

Cornerstone Therapeutics Reports First Quarter 2009 Financial Results

CARY, N.C., May 7, 2009 /PRNewswire-FirstCall via COMTEX/ -- Cornerstone Therapeutics Inc. (Nasdaq CM: CRTX), a specialty pharmaceutical company focused on acquiring, developing and commercializing significant products primarily for the respiratory market, today reported financial results for the first quarter ended March 31, 2009. Highlights:

- First quarter 2009 Net Revenues increased \$21.3 million to \$30.7 Million, or 225%
- Income from Operations increased \$9.0 million to \$10.4 Million, or 658%
- Net Income and Diluted Earnings Per Share increased to \$6.3 million and \$0.48, respectively

As previously disclosed, Critical Therapeutics, Inc. and Cornerstone BioPharma Holdings, Inc. (Cornerstone BioPharma) completed their merger on October 31, 2008, and the combined company was renamed Cornerstone Therapeutics Inc. (the Company). Cornerstone BioPharma was deemed to be the acquiring company for accounting purposes and the transaction was accounted for as a reverse acquisition in accordance with generally accepted accounting principles. Accordingly, the Company's financial statements for periods prior to the merger reflect the historical results of Cornerstone BioPharma, and not Critical Therapeutics, and Cornerstone Therapeutics' financial statements for all subsequent periods reflect the results of the combined company. In addition, unless specifically noted otherwise, the Company's financial results do not include the historical financial results of Critical Therapeutics (including sales of ZYFLO CR(R) and ZYFLO(R)) prior to the completion of the merger.

Financial Results for the Three Months Ended March 31, 2009 and 2008

First quarter 2009 net revenues increased \$21.3 million over first quarter 2008, or 225%, to \$30.7 million. Net product sales were \$30.5 million in the first quarter of 2009, compared to \$9.0 million in the same period of 2008, an increase of \$21.5 million, or 239%. Net product sales in the first quarters of 2009 and 2008 consisted of revenues from sales of the Company's AlleRx(R) family of products, which increased \$4.4 million in the most recent first quarter compared to 2008, Spectracef(R), which increased \$3.5 million in the most recent first quarter compared to 2008, Deconsal(R), and Balacet(R) 325 products. Additionally, net product sales in the 2009 first quarter also included \$8.6 million in sales of the HyoMax(R) line of products, which was launched in May 2008, and \$5.3 million in sales of ZYFLO CR and ZYFLO.

Gross profit was \$27.5 million in the quarter ended March 31, 2009, compared to \$8.8 million in the corresponding period of 2008. Gross margin (exclusive of amortization of product rights of \$511,000 and \$739,000 the three months ended March 31, 2009 and 2008, respectively) was 90% in the first quarter of 2009 and 94% in the first quarter of 2008.

Sales and marketing expenses were \$5.4 million in the 2009 first quarter, compared to \$3.9 million in the 2008 first quarter, an increase of approximately \$1.5 million, or 38%, which includes a \$776,000 increase in co-promotion expenses primarily relating to ZYFLO CR.

Royalty expenses were \$6.3 million in the first quarter of 2009, compared to \$1.2 million in the corresponding period of 2008, an increase of approximately \$5.1 million, or 405%. This increase was primarily due to the launch of the HyoMax line of products, which took place in May 2008, increased net product sales of the AlleRx family of products and royalties relating to ZYFLO CR and ZYFLO.

General and administrative expenses were \$3.8 million in the quarter ended March 31, 2009, compared to \$1.5 million in the quarter ended March 31, 2008, an increase of approximately \$2.3 million, or 147%. This increase was primarily due to a \$1.0 million increase related to public company legal and accounting costs and a \$0.6 million increase in employee and travel expenses resulting from our growth.

Research and development expenses were \$1.2 million in the 2009 first quarter, compared to \$98,000 in the 2008 first quarter, an increase of approximately \$1.1 million, or 1086%. Research and development expenses in the most

recent first quarter included additional expenses related to on-going pipeline development.

For the three months ended March 31, 2009, the Company had operating income of \$10.4 million, or 33.9% of net revenues, compared with operating income of \$1.4 million, or 14.9% of net revenues, for the same period in 2008, an increase of approximately 658%. The Company's first quarter 2009 net income and diluted earnings per share were \$6.3 million and \$0.48, respectively.

"We are extremely pleased with our financial performance in the first quarter, as we delivered substantial growth in operating income, and further strengthened our balance sheet," said Craig A. Collard, Cornerstone's President and Chief Executive Officer. "Also, our sales and marketing strategies for key products, including SPECTRACEF, ZYFLO CR and ALLERX, continued to gain traction with net product sales more than tripling year-over-year. In addition, our existing product pipeline continues to move forward."

As of March 31, 2009, the Company had \$10.7 million in cash and cash equivalents, an increase of \$1.5 million compared to December 31, 2008.

2009 Outlook

Following this strong start to the year, the Company is raising its full year guidance for net revenues from over \$80 million to over \$95 million. In addition, the Company is increasing its income from operations estimate from in excess of \$10 million to in excess of \$17 million. It should be noted that during the first quarter, the Company enjoyed limited competition within the market for its HYOMAX products, but the Company now faces generic competition across a number of HYOMAX product lines. To reiterate, the Company's guidance assumes an increase of approximately \$4.5 million in clinical development spend over 2008.

Conference Call Information

Cornerstone Therapeutics will host a conference call today at 8:30 AM ET to discuss its financial results for the quarter ended March 31, 2009. To participate in the live conference call, please dial 866-783-2137 (U.S. callers) or 857-350-1596 (international), and provide passcode 84050385. A live webcast of the call will also be available through the Investor Relations section of the Company's Web site. Please allow extra time prior to the webcast to register, download and install any necessary audio software.

The webcast will be archived for 30 days, and a telephone replay of the call will be available for seven days, beginning today at 11:30 AM ET at 888-286-8010 (U.S. callers) or 617-801-6888 (international), and provide passcode 21539068.

About Cornerstone Therapeutics

Cornerstone Therapeutics Inc. (NASDAQ CM: CRTX), headquartered in Cary, N.C., is a specialty pharmaceutical company focused on acquiring, developing and commercializing products primarily for the respiratory and related markets. The Company currently promotes multiple marketed products in the United States to respiratory-focused physicians and key retail pharmacies with its specialty sales force. The Company also has a late-stage clinical pipeline with five regulatory approval submissions targeted within the next three years. Key elements of the Company's strategy are to in-license or acquire rights to underpromoted, patent-protected, branded respiratory or related pharmaceutical products, or late-stage product candidates; implement life cycle management strategies to maximize the potential value and competitive position of the Company's currently marketed products, newly acquired products and product candidates that are currently in development; grow product revenue through the Company's specialty sales force which is focused on the respiratory and related markets; and maintain and strengthen the intellectual property position of the Company's currently marketed products, newly acquired products and product candidates.

Safe Harbor Statement

Statements in this press release regarding the progress and timing of our product development programs and related trials; our future opportunities; our strategy, future operations, 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. Any statements that are not statements of historical fact (including, without limitation, statements containing the words "anticipate," "believe," "could," "estimate," "intend," "may," "plan," "expect," "should," "target," "will," "would," and similar expressions) should also be considered to be forward-looking statements.

There are a number of important factors that could cause our actual results or events to differ materially from those indicated by such forward-looking statements, including risks relating to our critical accounting estimates and risks relating to our ability to realize anticipated synergies and cost savings from our October 2008 merger; our ability to develop and maintain the necessary sales, marketing, supply chain, distribution and manufacturing capabilities to commercialize our products, including difficulties relating to the manufacture of ZYFLO CR tablets; the possibility that the Food and Drug Administration (the FDA) will take enforcement action against us or one or more of our marketed drugs that do not have FDA-approved marketing applications; patient, physician and third-party payor 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 obtain and maintain regulatory approvals to market and sell our products that do have FDA approved marketing applications; our ability to enter into additional strategic licensing, collaboration or co-promotion transactions on favorable terms, if at all; 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 products under development and whether such results will be indicative of results obtained in later clinical trials; our ability to satisfy FDA and other regulatory requirements; our ability to obtain, maintain and enforce patent and other intellectual property protection for our products and product candidates; and the other factors described in Item 1A (Risk Factors) of our Annual Report on Form 10K, filed with the Securities and Exchange Commission (the SEC) on March 26, 2009, and other filings that we make with the SEC. 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, the statements in this press release reflect our expectations and beliefs as of the date of this release. We anticipate that subsequent events and developments will cause our expectations and beliefs 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. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, business development transactions, joint ventures or investments that we may make. These forward-looking statements should not be relied upon as representing our views as of any date after the date of this release.

ZYFLO CR(R), ZYFLO(R), AlleRx(R), Deconsal(R), Balacet(R) and HyoMax(R) are trademarks of Cornerstone Therapeutics Inc. SPECTRACEF is a trademark of Meiji Seika Kaisha, Ltd. and is licensed to the Company.

FINANCIAL TABLES FOLLOW

CORNERSTONE THERAPEUTICS INC.
CONDENSED STATEMENTS OF INCOME
(UNAUDITED)

(In thousands, except share and per share data)

| | Three months ended March 31, | |
|--|---------------------------------|---------|
| | 2009 | 2008 |
| Net revenues | \$30,705 | \$9,445 |
| Costs and expenses: | | |
| Cost of product sales (exclusive of amortization of product rights) | 3,201 | 565 |
| Sales and marketing | 5,395 | 3,908 |
| Royalties | 6,291 | 1,245 |
| General and administrative | 3,760 | 1,523 |
| Research and development | 1,162 | 98 |
| Amortization of product rights | 511 | 739 |
| Other charges | 26 | -- |
| Total costs and expenses | 20,346 | 8,078 |
| Income from operations | 10,359 | 1,367 |
| Other expenses: | | |
| Interest expense, net | (72) | (379) |
| Total other expenses | (72) | (379) |
| Income before income taxes | 10,287 | 988 |
| Provision for income taxes | (3,972) | (319) |

| | | |
|---|------------|-----------|
| Net income | \$6,315 | \$669 |
| | ----- | ----- |
| Net income per share, basic | \$0.53 | \$0.11 |
| | ----- | ----- |
| Net income per share, diluted | \$0.48 | \$0.10 |
| | ===== | ===== |
| Weighted-average common shares, basic | 12,023,747 | 5,934,496 |
| | ----- | ----- |
| Weighted-average common shares, diluted | 13,114,505 | 6,837,122 |
| | ===== | ===== |

CORNERSTONE THERAPEUTICS INC.
CONDENSED BALANCE SHEETS
(In thousands, except share and per share data)

| | March 31, 2009 (Unaudited) | December 31, 2008 (Audited) |
|--|----------------------------------|-----------------------------------|
| | ----- | ----- |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$10,736 | \$9,286 |
| Marketable securities | - | 300 |
| Accounts receivable, net | 16,981 | 13,660 |
| Inventories, net | 12,840 | 11,222 |
| Prepaid expenses | 1,985 | 1,081 |
| Deferred income tax asset | 2,839 | 2,428 |
| | ----- | ----- |
| Total current assets | 45,381 | 37,977 |
| | ----- | ----- |
| Property and equipment, net | 979 | 895 |
| Product rights, net | 17,191 | 17,702 |
| Goodwill | 13,231 | 13,231 |
| Amounts due from related parties | 38 | 38 |
| Deposits | 46 | 46 |
| | ----- | ----- |
| Total assets | \$76,866 | \$69,889 |
| | ----- | ----- |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$8,723 | \$10,288 |
| Accrued expenses | 20,088 | 19,052 |
| Current portion of license agreement liability | 2,654 | 2,543 |
| Current portion of capital lease | 9 | - |
| Income taxes payable | 3,580 | 2,937 |
| | ----- | ----- |
| Total current liabilities | 35,054 | 34,820 |
| | ----- | ----- |
| Long-term liabilities: | | |
| License agreement liability, less current portion | 2,313 | 2,313 |
| Capital Lease, less current portion | 47 | - |
| Deferred income tax liability | 3,457 | 3,330 |
| | ----- | ----- |
| Total long-term liabilities | 5,817 | 5,643 |
| | ----- | ----- |
| Total liabilities | 40,871 | 40,463 |
| | ----- | ----- |
| Commitments and contingencies | | |
| 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; 12,023,747 shares issued and outstanding as of March 31, 2009 and December 31, 2008, respectively | 12 | 12 |
| Additional paid-in capital | 33,773 | 33,519 |
| Retained Earning / accumulated deficit | 2,210 | (4,105) |

| | | |
|--|----------|----------|
| Total stockholders' equity | 35,995 | 29,426 |
| Total liabilities and stockholders' equity | \$76,866 | \$69,889 |

CORNERSTONE THERAPEUTICS INC.
CONDENSED STATEMENTS OF CASH FLOWS
(In thousands)
(UNAUDITED)

| | Three months ended March 31, | |
|---|---------------------------------|---------|
| | 2009 | 2008 |
| Cash flows from operating activities | 2009 | 2008 |
| Net income | \$6,315 | \$669 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Amortization and depreciation | 564 | 758 |
| Change in allowance for prompt payment discounts | 63 | 15 |
| Change in allowance for inventory obsolescence | 77 | (32) |
| Stock-based compensation | 254 | 84 |
| Benefit for deferred income taxes | (284) | - |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (3,384) | 609 |
| Inventories | (1,695) | (824) |
| Prepaid expenses | (904) | (169) |
| Accounts payable | (1,565) | (5) |
| Accrued expenses | 1,147 | 807 |
| Income taxes payable | 643 | 281 |
| Net cash provided by operating activities | 1,231 | 2,193 |
| Cash flows from investing activities | | |
| Advances to related parties | - | (13) |
| Proceeds from the sale of marketable securities | 300 | - |
| Purchase of property and equipment | (79) | (15) |
| Purchase of product rights | - | (1,000) |
| Collection of deposits | - | 10 |
| Net cash provided by / (used in) investing activities | 221 | (1,018) |
| Cash flows from financing activities | | |
| Proceeds from line of credit | - | 4,000 |
| Principal payments on line of credit | - | (5,000) |
| Principal payments on capital lease obligation | (2) | - |
| Net cash used in financing activities | (2) | (1,000) |
| Net increase in cash and cash equivalents | 1,450 | 175 |
| Cash and cash equivalents as of beginning of period | 9,286 | 241 |
| Cash and cash equivalents as of end of period | \$10,736 | \$416 |
| Supplemental disclosure of cash flow information | | |
| Cash paid during the period for interest | \$3 | \$24 |
| Cash paid during the period for income taxes | \$3,613 | \$38 |
| Supplemental schedule of non-cash investing and financing activities | | |
| Purchase of equipment under capital lease obligation | \$58 | \$- |