

CORNERSTONE THERAPEUTICS INC

Form 10-Q

November 08, 2012

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**Form 10-Q**

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

For the Quarterly Period Ended September 30, 2012

or

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

For the Transition Period From            to

Commission File Number: 000-50767

**CORNERSTONE THERAPEUTICS INC.**

(Exact Name of Registrant as Specified in Its Charter)

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<b>Delaware</b> (State or Other Jurisdiction of Incorporation or Organization)	<b>04-3523569</b> (I.R.S. Employer Identification No.)
<b>1255 Crescent Green Drive, Suite 250</b>  <b>Cary, North Carolina</b> (Address of Principal Executive Offices)	<b>27518</b> (Zip Code)
<b>(919) 678-6611</b> (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  No

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

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

Large accelerated filer  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

As of November 1, 2012, the registrant had 26,440,902 shares of Common Stock, \$0.001 par value per share, outstanding.

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**PART I FINANCIAL INFORMATION**

**Cautionary Statement Regarding Forward-Looking Statements**

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. For this purpose, any statements contained herein, other than statements of historical fact, including statements regarding the progress and timing of our product development programs and related trials; our future opportunities; our strategy, future operations, anticipated financial position, future revenues and projected costs; our management's prospects, plans and objectives; and any other statements about management's future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We may, in some cases, use words such as anticipate, believe, could, estimate, expect, intend, may, plan, project, should, target, will, would or other words to identify future events or outcomes to identify these forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including our critical accounting estimates; our ability to develop and maintain the necessary sales, marketing, supply chain, distribution and manufacturing capabilities to commercialize our products; our ability to replace the revenues from our marketed unapproved products, which we ceased manufacturing and distributing at the end of 2010, our propoxyphene products, which we voluntarily withdrew from the U.S. market in November 2010 at the request of the U.S. Food and Drug Administration, or FDA, and our anti-infective products, which we divested in March 2012; the adverse impact of returns of previously sold inventory; patient, physician and third-party payer acceptance of our products as safe and effective therapeutic products; our heavy dependence on the commercial success of a relatively small number of currently marketed products; our ability to maintain regulatory approvals to market and sell our products; our ability to obtain FDA approval to manufacture, market and sell our products and product candidates, including our lixivaptan compound, CRTX 080, and RETAVASE<sup>®</sup>; our ability to successfully and effectively launch our Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended Release Suspension product (formerly referred to as CRTX 067); our ability to enter into additional strategic licensing, product acquisition, collaboration or co-promotion transactions on favorable terms, if at all; our ability to manage and control unknown liabilities in connection with any acquisitions; our ability to successfully manage growth or integrate acquired businesses and operations; our ability to maintain compliance with NASDAQ listing requirements; adverse side effects experienced by patients taking our products; difficulties relating to clinical trials, including difficulties or delays in the completion of patient enrollment, data collection or data analysis; the results of preclinical studies and clinical trials with respect to our product candidates and whether such results will be indicative of results obtained in later clinical trials; our ability to develop and commercialize our product candidates before our competitors develop and commercialize competing products; our ability to satisfy FDA and other regulatory requirements; our substantial indebtedness and debt covenants; and our ability to obtain, maintain and enforce patent and other intellectual property protection for our products and product candidates. These and other risks are described in greater detail in Part I Item 1A. Risk Factors of our annual report on Form 10-K for the year ended December 31, 2011 filed with the Securities and Exchange Commission, or SEC, on March 6, 2012. Any material changes to the risk factors disclosed in the annual report are discussed below in Part II Item 1A. Risk Factors. If one or more of these factors materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. In addition, any forward-looking statements in this quarterly report on Form 10-Q represent our views only as of the date of this quarterly report on Form 10-Q and should not be relied upon as representing our views as of any subsequent date. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise, except as may be required by law. Our forward-looking statements do not reflect the potential impact of any acquisitions, mergers, dispositions, business development transactions, joint ventures or investments we may enter into or make.

**Table of Contents****ITEM 1. FINANCIAL STATEMENTS****CORNERSTONE THERAPEUTICS INC.****CONSOLIDATED BALANCE SHEETS****(In thousands, except share and per share data)**

	<b>September 30, 2012 (Unaudited)</b>	<b>December 31, 2011 (Note 1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 34,179	\$ 73,968
Accounts receivable, net	24,562	11,894
Inventories, net	38,173	9,419
Prepaid expenses	4,107	3,753
Income tax receivable	4,241	1,900
Deferred tax asset	1,228	2
Other current assets	13,035	6,112
Total current assets	119,525	107,048
Property and equipment, net	1,516	1,574
Product rights, net	247,766	106,960
Goodwill	38,324	15,218
Amounts due from related parties		38
Deferred tax asset, less current portion		523
Other assets	32	953
Total assets	\$ 407,163	\$ 232,314
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 20,232	\$ 10,012
Accrued expenses	39,308	37,125
Acquisition-related contingent payments	5,778	
Deferred revenue		1,428
Other current liabilities	464	90
Total current liabilities	65,782	48,655
Acquisition-related contingent payments, less current portion	37,633	8,800
Long-term debt	89,515	
Deferred tax liability	36,077	
Other long-term liabilities	4,936	56
Total liabilities	233,943	57,511
Commitments and contingencies, Note 8		
Stockholders equity		
Preferred stock \$0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding		
Common stock \$0.001 par value, 90,000,000 shares authorized; 26,305,033 and 25,803,864 shares issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	26	26
Additional paid-in capital	166,549	163,203

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Retained earnings	6,645	11,574
Total stockholders' equity	173,220	174,803
Total liabilities and stockholders' equity	\$ 407,163	\$ 232,314

The accompanying notes are an integral part of the consolidated financial statements.

**Table of Contents****CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)****(UNAUDITED)****(In thousands, except share and per share data)**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
Net revenues	\$ 37,525	\$ 25,180	\$ 81,157	\$ 83,216
Costs and expenses:				
Cost of product sales (exclusive of amortization of product rights)	14,397	9,960	31,984	29,183
Selling, general and administrative	12,933	11,239	32,745	36,113
Research and development	1,998	199	3,729	1,372
Gain on divestiture of product rights			(1,492)	
Transaction-related expenses	1,764		7,944	
Amortization of product rights	5,284	3,591	13,774	13,277
Change in acquisition-related contingent payments	(1,574)		(1,574)	
Total costs and expenses	34,802	24,989	87,110	79,945
Income (loss) from operations	2,723	191	(5,953)	3,271
Other expenses:				
Interest expense, net	(1,684)	(38)	(1,799)	(121)
Other expense, net	(215)		(215)	
Total other expenses	(1,899)	(38)	(2,014)	(121)
Income (loss) before income taxes	824	153	(7,967)	3,150
Benefit from (provision for) income taxes	425	(36)	3,038	(1,094)
Net income (loss)	\$ 1,249	\$ 117	\$ (4,929)	\$ 2,056
Comprehensive income (loss)	\$ 1,249	\$ 117	\$ (4,929)	\$ 2,056
Net income (loss) per share, basic	\$ 0.05	\$ 0.00	\$ (0.19)	\$ 0.08
Net income (loss) per share, diluted	\$ 0.05	\$ 0.00	\$ (0.19)	\$ 0.08
Weighted-average common shares, basic	26,245,765	25,782,481	26,040,695	25,646,455
Weighted-average common shares, diluted	26,603,258	26,331,700	26,040,695	26,223,317

The accompanying notes are an integral part of the consolidated financial statements.

**Table of Contents****CONSOLIDATED STATEMENTS OF CASH FLOWS****(UNAUDITED)****(In thousands)**

	<b>Nine Months Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>
<b>Cash flows from operating activities</b>		
Net (loss) income	\$ (4,929)	\$ 2,056
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Amortization and depreciation	14,267	11,146
Amortization of debt costs	26	
Provision for prompt payment discounts	2,390	2,781
Provision for inventory allowances	847	339
Acquisition accounting adjustment on inventory sold	3,061	
Gain on sale of product rights	(1,492)	
Loss on disposal of property and equipment	215	
Change in acquisition-related contingent payments	(1,574)	
Impairment of product rights		2,500
Stock-based compensation	2,027	1,586
Deferred revenue	(1,428)	(54,856)
Benefit from deferred income taxes	177	1,223
Changes in operating assets and liabilities:		
Accounts receivable	(7,654)	56,615
Inventories	(1,001)	2,540
Prepaid expenses and other assets	8,289	7,508
Accounts payable	(2,441)	2,003
Accrued expenses	(14,224)	(3,083)
Income taxes receivable	(2,341)	(2,007)
<b>Net cash (used in) provided by operating activities</b>	<b>(5,785)</b>	<b>30,351</b>
<b>Cash flows from investing activities</b>		
Acquisition of business, net of cash acquired	(125,921)	
Purchase of property and equipment	(265)	(574)
Proceeds from sale of product rights	3,000	
<b>Net cash used in investing activities</b>	<b>(123,186)</b>	<b>(574)</b>
<b>Cash flows from financing activities</b>		
Proceeds from term loans	90,000	
Payment of debt financing costs	(511)	
Proceeds from exercise of common stock options and warrants	1,157	368
Excess tax benefit from stock-based compensation	284	513
Payments related to net settlement of restricted stock	(122)	
Acquisition-related contingent payments	(1,603)	
Principal payments on capital lease obligation	(23)	(62)
<b>Net cash provided by financing activities</b>	<b>89,182</b>	<b>819</b>
Net (decrease) increase in cash and cash equivalents	(39,789)	30,596
<b>Cash and cash equivalents as of beginning of period</b>	<b>73,968</b>	<b>50,945</b>



<b>Cash and cash equivalents as of end of period</b>	\$ 34,179	\$ 81,541
<b>Supplemental schedule of non-cash investing and financing activities</b>		
Acquisition of business, contingent consideration at fair value	\$ 37,788	\$

The accompanying notes are an integral part of the consolidated financial statements.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1: ORGANIZATION AND BASIS OF PRESENTATION**

**Nature of Operations**

Cornerstone Therapeutics Inc., together with its subsidiaries (collectively, the Company), is a specialty pharmaceutical company focused on commercializing products for the hospital and related specialty markets. Key elements of the Company's strategy are to focus its commercial and development efforts in the hospital and related specialty product sector within the U.S. pharmaceutical marketplace; continue to seek out opportunities to acquire companies and marketed and/or registration-stage products that fit within the Company's focus areas; and generate revenues by marketing approved generic products through the Company's wholly owned subsidiary, Aristos Pharmaceuticals, Inc.

**Principles of Consolidation**

The Company's consolidated financial statements include the accounts of Cornerstone Therapeutics Inc. and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

**Reclassifications**

Royalty expense previously classified separately is included in cost of product sales in the accompanying consolidated statements of comprehensive income (loss). Transaction-related expenses previously included in selling, general and administrative expenses in the accompanying consolidated statements of comprehensive income (loss) are separately disclosed. Transaction-related expenses consist of (i) costs incurred to complete product or company acquisitions or other strategic transactions, including due diligence and legal, consulting and other related fees; (ii) integration costs related to completed transactions; and (iii) transaction-related fees associated with transactions that are not consummated. These reclassifications had no effect on net income (loss) as previously reported.

**Interim Financial Statements**

The accompanying unaudited consolidated financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of these financial statements. The consolidated balance sheet at December 31, 2011 has been derived from the Company's audited consolidated financial statements included in its annual report on Form 10-K for the year ended December 31, 2011. Certain footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States (GAAP) have been condensed or omitted. It is suggested that these financial statements be read in conjunction with the consolidated financial statements and notes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2011.

Operating results for the three and nine month periods ended September 30, 2012 are not necessarily indicative of the results for the full year.

**NOTE 2: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Use of Estimates**

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. The more significant estimates reflected in the Company's consolidated financial statements include certain judgments regarding revenue recognition, goodwill, product rights, acquisitions, inventory and stock-based compensation. Actual results could differ from those estimates or assumptions.

**Fair Value Measurements**

The carrying amounts of the Company's cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximated their fair values as of September 30, 2012 and December 31, 2011 due to the short-term nature of these financial instruments.

***Assets and Liabilities Measured at Fair Value on a Recurring Basis***

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The fair value for contingent consideration potentially payable related to the acquisition of EKR Holdings, Inc. and its wholly owned subsidiary, EKR Therapeutics, Inc. (collectively "EKR"), at June 26, 2012 was \$37.8 million, of which \$23.9 million related to a contingent consideration arrangement that existed prior to the acquisition date. The fair value of these liabilities is a Level 3 measurement in the fair value hierarchy which is defined as one with unobservable inputs. The Company uses a discounted cash flow

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analysis incorporating the probability of estimated future cash flows from potential milestones and royalty payments using a risk-adjusted discount rate. The liabilities are evaluated for remeasurement at the end of each reporting period and any changes are recorded in the Company's consolidated statements of comprehensive income (loss). The carrying amount of the liability may fluctuate significantly and actual amounts paid may be materially different from the carrying value of the liability.

The following table presents a reconciliation of contingent consideration obligations related to the EKR acquisition measured on a recurring basis using significant unobservable inputs (Level 3) for the nine-month period ended September 30, 2012 (in thousands):

	December 31, 2011	Issuances (1)	Payments (2)	Adjustments (3)	September 30, 2012
Acquisition-related contingent consideration (4)	\$	\$ 37,788	\$ (1,603)	\$ (1,574)	\$ 34,611

- (1) Relates to the EKR acquisition as described below in Note 3 and consisting of approximately \$13.9 million potentially payable for RETAVASE® and \$23.9 million potentially payable for CARDENE® I.V.
- (2) Relates to payments of acquisition-related contingent consideration with respect to CARDENE I.V.
- (3) Recognized as change in acquisition-related contingent payments in the consolidated statements of comprehensive income (loss). This amount represents fair value adjustments to the acquisition-related contingent consideration for CARDENE I.V.
- (4) Acquisition-related contingent consideration is classified as acquisition-related contingent payments in the accompanying consolidated balance sheets. In addition, acquisition-related contingent payments include \$8.8 million related to the Company's acquisition of Cardiokine, Inc. ( Cardiokine ) as described in Note 8.

**Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis**

There were no significant assets or liabilities that were re-measured at fair value on a non-recurring basis subsequent to initial recognition in the three and nine month periods ended September 30, 2012.

**Cash and Cash Equivalents**

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. The Company maintains its cash deposits with two federally insured banks. As of September 30, 2012, the majority of the Company's cash deposits were federally insured.

**Inventories**

Inventories are stated at the lower of cost or market value with cost determined under the first-in, first-out method and consist of raw materials, work in process and finished goods. Raw materials include the active pharmaceutical ingredient ( API ) for a product to be manufactured, work in process includes the bulk inventory of tablets or liquids that are in the process of being coated and/or packaged for sale, and finished goods include pharmaceutical products ready for commercial sale or distribution as samples.

Pre-approval inventory is expensed until it is probable that the inventory will be saleable. The Company capitalizes inventory costs associated with marketed products and certain products prior to regulatory approval and product launch, based on management's judgment of probable future commercial use and net realizable value. Capitalization of this inventory does not begin until the product candidate is considered to have a high probability of regulatory approval, which is generally after the Company has submitted a filing with the U.S. Food and Drug Administration ( FDA ). If the Company is aware of any specific risks or contingencies that are likely to impact the expected regulatory approval process or if there are any specific issues identified during the research process relating to safety, efficacy, manufacturing, marketing or labeling of the product candidate, the Company does not capitalize the related inventory. Once the Company capitalizes inventory for a product candidate that is not yet approved, the Company monitors, on a quarterly basis, the status of this candidate within the regulatory approval process, its projected sales volume and estimated selling price. The Company could be required to expense previously capitalized costs related to pre-approval inventory upon a change in its judgment of future commercial use and net realizable value, due to a denial or delay of approval by regulatory bodies, a delay in the timeline for commercialization or other potential factors. At September 30, 2012, inventories included \$14.3 million of costs capitalized as raw materials and work in process prior to regulatory approval of the Supplemental Biologics License Application ( sBLA ) for RETAVASE. The sBLA is intended to qualify SCIL Proteins Production in Germany ( SCIL ) as a new supplier of reteplase, the API for RETAVASE, and to modify the existing approved Biologics License Application to include an intermediate step in the finished good

manufacturing process.

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On a quarterly basis, the Company analyzes its inventory levels and records allowances for inventory that has become obsolete, inventory that has a cost basis in excess of the expected net realizable value and inventory that is in excess of expected demand based upon projected product sales.

The following table represents inventories, net as of September 30, 2012 and December 31, 2011 (in thousands):

	September 30, 2012	December 31, 2011
Raw materials	\$ 6,233	\$ 2,791
Work in process	14,027	1,663
Finished goods:		
Pharmaceutical products - trade	19,776	4,566
Pharmaceutical products - samples	30	849
Total	40,066	9,869
Inventory allowances	(1,893)	(450)
Inventories, net	\$ 38,173	\$ 9,419

The increase in inventories primarily reflects the acquisition of EKR's inventories, which were initially recorded at fair value (as described in Note 3). In the three and nine month periods ended September 30, 2012, cost of product sales included \$2.9 million and \$3.1 million, respectively, of acquisition accounting adjustments related to sales of acquired CARDENE I.V. inventory that was sold during the periods.

**Revenue Recognition**

The Company's consolidated net revenues represent the Company's net product sales and license and royalty agreement revenues. The following table sets forth the categories of the Company's net revenues (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Gross product sales	\$ 57,793	\$ 37,873	\$ 122,267	\$ 133,345
Sales allowances	(20,268)	(12,695)	(41,114)	(50,228)
Net product sales	37,525	25,178	81,153	83,117
License and royalty agreement revenues		2	4	99
Net revenues	\$ 37,525	\$ 25,180	\$ 81,157	\$ 83,216

The Company records all of its revenue from product sales, license agreements and royalty agreements when realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the seller's price to the buyer is fixed or determinable; and (4) collectability is reasonably assured.

**Net Product Sales**

*Product Sales.* The Company recognizes revenue from its product sales upon transfer of title, which occurs when product is received by its customers. The Company sells its products primarily to large national wholesalers, which have the right to return the products they purchase. The Company is required to reasonably estimate the amount of future returns at the time of revenue recognition. The Company recognizes product sales net of estimated allowances for product returns, rebates, price adjustments, chargebacks, and prompt payment and other discounts.

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When the Company cannot reasonably estimate the amount of future product returns, it records revenues when the risk of product return has been substantially eliminated.

As of September 30, 2012 and December 31, 2011, the Company had \$0 and \$1.4 million, respectively, of deferred revenue related to sales for which future returns could not be reasonably estimated at the time of sale. Deferred revenue, prior to June 30, 2012, was recognized when the product was sold through to the end user based upon estimates of prescriptions filled. To estimate product sold through to end users, the Company relied on third-party information, including prescription data and information obtained from significant distributors with respect to their inventory levels and sell-through to customers. Deferred revenue was recorded net of estimated allowances for rebates, price adjustments, chargebacks, and prompt payment and other discounts. Estimated allowances were recorded and classified as accrued expenses in the accompanying consolidated balance sheets as of December 31, 2011. During the three months ended September 30, 2012 the remaining balance of deferred revenue was reclassified to accrued expenses.

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*Product Returns.* Consistent with industry practice, the Company offers contractual return rights that allow its customers to return the majority of its products within an 18-month period that begins six months prior to and ends twelve months subsequent to expiration of the products. The Company's currently marketed products have expiration periods ranging from 18-24 months from the date of manufacture. The Company adjusts its estimate of product returns if it becomes aware of other factors that it believes could significantly impact its expected returns. These factors include actual return rates for expired and open lots, historical and forecasted product sales and consumer consumption data reported by external information management companies, estimated expiration dates or remaining shelf life of inventory in the distribution channel, estimates of inventory levels of its products in the distribution channel and any significant changes to these levels, and competitive issues such as new product entrants and other known changes in sales trends. The Company evaluates this reserve on a quarterly basis, assessing each of the factors described above, and adjusts the reserve through adjustments to net revenues in the period in which the information that gives rise to the adjustment becomes known.

*Rebates.* The liability for government program rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each program's administrator.

*Price Adjustments and Chargebacks.* The Company's estimates of price adjustments and chargebacks are based on its estimated mix of sales to various third-party payers, which are entitled either contractually or statutorily to discounts from the Company's listed prices of its products. These estimates are also based on the contract fees the Company pays to certain group purchasing organizations (GPOs). In the event that the sales mix to third-party payers or the contract fees paid to GPOs are different from the Company's estimates, the Company may be required to pay higher or lower total price adjustments and/or chargebacks than it has estimated.

The Company, from time to time, offers certain promotional product-related incentives to its customers. These programs include certain product incentives to pharmacy customers and other sales stocking allowances. The Company has voucher programs for ZYFLO CR<sup>®</sup> whereby the Company offers a point-of-sale subsidy to retail consumers. The Company estimates its liabilities for these voucher programs based on the historical redemption rates for similar completed programs used by other pharmaceutical companies as reported to the Company by a third-party claims processing organization and actual redemption rates for the Company's completed programs. In addition, the Company offers a customer loyalty program for CARDENE I.V. The Company estimates its liability for this program based on historical participation and redemption rates as well as projected sales for individual customers during the program evaluation period. The Company accounts for the costs of these special promotional programs as price adjustments, which are a reduction of gross revenue.

*Prompt Payment Discounts.* The Company typically offers its wholesale customers a prompt payment discount of 2% as an incentive to remit payments within the first 30 to 35 days after the invoice date depending on the customer and the products purchased.

## **Comprehensive Income**

On January 1, 2012, the Company adopted the new presentation requirements under ASU 2011-05, Comprehensive Income (Topic 220), *Presentation of Comprehensive Income in U.S. GAAP* (ASU 2011-05) and ASU 2011-12 Comprehensive Income (Topic 220), *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU 2011-05* (ASU 2011-12). ASU 2011-05 requires that comprehensive income and the related components of net income and of other comprehensive income be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 also requires reclassification adjustments from other comprehensive income to net income be presented on the face of the financial statements. However, in December 2011, the Financial Accounting Standards Board (FASB) issued ASU 2011-12 to defer the requirement to present reclassification adjustments from other comprehensive income on the face of the financial statements and allow entities to continue to report reclassifications out of accumulated other comprehensive income consistent with the requirements in effect before ASU 2011-05. The Company has no adjustments between net income and comprehensive income. The adoption of this guidance is not material to the Company or its presentation of its consolidated financial statements.



**Table of Contents****NOTE 3: ACQUISITION OF EKR****Description of Transaction**

On June 26, 2012, the Company completed its acquisition of EKR, a specialty pharmaceutical company focused on serving the acute-care hospital setting, for an estimated consideration of approximately \$164.2 million. As part of the transaction, the Company acquired the product rights to the cardiovascular products CARDENE I.V. and RETAVASE. The Company made an upfront payment of \$126.4 million, subject to customary post-closing adjustments, and may pay a series of contingent consideration payments related to CARDENE I.V. and RETAVASE if certain milestones are achieved. The fair value for contingent consideration was determined to be \$37.8 million.

**Basis of Presentation**

The transaction has been accounted for as a business combination under the acquisition method of accounting, which requires, among other things, that the assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date. The results of operations of EKR were consolidated beginning on the date of the merger. Acquisition-related costs are not included as a component of the acquisition accounting, but are recognized as expenses in the periods in which the costs are incurred. Any changes within the measurement period resulting from facts and circumstances that existed as of the acquisition date may result in retrospective adjustments to the provisional amounts recorded at the acquisition date.

**Fair Value of Consideration Transferred**

A summary of the purchase price is as follows (in thousands):

Cash paid for EKR's outstanding shares	\$ 126,437
Acquisition-related contingent consideration	37,788
<b>Total fair value of consideration</b>	<b>\$ 164,225</b>

**Assets Acquired and Liabilities Assumed**

The total purchase price was allocated to the acquired tangible and intangible assets and assumed liabilities of EKR based on their estimated fair values as of June 26, 2012. The excess of the purchase price over the estimated fair values of the assets acquired and liabilities assumed was allocated to goodwill.

The following table presents the preliminary allocation of the total fair value of consideration transferred, as shown above, to the acquired tangible and intangible assets and assumed liabilities of EKR based on their estimated fair values as of the closing date of the transaction, measurement period adjustments recorded since the acquisition date and the as adjusted allocations of the total fair value (in thousands):

	June 26, 2012 (As initially reported)	Measurement Period Adjustments (1)	June 26, 2012 (As adjusted)
Cash	\$ 516	\$	\$ 516
Accounts receivable, net	7,724	(324)	7,400
Inventory, net	32,226		32,226
Prepaid expenses and other assets	14,704	333	15,037
Identifiable intangibles	154,123		154,123
Deferred tax assets	28,873		28,873
Accounts payable	(10,618)	(993)	(11,611)
Accrued liabilities	(21,509)	133	(21,376)
Deferred tax liability related to intangibles acquired	(64,069)		(64,069)

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Total identifiable net assets	\$	141,970	\$	(851)	\$	141,119
Goodwill		22,255		851		23,106
Total fair value of consideration	\$	164,225	\$		\$	164,225

- (1) The measurement period adjustments primarily reflect changes in other receivables, prepaid expenses, accrued liabilities and estimated sales allowances. The measurement period adjustments were made to reflect facts and circumstances existing as of the acquisition date, and did not result from intervening events subsequent to the acquisition date. The Company believes that this information provides a reasonable basis for estimating the fair values but is waiting for additional information necessary to finalize these amounts, including potential post-closing working capital and other measurement period adjustments that existed at the closing date. Thus, the Company's provisional measurements of fair value are subject to change.

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The Company recorded \$154.1 million in identifiable intangibles at fair value, consisting of \$158.4 million in acquired product rights, partially offset by \$4.3 million related to an unfavorable contract liability. The fair value of the product rights is allocated as \$131.6 million for CARDENE I.V. and \$26.9 million for RETAVASE. CARDENE I.V. product rights will be amortized over 15 years. RETAVASE product rights will be amortized over approximately 12 years beginning upon commercial launch. The unfavorable contract liability resulted from an existing supply contract that was determined to have terms that were less favorable than market. The liability was recorded at fair value determined based on the discounted cash flows resulting from the Company's estimated loss that will be incurred on the manufacturing of RETAVASE inventory for the provider of RETAVASE in the European market. The fair value as of June 30, 2012 was \$4.3 million and is classified in other long-term liabilities on the consolidated balance sheet as of September 30, 2012. The value of the contract will be amortized and recorded as an offset to cost of product sales based on inventory movement over the life of the contract.

Acquired inventory was recorded at fair value and includes an acquisition accounting adjustment of approximately \$19.4 million to increase inventory to its fair value.

The Company recorded \$11.8 million in indemnification assets and liabilities corresponding to (i) certain litigation and contractual liabilities included in accrued expenses and (ii) anticipated income tax refunds related to federal net operating loss (NOL) carryback claims and EKR's 2012 short period tax return. EKR's former shareholders are responsible for specified litigation and contractual liabilities included in acquired accrued expenses and for tax liabilities related to pre-closing periods and have fully indemnified the Company against losses related to these matters. EKR's former shareholders are also generally entitled to the benefit of tax refunds associated with pre-closing periods. At the time of the acquisition, these indemnification assets and liabilities were classified in other current assets, accounts payable and accrued expenses. The measurement period adjusted balances are reflected on the accompanying consolidated balance sheet as of September 30, 2012. The Company expects the full amount of the liabilities related to these matters to be covered by the EKR shareholders.

At the closing of the acquisition, the fair value for contingent consideration potentially payable was \$37.8 million, of which \$23.9 million related to a contingent consideration arrangement related to the ready-to-use formulation of CARDENE I.V. that existed prior to the acquisition date. The fair value of these liabilities was determined using a discounted cash flow analysis incorporating the estimated future cash flows from potential milestones and royalty payments. The liabilities were evaluated as of September 30, 2012 as discussed above in Note 2. The Company will continue to evaluate these liabilities for remeasurement at the end of each reporting period and any change will be recorded in the Company's consolidated statement of comprehensive income (loss). The carrying amount of the liability may fluctuate significantly and actual amounts paid may be materially different from the carrying value of the liability.

Goodwill was calculated as the difference between the fair value of the consideration and the preliminary values assigned to the assets acquired and liabilities assumed. The purchase price and goodwill allocation are expected to be finalized during the remainder of fiscal 2012 as the Company completes its process of evaluating all relevant data associated with the transaction. None of the goodwill will be deductible for tax purposes.

In connection with the acquisition, during the nine months ended September 30, 2012 the Company incurred \$7.3 million of transaction-related costs, which include severance and advisory, legal, valuation and accounting services. These costs were expensed as incurred and are included in transaction-related expenses on the accompanying consolidated statements of comprehensive income (loss).

**Actual and Pro Forma Impact of the Transaction (Unaudited)**

Net revenues and net income for EKR of \$13.5 million and \$2.1 million, respectively, are included in the Company's consolidated statements of comprehensive income (loss) from the acquisition date, June 26, 2012 through September 30, 2012.

The following table presents pro forma results of operations and gives effect to the transaction as if the transaction had been consummated on January 1, 2011 (in thousands, except per share data). The unaudited pro forma results of operations have been prepared for comparative purposes only and are not necessarily indicative of what would have occurred had the business combination been completed at the beginning of the period or of the results that may occur in the future. Furthermore, the pro forma financial information does not reflect the impact of any reorganization or restructuring expenses or operating efficiencies resulting from combining the two companies (in thousands).

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Net revenues	\$ 37,525	\$ 40,645	\$ 107,428	\$ 125,434

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Net income (loss)	\$ 2,068	\$ (3,628)	\$ (4,048)	\$ (2,648)
Basic earnings (loss) per share	\$ 0.08	\$ (0.14)	\$ (0.16)	\$ (0.10)
Diluted earnings (loss) per share	\$ 0.08	\$ (0.14)	\$ (0.16)	\$ (0.10)

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The unaudited pro forma consolidated results were prepared using the acquisition method of accounting and are based on the historical financial information of the Company and EKR, reflecting the Company's and EKR's results of operations for the three and nine month periods ended September 30, 2012 and 2011. The historical financial information has been adjusted to give effect to the pro forma events that are: (i) directly attributable to the acquisition, (ii) factually supportable and (iii) expected to have a continuing impact on the combined results. The unaudited pro forma consolidated results reflect primarily the following pro forma adjustments:

Additional interest expense related to the long-term debt used to fund the acquisition;

Additional amortization expense related to the fair value of identifiable intangible assets acquired; and

Removal of acquisition-related transaction costs.

**NOTE 4: GOODWILL AND INTANGIBLE ASSETS****Goodwill**

The changes in the carrying amount of goodwill during the nine-month period ended September 30, 2012 were as follows (in thousands):

	December 31, 2011	Additions (1)	Adjustments (2)	September 30, 2012
Carrying amount of goodwill	\$ 15,218	\$ 22,255	\$ 851	\$ 38,324

(1) Relates to the EKR acquisition as described above in Note 3.

(2) Relates to the impact of measurement period adjustments related to the EKR acquisition as described above in Note 3.

As described in Note 3, the allocation of the goodwill balance associated with the EKR acquisition is provisional and subject to the completion of the valuation of the assets acquired and liabilities assumed. No amount of the goodwill balance at September 30, 2012 will be deductible for income tax purposes.

**Product Rights****Product Rights and In-Process Research and Development (IPR&D)**

The following tables represent product rights, net as of September 30, 2012 and December 31, 2011 (in thousands):

	September 30, 2012			Weighted-Average Amortization Period (yrs.)
	Gross Carrying Amount	Accumulated Amortization	Net Amount	
CUROSURF®	\$ 107,606	\$ 33,179	\$ 74,427	10.0
ZYFLO®	11,500	6,285	5,215	7.1
CARDENE I.V.	131,556	2,290	129,266	15.0
RETAVASE	26,858		26,858	n/a
CRTX 080	11,500		11,500	n/a
Other	575	75	500	n/a

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Total	\$ 289,595	\$ 41,829	\$ 247,766	13.0
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	December 31, 2011			Weighted-Average Amortization Period (yrs.)
	Gross Carrying Amount	Accumulated Amortization	Net Amount	
CUROSURF	\$ 107,606	\$ 25,109	\$ 82,497	10.0
Factive®	7,613	3,636	3,977	0.5
Spectracef®	4,505	2,437	2,068	0.5
ZYFLO	11,500	5,082	6,418	7.1
CRTX 080	11,500		11,500	n/a
Other	575	75	500	n/a
<b>Total</b>	<b>\$ 143,299</b>	<b>\$ 36,339</b>	<b>\$ 106,960</b>	<b>8.9</b>

The Company amortizes the product rights related to its currently marketed products over their estimated useful lives, which range from seven to fifteen years. As of September 30, 2012, the Company had \$38.9 million of product rights related to RETAVASE, its Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended Release Suspension product (formerly referred to as CRTX 067), and its product candidate CRTX 080, all of which are expected to be launched in the future. The Company expects to begin amortization upon the commercial launch of these products, which the Company targets launching shortly following regulatory approval. The rights will be amortized over the estimated useful lives of these products.

Aggregate annual amortization expense of product rights (excluding the rights related to products expected to be launched) for each of the five succeeding fiscal years is estimated as follows (in thousands):

2012	\$ 18,765
2013	21,136
2014	21,136
2015	21,136
2016	19,531
Thereafter	120,784
	<b>\$ 222,488</b>

**Divestiture of Anti-infective Product Rights**

In March 2012, the Company entered into asset purchase agreements with each of Merus Labs International Inc. ( Merus ) and Vansen Pharma Inc. ( Vansen ) pursuant to which the Company sold all of its rights to the anti-infective drugs Factive and Spectracef. In exchange for cash consideration and the assumption of certain product-related liabilities, Merus acquired all of the Company's rights to Factive, together with all of the Company's Factive product inventory and certain other related assets. In exchange for cash consideration and the assumption of certain product-related liabilities, Vansen acquired all of the Company's rights to the Spectracef family of products, together with all of the Company's Spectracef product inventory and certain other related assets. Vansen also agreed to make offers of employment to certain employees of the Company with responsibility for the distribution and sales of Spectracef. Pursuant to a separate co-promotion agreement, Vansen agreed to co-promote the Company's ZYFLO CR and ZYFLO products to certain physicians for an initial period of 24 months.

In connection with the transaction, the Company divested approximately \$3.8 million in product rights, net of accumulated amortization, \$2.5 million in inventory and product samples, and other assets of \$1.4 million. In addition, Merus and Vansen assumed product-related liabilities of approximately \$4.1 million. Total cash consideration for the divestiture was \$6.2 million, of which \$1.2 million was recorded as a receivable from the buyers. Under the asset purchase agreement for Factive, the Company retained certain royalty obligations to LG Life Sciences, Ltd. and Oscient Pharmaceuticals Corporation through the end of September 30, 2014. The Company calculated the fair value of the expected royalty payments and recorded a contingent liability of \$1.1 million, which is included in other current and other long-term liabilities. The Company also recognized a gain on the divestiture of \$1.5 million which is included in the consolidated statements of comprehensive income (loss).





**Table of Contents****NOTE 5: ACCRUED EXPENSES**

The components of accrued expenses are as follows (in thousands):

	September 30, 2012	December 31, 2011
Accrued product returns	\$ 12,896	\$ 13,211
Accrued rebates	1,754	2,634
Accrued price adjustments and chargebacks	10,938	9,159
Accrued compensation and benefits	2,825	2,559
Accrued royalties	3,766	3,046
Accrued taxes	6,578	5,668
Accrued expenses, other	551	848
Total accrued expenses	\$ 39,308	\$ 37,125

**NOTE 6: LONG TERM DEBT***Term Loans A and B*

On June 21, 2012, the Company entered into a credit agreement (the Credit Agreement) with Chiesi Farmaceutici S.p.A. (Chiesi) in connection with its acquisition of EKR. The Credit Agreement governs the senior secured term loan facility with Chiesi (the Term Loan Facility), which is comprised of a five-year Term Loan A of \$60.0 million and a five-year Term Loan B of \$30.0 million (the Term Loans). The Term Loans were funded on June 25, 2012 and the acquisition of EKR closed on June 26, 2012.

Term Loan A and Term Loan B bear interest at rates of 7.5% and 6.5% per year, respectively, payable quarterly in arrears on the last business day of each fiscal quarter beginning on September 28, 2012. Term Loan A requires quarterly principal payments of \$3.5 million commencing on the fiscal quarter ending December 31, 2014 with any remaining balance due at maturity. Term Loan B principal is payable at maturity. The Term Loans are due and payable on June 23, 2017, unless previously prepaid or, in the case of Term Loan B, converted into shares of common stock, prior to such date.

The Company may prepay the Term Loans, in whole or in part without any premium or penalty, provided any prepayments of principal amounts are \$5.0 million or whole multiples of \$1.0 million in excess thereof, plus any accrued and unpaid interest. The prepayments will be applied first, ratably to the remaining installments of principal of the Term Loan A (excluding the payment due at maturity), second, to any remaining amounts outstanding on Term Loan A, and third, to the outstanding principal on Term Loan B.

The Company is required to prepay all or a portion of the Term Loan Facility under the following conditions: (i) if the Company's ratio of consolidated secured debt to Consolidated EBITDA (as defined in the Credit Agreement) is at least 2 to 1 for any fiscal year ending on or after December 31, 2013, by using 50% of the Company's Consolidated Excess Cash (as defined in the Credit Agreement), or (ii) if the Company undertakes certain asset sales or sales of capital stock and does not reinvest the proceeds according to the terms of the Credit Agreement.

Term Loan B contains a conversion option for a two-year period, expiring on June 21, 2014, which provides Chiesi the option, exercisable in its sole discretion, to convert all or a portion of the Term Loan B into shares of common stock at a conversion price equal to \$7.098 per share, subject to adjustment under certain conditions. Conversions shall be no less than \$5.0 million unless the remaining principal amount of Term Loan B is less than \$5.0 million.

The Credit Agreement contains customary representations, covenants and events of default. Upon an Event of Default (as defined in the Credit Agreement), (i) the interest rates for Term Loan A and Term Loan B will each increase by 2% and (ii) Chiesi may declare all outstanding principal and accrued but unpaid interest under the Term Loan Facility to be immediately due and payable. In addition, the Company is subject to covenants prohibiting the payment of any dividends (other than stock dividends) and restricting or limiting other restricted payments, certain corporate activities, transactions with affiliates, incurrence of debt (which debt limit expressly permits, among other things, a secured working capital facility of up to \$25 million), liens on properties and asset dispositions. The Company is not subject to any financial covenants other than the mandatory prepayment provisions discussed above.

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In connection with the Term Loans, the Company incurred an estimated \$511,000 of debt financing costs, which primarily consisted of legal and other professional fees. These costs are being amortized and are recorded as additional interest expense through the maturity of the loans.

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The following table summarizes information on the Term Loans as of September 30, 2012 (in thousands):

	Maturity Date	September 30, 2012
Term Loan A (7.5% interest payable quarterly and principal payable in quarterly installments of \$3.5 million starting on December 31, 2014)	June 2017	
Principal amount		\$ 60,000
Unamortized debt financing costs		(322)
Net carrying amount		59,678
Term Loan B (6.5% interest payable quarterly and principal payable upon maturity, with conversion option through June 21, 2014)	June 2017	
Principal amount		30,000
Unamortized debt financing costs		(163)
Net carrying amount		29,837
Total debt, carrying amount		89,515
Less: current portion		
Total long-term debt, carrying amount		\$ 89,515

**NOTE 7: STOCK-BASED COMPENSATION****Stock Options**

The Company uses the Black-Scholes-Merton option pricing model to determine the fair value of its stock options. The determination of the fair value of stock-based payment awards on the date of grant using an option pricing model is affected by the Company's stock price, as well as assumptions regarding a number of complex and subjective variables. These variables include the Company's expected stock price volatility over the term of the awards, actual employee exercise behaviors, risk-free interest rate and expected dividends.

There were 603,200 and 438,390 stock options granted and exercised, respectively, during the nine months ended September 30, 2012.

The following table shows the assumptions used to value stock options on the date of grant, as follows:

	Nine Months Ended September 30, 2012
Estimated dividend yield	0.0%
Expected stock price volatility	80%
Risk-free interest rate	0.62-0.71%
Expected life of option (in years)	5.00
Weighted-average grant date fair value per share of options granted	\$3.60

The Company has not paid and does not anticipate paying cash dividends; therefore, the expected dividend rate was assumed to be 0%. The expected stock price volatility was based on the Company's historical volatility for the five year period preceding the grant date. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected life assumption. The expected life was estimated based on historical exercise patterns for previous grants, taking into account employee exercise strategy and cancellation behavior.

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As of September 30, 2012, the aggregate intrinsic values of options outstanding and exercisable were \$1.5 million.

As of September 30, 2012, there was \$3.6 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.38 years.

### **Restricted Stock**

During the nine months ended September 30, 2012, no shares of restricted stock were issued and 83,970 shares vested. As of September 30, 2012, there were 135,810 restricted common shares outstanding and \$769,000 of total unrecognized compensation cost related to unvested restricted stock, which is expected to be recognized over a weighted-average period of 1.82 years.

### **Stock-Based Compensation Expense**

Total stock-based compensation expense recognized based on the total grant date fair value of options and shares vested was approximately \$684,000 and \$702,000 for the three months ended September 30, 2012 and 2011, respectively, and \$2.0 million and \$1.6 million for the nine months ended September 30, 2012 and 2011, respectively.

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### **NOTE 8: COMMITMENTS AND CONTINGENCIES**

#### **Lease Obligations**

The Company leases its facilities and certain equipment under non-cancelable operating leases expiring at various dates through 2016. The Company recognizes lease expense on a straight-line basis over the term of the lease, excluding renewal periods, unless renewal of the lease is reasonably assured. Lease expense was approximately \$894,000 and \$254,000 for the three months ended September 30, 2012 and 2011, respectively, and approximately \$1.3 million and \$843,000 for the nine months ended September 30, 2012 and 2011, respectively.

In connection with the acquisition of EKR, the Company assumed the lease for office space in Bedminster, NJ that was scheduled to extend through December 15, 2015. The lease was subsequently terminated in August 2012, effective September 30, 2012. The Company paid lease termination fees, of which \$541,000 was recorded as lease expense during the three months ended September 30, 2012.

#### **Supply Agreements**

The Company has various supply agreements with certain vendors and pharmaceutical manufacturers. Financial commitments related to these agreements totaled approximately \$38.6 million as of September 30, 2012, which includes any minimum amounts payable and penalties for failure to satisfy purchase commitments that the Company has determined to be probable and that are reasonably estimable. Since many of these commitment amounts are dependent on variable components of the agreements, actual payments and the timing of those payments may differ from management's estimates. As of September 30, 2012, the Company had outstanding purchase orders related to inventory, excluding commitments under supply agreements, totaling approximately \$22.0 million.

#### **Royalty Agreements**

The Company has contractual obligations to pay royalties to the former owners or current licensors of certain product rights that have been acquired by or licensed to the Company. These royalties are typically based on a percentage of net sales of the particular licensed product and are included in cost of product sales in the consolidated statements of comprehensive income (loss). For the three months ended September 30, 2012 and 2011, total royalty expenses were \$684,000 and \$1.6 million, respectively, and for the nine months ended September 30, 2012 and 2011, total royalty expenses were \$3.5 million and \$6.3 million, respectively.

#### **Collaboration Agreements**

The Company is committed to make potential future milestone payments to third parties as part of licensing, distribution and development agreements. Payments under these agreements generally become due and payable only upon achievement of certain development, regulatory and/or commercial milestones. The Company may be required to make \$8.4 million in additional payments to various parties if all milestones under the agreements are met. Because the achievement of milestones is neither probable nor reasonably estimable, such contingent payments have not been recorded on the accompanying consolidated balance sheets. The Company is also obligated to pay royalties on net sales or gross profit, if any, of certain product candidates currently in its portfolio following their commercialization.

In addition, in connection with its acquisition of Cardiokine in December 2011, the Company recorded an \$8.8 million contingent liability for additional consideration potentially payable under the merger agreement. The Company agreed to pay potential consideration consisting of each of the following: (1) either \$7.0 million or \$8.5 million if Cardiokine's pending new drug application (NDA) for its lixivaptan compound, CRTX 080, is approved for sale by the FDA; (2) up to \$147.5 million based on the achievement of certain sales related milestones (\$7.5 million at \$75 million, \$15 million at \$150 million, \$25 million at \$250 million and \$100 million at \$500 million, each payable at the first time the annual sales reach the relevant milestone); (3) quarterly earnout payments of 8% or 12% of net sales of the approved product, with such rate being dependent upon the scope of the labeling which the FDA may approve for the product; and (4) one-half of any proceeds realized from the license of the approved product outside the United States (collectively, the Purchase Consideration). The Purchase Consideration will be paid first to a subsidiary of Pfizer Inc. (Pfizer), the licensor of certain rights to the lixivaptan compound, in satisfaction of Cardiokine's payment obligations to Pfizer, until Pfizer has been paid a total of \$20 million. Thereafter, any further Purchase Consideration will be paid in accordance with the merger agreement to certain other parties for which obligations existed and then directly to Cardiokine's former stockholders. The initial fair value of this liability is a level 3 measurement and was determined using a probability-weighted discounted cash flow analysis incorporating the estimated future cash flows from potential milestones and royalty payments discounted to present value using a discount rate of 21.5%. The liability will be periodically assessed based on events and circumstances related to the underlying milestones, and any change in fair value will be recorded in the Company's consolidated statement of comprehensive income (loss). The carrying amount of the liability may fluctuate significantly and actual amounts paid may be materially different from the carrying value of the liability. During the three and nine months ended September 30, 2012, there were no events or circumstances that would have required a revaluation of the liability.



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As of September 30, 2012, the Company had outstanding financial commitments related to ongoing research and development contracts totaling approximately \$3.1 million.

### **Co-Promotion and Marketing Services Agreements**

The Company has entered into a co-promotion and marketing services agreement and two co-promotion agreements that grant third parties exclusive rights to promote certain of the Company's products in conjunction with the Company. Under these agreements, the third parties are responsible for various costs associated with their promotional activities, including the product samples distributed by their sales representatives. The Company is generally required to pay the third parties co-promotion fees based on preset formulas and is also responsible for certain costs under the agreements. In addition, certain of these agreements are subject to sunset fees that require the Company to pay additional fees in the event of certain defined terminations of the applicable agreement.

As of September 30, 2012, the Company had outstanding financial commitments related to various marketing and analytical service agreements totaling approximately \$2.7 million.

### **Severance**

Selected executive employees of the Company have employment agreements which provide for severance payments of up to two times base salary, bonuses and benefits upon termination, depending on the reasons for the termination. The executive would also be required to execute a release and settlement agreement. On September 24, 2012, the Company's Chief Financial Officer and Treasurer was notified of the Company's determination to exercise its rights under his employment agreement to terminate his employment; however, he remained an employee of the Company through October 19, 2012. As of September 30, 2012, the Company accrued \$287,000 as an estimate of cash severance to be paid following the termination of his employment and estimates that it will record approximately \$300,000 of additional stock compensation expense in the fourth quarter of 2012 upon acceleration of options and vesting of restricted stock in accordance with the provisions of his employment agreement and his separation and release agreement, which was effective on October 19, 2012.

In connection with the acquisition of EKR, the Company incurred and recorded \$1.6 million in accrued severance costs related to former EKR employees and certain EKR employees providing services for a stated transition period. As of September 30, 2012, \$237,000 of these costs remain recorded as accrued severance and are included in accrued expenses on the consolidated balance sheet.

### **Legal Proceedings**

The Company is involved in lawsuits, claims, investigations and proceedings related to its business. There are no matters pending that the Company currently believes are reasonably possible of having a material impact to its business, consolidated financial condition, results of operations or cash flows.

### **NOTE 9: INCOME TAXES**

The Company computes an estimated annual effective tax rate for interim financial reporting purposes. The estimated annual effective tax rate is used to compute the tax expense or benefit related to ordinary income or loss. Tax expense or benefit related to all other items is individually computed and recognized when the items occur. The Company's effective tax rate for the three and nine months ended September 30, 2012 was (51.6)% and 38.1%, respectively. The Company's effective tax rate for the three and nine months ended September 30, 2011 was 23.5% and 34.7%, respectively. The change in the effective tax rate for the three-month period ended September 30, 2012 compared to the three-month period ended September 30, 2011 was due to the Company's projected losses for 2012 as compared to 2011. The change in the effective tax rate for the nine-month period ended September 30, 2012 compared to the nine-month period ended September 30, 2011 was due primarily to the tax impact of nondeductible transaction costs incurred in connection with the acquisition of EKR and the Company's projected losses for 2012 as compared to 2011.

The estimated annual effective tax rate for the year ending December 31, 2012 includes a benefit of approximately 12.8% related to a reduction in the valuation allowance offsetting deferred tax assets. As of December 31, 2011, the Company had provided a valuation allowance for substantially all of its gross deferred tax assets acquired as a result of the merger with Critical Therapeutics in October 2008 that relate to NOL carryforwards, state net economic loss carryforwards and federal tax credits due to uncertainty regarding the Company's ability to fully realize these assets. In addition, during December 2011, the Company completed its acquisition of Cardiokine. As a result of the acquisition, the Company acquired various gross deferred tax assets including federal tax credits and NOLs. Due to uncertainty regarding the Company's ability to fully realize the tax credits and NOLs, a valuation allowance has been provided. This determination considered the limitations on the utilization of NOLs and tax credits imposed by Section 382 and 383, respectively, of the Internal Revenue Code. The reversal of the valuation

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allowance that relates to the Company's use of these deferred tax assets in 2012 is projected to be \$644,000 and will be recorded as an additional tax benefit. The Company has not established any other valuation allowances, and it will continue to assess the realizability of its deferred tax assets and the corresponding impact on the valuation allowance.

As a result of the acquisition of EKR, the Company acquired various deferred tax assets and liabilities, including \$28.9 million of deferred tax assets and \$64.1 million of deferred tax liabilities.



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The 2008 through 2011 tax years of the Company are open to examination by federal and state tax authorities. Currently Cardiokine and EKR are under audit by the federal authorities. EKR is also currently under audit in the state of New Jersey. The Company is fully indemnified by the former shareholders and participating equityholders of EKR and Cardiokine, respectively, for any losses related to audits by federal and state tax authorities for pre-acquisition periods.

There was a change in unrecognized tax positions for the nine months ended September 30, 2012. During the second quarter of 2012 the Company had a change in judgment related to a tax position taken in a prior period. The change was a result of additional guidance provided by the Internal Revenue Service. The Company reduced its unrecognized tax positions by \$382,000 during the second quarter. As of September 30, 2012, the Company has no unrecognized tax benefits. The Company does not reasonably expect any additional changes to the amount of unrecognized tax benefits within the next 12 months.

**NOTE 10: RELATED PARTY TRANSACTIONS**

Chiesi, the Company's majority stockholder, manufactures all of the Company's requirements for CUROSURF pursuant to a license and distribution agreement that became effective on July 28, 2009. Inventory purchases from Chiesi aggregated \$6.4 million and \$18.5 million for the three and nine months ended September 30, 2012, respectively, and \$5.6 million and \$15.2 million for the three and nine months ended September 30, 2011, respectively. As of September 30, 2012, the Company had accounts payable of \$1.5 million due to Chiesi.

As discussed in Note 6, on June 21, 2012, the Company entered into the Term Loan Facility with Chiesi in connection with its acquisition of EKR. The Term Loan Facility, which is governed by the Credit Agreement, includes a Term Loan A of \$60.0 million and Term Loan B of \$30.0 million. The Term Loans were funded on June 25, 2012 and the acquisition of EKR closed on June 26, 2012. As of September 30, 2012, the net carrying value of the Term Loans was \$89.5 million, net of capitalized unamortized debt financing costs. During the three and nine months ended September 30, 2012, the Company paid \$1.8 million of interest expense less withholding tax to Chiesi related to the Term Loans. There was no accrued interest payable due to Chiesi as of September 30, 2012.

**NOTE 11: NET INCOME (LOSS) PER SHARE**

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of common shares outstanding during each period. Diluted net income (loss) per share is computed by dividing net income (loss) adjusted by the sum of the weighted-average number of common shares and dilutive common share equivalents outstanding during the period. In periods for which the convertible term loan is determined to be dilutive to earnings per share, net income is adjusted for interest expense related to the convertible term loan, net of tax effects. Dilutive common share equivalents consist of the incremental common shares issuable upon the exercise of stock options and warrants, the impact of unvested restricted stock and the impact of the convertible debt.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
<b>Numerator:</b>				
Net income (loss)	\$ 1,249	\$ 117	\$ (4,929)	\$ 2,056
<b>Denominator:</b>				
Weighted-average common shares, basic	26,245,765	25,782,481	26,040,695	25,646,455
Dilutive effect of stock options and warrants	331,004	509,126		536,677
Dilutive effect of restricted stock	26,489	40,093		40,185
Dilutive effect of convertible debt				
Weighted-average common shares, diluted	26,603,258	26,331,700	26,040,695	26,223,317
Net income (loss) per share, basic	\$ 0.05	\$ 0.00	\$ (0.19)	\$ 0.08
Net income (loss) per share, diluted	\$ 0.05	\$ 0.00	\$ (0.19)	\$ 0.08
Anti-dilutive weighted-average shares	1,520,234	1,438,236	2,845,845	1,525,532

As of September 30, 2012 and 2011, there were 135,810 and 226,710 shares of unvested restricted stock outstanding that contain non-forfeitable rights to dividends. These securities are considered to be participating securities under the two-class method for determining basic and fully diluted net income (loss) per share. Because the treasury stock method and the two-class method yield the same result for both basic and diluted net income (loss) in each of the periods presented, only the treasury stock method has been disclosed.

**NOTE 12: SUBSEQUENT EVENTS**

On October 31, 2012, the Company received a Complete Response Letter ( CRL ), from the FDA following the FDA s review of a New Drug Application for lixivaptan, CRTX 080, for the treatment of symptomatic hypervolemic and euvolemic hyponatremia

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associated with heart failure and syndrome of inappropriate antidiuretic hormone (SIADH), respectively. The FDA has requested the Company complete additional clinical studies to further evaluate the efficacy and safety of lixivaptan in both heart failure patients and SIADH patients. The Company intends to request an End-of-Review meeting with the Division of Cardiovascular and Renal Drug Products of the FDA to better understand the contents of the CRL and the nature and scope of the additional clinical trials requested by the FDA. Following such meeting, the Company will determine appropriate action regarding its CRTX 080 development program. Any significant change in this development program as a result of the CRL and the planned FDA meeting could result in a change in the value of the contingent consideration and the indefinite lived intangible assets related to this development program.

On November 6, 2012, the Company and Chiesi entered into a License and Distribution Agreement ( Distribution Agreement ) pursuant to which Chiesi granted the Company an exclusive license to market and sell Chiesi s BETHKIS product in the United States. BETHKIS is an FDA-approved inhaled tobramycin-based product indicated for the management of cystic fibrosis patients with Pseudomonas aeruginosa. In consideration for the grant of the license, the Company will make an initial payment of \$1.0 million and will make a milestone payment of \$2.5 million upon the first commercial sale of the product in the United States. The Company will also be required to pay certain costs related to a Phase IV clinical trial with respect to the product and quarterly royalties based on a percentage of net sales.

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### **ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion is designed to provide a better understanding of our unaudited consolidated financial statements, including a brief discussion of our business and products, key factors that impact our performance and a summary of our operating results. You should read the following discussion and analysis of financial condition and results of operations together with our unaudited consolidated financial statements and the related notes included in Part I Item 1. Financial Statements of this quarterly report on Form 10-Q and the consolidated financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our annual report on Form 10-K for the year ended December 31, 2011. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors including, but not limited to, those set forth under Part I Item 1A. Risk Factors of our annual report on Form 10-K for the year ended December 31, 2011 and any material changes to those risk factors discussed below in Part II Item 1A. Risk Factors.*

#### **Executive Overview**

##### ***Strategy***

We are a specialty pharmaceutical company focused on commercializing products for the hospital and related specialty markets. We are actively seeking to acquire or develop additional products for these markets.

Our strategy is to:

Focus our commercial and development efforts in the hospital and related specialty product sector within the U.S. pharmaceutical marketplace;

Acquire companies, marketed and/or registration-stage products, and late-stage development products that fit within our focus areas; and

Market approved generic products through our wholly-owned subsidiary, Aristos Pharmaceuticals, Inc., or Aristos. We believe this strategy will allow us to increase our revenues, improve our margins and profitability and enhance stockholder value.

##### ***Third Quarter 2012 Highlights***

The following summarizes certain key financial measures for the three months ended September 30, 2012:

Cash and cash equivalents were \$34.2 million at September 30, 2012.

Net product sales increased 49% to \$37.5 million for the three months ended September 30, 2012 compared to the three months ended September 30, 2011.

Our income from operations was \$2.7 million for the three months ended September 30, 2012 compared to income from operations of \$191,000 for the three months ended September 30, 2011 when calculated in accordance with accounting principles generally accepted in the United States, or GAAP. On a non-GAAP basis, we had income from operations of \$11.8 million for the three months ended September 30, 2012 compared to \$4.5 million for the three months ended September 30, 2011.

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Our net income was \$1.2 million for the three months ended September 30, 2012 compared to our net income of \$117,000 for the three months ended September 30, 2011 when calculated on a GAAP basis. On a non-GAAP basis, we had net income of \$5.6 million for the three months ended September 30, 2012 compared to \$3.4 million for the three months ended September 30, 2011.

Key developments in the three months ended September 30, 2012 included:

Integration of EKR Therapeutics, Inc., or EKR, into our existing operations within 90 days post-closing realizing significant cost synergies primarily through the elimination of duplicative administrative functions;

Alignment of our combined (Cornerstone and EKR) sales force which significantly expanded our reach in the U.S hospital market;

Expansion of our commercial infrastructure to include a national accounts team providing us with the capability to contract efficiently upon launch of new hospital products and react quickly to changes in the hospital market;

Progress in development and regulatory activities for RETAVASE<sup>®</sup> API supplier approval; and

Progress towards launch of our Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended Release Suspension product.

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### ***Opportunities and Trends***

We continue to execute on our strategic plan, which calls for promoting CUROSURF® and CARDENE® I.V. with our hospital-based sales force and managing the life cycle of ZYFLO® and ZYFLO CR® through non-personal promotion. We believe that the additions of CARDENE I.V. and, if approved, RETAVASE and CRTX 080 to our product portfolio will give us the opportunity to strengthen our existing relationships within the cardiology community and position the Company for long-term growth in the hospital and related specialty markets. In addition, we continue to leverage our relationship with Chiesi Farmaceutici S.p.A., or Chiesi, with the recent completion of an agreement to license BETHKIS®, an inhaled tobramycin-based product indicated for the management of cystic fibrosis patients six years of age and older with *Pseudomonas aeruginosa*, in the United States.

We are currently focused on the following operational initiatives:

Leveraging our new commercial structure, including our expanded hospital sales and national accounts team, to integrate new products into the hospital market more efficiently;

Launching BETHKIS pursuant to our license agreement with Chiesi, effective November 6, 2012;

Securing FDA approval for a new API supplier to allow for re-launch of RETAVASE;

Launching our Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended Release Suspension product, which we expect to be distributed by Aristos; and

Evaluating the Complete Response Letter, or CRL, received on October 31, 2012 from the FDA following its review of our new drug application, or NDA, for lixivaptan, or CRTX 080 and determining the appropriate actions for our related development program.

If we can conclude each of these operational initiatives successfully, our sales force will be actively promoting up to five products within the hospital and related specialty market channels. We believe that the active promotion of multiple hospital products by our sales force, combined with the experience and expertise of our management team, will position us well to drive the future growth of our revenue and income.

### **Acquisition of EKR Therapeutics, Inc.**

On June 26, 2012, we completed our acquisition of EKR, a specialty pharmaceutical company focused on serving the acute-care hospital setting, for an estimated consideration of approximately \$164.2 million. As part of the transaction, we acquired the product rights to EKR's cardiovascular products, CARDENE I.V. and RETAVASE. We made an upfront payment of \$126.4 million, subject to customary post-closing adjustments, and may pay a series of contingent consideration payments related to RETAVASE of up to \$25 million if certain milestones are achieved. The fair value for contingent consideration was determined to be \$37.8 million, of which \$23.9 million related to a contingent consideration arrangement related to the ready-to-use formulation of CARDENE I.V. that existed prior to the acquisition date.

### **Acquisition of BETHKIS**

On November 6, 2012, we entered into a License and Distribution Agreement ( *Distribution Agreement* ) with Chiesi pursuant to which Chiesi granted us an exclusive license to market and sell Chiesi's BETHKIS product in the United States. BETHKIS is an FDA-approved inhaled tobramycin-based product indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa*. In consideration for the grant of the license, we will make an initial payment of \$1.0 million and will make a milestone payment of \$2.5 million upon the first commercial sale of the product. We will also be required to pay certain costs related to a Phase IV clinical trial with respect to the product and quarterly royalties based on a percentage of net sales.



**Table of Contents****Results of Operations****Comparison of the Three Months Ended September 30, 2012 and 2011**

The following table sets forth certain consolidated statement of comprehensive income data and certain non-GAAP financial information for the periods indicated (in thousands, except percentages and per share data):

	Three Months Ended September 30,		Change	
	2012	2011	\$	%
<i>Net product sales</i>				
CUROSURF	\$ 9,963	\$ 9,347	\$ 616	7%
ZYFLO product family	14,495	8,316	6,179	74
CARDENE I.V. product family	12,778		12,778	100
ALLERX® Dose Pack products		5,437	(5,437)	(100)
Anti-infective products	281	1,645	(1,364)	(83)
Other products	8	433	(425)	(98)
Total net product sales	37,525	25,178	12,347	49
<i>License and royalty agreement revenues</i>		2	(2)	(100)
Net revenues	37,525	25,180	12,345	49
Cost of product sales (exclusive of amortization of product rights)	14,397	9,960	4,437	45
Selling, general and administrative	12,933	11,239	1,694	15
Research and development	1,998	199	1,799	NM
Transaction-related expenses	1,764		1,764	100
Amortization of product rights	5,284	3,591	1,693	47
Change in acquisition-related contingent payments	(1,574)		(1,574)	(100)
Income from operations	2,723	191	2,532	NM
Total other expenses, net	(1,899)	(38)	(1,861)	NM
Income before income taxes	824	153	671	NM
Benefit from (provision for) income taxes	425	(36)	461	NM
Net income	\$ 1,249	\$ 117	\$ 1,132	NM
Net income per share, diluted	\$ 0.05	\$ 0.00	\$ 0.05	100
Non-GAAP income from operations (1)	\$ 11,809	\$ 4,484	\$ 7,325	163
Non-GAAP net income (1)	\$ 5,649	\$ 3,400	\$ 2,249	66
Non-GAAP net income per share, diluted (1)	\$ 0.19	\$ 0.13	\$ 0.06	46

(1) A reconciliation of our non-GAAP financial measures to the comparable GAAP measures is included below.

NM Not meaningful.

**Net Revenues***Net Product Sales.*



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CUROSURF net product sales increased \$616,000, or 7%, during the three months ended September 30, 2012 compared to the three months ended September 30, 2011, primarily due to increased unit volume and a reduction in our fees paid to distributors, partially offset by an increase in our estimated rate for product returns.

ZYFLO CR and ZYFLO net product sales increased \$6.2 million, or 74%, during the three months ended September 30, 2012 compared to the three months ended September 30, 2011, primarily due to a reduction in our fees paid to distributors, other adjustments to sales allowances, and price increases.

CARDENE I.V. net product sales were \$12.8 million during the three months ended September 30, 2012. We acquired the CARDENE I.V. product rights in our acquisition of EKR on June 26, 2012.

ALLERX Dose Pack net product sales decreased \$5.4 million during the three months ended September 30, 2012 compared to the three months ended September 30, 2011. There were no sales of ALLERX Dose Pack during the three months ended September 30, 2012 and, there are no future sales expected based on management's reasonable belief that all inventory in the channel has been previously sold and adequate reserves have been established for anticipated returns.

Net product sales from our anti-infective products decreased \$1.4 million, or 83%, during the three months ended September 30, 2012 compared to the three months ended September 30, 2011, due to our divestiture of the product rights and certain related assets and liabilities in early March 2012, partially offset by adjustments made to our prior estimates of sales allowances.

Net product sales from other products decreased \$425,000, or 98%, during the three months ended September 30, 2012 compared to the three months ended September 30, 2011. This decrease relates primarily to the elimination of certain products from our portfolio.

**Table of Contents***Costs and Expenses*

*Cost of Product Sales.* Cost of product sales (exclusive of amortization of product rights of \$5.3 million and \$3.6 million for the three months ended September 30, 2012 and 2011, respectively) increased \$4.4 million, or 45%, during the three months ended September 30, 2012 compared to the three months ended September 30, 2011 primarily due to the addition of CARDENE I.V. for which acquired inventory was recorded at fair value. The total accounting adjustment was \$2.9 million. Cost of product sales consists primarily of standard costs for each of our commercial products, distribution costs, royalties and inventory allowances.

Gross profit (exclusive of license and royalty agreement revenues and amortization of product rights) was as follows (dollars in thousands):

	Three Months Ended September 30,		Change	
	2012	2011	\$	%
Net product sales	\$ 37,525	\$ 25,178	\$ 12,347	49%
Cost of product sales (exclusive of amortization of product rights)	14,397	9,960	4,437	45
<b>Gross profit</b>	<b>\$ 23,128</b>	<b>\$ 15,218</b>	<b>7,910</b>	<b>52</b>
Gross margin	62%	60%		

Gross margin of net product sales for the three months ended September 30, 2012 increased two percentage points compared to the three months ended September 30, 2011. This increase resulted from a decrease in royalty expenses partially offset by the addition of CARDENE I.V. to our product mix, which has a lower gross margin than ALLERX. We have not recognized any ALLERX net product sales after June 30, 2012.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses increased \$1.7 million, or 15%, during the three months ended September 30, 2012 compared to the three months ended September 30, 2011. This increase was primarily due to increased copromotion expense and spending for marketed product support related to ZYFLO, partially offset by reductions in salaries, travel and other related employee benefits related to respiratory sales force and sample costs resulting from our divestiture of our Factive® and Spectracef® product rights and our respiratory sales force in March 2012.

*Research and Development Expenses.* Research and development expenses increased \$1.8 million during the three months ended September 30, 2012 compared to the three months ended September 30, 2011. This increase was primarily driven by development costs related to CRTX 080, which we acquired in December 2011 from Cardiokine, Inc., or Cardiokine, as well as certain costs we incurred to advance the regulatory approval of the Supplemental Biologics License Application ( sBLA ) for RETAVASE, which we acquired in connection with our June 2012 acquisition of EKR. Our product development expenses for particular product candidates vary significantly from period to period depending on the product development stage and the nature and extent of the activities undertaken to advance the product candidate s development in a given reporting period.

*Transaction-related Expenses.* Transaction-related expenses were \$1.8 million during the three months ended September 30, 2012 which primarily related to compensation for transition employees and termination of EKR s building lease in connection with our acquisition of EKR.

*Amortization of Product Rights.* Amortization of product rights increased \$1.7 million, or 47%, during the three months ended September 30, 2012 compared to the three months ended September 30, 2011. This increase was primarily due to \$2.2 million of amortization related to our CARDENE I.V. product rights which we acquired on June 26, 2012, partially offset by reduced amortization resulting from our divestiture of our anti-infective product rights.

*Change in Acquisition-related Contingent Payments.* Acquisition-related contingent payments were adjusted by \$1.6 million during the three months ended September 30, 2012 due to a fair value adjustment based on revised forecasted sales related to CARDENE I.V.

*Benefit from (Provision for) Income Taxes*

The benefit from income taxes was \$425,000 for the three months ended September 30, 2012 compared to a provision of \$36,000 for the three months ended September 30, 2011. Our effective tax rates for the three months ended September 30, 2012 and 2011 were (51.6)% and 23.5%, respectively. The change in the effective tax rate was due to our projected losses for 2012 as compared to 2011.



**Table of Contents****Comparison of the Nine Months Ended September 30, 2012 and 2011**

The following table sets forth certain consolidated statement of comprehensive (loss) income data and certain non-GAAP financial information for the periods indicated (in thousands, except percentages and per share data):

	Nine Months Ended September 30,		Change	
	2012	2011	\$	%
<i>Net product sales</i>				
CUROSURF	\$ 26,845	\$ 25,402	\$ 1,443	6%
ZYFLO product family	37,731	22,313	15,418	69
CARDENE I.V. product family	13,514		13,514	100
ALLERX Dose Pack products	(1,125)	26,191	(27,316)	(104)
Anti-infective products	3,374	11,278	(7,904)	(70)
Other products	814	(2,067)	2,881	139
Total net product sales	81,153	83,117	(1,964)	(2)
<i>License and royalty agreement revenues</i>	4	99	(95)	(96)
Net revenues	81,157	83,216	(2,059)	(2)
Cost of product sales (exclusive of amortization of product rights)	31,984	29,183	2,801	10
Selling, general and administrative	32,745	36,113	(3,368)	(9)
Research and development	3,729	1,372	2,357	172
Gain on divestiture of product rights	(1,492)		(1,492)	(100)
Transaction-related expenses	7,944		7,944	100
Amortization of product rights	13,774	13,277	497	4
Change in acquisition-related contingent payments	(1,574)		(1,574)	(100)
(Loss) income from operations	(5,953)	3,271	(9,224)	(282)
Total other expenses, net	(2,014)	(121)	(1,893)	NM
(Loss) income before income taxes	(7,967)	3,150	(11,117)	NM
Benefit from (provision for) income taxes	3,038	(1,094)	4,132	NM
Net (loss) income	\$ (4,929)	\$ 2,056	\$ (6,985)	NM
Net (loss) income per share, diluted	\$ (0.19)	\$ 0.08	\$ (0.27)	NM
Non-GAAP income from operations (1)	\$ 17,813	\$ 18,134	\$ (321)	(2)
Non-GAAP net income (1)	\$ 9,774	\$ 11,757	\$ (1,983)	(17)
Non-GAAP net income per share, diluted (1)	\$ 0.36	\$ 0.45	\$ (0.09)	(20)

(1) A reconciliation of our non-GAAP financial measures to the comparable GAAP measures is included below.

NM Not meaningful.

**Net Revenues**

*Net Product Sales.*

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CUROSURF net product sales increased \$1.4 million, or 6%, during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011, primarily due to increased unit volume, partially offset by an increase in our estimated rate for product returns.

ZYFLO CR and ZYFLO net product sales increased \$15.4 million, or 69%, during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 due to both an increase in unit volume and a price increase.

CARDENE I.V. net product sales were \$13.5 million during the nine months ended September 30, 2012. We acquired the CARDENE I.V. product rights in our acquisition of EKR on June 26, 2012, and net product sales include CARDENE I.V. sales following the acquisition date.

ALLERX Dose Pack net product sales decreased \$27.3 million during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011. There were no sales of ALLERX Dose Pack during the three months ended September 30, 2012 and, there are no future sales expected based on management's reasonable belief that all inventory in the channel has been previously sold and adequate reserves have been established for anticipated returns. In addition, during the nine months ended September 30, 2012, we recorded an additional reduction to revenue of \$1.3 million for product returns which exceeded our initial estimates.

Net product sales from our anti-infective products decreased \$7.9 million, or 70%, during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011, primarily due to our divestiture of the product rights and certain related assets and liabilities in early March 2012, partially offset by adjustments made to our prior estimates of sales allowances.

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Net product sales from other products increased \$2.9 million during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011. The primary reason for this increase was the approximately \$3.9 million of propoxyphene/acetaminophen product returns in the three months ended September 30, 2011 resulting from our voluntary withdrawal of these products from the market. Excluding the impact of these returns, our net product sales from other products decreased approximately \$1.0 million due to the elimination of certain products from our portfolio.

*Costs and Expenses*

*Cost of Product Sales.* Cost of product sales (exclusive of amortization of product rights of \$13.8 million and \$13.3 million for the nine months ended September 30, 2012 and 2011, respectively) increased \$2.8 million, or 10%, during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 primarily due to the addition of CARDENE I.V. for which acquired inventory was recorded at fair value. The total accounting adjustment was \$3.1 million. Cost of product sales consists primarily of standard costs for each of our commercial products, distribution costs, royalties and inventory allowances.

Gross profit (exclusive of license and royalty agreement revenues and amortization of product rights) was as follows (dollars in thousands):

	Nine Months Ended		Change	
	September 30, 2012	September 30, 2011	\$	%
Net product sales	\$ 81,153	\$ 83,117	\$ (1,964)	(2)%
Cost of product sales (exclusive of amortization of product rights)	31,984	29,183	2,801	10
Gross profit	\$ 49,169	\$ 53,934	(4,765)	(9)
Gross margin	61%	65%		

Gross margin of net product sales for the nine months ended September 30, 2012 decreased four percentage points compared to the nine months ended September 30, 2011. This decrease was due to the addition of CARDENE I.V. to our product mix, which has a lower gross margin than ALLERX, partially offset by a decrease in royalty expenses. We have not recognized any ALLERX net product sales after June 30, 2012.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses decreased \$3.4 million, or 9%, during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011. This decrease was primarily due to reductions in salaries, travel and other related employee benefits related to respiratory sales force and sample costs resulting from our divestiture of our Factive and Spectracef product rights and our respiratory sales force in March 2012, partially, offset by increased copromotion expense and spending for marketed product support related to ZYFLO.

*Research and Development Expenses.* Research and development expenses increased \$2.4 million, or 172%, during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011. This increase was primarily driven by development costs related to CRTX 080, which we acquired in December 2011 from Cardiokine, as well as certain costs we incurred to advance the regulatory approval of the sBLA for RETAVASE, which we acquired in connection with our June 2012 acquisition of EKR. These costs were offset by a reduction in spend related to CRTX 073 and our Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended Release Suspension product during the nine months ended September 30, 2012 due to the timing of our product development expenses, which remains consistent with our development plan.

*Gain on Divestiture of Product Rights.* In March 2012, we entered into asset purchase agreements with each of Merus Labs International Inc., or Merus, and Vansen Pharma Inc., or Vansen, pursuant to which we sold all of our rights to the anti-infective drugs Factive and Spectracef, which resulted in a net gain on the divestiture of \$1.5 million for the nine months ended September 30, 2012. In connection with the sale of our rights to Spectracef and Factive, we divested approximately \$3.8 million in product rights, net of accumulated amortization, \$2.5 million in inventory and product samples, and other assets of \$1.4 million. In addition, Vansen and Merus assumed product-related liabilities of approximately \$4.1 million. Total cash consideration for the divestiture was \$6.2 million, of which \$1.2 million was recorded as a receivable from the buyers. Under the asset purchase agreement for Factive, we retained certain royalty obligations to LG Life Sciences, Ltd. and Oscient Pharmaceuticals Corporation through the end of September 30, 2014. We recorded a contingent liability of \$1.1 million based on the estimated fair value of these obligations, which is included in other current and other long-term liabilities.

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*Transaction-related Expenses.* Transaction-related expenses were \$7.9 million during the nine months ended September 30, 2012, of which \$7.3 million related to our acquisition of EKR.

*Amortization of Product Rights.* Amortization of product rights increased \$497,000, or 4%, during the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011. This increase was primarily due to \$2.3 million of amortization related to our CARDENE I.V. product rights which we acquired on June 26, 2012, partially offset by the impact of the \$2.5 million impairment of product rights recorded as amortization during the nine months ended September 30, 2011, when we made the decision to not pursue several product development projects that no longer aligned with our strategic focus.

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*Change in Acquisition-related Contingent Payments.* Acquisition-related contingent payments were adjusted by \$1.6 million during the nine months ended September 30, 2012 due to a fair value adjustment based on revised forecasted sales related to CARDENE I.V.

### *Benefit from (Provision for) Income Taxes*

The benefit from income taxes was \$3.0 million for the nine months ended September 30, 2012 compared to a provision of \$1.1 million for the nine months ended September 30, 2011. Our effective tax rates for the nine months ended September 30, 2012 and 2011 were 38.1% and 34.7%, respectively. The change in the effective tax rate was primarily due to the tax impact of nondeductible transaction costs incurred in connection with the acquisition of EKR and our projected losses for 2012 as compared to 2011.

### *Reconciliation of Non-GAAP Financial Measures*

To supplement the consolidated financial statements presented in accordance with GAAP, we use non-GAAP measures of certain components of financial performance. These non-GAAP measures include non-GAAP operating income, non-GAAP net income and non-GAAP net income per diluted share. Our management regularly uses supplemental non-GAAP financial measures to understand, manage and evaluate our business and make operating decisions. These non-GAAP measures are among the primary factors management uses in planning for and forecasting future periods.

These non-GAAP measures are not in accordance with, or an alternative to, measures prepared in accordance with GAAP and may be different from similarly titled non-GAAP measures used by other companies. In addition, these non-GAAP measures are not based on any comprehensive set of accounting rules or principles. The additional non-GAAP financial information presented herein should be considered in conjunction with, and not as a substitute for, or superior to, the financial information presented in accordance with GAAP (such as operating income (loss), net income (loss) and earnings (loss) per share) and should not be considered measures of our liquidity. These non-GAAP measures should only be used to evaluate our results of operations in conjunction with the corresponding GAAP measures.

The non-GAAP financial measures reflect adjustments for stock-based compensation expense, amortization of product rights, amortization of debt financing costs, acquisition adjustments related to inventory sold, transaction-related expenses, the change in acquisition-related contingent payments, and the gain on the divestiture of certain product rights. We exclude these items from our non-GAAP measures because we believe that their exclusion provides an additional means to assess the extent to which our efforts and execution of our strategy are reflected in our operating results. In particular, stock-based compensation expense is excluded primarily because it is a non-cash expense that is determined based on subjective assumptions, product rights amortization is excluded because it is not reflective of the cash-settled expenses incurred related to product sales; debt financing costs amortization is excluded because it is not reflective of the cash-settled expenses incurred related to the Term Loans; and the acquisition adjustment related to inventory sold, transaction-related expenses, our gain on acquisition contingent payments, and our gain on the divestiture of certain product rights are excluded because management believes they have no direct correlation to current operating results. Our management believes that these non-GAAP measures, when shown in conjunction with the corresponding GAAP measures, enhance investors' and management's overall understanding of our current financial performance and our prospects for the future.

The non-GAAP measures are subject to inherent limitations because (1) they do not reflect all of the expenses associated with the results of operations as determined in accordance with GAAP and (2) the exclusion of these items involved the exercise of judgment by management. Even though we have excluded stock-based compensation expense, amortization of product rights, amortization of debt financing costs, acquisition adjustments related to inventory sold, transaction-related expenses, the change in acquisition-related contingent payments, and the gain from the divestiture of product rights from the non-GAAP financial measures, stock-based compensation is an integral part of our compensation structure, the acquisition of additional companies and/or product rights and the divestiture of our Factive and Spectracef product rights are an important part of our business strategy, we have incurred substantial indebtedness to fund our growth strategy and transaction-related expenses, whether or not the transaction is successfully closed, may be significant cash expenses.



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The following tables reconcile our non-GAAP measures to the most directly comparable GAAP financial measures (in thousands, except share and per share data):

	For the three months ended September 30,		For the nine months ended September 30,	
	2012	2011	2012	2011
GAAP income (loss) from operations	\$ 2,723	\$ 191	\$ (5,953)	\$ 3,271
Add: stock-based compensation	684	702	2,027	1,586
Add: amortization of product rights	5,284	3,591	13,774	13,277
Add: amortization of debt financing costs	26		26	
Add: acquisition adjustments related to inventory sold	2,902		3,061	
Add: transaction-related expenses	1,764		7,944	
Less: change in acquisition-related contingent payments	(1,574)		(1,574)	
Less: gain on divestiture of product rights			(1,492)	
<b>Non-GAAP income from operations</b>	<b>\$ 11,809</b>	<b>\$ 4,484</b>	<b>\$ 17,813</b>	<b>\$ 18,134</b>
GAAP net income (loss)	\$ 1,249	\$ 117	\$ (4,929)	\$ 2,056
Add: stock-based compensation	684	702	2,027	1,586
Add: amortization of product rights	5,284	3,591	13,774	13,277
Add: amortization of debt financing costs	26		26	
Add: acquisition adjustments related to inventory sold	2,902		3,061	
Add: transaction-related expenses	1,764		7,944	
Less: change in acquisition-related contingent payments	(1,574)		(1,574)	
Less: gain on divestiture of product rights			(1,492)	
Less: tax effects related to above items (1)	(4,686)	(1,010)	(9,063)	(5,162)
<b>Non-GAAP net income</b>	<b>\$ 5,649</b>	<b>\$ 3,400</b>	<b>\$ 9,774</b>	<b>\$ 11,757</b>
GAAP net income (loss) per share, diluted	\$ 0.05	\$ 0.00	\$ (0.19)	\$ 0.08
<b>Non-GAAP net income per share, diluted (2)</b>	<b>\$ 0.19</b>	<b>\$ 0.13</b>	<b>\$ 0.36</b>	<b>\$ 0.45</b>
Shares used in diluted net income (loss) per share calculation:				
GAAP net income (loss)	26,603,258	26,331,700	26,040,695	26,223,317
Non-GAAP net income	30,829,800	26,331,700	27,948,621	26,223,317

- (1) Tax effects for the three months ended September 30, 2012 and 2011 are calculated using effective tax rates of 51.6% and 23.5% respectively. Tax effects for the nine months ended September 30, 2012 and 2011 are calculated using effective tax rates of 38.1% and 34.7% respectively.
- (2) The convertible term loan was determined to be dilutive to non-GAAP net income per share, diluted for the three and nine months ended September 30, 2012. As such, for the three and nine months ended September 30, 2012, non-GAAP net income was adjusted for \$245,000 and \$330,000 of interest expense related to the convertible term loan, net of tax effects, respectively. Non-GAAP net income adjusted for the related interest expense, net of tax effects, was divided by the sum of the weighted-average number of common shares and dilutive common share equivalents outstanding during the periods, as adjusted for the impact of the shares related to the convertible debt of approximately, or 4.2 million and 1.5 million shares for the three and nine months ended September 30, 2012, respectively.

**Liquidity and Capital Resources***Sources of Liquidity*

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We require cash to meet our operating expenses and for capital expenditures, acquisitions and in-licenses of rights to products. To date, we have funded our operations primarily from proceeds from our product sales, royalty agreement revenues and the investment from Chiesi. In June 2012, we entered into the Term Loans with Chiesi with proceeds of \$90.0 million, which are described below. These proceeds were used to fund our acquisition of EKR, along with \$36.4 million of our cash at the time of closing. As of September 30, 2012, we had \$34.2 million in cash and cash equivalents.

**Table of Contents****Cash Flows**

The following table provides information regarding our cash flows (in thousands):

	Nine Months Ended September 30,	
	2012	2011
Cash (used in) provided by:		
Operating activities	\$ (5,785)	\$ 30,351
Investing activities	(123,186)	(574)
Financing activities	89,182	819
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>\$ (39,789)</b>	<b>\$ 30,596</b>

*Net Cash (Used In) Provided By Operating Activities*

Our primary sources of operating cash flows are product sales. Our primary uses of cash in our operations are for funding working capital, selling, general and administrative expenses, royalties and transaction-related expenses.

Net cash used in operating activities for the nine months ended September 30, 2012 reflected our net loss of \$4.9 million, adjusted by non-cash expenses totaling \$18.5 million and changes in operating assets and liabilities from December 31, 2011 to September 30, 2012 totaling \$19.4 million. Accounts receivable and inventory increased by \$7.7 million and \$1.0 million, respectively, from December 31, 2011 to September 30, 2012. Prepaid expenses and other assets decreased by \$8.3 million, primarily due to tax refunds that were received and paid to the former shareholders of Cardiokine. Accounts payable, accrued expenses and other liabilities decreased by \$16.7 million from December 31, 2011 to September 30, 2012, primarily due to payments of liabilities acquired and decreases in certain sales allowances including those related to our divestiture of the anti-infective products. Income taxes receivable increased by \$2.3 million from December 31, 2011 to September 30, 2012.

Net cash provided by operating activities for the nine months ended September 30, 2011 reflected our net income of \$2.1 million, adjusted by non-cash expenses totaling \$35.3 million and changes in accounts receivable, inventories, deferred revenue, income taxes payable, accrued expenses and other operating assets and liabilities totaling \$63.6 million.

*Net Cash Used in Investing Activities*

Net cash used in investing activities for the nine months ended September 30, 2012 reflected approximately \$126 million of cash paid for our acquisition of EKR, net of cash acquired, \$3.0 million of proceeds allocated to the divested anti-infective product rights and purchase of property and equipment for \$265,000.

Net cash used in investing activities for the nine months ended September 30, 2011 reflected the purchase of property and equipment for \$574,000.

*Net Cash Provided by Financing Activities*

Net cash provided by financing activities for the nine months ended September 30, 2012 primarily reflected the proceeds from our long-term debt of \$90.0 million, proceeds from common stock option exercises of \$1.2 million and an excess tax benefit from stock compensation of \$284,000, partially offset by contingent payments relating to the acquisition-related contingent consideration with respect to CARDENE I.V. of \$1.6 million and payment of debt financing costs of \$511,000.

Net cash provided by financing activities for the nine months ended September 30, 2011 reflected proceeds from common stock option exercises of \$368,000 and an excess tax benefit from stock options of \$513,000, partially offset by principal payments on capital leases of \$62,000.

**Funding Requirements**

Our future capital requirements will depend on many factors, including the:

level of product sales and product returns of our currently marketed products and any additional products that we may market in the future;

scope, progress, results and costs of development activities for our current product candidates;

costs, timing and outcome of regulatory review of our product candidates;

number of, and development requirements for, additional product candidates that we pursue;

extent to which we acquire or invest in products, businesses and technologies;

costs of commercialization activities, including product marketing, sales and distribution;

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costs and timing of establishing manufacturing and supply arrangements for clinical and commercial supplies of our product candidates and products;

extent to which we are required to make mandatory prepayments and the required principal and interest payments related to our Term Loans;

extent to which we are required to make certain contingent payments in connection with our acquisitions;

extent to which we choose to establish collaboration, co-promotion, distribution or other similar arrangements for our marketed products and product candidates; and

costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending claims related to intellectual property owned by or licensed to us.

To the extent that our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. We have no committed external sources of funds. Additional equity or debt financing, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

As of September 30, 2012, we had \$34.2 million of cash and cash equivalents on hand. Based on our current operating plans, we believe that our existing cash and cash equivalents and anticipated revenues from product sales are sufficient to continue to fund our existing level of operating expenses, capital expenditure, debt service and acquisition-related contingent payment requirements for at least the next twelve months.

**Contractual Obligations**

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent contractual liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing, contingent royalty payments and/or scientific, regulatory or commercial milestone payments under development agreements. There have been no material changes outside the ordinary course of business to our contractual obligations during the nine months ended September 30, 2012 except for obligations that were transferred in connection with the divestiture of our anti-infective product rights, long-term debt entered into in June 2012 and contractual obligations assumed in connection with our acquisition of EKR. The following table summarizes our contractual obligations as of September 30, 2012 (in thousands):

Contractual Obligations	Total	Payments Due by Period			
		Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Long-term debt obligations (1)	\$ 117,356	\$ 1,648	\$ 16,579	\$ 38,693	\$ 60,436
Capital lease obligations	90	10	67	13	
Operating lease obligations (2)	2,050	150	1,149	751	
Purchase obligations (3)	67,362	13,142	36,447	17,533	240
<b>Total (4)</b>	<b>\$ 186,858</b>	<b>\$ 14,950</b>	<b>\$ 54,242</b>	<b>\$ 56,990</b>	<b>\$ 60,676</b>

- (1) Long-term debt obligations represent future minimum principal and interest payments due under both our Term Loan A and Term Loan B assuming that the loans remain outstanding until maturity, the conversion option for Term Loan B is not exercised and the default rate of

interest is not triggered.

- (2) Operating leases represent minimum payments under leases for our facilities, automobiles and certain equipment. Our total minimum lease payments for our corporate headquarters are \$491,000 in 2012 (of which we paid \$355,000 during the first nine months of 2012), \$536,000 in 2013, \$584,000 in 2014, \$599,000 in 2015 and \$152,000 thereafter.
- (3) Purchase obligations represent fixed or minimum payments under manufacturing and supply agreements with third-party manufacturers of \$38.6 million; clinical trial and research agreements with contract research organizations and consultants of \$3.1 million; agreements with providers of marketing analytical services of \$2.7 million; and open purchase orders for the acquisition of goods and services in the ordinary course of business of \$23.0 million.
- (4) Excluded from the contractual obligations table are (i) potential payments of up to \$169 million for contingent consideration that we may be required to pay in connection with our acquisitions of Cardiokine and EKR; (ii) \$8.4 million in potential future milestone payments as part of our other licensing, distribution and development agreements; (iii) a contingent liability of \$1.1 million related to our divestiture of Factive; and (iv) anticipated payments under the assumed contingent consideration arrangement related to the ready-to-use formulation of CARDENE I.V., which is based on a percentage of net sales. We have excluded these potential liabilities and milestone payments from the contractual obligations table because we are unable to precisely predict the timing or ultimate cash settlement amounts of these payments.

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### ***Term Loan Facility***

On June 21, 2012, we entered into the Credit Agreement with Chiesi in connection with our acquisition of EKR. The Credit Agreement governs the senior secured term loan facility with Chiesi (the Term Loan Facility), which is comprised of a five-year Term Loan A of \$60.0 million and five-year Term Loan B of \$30.0 million, which we refer to as the Term Loans. The Term Loans were funded on June 25, 2012 and the acquisition of EKR closed on June 26, 2012. The proceeds of the Term Loan Facility were used, together with our cash on hand, to finance the acquisition of EKR and the related fees and expenses incurred by us in connection with the acquisition. All obligations under the Term Loan Facility are guaranteed by our domestic subsidiaries, and are secured by a security interest in substantially all of the assets of the Company and its domestic subsidiaries. Under the Credit Agreement, Chiesi is the administrative agent and collateral agent in respect of the Term Loan Facility.

Term Loan A and Term Loan B bear interest at rates of 7.5% and 6.5% per year, respectively, payable quarterly in arrears on the last business day of each fiscal quarter beginning on September 28, 2012. Term Loan A requires quarterly principal payments of \$3.5 million commencing on the fiscal quarter ending December 31, 2014 with any balance due at maturity. The Term Loans are due and payable on June 23, 2017, unless previously prepaid or in the case of Term Loan B, converted into shares of common stock, prior to such date.

We may prepay the Term Loans, in whole or in part without any premium or penalty, provided any prepayments of principal amounts are \$5.0 million or whole multiples of \$1.0 in excess thereof, plus any accrued and unpaid interest. The prepayments will be applied first, ratably to the remaining installments of principal of the Term Loan A (excluding the payment due at maturity), second, to any remaining amounts outstanding on Term Loan A, and third, to the outstanding principal on Term Loan B.

We are required to prepay all or a portion of the Term Loan Facility under the following conditions: (i) if our ratio of consolidated secured debt to Consolidated EBITDA (as defined in the Credit Agreement) is at least 2 to 1 for any fiscal year ending on or after December 31, 2013, by using 50% of our Consolidated Excess Cash (as defined in the Credit Agreement), or (ii) if we undertake certain asset sales or sales of capital stock and do not reinvest the proceeds according to the terms of the Credit Agreement.

Term Loan B contains a conversion option for a two-year period, expiring on June 21, 2014, which provides Chiesi the option, exercisable in its sole discretion, to convert all or a portion of the Term Loan B into shares of common stock at a conversion price equal to \$7.098 per share, subject to adjustment under certain conditions. Conversions shall be no less than \$5.0 million unless the remaining principal amount of Term Loan B is less than \$5.0 million.

The Term Loans are collateralized by substantially all of our assets, including the assets of our subsidiaries that are guarantors of the Term Loans. The Credit Agreement contains customary representations, covenants and events of default. Upon an Event of Default (as defined in the Credit Agreement), (i) the interest rates for Term Loan A and Term Loan B will each increase by 2% and (ii) Chiesi may declare all outstanding principal and accrued but unpaid interest under the Term Loan Facility to be immediately due and payable. In addition, we are subject to covenants prohibiting the payment of any dividends (other than stock dividends) and restricting or limiting other restricted payments, certain corporate activities, transactions with affiliates, incurrence of debt (which debt limit expressly permits, among other things, a secured working capital facility of up to \$25 million), liens on properties and asset dispositions. We are not subject to any financial covenants other than the mandatory prepayment provisions discussed above.

In connection with the Term Loans, we incurred \$511,000 of debt financing costs, which primarily consisted of legal and other professional fees. These costs are being amortized and are recorded as additional interest expense through the maturity of the loans.

### **Off-Balance Sheet Arrangements**

Since inception, we have not engaged in any off-balance sheet arrangements, including structured finance, special purpose entities or variable interest entities.

### **Critical Accounting Policies and Estimates**

Our consolidated financial statements have been prepared in accordance with GAAP. For information regarding our critical accounting policies and estimates, please refer to Management's Discussion and Analysis of Financial Condition and Results of Operations-Critical Accounting Policies and Estimates contained in our annual report on Form 10-K for the year ended December 31, 2011 and Note 2 to our consolidated financial statements contained therein. There have been no material changes to the critical accounting policies previously disclosed in that report, except as disclosed below.

*Inventory*

Inventory consists of raw materials, work in process and finished goods. Raw materials include the API for a product to be manufactured, work in process includes the bulk inventory of tablets or liquids that are in the process of being coated and/or packaged for sale, and finished goods include pharmaceutical products ready for commercial sale or distribution as samples. Inventory is stated at the lower of cost or market value with cost determined under the first-in, first-out (FIFO) method. Our estimate of the net realizable value of our inventories is subject to judgment and estimation. The actual net realizable value of our inventories could vary



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significantly from our estimates and could have a material effect on our financial condition and results of operations in any reporting period. In evaluating whether inventory is stated at the lower of cost or market, we consider such factors as the amount of inventory on hand and in the distribution channel, estimated time required to sell such inventory, remaining shelf life and current and expected market conditions, including levels of competition. On a quarterly basis, we analyze our inventory levels and record allowances for inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory that is in excess of expected demand based upon projected product sales. As of September 30, 2012, we had \$38.2 million in inventory, which was net of an inventory reserve of \$1.9 million.

We expense costs relating to the purchase and production of pre-approval inventories for which the sole use is pre-approval products as research and development expense in the period incurred until such time as we believe future commercialization is probable and future economic benefit is expected to be recognized. With respect to capitalization of unapproved product candidates, we produce inventory in preparation for the launch of the product and in amounts sufficient to support forecasted initial market demand. Typically, capitalization of such inventory does not begin until the product candidate is considered to have a high probability of regulatory approval. This generally will occur only after we have submitted an NDA to the FDA, and only if our assessment of the status of the regulatory review has led us to conclude there is a high probability of receiving regulatory approval. If we are aware of any specific risks or contingencies that are likely to impact the regulatory approval process or if there are any specific issues identified during our research and development process relating to safety, efficacy or manufacturing of the product candidate, we would not capitalize the related inventory.

We manage the levels of inventory at each stage of the manufacturing process to optimize the shelf life of the inventory and avoid product expiration issues relative to anticipated market demand following launch. On a quarterly basis, we evaluate all inventory, including inventory capitalized for which regulatory approval has not yet been obtained, to determine if any lower of cost or market adjustment is required. As our evaluation relates to pre-approval inventory, we consider several factors, including expected timing of FDA approval, projected sales volume, expiration dates of the inventory and estimated selling price. Projected sales volume is based on several factors including market research, sales of similar products and competition in the market. Estimated sales price is based on the price of existing products sold for the same indications, market research and expected market demand.

Once we have capitalized inventory for a product candidate that is not yet approved, we will monitor, on a quarterly basis, the status of such candidate within the regulatory approval process. We could be required to expense previously capitalized costs related to pre-approval inventory upon a change in our judgment of future commercialization and future economic benefit expected to be recognized, due to a denial or delay of approval by the FDA, a delay in the timeline for commercialization or other potential factors. At September 30, 2012, pre-approval inventory included \$14.3 million of costs capitalized as raw materials and work in process prior to regulatory approval of the sBLA for RETAVASE.

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

#### **Interest Rate Risk**

Our exposure to market risk is confined to our cash equivalents, all of which have maturities of less than three months and bear and pay interest in U.S. dollars. Since we invest in highly liquid, relatively low yield investments, we do not believe interest rate changes would have a material impact on us.

Our risk associated with fluctuating interest expense includes future capital leases and other short-term debt obligations we may incur in our normal operations.

As of September 30, 2012, our outstanding long-term debt of \$89.5 million in principal consists of two fixed rate Term Loans which do not expose us to risk related to rising interest rates. We do not have any other instruments with interest rate exposure.

#### **Foreign Currency Exchange Risk**

The majority of our transactions occur in U.S. dollars and we do not have investments in foreign countries. Therefore, we are not subject to significant foreign currency exchange risk. We currently have one supply agreement denominated in Euros and two development agreements denominated in foreign currencies, Euros and Swiss francs, respectively. Unfavorable fluctuations in these exchange rates could have a negative impact on our consolidated financial statements. The impact of changes in the exchange rates related to these contracts was immaterial to our consolidated financial statements for the three and nine months ended September 30, 2012 and 2011. To date, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. These circumstances may change.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures**

As of September 30, 2012, our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(b) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of September 30, 2012, our disclosure controls and procedures were effective in ensuring that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, including ensuring that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

#### **Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

Please see Part I Item 3. Legal Proceedings of our annual report on Form 10-K for the year ended December 31, 2011 for a description of certain pending legal proceedings to which we are subject. There have been no material developments in these legal proceedings since the filing of the Form 10-K on March 6, 2012 except as disclosed below.

#### **ONY Litigation**

On December 2, 2011, ONY, Inc., or ONY, the maker of Infasurf<sup>®</sup>, a natural lung surfactant that is a competitor to CUROSURF, filed suit in United States District Court for the Western District of New York against us, Chiesi, and various other individuals and entities in connection

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with an article appearing in the September 2011 issue of the *Journal of Perinatology*, based on a retrospective study sponsored by Chiesi, that concluded that Infasurf was associated with significantly higher mortality rates than CUROSURF. ONY alleged that the article was false and misleading because it did not discuss all of the relevant data and literature and the underlying study was based on manipulated data. ONY asserted a claim under federal law against us for false advertising based on our dissemination of and references to the article in our promotional activities, as well as state law claims for tortious interference with existing and prospective contracts, injurious falsehood and violation of New York's deceptive trade practices statute.

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On January 17, 2012, we filed a motion to dismiss the action for failure to state a claim on which relief could be granted and on May 18, 2012 the Court issued an order granting the motion to dismiss. On June 14, 2012, ONY notified the United States Court of Appeals for the Second Circuit that it intended to appeal that order. Appellate briefs are expected to be filed with the court in the coming weeks.

### **Propoxyphene Litigation**

On January 11, 2012, we were served with a complaint in the California Superior Court for the County of San Francisco by Mary and George Keene and 30 other individual plaintiffs. The suit names numerous pharmaceutical companies, including Cornerstone BioPharma, Inc. and Cornerstone BioPharma Holdings, Inc., which are two of our subsidiaries. The plaintiffs allege that they (or decedents) suffered personal injury related to their ingestion of prescription medication containing the active pharmaceutical ingredient, or API, propoxyphene marketed and sold as generic and/or brand-name drugs under various names by the defendant companies. The plaintiffs seek compensatory and exemplary damages, together with interest, costs of suit, attorneys' fees, leave to amend as additional facts are gathered, and any other relief that the court deems just, equitable, and proper. The suit was removed to the United States District Court for the Northern District of California on January 23, 2012, the suit was stayed in the Northern District on February 1, 2012, and the suit was transferred to the pending Multi District Litigation, or MDL, proceedings in the United States District Court, Eastern District of Kentucky (Northern Division) on March 2, 2012. On July 4, 2012, Plaintiffs filed a motion to remand the case to the Superior Court of the State of California, San Francisco County and that motion was granted and the case was remanded on September 13, 2012.

In February 2012, we were served with complaints in four additional cases: one in Tennessee (*Anderson, et al. v. Eli Lilly and Company, et al.*, U.S. District Court, Eastern District of Tennessee (Greeneville), filed November 18, 2011); another in Tennessee (*Holland, individually and as Administrator of the Estate of Mary Taylor v. Eli Lilly and Company, et al.*, U.S. District Court, Western District of Tennessee (Jackson), filed November 18, 2011); one in Mississippi (*McAlpine v. Eli Lilly and Company, et al.*, U.S. District Court, Northern District of Mississippi (Western Division), filed November 18, 2011); and one in Louisiana (*Reynolds v. Eli Lilly and Company, et al.*, U.S. District Court, Eastern District of Louisiana (New Orleans), filed November 17, 2011). The suits name numerous pharmaceutical companies, including Cornerstone BioPharma, Inc. and Cornerstone BioPharma Holdings, Inc., and one suit names Aristos. The plaintiffs in the lawsuits generally allege that they (or decedents) suffered personal injury related to their ingestion of prescription medication containing the API propoxyphene, marketed and sold as generic and/or brand-name drugs under various names by the defendant companies. The plaintiffs seek compensatory and exemplary damages, together with interest, costs of suit, attorneys' fees, leave to amend as additional facts are gathered, and any other relief that the court deems just, equitable, and proper. All four cases have been consolidated with the MDL proceedings in the United States District Court, Eastern District of Kentucky (Northern Division).

On November 15, 2011, a motion was filed to dismiss plaintiffs' complaints in multiple cases pending in the MDL proceedings on the basis of preemption. On June 22, 2012, the Court issued an order dismissing all generic defendants from the cases pending in the MDL proceedings, including Cornerstone BioPharma Inc., Cornerstone BioPharma Holdings Inc., and Aristos Pharmaceuticals, Inc. from the *Anderson, Holland, McAlpine*, and *Reynolds* cases. That ruling has been appealed, but the court has not yet set a briefing schedule.

### **ITEM 1A. RISK FACTORS**

We operate in a rapidly changing environment that involves a number of risks that could materially and adversely affect our business, financial condition, prospects, operating results or cash flows. For a detailed discussion of the risk factors that should be understood by any investor contemplating an investment in our stock, please refer to Item 1A of our annual report on Form 10-K for the year ended December 31, 2011, which was filed with the SEC on March 6, 2012. There have been no material changes from the risk factors previously disclosed in that annual report on Form 10-K.

***We have incurred and may in the future incur significant indebtedness, which indebtedness may restrict the manner in which we conduct business and limit our ability to implement elements of our growth strategy.***

We have incurred significant indebtedness in connection with our recent acquisition of EKR. Subject to the terms of our existing indebtedness, we may also incur additional indebtedness to meet future financing needs, which would increase our total debt. Our current indebtedness contains (and any future indebtedness may contain) restrictions on the manner in which we conduct our business and limitations on our ability to implement elements of our growth strategy, including with respect to:

limitations on our ability to obtain additional debt financing;

the allocation of a substantial portion of our cash flow from operations to service our debt, thus reducing the amount of our cash flow available for other purposes;

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requiring us to issue debt or equity securities or to sell some of our core assets, possibly on unfavorable terms, to meet payment obligations;

compromising our flexibility to plan for, or react to, competitive challenges in our business;

the possibility that we are put at a competitive disadvantage relative to competitors that do not have as much debt as us, and competitors that may be in a more favorable position to access additional capital resources; and

limitations on our ability to execute business development activities to support our strategies.

*To service our Term Loan Facility, we will require a significant amount of cash. Our ability to generate cash depends on many factors beyond our control.*

Our ability to make the payments required under our Term Loan Facility will depend on our ability to generate cash in the future. Our ability to generate cash is, to a certain extent, subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control. Our business may not generate sufficient cash flow from operations to enable us to pay our indebtedness or to fund our other liquidity needs. We may need to refinance all or a portion of our indebtedness on or before maturity, sell assets, reduce or delay capital expenditures, seek additional equity financing or seek third-party financing to satisfy such obligations. We may not be able to refinance any of our indebtedness on commercially reasonable terms or at all. Our inability to satisfy our obligations under our existing and any future indebtedness could materially and adversely affect our financial condition and business.

*If we do not comply with the covenants in the Credit Agreement governing the Term Loan Facility or otherwise default under the Credit Agreement, we may not have the funds necessary to pay all of our indebtedness that could become due.*

The Credit Agreement requires us to comply with certain covenants. In particular, the Credit Agreement prohibits us from incurring any additional indebtedness, except in specified circumstances. The Credit Agreement also restricts our ability to acquire and dispose of assets, engage in mergers and reorganizations, or make investments. A violation of any of these covenants could cause an event of default under the Credit Agreement.

If we default under the Credit Agreement because of a covenant breach or otherwise, all outstanding amounts could become immediately due and payable. We may not have sufficient funds or the ability to raise sufficient funds to repay all of the outstanding amounts, and any acceleration of amounts due under the Credit Agreement would materially and adversely affect our financial condition and our business.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

The following table lists all repurchases during the three months ended September 30, 2012 of our common stock by or on behalf of us or any affiliated purchaser.

**Issuer Purchases of Equity Securities**

	Total Number of Shares Purchased (1)	Average Price Paid per Share (2)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs
July 1, 2012 - July 31, 2012		\$	\$	\$
August 1, 2012 - August 31, 2012	847	7.22		
September 1, 2012 - September 30, 2012	6,101	6.29		

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Total	6,948	\$	6.40	\$	\$
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- (1) Represents shares that were surrendered to us by holders of restricted common stock under the 2004 Stock Incentive Plan to satisfy employee tax withholding obligations arising in connection with the vesting of their shares. We subsequently retired all of these surrendered shares.
- (2) Represents the average price paid per share for shares surrendered to us in satisfaction of employee tax withholding obligations.

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**ITEM 6. EXHIBITS**

The exhibits listed in the accompanying exhibit index are filed as part of this quarterly report on Form 10-Q, and such exhibit index is incorporated by reference herein.



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**SIGNATURES**

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

**CORNERSTONE THERAPEUTICS INC.**

Date: November 8, 2012

/s/ Craig Collard  
Craig Collard  
*Chief Executive Officer*  
*(Principal Executive Officer)*

Date: November 8, 2012

/s/ Alastair McEwan  
Alastair McEwan  
*Chief Financial Officer and Treasurer*  
*(Principal Financial Officer)*

Date: November 8, 2012

/s/ Ira Duarte  
Ira Duarte  
*Director, Accounting and Financial Planning and Analysis*  
*(Principal Accounting Officer)*

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**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the Unaudited Consolidated Balance Sheets, (ii) the Unaudited Consolidated Statements of Comprehensive Income (Loss), (iii) the Unaudited Consolidated Statements of Cash Flows, and (iv) Notes to Unaudited Consolidated Financial Statements.

\* Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.