

CORNERSTONE THERAPEUTICS INC

Form 10-Q

August 09, 2012

[Table of Contents](#)

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 June 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)

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

Delaware (State or Other Jurisdiction of Incorporation or Organization)	04-3523569 (I.R.S. Employer Identification No.)
1255 Crescent Green Drive, Suite 250 Cary, North Carolina (Address of Principal Executive Offices)	27518 (Zip Code)
(919) 678-6611 (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 August 2, 2012, the registrant had 26,367,090 shares of Common Stock, \$0.001 par value per share, outstanding.

Table of Contents

CORNERSTONE THERAPEUTICS INC.

FORM 10-Q

TABLE OF CONTENTS

	Page
<u>PART I FINANCIAL INFORMATION</u>	3
<u>Cautionary Statement Regarding Forward-Looking Statements</u>	3
Item 1. <u>Financial Statements</u>	4
<u>Consolidated Balance Sheets as of June 30, 2012 (Unaudited) and December 31, 2011</u>	4
<u>Consolidated Statements of Comprehensive (Loss) Income for the Three and Six Months Ended June 30, 2012 and 2011 (Unaudited)</u>	5
<u>Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2012 and 2011 (Unaudited)</u>	6
<u>Notes to Consolidated Financial Statements (Unaudited)</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	32
Item 4. <u>Controls and Procedures</u>	32
<u>PART II OTHER INFORMATION</u>	32
Item 1. <u>Legal Proceedings</u>	32
Item 1A. <u>Risk Factors</u>	33
Item 2. <u>Unregistered Sales of Securities and Use of Proceeds</u>	34
Item 6. <u>Exhibits</u>	35
<u>SIGNATURES</u>	36
<u>EXHIBIT INDEX</u>	37

Table of Contents

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 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. 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 that convey uncertainty of future events or outcomes in 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®; 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)**

	June 30, 2012 (Unaudited)	December 31, 2011 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 38,558	\$ 73,968
Accounts receivable, net	19,566	11,894
Inventories, net	41,740	9,419
Prepaid expenses	3,567	3,753
Income tax receivable	1,691	1,900
Deferred income tax asset	36	2
Other current assets	14,389	6,112
Total current assets	119,547	107,048
Property and equipment, net	1,762	1,574
Product rights, net	253,050	106,960
Goodwill	37,473	15,218
Amounts due from related parties		38
Deferred income tax asset, less current portion		523
Other assets	179	953
Total assets	\$ 412,011	\$ 232,314
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 22,244	\$ 10,012
Accrued expenses	44,099	37,125
Acquisition-related contingent payments	6,134	
Deferred revenue	381	1,428
Other current liabilities	451	90
Total current liabilities	73,309	48,655
Acquisition-related contingent payments, less current portion	40,454	8,800
Long-term debt	89,489	
Deferred tax liability	32,765	
Other long-term liabilities	5,031	56
Total liabilities	241,048	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; 26,202,162 and 25,803,864 shares issued and outstanding as of June 30, 2012 and December 31, 2011, respectively	26	26

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

Additional paid-in capital	165,541	163,203
Retained earnings	5,396	11,574
Total stockholders' equity	170,963	174,803
Total liabilities and stockholders' equity	\$ 412,011	\$ 232,314

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Net revenues	\$ 21,471	\$ 28,039	\$ 43,632	\$ 58,036
Costs and expenses:				
Cost of product sales (exclusive of amortization of product rights)	8,901	9,189	17,587	19,223
Selling, general and administrative	8,890	11,604	19,812	24,874
Research and development	686	614	1,731	1,173
Gain on divestiture of product rights			(1,492)	
Transaction-related expenses	5,438		6,180	
Amortization of product rights	3,189	6,092	8,490	9,686
Total costs and expenses	27,104	27,499	52,308	54,956
(Loss) income from operations	(5,633)	540	(8,676)	3,080
Other expenses:				
Interest expense, net	(113)	(42)	(115)	(83)
Total other expenses	(113)	(42)	(115)	(83)
(Loss) income before income taxes	(5,746)	498	(8,791)	2,997
Benefit from (provision for) income taxes	1,393	(301)	2,613	(1,058)
Net (loss) income	\$ (4,353)	\$ 197	\$ (6,178)	\$ 1,939
Comprehensive (loss) income	\$ (4,353)	\$ 197	\$ (6,178)	\$ 1,939
Net (loss) income per share, basic	\$ (0.17)	\$ 0.01	\$ (0.24)	\$ 0.08
Net (loss) income per share, diluted	\$ (0.17)	\$ 0.01	\$ (0.24)	\$ 0.07
Weighted-average common shares, basic	26,058,941	25,673,667	25,937,656	25,577,314
Weighted-average common shares, diluted	26,058,941	26,246,073	25,937,656	26,167,997

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

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

	Six Months Ended June 30,	
	2012	2011
Cash flows from operating activities		
Net (loss) income	\$ (6,178)	\$ 1,939
Adjustments to reconcile net income to net cash (used in) provided by operating activities:		
Amortization and depreciation	8,788	7,429
Provision for prompt payment discounts	1,257	1,998
Provision for (recovery of) inventory allowances	261	(235)
Acquisition accounting adjustment on inventory sold	159	
Gain on sale of product rights	(1,492)	
Impairment of product rights		2,500
Stock-based compensation	1,343	884
Deferred revenue	(1,047)	(24,765)
Provision for deferred income taxes	(1,943)	468
Changes in operating assets and liabilities:		
Accounts receivable	(1,205)	48,645
Inventories	(1,080)	1,366
Prepaid expenses and other assets	6,995	9,009
Accounts payable	8,492	1,358
Accrued expenses	(17,414)	(7,925)
Income taxes receivable	209	(1,212)
Net cash (used in) provided by operating activities	(2,855)	41,459
Cash flows from investing activities		
Acquisition of business, net of cash acquired	(125,920)	
Purchase of property and equipment	(99)	(333)
Proceeds from sale of product rights	3,000	
Net cash used in investing activities	(123,019)	(333)
Cash flows from financing activities		
Proceeds from term loans	90,000	
Payment of debt financing costs	(511)	
Proceeds from exercise of common stock options and warrants	818	311
Excess tax benefit from stock-based compensation	256	452
Payments related to net settlement of restricted stock	(79)	
Principal payments on capital lease obligation	(20)	(41)
Net cash provided by financing activities	90,464	722
Net (decrease) increase in cash and cash equivalents	(35,410)	41,848
Cash and cash equivalents as of beginning of period	73,968	50,945
Cash and cash equivalents as of end of period	\$ 38,558	\$ 92,793

Supplemental schedule of non-cash investing and financing activities

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

Acquisition of business, contingent consideration at fair value \$ 37,788 \$

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

Table of Contents

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, niche respiratory 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 (loss) income. Transaction-related expenses previously included in selling, general and administrative expenses in the accompanying consolidated statements of comprehensive (loss) income 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 six month period ended June 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 June 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

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

The fair value for contingent consideration potentially payable related to our acquisition of EKR Holdings, Inc. and its wholly owned subsidiary, EKR Therapeutics, Inc. (collectively EKR), 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 unobservable inputs. At the acquisition date, the Company used a discounted cash flow analysis incorporating the probability of estimated future cash flows from potential milestones and royalty payments using a risk-

Table of Contents

adjusted discount rate. The liabilities will be evaluated for remeasurement at the end of each reporting period and any change will be recorded in the Company's consolidated statements of comprehensive (loss) income. The carrying amount of the liability may fluctuate significantly and actual amounts paid may be materially different from the carrying value of the liability. There were no events or circumstances that would have required a revaluation of the liability since the acquisition date.

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 six month periods ended June 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 June 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 June 30, 2012, inventories included \$13.9 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.

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 June 30, 2012 and December 31, 2011 (in thousands):

	June 30, 2012	December 31, 2011
Raw materials	\$ 8,983	\$ 2,791
Work in process	11,461	1,663
Finished goods:		
Pharmaceutical products - trade	22,859	4,566
Pharmaceutical products - samples	38	849
Total	43,341	9,869

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

Inventory allowances	(1,601)	(450)
Inventories, net	\$ 41,740	\$ 9,419

Table of Contents

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 six month periods ended June 30, 2012, cost of product sales included \$159,000 of acquisition accounting adjustments related to sales of acquired CARDENE® I.V. inventory that were 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		Six Months Ended	
	June 30,		June 30,	
	2012	2011	2012	2011
Gross product sales	\$ 30,288	\$ 44,277	\$ 64,474	\$ 95,472
Sales allowances	(8,817)	(16,313)	(20,846)	(37,533)
Net product sales	21,471	27,964	43,628	57,939
License and royalty agreement revenues		75	4	97
Net revenues	\$ 21,471	\$ 28,039	\$ 43,632	\$ 58,036

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. 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 June 30, 2012 and December 31, 2011, the Company had \$381,000 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. The deferred revenue is recognized when the product is sold through to the end user based upon estimates of prescriptions filled. To estimate product sold through to end users, the Company relies 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 is recorded net of estimated allowances for rebates, price adjustments, chargebacks, and prompt payment and other discounts. Estimated allowances are recorded and classified as accrued expenses in the accompanying consolidated balance sheets as of June 30, 2012 and December 31, 2011.

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 18-36 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.

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

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.

Table of Contents

The Company, from time to time, offers certain promotional product-related incentives to its customers. These programs include sample cards to retail consumers, certain product incentives to pharmacy customers and other sales stocking allowances. The Company has voucher programs for certain branded products 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. 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 90 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.

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 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. As of June 30, 2012, the assumptions used for determining the fair value of the contingent consideration arrangements have not changed significantly from those used at the acquisition date.

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 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
Total fair value of consideration	\$ 164,225

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.

Table of Contents

The Company's 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 is as follows (in thousands):

Cash	516
Accounts receivable, net	7,724
Inventory, net	32,226
Prepaid expenses and other assets	14,704
Identifiable intangibles at fair value	154,123
Deferred tax assets	28,873
Accounts payable	(2,690)
Accrued liabilities	(29,437)
Deferred tax liability related to intangibles acquired	(64,069)
Total identifiable net assets	\$ 141,970
Goodwill	22,255
Total fair value of consideration	\$ 164,225

The Company recorded \$154.1 million in identifiable intangible assets at fair value, of which \$158.4 million relates to acquired product rights and \$4.3 million 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 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. 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 corresponding with (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. These indemnification assets are classified in other current assets offset by liabilities classified in accrued expenses on the accompanying consolidated balance sheet as of June 30, 2012 and represent management's best estimates of these amounts at the acquisition date. 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 will be evaluated for remeasurement at the end of each reporting period and any change will be recorded in the Company's consolidated statement of comprehensive (loss) income. 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 six months ended June 30, 2012 the Company incurred approximately \$5.6 million of transaction-related costs, which include severance and advisory, legal, valuation and accounting services. These costs were expensed as incurred

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

and are included in transaction-related expenses on the accompanying consolidated statements of comprehensive (loss) income.

Actual and Pro Forma Impact of the Transaction (Unaudited)

Net revenues and net loss for EKR of \$736,000 and \$420,000, respectively, are included in the Company's consolidated statements of comprehensive (loss) income from the acquisition date, June 26, 2012 through June 30, 2012.

Table of Contents

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.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Net revenues	\$ 32,075	\$ 39,429	\$ 69,903	\$ 84,790
Net loss	\$ (10,096)	\$ (523)	\$ (8,542)	\$ (2,790)

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 six month periods ending June 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 our long-term debt used to fund the acquisition (approximately \$1.7 million for the three months ended June 30, 2012 and 2011 and \$3.3 million for the six months ended June 30, 2012 and 2011)

Additional amortization expense (approximately \$2.2 million for the three months ended June 30, 2012 and 2011 and \$4.4 million for the six months ended June 30, 2012 and 2011) related to the fair value of identifiable intangible assets acquired.

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

The Company's goodwill balance as of June 30, 2012 and December 31, 2011 was \$37.5 million and \$15.2 million, respectively. The \$22.3 million increase in goodwill is related to the June 26, 2012 acquisition of EKR. There have been no other adjustments to goodwill since December 31, 2011. No amount of the goodwill balance at June 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 June 30, 2012 and December 31, 2011 (in thousands):

	June 30, 2012			Weighted-Average Amortization Period (yrs.)
	Gross Carrying Amount	Accumulated Amortization	Net Amount	
CUROSURF®	\$ 107,606	\$ 30,489	\$ 77,117	10.0
ZYFLO®	11,500	5,884	5,616	7.1
CARDENE I.V.	131,556	97	131,459	15.0
RETAVASE	26,858		26,858	n/a
CRTX 080	11,500		11,500	n/a

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

Other	575	75	500	n/a
Total	\$ 289,595	\$ 36,545	\$ 253,050	13.0

Table of Contents

	December 31, 2011			Weighted-Average
	Gross Carrying Amount	Accumulated Amortization	Net Amount	Amortization Period (yrs.)
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
Total	\$ 143,299	\$ 36,339	\$ 106,960	8.9

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 June 30, 2012, the Company had \$38.9 million of product rights related to RETAVASE and its product candidates, CRTX 067 and 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 is expected to be shortly after regulatory approval. The rights will be amortized over the estimated useful lives of these products.

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 (loss) income.

NOTE 5: ACCRUED EXPENSES

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

	June 30, 2012	December 31, 2011
Accrued product returns	\$ 12,876	\$ 13,211
Accrued rebates	2,130	2,634
Accrued price adjustments and chargebacks	11,398	9,159
Accrued compensation and benefits	3,799	2,559
Accrued royalties	4,401	3,046
Accrued taxes	8,759	5,668
Accrued expenses, other	736	848
Total accrued expenses	\$ 44,099	\$ 37,125

Table of Contents**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.

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.

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

	Maturity Date	June 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		(341)
Net carrying amount		59,659

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

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	(170)
Net carrying amount	29,830
Total debt, carrying amount	\$ 89,489
Less: current portion	\$
Total long-term debt, carrying amount	\$ 89,489

Table of Contents**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 555,950 and 351,466 stock options granted and exercised, respectively, during the six months ended June 30, 2012.

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

	Six Months Ended June 30, 2012
Estimated dividend yield	0.0%
Expected stock price volatility	80%
Risk-free interest rate	0.72-0.78%
Expected life of option (in years)	5.00
Weighted-average grant date fair value per share of options granted	\$3.56

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.

As of June 30, 2012, the aggregate intrinsic value of options outstanding and exercisable was \$3.5 million and \$2.7 million, respectively.

As of June 30, 2012, there was \$4.0 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.48 years.

Restricted Stock

During the six months ended June 30, 2012, no shares of restricted stock were issued and 61,075 shares vested. As of June 30, 2012, there were 158,705 restricted common shares outstanding and \$922,000 of total unrecognized compensation cost related to unvested restricted stock, which is expected to be recognized over a weighted-average period of 2.14 years.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized based on the total grant date fair value of shares vested was approximately \$668,000 and \$505,000 for the three months ended June 30, 2012 and 2011, respectively and \$1.3 million and \$884,000 for the six months ended June 30, 2012 and 2011, respectively.

Table of Contents

NOTE 8: COMMITMENTS AND CONTINGENCIES

Lease Obligations

The Company leases its facilities, certain equipment and automobiles 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 \$190,000 and \$275,000 for the three months ended June 30, 2012 and 2011, respectively, and approximately \$424,000 and \$589,000 for the six months ended June 30, 2012 and 2011, respectively.

In connection with the acquisition of EKR, the Company assumed the lease for office space in Bedminster, NJ that extends through December 15, 2015. Annual lease expense for this office space is approximately \$600,000.

Supply Agreements

The Company has various supply agreements with certain vendors and pharmaceutical manufacturers. Financial commitments related to these agreements totaled approximately \$42.8 million as of June 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 June 30, 2012, the Company had outstanding purchase orders related to inventory, excluding commitments under supply agreements, totaling approximately \$26.8 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 (loss) income. For the three months ended June 30, 2012 and 2011, total royalty expenses were \$1.2 million and \$2.1 million, respectively and for the six months ended June 30, 2012 and 2011, total royalty expenses were \$2.8 million and \$4.6 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, Inc. (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 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 (loss) income. 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 six months ended June 30, 2012, there were no events or circumstances that would have required a revaluation of the liability.

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

As of June 30, 2012, the Company had outstanding financial commitments related to ongoing research and development contracts totaling approximately \$4.3 million.

Table of Contents

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 June 30, 2012, the Company had outstanding financial commitments related to various marketing and analytical service agreements totaling approximately \$2.4 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. As of June 30, 2012, the Company had no amounts recorded as accrued severance for executives under such agreements.

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 that will continue to provide services for a stated transition period. As of June 30, 2012, 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 our 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 six months ended June 30, 2012 was (24.2)% and (29.7)%, respectively. The Company's effective tax rate for the three and six months ended June 30, 2011 was 60.4% and 35.3%, respectively. The change in the effective tax rate for the three-month period ended June 30, 2012 compared to the three-month period ended June 30, 2011 was due 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 change in the effective tax rate for the six-month period ended June 30, 2012 compared to the six-month period ended June 30, 2011 was due primarily to the tax impact of nondeductible transaction costs incurred in connection with the acquisition of EKR.

The estimated annual effective tax rate for the year ending December 31, 2012 includes a benefit of approximately 6.6% 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 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.

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

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.

There was a change in unrecognized tax positions for the six months ended June 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

Table of Contents

guidance provided by the Internal Revenue Service. The Company reduced its unrecognized tax positions by \$382,000 during the second quarter. As of June 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 \$5.2 million and \$12.1 million for the three and six months ended June 30, 2012, respectively, and \$6.0 million and \$9.8 million for the three and six months ended June 30, 2011, respectively. As of June 30, 2012, the Company had accounts payable of \$1.3 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 June 30, 2012, the net carrying value of the Term Loans was \$89.5 million, net of capitalized debt financing costs, and approximately \$90,000 was recorded as accrued interest payable to Chiesi.

NOTE 11: NET (LOSS) INCOME PER SHARE

Basic net (loss) income per share is computed by dividing net (loss) income by the weighted-average number of common shares outstanding during each period. Diluted net (loss) income per share is computed by dividing net (loss) income 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 (loss) income per share (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Numerator:				
Net (loss) income	\$ (4,353)	\$ 197	\$ (6,178)	\$ 1,939
Denominator:				
Weighted-average common shares, basic	26,058,941	25,673,667	25,937,656	25,577,314
Dilutive effect of stock options and warrants		519,310		550,452
Dilutive effect of restricted stock		53,096		40,231
Dilutive effect of convertible debt				
Weighted-average common shares, diluted	26,058,941	26,246,073	25,937,656	26,167,997
Net income (loss) per share, basic	\$ (0.17)	\$ 0.01	\$ (0.24)	\$ 0.08
Net income (loss) per share, diluted	\$ (0.17)	\$ 0.01	\$ (0.24)	\$ 0.07
Anti-dilutive weighted-average shares(1)	3,213,867	1,581,781	3,054,686	1,569,180

- (1) Anti-dilutive weighted-average shares include 1.4 million potential shares issuable for stock options, unvested restricted stock and convertible debt that were excluded from the calculation of diluted loss per share as the impact would have been anti-dilutive for both the three and six months ended June 30, 2012. The potential dilutive effect on the weighted average common shares outstanding would have been 634,254 and 554,954 for the three and six month periods ended June 30, 2012, respectively.

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

As of June 30, 2012 and 2011, there were 158,705 and 183,640 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 (loss) income per share. Because the treasury stock method and the two-class method yield the same result for both basic and diluted net (loss) income in each of the periods presented, only the treasury stock method has been disclosed.

NOTE 12: SUBSEQUENT EVENTS

The Company has evaluated all events or transactions that occurred after June 30, 2012. The Company did not have any material subsequent events that require adjustment or disclosure in these financial statements.

Table of Contents

NOTE 13: RECENT ACCOUNTING PRONOUNCEMENTS

In July 2012, the FASB issued ASU 2012-02, *Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment* (ASU 2012-02), which amends current guidance to allow a company to first assess qualitative factors to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired. The amendment gives examples of events and circumstances that an entity should consider that may impact the significant inputs used to determine the fair value or useful life of an indefinite-lived intangible asset. ASU 2012-02 is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012 with early adoption permitted. The Company plans to adopt ASU 2012-02 during the third quarter of 2012 and does not expect it to have a material impact upon its financial position and results of operations.

Table of Contents

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, niche respiratory 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.

Second Quarter 2012 Highlights

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

Cash and cash equivalents were \$38.6 million at June 30, 2012.

Net product sales from CUROSURF® and our ZYFLO® family of products were \$20.1 million and \$40.1 million for the three and six months ended June 30, 2012, respectively, compared to \$15.1 million and \$30.1 million for the three and six months ended June 30, 2011.

Our loss from operations was \$5.6 million for the three months ended June 30, 2012 compared to income from operations of \$540,000 for the three months ended June 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 \$3.8 million for the three months ended June 30, 2012 compared to \$7.1 million for the three months ended June 30, 2011.

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

Our net loss was \$4.4 million for the three months ended June 30, 2012 compared to our net income of \$197,000 for the three months ended June 30, 2011 when calculated on a GAAP basis. On a non-GAAP basis, we had net income of \$2.8 million for the three months ended June 30, 2012 compared to \$2.8 million for the three months ended June 30, 2011.

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

On June 26, 2012, we completed our acquisition of EKR Holdings, Inc. and its wholly owned subsidiary, EKR Therapeutics, Inc., which we refer to collectively herein as EKR, giving us the product rights to EKR's cardiovascular products, CARDENE® I.V. and RETAVASE®. Consideration included a closing cash payment of \$125.0 million and an additional \$1.4 million for estimated incremental net working capital. In addition, we may be required to make contingent payments of up to \$25.0 million over the first three years following commercial relaunch of RETAVASE;

In connection with our acquisition of EKR, on June 21, 2012, we entered into a credit agreement with Chiesi Farmaceutici S.p.A., or Chiesi, providing for two term loans, Term Loan A of \$60.0 million and a convertible Term Loan B of \$30.0 million (this credit agreement is referred to herein as the Credit Agreement);

On June 29, 2012 the U.S. Food and Drug Administration, or FDA, approved our Abbreviated New Drug Application, or ANDA, for CRTX 067, a generic hydrocodone polistirex and chlorpheniramine polistirex extended-release suspension product, which is a generic equivalent for the product currently sold under the Tussionex® brand name.

Table of Contents

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 promoting ZYFLO and ZYFLO CR[®] through third parties. We believe that the additions of CARDENE I.V. and, when approved, RETAVASE and CRTX 080 to our product portfolio will give us the opportunity to strengthen our existing relationships within the cardiology community.

We are currently focused on the following operational initiatives:

Efficiently integrating EKR's operations and realizing of cost synergies, primarily from alignment of our sales force which will significantly expand our reach in the U.S hospital market;

Obtaining regulatory approval to launch CRTX 080 which is currently under review by the FDA for the proposed indication of the treatment of symptomatic hypervolemic and euvolemic hyponatremia associated with heart failure and syndrome of inappropriate antidiuretic hormone, respectively;

Preparing to launch CRTX 067, which we expect to be distributed by Aristos; and

Securing approval for the re-launch of RETAVASE, which will include the inspection by the FDA of a new active ingredient manufacturing site and related drug substance and drug product stability data.

If we can conclude each of these operational initiatives successfully, our sales force will be actively promoting four products within the hospital channel. We believe that the active promotion of four 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.

As we focus on driving the growth of our products and the approval of our product candidates, we intend to maintain our focus on business development. We expect to continue to strengthen our alliance and partner relationships and to explore further licensing and acquisition opportunities. Our organization is fully committed to this effort as integral to the next phase in the execution of our growth strategy.

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 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. As of June 30, 2012, the assumptions used for determining the fair value of the contingent consideration arrangements have not changed significantly from those used at the acquisition date.

Table of Contents**Results of Operations****Comparison of the Three Months Ended June 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):

	Three Months Ended June 30,		Change	
	2012	2011	\$	%
<i>Net product sales</i>				
CUROSURF	\$ 9,269	\$ 8,547	\$ 722	8%
ZYFLO product family	10,788	6,585	4,203	64
CARDENE I.V. product family	736		736	NM
ALLERX® Dose Pack products	(131)	9,173	(9,304)	NM
Anti-infective products	172	3,556	(3,384)	(95)
Other products	637	103	534	518
Total net product sales	21,471	27,964	(6,493)	(23)
<i>License and royalty agreement revenues</i>		75	(75)	NM
Net revenues	21,471	28,039	(6,568)	(23)
Cost of product sales (exclusive of amortization of product rights)	8,901	9,189	(288)	(3)
Selling, general and administrative	8,890	11,604	(2,714)	(23)
Research and development	686	614	72	12
Transaction-related expenses	5,438		5,438	NM
Amortization of product rights	3,189	6,092	(2,903)	(48)
(Loss) income from operations	(5,633)	540	(6,173)	NM
Total other expenses, net	(113)	(42)	71	169
(Loss) income before income taxes	(5,746)	498	(6,244)	NM
Benefit from (provision for) income taxes	1,393	(301)	(1,694)	NM
Net (loss) income	\$ (4,353)	\$ 197	\$ (4,550)	NM
Net (loss) income per share, diluted	\$ (0.17)	\$ 0.01	\$ (0.18)	NM
Non-GAAP income from operations (1)	\$ 3,821	\$ 7,137	\$ (3,316)	(46)
Non-GAAP net income (1)	\$ 2,809	\$ 2,807	\$ 2	NM
Non-GAAP net income per share, diluted (1)	\$ 0.11	\$ 0.11	\$	NM

(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.

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

CUROSURF net product sales increased \$722,000, or 8%, during the three months ended June 30, 2012 compared to the three months ended June 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 \$4.2 million, or 64%, during the three months ended June 30, 2012 compared to the three months ended June 30, 2011, due to both an increase in unit volume and a price increase.

CARDENE I.V. net product sales were \$736,000 during the three months ended June 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 from the acquisition date through June 30, 2012.

ALLERX Dose Pack net product sales decreased \$9.3 million during the three months ended June 30, 2012 compared to the three months ended June 30, 2011. In March 2011, the FDA announced that it intended to initiate enforcement action against marketed unapproved prescription cough, cold and allergy products manufactured on or after June 1, 2011 or shipped on or after August 30, 2011 (this announcement is referred to as the March 2011 FDA Announcement). We expected this action, and all of our marketed unapproved products had already been manufactured and shipped prior to December 31, 2010. Deferred revenue related to the 2010 sales was recognized in 2011 and 2012 as revenue as prescriptions were filled. The decrease in product sales was primarily due to the March 2011 FDA Announcement, which caused a decline in prescriptions as well as substantial product returns from our distribution partners.

Net product sales from our anti-infective products decreased \$3.4 million, or 95%, during the three months ended June 30, 2012 compared to the three months ended June 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.

Table of Contents

Net product sales from other products increased \$534,000, or 518%, during the three months ended June 30, 2012 compared to the three months ended June 30, 2011. The primary reason for this increase was the approximately \$515,000 of propoxyphene/acetaminophen product returns in the three months ended June 30, 2011 resulting from our voluntary withdrawal of these products from the market. Excluding the impact of these returns, the decrease in our net product sales from other products was insignificant.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of \$3.2 million and \$8.5 million for the three months ended June 30, 2012 and 2011, respectively) decreased \$288,000, or 3%, during the three months ended June 30, 2012 compared to the three months ended June 30, 2011. 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 June 30,		Change	
	2012	2011	\$	%
Net product sales	\$ 21,471	\$ 27,964	\$ (6,493)	(23)%
Cost of product sales (exclusive of amortization of product rights)	8,901	9,189	(288)	(3)
Gross profit	\$ 12,570	\$ 18,775	(6,205)	(33)%
Gross margin	59%	67%		

Gross margin of net product sales for the three months ended June 30, 2012 decreased eight percentage points compared to the three months ended June 30, 2011. This decrease resulted because a relatively higher percentage of our total net product sales during the three months ended June 30, 2012 was derived from products that have lower gross margins, specifically CUROSURF.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased \$2.7 million, or 23%, during the three months ended June 30, 2012 compared to the three months ended June 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.

Research and Development Expenses. Research and development expenses increased \$72,000, or 12%, during the three months ended June 30, 2012 compared to the three months ended June 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. These costs were offset by a reduction in spend related to CRTX 073 and CRTX 067 during the three months ended June 30, 2012 due to the timing of our product development expenses, which remains consistent with our development plan. 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 \$5.4 million during the three months ended June 30, 2012 which primarily related to our acquisition of EKR.

Amortization of Product Rights. Amortization of product rights decreased \$2.9 million, or 48%, during the three months ended June 30, 2012 compared to the three months ended June 30, 2011. This decrease was primarily due to the impact of an additional \$2.5 million impairment of product rights recorded as amortization during the three months ended June 30, 2011, when we made the decision to not pursue several product development projects that no longer aligned with our strategic focus.

Benefit from (Provision for) Income Taxes

The benefit from income taxes was \$1.4 million for the three months ended June 30, 2012 compared to a provision of \$301,000 for the three months ended June 30, 2011. Our effective tax rates for the three months ended June 30, 2012 and 2011 were (24.2)% and 60.4%, respectively. The change in the effective tax rate was 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.

Table of Contents**Comparison of the Six Months Ended June 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):

	Six Months Ended June 30,		Change	
	2012	2011	\$	%
<i>Net product sales</i>				
CUROSURF	\$ 16,882	\$ 16,055	\$ 827	5%
ZYFLO product family	23,236	13,997	9,239	66
CARDENE I.V. product family	736		736	NM
ALLERX Dose Pack products	(1,125)	20,754	(21,879)	NM
Anti-infective products	3,093	9,633	(6,540)	(68)
Other products	806	(2,500)	3,306	NM
Total net product sales	43,628	57,939	(14,311)	(25)
<i>License and royalty agreement revenues</i>	4	97	(93)	(96)
Net revenues	43,632	58,036	(14,404)	(25)
Cost of product sales (exclusive of amortization of product rights)	17,587	19,223	(1,636)	(9)
Selling, general and administrative	19,812	24,873	(5,061)	(20)
Research and development	1,731	1,173	558	48
Gain on divestiture of product rights	(1,492)		(1,492)	NM
Transaction-related expenses	6,180		6,180	NM
Amortization of product rights	8,490	9,687	(1,197)	(12)
(Loss) income from operations	(8,676)	3,080	(11,756)	NM
Total other expenses, net	(115)	(83)	32	39
(Loss) income before income taxes	(8,791)	2,997	(11,788)	NM
Benefit from (provision for) income taxes	2,613	(1,058)	(3,671)	NM
Net (loss) income	\$ (6,178)	\$ 1,939	\$ (8,117)	NM
Net (loss) income per share, diluted	\$ (0.24)	\$ 0.07	\$ (0.31)	NM
Non-GAAP income from operations (1)	\$ 6,004	\$ 13,650	\$ (7,646)	(56)
Non-GAAP net income (1)	\$ 4,139	\$ 8,778	\$ (4,639)	(53)
Non-GAAP net income per share, diluted (1)	\$ 0.16	\$ 0.34	\$ (0.18)	(53)

(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.*

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

CUROSURF net product sales increased \$827,000, or 5%, during the six months ended June 30, 2012 compared to the six months ended June 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 \$9.2 million, or 66%, during the six months ended June 30, 2012 compared to the six months ended June 30, 2011 due to both an increase in unit volume and a price increase.

CARDENE I.V. net product sales were \$736,000 during the six months ended June 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 from the acquisition date through June 30, 2012.

ALLERX Dose Pack net product sales decreased \$21.9 million during the six months ended June 30, 2012 compared to the six months ended June 30, 2011. In March 2011, the FDA issued the March 2011 FDA Announcement. We expected this action, and all of our marketed unapproved products had already been manufactured and shipped prior to December 31, 2010. Deferred revenue related to the 2010 sales was recognized in 2011 and 2012 as revenue as prescriptions were filled. The decrease in product sales was primarily due to the March 2011 FDA Announcement, which caused a decline in prescriptions as well as substantial product returns from our distribution partners. During the six months ended June 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 \$6.5 million, or 68%, during the six months ended June 30, 2012 compared to the six months ended June 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.

Net product sales from other products increased \$3.3 million during the six months ended June 30, 2012 compared to the six months ended June 30, 2011. The primary reason for this increase was the approximately \$3.9 million of propoxyphene/acetaminophen product returns in the three months ended June 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 \$600,000 due to lower net prices and lower net unit volume as a result of increased competition from other manufacturers.

Table of Contents*Costs and Expenses*

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of \$8.5 million and \$9.7 million for the six months ended June 30, 2012 and 2011, respectively) decreased \$1.6 million, or 9%, during the six months ended June 30, 2012 compared to the six months ended June 30, 2011.

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

	Six Months Ended June 30,		Change	
	2012	2011	\$	%
Net product sales	\$ 43,628	\$ 57,939	\$ (14,311)	(25)%
Cost of product sales (exclusive of amortization of product rights)	17,587	19,223	(1,636)	(9)
Gross profit	\$ 26,041	\$ 38,716	(12,675)	(33)%
Gross margin	60%	67%		

Gross margin of net product sales for the six months ended June 30, 2012 decreased seven percentage points compared to the six months ended June 30, 2011. This decrease was due to a relatively higher percentage of our total net product sales during the first six months of 2012 derived from products that have lower gross margins, specifically CUROSURF.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased \$5.1 million, or 20%, during the six months ended June 30, 2012 compared to the six months ended June 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.

Research and Development Expenses. Research and development expenses increased \$558,000, or 48%, during the six months ended June 30, 2012 compared to the six months ended June 30, 2011. This increase was primarily driven by development costs related to CRTX 080, which we acquired in December 2011 from Cardiokine. These costs were offset by a reduction in spend related to CRTX 073 and CRTX 067 during the six months ended June 30, 2012 due to the timing of our product development expenses, which remains consistent with our development plan. 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.

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 six months ended June 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.

Transaction-related Expenses. Transaction-related expenses were \$6.2 million during the six months ended June 30, 2012, of which \$5.6 million related to our acquisition of EKR.

Amortization of Product Rights. Amortization of product rights decreased \$1.2 million, or 12%, during the six months ended June 30, 2012 compared to the six months ended June 30, 2011. This decrease was primarily due to the impact of an additional \$2.5 million impairment of product rights recorded as amortization during the six months ended June 30, 2011, when we made the decision to not pursue several product development projects that no longer aligned with our strategic focus, partially offset by the additional \$2.2 million of amortization recorded in the six months ended June 30, 2012 related to our reduction of the useful lives of our anti-infective products prior to their divestiture.

Benefit from (Provision for) Income Taxes

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

The benefit from income taxes was \$2.6 million for the six months ended June 30, 2012 compared to a provision of \$1.1 million for the six months ended June 30, 2011. Our effective tax rates for the six months ended June 30, 2012 and 2011 were (29.7)% and 35.3%, respectively. The change in the effective tax rate was primarily due to the tax impact of nondeductible transaction costs incurred in connection with our acquisition of EKR.

Table of Contents

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, acquisition adjustments related to inventory sold, transaction-related expenses 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, and the acquisition adjustment related to inventory sold, transaction-related expenses 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, acquisition adjustments related to inventory sold, transaction-related expenses 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 and transaction-related expenses, whether or not the transaction is successfully closed, may be significant cash expenses.

Table of Contents

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		For the six months ended	
	June 30,		June 30,	
	2012	2011	2012	2011
GAAP (loss) income from operations	\$ (5,633)	\$ 540	\$ (8,676)	\$ 3,080
Add: stock-based compensation	668	505	1,343	884
Add: amortization of product rights	3,189	6,092	8,490	9,686
Add: acquisition adjustments related to inventory sold	159		159	
Add: transaction-related expenses	5,438		6,180	
Less: gain on divestiture of product rights			(1,492)	
Non-GAAP income from operations	\$ 3,821	\$ 7,137	\$ 6,004	\$ 13,650
GAAP net (loss) income	\$ (4,353)	\$ 197	\$ (6,178)	\$ 1,939
Add: stock-based compensation	668	505	1,343	884
Add: amortization of product rights	3,189	6,092	8,490	9,686
Add: acquisition adjustments related to inventory sold	159		159	
Add: transaction-related expenses	5,438		6,180	
Less: gain on divestiture of product rights			(1,492)	
Less: tax effects related to above items(1)	(2,292)	(3,987)	(4,363)	(3,731)
Non-GAAP net income	\$ 2,809	\$ 2,807	\$ 4,139	\$ 8,778
GAAP net (loss) income per share, diluted	\$ (0.17)	\$ 0.01	\$ (0.24)	\$ 0.07
Non-GAAP net income per share, diluted	\$ 0.11	\$ 0.11	\$ 0.16	\$ 0.34
Shares used in diluted net (loss) income per share calculation:				
GAAP net (loss) income	26,058,941	26,246,073	25,937,656	26,167,997
Non-GAAP net income	26,693,195	26,246,073	26,492,610	26,167,997

- (1) Tax effects for the three months ended June 30, 2012 and 2011 are calculated using effective tax rates of 24.2% and 60.4% respectively. Tax effects for the six months ended June 30, 2012 and 2011 are calculated using effective tax rates of 29.7% and 35.3% respectively.

Liquidity and Capital Resources**Sources of Liquidity**

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 June 30, 2012, we had \$38.6 million in cash and cash equivalents.

Cash Flows

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

	Six Months Ended	
	June 30,	
	2012	2011
Cash (used in) provided by:		
Operating activities	\$ (2,855)	\$ 41,459
Investing activities	(123,019)	(333)
Financing activities	90,464	722
Net (decrease) increase in cash and cash equivalents	\$ (35,410)	\$ 41,848

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 six months ended June 30, 2012 reflected our net loss of \$6.2 million, adjusted by non-cash expenses totaling \$7.3 million and changes in operating assets and liabilities from December 31, 2011 to June 30, 2012 totaling \$4.0 million. Accounts receivable and inventory increased by \$1.2 million and \$1.1 million, respectively, from December 31,

Table of Contents

2011 to June 30, 2012. Prepaid expenses and other assets decreased by 7.0 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 \$8.9 million from December 31, 2011 to June 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 decreased by \$209,000 from December 31, 2011 to June 30, 2012.

Net cash provided by operating activities for the six months ended June 30, 2011 reflected our net income of \$1.9 million, adjusted by non-cash expenses totaling \$13.0 million and changes in accounts receivable, inventories, deferred revenue, income taxes payable, accrued expenses and other operating assets and liabilities totaling \$26.6 million.

Net Cash Used in Investing Activities

Net cash used in investing activities for the six months ended June 30, 2012 reflected the cash paid for our acquisition of EKR, net of cash acquired, cash proceeds allocated to the divested anti-infective product rights and purchase of property and equipment for \$99,000.

Net cash used in investing activities for the six months ended June 30, 2011 reflected the purchase of property and equipment for \$333,000.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2012 reflected proceeds from our long-term debt of \$90.0 million and proceeds from common stock option exercises of \$818,000, partially offset by payment of debt financing costs of \$511,000, principal payments on capital leases, purchases of treasury of stock and an excess tax benefit from stock options.

Net cash provided by financing activities for the six months ended June 30, 2011 reflected proceeds from common stock option exercises of \$311,000 and an excess tax benefit from stock options of \$452,000, partially offset by principal payments on capital leases of \$41,000.

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;

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

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

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 June 30, 2012, we had \$38.6 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.

Table of Contents**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 six months ended June 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 June 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)	\$ 119,094	\$ 3,386	\$ 16,579	\$ 38,693	\$ 60,436
Capital lease obligations	94	20	68	6	
Operating lease obligations (2)	4,263	596	2,316	1,351	
Purchase obligations (3)	76,888	24,181	34,872	17,539	296
Total (4)	\$ 200,339	\$ 28,183	\$ 53,835	\$ 57,589	\$ 60,732

- (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 (including the assumed lease in Bedminster for EKR's former office space), automobiles and certain equipment. Our total minimum lease payments for our corporate headquarters are \$491,000 in 2012 (of which we paid \$216,000 during the first six 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 \$42.8 million; clinical trial and research agreements with contract research organizations and consultants of \$4.3 million; agreements with providers of marketing analytical services of \$2.4 million; and open purchase orders for the acquisition of goods and services in the ordinary course of business of \$27.4 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.

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.

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

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.

Table of Contents

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 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.

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 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 June 30, 2012, we had \$41.7 million in inventory, which was net of an inventory reserve of \$1.6 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

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

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.

Table of Contents

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 June 30, 2012, pre-approval inventory included \$13.9 million of costs capitalized as raw materials and work in process prior to regulatory approval of the Supplemental Biologics Application for RETAVASE.

Recent Accounting Pronouncements

See Note 13 to our consolidated financial statements included in Part I Item 1. Financial Statements of this quarterly report on Form 10-Q, for a description of recent accounting pronouncements, including the expected dates of adoption and estimated effects, if any, on our consolidated financial statements.

Table of Contents

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 June 30, 2012, our outstanding long-term debt of \$90 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 six months ended June 30, 2012 and 2011. We do not believe a fluctuation in these exchange rates would have a material impact on us. 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 June 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 June 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 June 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[®], 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 with an article appearing in the September 2011 issue of the *Journal of Perinatology*, based on a retrospective study sponsored by Chiesi, that

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

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.

Table of Contents

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.

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 is currently pending before the court in the United States District Court, Eastern District of Kentucky (Northern Division).

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.

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;

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

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;

Table of Contents

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 June 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)	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs	
			Publicly Announced Plans or Programs	May
April 1, 2012	April 30, 2012	\$	\$	\$
May 1, 2012	May 31, 2012	9,734	5.04	
June 1, 2012	June 30, 2012	787	5.94	

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

Total	10,521	\$	5.11	\$	\$
-------	--------	----	------	----	----

- (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.

Table of Contents

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.

Table of Contents

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: August 9, 2012

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

Date: August 9, 2012

/s/ Vincent T. Morgus
Vincent T. Morgus
Executive Vice President,
Finance, Chief Financial Officer and Treasurer
(Principal Financial Officer)

Date: August 9, 2012

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

Table of Contents**EXHIBIT INDEX**

Exhibit No.	Description
2.1**	Agreement and Plan of Merger among Cornerstone Therapeutics Inc., Stone Acquisition Sub, Inc., EKR Holdings, Inc., and EKR Therapeutics, Inc. dated May 14, 2012 (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K dated May 14, 2012).
2.2	Amendment No. 1, dated June 26, 2012, to Agreement and Plan of Merger among Cornerstone Therapeutics Inc., Stone Acquisition Sub, Inc., EKR Holdings, Inc., and EKR Therapeutics, Inc. dated May 14, 2012 (incorporated by reference to Exhibit 2.2 to the Registrant's Current Report on Form 8-K dated June 21, 2012).
10.1	Commitment Letter between Cornerstone Therapeutics Inc. and Chiesi Farmaceutici S.p.A. dated May 14, 2012 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated May 14, 2012).
10.2	Credit Agreement among Cornerstone Therapeutics Inc., Chiesi Farmaceutici S.p.A., as administrative agent and the initial lender, and the other lenders from time to time party thereto dated June 21, 2012 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated June 21, 2012).
10.3+	Amended and Restated Development and Manufacturing Agreement between EKR Therapeutics, Inc. and Baxter Healthcare Corporation dated April 9, 2009.
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 June 30, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the Unaudited Consolidated Balance Sheets, (ii) the Unaudited Consolidated Statements of Comprehensive (Loss) Income, (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.
**	Pursuant to Regulation S-K, Item 601(b)(2), certain schedules to this exhibit have not been filed herewith. A list of omitted schedules is included in the agreement. The Registrant agrees to furnish supplementally a copy of any such schedule to the Securities and Exchange Commission upon request; provided, however, that the Registrant may request confidential treatment of omitted items.
+	Portions of the exhibit have been omitted pursuant to a request for confidential treatment, which portions have been separately filed with the Securities and Exchange Commission.