

CORNERSTONE THERAPEUTICS INC

Form 10-Q

May 15, 2012

[Table of Contents](#)

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

Washington, DC 20549

**Form 10-Q**

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

For the Quarterly Period Ended March 31, 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

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

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

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

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

Large accelerated filer  Accelerated filer

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

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

As of May 10, 2012, the registrant had 26,257,547 shares of Common Stock, \$0.001 par value per share, outstanding.

**Table of Contents**

**CORNERSTONE THERAPEUTICS INC.**

**FORM 10-Q**

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	<b>3</b>
<b><u>Cautionary Statement Regarding Forward-Looking Statements</u></b>	<b>3</b>
Item 1. <b><u>Financial Statements</u></b>	<b>4</b>
<b><u>Consolidated Balance Sheets as of March 31, 2012 (Unaudited) and December 31, 2011</u></b>	<b>4</b>
<b><u>Consolidated Statements of Comprehensive (Loss) Income for the Three Months Ended March 31, 2012 and 2011 (Unaudited)</u></b>	<b>5</b>
<b><u>Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2012 and 2011 (Unaudited)</u></b>	<b>6</b>
<b><u>Notes to Consolidated Financial Statements (Unaudited)</u></b>	<b>7</b>
Item 2. <b><u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	<b>16</b>
Item 3. <b><u>Quantitative and Qualitative Disclosures about Market Risk</u></b>	<b>24</b>
Item 4. <b><u>Controls and Procedures</u></b>	<b>24</b>
<b><u>PART II OTHER INFORMATION</u></b>	<b>24</b>
Item 1. <b><u>Legal Proceedings</u></b>	<b>24</b>
Item 1A. <b><u>Risk Factors</u></b>	<b>25</b>
Item 2. <b><u>Unregistered Sales of Securities and Use of Proceeds</u></b>	<b>25</b>
Item 6. <b><u>Exhibits</u></b>	<b>25</b>
<b><u>SIGNATURES</u></b>	<b>26</b>
<b><u>EXHIBIT INDEX</u></b>	<b>27</b>

---

**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. 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 market and sell our products under development; 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; 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)**

	March 31, 2012 (Unaudited)	December 31, 2011 (Note 1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 74,199	\$ 73,968
Accounts receivable, net	14,000	11,894
Inventories, net	9,167	9,419
Prepaid expenses	2,534	3,753
Income tax receivable	801	1,900
Deferred income tax asset	168	2
Other current assets	6,788	6,112
Total current assets	107,657	107,048
Property and equipment, net	1,394	1,574
Product rights, net	97,825	106,960
Goodwill	15,218	15,218
Amounts due from related parties	38	38
Deferred income tax asset, less current portion	1,579	523
Other assets	72	953
Total assets	\$ 223,783	\$ 232,314
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 9,093	\$ 10,012
Accrued expenses	30,280	37,125
Deferred revenue	820	1,428
Other current liabilities	430	90
Total current liabilities	40,623	48,655
Acquisition-related contingent liability	8,800	8,800
Other long-term liabilities	670	56
Total liabilities	50,093	57,511
Commitments and contingencies, Note 6		
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; 25,845,194 and 25,803,864 shares issued and outstanding as of March 31, 2012 and December 31, 2011, respectively	26	26
Additional paid-in capital	163,915	163,203
Retained earnings	9,749	11,574

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

Total stockholders' equity	173,690	174,803
Total liabilities and stockholders' equity	\$ 223,783	\$ 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)**

	<b>Three Months Ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
Net revenues	\$ 22,161	\$ 29,997
Costs and expenses:		
Cost of product sales (exclusive of amortization of product rights)	8,686	10,034
Selling, general and administrative	11,664	13,269
Research and development	1,045	559
Gain on divestiture of product rights	(1,492)	
Amortization of product rights	5,301	3,595
Total costs and expenses	25,204	27,457
(Loss) income from operations	(3,043)	2,540
Other expenses, net:		
Interest expense, net	(2)	(41)
Total other expenses	(2)	(41)
(Loss) income before income taxes	(3,045)	2,499
Benefit from (provision for) income taxes	1,220	(757)
Net (loss) income	\$ (1,825)	\$ 1,742
Comprehensive (loss) income	\$ (1,825)	\$ 1,742
Net (loss) income per share, basic	\$ (0.07)	\$ 0.07
Net (loss) income per share, diluted	\$ (0.07)	\$ 0.07
Weighted-average common shares, basic	25,817,185	25,479,891
Weighted-average common shares, diluted	25,817,185	26,088,851

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
<b>Cash flows from operating activities</b>		
Net (loss) income	\$ (1,825)	\$ 1,742
Adjustments to reconcile net income to net cash (used in) provided by operating activities:		
Amortization and depreciation	5,455	3,713
Provision for prompt payment discounts	664	1,067
Provision for (recovery of) inventory allowances	12	(268)
Gain on sale of product rights	(1,492)	
Stock-based compensation	675	379
Deferred revenue	(608)	(13,210)
Provision for deferred income taxes	(1,222)	251
Changes in operating assets and liabilities:		
Accounts receivable	(2,770)	35,239
Inventories	(325)	2,141
Prepaid expenses and other assets	1,424	6,599
Accounts payable	(1,969)	705
Accrued expenses	(1,827)	(3,580)
Income taxes receivable	1,099	421
Net cash (used in) provided by operating activities	(2,709)	35,199
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	(80)	(57)
Proceeds from sale of product rights	3,000	
Net cash provided by (used in) investing activities	2,920	(57)
<b>Cash flows from financing activities</b>		
Proceeds from exercise of common stock options and warrants	23	9
Excess tax benefit from stock-based compensation	38	2
Purchase of treasury stock	(24)	
Principal payments on capital lease obligation	(17)	(20)
Net cash provided by (used in) financing activities	20	(9)
Net increase in cash and cash equivalents	231	35,133
<b>Cash and cash equivalents as of beginning of period</b>	<b>73,968</b>	<b>50,945</b>
<b>Cash and cash equivalents as of end of period</b>	<b>\$ 74,199</b>	<b>\$ 86,078</b>

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 internal 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**

Royalties previously classified separately are included in cost of product sales in the accompanying consolidated statements of comprehensive (loss) income. This reclassification had no effect on net income 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 disclosure normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States (GAAP) has 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 month period ended March 31, 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.

**Concentrations of Credit Risk and Limited Suppliers**

The financial instruments that potentially subject the Company to concentrations of credit risk are cash, cash equivalents and accounts receivable. The Company's cash and cash equivalents are maintained with one financial institution.

The Company relies on certain materials used in its development and third-party manufacturing processes, most of which are procured from a single source. The Company purchases its pharmaceutical ingredients pursuant to long-term supply agreements with a limited number of suppliers. The failure of a supplier, including a subcontractor, to deliver on schedule could delay or interrupt the development or commercialization process and thereby adversely affect the Company's operating results. In addition, a disruption in the commercial supply of or a significant increase in the cost of the active pharmaceutical ingredient (API) from any of these sources could have a material adverse effect on the Company's business, financial position and results of operations. During the three months ended March 31, 2012, two suppliers individually

## Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

represented more than 10% of the Company's total inventory purchases, or a total of 89% of the Company's total inventory purchases. Amounts due to these suppliers represented 28% of total accounts payable as of March 31, 2012.

**Table of Contents**

The Company sells its products primarily to large national wholesalers, which in turn resell the products to smaller or regional wholesalers, hospitals, retail pharmacies, chain drug stores, government agencies and other third parties. The following table lists the Company's customers that individually comprised greater than 10% of total gross product sales for the three months ended March 31, 2012 and 2011 or 10% of total accounts receivable as of March 31, 2012 and December 31, 2011:

	Three Months Ended March 31, 2012	Three Months Ended March 31, 2011	March 31, 2012	December 31, 2011
	Gross Product Sales	Gross Product Sales	Accounts Receivable	Accounts Receivable
Cardinal Health, Inc.	36%	39%	39%	52%
McKesson Corporation	38	35	48	22
AmerisourceBergen Drug Corporation	21	21	10	21
Total	95%	95%	97%	95%

**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 a federally insured bank. As of March 31, 2012, all cash deposits were federally insured.

**Accounts Receivable**

The Company typically requires its customers to remit payments within the first 30 to 90 days, depending on the customer and the products purchased. In addition, the Company offers wholesale distributors a prompt payment discount if they make payments within these deadlines. This discount is generally 2%, but may be higher in some instances due to product launches or customer and/or industry expectations. Because the Company's wholesale distributors typically take the prompt payment discount, the Company accrues 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of sale, and the Company applies earned discounts at the time of payment. The Company adjusts the accrual periodically to reflect actual experience. Historically, these adjustments have not been material.

The Company performs ongoing credit evaluations and does not require collateral. As appropriate, the Company establishes provisions for potential credit losses. In the opinion of management, no allowance for doubtful accounts was necessary as of March 31, 2012 or December 31, 2011. The Company writes off accounts receivable when management determines they are uncollectible and credits payments subsequently received on such receivables to bad debt expense in the period received. There were no write-offs during the three months ended March 31, 2012 or 2011.

The following table represents accounts receivable, net as of March 31, 2012 and December 31, 2011 (in thousands):

	March 31, 2012	December 31, 2011
Accounts receivable	\$ 14,252	\$ 12,479
Less allowance for prompt payment discounts	(252)	(585)
Accounts receivable, net	\$ 14,000	\$ 11,894

**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 API for a product to be manufactured, work in process includes the bulk inventory of tablets 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.

## Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

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.

**Table of Contents**

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

	March 31, 2012	December 31, 2011
Raw materials	\$ 2,980	\$ 2,791
Work in process	1,413	1,663
Finished goods:		
Pharmaceutical products - trade	4,919	4,566
Pharmaceutical products - samples	48	849
Total	9,360	9,869
Inventory allowances	(193)	(450)
Inventories, net	\$ 9,167	\$ 9,419

**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 March 31,	
	2012	2011
Gross product sales	\$ 34,186	\$ 51,195
Sales allowances	(12,029)	(21,220)
Net product sales	22,157	29,975
License and royalty agreement revenues	4	22
Net revenues	\$ 22,161	\$ 29,997

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 March 31, 2012 and December 31, 2011, the Company had \$820,000 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

## Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

payment and other discounts. Estimated allowances are recorded and classified as accrued expenses in the accompanying consolidated balance sheets as of March 31, 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 an 18-month expiration period 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.

---

## **Table of Contents**

*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 connection with the Company's sales of CUROSURF. In the event that the sales mix to third-party payers or the contract fees paid to GPOs are different from the Company's estimates, the Company may be required to pay higher or lower total price adjustments and/or chargebacks than it has estimated.

The Company, from time to time, offers certain promotional product-related incentives to its customers. These programs include sample cards to retail consumers, certain product incentives to pharmacy customers and other sales stocking allowances. The Company has initiated 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 (see Accounts Receivable above).

### **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 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: GOODWILL AND INTANGIBLE ASSETS**

#### **Goodwill**

The Company's goodwill balance as of March 31, 2012 and December 31, 2011 was \$15.2 million, of which \$13.2 million related to the October 31, 2008 merger whereby the Company, which was then known as Critical Therapeutics, Inc. (Critical Therapeutics), merged (through a transitory subsidiary) with Cornerstone BioPharma Holdings, Inc., which was deemed to be the acquiring company for accounting purposes (the Merger) and the remaining \$2.0 million related to the December 30, 2011 acquisition of Cardiokine, Inc. (Cardiokine). No amount of the goodwill balance at March 31, 2012 will be deductible for income tax purposes.

#### **Product Rights**

##### *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.





**Table of Contents**

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 Pharmaceutical 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.

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

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

	00000000	00000000	00000000	00000000
	March 31, 2012			
	Gross			Weighted-
	Carrying	Accumulated	Net	Average
	Amount	Amortization	Amount	Amortization
				Period (yrs.)
CUROSURF	\$ 107,606	\$ 27,798	\$ 79,808	10.0
ZYFLO®	11,500	5,483	6,017	7.2
CRTX 080	11,500		11,500	n/a
CRTX 067	500		500	n/a
Other	75	75		n/a
Total	\$ 131,181	\$ 33,356	\$ 97,825	9.7

	00000000	00000000	00000000	00000000
	December 31, 2011			
	Gross			Weighted-
	Carrying	Accumulated	Net	Average
	Amount	Amortization	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	7.2
CRTX 080	11,500		11,500	n/a
CRTX 067	500		500	n/a
Other	75	75		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 ten years. As of March 31, 2012, the Company had \$12.0 million of product rights related to its product candidates, CRTX 067 and CRTX 080, both 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 the new products.



**Table of Contents****NOTE 4: ACCRUED EXPENSES**

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

	<b>March 31, 2012</b>	<b>December 31, 2011</b>
Accrued product returns	\$ 9,302	\$ 13,211
Accrued rebates	2,347	2,634
Accrued price adjustments and chargebacks	8,060	9,159
Accrued compensation and benefits	1,436	2,559
Accrued royalties	3,123	3,046
Accrued taxes	5,318	5,668
Accrued expenses, other	694	848
 Total accrued expenses	 \$ 30,280	 \$ 37,125

**NOTE 5: 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 415,950 and 24,372 stock options granted and exercised, respectively, during the three months ended March 31, 2012.

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

	<b>Three Months Ended March 31, 2012</b>
Estimated dividend yield	0.0%
Expected stock price volatility	80%
Risk-free interest rate	0.87-0.90%
Expected life of option (in years)	5.00
Weighted-average grant date fair value per share of options granted	\$3.65

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 March 31, 2012, the aggregate intrinsic value of options outstanding and exercisable was \$3.9 million and \$3.4 million, respectively.

As of March 31, 2012, there was \$4.4 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of 2.75 years.

**Restricted Stock**

## Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

During the three months ended March 31, 2012, no shares of restricted stock were issued and 20,680 shares vested. As of March 31, 2012, there were 199,100 restricted common shares outstanding and \$1.0 million of total unrecognized compensation cost related to unvested restricted stock, which is expected to be recognized over a weighted-average period of 2.18 years.

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

Total stock-based compensation expense recognized based on the total grant date fair value of shares vested was approximately \$675,000 and \$379,000 for the three months ended March 31, 2012 and 2011, respectively.

---

## **Table of Contents**

### **NOTE 6: 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 \$234,000 and \$314,000 for the three months ended March 31, 2012 and 2011, respectively.

#### **Supply Agreements**

The Company has entered into various supply agreements with certain vendors and pharmaceutical manufacturers. Financial commitments related to these agreements totaled approximately \$1.2 million as of March 31, 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 March 31, 2012, the Company had outstanding purchase orders related to inventory, excluding commitments under supply agreements, totaling approximately \$10.2 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 March 31, 2012 and 2011, total royalty expenses were \$1.6 million and \$2.5 million, respectively.

#### **Collaboration Agreements**

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

In addition, in connection with its acquisition of Cardiokine in December 2011, the Company recorded an \$8.8 million contingent liability for additional consideration potentially payable under the merger agreement. The Company agreed to pay potential consideration consisting of each of the following: (1) either \$7.0 million or \$8.5 million if Cardiokine's pending 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 \$20,000,000. 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 months ended March 31, 2012, there were no events or circumstances that would have required a revaluation of the liability.

As of March 31, 2012, the Company had outstanding financial commitments related to ongoing research and development contracts totaling approximately \$3.3 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, the two co-promotion agreements are subject to sunset fees that require the Company to pay additional fees for up to three months in the event of certain defined terminations of the applicable agreement.

As of March 31, 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 March 31, 2012, the Company had no amounts recorded as accrued severance for executives.

### **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 7: 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 month periods ended March 31, 2012 and 2011 was (40.1)% and 30.3%, respectively. The change in the effective tax rate was due primarily to the tax impact of projected losses for 2012 as compared to 2011.

The estimated annual effective tax rate for the year ending December 31, 2012 includes a benefit of approximately 10.2% 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 that relate to federal net operating loss carryforwards (NOLs), state net economic loss carryforwards (NELs) 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 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.

The 2008 through 2011 tax years of the Company are open to examination by federal and state tax authorities. The Company has not been informed by any tax authorities for any jurisdiction that any of its tax years are under examination.

There were no changes in unrecognized tax positions for the three months ended March 31, 2012. As of March 31, 2012, the Company has \$382,000 of unrecognized tax benefits. The Company does not reasonably expect any change to the amount of unrecognized tax benefits within the next 12 months.

### **NOTE 8: RELATED PARTY TRANSACTIONS**

Chiesi Farmaceutici S.p.A. (Chiesi), the Company's majority stockholder, manufactures all of the Company's requirements for CUROSURF pursuant to a license and distribution agreement that became effective on July 28, 2009. Inventory purchases from Chiesi aggregated \$6.9 million for the three months ended March 31, 2012. As of March 31, 2012, the Company had accounts payable of \$2.0 million due to Chiesi.





**Table of Contents****NOTE 9: 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 by the sum of the weighted-average number of common shares and dilutive common share equivalents outstanding during the period. Dilutive common share equivalents consist of the incremental common shares issuable upon the exercise of stock options and warrants and the impact of non-vested restricted stock grants.

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

	<b>Three Months Ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
<b>Numerator:</b>		
Net (loss) income	\$ (1,825)	\$ 1,742
<b>Denominator:</b>		
Weighted-average common shares, basic	25,817,185	25,479,891
Dilutive effect of stock options, warrants and restricted stock		608,960
Weighted-average common shares, diluted	25,817,185	26,088,851
Net income per share, basic	\$ (0.07)	\$ 0.07
Net income per share, diluted	\$ (0.07)	\$ 0.07
Anti-dilutive weighted-average shares	2,045,152	1,556,578

As of March 31, 2012 and 2011, there were 199,100 and 220,570 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 10: SUBSEQUENT EVENTS**

On May 14, 2012, Company entered into an Agreement and Plan of Merger (the **Merger Agreement**) pursuant to which it will acquire EKR Holdings, Inc. ( **EKR** ), a privately held specialty pharmaceutical company focused on the acute-care hospital setting. The Merger Agreement requires the Company to pay up to approximately \$150 million to acquire EKR on a cash-free, debt-free basis. Pursuant to the Merger Agreement, the Company will pay an upfront cash purchase price of approximately \$125 million, subject to working capital and similar adjustments. In addition, the Merger Agreement requires the Company to pay certain contingent consideration of up to \$25 million upon the achievement of certain milestones related to regulatory approval of a new manufacturer for EKR's Retavase® product and net sales of Retavase during approximately the first three years following commercial relaunch of Retavase (collectively, the **Merger Consideration**).

The Merger Agreement contains customary representations, warranties and covenants, including covenants relating to obtaining the requisite approvals of EKR's shareholders, restricting the solicitation of competing acquisition proposals by EKR, and EKR's conduct of its business between the date of signing the Merger Agreement and the closing of the Merger.

Consummation of the Merger is subject to a number of closing conditions, including adoption of the Merger Agreement by EKR's stockholders, expiration or termination of any waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, and other customary closing conditions as set forth in the Merger Agreement.

In connection with the execution of the Merger Agreement, on May 14, 2012, the Company entered into a debt financing commitment letter (the **Commitment Letter**) with Chiesi pursuant to which Chiesi has agreed to provide a senior secured term loan facility (the **Facility**) comprised of (i) a five-year Term Loan A of up to \$60 million at 7.5% interest per annum and (ii) a five-year Term Loan B of up to \$30 million at 6.5% per annum. Principal and interest amounts outstanding under Term Loan B may be converted into common stock of the Company at \$7.098 per share at Chiesi's option at any time during the 24 months following the closing of the debt financing.

## Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

The proceeds of the Facility will be used, together with cash on hand of the Company and EKR, to finance the Merger Consideration and the fees and expenses incurred in connection with the Merger. All obligations under the Facility will be guaranteed by the Company's domestic subsidiaries, including EKR, after giving effect to the Merger, and will be secured by a security interest in substantially all of the assets of the Company and its domestic subsidiaries. The funding under the Facility is not a condition to the obligations of the Company under the terms of the Merger Agreement.

The Facility is subject to the negotiation of mutually acceptable definitive loan documentation, which will contain customary conditions to borrowing, representations, warranties, covenants and events of default, together with other customary loan document provisions and other terms and provisions to be mutually agreed. Additionally, Chiesi's obligation to provide the financing is subject to the satisfaction of specified conditions, including, but not limited to, the consummation of the Merger in accordance with the terms of the Merger Agreement, the accuracy of specified representations and warranties and the absence of specified defaults or events of defaults.

### **NOTE 11: RECENT ACCOUNTING PRONOUNCEMENTS**

There were no recent accounting pronouncements that have not yet been adopted by the Company that are expected to have a material impact on the Company's consolidated financial statements.

## **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 internal 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.

##### ***First Quarter 2012 Highlights***

The following summarizes certain key financial measures for the three months ended March 31, 2012:

Cash and cash equivalents were \$74.2 million at March 31, 2012.

Net product sales from CUROSURF and our ZYFLO family of products were \$20.1 million for the first quarter of 2012 compared to \$14.9 million for the three months ended March 31, 2011.

Our loss from operations was \$3.0 million for the three months ended March 31, 2012 compared to income from operations of \$2.5 million for the three months ended March 31, 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 \$2.2 million for the three months ended March 31, 2012 compared to non-GAAP income from operations of \$6.5 million for the three months ended March 31, 2011.

## Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

Our net loss was \$1.8 million for the three months ended March 31, 2012 compared to our net income of \$1.7 million for the three months ended March 31, 2011 when calculated on a GAAP basis. On a non-GAAP basis, we had net income of \$1.3 million for the three months ended March 31, 2012 compared to non-GAAP net income of \$4.5 million for the three months ended March 31, 2011.

## **Table of Contents**

Consistent with our strategy, during March 2012, we sold all of our rights to our anti-infective products, Factive and Spectracef, to Merus Labs International Inc., or Merus, and to Vansen Pharma Inc., or Vansen, respectively, in exchange for cash consideration and the assumption of certain product-related liabilities. In connection with the divestiture, Vansen offered certain of our respiratory sales force personnel employment to continue to support distribution and sales of Factive and Spectracef. Pursuant to a separate co-promotion agreement, we agreed to pay Vansen to co-promote our ZYFLO CR and ZYFLO products to certain physicians for an initial period of 24 months. Divesting our anti-infective products and associated commercial infrastructure and establishing this co-promotion agreement for our ZYFLO family of products allows us to focus our resources and efforts towards growing our hospital and related specialty market presence in the United States. The divestiture of our anti-infective products also means we will no longer face the challenges of competing in the primary care marketplace.

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

We continue to execute on our strategic plan, which calls for promoting both CUROSURF and ZYFLO; sharpening our focus on the hospital and related specialty markets; and continuing our business development efforts to expand our product portfolio. We also continue to progress both CRTX 067 and CRTX 080 through the regulatory approval process. We believe these actions, combined with the experience and expertise of our management team, position us well to drive the future growth of our revenue and income.

As we continue to focus on the growth of our existing products and product candidates, we also continue to position ourselves to execute upon the licensing and acquisition opportunities that will drive our next phase of growth. Our organization is fully committed to this effort, and we believe we will be successful in executing upon our corporate strategy in ways that will drive this future growth. In order to do so, we will need to continue to maintain our strategic direction, manage and deploy our available cash efficiently and strengthen our alliance and partner relationships.

During 2012 we are focused on the following four key initiatives:

growing revenues from our existing product portfolio;

acquiring companies and/or acquiring or licensing the rights to specialty products;

gaining regulatory approval for and launching CRTX 067; and

advancing our product pipeline, in particular, CRTX 080.

**Table of Contents****Results of Operations****Comparison of the Three Months Ended March 31, 2012 and 2011**

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

	Three Months Ended		Change	
	2012	March 31, 2011	\$	%
<i>Net product sales</i>				
CUROSURF	\$ 7,613	\$ 7,508	\$ 105	1%
ZYFLO product family	12,448	7,412	5,036	68
ALLERX® Dose Pack products	(994)	11,581	(12,575)	NM
Anti-infective products	2,921	6,077	(3,156)	(52)
Other products	169	(2,603)	2,772	NM
<b>Total net product sales</b>	<b>22,157</b>	<b>29,975</b>	<b>(7,818)</b>	<b>(26)</b>
<i>License and royalty agreement revenues</i>	4	22	(18)	(82)
<b>Net revenues</b>	<b>22,161</b>	<b>29,997</b>	<b>(7,836)</b>	<b>(26)</b>
Cost of product sales (exclusive of amortization of product rights)	8,686	10,034	(1,348)	(13)
Selling, general and administrative	11,664	13,269	(1,605)	(12)
Research and development	1,045	559	486	87
Gain on divestiture of product rights	(1,492)		1,492	NM
Amortization of product rights	5,301	3,595	1,706	47
<b>(Loss) income from operations</b>	<b>(3,043)</b>	<b>2,540</b>	<b>(5,583)</b>	<b>NM</b>
Total other expenses, net	(2)	(41)	(39)	(95)
<b>(Loss) income before income taxes</b>	<b>(3,045)</b>	<b>2,499</b>	<b>(5,544)</b>	<b>NM</b>
Benefit from (provision for) income taxes	1,220	(757)	(1,977)	NM
<b>Net (loss) income</b>	<b>\$ (1,825)</b>	<b>\$ 1,742</b>	<b>\$ (3,567)</b>	<b>NM</b>
Net (loss) income per share, diluted	\$ (0.07)	\$ 0.07	\$ (0.14)	NM
<b>Non-GAAP income from operations (1)</b>	<b>\$ 2,183</b>	<b>\$ 6,514</b>	<b>\$ (4,331)</b>	<b>(66)%</b>
Non-GAAP net income (1)	\$ 1,307	\$ 4,512	\$ (3,205)	(71)%
<b>Non-GAAP net income per share, diluted (1)</b>	<b>\$ 0.05</b>	<b>\$ 0.17</b>	<b>\$ (0.12)</b>	<b>(71)%</b>

(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 \$105,000, or 1%, during the three months ended March 31, 2012 compared to the three months ended March 31, 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 \$5.0 million, or 68%, during the three months ended March 31, 2012 compared to the three months ended March 31, 2011, due to both an increase in unit volume and a price increase.

ALLERX Dose Pack net product sales decreased \$12.6 million during the three months ended March 31, 2012 compared to the three months ended March 31, 2011. In March 2011, the United States Food and Drug Administration, or 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 is 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 three months ended March 31, 2012, we recorded an additional expense of \$1.1 million for product returns which exceeded our initial estimates.

**Table of Contents**

Net product sales from our anti-infective products decreased \$3.2 million, or 52%, during the three months ended March 31, 2012 compared to the three months ended March 31, 2011, primarily due to our divestiture of the product rights and certain related assets and liabilities in early March 2012.

Net product sales from other products increased \$2.8 million during the three months ended March 31, 2012 compared to the three months ended March 31, 2011. The primary reason for this increase was the approximately \$3.4 million of propoxyphene/acetaminophen product returns in the first three months of March 31, 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 actually decreased approximately \$600,000 due to lower net prices and lower unit volume as a result of increased competition from other manufacturers.

*Costs and Expenses*

*Cost of Product Sales.* Cost of product sales (exclusive of amortization of product rights of \$5.3 million and \$3.6 million for the three months ended March 31, 2012 and 2011, respectively) decreased \$1.3 million, or 13%, during the three months ended March 31, 2012 compared to the three months ended March 31, 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		Change	
	2012	2011	\$	%
Net product sales	\$ 22,157	\$ 29,975	\$ (7,818)	(26)%
Cost of product sales (exclusive of amortization of product rights)	8,686	10,034	(1,348)	(13)
Gross profit	\$ 13,471	\$ 19,941	\$ (6,470)	(32)%
Gross margin	61%	67%		

Gross margin of net product sales for the three months ended March 31, 2012 decreased six percentage points compared to the three months ended March 31, 2011. This decrease resulted because a relatively higher percentage of our total net product sales during the three months ended March 31, 2012 was derived from products that have lower gross margins, specifically CUROSURF. We expect that gross margin will continue to decline primarily because CUROSURF has a lower gross margin than our other products until we are able to commercialize or acquire products with higher gross margins.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses decreased \$1.6 million, or 12%, during the three months ended March 31, 2012 compared to the three months ended March 31, 2011. This decrease was primarily due to decreases 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 during the three months ended March 31, 2012.

*Research and Development Expenses.* Research and development expenses increased \$486,000, or 87%, during the three months ended March 31, 2012 compared to the three months ended March 31, 2011. This increase was primarily driven by development costs related to CRTX 080, which was acquired in December 2011 from Cardiokine, Inc., or Cardiokine. These costs were offset by a reduction in spend related to CRTX 073 during the three months ended March 31, 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 2011, we divested of our Factive and Spectracef product rights which resulted in a net gain on the divestiture of \$1.5 million for the three months ended March 31, 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 Pharmaceutical 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.

---

**Table of Contents**

*Amortization of Product Rights.* Amortization of product rights increased \$1.7 million, or 47%, during the three months ended March 31, 2012 compared to the three months ended March 31, 2011. At December 31, 2011, we reviewed the product rights for Factive and Spectracef for impairment and determined that no impairment was necessary. However, we reduced the useful lives of these product rights to six months as of December 31, 2011 based on our estimate of the period during which we expected to continue to benefit from these rights. As discussed above, these product rights along with certain related assets and liabilities were divested in March 2012.

*Benefit from (Provision for) Income Taxes*

The benefit from income taxes was \$1.2 million for the three months ended March 31, 2012 compared to a provision of \$757,000 for the three months ended March 31, 2011. Our effective tax rates for the three months ended March 31, 2012 and 2011 were (40.1)% and 30.3%, respectively. The change in the effective tax rate was due primarily to the tax impact of projected losses for 2012 as compared to 2011.

*Reconciliation of Non-GAAP Financial Measures*

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

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

The non-GAAP financial measures reflect adjustments for stock-based compensation expense, amortization of product rights, transaction-related expenses and the gain on the divestiture of certain product rights. Transaction-related expenses consist of (1) costs incurred to complete product or company acquisitions or other strategic transactions, including due diligence and legal, consulting and other related fees; (2) integration costs related to our completed transactions; and (3) transaction-related fees associated with transactions that are not consummated. 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 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, 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 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	
	March 31,	
	2012	2011
GAAP (loss) income from operations	\$ (3,043)	\$ 2,540
Add: stock-based compensation	675	379
Add: amortization of product rights	5,301	3,595
Add: transaction-related expenses(1)	742	
Less: gain on divestiture of product rights	(1,492)	
Non-GAAP income from operations	\$ 2,183	\$ 6,514
GAAP net (loss) income	\$ (1,825)	\$ 1,742
Add: stock-based compensation	675	379
Add: amortization of product rights	5,301	3,595
Add: transaction-related expenses(1)	742	
Less: gain on divestiture of product rights	(1,492)	
Less: tax effects related to above items(2)	(2,094)	(1,204)
Non-GAAP net income	\$ 1,307	\$ 4,512
GAAP net (loss) income per share, diluted	\$ (0.07)	\$ 0.07
Non-GAAP net income per share, diluted	\$ 0.05	\$ 0.17
Shares used in diluted net income per share calculation:		
GAAP net income	25,817,185	26,088,851
Non-GAAP net income	26,292,839	26,088,851

- (1) Transaction-related expenses include costs related to our completed divestiture of our anti-infective franchise and certain transaction-related fees associated with both anticipated transactions and certain transactions that were not consummated.  
(2) Tax effects for three months ended March 31, 2012 and 2011 are calculated using effective tax rates of (40.1)% and 30.3%, 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 product sales, royalty agreement revenues and the investment from Chiesi. As of March 31, 2012, we had \$74.2 million in cash and cash equivalents.

**Cash Flows**

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

Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

	Three Months Ended	
	March 31,	
	2012	2011
Cash (used in) provided by:		
Operating activities	\$ (2,709)	\$ 35,199
Investing activities	2,920	(57)
Financing activities	20	(9)
Net increase in cash and cash equivalents	\$ 231	\$ 35,133

## **Table of Contents**

### *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 and royalties.

Net cash used in operating activities for the three months ended March 31, 2012 reflected our net loss of \$1.8 million, adjusted by non-cash expenses totaling \$3.5 million and changes operating assets and liabilities from December 31, 2011 to March 31, 2012 totaling \$4.4 million. Accounts receivable and inventory increased by \$2.8 million and \$325,000, respectively, from December 31, 2011 to March 31, 2012. Prepaid expenses and other assets decreased by \$1.4 million, primarily due to the amortization of regulatory fees and the receipt of a tax refund and prepaid inventory. Accounts payable decreased by \$2.0 million from December 31, 2011 to March 31, 2012, primarily due to payment of liabilities acquired in our transaction with Cardiokine. Accrued expenses decreased by \$1.8 million from December 31, 2011 to March 31, 2012, primarily due to the payment of annual bonuses and decreases in certain sales allowances. Income taxes receivable decreased by \$1.1 million from December 31, 2011 to March 31, 2012.

Net cash provided by operating activities for the three months ended March 31, 2011 reflected our net income of \$1.7 million, adjusted by non-cash expenses totaling \$8.1 million and changes in accounts receivable, inventories, income taxes payable, accrued expenses and other operating assets and liabilities totaling \$41.5 million.

### *Net Cash Provided By (Used in) Investing Activities*

Net cash provided by investing activities for the three months ended March 31, 2012 reflected the cash proceeds allocated to the divested anti-infective product rights and purchase of property and equipment for \$80,000.

Net cash used in investing activities for the three months ended March 31, 2011 reflected the purchase of property and equipment for \$57,000.

### *Net Cash Provided by (Used in) Financing Activities*

Net cash provided by financing activities for the three months ended March 31, 2012 reflected principal payments on capital leases of \$17,000 and purchases of treasury of stock of \$24,000, partially offset by proceeds from common stock option exercises of \$23,000 and an excess tax benefit from stock options of \$38,000.

Net cash used in financing activities for the three months ended March 31, 2011 reflected principal payments on capital leases of \$20,000, partially offset by proceeds from common stock option exercises of \$9,000 and an excess tax benefit from stock options of \$2,000.

### ***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;

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

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

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

## Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

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

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

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

the extent to which we are required to make certain contingent payments in connection with our acquisition of Cardiokine;

**Table of Contents**

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

the 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 March 31, 2012, we had \$74.2 million of cash and cash equivalents on hand. Based on our current operating plans, we believe that our existing cash and cash equivalents and anticipated revenues from product sales are sufficient to continue to fund our existing level of operating expenses and capital expenditure requirements for at least the next twelve months.

**Contractual Obligations**

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent contractual liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing, contingent royalty payments and/or scientific, regulatory or commercial milestone payments under development agreements. There have been no material changes outside the ordinary course of business to our contractual obligations during the three months ended March 31, 2012 except for obligations that were transferred in connection with the divestiture of our anti-infective product rights. The following table summarizes our contractual obligations as of March 31, 2012 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Capital lease obligations	\$ 28	\$ 11	\$ 17	\$	\$
Operating leases(1)	2,352	461	1,140	751	
Purchase obligations(2)	17,531	14,522	2,785	224	
Total contractual obligations(3)	\$ 19,911	\$ 14,994	\$ 3,942	\$ 975	\$

- (1) Operating leases include minimum payments under leases for our facilities, automobiles and certain equipment. Our total minimum lease payments for the corporate headquarters are \$491,000 in 2012 (of which we paid \$92,000 during the first three months of 2012), \$536,000 in 2013, \$584,000 in 2014, \$599,000 in 2015 and \$152,000 thereafter.
- (2) Purchase obligations include fixed or minimum payments under manufacturing and supply agreements with third-party manufacturers of \$1.2 million; clinical trial and research agreements with contract research organizations and consultants of \$3.3 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 \$10.6 million.
- (3) Excluded from the contractual obligations table are potential payments of up to \$156 million for contingent consideration that we may be required to pay in connection with our acquisition of Cardiokine and \$8.4 million in potential future milestone payments as part of our licensing, distribution and development agreements, as well as a contingent liability of \$1.1 million related to our divestiture of Factive. 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.

**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**

## Edgar Filing: CORNERSTONE THERAPEUTICS INC - Form 10-Q

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.



## **Table of Contents**

### **Recent Accounting Pronouncements**

As discussed in Note 11 to our consolidated financial statements included in Part I Item 1. Financial Statements of this quarterly report on Form 10-Q, there are no recent accounting pronouncements that we have not yet adopted that are expected to have a material impact on our consolidated financial statements.

### **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 is limited to future capital leases and other short-term debt obligations we may incur in our normal operations. 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 two development agreements denominated in foreign currencies, Euros and Swiss francs. 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 months ended March 31, 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 March 31, 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 March 31, 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 March 31, 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.



**Table of Contents****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.

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

There were no sales of unregistered securities during the three months ended March 31, 2012.

The following table lists all repurchases during the three months ended March 31, 2012 of our common stock by or on behalf of us or any affiliated purchaser.

**Issuer Purchases of Equity Securities**

		Total Number of Shares Purchased (1)	Average Price Paid per Share (2)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs
January 1, 2012	January 31, 2012		\$	\$	\$
February 1, 2012	February 29, 2012	3,722	6.48		
March 1, 2012	March 31, 2012				
Total		3,722	\$ 6.48	\$	\$

- (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.

**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: May 15, 2012

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

Date: May 15, 2012

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

Date: May 15, 2012

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

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
2.1+ **	Asset Purchase Agreement between the Registrant and Vansen Pharma, Inc. dated March 7, 2012.
2.2+ **	Asset Purchase Agreement between the Registrant and Merus Labs International Inc. dated March 7, 2012.
10.1+	Copromotion Agreement between the Registrant and Vansen Pharma, Inc. dated March 7, 2012 (included as Exhibit F in Exhibit 2.1 hereto).
10.2	Consent and Waiver, dated March 7, 2012, with respect to Co-Promotion and Marketing Services Agreement between the Registrant and Dey, L.P. dated March 13, 2007.
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 March 31, 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, tagged as blocks of text.
*	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.