

CORNERSTONE THERAPEUTICS INC

Form 10-Q

November 08, 2012

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-Q

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

For the Quarterly Period Ended September 30, 2012

or

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

For the Transition Period From to

Commission File Number: 000-50767

CORNERSTONE THERAPEUTICS INC.

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

Large accelerated filer Accelerated filer

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

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

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

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PART I FINANCIAL INFORMATION

Cautionary Statement Regarding Forward-Looking Statements

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

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

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

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

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

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

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

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

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

	Nine Months Ended September 30,	
	2012	2011
Cash flows from operating activities		
Net (loss) income	\$ (4,929)	\$ 2,056
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Amortization and depreciation	14,267	11,146
Amortization of debt costs	26	
Provision for prompt payment discounts	2,390	2,781
Provision for inventory allowances	847	339
Acquisition accounting adjustment on inventory sold	3,061	
Gain on sale of product rights	(1,492)	
Loss on disposal of property and equipment	215	
Change in acquisition-related contingent payments	(1,574)	