

CRITICAL THERAPEUTICS INC

Form 8-K

October 24, 2008

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

**FORM 8-K
CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **October 23, 2008**

Critical Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

000-50767

(Commission
File Number)

04-3523569

(IRS Employer
Identification No.)

60 Westview Street, Lexington, Massachusetts

(Address of Principal Executive Offices)

02421

(Zip Code)

Registrant's telephone number, including area code: **(781) 402-5700**

Not applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01 Other Events.

On October 23, 2008, Critical Therapeutics, Inc. ("Critical Therapeutics") filed with the Securities and Exchange Commission under cover of Schedule 14A a Supplement No. 2, dated October 22, 2008, to the Proxy Statement/Prospectus, dated October 3, 2008, relating to Critical Therapeutics' proposed business combination with Cornerstone BioPharma Holdings, Inc. ("Cornerstone"), which included the following information relating to Cornerstone's financial results for the three and nine months ended September 30, 2008.

The following information related to Cornerstone's financial results for the three and nine months ended September 30, 2008 and September 30, 2007 is meant to be read together with the sections entitled "Selected Historical Consolidated Financial Data of Cornerstone" and "Cornerstone's Management's Discussion and Analysis of Financial Condition and Results of Operations" and Cornerstone's financial statements and accompanying notes included in the Proxy Statement/Prospectus. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Prior results are not necessarily indicative of future performance. Cornerstone's future performance may differ materially from its previous results and from those anticipated in these forward-looking statements due to many important factors, including, but not limited to, those set forth in the section entitled "Risks Related to Cornerstone" in the Proxy Statement/Prospectus.

Comparison of the Three Months Ended September 30, 2008 and 2007

Net Revenues

Net Product Sales. Net product sales were \$20.1 million in the three months ended September 30, 2008, compared to \$7.4 million in the three months ended September 30, 2007, an increase of approximately \$12.8 million, or 174%. The increase in net product sales was primarily due to a \$2.5 million increase in net product sales of the AlleRx[®], or ALLERX, Dose Pack family of products and a \$12.5 million of net product sales of Cornerstone's HyoMax[®], or HYOMAX, line of products. Cornerstone launched its first HYOMAX product in May 2008, followed by its second and third HYOMAX products in June 2008 and its fourth HYOMAX product in July 2008. These increases were offset, in part, by a \$2.1 million decrease in net product sales of Spectracef[®], or SPECTRACEF, primarily due to decreased wholesaler purchasing activity in the three months ended September 30, 2008 as there was sufficient supply of product in the distribution channel. Cornerstone management believes the amount of product in the distribution channel has now been reduced such that future prescription demand will necessitate additional purchases by wholesalers.

Royalty Agreement Revenues. Royalty agreement revenues were \$457,000 in the three months ended September 30, 2008, compared to \$545,000 in the three months ended September 30, 2007, a decrease of approximately \$88,000, or 16%.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of \$109,000 and \$768,000 in the three months ended September 30, 2008 and 2007, respectively) was \$1.6 million in the three months ended September 30, 2008, compared to \$848,000 in the three months ended September 30, 2007. Gross margin (exclusive of amortization of product rights of \$109,000 and \$768,000 in the three months ended September 30, 2008 and 2007, respectively) was approximately 92% in the three months ended September 30, 2008 and 88% in the three months ended September 30, 2007. The 4% gross margin increase was primarily due to sales of Cornerstone's HYOMAX products.

Sales and Marketing Expenses. Sales and marketing expenses were \$3.8 million in the three months ended September 30, 2008, compared to \$2.7 million in the three months ended September 30, 2007, an increase of approximately \$1.0 million, or 37%. This increase was primarily due to a \$376,000 increase in advertising and promotion expenses, a \$317,000 increase in labor, benefits and related employee expenses as a result of additional

headcount and a \$156,000 increase in co-promotion expenses relating to Balacet[®] 325, or BALACET 325.

Royalty Expenses. Royalty expenses were \$6.8 million in the three months ended September 30, 2008, compared to \$1.1 million in the three months ended September 30, 2007, an increase of approximately \$5.5 million, or 497%. This increase was due to \$5.8 million of royalty expenses related to sales of the HYOMAX line of products in the three months ended September 30, 2008.

General and Administrative Expenses. General and administrative expenses were \$2.3 million in the three months ended September 30, 2008, compared to \$1.0 million in the three months ended September 30, 2007, an increase of approximately \$1.3 million, or 137%. This increase was primarily due to an \$816,000 increase

in legal and consulting fees related to the proposed merger with Critical Therapeutics and \$284,000 in expenses related to Aristos Pharmaceuticals, Inc., or Aristos, which began operations in November 2007. Cornerstone formed Aristos to launch authorized generic versions of Cornerstone's products that become subject to generic competition and to acquire or in-license generic versions of products with little or no generic competition, such as the HYOMAX line of products, that Cornerstone's management believes offer attractive returns on investment, regardless of whether such products fall within the respiratory market, which is Cornerstone's primary focus.

Research and Development Expenses. Research and development expenses were \$568,000 in the three months ended September 30, 2008, compared to \$191,000 in the three months ended September 30, 2007, an increase of approximately \$377,000, or 197%. This increase was primarily due to increased expenses related to the SPECTRACEF life cycle extension programs and the hydrocodone cough suppressant product candidates, CBP 067 and CBP 069.

Amortization and Depreciation Expenses. Amortization and depreciation expenses were \$128,000 in the three months ended September 30, 2008, compared to \$787,000 in the three months ended September 30, 2007, a decrease of approximately \$659,000, or 84%. This decrease was primarily due to a \$630,000 decrease in amortization expense associated with the BALACET product rights due to these product rights being fully amortized as of March 31, 2008.

Other Expenses

Interest expense, net, was \$336,000 in the three months ended September 30, 2008, compared to \$368,000 in the three months ended September 30, 2007, a decrease of approximately \$32,000, or 9%.

Provision for Income Taxes

The provision for income taxes from continuing operations was \$2.4 million in the three months ended September 30, 2008, compared to \$147,000 in the three months ended September 30, 2007. This increase in the provision for income taxes was due to the increase in income before income taxes from \$764,000 in the three months ended September 30, 2007 to \$5.0 million in the three months ended September 30, 2008. The effective tax rate was 46.8% in the three months ended September 30, 2008 and 19.2% in the three months ended September 30, 2007. The increase in the effective tax rate in the three months ended September 30, 2008 was primarily due to the full utilization during the year of net operating loss carryforwards.

Comparison of the Nine Months Ended September 30, 2008 and 2007

Net Revenues

Net Product Sales. Net product sales were \$42.9 million in the nine months ended September 30, 2008, compared to \$20.8 million in the nine months ended September 30, 2007, an increase of approximately \$22.0 million, or 100%. The increase in net product sales was primarily due to \$17.0 million of net product sales of Cornerstone's HYOMAX line of products and a \$7.0 million increase in net product sales of the ALLERX Dose Pack family of products. These increases were offset, in part, by a \$3.3 million decrease in net product sales of SPECTRACEF primarily due to decreased wholesaler purchasing activity in the nine months ended September 30, 2008 as there was sufficient supply of product in the distribution channel. Cornerstone management believes the amount of product in the distribution channel has now been reduced such that future prescription demand will necessitate additional purchases by wholesalers.

Royalty Agreement Revenues. Royalty agreement revenues were \$1.2 million in the nine months ended September 30, 2008, compared to \$1.3 million in the nine months ended September 30, 2007, a decrease of approximately \$24,000,

or 2%, primarily due to reduced royalty agreement revenues from the Propoxyphene-APAP 100-500 product.

Costs and Expenses

Cost of Product Sales. Cost of product sales (exclusive of amortization of product rights of \$957,000 and \$2.4 million in the nine months ended September 30, 2008 and 2007, respectively) was \$3.1 million in the

nine months ended September 30, 2008, compared to \$2.4 million in the nine months ended September 30, 2007. Gross margin (exclusive of amortization of product rights of \$957,000 and \$2.4 million in the nine months ended September 30, 2008 and 2007, respectively) was approximately 93% in the nine months ended September 30, 2008 and 89% in the nine months ended September 30, 2007. The 4% gross margin increase was primarily due to sales of Cornerstone's HYOMAX products.

Sales and Marketing Expenses. Sales and marketing expenses were \$11.3 million in the nine months ended September 30, 2008, compared to \$7.6 million in the nine months ended September 30, 2007, an increase of approximately \$3.7 million, or 49%. This increase was primarily due to a \$1.0 million increase in advertising and promotion expenses, a \$1.1 million increase in labor, benefits and related employee expenses as a result of additional headcount and a \$1.3 million increase in co-promotion expenses relating to BALACET 325.

Royalty Expenses. Royalty expenses were \$11.6 million in the nine months ended September 30, 2008, compared to \$2.8 million in the nine months ended September 30, 2007, an increase of approximately \$8.9 million, or 319%. This increase was primarily due to \$8.1 million of royalty expenses related to sales of the HYOMAX line of products in the nine months ended September 30, 2008.

General and Administrative Expenses. General and administrative expenses were \$6.0 million in the nine months ended September 30, 2008, compared to \$3.0 million in the nine months ended September 30, 2007, an increase of approximately \$3.0 million, or 99%. This increase was primarily due to a \$1.9 million increase in legal and other professional fees related to the proposed merger with Critical Therapeutics and \$767,000 in expenses related to Aristos.

Research and Development Expenses. Research and development expenses were \$1.2 million in the nine months ended September 30, 2008, compared to \$304,000 in the nine months ended September 30, 2007, an increase of approximately \$869,000, or 286%. This increase was primarily due to increased expenses related to the SPECTRACEF life cycle extension programs and the hydrocodone cough suppressant product candidates.

Amortization and Depreciation Expenses. Amortization and depreciation expenses were \$1.0 million in the nine months ended September 30, 2008, compared to \$2.5 million in the nine months ended September 30, 2007, a decrease of approximately \$1.5 million, or 59%. This decrease was primarily due to a \$1.2 million decrease in amortization expense associated with the BALACET product rights due to these product rights being fully amortized as of March 31, 2008.

Other Expenses

Interest expense, net, was \$1.1 million in the nine months ended September 30, 2008, compared to \$1.0 million in the nine months ended September 30, 2007, an increase of approximately \$33,000, or 3%.

Provision for Income Taxes

The provision for income taxes from continuing operations was \$3.2 million in the nine months ended September 30, 2008, compared to \$681,000 in the nine months ended September 30, 2007. This increase in the provision for income taxes was due to the increase in income before income taxes from \$2.3 million in the nine months ended September 30, 2007 to \$8.7 million in the nine months ended September 30, 2008. The effective tax rate was 36.8% in the nine months ended September 30, 2008 and 29.6% in the nine months ended September 30, 2007. The increase in the effective tax rate in the nine months ended September 30, 2008 was primarily due to the full utilization during the year of net operating loss carryforwards.

Liquidity

Cash and cash equivalents totaled \$4.5 million at September 30, 2008, compared with \$19,000 at June 30, 2008 and \$241,000 at December 31, 2007. The increase in Cornerstone's cash and cash equivalents was primarily due to Cornerstone's net income of \$5.5 million in the nine months ended September 30, 2008. As of September 30, 2008 and June 30, 2008, Cornerstone had no outstanding balance on, and \$3.9 million of borrowing availability under, its line of credit with Paragon Commercial Bank, or the Paragon line of credit. As of December 31, 2007, Cornerstone had a \$1.75 million outstanding balance on, and \$2.25 of borrowing availability under, the Paragon line of credit.

CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**CONSOLIDATED BALANCE SHEETS**

	September 30, 2008 (Unaudited) (In thousands, except share and per share data)	December 31, 2007 (Audited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,500	\$ 241
Marketable security	8	8
Accounts receivable, net	17,611	6,529
Amounts due from related parties	55	648
Inventories, net	3,150	2,998
Prepaid expenses	1,002	278
Total current assets	26,326	10,702
Property and equipment, net	176	209
Other assets:		
Product rights, net	6,229	4,936
Amounts due from related parties	38	29
Deposits	92	33
Total other assets	6,359	4,998
Total assets	\$ 32,861	\$ 15,909
Liabilities		
Current liabilities:		
Accounts payable	\$ 3,544	\$ 2,214
Accrued expenses	20,250	11,163
Current portion of license agreement liability	1,000	576
Line of credit		1,750
Income taxes payable	2,688	130
Total current liabilities	27,482	15,833
Long-term liabilities:		
License agreement liability, less current portion	2,959	2,959
Note payable, related party	8,952	9,412

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Total long-term liabilities	11,911	12,371
Total liabilities	39,393	28,204
Stockholders' deficit		
Common stock \$0.0001 par value, 50,000,000 shares authorized		
24,926,150 shares issued and outstanding	2	2
Additional paid-in capital	1,057	801
Accumulated deficit	(7,591)	(13,098)
Total stockholders' deficit	(6,532)	(12,295)
Total liabilities and stockholders' deficit	\$ 32,861	\$ 15,909

CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
	(Unaudited)			
	(In thousands, except share and per share data)			
Net revenues	\$ 20,590	\$ 7,902	\$ 44,102	\$ 22,105
Costs and expenses:				
Cost of product sales (exclusive of amortization of product rights of \$109 and \$768 in the three months ended September 30, 2008 and 2007, respectively, and \$957 and \$2,421 in the nine months ended September 30, 2008 and 2007, respectively)	1,604	848	3,102	2,364
Sales and marketing	3,775	2,746	11,309	7,598
Royalties	6,844	1,146	11,648	2,777
General and administrative	2,254	953	6,027	3,031
Research and development	568	191	1,173	304
Amortization and depreciation	128	787	1,014	2,473
Other charges	35	99	62	230
Total costs and expenses	15,208	6,770	34,335	18,777
Income from operations	5,382	1,132	9,767	3,328
Other expenses:				
Interest expense, net	(336)	(368)	(1,056)	(1,025)
Other expenses			(2)	
Total other expenses	(336)	(368)	(1,058)	(1,025)
Income before income taxes	5,046	764	8,709	2,303
Provision for income taxes	2,363	147	3,202	681
Net income	\$ 2,683	\$ 617	\$ 5,507	\$ 1,622
Net income per share, basic	\$ 0.11	\$ 0.02	\$ 0.22	\$ 0.07
Net income per share, diluted	\$ 0.09	\$ 0.02	\$ 0.19	\$ 0.06
Weighted-average common shares, basic	24,926,150	24,926,150	24,926,150	24,926,150

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Weighted-average common shares, diluted	28,981,844	27,503,556	28,906,561	27,271,698
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CORNERSTONE BIOPHARMA HOLDINGS, INC. AND SUBSIDIARIES**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Nine Months Ended September 30, 2008 2007 (Unaudited) (In thousands)	
Cash flows from operating activities		
Net income	\$ 5,507	\$ 1,622
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization and depreciation	1,014	2,474
Stock-based compensation	256	725
Changes in operating assets and liabilities:		
Accounts receivable, net	(11,082)	(5,667)
Amounts due from related parties	(55)	117
Inventories, net	(152)	(904)
Prepaid expenses	(723)	(176)
Accounts payable	1,330	278
Accrued expenses	9,511	1,648
Income taxes payable	2,558	673
Net cash provided by operating activities	8,164	790
Cash flows from investing activities		
Advances to related parties	(20)	(679)
Proceeds from collection of advances to related parties	658	209
Purchase of property and equipment	(24)	(52)
Purchase of product rights	(2,250)	(75)
Collection of deposits	20	50
Payment of deposits	(79)	(5)
Net cash used in investing activities	(1,695)	(552)
Cash flows from financing activities		
Proceeds from line of credit	5,500	6,500
Principal payments on line of credit	(7,250)	(6,250)
Principal payments on notes payable	(460)	
Net cash (used in) provided by financing activities	(2,210)	250
Net increase in cash and cash equivalents	4,259	488
Cash and cash equivalents as of beginning of period	241	116
Cash and cash equivalents as of end of period	\$ 4,500	\$ 604

Supplemental disclosure of cash flow information

Cash paid during the period for interest	\$	58	\$	116
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Supplemental disclosure of non-cash flow investing and financing activities

Product rights acquired through issuance of a license agreement	\$		\$	2,565
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SIGNATURE

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 hereunto duly authorized.

Date: October 24, 2008

CRITICAL THERAPEUTICS, INC.

By: /s/ Thomas P. Kelly
Thomas P. Kelly
Chief Financial Officer and Senior Vice
President of Finance and Corporate
Development