

CORNERSTONE THERAPEUTICS INC

Form 8-K/A

November 14, 2008

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

**FORM 8-K/A  
Amendment No. 1  
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 30, 2008**

**Cornerstone Therapeutics Inc.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**000-50767**  
(Commission  
File Number)

**04-3523569**  
(IRS Employer  
Identification No.)

**2000 Regency Parkway, Suite 255, Cary, NC**  
(Address of Principal Executive Offices)

**27518**  
(Zip Code)

Registrant's telephone number, including area code: **(919) 678-6611**

**Critical Therapeutics, Inc.**

**60 Westview Street, Lexington, Massachusetts 02421**

(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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Ex-16.3 Letter from Deloitte & Touche LLP to the SEC dated November 14, 2008

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**Explanatory Note**

On November 5, 2008, Cornerstone Therapeutics Inc. ( Cornerstone ) filed a Current Report on Form 8-K (the Original Filing ) in connection with the completion of the business combination of Critical Therapeutics, Inc. ( Critical Therapeutics ) and Cornerstone BioPharma Holdings, Inc. ( CBHI ), in accordance with the terms of the Agreement and Plan of Merger, dated as of May 1, 2008, as amended, by and among Critical Therapeutics, Neptune Acquisition Corp., a wholly owned subsidiary of Critical Therapeutics, and CBHI (the Merger Agreement ), pursuant to which CBHI became a wholly owned subsidiary of Critical Therapeutics (the Merger ). Immediately following the Merger, Critical Therapeutics changed its name to Cornerstone Therapeutics Inc. ( Cornerstone ).

Cornerstone is filing this Amendment No. 1 on Form 8-K/A for the sole purpose of revising the disclosure in Item 4.01 of the Original Filing in accordance with Item 304(a)(1)(ii) of Regulation S-K to provide additional detail regarding the explanatory paragraph contained in the audit reported dated March 27, 2008 of Deloitte & Touche LLP relating to the ability of Critical Therapeutics to continue as a going concern.

Filed as an exhibit with this Amendment No. 1 is a new letter from Deloitte & Touche LLP to the Securities and Exchange Commission in accordance with Item 304(a)(3) of Regulation S-K relating to the disclosures made pursuant to Item 4.01. Accordingly, an updated Exhibit Index also is included with this Amendment No. 1.

This Amendment No. 1 does not change any of the other disclosures contained in the Original Filing. This Amendment No. 1 continues to speak as of the date of the Original Filing and Cornerstone has not updated or amended the disclosures contained therein to reflect events that have occurred since the date of the Original Filing. Accordingly, this Amendment No. 1 should be read in conjunction with any filings made by Cornerstone with the Securities and Exchange Commission subsequent to the date of the Original Filing.

**Item 4.01. Changes in Registrant s Certifying Accountant.**

The Merger was treated as a reverse acquisition for accounting purposes and, as such, the historical financial statements of the accounting acquirer, CBHI, will be the historical financial statements of Cornerstone. Prior to the closing of the Merger, CBHI s independent registered public accounting firm was Grant Thornton LLP ( Grant Thornton ), and Critical Therapeutics independent registered public accounting firm was Deloitte & Touche LLP ( Deloitte ). On October 31, 2008, following the closing of the Merger, the Audit Committee of Cornerstone s Board of Directors (the Audit Committee ) unanimously approved the retention of Grant Thornton as Cornerstone s independent registered public accounting firm and approved the dismissal of Deloitte as Cornerstone s independent registered public accounting firm.

***Deloitte***

Deloitte s reports on Critical Therapeutics financial statements for the years ended December 31, 2007 and 2006 did not contain any adverse opinion or disclaimer of opinion, and such reports were not qualified or modified as to uncertainty, audit scope or accounting principles, except that Deloitte s report dated March 27, 2008 contained an explanatory paragraph relating to Critical Therapeutics ability to continue as a going concern.

Prior to the Merger, Critical Therapeutics experienced significant operating losses in each year since its inception in 2000. Critical Therapeutics reported net losses of \$48.8 million in the year ended

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December 31, 2006, \$37.0 million in the year ended December 31, 2007 and \$19.4 million in the nine months ended September 30, 2008. Critical Therapeutics reported an accumulated deficit of approximately \$191.4 million as of December 31, 2007 and approximately \$211 million as of September 30, 2008. Critical Therapeutics reported revenue from the sale of its two marketed products, ZYFLO® (zileuton) tablets and ZYFLO CR® (zileuton) extended-release tablets, of \$11.0 million for the year ended December 31, 2007 and \$13.2 million for the nine months ended September 30, 2008, and did not record revenue from any other product. Management of Critical Therapeutics prior to the Merger reported that Critical Therapeutics would continue to incur substantial losses for the foreseeable future from spending significant amounts to fund research, development and commercialization efforts. These matters raised substantial doubt about Critical Therapeutics' ability to continue as a going concern as an independent, standalone company without obtaining additional financing.

During the years ended December 31, 2007 and 2006 and the interim period through October 31, 2008, (i) there were no disagreements with Deloitte on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Deloitte, would have caused Deloitte to make reference to the subject matter of the disagreements in connection with its reports, and (ii) except with respect to the material weakness described below, there were no reportable events (as described in Item 304(a)(1)(v) of Regulation S-K). As previously disclosed, in connection with the preparation of Critical Therapeutics' financial statements for the quarters ended June 30, 2007 and September 30, 2007, Critical Therapeutics management concluded that a material weakness in Critical Therapeutics' internal control over financial reporting existed. This material weakness related to the operation of controls over accounting for non-routine transactions, specifically the accrual of milestone obligations due under certain of Critical Therapeutics' contractual arrangements in accordance with generally accepted accounting principles. Critical Therapeutics' management determined that this material weakness had been remediated as of December 31, 2007 and did not report any material weakness in its Management's Report on Internal Control Over Financial Reporting included in Part II, Item 9A of Critical Therapeutics' Annual Report on Form 10-K for the year ended December 31, 2007.

Cornerstone provided Deloitte with a copy of the disclosures made pursuant to this Item 4.01 prior to the filing of the Original Filing. Cornerstone requested Deloitte to furnish Cornerstone with a letter addressed to the SEC stating whether it agrees with such disclosures and, if not, stating the respects in which it does not agree. Deloitte's letter, dated November 5, 2008, is attached hereto as Exhibit 16.1.

Cornerstone also provided Deloitte with a copy of the disclosures made pursuant to this Item 4.01 prior to the filing of Amendment No. 1. Cornerstone requested Deloitte to furnish Cornerstone with a letter addressed to the SEC stating whether it agrees with such disclosures and, if not, stating the respects in which it does not agree. Deloitte's letter, dated November 14, 2008, is attached hereto as Exhibit 16.3.

***Grant Thornton***

As mentioned above, following the closing of the Merger, Cornerstone's Audit Committee elected to continue CBHI's relationship with Grant Thornton and unanimously approved the retention of Grant Thornton as Cornerstone's independent registered public accounting firm.

Following CBHI's entry into the Merger Agreement, on May 20, 2008, CBHI's board of directors retained Grant Thornton, an independent public accounting firm registered with the Public Company Accounting Oversight Board (PCAOB), as CBHI's independent registered public accounting firm to report on CBHI's financial statements for the years ended December 31, 2007, 2006 and 2005.

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CBHI did not consult with Grant Thornton during the years ended December 31, 2007 or 2006, or the interim period through May 20, 2008, with respect to (i) the application of accounting principles to a specified transaction, either completed or proposed; (ii) the type of audit opinion that might be rendered on CBHI's financial statements; or (iii) any matter that was either the subject of a disagreement or a reportable event.

Critical Therapeutics did not consult with Grant Thornton during the years ended December 31, 2007 or 2006, or the interim period through October 31, 2008, with respect to (i) the application of accounting principles to a specified transaction, either completed or proposed; (ii) the type of audit opinion that might be rendered on Critical Therapeutics' financial statements; or (iii) any matter that was either the subject of a disagreement or a reportable event.

***Hughes Pittman Gupton***

The Merger Agreement required CBHI, within 15 business days after its entry into the Merger Agreement, to retain an independent public accounting firm registered with the PCAOB to report on CBHI's financial statements for the years ended December 31, 2007, 2006 and 2005 to be included in a registration statement on Form S-4 to be filed by Critical Therapeutics in connection with the Merger. Prior to entering into the Merger Agreement, CBHI's independent public accounting firm was Hughes Pittman & Gupton, LLP ( Hughes Pittman Gupton ), which had reported on CBHI's financial statements for those periods. Because Hughes Pittman Gupton is not registered with the PCAOB, CBHI retained Grant Thornton to report on its financial statements for those periods.

In connection with CBHI's decision to engage a new independent public accounting firm, on May 7, 2008, CBHI and Hughes Pittman Gupton mutually agreed that Hughes Pittman Gupton would no longer act as CBHI's independent public accounting firm. Hughes Pittman Gupton's reports on CBHI's financial statements for the years ended December 31, 2007, 2006 and 2005 did not contain any adverse opinion or disclaimer of opinion, and such reports were not qualified or modified as to uncertainty, audit scope, or accounting principles, except that Hughes Pittman Gupton's report dated August 2, 2007 contained an explanatory paragraph regarding CBHI's adoption of SFAS No. 123(R) on January 1, 2006.

During the years ended December 31, 2007 and 2006 and through May 7, 2008, the date that Hughes Pittman Gupton ceased being CBHI's independent public accounting firm, (i) there were no disagreements with Hughes Pittman Gupton on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Hughes Pittman Gupton, would have caused Hughes Pittman Gupton to make reference to the subject matter of the disagreements in connection with its reports, and (ii) there were no reportable events (as described in Item 304(a)(1)(v) of Regulation S-K).

Cornerstone provided Hughes Pittman Gupton with a copy of the disclosures made pursuant to this Item 4.01 prior to the filing of the Original Filing. Cornerstone requested Hughes Pittman Gupton to furnish Cornerstone with a letter addressed to the SEC stating whether it agrees with such disclosures and, if not, stating the respects in which it does not agree. Hughes Pittman Gupton's letter, dated November 5, 2008, is attached hereto as Exhibit 16.2.

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**Item 9.01. Financial Statements and Exhibits.**

*(a) Financial Statements of Businesses Acquired.*

The consolidated financial statements of CBHI, including the report of its independent registered public accounting firm, Grant Thornton LLP, required by this item have not been filed on this initial Current Report on Form 8-K but will be filed by amendment on or before January 14, 2009.

The unaudited consolidated financial statements of CBHI required by this item have not been filed on this initial Current Report on Form 8-K but will be filed by amendment on or before January 14, 2009.

*(b) Pro Forma Financial Information.*

The pro forma financial information required by this item has not been filed on this initial Current Report on Form 8-K but will be filed by amendment on or before January 14, 2009.

*(d) Exhibits.*

See Exhibit Index attached hereto.

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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.

CORNERSTONE THERAPEUTICS  
INC.

Date: November 14, 2008

By: /s/ David Price  
David Price  
Executive Vice President, Finance, and Chief Financial  
Officer

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**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description of Document</b>
Exhibit 2.1 *	Agreement and Plan of Merger, dated as of May 1, 2008, by and among Critical Therapeutics, Inc., Neptune Acquisition Corp. and Cornerstone BioPharma Holdings, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K dated May 1, 2008).
Exhibit 2.2 *	Amendment No. 1, dated as of August 7, 2008, to Agreement and Plan of Merger, dated as of May 1, 2008, among Critical Therapeutics, Inc., Neptune Acquisition Corp. and Cornerstone BioPharma Holdings, Inc. (incorporated by reference to Exhibit 2.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008).
Exhibit 3.1 *	Amendment to the Registrant's Certificate of Incorporation, effecting a 10-to-1 reverse stock split of Critical Therapeutics, Inc.'s common stock.
Exhibit 3.2 *	Amendment to the Registrant's Certificate of Incorporation, changing the name of the corporation from Critical Therapeutics, Inc. to Cornerstone Therapeutics Inc.
Exhibit 4.1 *	Form of the Registrant's Stock Certificate.
Exhibit 10.1 * +	Agreement between Patheon, Inc. (formerly known as MOVA Pharmaceutical Corporation) and Cornerstone BioPharma, Inc. dated August 8, 2007.
Exhibit 10.2 * +	Change of Scope Agreement between Patheon, Inc. (formerly known as MOVA Pharmaceutical Corporation) and Cornerstone BioPharma, Inc. dated November 20, 2007.
Exhibit 10.3 * +	Copromotion Agreement between Atley Pharmaceuticals, Inc. and Cornerstone BioPharma, Inc. dated April 2, 2007.
Exhibit 10.4 * +	First Amendment, dated July 1, 2008, to Copromotion Agreement between Atley Pharmaceuticals, Inc. and Cornerstone BioPharma, Inc. dated April 2, 2007.
Exhibit 10.5 * +	Manufacturing Agreement between Vintage Pharmaceuticals, LLC and Cornerstone BioPharma, Inc. (formerly known as Cornerstone Pharmaceuticals, Inc.) dated July 20, 2004.
Exhibit 10.6 * +	License and Supply Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated October 12, 2006.
Exhibit 10.7 *	Amendment No. 1, dated July 27, 2007, to License and Supply Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated October 12, 2006.

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<b>Exhibit No.</b>	<b>Description of Document</b>
Exhibit 10.8 * +	Letter Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated July 27, 2007.
Exhibit 10.9 * +	Formulation Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated January 11, 2008.
Exhibit 10.10 * +	Addendum, dated August 14, 2008, to License and Supply Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated October 12, 2006.
Exhibit 10.11 * +	Joint Development Agreement between Meiji Seika Kaisha, Ltd. and Cornerstone BioPharma, Inc. dated February 11, 2008.
Exhibit 10.12 * +	Patent License Agreement between Pharmaceutical Innovations, LLC and Cornerstone BioPharma, Inc. effective as of August 31, 2006.
Exhibit 10.13 * +	Amendment No. 1, dated August 10, 2007, to Patent License Agreement between Pharmaceutical Innovations, LLC and Cornerstone BioPharma, Inc. effective as of August 31, 2006.
Exhibit 10.14 *	Amendment No. 2, dated February 15, 2008, to Patent License Agreement between Pharmaceutical Innovations, LLC and Cornerstone BioPharma, Inc. effective as of August 31, 2006.
Exhibit 10.15 * +	Development, License and Services Agreement between Neos Therapeutics, L.P. and Cornerstone BioPharma, Inc. dated March 19, 2008.
Exhibit 10.16 * +	Development and Manufacturing Agreement by and among Neos Therapeutics, L.P., Coating Place, Inc. and Cornerstone BioPharma, Inc. effective February 27, 2008.
Exhibit 10.17 * +	Products Development Agreement between Neos Therapeutics, L.P. and Cornerstone BioPharma, Inc. dated August 27, 2008.
Exhibit 10.18 * +	Supply and Marketing Agreement between Sovereign Pharmaceuticals, LTD and Aristos Pharmaceuticals, Inc. dated May 1, 2008.
Exhibit 10.19 * +	Asset Purchase Agreement between Vintage Pharmaceuticals, LLC and Cornerstone BioPharma, Inc. (as assignee of Cornerstone Biopharma, Ltd. (formerly known as Cornerstone Pharmaceuticals Ltd.)) dated July 20, 2004.
Exhibit 10.20 *	Amendment No. 1, dated May 20, 2005, to Asset Purchase Agreement between Vintage Pharmaceuticals, LLC and Cornerstone BioPharma, Inc. (as assignee of Cornerstone Biopharma Ltd. (formerly known as Cornerstone Pharmaceuticals Ltd.)) dated July 20, 2004.

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**Exhibit No. Description of Document**

Exhibit 10.21 *	Amendment No. 2, dated November 16, 2005, to Asset Purchase Agreement between Vintage Pharmaceuticals, LLC and Cornerstone BioPharma, Inc. (as assignee of Cornerstone Biopharma Ltd. (formerly known as Cornerstone Pharmaceuticals Ltd.)) dated July 20, 2004.
Exhibit 10.22 *	Amendment No. 2, dated November 13, 2006, to Asset Purchase Agreement between Vintage Pharmaceuticals, LLC and Cornerstone BioPharma, Inc. (as assignee of Cornerstone Biopharma Ltd. (formerly known as Cornerstone Pharmaceuticals Ltd.)) dated July 20, 2004.
Exhibit 10.23 *	Amendment No. 3, dated December 7, 2006, to Asset Purchase Agreement between Vintage Pharmaceuticals, LLC and Cornerstone BioPharma, Inc. (as assignee of Cornerstone Biopharma Ltd. (formerly known as Cornerstone Pharmaceuticals Ltd.)) dated July 20, 2004.
Exhibit 10.24 *	Lease Agreement between Regency Park Corporation and Cornerstone BioPharma, Inc. dated August 11, 2004.
Exhibit 10.25 *	Addendum No. 1, dated January 18, 2005, to Lease Agreement between Regency Park Corporation and Cornerstone BioPharma, Inc. dated August 11, 2004.
Exhibit 10.26 *	Lease Agreement between Crescent Lakeside, LLC and Cornerstone BioPharma Holdings, Inc. dated May 1, 2008.
Exhibit 10.27 *	Executive Employment Agreement between Cornerstone BioPharma, Inc. and Craig A. Collard dated March 1, 2006.
Exhibit 10.28 *	Executive Retention Agreement between Cornerstone BioPharma, Inc. and Craig A. Collard dated February 8, 2006.
Exhibit 10.29 *	Executive Employment Agreement between Cornerstone BioPharma, Inc. and Chenyqua Baldwin dated March 1, 2006.
Exhibit 10.30 *	Executive Employment Agreement between Cornerstone BioPharma, Inc. and Brian Dickson dated March 1, 2006.
Exhibit 10.31 *	Agreement Regarding Employment, Employee Duties, Ownership of Employee Developments, and Confidentiality between Cornerstone BioPharma, Inc. and George Esgro dated March 3, 2008.
Exhibit 10.32 *	Executive Employment Agreement between Cornerstone BioPharma, Inc. and Steven Lutz dated March 1, 2006.
Exhibit 10.33 *	Executive Employment Agreement between Cornerstone BioPharma Holdings, Inc. and David Price dated August 20, 2008.
Exhibit 10.34 *	Amended and Restated Restricted Stock Agreement between Cornerstone BioPharma Holdings, Inc. and David Price dated October 31, 2008.

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<b>Exhibit No.</b>	<b>Description of Document</b>
Exhibit 10.35 *	Form of Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement, entered into between Cornerstone BioPharma, Inc. and each of Chenyqua Baldwin, Craig A. Collard, Brian Dickson, Steven Lutz and Alastair McEwan.
Exhibit 10.36 *	Form of Indemnification Agreement, entered into between Cornerstone BioPharma Holdings, Inc. and each of Craig Collard and Alastair McEwan.
Exhibit 10.37 *	Cornerstone BioPharma Holdings, Inc. 2005 Stock Incentive Plan (as Amended and Restated effective October 31, 2008).
Exhibit 10.38 *	Cornerstone BioPharma Holdings, Inc. 2005 Stock Option Plan (as Amended and Restated effective October 31, 2008).
Exhibit 10.39 *	Form of Nonstatutory Stock Option Agreement Granted Under the 2005 Stock Incentive Plan.
Exhibit 10.40 *	Form of Nonstatutory Employee Stock Option Agreement Granted Under the 2005 Stock Option Plan.
Exhibit 10.41 *	Commercial Note issued by Cornerstone BioPharma Holdings, Inc. to Paragon Commercial Bank dated April 21, 2005.
Exhibit 10.42 *	Security Agreement by Cornerstone BioPharma Holdings, Inc. in favor of Paragon Commercial Bank dated April 21, 2005.
Exhibit 10.43 *	Modification Agreement among Paragon Commercial Bank, Cornerstone BioPharma Holdings, Inc., Charles W. Cleary (as trustee), Carolina Pharmaceuticals, Inc. (as guarantor) and Craig A. Collard (as guarantor) dated April 10, 2006.
Exhibit 10.44 *	Modification Agreement among Paragon Commercial Bank, Cornerstone BioPharma Holdings, Inc., Charles W. Cleary (as trustee), Carolina Pharmaceuticals, Inc. (as guarantor) and Craig A. Collard (as guarantor) dated July 31, 2007.
Exhibit 10.45 *	Letter Agreement among Paragon Commercial Bank, Cornerstone BioPharma Holdings, Inc., Craig A. Collard (as guarantor), Aristos Pharmaceuticals, Inc. (as guarantor) and Cornerstone BioPharma, Inc. (as guarantor) dated June 23, 2008.
Exhibit 10.46 *	Modification Agreement among Paragon Commercial Bank, Cornerstone BioPharma Holdings, Inc., John S. Towles (as trustee), Craig A. Collard (as guarantor), Aristos Pharmaceuticals, Inc. (as guarantor) and Cornerstone BioPharma, Inc. (as guarantor) dated June 25, 2008.
Exhibit 10.47 *	Unconditional Guaranty by Cornerstone BioPharma, Inc. in favor Paragon Commercial Bank dated June 25, 2008.

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**Exhibit No.      Description of Document**

Exhibit 10.48 *	Security Agreement by Cornerstone BioPharma, Inc. and Cornerstone BioPharma Holdings, Inc. in favor of Paragon Commercial Bank dated June 25, 2008.
Exhibit 10.49 *	Unconditional Guaranty by Aristos Pharmaceuticals, Inc. in favor of Paragon Commercial Bank dated June 25, 2008.
Exhibit 10.50 *	Security Agreement by Aristos Pharmaceuticals, Inc. and Cornerstone BioPharma Holdings, Inc. in favor of Paragon Commercial Bank dated June 25, 2008.
Exhibit 10.51 *	Letter from Paragon Commercial Bank to Cornerstone BioPharma Holdings, Inc. dated October 29, 2008.
Exhibit 16.1 *	Letter from Deloitte & Touche LLP to the SEC dated November 5, 2008.
Exhibit 16.2 *	Letter from Hughes Pittman & Gupton, LLP to the SEC dated November 5, 2008.
Exhibit 16.3 **	Letter from Deloitte & Touche LLP to the SEC dated November 14, 2008.
Exhibit 99.1 *	Press release dated November 3, 2008.
Exhibit 99.2 *	Press release dated November 5, 2008.
Exhibit 99.3 *	Risk Factors of the Registrant.

\* Filed with the Current Report on Form 8-K originally filed with the Securities and Exchange Commission on November 5, 2008.

\*\* Filed herewith.

+ Confidential treatment requested as to certain portions, which portions have been omitted and filed separately

with the  
Securities and  
Exchange  
Commission.