. Except as otherwise permitted for disclosures pursuant to clause 12.3, the disclosing Party shall use all commercially reasonable efforts to preserve the confidentiality of this Agreement and the terms thereof notwithstanding any required disclosure. A Party will give the other Party written notice of any required disclosure under (ii) above, which notice shall, to the extent reasonably practicable, be given a reasonable period of time in advance of such required disclosure. In the event either Party is required to file this Agreement with the U.S. Securities and Exchange Commission or any comparable non-U.S. governmental entity, such Party shall apply for confidential treatment of this Agreement to the fullest extent permitted by applicable law, shall provide the other Party a copy of the confidential treatment request far enough in advance of its filing to give the other Party a meaningful opportunity to comment thereon, and shall incorporate in such confidential treatment request any reasonable comments of the other Party.

12.3 The Parties will mutually agree on a press release to be issued by Licensor upon execution of this Agreement or reasonably soon thereafter, which shall contain, at a minimum, Ethicor's name and the key financial terms, excluding, without limitation, the royalty rates and other amounts to be paid hereunder. 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, such consent not be unreasonably withheld or delayed by such 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. 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.

12.4 The Parties acknowledge and agree that the certain Confidential Disclosure Agreement between the Parties dated as of February 5, 2013 (as amended from time to time) (the '**Confidential Disclosure Agreement**') shall remain in full force and effect as it relates to Confidential Information (as defined therein) disclosed by Ligand to Ethicor prior to the Effective Date.

### 13. FORCE MAJEURE

13.1 The obligations of each Party under this Agreement shall be suspended during the period and to the extent that such Party is prevented or hindered from complying therewith by any cause beyond its reasonable control including (insofar as beyond such control but without prejudice to the generality of the foregoing expression) strikes, lock-outs, labour disputes, act of God, war, riot, civil commotion, terrorist activity, malicious damage, fire, flood or storm.

13.2 In the event of either Party being so hindered or prevented, such Party shall give notice of suspension as soon as reasonably possible to the other Party stating the date and extent of such suspension and the cause thereof and the omission to give such notice shall forfeit the rights of such Party to claim such suspension. Any Party whose obligations have been suspended as aforesaid shall resume the performance of such obligations as soon as reasonably possible after the removal of the cause and shall so notify the other Party; provided, however, that no suspension shall continue for [\*\*\*]. In the event that performance of obligations have been suspended for [\*\*\*], then the unaffected Party may terminate this Agreement under clause 8.2.

### 14. ENTIRE AGREEMENT

This Agreement, and the Confidential Disclosure Agreement, constitutes the entire understanding between the Parties hereto with respect to the subject matter hereof and supersedes all prior agreements, negotiations and discussion between the Parties hereto relating thereto.

### 15. AMENDMENTS

Save as expressly provided herein, no amendment or variation of this Agreement shall be effective unless in writing and signed by a duly authorised representative of the Parties hereto.

### 16. ASSIGNMENT

Neither Party may transfer or assign this Agreement or assign any rights hereunder or delegate any duties hereunder without the other Party's prior, written consent, such consent not to be unreasonably withheld. Notwithstanding the foregoing: [\*\*\*]. Subject to the foregoing, this Agreement will bind and inure to the benefit of the Parties and their respective successors and permitted assigns.

#### 17.WAIVER

The failure of a Party hereto to exercise or enforce any right under this Agreement shall not be deemed to be a waiver thereof nor operate so as to bar the exercise or enforcement thereof at any time or times thereafter.

#### 18.COUNTERPARTS

This Agreement may be signed in any number of counterparts, all of which taken together shall constitute one and the same agreement. Any Party may enter into this Agreement by signing any such counterpart.

#### 19.NOTICES

Any notice required to be given pursuant to this Agreement shall be in writing and shall be given by delivering the same by hand at, or by sending the same by prepaid first class post (airmail if to an address outside the country of posting) or by facsimile transmission using the relevant number set out in this Agreement or to the address of the relevant Party set out in this Agreement or such other address as either Party may notify to the other from time to time. Any such notice given as aforesaid shall be deemed to have been given at the time of delivery (if delivered by hand) or received the first working day next following the day of sending (if sent by facsimile transmission) and when received (if sent by post). Facsimile transmissions should be made to the Licensor's Facsimile Number and Ethicor's Facsimile Number.

#### 20.RIGHTS OF THIRD PARTIES

A Person who is not a party to this Agreement has no rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement, but this does not affect any right or remedy of a third party which exists or is available apart from under that Act.

#### 21.GOVERNING LAW AND DISPUTE RESOLUTION

21.1 This Agreement shall be governed by and construed in accordance with English law.

21.2 The Parties agree that the procedures set forth in this clause 21.2 shall be the exclusive mechanism for resolving any bona fide disputes, controversies or claims (collectively, "**Disputes**") between the Parties that arise from time to time pursuant to this Agreement relating to any Party's rights and/or obligations hereunder that cannot be resolved through good faith negotiation between the Parties.

(a) Any Dispute shall first be referred to the Chief Executive Officer of Licensor (or such individual's designee) and the Chief Executive Officer of Ethicor (or such individual's designee) (each an '**Executive**') for attempted resolution by good faith negotiations. Any such Dispute shall

be submitted to such Executives no later than[\*\*\*] following such request by either Party. Such Executives shall attempt in good faith to resolve any such Dispute within [\*\*\*] after submission of the Dispute. In the event the Executives are unable to resolve the Dispute, the Parties shall otherwise negotiate in good faith and use reasonable efforts to settle.

(b) If the Parties are not able to fully settle a Dispute pursuant to clause 21.2(a) above, and a Party wishes to pursue the matter, each such Dispute that is not an Excluded Claim shall be finally resolved by binding arbitration under the London Court of International Arbitration Rules, which rules are deemed to be incorporated by reference into this clause. The seat, or legal place, of arbitration shall be London, England, or such other venue as the Parties agree. The language to be used in the arbitral proceedings shall be English. The losing Party shall bear all costs and expenses (including travel, food, and lodging) and attorneys' fees and all of the arbitrators' fees and any administrative fees of arbitration. Judgment on any award may be entered in any court having jurisdiction thereof.

As used in this Section, the term "Excluded Claim" shall mean (a) the validity or infringement of a patent, trademark or copyright; or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

*(signature page follows)*

IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed by their respective duly authorized officers in counterpart originals, effective as of the date first above written.

**LIGAND PHARMACEUTICALS INCORPORATED**

**ETHICOR PHARMACEUTICALS LTD**

By: /s/ Charles Berkman

Print Name: Charles Berkman

Title: VP, General Counsel & Secretary

By: /s/ Bruce H. Green

Print Name: Bruce H. Green

Title: Vice President Business Development – North America

## **SCHEDULE 1**

### **The Territory**

**Territory** means [\*\*\*].

As of the Commencement Date, the countries that are within the Territory consist of the following:

[\*\*\*]

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.

**Exhibit 10.3**

**LICENSE AGREEMENT**

**BETWEEN**

**CYDEX PHARMACEUTICALS, INC.**

**AND**

**CURX PHARMACEUTICALS, INC.**

**DATED: August 12, 2013**

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## LICENSE AGREEMENT

**THIS LICENSE AGREEMENT** (this “**Agreement**”) is made this 12th day of August, 2013 (the “**Effective Date**”) between:

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

**CURX PHARMACEUTICALS, INC.**, a Delaware corporation, with offices at 3210 Merryfield Row, San Diego, CA 92121 (“**Company**”).

### **RECITALS**

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

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

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

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

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

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

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

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

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

“**Captisol**” means [\*\*\*]. CyDex supplies such material under the Captisol® brand.

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[\*\*\*]

“**Captisol Data Package**” means (i) all toxicology/safety and other relevant scientific safety data owned, licensed or developed by CyDex and its Affiliates relating to Captisol; (ii) all toxicology/safety and other relevant scientific data owned, licensed or developed by the licensees or sublicensees of CyDex or its Affiliates or other Third Parties (to the extent permitted in the applicable license or other agreements between CyDex and/or its Affiliates and such licensees, sublicensees or other Third Parties); and [\*\*\*], in each case of (i), (ii) and (iii) above, solely to the extent directly relating to Captisol alone (and not in conjunction with a product formulation).

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

“**Company Indemnitees**” has the meaning specified in **Section 10.1**.

“**Competing Product**” shall mean [\*\*\*].

“**Compound**” means [\*\*\*].

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

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

“**CyDex Indemnitees**” has the meaning specified in **Section 10.2**.

“**CyDex Data and Records**” means all data, information, results, regulatory filings and records previously developed, created or otherwise in the possession of CyDex as of the Effective Date relevant or otherwise relating specifically to the research, development or registration of the Compound (or the Compound formulated with Captisol).

“**CyDex Materials**” means all quantities of the Compound (or the Compound formulated with Captisol) in CyDex’s possession or control as of the Effective Date.

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

“**DMF**” means a Drug Master File (or similar dossier filed with an equivalent regulatory body in another country) for Captisol, as filed as of the Effective Date, or as hereafter updated from time to time during the Term, by CyDex with the FDA (or equivalent regulatory body in another country).

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

“**Field**” means the entire field of prevention, diagnosis and treatment of all human diseases and disorders via intravenous or intramuscular drug administration, [\*\*\*].

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

“**Indemnified Party**” has the meaning specified in **Section 10.4**.

“**Indemnifying Party**” has the meaning specified in **Section 10.4**.

“**Licensed Intellectual Property**” means the Licensed Patents and the Licensed Know-How Rights.

“**Licensed Know-How Rights**” means, collectively, all trade secret and know-how rights of CyDex which relate to the formulation of the Compound with Captisol, including proprietary and confidential information contained in the Captisol Data Package.

“**Licensed Patents**” means all patents and patent applications in the Territory which cover Captisol and which now or at any time during the Term are owned by or licensed to CyDex or any CyDex Affiliate with the right to sublicense, including any and all extensions, renewals, continuations, substitutions, continuations-in-part, divisions, patents-of-addition, reissues, reexaminations and/or supplementary protection certificates to any such patents. Set forth in *Exhibit A* attached hereto is a list of the Licensed Patents as of the Effective Date.

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

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

“**Marketing Approval**” means final approval of an NDA by the FDA, or final approval of a comparable document filed with an equivalent health regulatory authority in any other country or in the European Union (using the centralized process or mutual recognition), including all required marketing, pricing or reimbursement approvals; provided, that if any sale for use or consumption by a member of the general public of a Licensed Product has occurred in any country (or within any country within a region) in compliance with that country’s applicable laws, it shall be conclusively deemed for purposes of this Agreement that all required marketing, pricing and reimbursement approvals in such country and in such (entire) region have been obtained.

“**Minnesota Agreement**” means, [\*\*\*].

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

“**Net Sales**” means [\*\*\*], less:

- (i) [\*\*\*];
- (ii) [\*\*\*];
- (iii) [\*\*\*];
- (iv) [\*\*\*];
- (v) [\*\*\*];

- (vi) [\*\*\*];  
and
- (vii) [\*\*\*].

Such amounts shall be determined from the books and records of Company and its Affiliates and Sublicensees, maintained in accordance with United States generally accepted accounting principles, consistently applied, or, in the case of foreign Sublicensees, similar accounting principles, consistently applied. [\*\*\*].

“**Non-Royalty Income**” means [\*\*\*].

“**Notice of Termination**” has the meaning specified in **Section 13.3**.

“**Orphan Drug Designation**” means official written designation from the FDA (or other applicable US regulatory body, if the FDA is no longer the applicable US regulatory body for making such designations for the purposes of the Orphan Drug Act) that a product has been granted special status under the Orphan Drug Act in connection with its use to treat a rare disease or condition.

“**Phase III Clinical Trial**” means any human clinical trial designed and intended to confirm with statistical significance the efficacy and safety of a Licensed Product as a basis for an NDA and to otherwise meet the requirements described under 21 C.F.R. §312.21(c) (as hereafter modified or amended) and any of its foreign equivalents.

[\*\*\*]

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

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

“**Safety Agreement**” has the meaning specified in **Section 7.4**.

“**SEC**” means the United States Securities and Exchange Commission.

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

“**Sublicensees**” has the meaning specified in **Section 2.3**.

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

“**Territory**” means the entire world.

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

“**Third Party Infringement**” has the meaning specified in **Section 12.3**.

“**Upstream Licensor**” has the meaning specified in **Section 2.6**.

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

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

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

(a) **Licensed Intellectual Property**. Subject to the terms and conditions of this Agreement, including but not limited to payment of the amounts set forth in **Section 4.1** below, CyDex hereby grants to Company an exclusive, nontransferable (except with respect to the assignment provision in **Section 14.15**) limited license during the Term under the Licensed Intellectual Property, solely to make, have made (pursuant to **Section 2.4**), develop, use, sell, offer for sale, import and export, or otherwise commercialize Licensed Products in the Territory in and for the Field. (No license, exclusive or nonexclusive, is granted hereunder under the Licensed Patents, except to so make, have made, use, sell, offer for sale and import the Licensed Products in the Territory in and for the Field.) Notwithstanding the foregoing, to the extent that any Licensed Intellectual Property is licensed to CyDex or its Affiliates by a Third Party on a non-exclusive basis, the license granted to Company in the foregoing sentence shall be non-exclusive. For clarity, as CyDex is unable to grant Company any rights that it does not have, in the event that CyDex obtains a non-exclusive license from a Third Party (including without limitation being potentially non-exclusive as a result of rights inhering in the United States Government under Chapter 18, Title 35 of the United States Code and regulations thereunder (or otherwise) by virtue of the fact that the licensed invention was funded by the United States Government), then CyDex shall pass on such rights to Company hereunder via a license that grants rights that are to such extent non-exclusive. It is understood that all references in this Agreement to “licenses” from CyDex to Company (and other forms of the word “license”) include sublicenses from CyDex (as sublicensor) to Company (as sublicensee). Company may not make, use, sell, offer for sale, or import the Licensed Products for any other purposes than those granted to it in this Agreement. Company may not sublicense the Licensed Intellectual Property, except as expressly set forth in **Sections 2.3** and **2.4** below.

(b) **Captisol Data Package**. CyDex shall make its personnel reasonably available to Company and its Contract Manufacturers to respond to informational inquiries and provide technical assistance related to the Captisol Data Package.

(c) **Scope of Licenses**. CyDex grants no licenses or rights to use other than as expressly set forth herein. Without limiting the generality of the foregoing, CyDex grants no rights to Company to manufacture, import, sell or offer for sale bulk Captisol; [\*\*\*]. Licensee acknowledges that not all rights of CyDex related to Captisol are included within the rights licensed hereunder, given that CyDex shall supply Company’s requirements of Captisol for the Licensed Products. Company shall not attempt to reverse engineer, deconstruct or in any way determine the structure or composition of Captisol except as and to the extent reasonably required to determine an optimal formulation of the

Licensed Product, and such structure and composition of Captisol (as and if so determined) shall be considered Confidential Information of CyDex; [\*\*\*]. CyDex shall not be liable to Company for violation of Company's exclusive rights hereunder by parties which are not Affiliates or licensees of CyDex [\*\*\*]. Company acknowledges and agrees that except as is expressly set forth in this Agreement [\*\*\*].

**2.2 Grant of License from Company to CyDex.** Company hereby grants to CyDex a nonexclusive, transferable, perpetual, worldwide and royalty-free license, with the right to grant sublicenses (through multiple tiers of sublicensees), under Company's and its Affiliates' and Sublicensees' rights in and to Captisol Improvements to develop, make, have made, use, market, distribute, import, sell and offer for sale Captisol, any Captisol Improvement and products formulated with Captisol or any Captisol Improvement (other than the Licensed Products in the Field). If during the Term any of (a) Company, (b) Affiliates to whom Company has provided rights under the licenses granted to Company by CyDex pursuant to **Section 2.1**, or (c) Sublicensees pursuant to the practice of their respective sublicenses from Company under **Section 2.3**, file any patent application claiming any Captisol Improvement anywhere in the world, CyDex shall be deemed automatically to have a nonexclusive, transferable, perpetual, worldwide and royalty-free license, with the right to grant sublicenses (through multiple tiers of sublicensees), under the claims relating specifically to any Captisol Improvement to make, have made, use, market, distribute, import, sell, and offer for sale Captisol and all products formulated with Captisol (other than the Licensed Products in the Field during the Term). Company shall provide prompt notice of any Captisol Improvement.

**2.3 Sublicensing.** Company shall have the right to grant sublicenses (through one or more tiers of sublicenses) to its Affiliates and licensees of the Licensed Products (collectively "**Sublicensees**") under the licenses granted to Company pursuant to **Section 2.1**; [\*\*\*]. Other than as specifically provided in this **Section 2.3** and **Section 2.4**, Company shall not have the right to grant sublicenses to any Third Party under the licenses granted pursuant to **Section 2.1**. Company shall ensure that all of its Sublicensees shall comply with the terms and conditions of this Agreement and Company shall be and remain fully responsible for the compliance by such Sublicensees with the terms and conditions of this Agreement as if such Sublicensees were Company hereunder.

**2.4 Contracting.** Company may manufacture the Licensed Products ([\*\*\*]) or contract the manufacture of the Licensed Products ([\*\*\*]) with Third Party manufacturers (collectively "**Contract Manufacturers**"). To the extent necessary to engage a Contract Manufacturer for a Licensed Product, Company shall be permitted under this Agreement to grant any such Contract Manufacturer a sublicense under the licenses granted to Company pursuant to **Section 2.1** solely for such purposes; [\*\*\*]. Company shall ensure that all of its Contract Manufacturers shall comply with the terms and conditions of this Agreement and shall remain fully responsible for the compliance by such Contract Manufacturers with the terms and conditions of this Agreement as if such Contract Manufacturers were Company hereunder.

**2.5 Bankruptcy Code.** All rights and licenses granted under or pursuant to this Agreement by CyDex to Company are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The parties agree that Company, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. All rights and licenses granted under or pursuant to this Agreement by Company to CyDex are, and shall otherwise

be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to “intellectual property” as defined under Section 101 of the Bankruptcy Code. The parties agree that, as a licensee of such rights under this Agreement, CyDex shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code.

**2.6 Compliance with Upstream Licenses.** [\*\*\*]. In addition, CyDex represents and warrants that [\*\*\*] to such Upstream Licensors and covenants that [\*\*\*]. Furthermore, CyDex represents and warrants that [\*\*\*].

**2.7 Negative Covenants by CyDex.**

(a) During the Term (on a country-by-country basis), neither CyDex nor any of its Affiliates shall directly themselves, nor provide any Third Party any assistance whatsoever, nor grant any Third Party any right or license under any of the Licensed Intellectual Property to, research, develop, modify, make, have made, import, export, use, promote, market, distribute, package, offer for sale, sell, or otherwise commercially exploit Licensed Products [\*\*\*].

(b) During the Term (on a country-by-country basis), neither CyDex nor any of its Affiliates shall supply Captisol to any Third Party (other than a Company designee) which it [\*\*\*]. If during the Term (on a country-by-country basis), any such Third Party utilizes such Captisol (supplied by CyDex or any of its Affiliates) [\*\*\*], CyDex shall immediately cease and cause its Affiliates and any other Third Party to immediately cease supplying Captisol to the offending Third Party for the duration of the Term or until (if sooner) assurances reasonably satisfactory to Company [\*\*\*].

(c) [\*\*\*].

**2.8 Technology Transfer.**

For a period of [\*\*\*] after the Effective Date, CyDex shall make its personnel available to Company and its contract manufacturer to respond to informational inquiries and provide technical assistance related to the Licensed Know-How Rights and the Captisol Data Package. Beginning on the earlier of (i) [\*\*\*] after the first contact by Company or its contract manufacturer relating to the technology transfer or (ii) [\*\*\*] after the Effective Date, Company shall compensate CyDex at the rate of [\*\*\*] for the time of CyDex personnel incurred to provide such services or in the event that other services are requested and provided. Such technology transfer shall not include information related to the manufacture of bulk Captisol.

**3. MANUFACTURE AND SUPPLY OF CAPTISOL; TECHNOLOGY AND MATERIAL TRANSFER.**

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

**3.2** [\*\*\*].

(a) **Technology Transfer.** CyDex shall use its reasonable commercial efforts to, as soon as reasonably practicable after the Effective Date, communicate and transfer to Company (as Confidential Information), at CyDex’s cost and expense, all CyDex Data and Records.

(b) **Material Transfer.** CyDex shall use its reasonable commercial efforts to, as soon as reasonably practicable after the Effective Date, transfer to Company, at CyDex’s cost and expense, all CyDex Materials.

(c) **Ongoing.** It is understood that other than the CyDex Materials, it shall be Company’s responsibility to obtain, at Company’s sole expense and from sources other than CyDex, all materials ([\*\*\*) needed by Company for its activities in connection with this Agreement; provided, that the foregoing is subject to Company’s obligation to purchase all Captisol from CyDex pursuant to the Supply Agreement.

**4. COMPENSATION.**

**4.1 Payments and Royalties for Licenses.**

(d) **Intentionally left blank.**

(e) **Milestone Payments.** Within [\*\*\*) following the occurrence of each and any of the milestone events listed below, Company shall provide written notice to CyDex of the achievement of such milestone event, accompanied by payment to CyDex of the applicable non-refundable milestone fee listed next to such event in further consideration of the rights granted Company hereunder. [\*\*\*) [\*\*\*)

	Milestone	Milestone Payment
[***)	[***)	[***)
[***)	[***)	[***)
[***)	[***)	[***)
[***)	[***)	[***)
[***)	[***)	[***)
[***)	[***)	[***)
[***)	[***)	[***)
[***)	[***)	[***)
[***)	[***)	[***)
[***)	[***)	[***)
[***)	[***)	[***)

For the avoidance of doubt, Company and CyDex agree that [\*\*\*)

(f) **Royalties.**

(i) In addition to amounts payable pursuant to **Section 4.1(b)** above, Company shall make royalty payments to CyDex [\*\*\*) in an amount equal to [\*\*\*) of the applicable Net Sales during [\*\*\*)]; provided that the royalty rate shall be [\*\*\*) for the [\*\*\*) million of [\*\*\*) and

shall be [\*\*\*] for the [\*\*\*] million of [\*\*\*]. Company and CyDex agree to work in good faith to true up any over-payments or under-payments. Notwithstanding the royalty rates set forth in the first sentence of this subsection, the applicable royalty rate for any Net Sales of a Licensed Product which is not covered by a Valid Claim at the time of such sale shall be [\*\*\*].

(ii) In the event that a Licensed Product is commercialized in combination with one or more products which are themselves not Licensed Products under this Agreement for a single price, the Net Sales for such Licensed Product shall be calculated by [\*\*\*].

(iii) All royalties payable to CyDex pursuant to **Section 4.1(c)** shall be due and payable within [\*\*\*] after the conclusion of [\*\*\*], provided that within [\*\*\*] after the conclusion of [\*\*\*] Company may provide notice to CyDex of any adjustments necessary to account for any royalties which were overpaid or underpaid for such prior [\*\*\*] (as determined from Company's [\*\*\*]), and the parties shall promptly true-up for any such adjustments which are mutually determined in good faith to be correct.

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

**4.2 Taxes.** All amounts due hereunder exclude and shall be paid in full to CyDex without reduction for all applicable withholding, sales, use, and other taxes, and Company shall be responsible for payment of all such taxes (other than taxes based on CyDex's income) and duties and any related penalties and interest, arising from the payment of amounts due under this Agreement. The parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by Company to CyDex under this Agreement. To the extent Company is required to withhold taxes on any payment to CyDex, Company shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to CyDex official receipts issued by the appropriate taxing authority and/or an official tax certificate, or such other evidence as CyDex may reasonably request, to establish that such taxes have been paid. CyDex shall provide Company any tax forms that may be reasonably necessary in order for Company to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the party bearing such withholding tax or value added tax. CyDex shall indemnify and hold Company harmless from and against any penalties, interest or other tax liability arising from any failure by Company (at the express request of CyDex) to withhold or by Company reduction (at the express request of CyDex) in its withholding.

**4.3 Payments.** Cumulative with and not exclusive of any and all other available remedies, payments that are not made when due hereunder, and which are not otherwise subject to a good faith dispute, shall accrue interest, from due date until paid, at a rate equal to [\*\*\*]. All amounts due hereunder are stated in, and shall be paid in, U.S. Dollars. With respect to sales not denominated in U.S. Dollars,

Company shall convert the Net Sales from the applicable foreign currency into U.S. Dollars at the [\*\*\*]. Based on the resulting sales in U.S. Dollars, the then applicable royalties shall be calculated.

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

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

**5.2 Quarterly Financial Reports.** Within [\*\*\*] following the conclusion of [\*\*\*] during the Term, Company shall provide CyDex with a written report with respect to such [\*\*\*] that sets forth sales of the Licensed Products in the Territory during such [\*\*\*] (on a Licensed-Product-by-Licensed-Product basis and on a country-by-country basis). Such report shall include Net Sales and royalties due for each Licensed Product.

**(a) Annual Milestone Reports.** By [\*\*\*] during the Term, Company shall provide CyDex with written reports that describe in reasonable detail Company's progress made toward achievement of the milestones specified in **Section 4.1(b)** above during such [\*\*\*] and set forth such other information regarding Captisol as mutually agreed upon by the parties. Company shall also provide [\*\*\*] regarding any significant changes to the expected completion of any such milestones outlined in [\*\*\*] or any change that may materially affect the Supply Agreement or orders placed thereunder.

**5.3 Audit.** Upon at least [\*\*\*] advance written notice by CyDex, Company shall permit CyDex's independent, Third Party certified public accountant, reasonably acceptable to Company, to have access during normal business hours to such of the records of Company as may be reasonably necessary to verify the royalty reports under **Section 5.2(a)** in respect of [\*\*\*]. Except as described in the next paragraph, all such audits shall be conducted at the expense of CyDex and [\*\*\*]. In the event such accountant concludes that additional payments of any kind as required by this Agreement were owed to CyDex during such period, the additional amounts shall be paid within [\*\*\*] days of the date CyDex delivers to Company such accountant's written report so concluding [\*\*\*]. The fees charged by such accountant shall be paid by CyDex, unless the audit discloses that the amounts payable by Company for the audited period are more than [\*\*\*] of the amounts actually paid for such period, in which case Company shall pay the reasonable fees and expenses charged by the accountant ([\*\*\*]). In the event such accountant concludes that there was an overpayment by Company to CyDex during such period, at Company's option, the overpayment shall be [\*\*\*]. The independent certified public accountant shall keep confidential any information obtained during such inspection in accordance with the provisions set forth in **Section 8** hereof and shall report to CyDex and Company only the amounts of Net Sales and royalties due and payable. The parties agree that all information subject to review under this **Section 5.3** or under any sublicense agreement is the Confidential Information of Company and that CyDex shall cause its accountant to retain all such information in confidence.

## **6. DEVELOPMENT AND COMMERCIALIZATION BY COMPANY.**

**6.1 Diligence.** As between CyDex and Company, from and after the Effective Date Company shall be responsible for all non-clinical and clinical development of the Licensed Products, all commercialization of the Licensed Products, and all storage, handling and use of physical quantities of the Compound and/or the Compound formulated with Captisol (including, without limitation, the CyDex Materials). Notwithstanding the preceding sentence, Company agrees that, during the Term, it

shall use, and shall require its Affiliates and Sublicensees to use, commercially reasonable efforts to develop the Licensed Products, to obtain Marketing Approvals in the Territory for the Licensed Products, and to market, promote, and sell Licensed Products thereafter in each country in which Marketing Approval is obtained. For clarity, Company shall be under no obligation to market a Licensed Product if it determines, in its reasonable business judgment, that such an effort is not commercially viable for Company. During the Term, Company shall, [\*\*\*], provide to CyDex a detailed written update report of Company's activities, progress and outlook in developing Licensed Products.

**6.2 Costs and Expenses.** Company shall be solely responsible for all costs and expenses related to its development and commercialization of the Licensed Products, including without limitation costs and expenses associated with all preclinical activities and clinical trials, and all regulatory filings and proceedings relating to the Licensed Products, and all commercialization of Licensed Products.

**6.3 In Vivo Studies.** If Company wishes to conduct any in vivo study (preclinical or clinical, in animals or in humans, each a "Study") of a Licensed Product utilizing Captisol, the following provisions shall apply:

**(d) Dosing.** Company shall not exceed the maximum allowable dosing levels of Captisol specified in CyDex's then-current clinical dosing matrix (which shall be provided by CyDex to Company from time to time) without the written consent of CyDex.

**(e) Compliance with Laws.** Company represents and warrants that each Study shall be performed in accordance with all applicable laws, regulations and requirements. Company shall provide or cause to be provided all appropriate warnings to participants enrolled in each Study and obtain or cause to be obtained appropriate documentation of informed consent from all participants in each such Study.

**(f) Adverse Events.** Company agrees to immediately inform CyDex if any adverse effects are observed and ascribed to Captisol in any Study in accordance with **Section 7.3** hereof. To accurately track adverse events and preserve the validity of each Study, Company agrees that, (i) for so long as CyDex is in compliance with the terms of the Supply Agreement and (ii) until the royalties are no longer due under this Agreement, it shall only use Captisol supplied by CyDex for each such Study conducted under the scope of this Agreement, and shall not use any other [\*\*\*] supplied by a Third Party.

**(g) Reporting and Study Data .** Within [\*\*\*], Company shall provide to CyDex a summary of the data and results of each Study, if any, that pertain solely to Captisol, and subject to **Section 8**, Company hereby grants to CyDex a non-exclusive, royalty-free license (with the right to sublicense) to use and disclose such data solely as necessary for regulatory purposes, including without limitation to update the DMF for Captisol.

**(h) Responsibility.** Company has the freedom to formulate and design each Study, and (as between Company and CyDex) Company is solely responsible for executing each Study; and so it is reasonable that, and the parties agree that, Company shall be solely responsible therefor and for any effects or consequences of the formulation, design and execution of each Study except to the extent any such effects or consequences result from the negligence or misconduct of CyDex.

(i) **Review of Regulatory Filings and Publications** . At least [\*\*\*] before a submission of any proposed written publication material or regulatory submission (which shall be subject to the restrictions of **Section 8** hereof), Company shall provide to CyDex for CyDex's review and comment a copy of any proposed written publication, material or regulatory submission reporting results of a Study where such publication material refers to Captisol ([\*\*\*]). Company shall give due consideration and reasonably incorporate any input that CyDex provides regarding Captisol ([\*\*\*]).

**6.4 Right of Reference.** Company shall have the right to reference the DMF solely in connection with Company's regulatory filings (including INDs, NDAs, etc.) submitted in connection with obtaining Marketing Approval for a Licensed Product. CyDex shall use reasonable commercial efforts to keep its DMF in good standing throughout the Term.

**6.5 Access to Company's Data.** CyDex shall have the right to reference and utilize all toxicology/safety and other relevant scientific data developed on Captisol alone (and not in conjunction with a Licensed Product) by Company, its Sublicensees or Affiliates, at no cost to CyDex. Upon request by CyDex, Company shall either provide CyDex, at CyDex's sole expense, with a copy of all such data or shall make such data accessible to CyDex at times and locations reasonably agreeable to CyDex and Company subject to the provisions of **Section 8**.

**6.6 Insurance.** During the Term and for [\*\*\*] years thereafter, Company shall obtain and maintain, at its own cost and expense, commercial general liability insurance and product liability insurance in amounts, that are reasonable and customary in the United States pharmaceutical and biotechnology industry for companies engaged in comparable activities (as indicated to Company by its insurance advisors), with CyDex identified as an additional named insured. It is understood and agreed that this insurance shall not be construed to limit Company's liability with respect to its indemnification obligations hereunder. Company shall provide to CyDex upon request a certificate evidencing the insurance Company is required to obtain and keep in force under this **Section 6.6**.

## **7. REGULATORY MATTERS.**

**7.1 Captisol Information Submitted for Regulatory Review.** Except as otherwise set forth herein, Company shall be solely responsible for all communications with regulatory agencies in connection with the Licensed Products, provided CyDex shall reasonably cooperate with Company with respect to any interactions with regulatory authorities concerning Captisol. Company shall provide CyDex with copies of the portions of all regulatory submissions containing [\*\*\*] and shall allow CyDex to review and comment upon said submissions. The contents of each such submission shall be deemed to be Confidential Information of Company, subject to the terms and provisions of **Section 8** below. Company shall promptly inform CyDex of meetings with the FDA (or other regulatory agencies in the Territory) regarding [\*\*\*]. If Company submits written responses to the FDA that include [\*\*\*]. 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, from time to time, with (a) relevant material information currently known to it regarding handling precautions, toxicity and hazards with respect to Captisol, and (b) the then-current material safety data sheet for Captisol. Notwithstanding the foregoing or anything in this Agreement to the contrary, Company is solely responsible for (i) use of all documentation provided by CyDex, including without limitation, use in any regulatory submission to the FDA or any other regulatory agency in the Territory, (ii) document

control and retention, and (iii) determining the suitability of any documentation provided by CyDex hereunder for use in any regulatory submission.

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

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

## **8. CONFIDENTIALITY.**

**8.1 Definition.** Company and CyDex each recognizes that during the Term, it may be necessary for a party (the "**Disclosing Party**") to provide Confidential Information (as defined herein) to the other party (the "**Receiving Party**") that is highly valuable, the disclosure of which would be highly prejudicial to such party. The disclosure and use of Confidential Information shall be governed by the provisions of this **Section 8**. Neither Company nor CyDex shall use the other's Confidential Information except as expressly permitted in this Agreement. For purposes of this Agreement, "**Confidential Information**" means all information disclosed by the Disclosing Party to the Receiving Party and which reasonably ought to have been understood to be confidential and/or non-public information at the time disclosed to the Receiving Party, or which is designated in writing by the Disclosing Party as "Confidential" (or equivalent), or which when disclosed orally to the Receiving Party is declared to be confidential by the Disclosing Party and is so confirmed in a writing delivered to the Receiving Party within [\*\*\*] of such oral disclosure, including but not limited to product

specifications, data, know-how, formulations, product concepts, sample materials, business and technical information, financial data, batch records, trade secrets, processes, techniques, algorithms, programs, designs, drawings, and any other information related to a party's present or future products, sales, suppliers, customers, employees, investors or business. Without limiting the generality of the foregoing, CyDex's Confidential Information includes all materials provided as part of the Captisol Data Package.

**8.2 Obligation.** CyDex and Company agree that they will disclose the other party's Confidential Information to its own (or its 100% stockholder's, or with respect to Company, its Sublicensees') officers, employees, consultants and agents only if and to the extent necessary to carry out their respective responsibilities under this Agreement or in accordance with the exercise of their rights under this Agreement, and such disclosure shall be limited to the maximum extent possible consistent with such responsibilities and rights. Except as set forth in the foregoing sentence, neither party shall disclose Confidential Information of the other to any Third Party without the other's prior written consent. In all events, however, any and all disclosure to a Third Party shall be pursuant to the terms of a non-disclosure/nonuse agreement no less restrictive than this **Section 8**. The party which disclosed Confidential Information of the other to any Third Party shall be responsible and liable for any disclosure or use by such Third Party (or its disclosees) which would have violated this Agreement if committed by the party itself. Neither party shall use Confidential Information of the other except as expressly allowed by and for the purposes of this Agreement. Each party shall take such action to preserve the confidentiality of each other's Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information (but in no event less than a reasonable standard of care). Upon expiration or termination of this Agreement, each party, upon the other's request, shall return or destroy (at disclosing party's discretion) all the Confidential Information disclosed to the other party pursuant to this Agreement, including all copies and extracts of documents, within [\*\*\*] of the request, except for [\*\*\*].

**8.3 Exceptions.** The use and non-disclosure obligations set forth in this **Section 8** shall not apply to any Confidential Information, or portion thereof, that the Receiving Party can demonstrate by competent evidence:

- (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 or its disclosees;
- (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 before the execution of this Agreement;
- (iv) is made available to the Receiving Party by an independent Third Party without obligation of confidentiality; provided, however, that to the Receiving Party's knowledge, such information was not obtained by said Third Party, directly or indirectly, from the Disclosing Party hereunder; or
- (v) is independently developed by an employee of the Receiving Party not accessing or utilizing the Disclosing Party's information.

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

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

#### **8.5 Third Party Information.**

(a) Company acknowledges that CyDex's Confidential Information and DMF include information developed by [\*\*\*] that is confidential to both CyDex and [\*\*\*]. Only to the extent that confidential information of [\*\*\*] is disclosed to Company hereunder, and only as required by CyDex's pre-existing contractual obligations to [\*\*\*], then [\*\*\*] is a limited third party beneficiary of only this **Section 8** of this Agreement and may seek remedies pursuant to it, but only in accordance with its terms.

(b) The parties acknowledge that the defined term "Confidential Information" shall include not only a Disclosing Party's own Confidential Information but also Confidential Information of a Third Party which is in the possession of a Disclosing Party. Both parties agree not to disclose to the other party any Confidential Information of a Third Party which is in the possession of such party, unless the other party has given an express prior written consent (which specifies the owner of such Confidential Information) to receive such particular Confidential Information.

**8.6 Public Announcements.** The parties shall mutually agree on any press release to be issued upon execution of this Agreement; such release to include, at CyDex's sole discretion, a description of the milestones and royalty obligations of this Agreement. Neither party shall make any subsequent public announcement concerning this Agreement or the terms hereof not previously made public without the prior written approval of the other party with regard to the form, content, and precise timing of such announcement, except as may be required to be made by either party in order to comply with applicable law, regulations, court orders, or tax, securities filings, financing arrangements, acquisitions, or sublicenses. Such consent shall not be unreasonably withheld or delayed by such other party. Before any such public announcement, the party wishing to make the announcement shall submit a draft of the proposed announcement to the other party in sufficient time to enable such other party to consider and comment thereon.

## **9. REPRESENTATIONS AND WARRANTIES.**

**9.1 Mutual Representations and Warranties.** Each party represents and warrants to the other that, as of the Effective Date:

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

(v) it has the full power and right to enter into this Agreement and to perform its obligations hereunder;

(vi) 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;

(vii) 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;

(viii) 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;

(ix) 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

(x) it has not entered into any agreement with any Third Party that is in conflict with the rights granted to the other party pursuant to this Agreement.

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

(vi) that it has no knowledge of any unsettled past or current, and has not received notice of any threatened, patent, trade secret or other intellectual property dispute with any Third Party that actually or is reasonably likely to have a material adverse effect on the Licensed Intellectual Property;

(vii) the Licensed Intellectual Property are not subject to any outstanding injunction, judgment order, ruling or charge and CyDex knows of no pending or threatened claim or action which challenges the validity, legality, enforceability or use of the Licensed Intellectual Property;

(viii) to CyDex's knowledge, CyDex has the full right, power and authority to grant all of the licenses granted to Company under this Agreement;

(ix) as of the Effective Date, CyDex has not granted to any Third Party any license to any of the Licensed Intellectual Property which conflicts with the exclusive license hereunder; and

(x) to CyDex's knowledge, through the Effective Date CyDex has filed and maintained with the appropriate regulatory authorities in all major countries in the Territory all permits, licenses, regulatory filings (including the DMF) and approvals related to Captisol and the manufacture and sale thereof, necessary for CyDex to carry out its obligations and for Company to exercise its rights under this Agreement and the Supply Agreement.

**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 Intellectual Property, or the Licensed Products, including but not limited to the implied warranties of merchantability and fitness for a particular purpose, title and non-infringement of third party rights. Each party's warranties under this Agreement are solely for the benefit of the other party and may be asserted only by the other party and not by any Affiliate, Sublicensee or any customer of the other party, its Affiliates or Sublicensees. Each party, its Affiliates and Sublicensees shall be solely responsible for all representations and warranties that it, its Affiliates or Sublicensees make to any customer of such party, its Affiliates or Sublicensees.

## **10. INDEMNIFICATION.**

**10.1 By CyDex.** CyDex shall defend, indemnify and hold Company and its Affiliates and Sublicensees, and each of their respective directors, officers, agents and employees (collectively, the "**Company Indemnitees**"), harmless from and against any and all losses, judgments, damages, liabilities, settlements, penalties, fines, costs and expenses of attorneys and other professionals) (collectively, "**Losses**") incurred by the Company Indemnitees as a result of any claim, demand, action or other proceeding (each, a "**Claim**") by a Third Party, to the extent such Losses arise out of (i) CyDex's breach of this Agreement or the Supply Agreement, including without limitation any of its representations and warranties set forth herein or therein; (ii) the research, development, manufacture, use, handling, promotion, marketing, distribution, importation, sale or offering for sale of Captisol by CyDex, its Affiliates, distributors, licensees or agents (for clarity, such terms shall not include Company in any event); (iii) infringement of a Third Party's intellectual property rights in connection with the Company's use of Captisol; (iv) interactions and communications by CyDex, its Affiliates, manufacturers, distributors or agents with governmental authorities, physicians or other Third Parties relating to Captisol, including the Captisol Data Package; or (v) the grossly negligent or willful misconduct of CyDex or its Affiliates or any of their respective officers, directors, employees or agents; all except to the extent that such Losses are primarily caused by a Company Indemnitee's breach of this Agreement, gross negligence or willful misconduct.

**10.2 By Company.** Company shall defend, indemnify and hold CyDex and its Affiliates, and each of their respective directors, officers, agents and employees (collectively, the "**CyDex Indemnitees**"), harmless from and against any and all Losses incurred by the CyDex Indemnitees as a result of any Claim by a Third Party, to the extent such Losses arise out of: (i) Company's breach of this Agreement or the Supply Agreement, including without limitation any of its representations and warranties herein or therein; (ii) any Study conducted by or on behalf of Company (whether before or after the Effective Date); (iii) the research, development, manufacture, use, handling, promotion,

marketing, distribution, importation, sale or offering for sale of Licensed Products by Company, its Affiliates, Sublicensees, Contract Manufacturers, distributors or agents (for clarity, such terms shall not include CyDex in any event); (iv) infringement of a Third Party's intellectual property rights in the making, having made, using, selling, offering for sale and importing of Licensed Products, but only to the extent that any such infringement Claim is unrelated to Captisol; (v) interactions and communications by Company, its Affiliates, Sublicensees, distributors or agents with governmental authorities, physicians or other Third Parties relating to Licensed Products and/or Captisol; or (vi) the grossly negligent or willful misconduct of Company or its Affiliates, Sublicensees, Contract Manufacturers, distributors or agents or any of their respective officers, directors, managers, employees or agents; all except to the extent that such Losses are primarily caused by a CyDex Indemnitee's breach of this Agreement, gross negligence or willful misconduct.

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

**10.4 Procedure.** The party intending to claim indemnification under this **Section 10** (an "**Indemnified Party**") shall promptly notify the other party (the "**Indemnifying Party**") of any Claim in respect of which the Indemnified Party intends to claim such indemnification (provided, that no delay or deficiency on the part of the Indemnified Party in so notifying the Indemnifying Party will relieve the Indemnifying Party of any liability or obligation under this Agreement except to the extent the Indemnifying Party has suffered actual prejudice directly caused by the delay or other deficiency), and the Indemnifying Party shall assume the defense thereof (with counsel selected by the Indemnifying Party and reasonably satisfactory to the Indemnified Party) whether or not such Claim is rightfully brought; *provided, however*, that an Indemnified Party shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnified Party, unless the Indemnifying Party does not assume the defense or unless a representation of both the Indemnified Party and the Indemnifying Party by the same counsel would be inappropriate due to the actual or potential differing interests between them, in which case the reasonable fees and expenses of counsel retained by the Indemnified Party shall be paid by the Indemnifying Party. (Provided, that in no event shall the Indemnifying Party be required to pay for more than one separate counsel no matter the number or circumstances of all Indemnified Parties.) The Indemnified Party, and its employees and agents, shall cooperate fully with the Indemnifying Party and its legal representatives in the investigations of any Claim. The Indemnifying Party shall not be liable for the indemnification of any Claim settled (or resolved by consent to the entry of judgment) without the written consent of the Indemnifying Party. Also, if the Indemnifying Party shall control the defense of any such Claim, the Indemnifying Party shall have the right to settle such Claim; *provided*, that the Indemnifying Party shall obtain the prior written consent (which shall not be unreasonably withheld or delayed) of the Indemnified Party before entering into any settlement of (or resolving by consent to the entry of judgment upon) such Claim unless (A) there is no finding or admission of any violation of law or any violation of the rights of any Person by an Indemnified Party, no requirement that the Indemnified Party admit fault or culpability, and no adverse effect on any other claims that may be made by or against the Indemnified Party and (B) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party and such settlement does not require the Indemnified Party to take (or refrain from taking) any action.

Regardless of who controls the defense, the other party hereto shall reasonably cooperate in the defense as may be requested. Without limitation, the Indemnified Party, and its directors, officers, advisers,

agents and employees, shall cooperate fully with the Indemnifying Party and its legal representatives in the investigations of any Claim.

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

EXCEPT FOR DAMAGES FOR WHICH A PARTY IS RESPONSIBLE PURSUANT TO ITS INDEMNIFICATION OBLIGATIONS SET FORTH IN **SECTION 10**, EACH PARTY SPECIFICALLY DISCLAIMS ALL LIABILITY FOR AND SHALL IN NO EVENT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES, EXPENSES, LOST PROFITS, LOST SAVINGS, INTERRUPTIONS OF BUSINESS OR OTHER DAMAGES OF ANY KIND OR CHARACTER WHATSOEVER ARISING OUT OF OR RELATED TO THIS AGREEMENT OR RESULTING FROM THE MANUFACTURE, HANDLING, MARKETING, SALE, DISTRIBUTION OR USE OF LICENSED PRODUCTS OR THE LICENSED INTELLECTUAL PROPERTY, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. EACH PARTY SHALL HAVE NO REMEDY, AND EACH PARTY SHALL HAVE NO LIABILITY, OTHER THAN AS EXPRESSLY SET FORTH IN THIS AGREEMENT AND THE SUPPLY AGREEMENT. EXCEPT WITH RESPECT TO THE INDEMNIFICATION SPECIFICALLY PROVIDED IN **SECTION 10**, A BREACH OF **SECTION 2.7** OR CLAIMS FOR NON-PAYMENT OF MILESTONES OR ROYALTIES DUE HEREUNDER, [\*\*\*]. NO ACTION, REGARDLESS OF FORM, ARISING OUT OF OR RELATED TO THIS AGREEMENT MAY BE BROUGHT BY EITHER PARTY [\*\*\*].

## **12. MANAGEMENT OF INTELLECTUAL PROPERTY.**

### **12.1 Ownership.**

(c) **Existing and Acquired Rights**. Each party shall maintain its ownership and other rights with respect to intellectual property owned or controlled by such party before the Effective Date. Each party shall own any intellectual property acquired by such party outside of this Agreement after the Effective Date.

(d) **New Rights**. The ownership of discoveries, inventions, improvements and other technology, whether or not patentable, made by Company's and/or CyDex's personnel and related to the subject matter of this Agreement shall be determined in accordance with US patent law and state intellectual-property law, as applicable.

### **12.2 Prosecution and Maintenance.**

(a) **Existing Rights (Licensed Patents)**. During the Term CyDex shall conduct the maintenance, [\*\*\*]. Each party shall reasonably cooperate with the prosecuting party in connection with its prosecution and maintenance activities at the prosecuting party's request and expense, including by making scientists and scientific records reasonably available to the prosecuting party.

(b) **New Rights**. The parties shall cooperate to take whatever, if any, reasonable actions they mutually agree upon in writing and in their respective discretion to prosecute patent applications and maintain patents covering rights which are jointly owned in accordance with

**Section 12.1(b).** Such agreement shall include actions to be taken by each party and the allocation of expenses related to such action. Neither party shall seek patent protection covering such rights without such agreement.

(c) For the avoidance of doubt, subject to **Sections 12.2(a)** and **(b)** each party shall be [\*\*\*].

### **12.3 Infringement by Third Parties .**

(a) Each party shall promptly notify the other party in writing of any actual or threatened infringement, misappropriation or other violation by a Third Party of any Licensed Intellectual Property in the Field and in the Territory (“**Third Party Infringement**”) of which it becomes aware.

(b) **Existing Rights (Licensed Patents).** CyDex shall have the right (but not the obligation), at its own expense, to initiate and control any action to enforce the Licensed Patents against any Third Party Infringement and may name Company as a party plaintiff solely to the extent required to maintain standing; [\*\*\*]. [\*\*\*]. Company shall give CyDex timely notice of any proposed settlement of any such action instituted by Company. Any recoveries resulting from an action relating to a claim of Third Party Infringement of the Licensed Patents (including any recoveries resulting from settlement) shall be [\*\*\*].

(c) **New Rights.** The parties shall cooperate to take whatever, if any, action they mutually agree upon in writing and in their respective discretion against the alleged infringer of rights which are jointly owned in accordance with **Section 12.1(b)**. Such agreement shall include actions to be taken by each party and the allocation of expenses and recoveries related to such action. Neither party shall take any such action against the alleged infringer without the written consent of the other party.

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

### **13. TERM AND TERMINATION.**

**13.1 Term.** The term of this Agreement (the “**Term**”) shall commence on the Effective Date and shall continue in effect thereafter on a country-by-country and Licensed Product-by-Licensed Product basis until the later of [\*\*\*].

**13.2 Termination for Convenience.** Company may terminate this Agreement at its election, upon [\*\*\*] prior express written notice to CyDex. CyDex may terminate this Agreement, upon express written notice to Company in the event that the [\*\*\*]. If this Agreement is terminated pursuant to this **Section 13.2**, within [\*\*\*] after such termination Company shall pay to CyDex all payments owing at the date of termination.

**13.3 Termination for Breach.** If either party should materially violate or fail to perform any material term or covenant of this Agreement, then the other party may give written notice of such default to such party. If such party should fail to cure such default within [\*\*\*] (or [\*\*\*] with respect to any payment obligation not otherwise subject to a good faith dispute) after such notice, the other

party shall have the right to terminate this Agreement by a second written notice (a “ **Notice of Termination**”) to such party. If Notice of Termination is sent to such party, this Agreement shall automatically terminate on the effective date of such notice. The parties agree that any failure by Company to pay when due (subject to the [\*\*\*] cure period) [\*\*\*] of such portion of any amount of money owing from Company to CyDex as is not disputed in good faith by Company shall conclusively be deemed to constitute a “material” breach.

**13.4 Termination for Bankruptcy.** Either party may terminate this Agreement immediately upon written notice to the other party in the event that the other party has a petition in bankruptcy filed against it that is not dismissed within [\*\*\*] of such filing, files a petition in bankruptcy, or makes an assignment for the benefit of creditors.

**13.5 Termination of the Supply Agreement .** If the Supply Agreement is terminated in accordance with its terms (except a termination of the Supply Agreement by Company for CyDex’s material breach), CyDex shall have the right to terminate this Agreement with [\*\*\*] prior written notice to Company.

**13.6 Effect of Termination .**

(a) Following the termination by Company under **Section 13.2** or by CyDex for Company’s breach under **Section 13.3**, all rights granted to Company herein shall immediately terminate and each party shall promptly return all relevant records and materials in its possession or control containing the other party’s Confidential Information with respect to which the former party does not retain rights hereunder, except for one archival copy (and such electronic copies that exist as part of the receiving party’s computer systems, network storage systems and electronic backup systems) of such materials solely to be able to monitor its obligations that survive under this Agreement.

(b) Upon the natural expiration of the Term as to a country, the licenses granted in **Section 2.1** shall become perpetual, fully paid-up and royalty-free as to such country.

**13.7 Survival.** Notwithstanding any other provisions of this Agreement, any liability or obligation of either party to the other for acts or omissions before the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement. Such termination or expiration shall not relieve either party from obligations that are expressly indicated or obviously intended to survive termination or expiration of this Agreement, nor shall any termination or expiration of this Agreement relieve Company of its obligation to pay CyDex, subject to the terms herein, (i) royalties for Licensed Products sold by Company, its Affiliates or Sublicensees, arising under **Section 4.1(c)**, or (ii) sums due in respect of Captisol shipped before termination or expiration of this Agreement. **Sections 2.2** (Grant of License from Company to CyDex), **4.2** (Taxes), **4.3** (Late Payments), **5** (Records; Reports; Audit), **6.3(d)** (Reporting and Study Data), **6.5** (Access to Company’s Data), **7.3** (Adverse Event Reporting), **8** (Confidentiality), **9.3** (Disclaimer), **10** (Indemnification), **11** (Limitation of Liability), **12** (Management of Intellectual Property), **13** (Term and Termination), and **14** (General Provisions) shall survive termination or expiration of this Agreement.

**14. GENERAL PROVISIONS.**

**14.1 Relationship of Parties.** Each of the parties hereto is an independent contractor and nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer-

employee or joint venture relationship between the parties. No party shall have the right to, and each party agrees not to purport to, incur any debts or make any commitments or contracts for the other. During the [\*\*\*], Company shall not solicit, induce, encourage or attempt to induce or encourage any employee of CyDex to terminate his or her employment with CyDex or to breach any other obligation to CyDex; provided, that this sentence is not meant to encompass general solicitations such as may be found in newspaper advertisements and the like.

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

### **14.3 Arbitration.**

**(a) Procedure.** Any and all disputes or controversies arising out of or relating to this Agreement shall be exclusively and finally resolved by binding arbitration in accordance with the commercial arbitration rules of the American Arbitration Association then in effect, in San Diego, California. The arbitration shall be conducted by an arbitrator reasonably knowledgeable about the pharmaceutical industry and acceptable to CyDex and Company. If CyDex and Company cannot agree on a single arbitrator within [\*\*\*] after a demand for arbitration has been made, CyDex shall appoint an arbitrator, Company shall appoint an arbitrator, the two (2) arbitrators shall appoint a third arbitrator, and the three arbitrators shall hear and decide the issue in controversy. If either party fails to appoint an arbitrator within [\*\*\*] after service of the demand for arbitration, then the arbitrator appointed by the other party shall arbitrate any controversy in accordance with this **Section 14.3(a)**. Except as to the selection of arbitrators, the arbitration proceedings shall be conducted promptly and in accordance with the rules of the American Arbitration Association then in effect. The expenses of any arbitration, [\*\*\*].

**(b) Confidentiality of Proceedings.** All arbitration proceedings hereunder shall be confidential and the arbitrator(s) shall issue appropriate protective orders to safeguard each party's Confidential Information. Except as required by law, no party shall make (or instruct the arbitrator(s) to make) any public announcement with respect to the proceedings or decision of the arbitrator(s) without prior written consent of the other party.

**(c) Interim Equitable Relief.** Each party shall, in addition to all other remedies accorded by law (or in equity) and permitted by this Agreement, be entitled to equitable relief (including but not limited to interim injunctive relief) in any court having jurisdiction to protect its interests. Neither party shall commence any court proceeding or action against the other to resolve any dispute, except (i) to enforce an arbitral award rendered pursuant to this **Section 14.3**, or (ii) for such interim injunctive relief.

**(d) Binding Effect.** The provisions of this **Section 14.3** shall survive any expiration or termination of this Agreement, and shall be severable and binding on the parties hereto,

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

**14.4 Costs and Expenses.** Except as otherwise expressly provided in this Agreement, each party shall bear all costs and expenses associated with the performance of such party's obligations under this Agreement.

**14.5 Further Assurances.** The parties hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

**14.6 Force Majeure.** Neither party shall be liable for failure to perform, or delay in the performance of, its obligations under this Agreement (other than payment obligations) when such failure or delay is caused by an event of force majeure. For purposes of this Agreement, an event of force majeure means any event or circumstance beyond the reasonable control of the affected party and not reasonably preventable using industry standard practices, including but not limited to, war, insurrection, riot, fire, flood or other unusual weather condition, explosion, act of God, peril of the sea, sabotage, accident, embargo, act of governmental authority, compliance with governmental order on national defense requirements, or inability due to general industry wide shortages to obtain fuel, power, raw materials, labor or transportation facilities. If, due to any event of force majeure, either party shall be unable to fulfill its obligations under this Agreement (other than payment obligations), the affected party shall immediately notify the other party of such inability and of the period during which such inability is expected to continue, shall use reasonable commercial efforts to cure and remedy such non-performance and the time for performance shall be extended for a number of days equal to the duration of the force majeure, and the parties shall meet promptly to determine an equitable solution to the effects of such event.

**14.7 Notices.** Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person, sent by certified mail, postage pre-paid, or transmitted by email or by express courier service to the party to which it is directed at its physical or email address shown below or such other physical or email address as such party shall have last given by notice to the other party in accordance with this **Section 14.7**:

*If to CyDex, to:*

CyDex Pharmaceuticals, Inc.  
c/o Ligand Pharmaceuticals Incorporated  
11119 North Torrey Pines Road, Suite 200  
La Jolla, CA 92037  
Attention: Vice President and Secretary  
Email: cberkman@ligand.com

*If to Company, to:*

CURx Pharmaceuticals, Inc.  
[\*\*\*]  
[\*\*\*]  
Attention: Chief Executive Officer  
Email: [\*\*\*]

*With a copy to:*

Ligand Pharmaceuticals Incorporated  
11119 North Torrey Pines Road, Suite 200  
La Jolla, CA 92037  
Attention: General Counsel  
Email: cberkman@ligand.com

Agiletic Law group, PC  
10935 Vista Sorrento Parkway, #370  
San Diego, CA 92130  
Attention : James Cartoni  
Email : jim@agiletic.com

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, [\*\*\*] after the date of mailing shall be deemed the date on which such notice, request or communication was given.

**14.8 Use of Name.** Neither party shall have any right, express or implied, to use in any manner the name or other designation of the other party or any other trade name or trademark of the other party for any purpose, except as may be required by applicable law or regulation or with the written approval of the other party, such approval not to be unreasonably withheld.

**14.9 Public Announcements.** No party shall use the name, trademark, trade name or logo of the other party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or public disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other party, such permission not to be unreasonably withheld, except as may be required by law or required by the rules of an applicable US national securities exchange or as permitted by **Section 14.8**. The parties agree that a party may disclose this Agreement and its terms, and material developments or material information generated under this Agreement, in securities filings with the SEC (or equivalent foreign agency), or taxing authorities, to the extent required by law after complying with the procedure set forth in this **Section 14.9**.

**14.10 Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of California (without giving effect to any conflicts of law principles that require the application of the law of a different state). The parties agree that the United Nations Convention on Contracts for the International Sale of Goods shall be inapplicable to this Agreement and the Supply Agreement and transactions hereunder and thereunder.

**14.11 Entire Agreement; Amendment.** This Agreement and the Supply Agreement and all Exhibits attached hereto or thereto contain the entire agreement of the parties relating to the subject matter hereof and thereof and supersede any and all prior or contemporaneous agreements, written or oral, between CyDex and Company relating to the subject matter hereof and thereof. Notwithstanding the foregoing, any confidential information which was disclosed under such prior agreements shall

remain confidential and shall be subject to the nondisclosure and nonuse provisions set forth in **Section 8** of this Agreement. This Agreement may not be amended unless agreed to in writing by both parties.

**14.12 Binding Effect.** This Agreement shall be binding upon, and the rights and obligations hereof shall apply to CyDex and Company and any successor(s) and permitted assigns. The name of a party appearing herein shall be deemed to include the names of such party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement.

**14.13 Waiver.** The rights of either party under this Agreement may be exercised from time to time, singularly or in combination, and the exercise of one or more such rights shall not be deemed to be a waiver of any one or more of the others. No waiver of any breach of a term, provision or condition of this Agreement shall be deemed to have been made by either party unless such waiver is addressed in writing and signed by an authorized representative of that party. The failure of either party to insist upon the strict performance of any of the terms, provisions or conditions of this Agreement, or to exercise any option contained in this Agreement, shall not be construed as a waiver or relinquishment for the future of any such term, provision, condition or option or the waiver or relinquishment of any other term, provision, condition or option.

**14.14 Severability.** If any provision of this Agreement is determined by a final and binding court or arbitration judgment to be invalid, illegal or unenforceable to any extent, such provision shall not be not affected or impaired up to the limits of such invalidity, illegality or unenforceability; the validity, legality and enforceability of the remaining provisions of this Agreement shall not be affected or impaired in any way; and the parties agree to negotiate in good faith to replace such invalid, illegal and unenforceable provision (or portion of provision) with a valid, legal and enforceable provision that achieves, to the greatest lawful extent under this Agreement, the economic, business and other purposes of such invalid, illegal or unenforceable provision (or portion of provision). This Agreement shall not be invalidated by any future determination that any or all of the Licensed Patents have expired or been invalidated.

**14.15 Assignment.** Neither party may assign its rights or delegate its obligations under this Agreement, in whole or in part, by operation of law or otherwise, to any Third Party without the prior written consent of the other party, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, either party may assign in whole or in part its rights and/or delegate in whole or in part its obligations under this Agreement to an Affiliate or to any Third Party successors (including with respect to Company, Third Party successors to one or more Licensed Products), whether by way of merger, sale of assets to which this Agreement relates, sale of stock or otherwise, without prior written consent, and CyDex may without prior written consent assign CyDex's future titles, rights and obligations under this Agreement to [\*\*\*]. As a condition to any permitted assignment hereunder, the assignor must guarantee the performance of the terms and obligations of this Agreement by any assignee, and the assignee must expressly assume (for the express benefit of the party hereto which is not the assignor) the performance of the terms and obligations of this Agreement by such assignee; provided that this sentence shall not apply to an assignment of CyDex's future titles, rights and obligations under this Agreement to [\*\*\*]. Any assignment not in accordance with this **Section 14.15** shall be void.

**14.16 No Implied License.** No right or license is granted to Company hereunder by implication, estoppel, or otherwise to any know-how, patent or other intellectual property right owned or controlled by CyDex or its Affiliates, except by an express license granted hereunder.

**14.17 Third Party Beneficiaries.** Except as set forth in Section 14.23 hereof and except for the rights of Indemnified Parties pursuant to **Section 10** hereof, and subject to Pfizer's rights under **Section 8.5** hereof, the terms and provisions of this Agreement are intended solely for the benefit of each party hereto and their respective successors or permitted assigns and it is not the intention of the parties to confer third-party beneficiary rights upon any other person, including without limitation Sublicensees. The enforcement of any obligation of CyDex under this Agreement shall only be pursued by Company or a Company Indemnitee, and not Sublicensees (unless otherwise a Company Indemnitee).

**14.18 Remedies Cumulative; Right of Set-Off.** Except as provided in **Section 11**, any enumeration of a party's rights and remedies in this Agreement is not intended to be exclusive, and a party's rights and remedies are intended to be cumulative to the extent permitted by law and include any rights and remedies authorized in law or in equity. Notwithstanding anything to the contrary in this Agreement, Company shall not have a right to set-off any royalties, milestones or other amount due to CyDex under this Agreement and/or the Supply Agreement against any damages incurred by Company for a breach by CyDex of this Agreement and/or the Supply Agreement.

**14.19 Interpretation.** The language used in this Agreement is the language chosen by the parties to express their mutual intent, and no provision of this Agreement shall be interpreted for or against any party because that party or its attorney drafted the provision.

**14.20 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.

**14.21 Construction.** Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa, and (d) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation", "inter alia" or words of similar import.

**14.22 Counterparts.** This Agreement may be executed in counterparts (facsimile and electronic transmission included), each of which shall constitute an original document, but both of which shall constitute one and the same instrument.

**14.23 [\*\*\*].** In addition to and not in derogation of its obligations to and agreements with CyDex as set forth herein, Company hereby agrees, for the benefit of CyDex and separately for the benefit of the [\*\*\*].

*[Remainder of this page left blank intentionally]*

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

**CYDEX PHARMACEUTICALS, INC.**

By: /s/ Charles Berkman

Name: Charles Berkman

Title: Vice President and Secretary

**CURX PHARMACEUTICALS, INC.**

By: /s/ Dinendra Sen

Name: Dinendra Sen

Title: Chief Executive Officer



**PATENTS CONTINUED**

[***]				
Country	Filing Date	Serial No.	Patent No.	Expiration Date
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		





**PATENTS CONTINUED**

[***]				
Country	Filing Date	Application No.	Patent No.	Expiration Date
[***]	[***]	[***]		
[***]	[***]	[***]		

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.

**Exhibit 10.4**

**SUPPLY AGREEMENT**

**BETWEEN**

**CYDEX PHARMACEUTICALS, INC.**

**AND**

**CURX PHARMACEUTICALS, INC.**

**DATED: August 12, 2013**

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## SUPPLY AGREEMENT

**THIS SUPPLY AGREEMENT** (this “**Agreement**”) is made this 12th day of August, 2013 (the “**Effective Date**”) between:

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

**CURX PHARMACEUTICALS, INC.**, a Delaware corporation, with offices at 3210 Merryfield Row, San Diego, CA 92121 (“**Company**”).

### **RECITALS**

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

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

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

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

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

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

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

“**Captisol**” means [\*\*\*].

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

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

“**Commercial Grade Shortfall**” shall have the meaning defined in **Section 4.2**.

“**Defect**” and “**Defective**” shall have the meanings defined in **Section 3.6(b)**.

“**Detailed Forecast**” shall have the meaning defined in **Section 3.2**.

“**First Commercial Order Date**” shall have the meaning defined in **Section 3.1**.

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“**GMP**” means manufactured under conditions of current good manufacturing practices for bulk excipients as set forth in U.S. Pharmacopeia <1078> as of the Effective Date or any successor thereto.

“**Latent Defect**” shall have the meaning defined in **Section 3.6(c)**.

“**Minimum Remaining Shelf Life**” means with respect to Captisol, a remaining shelf life of not less [\*\*\*].

“**Notice**” shall have the meaning defined in **Section 4.1**.

“**Notice of Termination**” shall have the meaning defined in **Section 6.2**.

“**Permitted Purchaser Requirements**” [\*\*\*].

“**Permitted Purchasers**” means, collectively: (i) Company; (ii) Affiliates of Company; (iii) Sublicensees of Company; and (iv) all Contract Manufacturers for Company, Affiliates of Company and Sublicensees permitted in accordance with the License Agreement.

“**Purchase Volume Limitations**” shall have the meaning defined in **Section 3.3**.

“**Specifications**” means the specifications for Captisol set forth in **Exhibit B** hereto, as such may be amended from time to time pursuant to **Section 3.10**.

“**Term**” shall have the meaning defined in **Section 6.1**.

“**Testing Methods**” shall have the meaning defined in **Section 3.6(a)**.

“**Third-Party Manufacturer**” shall have the meaning defined in **Section 2.3**.

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

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

**2.1 Purchase Commitment.** Subject to the provisions of this Agreement and during the Term of this Agreement, Company agrees that Company and the other Permitted Purchasers shall purchase from CyDex and CyDex shall supply [\*\*\*] of the Permitted Purchaser Requirements for Captisol during the Term. This Agreement and the License Agreement do not grant Company or any other Permitted Purchaser the right to manufacture (or have manufactured on their behalf) under Licensed Patents, Captisol, without CyDex’s prior written consent except as otherwise set forth in this Agreement.

**2.2 Supply Commitment.** CyDex agrees that CyDex shall produce (or have produced for it as set forth in **Section 2.3**), sell and deliver to Company and the other Permitted Purchasers [\*\*\*] of the Permitted Purchaser Requirements, subject to the provisions of this Agreement. CyDex shall only be required to sell Captisol pursuant to this Agreement. Company shall place orders for Captisol on behalf of itself and the other Permitted Purchasers, and shall guarantee payment to CyDex of all amounts payable with respect thereto. This Agreement does not grant Company or any other Permitted Purchaser

the right to manufacture (or have manufactured on their behalf) under any CyDex intellectual property rights, Captisol.

**2.3 Third-Party Manufacturers.** Without limiting CyDex's responsibility under this Agreement, CyDex shall have the right, [\*\*\*]. CyDex shall warrant that such Captisol shall, at a minimum, meet the Specifications as set forth in *Exhibit B* and the Minimum Remaining Shelf Life and have been manufactured in accordance with all applicable laws and regulations, including under conditions of GMP and under the same DMF and manufacturing processes referenced in Company's IND or NDA. [\*\*\*].

**2.4 Restrictions.** Company covenants and agrees that: (a) all Captisol supplied by CyDex pursuant to this Agreement shall be used only in Licensed Products (except for testing, etc., required by Company, Permitted Purchasers and/or regulatory authorities, in relation to Licensed Products); (b) Company shall obtain the written agreement of each Permitted Purchaser to not resell Captisol as a standalone product and only use Captisol in accordance with (a) above; (c) except as provided in **Section 3.8(c)**, Company shall not make or have made, and shall not permit any other Permitted Purchaser to make or have made, Captisol; and (d) Company and its Affiliates shall not sell, deliver or transfer to anyone any Captisol supplied by CyDex pursuant to this Agreement.

### **3. SUPPLY TERMS.**

**3.1 Long-Term Forecast.** Company shall use reasonable efforts to provide to CyDex, at least [\*\*\*] before the date on which Company anticipates issuing its first purchase order to CyDex for Commercial Grade Captisol (the "**First Commercial Order Date**"), a non-binding forecast setting forth Company's estimate of the required quantities of Commercial Grade Captisol for each of the following [\*\*\*]. Such non-binding long-term forecast shall thereafter be updated by Company at least once every [\*\*\*]. In the event that any such [\*\*\*] forecast estimates quantities of Captisol in excess of [\*\*\*], the detailed forecasting requirements of Section 3.2 below shall become applicable.

**3.2 Binding Detailed Forecast.** At least [\*\*\*] before the First Commercial Order Date, Company shall provide to CyDex a detailed rolling forecast setting forth Company's requirements (inclusive of all Permitted Purchaser Requirements) and anticipated delivery schedules for Commercial Grade Captisol for [\*\*\*] (the "**Detailed Forecast**") which includes the [\*\*\*] in which the First Commercial Order Date occurs and [\*\*\*]. For purposes of this Agreement, [\*\*\*]. The Detailed Forecast shall thereafter be updated by Company [\*\*\*] on a rolling basis, no later than the [\*\*\*], so that in [\*\*\*] CyDex shall have been provided with a rolling Detailed Forecast for [\*\*\*] commencing on the [\*\*\*] following the date on which such Detailed Forecast is submitted. The Detailed Forecast shall be firm and binding on Company, subject to the permissible variances set forth in **Section 3.3** below, with respect to the [\*\*\*]. [\*\*\*] of such Detailed Forecast shall not be binding and shall be provided for the sole purpose of planning; provided, that if Company fails to provide any updated Detailed Forecast in accordance with this **Section 3.2**, the Detailed Forecast last provided by Company shall be deemed to be Company's binding Detailed Forecast for the [\*\*\*], and with the same quantity and timing as had been forecasted (or deemed to be forecasted) for the [\*\*\*] of the prior Detailed Forecast being repeated as the forecasted quantity and timing for the new Detailed Forecast's [\*\*\*].

**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 [\*\*\*], 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 the [\*\*\*], 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 [\*\*\*], 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 Supply.

(a) **Purchase Orders.** Together with each Detailed Forecast provided under **Section 3.2**, Company shall place a firm purchase order with CyDex, for Company's order of Commercial Grade Captisol for the [\*\*\*] of the Detailed Forecast for delivery consistent with the Detailed Forecast. Each purchase order, for all grades of Captisol, shall specify: (i) the grade of Captisol ordered (*i.e.*, Commercial Grade Captisol or Clinical Grade Captisol); (ii) quantities; (iii) delivery dates; and (iv) reasonable shipping instructions and packaging requirements. Any firm purchase order for Captisol, to the extent it does not request more or less than the Purchase Volume Limitations (in the case of Commercial Grade Captisol ordered) nor request a delivery date less than [\*\*\*] nor more than [\*\*\*] after the date of such purchase order (in the case of any grade of Captisol ordered), shall be deemed accepted by CyDex upon receipt by CyDex. With respect to quantities of Commercial Grade Captisol ordered pursuant to such purchase order that exceed the Purchase Volume Limitations, CyDex shall not be obligated to accept the excess portion of such purchase order but nevertheless shall use good faith efforts to fill such orders for such excess quantities. If CyDex, despite the use of good faith efforts, is unable to supply such quantities that exceed the Purchase Volume Limitations for Commercial Grade Captisol in the desired delivery schedule, such inability to supply shall not be deemed for any purpose to be a breach of this Agreement by CyDex or an inability by CyDex to supply, [\*\*\*]. If any purchase order or other document submitted by Company hereunder or any other document passing between the parties contains terms or conditions in addition to or inconsistent with the terms of this Agreement, the terms of this Agreement shall control and prevail and the parties hereby agree that such additional or inconsistent terms shall simply be ignored and deemed not to exist, unless they are handwritten and expressly identified as being additional to or inconsistent with this **Section 3.4** and are signed by officers of both parties next to the handwriting.

(b) [\*\*\*].

**3.5 Delivery.** Unless otherwise agreed in writing by the parties, Captisol shall be delivered [\*\*\*]. Title and risk of loss and/or damage to Captisol shall pass to Company upon delivery of Captisol to Company at [\*\*\*]. Company acknowledges the inherent risk that a batch of Captisol may be lost in production or shipment, and Company shall use commercially reasonable efforts to maintain a sufficient inventory of Captisol in the event of late delivery by CyDex. Quantities actually delivered to Company pursuant to an accepted purchase order may vary from the quantities reflected in such purchase order by up to [\*\*\*] and still be deemed to be in compliance with such purchase order; *provided, however*, that Company shall only be invoiced and required to pay for the quantities of Captisol that Company actually ordered and CyDex actually delivered to Company. CyDex shall, if requested by Company,

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 previously delivered.

### 3.6 Quality Control; Acceptance and Rejection.

(a) **Quality Control.** The Parties shall negotiate in good faith a mutually agreeable Quality Agreement. The Quality Agreement shall clearly describe audit rights and procedures, which shall be consistent with this Agreement. CyDex shall conduct or have conducted quality control testing of Captisol before shipment in accordance with the Quality Agreement, Specifications, all applicable laws and regulations, including GMP and other CyDex-approved quality control testing procedures (the “**Testing Methods**”). CyDex shall retain or have retained accurate and complete records pertaining to such testing. Each shipment of Captisol hereunder shall be accompanied by a certificate of analysis for each lot of Captisol therein signed by the responsible quality control official of CyDex.

(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. Company or its designee shall have the right to reject by notice to CyDex any shipment of Captisol that does not conform in all material respects with the Specifications, DMF, the Minimum Remaining Shelf Life, applicable laws and regulations, including GMP or is otherwise materially defective or materially not in compliance with the applicable purchase order (including any packaging instructions set forth therein) or the terms of this Agreement at the time of delivery pursuant to **Section 3.5** when tested in accordance with the Testing Methods (such Captisol thereby having a “**Defect**” and upon proper rejection, deemed “**Defective**”). All shipments of Captisol shall be deemed accepted by Company unless CyDex receives written notice of rejection from Company within such [\*\*\*] period describing the reasons for the rejection in reasonable detail. 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 as provided in **Section 10.1** of the License Agreement or except in circumstances where the Defect is deemed a Latent Defect.

(c) **Latent Defects.** As soon as either party becomes aware of any Defect in any Captisol lot which either (i) existed at the time of acceptance but was not discovered after a reasonable inspection or (ii) arose, before the [\*\*\*] after actual or deemed acceptance, by no fault of any Permitted Purchasers (each such Defect, a “**Latent Defect**”), it shall promptly notify the other party of such event (including reasonable details and the lot involved). If Captisol accepted by Company becomes non-conforming by virtue of the Latent Defect, Company may place the lot on quality assurance hold pending CyDex’s investigation and a final resolution of the claimed Latent Defect. In the event that such Captisol is found to contain a Latent Defect, such Captisol shall be deemed rejected as of the date of the notice, and the rights and obligations of the parties with respect to the rejected Captisol shall thereafter be governed by the same process as governs acceptance testing set forth below.

(d) **Confirmation.** After its receipt of a notice of rejection from Company pursuant to **Section 3.6(b)** or (c) above, CyDex shall notify Company as soon as reasonably practical whether it accepts Company’s basis for rejection and Company shall cooperate with CyDex in determining whether such rejection was necessary or justified. If the parties are unable to agree as to whether a shipment of Captisol supplied by CyDex or its Third-Party Manufacturer hereunder is Defective, such question shall be submitted to an independent quality control laboratory mutually agreed upon by the parties. The

findings of such independent laboratory shall be binding upon the parties. The cost of the independent quality control laboratory shall be borne [\*\*\*].

(e) **Return or Destruction of Rejected Shipments.** Company may not return or destroy any batch of Captisol until it receives written notification from CyDex that CyDex does not dispute that the batch or material portion thereof is Defective. CyDex shall 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, or, if the request so states, Company shall promptly return the rejected batch of Captisol to CyDex. In each case, [\*\*\*].

(f) **Independent Testing.** If there is a dispute as to whether any batch is Defective or has been properly rejected, then the Parties shall designate a mutually acceptable Third Party laboratory to make a determination on such matter from a sample obtained from the rejected batch. The decision of the Third Party laboratory shall be binding on all parties hereto and all expenses related to such Third Party investigation shall be [\*\*\*]. Should such Third Party laboratory confirm Company's claim, the batch shall be deemed to be Defective and properly rejected and may be returned or destroyed in accordance with CyDex's instructions.

(g) **Refund or Replacement.** Company shall not be required to pay any invoice with respect to any shipment of Captisol properly rejected pursuant to this **Section 3.6**. Notwithstanding the foregoing, Company shall be obligated to pay in full for any rejected shipment of Captisol that is not subsequently determined to be Defective, irrespective of whether Company has already paid CyDex for a replacement shipment. If Company pays in full for a shipment of Captisol and subsequently properly rejects such shipment in accordance with this **Section 3.6**, Company shall be entitled, upon confirmation that such shipment or material portion thereof is Defective, [\*\*\*]. Company acknowledges and agrees that, except for the indemnification obligations set forth in **Section 10.1** of the License Agreement, Company's rights to [\*\*\*] shall be Company's sole and exclusive remedy, and CyDex's sole obligation, with respect to Defective or non-conforming Captisol delivered hereunder.

(h) **Exceptions.** Company's [\*\*\*] set forth in this **Section 3.6** shall not apply to any Captisol that is Defective due to damage (i) caused by Company, its Affiliates or Permitted Purchasers or their respective employees or agents, including but not limited to misuse, neglect, improper storage, transportation or use beyond any dating provided or (ii) that occurs after delivery of such Captisol to the carrier at the point of delivery, including but not limited to any damage caused thereafter by accident, fire or other hazard; and CyDex shall have no liability or responsibility to Company with respect thereto.

**3.7 Facilities and Inspections.** CyDex shall permit, and shall use reasonable commercial efforts to induce each Third-Party Manufacturer to permit, a reasonable and limited number of Company's authorized representatives, during normal working hours and upon reasonable prior notice to CyDex but in no event less than [\*\*\*] prior notice (subject to Third-Party Manufacturer's consent to be reasonably sought by CyDex), to confidentially inspect for a reasonable and limited number of days that portion of all CyDex facilities utilized for the manufacture, preparation, processing, storage or quality control of Captisol or such facilities of any Third-Party Manufacturer, no more frequently than [\*\*\*]. Company's authorized representatives shall be accompanied by CyDex personnel at all times, shall be qualified to conduct such manufacturing audits, shall comply with all applicable rules and regulations relating to facility security, health and safety. Company shall ensure that its authorized representatives conduct each manufacturing audit in such a manner as to not interfere with the normal and ordinary operations of CyDex or its Third-Party Manufacturer. Except as expressly set forth in this **Section 3.7**, Company, Permitted Purchasers and their respective employees or representatives shall not have access to CyDex's facilities or the facilities of any Third-Party Manufacturer.

**3.8 Inability to Supply.**

(a) [\*\*\*]. CyDex may in its discretion [\*\*\*].

(b) **Notice.** CyDex shall use reasonable commercial efforts to, within [\*\*\*] after CyDex's receipt of a purchase order from Company, notify Company if CyDex knows it will be unable to supply at the scheduled delivery time any quantity of non-Defective Captisol ordered by Company.

(c) [\*\*\*]. If CyDex is unable to supply to Company and/or its Permitted Purchasers the quantity of non-Defective Captisol that CyDex is required to supply hereunder, CyDex shall [\*\*\*].

**3.9 Product Recalls.** If any Captisol should be alleged or proven to be Defective, Company shall notify CyDex immediately, and both parties shall cooperate fully regarding the investigation and disposition of any such matter. If (i) Company recalls any Licensed Product, or (ii) the FDA requires the recall of any Licensed Product, and in either case such recall is [\*\*\*]. Company shall ensure that Permitted Purchasers maintain records of all sales of Licensed Product sufficient to adequately administer any such recall consistent with applicable laws and regulations.

**3.10 Regulatory Status and Specifications.**

(a) CyDex shall be solely responsible for maintaining the necessary approvals and authorizations for Captisol from applicable regulatory authorities, including updating and maintaining the DMF.

(b) CyDex shall promptly notify Company on becoming aware of any matters that are likely to affect adversely the regulatory status of Captisol or the ability of CyDex to supply Captisol in accordance with the terms of this Agreement.

(c) Except as set forth herein, CyDex may, after [\*\*\*], make [\*\*\*], CyDex shall nonetheless continue to provide Captisol with Captisol under the unmodified Specifications and manufacturing process under the terms of this Agreement until such time that Company has obtained any required approvals for the Specification change or the manufacturing process, as applicable, for Captisol by the FDA and other applicable major-market regulatory agencies (but only for so long as

Company has not failed to diligently pursue all required approvals for the Specification change or the manufacturing process, as applicable, from the FDA and other applicable major-market regulatory agencies).

(d) In the event that the FDA or another applicable regulatory agency having jurisdiction requires Company to implement any changes to the Specifications or the manufacturing process for Captisol, or Company desires to change (including to narrow any ranges within) the Specifications or the manufacturing process for Captisol and CyDex elects in its sole discretion to accommodate such desire, CyDex shall make all such changes required by the FDA or other applicable regulatory agency or requested by Company. CyDex shall promptly advise Company as to any lead-time changes or other terms that may result from a change to the Specifications or the manufacturing process for Captisol. (In such a case, the lead-times specified in and the other provisions of **Section 3.10(c)** shall be inapplicable.) Company shall bear the costs including the costs CyDex actually incurred for materials already purchased expressly for Company, its Affiliates or Sublicensees which cannot be sold to a third party and are rendered unusable by a change in Specifications or the manufacturing process for Captisol requested by Company and agreed to by CyDex.

(e) The parties shall use commercially reasonable efforts to cooperate with each other in order to carry out the intent and purposes of this **Section 3.10**. [\*\*\*].

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

#### **4. COMPENSATION.**

**4.1 One-Time Payment and Captisol Pricing** . Company shall pay to CyDex within [\*\*\*] from the Effective Date a non-refundable, one-time fee of \$[\*\*\*] in partial consideration of the rights granted to Company under this Agreement. In addition, the purchase prices for Captisol pursuant to this Agreement are as specified in *Exhibit A*. CyDex reserves the right to increase such purchase prices set forth in *Exhibit A* on [\*\*\*].

**4.2 Shortfall Reimbursement (Take or Pay)**. If Company fails to order (pursuant to and in compliance with **Article 3**) for [\*\*\*] of any Detailed Forecast a quantity of Commercial Grade Captisol to be delivered during [\*\*\*] (or within [\*\*\*]) 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 for delivery in [\*\*\*] (or within [\*\*\*] after the firm purchase order is placed), the “**Commercial Grade Shortfall**”), then Company shall either (a) pay CyDex [\*\*\*] of the purchase price hereunder for the Commercial Grade Shortfall amount and in such case shall not be entitled to receive delivery of such Commercial Grade Shortfall amount or (b) pay CyDex [\*\*\*] of the purchase price hereunder for the Commercial Grade Shortfall amount and in such case shall be entitled to receive delivery of such Commercial Grade Shortfall amount. In either event, such payment must be made within [\*\*\*]. This **Section 4.2** is based on the time stated for delivery in the original order, as opposed to the time delivery is actually made.

**4.3 Payments; Taxes.** All amounts due hereunder are stated in, and shall be paid in, U.S. Dollars. Payment of CyDex's invoices shall be made, except to the extent disputed in good faith, within [\*\*\*] of Company's receipt of such invoices. The purchase prices for Captisol specified in *Exhibit A* exclude all applicable sales, use, and other taxes, and Company shall be responsible for payment of all such taxes (other than taxes based on CyDex's income), fees, duties, and charges, and any related penalties and interest, arising from the payment of amounts due hereunder. Cumulative with and not exclusive of any and all other available remedies, unpaid and undisputed balances shall accrue interest, [\*\*\*]. If any amount due hereunder and not subject to a reasonable, good-faith dispute by Company remains outstanding for more than [\*\*\*] after its due date, CyDex may, in addition to any other rights or remedies it may have, refuse to ship Captisol hereunder except upon payment by Company in advance.

## **5. REPRESENTATIONS AND WARRANTIES.**

**5.1 Limited Warranty.** CyDex warrants solely to Company that:

(b) All Captisol sold to Company pursuant to this Agreement shall conform to the respective Specifications (as applicable for Clinical Grade Captisol or Commercial Grade Captisol), the DMF, the Minimum Remaining Shelf Life and all applicable laws, including GMP, at the time of delivery and shall not, before the [\*\*\*] after actual or deemed acceptance, be subject to any Latent Defects;

(c) CyDex, its Affiliates and its Third-Party Manufacturers are not a debarred entity and have not used and will not use in any capacity the services of any individual or entity debarred under 21 U.S.C. §335(a) or (b) of the Federal Food, Drug and Cosmetic Act in connection with its obligations hereunder;

(d) To CyDex's knowledge, CyDex, its Affiliates and its Third-Party Manufacturers hold, and are operating in material compliance with, all permits, licenses, franchises, authorizations and clearances of the FDA and/or any other regulatory authority required in connection with the manufacture and supply of Captisol, except where the failure to so hold or be so operating does not have and would not reasonably be expected to have a material adverse effect on (i) CyDex and/or its ability to supply Captisol and/or (ii) Company and/or its ability to obtain Captisol and/or exploit Licensed Products;

(e) CyDex does not know of any actual or threatened enforcement actions relating to the manufacture and/or supply of Captisol against CyDex, its Affiliates or its Third-Party Manufacturers by the FDA or any other federal, state or major-market foreign regulatory authority.

**5.2 Representations, Warranties.** The provisions of **Section 9.1** (Mutual Representations and Warranties) of the License Agreement are incorporated herein by reference as if fully set forth herein, with references therein to "this Agreement" being understood to refer to this Supply Agreement rather than to the License Agreement.

**5.3 Disclaimer.** The warranties set forth in this **Section 5** are provided in lieu of, and EACH PARTY HEREBY DISCLAIMS, ALL OTHER WARRANTIES, EXPRESS AND IMPLIED, relating to the subject matter of this agreement or Captisol, including but not limited to the implied warranties of merchantability, non-infringement and fitness for a particular purpose. CyDex's warranties under this Agreement are solely for the benefit of Company and may be asserted only by Company and not any Affiliate, Permitted Purchaser or other Third Party (other than a Company Indemnitee with

respect to an indemnification claim). Company shall be solely responsible for all representations and warranties that Company or its Affiliates make to any Permitted Purchaser.

## **6. TERM AND TERMINATION.**

**6.1 Term.** The term of this Agreement (the “**Term**”) shall commence on the Effective Date and, unless terminated earlier as set forth herein, shall continue until the earlier of (a) termination of the License Agreement in its entirety or (b) [\*\*\*] after Company provides written notice to CyDex of its intent to terminate this Agreement for convenience.

**6.2 Termination for Breach.** If either party should materially breach or violate or fail to perform any material term or covenant of this Agreement, then the other party may give written notice of such default to the first party. If such party should fail to cure such default within [\*\*\*] (or [\*\*\*] with respect to any payment obligation) of the date of such notice, the other party shall have the right to terminate this Agreement by a second written notice (a “**Notice of Termination**”) to the first party. If Notice of Termination is sent to such first party, this Agreement shall automatically terminate on the effective date of such notice. The parties agree that any failure by Company to pay when due (subject to the [\*\*\*] cure period) [\*\*\*] of such portion of any amount of money owing from Company to CyDex as is not disputed in good faith by Company shall conclusively be deemed to constitute a “material” breach.

**6.3 Termination for Bankruptcy.** Either party may terminate this Agreement immediately upon written notice to the other party in the event that the first party has a petition in bankruptcy filed against it that is not dismissed within [\*\*\*] of such filing, files a petition in bankruptcy or makes an assignment for the benefit of creditors.

**6.4 Effect of Termination.** Upon the termination of this Agreement by CyDex under **Section 6.2**, (a) Company shall no longer have any rights to purchase Captisol (subject to any election CyDex may make under the last sentence of **Section 6.5**) and (b) each party shall promptly return all relevant records and materials in its possession or control containing the other party’s Confidential Information with respect to which the former party does not retain rights hereunder; [\*\*\*].

**6.5 Survival.** Notwithstanding any other provisions of this Agreement, any liability or obligation of either party to the other for acts or omissions before the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement. Such termination or expiration shall not relieve either party from obligations that are expressly indicated to survive termination or expiration of this Agreement, nor shall any termination or expiration of this Agreement relieve Company of its obligation to pay CyDex sums due in respect of Captisol shipped before termination or expiration of this Agreement. **Sections** 2.4 (Restrictions), 3.5 (Delivery), 3.6 (Quality Control; Acceptance and Rejection), 3.7 (Facilities and Inspections), 3.9 (Product Recalls), 4.3 (Payments; Taxes), 5.2 (Representations, Warranties), 5.3 (Disclaimer), 6.4 (Effect of Termination), 6.5 (Survival) and 7 (General Provisions) shall survive termination or expiration of this Agreement. CyDex shall have the option, in its discretion, either to cancel all outstanding Captisol orders properly made before and pending at the time of termination or to honor and enforce all outstanding Captisol orders properly made before and pending at the time of termination.

## **7. GENERAL PROVISIONS.**

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

*[Remainder of this page left blank intentionally]*

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

**CYDEX PHARMACEUTICALS, INC.**

By: /s/ Charles Berkman

Name: Charles Berkman

Title: Vice President and Secretary

**CURX PHARMACEUTICALS, INC.**

By: /s/ Dinendra Sen

Name: Dinendra Sen

Title: Chief Executive Officer

**EXHIBIT A**

**PURCHASE PRICES FOR CAPTISOL**

*All prices are [\*\*\*].*

*All prices exclude shipping and insurance.*

Grade of Captisol	Price per Kg	Minimum Order Size
Clinical Grade	US\$[***]	[***] kg
Commercial Grade	US\$[***]	[***] kg

[\*\*\*].

\* \* \* \* \*

**EXHIBIT B: SPECIFICATIONS**

[\*\*\*]

**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 officers 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 officers 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: November 8, 2013

/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 officers 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 officers 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: November 8, 2013

/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 September 30, 2013, 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 September 30, 2013, 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 September 30, 2013, 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 September 30, 2013, 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: November 8, 2013

/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 September 30, 2013, 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 September 30, 2013, 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 September 30, 2013, 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 September 30, 2013, 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: November 8, 2013

/s/ John P. Sharp

John P. Sharp

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