LIGAND PHARMACEUTICALS INC

Form 10-Q November 08, 2013

**Table of Contents** 

**UNITED STATES** 

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FΟ	DI	/T 1	Λ	$\cap$
$\Gamma()$	ĸν	1 1	1)-	( )

x 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

o Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the Transition Period From to . Commission File Number: 001-33093

# LIGAND PHARMACEUTICALS INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware 77-0160744
(State or other jurisdiction of incorporation or organization) Identification No.)

11119 North Torrey Pines Road, Suite 200 92037 La Jolla, CA (Zip Code)

(Address of principal executive offices)

(858) 550-7500

(Registrant's Telephone Number, Including Area Code)

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

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 Filero

Accelerated Filer

X

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

Smaller Reporting Company o

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

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

# Table of Contents

# LIGAND PHARMACEUTICALS INCORPORATED QUARTERLY REPORT

# FORM 10-Q

TABL	E OF CONTENTS	
PART	I. FINANCIAL INFORMATION	
	ITEM 1. Financial Statements	<u>3</u>
	Condensed Consolidated Balance Sheets as of September 30, 2013 (Unaudited) and December 31, 2012	<u>3</u>
	Condensed Consolidated Statements of Operations for the three and nine months ended September 30.	1
	<u>2013 and 201</u> 2 (Unaudited)	<u>4</u>
	Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended	<u>5</u>
	September 30, 2013 and 2012 (Unaudited)	<u> </u>
	Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2013 and	<u>6</u>
	<u>201</u> 2 (Unaudited)	<u>U</u>
	Notes to Condensed Consolidated Financial Statements	<u>7</u>
		<u>25</u>
	ITEM 3. Quantitative and Qualitative Disclosures about Market Risk	<u>34</u>
	ITEM 4. Controls and Procedures	<u>35</u>
PART	II. OTHER INFORMATION	
	ITEM 1. Legal Proceedings	<u> 36</u>
	ITEM 1A. Risk Factors	<u>37</u>
		<u>46</u>
<u>SIGN</u>	<u>ATURE</u>	<u>47</u>

# **Table of Contents**

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
ASSETS		
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
LIABILITIES AND STOCKHOLDERS' EQUITY		
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,	(42,280	) (42,280	)
2012, respectively		26.40.7	
Total stockholders' equity	44,815	26,485	
Total liabilities and stockholders' equity	\$101,677	\$104,260	

See accompanying notes.

# Table of Contents

# LIGAND PHARMACEUTICALS INCORPORATED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(in thousands, except share data)

	Three Months Ended September 30,		Nine Months Ended September 30,		Ended			
	2013		2012		2013		2012	
Revenues:								
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	553		1,344		5,511		4,347	
revenues								
Total revenues	13,005		6,375		34,237		17,753	
Operating costs and expenses:								
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	9,935		7,800		25,719		21,833	
Income (loss) from operations	3,070		(1,425	)	8,518		(4,080	)
Other (expense) income:								
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	(1,045	)	1,373		(1,318	)	(735	)
Income (loss) before income taxes	2,025		(52	)	7,200	·	(4,815	)
Income tax expense	(60	)	(142	)	(237	)	(445	)
Income (loss) from continuing operations	1,965		(194	)	6,963	·	(5,260	)
Discontinued operations:			•					
Gain on sale of Avinza Product Line before income taxes			_		2,588		3,656	
Income tax benefit on discontinued operations			_		<del>_</del>		14	
Income from discontinued operations					2,588		3,670	
Net income (loss):	\$1,965		\$(194	)	\$9,551		\$(1,590	)
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)	\$0.10		\$(0.01	)			\$(0.08	)
	,		, (				, (	
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)	\$0.09		\$(0.01	)	\$0.46		\$(0.08	)
(2000)	70.07		+ (0.01	,	700		+ (0.00	,
Weighted average number of common shares-basic	20,357,55	8	19,917,676		20,268,261		19,791,793	3
Weighted average number of common shares-diluted	20,843,74		19,917,676		20,562,622		19,791,793	
are range named of common shares and	20,010,77	_	17,717,070		20,202,022	-	-2,121,120	•

See accompanying notes.

# Table of Contents

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

	Three mo	onths ended	Nine months ended		
	Septemb	er 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)	\$2,771	\$(194)	\$11,752	\$(1,590)	

See accompanying notes.

# Table of Contents

# LIGAND PHARMACEUTICAL INCORPORATED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

(in thousands)

	Nine Months Ended		
	Septembe		
	2013	2012	
Operating activities			
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	)
Investing activities			
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	
Financing activities			
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	
Supplemental Disclosure of cash flow information			

Interest paid	\$1,566	\$1,854
Taxes paid	5	15
Supplemental schedule of non-cash activity		
Liability for commercial license rights	\$1,000	\$
Accrued inventory purchases	227	449
Unrealized gain on AFS investments	2,201	
See accompanying notes.		

\_

#### **Table of Contents**

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.

#### **Table of Contents**

#### 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 September 30,		Nine months ended 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)	\$1,965	\$(194	)	\$9,551	\$(1,590	)
Shares used to compute basic income (loss) per share Dilutive potential common shares:	20,357,558	19,917,676		20,268,261	19,791,793	
Restricted stock	77,609	_		62,051	_	
Stock options	408,575			232,310		
Shares used to compute diluted income (loss) per share	20,843,742	19,917,676		20,562,622	19,791,793	
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)	\$0.10	\$(0.01	)	\$0.47	\$(0.08	)

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)	\$0.09	\$(0.01	)	\$0.46	\$(0.08	)
8						

#### **Table of Contents**

#### 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
September 30, 2013				
Available-for-sale securities	\$1,426	\$2,201	<b>\$</b> —	\$3,627
Certificates of deposit - restricted	1,341	_		1,341
	\$2,767	\$2,201	<b>\$</b> —	\$4,968
December 31, 2012				
Available-for-sale securities	\$1,426	<b>\$</b> —	<b>\$</b> —	\$1,426
Certificates of deposit-restricted	1,341	_	_	1,341
•	\$2,767	<b>\$</b> —	<b>\$</b> —	\$2,767

#### 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.

#### **Table of Contents**

# Property and Equipment

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

	September 30,	December 31,
	2013	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,	December 31,
	2013	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

#### **Table of Contents**

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.

#### **Table of Contents**

#### Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

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

# Other Long-Term Liabilities

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

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

# 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

#### **Table of Contents**

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

#### **Table of Contents**

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 September 30,		Nine months ended 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
-	\$1,533	\$1,013	\$4,149	\$3,116

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 September 30,		Nine months 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.

#### **Table of Contents**

#### 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 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

#### **Table of Contents**

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.

#### **Table of Contents**

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.

# **Table of Contents**

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

		Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
	Total	(Level 1)	(Level 2)	(Level 3)
Assets:				
Current portion of co-promote termination payments receivable	\$4,507	\$—	<b>\$</b> —	\$4,507
Available-for-sale securities	3,627	_	_	3,627
Long-term portion of co-promote termination payments receivable	8 8,387	_	_	8,387
Total assets	\$16,521	<b>\$</b> —	<b>\$</b> —	\$16,521
Liabilities:				
Current portion of contingent liabilities - CyDex	\$1,879	<b>\$</b> —	<b>\$</b> —	\$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
Total liabilities	\$23,869	\$1,736	<b>\$</b> —	\$22,133

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

Tun Value Weasurements at Reporting Bute Comg		Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
	Total	(Level 1)	(Level 2)	(Level 3)
Assets:				
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 8,207	_	_	8,207
Total assets	\$13,960	<b>\$</b> —	<b>\$</b> —	\$13,960
Liabilities:				
Current portion of contingent liabilities - CyDex	\$356	<b>\$</b> —	<b>\$</b> —	\$356
Current portion of co-promote termination liability	4,327			4,327
Long-term portion of contingent liabilities - CyDex	10,543	_	_	10,543
	214	_		214

Liability for restricted investments owed to former

licensees

Long-term portion of co-promote termination liability 8,207 — 8,207

Total liabilities \$23,647 \$— \$— \$23,647

#### **Table of Contents**

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

Assets	
--------	--

1 155 4 65		
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	\$16,521	
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 a expense	as other 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	\$22,133	
<u>-</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):

#### **Table of Contents**

Net present value of payments based on estimated future net Avinza product sales as of December 31,	\$12,534	
2012	\$12,334	
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-	December 2014	57	14			71
Lawrence, KS	December 2014	31	14	<del></del>	_	/ 1
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
Total operating lease obligations		\$5,503	\$8,261	\$1,446	\$560	\$15,770
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	<b>\$</b> —	\$—	\$1,670
Office and research facility- Cranbury, NJ	August 2014 and 2016	340	661	_	_	1,001
Net operating lease obligations		\$4,264	\$6,829	\$1,446	\$560	\$13,099

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.

## **Table of Contents**

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.

## Table of Contents

## 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 Dece	mbei			+ ,	
	Ligand		CyDex		Total	
Total assets	\$28,731		\$75,529		\$104,260	
Total dissolis	Ψ20,721		Ψ 7 5 ,5 <b>2</b> 5		φ101,200	
Operating Data:	For the three months ended September 30, 2013				013	
	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	e mo	nths ended So	ente	ember 30, 20	)13
	Ligand	- 1110	CyDex	P	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		(04	,	2,588	
dani on saic of Avinza Froduct Line before medite taxes	2,300				2,300	
	For the three months ended September 30, 201				012	
	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	e mo	nths ended S	epte	ember 30, 20	)12
	Ligand		CyDex	1	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	)		
Gain on sale of Avinza Product Line before income taxes	3,656			,	3,656	
Income tax benefit from discontinued operations	14				14	

### **Table of Contents**

### 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,	December 31,
	2013	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
Total current portion of notes payable	\$12,375	\$14,835
Long-term portion notes payable, 8.64%, due August 1, 2014	<b>\$</b> —	\$9,837
Long-term portion notes payable, 8.9012%, due August 1, 2014	_	3,606
Total long-term portion of notes payable	<b>\$</b> —	\$13,443

## 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	I	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	9	\$14.90	7.8	\$11,358
Granted	439,929	2	23.61		
Exercised	(158,889	) ]	14.76		
Forfeited	(73,978	) 1	16.72		
Cancelled	(27,780	) 2	28.32		
Balance as of September 30, 2013	1,805,888	1	16.74	7.71	48,322
Exercisable as of September 30, 2013	943,027	1	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.

### **Table of Contents**

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:

		Weighted-
		Average
	Shares	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

### **Table of Contents**

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; Pharmacopeia, LLC; Neurogen Corporation, CyDex Pharmaceuticals, Inc., Metabasis Therapeutics, and Nexus Equity VI LLC, or Nexus.

### **Table of Contents**

#### 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,

### **Table of Contents**

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.

### **Table of Contents**

## 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.

Program	Disease/Indication	Development Phase
Selective Androgen Receptor Modulator	Various	Phase II-ready
Glucagon Receptor Antagonist	Diabetes	Phase I-ready
HepDirect <sup>TM</sup>	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.

### **Table of Contents**

#### 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.

### **Table of Contents**

## **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.

### **Table of Contents**

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 a 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.

### **Table of Contents**

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

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

## **Table of Contents**

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.

## **Table of Contents**

## 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.

### **Table of Contents**

#### 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.

### **Table of Contents**

#### 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.

### **Table of Contents**

### 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

### **Table of Contents**

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.

## **Table of Contents**

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.

### **Table of Contents**

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.

### **Table of Contents**

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.

#### **Table of Contents**

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.

#### **Table of Contents**

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.

#### **Table of Contents**

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.

#### **Table of Contents**

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 Pharmacopeia, 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.

#### **Table of Contents**

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.

#### **Table of Contents**

# 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

# Table of Contents

10.4 †

# INDEX TO EXHIBITS

Exhibit Number	Description
2.1 (1)	Agreement and Plan of Merger, by and among the Company, Pharmacopeia, 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 Pharmceuticals, 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.
48	

#### **Table of Contents**

#### Exhibit Number Description

- Certification by Principal Financial Officer, Pursuant to 18 U.S.C. Section 1350, as adopted 32.2\* pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. 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 101.1 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.

- 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.
- This exhibit was previously filed as part of, and is hereby incorporated by reference to the numbered exhibit filed (2) 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.
- This exhibit was previously filed as part of, and is being incorporated by reference to the numbered exhibit filed (6) with the Company's Current Report on Form 8-K filed on October 28, 2009.
- 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.
- This exhibit was previously filed as part of, and is hereby incorporated by reference to the numbered exhibit filed (9) with the Company's Current Report on Form 8-K filed on January 26, 2011.
- 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.
- This exhibit was previously filed as part of and is hereby incorporated by reference to same numbered exhibit (11) filed with the Company's Quarterly Report on Form 10-Q for the period ended March 31, 1999.
- 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.
- 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.
- 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.
- 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.
- This exhibit was previously filed as part of, and is hereby incorporated by reference to the same numbered exhibit (16) filed with the Company's Current Report on Form 8-K filed on April 9, 2013.
  - This exhibit was previously filed as part of, and is hereby incorporated by reference to the same numbered exhibit
- (17) filed with the Company's Registration Statement on Form S-1 (No. 33-47257) filed on April 16, 1992 as
- 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.
- 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
- 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.

#### **Table of Contents**

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.