

CORNERSTONE THERAPEUTICS INC

Form 8-K

November 05, 2008

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**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 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:

- 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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SIGNATURE

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Item 1.01. Entry into a Material Definitive Agreement.

Background

On October 31, 2008, Critical Therapeutics, Inc. (Critical Therapeutics) completed its business combination with 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). Following the closing of the Merger, the business conducted by Cornerstone includes the business conducted by CBHI immediately prior to the Merger, and the following CBHI agreements and arrangements effectively became agreements and arrangements of Cornerstone. Unless the context otherwise requires, all references herein to Cornerstone refer to Cornerstone Therapeutics Inc. and its wholly owned subsidiaries after the effective time of the Merger, and all references to CBHI refer to Cornerstone BioPharma Holdings, Inc. and its wholly owned subsidiaries and predecessor entities prior to the effective time of the Merger.

Material Agreements

Patheon Inc. Agreement

On August 8, 2007, Cornerstone BioPharma, Inc. (CBI), a wholly owned subsidiary of CBHI, and Patheon Inc., formerly known as MOVA Pharmaceutical Corporation (Patheon), entered into an agreement (the Patheon Agreement), as amended by the change of scope dated November 20, 2007 (the Change of Scope), whereby Patheon agreed to perform certain development services in connection with Spectracef® (cefditoren pivoxil) (SPECTRACEF) Once Daily. SPECTRACEF is a registered trademark of Meiji Seika Kaisha, Ltd. (Meiji). SPECTRACEF Once Daily is a single tablet, once-daily dosage of SPECTRACEF. CBI filed an investigational new drug application (IND) with the U.S. Food and Drug Administration (the FDA) in July 2008 for SPECTRACEF Once Daily, which has since been approved by the FDA, and expects to commence a clinical trial in the fourth quarter of 2008 to evaluate the pharmacokinetic profile of a formulation of SPECTRACEF Once Daily developed by Patheon. The Patheon Agreement terminates upon the completion of the development services by Patheon. CBI may terminate the Patheon Agreement, including the Change of Scope, immediately for any business purpose. Either party may terminate the Patheon Agreement if the other party breaches the contract and fails to remedy such breach within 30 days.

The foregoing description of the Patheon Agreement and the Change of Scope is not complete and is qualified in its entirety by reference to the documents attached hereto as Exhibits 10.1 and 10.2, respectively, which are incorporated herein by reference.

Atley Pharmaceuticals, Inc. Co-promotion Agreement

On April 2, 2007, CBI and Atley Pharmaceuticals, Inc. (Atley) entered into a co-promotion agreement (the Atley Co-promotion Agreement), to co-promote Balacet 325 (propoxyphene napsylate and acetaminophen) (BALACET 325). Balacet is registered trademark of Cornerstone. On July 1, 2008, the parties agreed to amend the Atley Co-promotion Agreement (the Atley First Amendment) to include Propoxyphene-APAP 100-325 (APAP 325) and any other generic formulation of BALACET 325.

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Under the Atley Co-promotion Agreement, as amended, CBI agreed to pay Atley fees based on a percentage of the net profits from sales of BALACET 325, and any generic formulations thereof marketed by CBI, above a specified baseline within assigned sales territories. The parties have agreed to revise the baseline semi-annually to ensure that the baseline is attainable using commercially reasonable efforts.

Atley's sales representatives are mainly located in the southeastern, southwestern and midwestern United States. Atley is required under the Atley Co-promotion Agreement to maintain a trained sales force of at least 40 representatives to detail BALACET 325 and generic formulations thereof and an incentive compensation plan to encourage superior performance by its sales representatives. Atley promotes BALACET 325 and generic formulations thereof to pain specialists and primary care providers and other specialists within Atley's assigned sales territories.

The Atley Co-promotion Agreement expires on April 2, 2010, unless extended by mutual agreement of the parties. In addition to customary provisions permitting termination, either party may terminate the Atley Co-promotion Agreement without cause upon 60 days' advance notice or upon the failure of the parties to agree on a revised specified baseline during the semi-annual review process. If Atley terminates the Atley Co-promotion Agreement based upon CBI's breach of such agreement, CBI terminates the Atley Co-promotion Agreement without cause or either party terminates because the parties cannot agree upon a revised specified baseline, then Atley is entitled to receive a termination fee for the six months following such termination, paid on a quarterly basis, equal to the average monthly detailing fee paid by CBI to Atley during the six months immediately preceding such termination.

The foregoing description of the Atley Co-promotion Agreement and the Atley First Amendment is not complete and is qualified in its entirety by reference to the documents attached hereto as Exhibits 10.3 and 10.4, respectively, which are incorporated herein by reference.

Vintage Pharmaceuticals, LLC Manufacturing Agreement

Effective July 20, 2004, CBI and Vintage Pharmaceuticals, LLC (Vintage) entered into a manufacturing agreement (the Vintage Manufacturing Agreement) at the same time CBI entered into an asset purchase agreement pursuant to which CBI acquired the rights to APAP 325 and Propoxyphene-APAP 100-500 (APAP 500). Pursuant to the Vintage Manufacturing Agreement, Vintage is obligated to manufacture BALACET 325 products, APAP 325 products and APAP 500 products in quantities ordered by CBI.

Under the Vintage Manufacturing Agreement, CBI is obligated to pay Vintage for the units delivered to CBI pursuant to purchase orders delivered to Vintage. Pursuant to the Vintage Manufacturing Agreement, Vintage granted CBI the exclusive right to manufacture the products named in the Vintage Manufacturing Agreement and not to subcontract or make any other agreements concerning the products. Also, during the term of the Vintage Manufacturing Agreement, Vintage agreed to exclusively supply CBI, and CBI agreed to not to enter into any agreement with any other person for the manufacture of the products.

The Vintage Manufacturing Agreement expires in June 2010 and will be automatically renewed for successive one-year periods unless either party provides written notice of termination at least one year prior to the end of the then current term. The Vintage Manufacturing Agreement contains customary provisions permitting termination based upon breach of the agreement.

The foregoing description of the Vintage Manufacturing Agreement is not complete and is qualified in its entirety by reference to the Vintage Manufacturing Agreement, which is attached hereto as Exhibit 10.5 and is incorporated herein by reference.

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Meiji Seika Kaisha, Ltd. License and Supply Agreement

Meiji License and Supply Agreement. On October 12, 2006, CBI and Meiji entered into a license and supply agreement (the Meiji License and Supply Agreement), as subsequently amended by amendment no. 1 dated July 27, 2007 (Meiji Amendment No. 1), a letter agreement dated July 27, 2007 (the Meiji Letter Agreement), a formulation agreement dated January 11, 2008 (the Meiji Formulation Agreement), and an addendum dated August 14, 2008 (the Meiji Addendum). The Meiji License and Supply Agreement granted CBI an exclusive, nonassignable U.S. license to manufacture and sell SPECTRACEF, using cefditoren pivoxil supplied by Meiji, for its currently approved therapeutic indications and to use Meiji s SPECTRACEF trademark in connection with the sale and promotion of SPECTRACEF for its currently approved therapeutic indications. The Meiji License and Supply Agreement also extended those rights to additional products and additional therapeutic indications of products containing cefditoren pivoxil supplied by Meiji that are to be jointly developed by Meiji and CBI and which Meiji and CBI agree to have covered by the Meiji License and Supply Agreement.

In consideration for the licenses Meiji granted to CBI, CBI agreed to pay Meiji a nonrefundable license fee of \$6 million in six installments over a period of five years from the date of the Meiji License and Supply Agreement. If a generic cefditoren product is launched in the United States prior to October 12, 2011, CBI will be released from its obligation to make any further license fee payments due after the date of launch, unless, as agreed in the Meiji Letter Agreement, CBI successfully launches SPECTRACEF 400 mg, SPECTRACEF Once Daily or SPECTRACEF Suspension and sales of these products substantially lessen the generic product s adverse effect on SPECTRACEF sales. If CBI is able to launch one of these SPECTRACEF line extensions and substantially mitigate the effect of generic competition, it will be required to continue paying Meiji a reasonable amount of the license fee as mutually agreed by the parties.

The Meiji License and Supply Agreement also requires CBI to make quarterly royalty payments based on the net sales of the cefditoren pivoxil products covered by the Meiji License and Supply Agreement. CBI is required to make these payments for a period of ten years from the date the particular product is launched by CBI.

Under the Meiji License and Supply Agreement, Meiji is CBI s exclusive supplier of cefditoren pivoxil. Pursuant to the Meiji Addendum, CBI is obligated to make aggregate combined purchases of the active pharmaceutical ingredient (API) cefditoren pivoxil, SPECTRACEF 200 mg, SPECTRACEF 400 mg and sample packs of SPECTRACEF 400 mg from Meiji exceeding specified dollar amounts annually over a five-year period. If CBI does not meet its minimum purchase requirement in a given year, CBI must pay Meiji an amount equal to 50% of the shortfall in that year. These minimum purchase requirements cease to apply if a generic cefditoren product is launched in the United States prior to October 12, 2011.

The term of the Meiji License and Supply Agreement, as amended by the Meiji Addendum, continues on a product-by-product basis until the expiration of 10 years from the launch date of each product. In addition, the term, on a product-by-product basis, automatically renews for subsequent one-year periods unless either party gives the other party six months prior written notice of its intention not to renew.

In addition to customary provisions permitting termination based upon bankruptcy protection, insolvency and breach of the Meiji License and Supply Agreement, Meiji may immediately terminate the Meiji License and Supply Agreement if CBI undergoes a change in control as defined in the agreement without Meiji s consent, which may not be unreasonably withheld; ceases selling SPECTRACEF for a period of 60 days, unless the cessation is due to a force majeure event or a failure or delay by Meiji in supplying cefditoren pivoxil; or promotes, markets or sells, either directly or indirectly through a third party, any

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pharmaceutical products in the United States of the same therapeutic class as cefditoren pivoxil. On or after April 1, 2012, CBI may terminate the agreement with 270 days prior written notice if a generic cefditoren product is launched in the United States that substantially lessens CBI's sales of SPECTRACEF. If the Meiji License and Supply Agreement is terminated by CBI based upon Meiji's bankruptcy, insolvency, or breach of the agreement, or by Meiji based upon CBI undergoing a change of control, then CBI has the right to continue selling the product from its existing inventory and to manufacture and sell additional product using its existing inventory of API, in each case for a period of 180 days after such termination.

If either Meiji or CBI desires to develop new products or new therapeutic indications of an existing product under the Meiji License and Supply Agreement, that party must notify the other party, and both parties must then discuss in good faith the joint development of the new product or therapeutic indication and agree on whether the Meiji License and Supply Agreement will cover the new product or therapeutic indication.

Meiji Letter Agreement. On July 27, 2007, Meiji and CBI entered into the Meiji Letter Agreement whereby the parties agreed that the terms and conditions of the Meiji License and Supply Agreement apply to SPECTRACEF 400 mg, SPECTRACEF Suspension and SPECTRACEF Once Daily once CBI receives the necessary FDA approvals for these SPECTRACEF line extensions, provided that there is a reduction to the royalty paid by CBI to Meiji to compensate for the development expenses. The Meiji Letter Agreement requires CBI to bear all of the development costs for SPECTRACEF 400 mg. The Meiji Letter Agreement further provides that CBI has the exclusive right to manufacture and sell these SPECTRACEF line extensions in the United States for their approved therapeutic indications and to use the SPECTRACEF trademark in connection with the sale of these SPECTRACEF line extensions for their approved therapeutic indications. The parties agreed to add a production site for the manufacture of SPECTRACEF 200 mg tablets and that Meiji would pay CBI a reimbursement fee for expenses to be incurred by CBI for regulatory work and filings in connection with adding the production site.

Meiji Formulation Agreement. On January 11, 2008, Meiji and CBI entered into the Meiji Formulation Agreement whereby the parties agreed on the allocation of expenses related to the development of SPECTRACEF Suspension and SPECTRACEF Once Daily, and Meiji made payments for the development of these product candidates to CBI in installments through June 30, 2008.

Addendum to License and Supply Agreement. On August 14, 2008, CBI and Meiji entered into the Meiji Addendum to expand the scope of the Meiji License and Supply Agreement. Under the Meiji Addendum, Meiji granted CBI an exclusive right to sell SPECTRACEF 200 mg and SPECTRACEF 400 mg manufactured by Meiji in the United States. The terms and conditions of the Meiji License and Supply Agreement continue to remain in full force and effect, except to the extent expressly varied or amended by the Meiji Addendum.

CBI will not have to pay any additional license fees for the additional licenses under the Meiji Addendum; however, the Meiji License and Supply Agreement requires CBI to make quarterly royalty payments based on the net sales covered by the Meiji Addendum for a period of 10 years from the launch date for each product.

Under the Meiji Addendum, Meiji will be CBI's exclusive supplier of SPECTRACEF 400 mg during the 10-year period so long as Meiji is able to supply 100% of CBI's requirements for this product. Additionally, Meiji is a non-exclusive supplier of SPECTRACEF 200 mg during the 10-year period. CBI is required to purchase from Meiji combined amounts of API, SPECTRACEF 200 mg, SPECTRACEF 400 mg and sample packs of SPECTRACEF 400 mg exceeding \$15.0 million for the first year beginning with the commercial launch of SPECTRACEF 200 mg or SPECTRACEF 400 mg manufactured by Meiji,

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whichever is earlier, \$20.0 million for year two, \$25.0 million for year three, \$30.0 million for year four and \$35.0 million for year five. If CBI does not meet its minimum purchase requirement in a given year, CBI must pay Meiji an amount equal to 50% of the shortfall in that year. CBI expects to exceed the minimum purchase requirements. If CBI is unable to meet the minimum purchase requirements, the parties will discuss in good faith measures they can take to address the situation. If CBI launches SPECTRACEF Once Daily, then the parties will discuss in good faith if any adjustments are required to the minimum purchase requirements.

The foregoing description the Meiji License and Supply Agreement, Meiji Amendment No. 1, the Meiji Letter Agreement, the Meiji Formulation Agreement and the Meiji Addendum is not complete and is qualified in its entirety by reference to the documents attached hereto as Exhibits 10.6, 10.7, 10.8, 10.9 and 10.10, respectively, which are incorporated herein by reference.

Meiji Joint Development Agreement

On February 11, 2008, CBI and Meiji entered into the Meiji Joint Development Agreement, which supplemented the Meiji License and Supply Agreement, as amended. Under the Meiji Joint Development Agreement, Meiji granted CBI the exclusive right to develop SPECTRACEF Suspension and SPECTRACEF Once Daily in the United States. Under the Meiji Joint Development Agreement, Meiji and CBI agreed on a development plan for SPECTRACEF Suspension and SPECTRACEF Once Daily; agreed that CBI would bear all expenses related to the development of these SPECTRACEF line extensions except as provided in the Meiji Formulation Agreement; and confirmed that, once approved, the terms and conditions of the Meiji License and Supply Agreement will apply to these SPECTRACEF line extensions, unless otherwise provided in the Meiji Joint Development Agreement.

The term of the Meiji Joint Development Agreement runs concurrently with the term of the Meiji License and Supply Agreement, unless earlier terminated. In addition to customary provisions permitting termination based upon bankruptcy protection, insolvency and breach of the agreement, either party may terminate the Meiji Joint Development Agreement after consultation with the other party and with 30 days prior written notice, if it becomes impossible or impracticable from a reasonable pharmaceutical point of view to continue the development of SPECTRACEF Suspension and SPECTRACEF Once Daily. If CBI terminates the Meiji Joint Development Agreement based on impossibility or impracticability from a reasonable pharmaceutical point of view, CBI's rights to SPECTRACEF Suspension and SPECTRACEF Once Daily under the Meiji Letter Agreement and the Meiji Joint Development Agreement will terminate, and CBI would be required to assist Meiji with further development of those product candidates if so requested by Meiji.

The foregoing description of the Meiji Joint Development Agreement is not complete and is qualified in its entirety by reference to the Meiji Joint Development Agreement, which is attached hereto as Exhibit 10.11 and is incorporated herein by reference.

Pharmaceutical Innovations, LLC Patent License Agreement

On August 31, 2006, CBI entered into a license agreement with Pharmaceutical Innovations, LLC (PI), as subsequently amended by amendment no. 1 dated August 10, 2007 and amendment no. 2 dated February 15, 2008 (PI License Agreement). Under the PI License Agreement, PI granted CBI an exclusive license in the United States and Puerto Rico and a nonexclusive license in all other markets to manufacture, package, market, distribute and otherwise exploit ALLERX Dose Pack products that are covered by claims under U.S. patent 6,843,372 (the 372 Patent), by corresponding foreign patents and foreign patent applications and by certain PI know-how related to those ALLERX Dose Pack products. AlleRx® is a registered trademark of Cornerstone. CBI also has the right

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to sublicense its rights under the PI License Agreement to third parties. The 372 Patent expires May 4, 2021. Pursuant to the terms of the PI License Agreement, CBI is obligated to pay PI royalties based on the net sales per calendar year of each product covered by the licensed PI patents or know-how. CBI agreed to a minimum annual royalty payment to PI throughout the term of the PI License Agreement. Royalties are payable with respect to the licensed patents until the earlier of the date all of the licensed patents expire or the date all of the licensed patents are determined to be invalid by a court or other governmental authority and such determination is no longer subject to appeal. Royalties are payable with respect to licensed know-how for a further period of seven years after the expiration of CBI's obligation to pay royalties with respect to the licensed patents.

PI is obligated to pay all costs and expenses for any action prosecuted by PI related to third-party infringement of any of PI's patents. If PI elects not to prosecute such an action, CBI is allowed to do so at its sole option.

The term of the PI License Agreement expires on the seventh anniversary of the earlier of the date that all the licensed patents expire or the date all licensed patents are determined to be invalid by a court or other governmental authority and such determination is no longer subject to appeal. The PI License Agreement contains customary provisions permitting termination based upon bankruptcy protection, insolvency and breach of the agreement. Following expiration of the agreement, CBI has a fully paid, perpetual license to continue to make use of the PI know-how to manufacture, package, market, distribute and otherwise exploit the ALLERX Dose Pack products covered by claims under the 372 Patent.

The foregoing description of the PI License Agreement is not complete and is qualified in its entirety by reference to the documents attached hereto as Exhibits 10.12, 10.13 and 10.14, which are incorporated herein by reference.

Neos Therapeutics, L.P. Development, License and Services Agreement

On March 19, 2008, CBI and Neos Therapeutics, L.P. (Neos) entered into a development, license and service agreement (the Neos Development Agreement) pursuant to which CBI obtained an exclusive license under Neos's patent-pending Dynamic Variable Release technology to develop, manufacture and commercialize a combination methscopolamine and antihistamine product in the United States, subject to obtaining necessary approvals from the FDA. Under the Neos Development Agreement, Neos is responsible for formulation of the licensed product, development and documentation of the manufacturing process for such product, and preparation of the chemistry, manufacturing and controls section of the new drug application to be submitted to the FDA (NDA) for such product. Following successful formulation, Neos is responsible for manufacturing the licensed product for use in connection with CBI's clinical trials and CBI's submission of an NDA for the licensed product. Neos also has the exclusive right to manufacture the licensed product for commercial sale following FDA approval pursuant to a separate supply agreement that the parties would enter into following FDA approval of the licensed product.

Under the Neos Development Agreement, CBI is obligated to pay Neos a minimum fee of approximately \$1.8 million for its performance of the development work under the agreement, plus hourly fees related to development work performed by Neos personnel as reflected in a mutually agreed development plan or otherwise approved by CBI. In consideration for Neos's exclusive license of patent-pending Dynamic Variable Release technology and related know-how in connection with the methscopolamine and antihistamine combination product, CBI is obligated to pay royalties determined as a percentage of the net sales of any licensed product.

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Until the earliest of the fifth anniversary of the initial NDA submission, the expiration of the Neos Development Agreement or the expiration of the supply agreement, Neos agreed that it will not, without CBI's prior written consent, utilize the manufacturing site, perform any services or permit any use of intellectual property, in each case, for the benefit of a third party in connection with development, manufacture, or commercialization of any combination pharmaceutical product for human use in the United States containing the methscopolamine and antihistamine API being developed for CBI. In addition, Neos has the exclusive right to manufacture the product for commercial sale following FDA approval pursuant to a separate supply agreement that the parties have agreed to negotiate in good faith.

The Neos Development Agreement expires on the earlier of March 19, 2013 or FDA approval of the NDA for the licensed product. In addition to customary provisions permitting termination based upon bankruptcy protection, insolvency and breach of the Neos Development Agreement, CBI may terminate the Neos Development Agreement with 90 days' prior written notice if Neos fails to meet any milestones or quality targets determined in the development plan, and may terminate the Neos Development Agreement immediately if Neos's manufacturing site is revoked as a current Good Manufacturing Practice manufacturing facility by the FDA. CBI also may immediately terminate the Neos Development Agreement if the product is unable to achieve a suitable pharmacokinetic profile as determined by the bioavailability study in the development plan or if CBI receives a complete response letter from the FDA with respect to the licensed product. Either party may terminate the Neos Development Agreement upon 30 days' notice if the other party cannot perform its obligations for any reason for 90 days.

If the NDA is approved by the FDA, Neos's license of its Dynamic Variable Release technology and related know-how to CBI and Neos's exclusive manufacturing rights with respect to any licensed product will continue in full force and effect despite the expiration of the Neos Development Agreement generally. Additionally, CBI's obligation to pay royalties with respect to any licensed product will continue until March 19, 2013 if no U.S. patent with a valid claim covering the licensed product has been issued or, if later, such date as there no longer exists a valid claim covering the licensed product under an issued U.S. patent or patent application.

The foregoing description of the Neos Development Agreement is not complete and is qualified in its entirety by reference to the Neos Development Agreement, which is attached hereto as Exhibit 10.15 and is incorporated herein by reference.

Neos Therapeutics, L.P. and Coating Place, Inc. Development and Manufacturing Agreement

On February 27, 2008, CBI, Neos and Coating Place, Inc. (Coating Place) entered into a development and manufacturing agreement (the Neos/Coating Place Development Agreement), pursuant to which CBI obtained an exclusive license under Neos's patent-pending Dynamic Variable Release technology and Dynamic Time Release Suspension technology and Coating Place's patent-pending drug resin complex technology to develop, manufacture and commercialize extended-release antihistamine and antitussive combination products to compete directly in the U.S. hydrocodone cough suppressant market, subject to obtaining necessary approvals from the FDA. CBI is obligated to use commercially reasonable efforts to develop and launch the licensed products as soon as practicable and thereafter to maximize sales of the licensed products in the United States.

In consideration for its rights under the Neos/Coating Place Development Agreement, CBI paid Neos and Coating Place aggregate upfront fees of \$500,000, and following product launch, CBI, Neos and Coating Place will share the net profits from sales of the licensed products equally.

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Under the Neos/Coating Place Development Agreement, CBI is obligated to reimburse Neos and Coating Place for their respective costs of performing the development work related to the licensed products. Prior to product launch, CBI is responsible for all expenses incurred for regulatory filings with the FDA, except the parties have agreed to share equally the Prescription Drug User Fee Act fees for licensed products. Following product launch, CBI's expenses of maintaining the FDA drug approval and its selling, marketing and distribution expenses will be deducted from gross profits from the sale of licensed products prior to the division of net profits among the parties.

Under the Neos/Coating Place Development Agreement, Coating Place has the exclusive right to supply Neos with the drug resin complex needed to manufacture the licensed products. Neos is responsible for formulation development related to the licensed products and has the exclusive right to manufacture the licensed products for commercial sale. CBI is responsible for all regulatory activities with respect to licensed products in the United States, including preparation and submission of an NDA and, following FDA approval, has the exclusive right to sell, market and distribute the licensed products.

The term of the Neos/Coating Place Development Agreement is 15 years from the date the first product is approved by the FDA, with the opportunity for one or more additional five-year successive terms, as mutually agreed by the parties. The Neos/Coating Place Development Agreement contains customary provisions permitting termination based upon bankruptcy protection, insolvency and breach of the agreement. Additionally, if CBI has failed to commercially launch the first product in the United States or Canada by the fifth anniversary of the agreement, any party may immediately terminate the agreement by written notice to the other parties. Additionally, upon the failure of clinical testing with respect to Neos's proposed formulation for the first product or CBI's receipt of an FDA rejection of CBI's drug approval application with respect to the first product, if CBI decides not to proceed with additional work or studies, then CBI has the right to immediately terminate the agreement by written notice to the other parties.

The foregoing description of the Neos/Coating Place Development Agreement is not complete and is qualified in its entirety by reference to the Neos/Coating Place Development Agreement, which is attached hereto as Exhibit 10.16 and is incorporated herein by reference.

Neos Therapeutics, L.P. Products Development Agreement

On August 27, 2008, CBI and Neos entered into a products development agreement (the "Neos Products Development Agreement"), which amended and restated an earlier agreement CBI and Neos had entered into in December 2006, pursuant to which CBI engaged Neos to develop extended-release liquid products to be sold by doctor's prescription only using Neos's patent-pending Dynamic Time Release Suspension technology, of the following types: an antinauseant/antitussive combination, an antihistamine/antitussive combination, an antihistamine/decongestant combination and an antitussive combination. Under the Neos Products Development Agreement, Neos is responsible for formulation of each licensed product; development and documentation of the manufacturing process for such product; and preparation of the chemistry, manufacturing and controls section of the NDA or other regulatory submission for such product. Following successful formulation, Neos is responsible for manufacturing the licensed product for use in connection with CBI's clinical trials and CBI's submission of an NDA or other regulatory submission to the FDA for the licensed product. Neos also has the exclusive right to manufacture the licensed product for commercial sale following FDA approval pursuant to a separate manufacturing agreement that the parties would enter into following FDA approval of the licensed product.

Under the Neos Products Development Agreement, CBI forgave debt owed by Neos totaling \$500,000. Neos, at its own expense, is obligated to develop the first product up to and including completion of the first clinical study in humans. CBI is obligated to pay Neos hourly fees related to development work performed by Neos personnel as reflected in a mutually agreed development plan or otherwise approved

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by CBI. In addition, CBI is obligated to pay certain milestone payments for additional work by Neos, including work performed in connection with regulatory approval and patent issuance. In connection with a manufacturing agreement, CBI will be obligated to pay royalties determined as a percentage of the net sales of any licensed product.

During the term of the Neos Products Development Agreement, each party has agreed that it will work exclusively with the other party in developing (or attempting to develop) the products for sale in the United States in accordance with the terms of the Neos Products Development Agreement.

The Neos Products Development Agreement expires on December 31, 2026. In addition to customary provisions permitting termination based upon bankruptcy protection, insolvency and breach of the agreement, the Neos Products Development Agreement may be terminated upon written notice by either party to the other that federal or state regulatory authorities with jurisdiction over a party and the products has effected, or will effect at a time certain, changes to the regulations or have instituted one or more enforcement actions that can, in the determination of the relevant party, be reasonably expected to result in the commercial infeasibility of the objectives of the Neos Products Development Agreement. The Neos Products Development Agreement may also be terminated upon written notice by CBI to Neos if CBI determines that continued investment in the development or commercialization of the products is not commercially advisable.

The foregoing description of the Neos Products Development Agreement is not complete and is qualified in its entirety by reference to the Neos Products Development Agreement, which is attached hereto as Exhibit 10.17 and is incorporated herein by reference.

Sovereign Pharmaceuticals, Ltd. Supply and Marketing Agreement

On May 1, 2008, Aristos Pharmaceuticals, Inc. (Aristos), a wholly owned subsidiary of CBHI, and Sovereign Pharmaceuticals, Ltd. (Sovereign) entered into a supply and marketing agreement (the Sovereign Supply Agreement), pursuant to which Aristos obtained the exclusive right to market, sell and distribute in the United States three of Sovereign s generic products, each containing the API hyoscyamine.

Under the Sovereign Supply Agreement, Aristos is obligated to use commercially reasonable efforts to market, sell and distribute each of the three hyoscyamine products manufactured by Sovereign to wholesalers and distributors in the United States in return for a share of the net profits realized from the sale of the products.

The initial term of the Sovereign Supply Agreement expires April 30, 2011 and will be automatically renewed for successive one-year terms unless either party provides written notice of termination. The Sovereign Supply Agreement contains customary provisions permitting termination based upon bankruptcy protection, insolvency and breach of the agreement. Aristos also may immediately terminate the agreement by written notice if Sovereign undergoes a change of control as defined in the agreement or if the FDA or other regulatory authority orders the discontinuance for any reason of the commercial sale of the products. Notwithstanding the expiration or termination of the Agreement, Aristos may continue to sell all hyoscyamine products in its inventory until such inventory is exhausted unless commercial sale of the products has been discontinued pursuant to orders of the FDA or other regulatory authority.

The foregoing description of the Sovereign Supply Agreement does not purport to be complete and is qualified in its entirety by reference to the Sovereign Supply Agreement, which is attached hereto as Exhibit 10.18 and is incorporated herein by reference.

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Vintage Pharmaceuticals, LLC Asset Purchase Agreement

On July 24, 2004, CBI and Vintage entered into an asset purchase agreement, as subsequently amended by amendment no. 1 dated May 20, 2005, amendment no. 2 dated November 16, 2005, amendment no. 2 dated November 13, 2006 and amendment no. 3 dated December 7, 2006 (the "Vintage Asset Purchase Agreement"), pursuant to which CBI obtained the rights, title and interest to BALACET 325 and APAP 500. Under the Vintage Asset Purchase Agreement, CBI has all rights to promotion, marketing, sale, distribution and manufacturing of these two products. In addition, Vintage granted CBI the right to market and sell an authorized generic version of BALACET 325 ("APAP 325").

CBI paid an \$8 million fee in connection with the Vintage Asset Purchase Agreement and is obligated to pay Vintage a royalty equal to a percentage of the net sales of BALACET 325, APAP 500 and APAP 325 each calendar quarter. The foregoing description of the Vintage Asset Purchase Agreement is not complete and is qualified in its entirety by reference to the documents attached hereto as Exhibits 10.19, 10.20, 10.21, 10.22 and 10.23, which are incorporated herein by reference.

Item 2.01. Completion of Acquisition or Disposition of Assets.

On October 31, 2008, pursuant to the Merger Agreement, Neptune Acquisition Corp. merged with and into CBHI, with CBHI becoming a wholly owned subsidiary of Critical Therapeutics, and Critical Therapeutics changed its name to Cornerstone Therapeutics Inc.

As a result of the Merger and after giving effect to a 10-to-1 reverse stock split, each outstanding share of CBHI's common stock automatically converted into the right to receive approximately 0.2380837 shares of Cornerstone's common stock. Each outstanding option and warrant to purchase shares of CBHI's common stock that was not exercised prior to the consummation of the Merger was assumed by Cornerstone at the effective time of the Merger and became an option or warrant, as applicable, to purchase shares of Cornerstone's common stock. The number of shares of Cornerstone's common stock subject to each assumed option and warrant was determined by multiplying the number of shares of CBHI's common stock that were subject to each option or warrant, as applicable, prior to the effective time of the Merger by the conversion ratio specified above and rounding that result down to the nearest whole number of shares of Cornerstone's common stock. The per share exercise price for the assumed options and warrants was determined by dividing the per share exercise price for CBHI's common stock subject to each option or warrant, as applicable, as in effect immediately prior to the effective time of the Merger by the conversion ratio specified above and rounding that result up to the nearest whole cent.

Following the closing of the Merger, former CBHI stockholders owned approximately 70%, and former Critical Therapeutics stockholders owned approximately 30%, of Cornerstone's common stock, after giving effect to shares issuable pursuant to outstanding options and warrants held by CBHI's stockholders immediately prior to the effective time of the Merger, but without giving effect to any shares issuable pursuant to options and warrants held by Critical Therapeutics' stockholders immediately prior to the effective time of the Merger. The issuance of the shares of Cornerstone's common stock to the former stockholders of CBHI was registered with the Securities and Exchange Commission (the "SEC") on a Registration Statement on Form S-4, as amended (Reg. No. 333-152442).

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The full text of the Merger Agreement, Amendment No. 1 to the Merger Agreement and the press release dated November 3, 2008 announcing the completion of the acquisition, are attached hereto as Exhibits 2.1, 2.2 and 99.1, respectively, and are incorporated herein by reference.

Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

Regency Park Corporation Lease Agreement

On August 11, 2004, CBI and Regency Park Corporation entered into a lease agreement, as amended (the Regency Lease), to lease its corporate headquarters. On January 18, 2005, CBI and Regency Park Corporation agreed to amend the lease agreement to add additional office space and adjust the annual rent accordingly. Currently, CBI's corporate headquarters occupies approximately 7,850 square feet of office space and is located at 2000 Regency Parkway, an office complex in Cary, North Carolina. The Regency Lease has five-year term expiring in October 2009. CBI paid an annual rent under the Regency Lease of approximately \$157,000 during 2007. Currently, the total monthly base rent under the Regency Lease is \$13,407 through January 31, 2009 and will increase to \$13,734 per month starting February 1, 2009 until October 31, 2009. In addition to rent, CBI is obligated to pay certain operating expenses and taxes. CBI is currently in negotiations with the landlord under the Regency Lease concerning the terms and conditions that would apply to an early termination of the Regency Lease in connection with the relocation of CBI's corporate headquarters as described below.

The foregoing description of the Regency Lease is not complete and is qualified in its entirety by reference to the documents attached hereto as Exhibits 10.24 and 10.25, which are incorporated herein by reference.

Crescent Lakeside, LLC Lease Agreement

On May 1, 2008, CBHI and Crescent Lakeside, LLC entered into a lease agreement (the Crescent Lease) for a new corporate headquarters, which will occupy approximately 14,900 square feet of office space. The new corporate headquarters will be located at 1255 Crescent Green in the Crescent Lakeside office complex in Cary, North Carolina. The Crescent Lease has an initial term that commences in December 2008 and expires in March 2016. CBHI also has an option to renew the Crescent Lease for an additional five-year term through March 2021. Under the Crescent Lease, CBHI will not be obligated to pay rent for the first two months (December 2008 and January 2009). Starting February 1, 2009 through January 31, 2010, the base rent under the Crescent Lease will be \$28,797 per month, or approximately \$350,000 for the year. Thereafter, CBHI will be subject to annual rent increases of approximately 3%. In addition to rent, CBHI is obligated to pay certain operating expenses and taxes. If CBHI complies with the terms of the Crescent Lease, then CBHI will have the right to extend the term of the Crescent Lease on the same terms and conditions, subject to an adjustment to the annual base rent, for an additional five-year period. In order to exercise this renewal right, CBHI must provide to Crescent Lakeside, LLC notice not less than 12 months prior to the expiration of the initial term of the Crescent Lease.

The foregoing description of the Crescent Lease is not complete and is qualified in its entirety by reference to the Crescent Lease, which is attached hereto as Exhibit 10.26 and is incorporated herein by reference.

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Paragon Line of Credit

On April 21, 2005, CBHI issued a Commercial Note (the *Commercial Note*) to Paragon Commercial Bank (*Paragon*), which was guaranteed by Craig A. Collard, CBHI's President and Chief Executive Officer. The Commercial Note was subsequently amended by (i) a Modification Agreement, dated April 10, 2006, among Paragon, CBHI, Charles W. Cleary (as trustee), Carolina Pharmaceuticals, Inc. (*CPI*) (as guarantor) and Craig A. Collard (as guarantor); (ii) a second Modification Agreement, dated July 31, 2007, among Paragon, CBHI, Charles W. Cleary (as trustee), CPI (as guarantor) and Craig A. Collard (as guarantor); (iii) a letter agreement, dated June 23, 2008, among Paragon, CBHI, Craig A. Collard (as guarantor), Aristos (as guarantor) and CBI (as guarantor); (iv) a third Modification Agreement, dated June 25, 2008, among Paragon, CBHI, John S. Towles (as trustee) and Craig A. Collard (as guarantor), Aristos (as guarantor), CBI (as guarantor) and CPI (as guarantor); and (v) a letter from Paragon to CBHI, dated October 29, 2008 (collectively, the *Line of Credit Agreement*).

The Line of Credit Agreement provides CBHI a revolving credit facility (the *Line of Credit*) of up to \$4 million, subject to a monthly borrowing base equal to 75% of CBHI's, CBI's and Aristos's accounts receivable outstanding 90 days or less and 100% of a \$500,000 assignment of deposit from Craig A. Collard. Up to \$1.5 million of the Line of Credit is segmented for standby letters of credit. Interest is due monthly with any outstanding principal and interest due on June 15, 2009, the maturity date of the Line of Credit. Amounts outstanding under the Line of Credit bear interest at a variable rate equal to the Wall Street Journal prime rate, which was 5.00% as of September 30, 2008. In connection with the issuance of the Commercial Note, on April 21, 2005, CBHI entered into a Security Agreement in favor of Paragon. In connection with the third Modification Agreement, on June 25, 2008, Aristos and CBI, along with CBHI, each entered into Security Agreements in favor of Paragon. The Security Agreements grant Paragon a security interest in CBHI's, Aristos's and CBI's personal property, intangible assets, inventory and accounts receivable. In addition, on June 25, 2008, each of Aristos and CBI entered into an Unconditional Guaranty in favor of Paragon whereby they each guarantee CBHI's performance under the Line of Credit Agreement. The Line of Credit is also secured by a \$2 million deed of trust on Mr. Collard's residence.

The Line of Credit Agreement requires CBHI to not incur any additional bank debt without Paragon's prior written consent and to provide Paragon with certain financial information. The Line of Credit Agreement also requires Craig A. Collard to be primarily employed as an executive officer of Cornerstone, maintain \$2 million in liquid assets and assign a \$500,000 deposit to Paragon.

The Line of Credit Agreement further provides that a default will occur thereunder if, among other things, CBHI fails to make payments when due; any party fails to perform its obligations under the Line of Credit Agreement or any security agreement or guaranty agreement related to the Line of Credit Agreement; any party to the Line of Credit Agreement dies, dissolves, merges, consolidates, experiences a change of control or otherwise ceases to exist; any party to the Line of Credit Agreement files an application for a receiver or a petition for bankruptcy; any party fails to furnish any requested financial information to Paragon; Paragon deems itself insecure or that an adverse change in any party has occurred; any party fails to perform any other obligation to Paragon; or any guaranty of the Line of Credit Agreement is terminated.

As of October 31, 2008, there was no outstanding balance on and \$3.9 million of borrowing availability under the Line of Credit.

The foregoing description of the Line of Credit Agreement and the related security agreements and guaranty agreements is not complete and is qualified in its entirety by reference to the documents attached hereto

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as Exhibits 10.41, 10.42, 10.43, 10.44, 10.45, 10.46, 10.47, 10.48, 10.49, 10.50 and 10.51, which are incorporated herein by reference.

Item 2.05. Costs Associated with Exit or Disposal Activities.

On October 30, 2008, subject to the closing of the Merger, Critical Therapeutics committed to a plan of termination that will result in the termination of approximately 28 employees. The plan includes the payment of severance, the acceleration of certain employee benefits, outplacement assistance and automobile lease termination fees (separation costs). In addition, on October 31, 2008, following the closing of the Merger, Cornerstone formally committed to a plan to close Cornerstone s offices in Lexington, Massachusetts. The objective of these plans (collectively, the Integration Plan) is to achieve operational efficiencies and eliminate redundant costs resulting from the Merger. Cornerstone expects to complete the Integration Plan by December 31, 2008. Cornerstone estimates that the costs associated with the Integration Plan will include between \$2.6 million and \$3.0 million in separation costs and will include approximately \$120,000 in lease termination costs. Cornerstone estimates that between \$2.6 million and \$3.0 million of these costs will be cash expenditures.

Item 3.03. Material Modification to Rights of Security Holders.

On October 31, 2008, Cornerstone adopted a new form of stock certificate representing its common stock on and after the effective time of the Merger. The form of stock certificate is attached hereto as Exhibit 4.1 and is incorporated herein by reference.

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.

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

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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.

Cornerstone provided Deloitte with a copy of the disclosures made pursuant to this Item 4.01 prior to the filing of this Current Report on Form 8-K. 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.

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.

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

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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 this Current Report on Form 8-K. 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.

Item 5.01. Changes in Control of Registrant.

Reference is made to Item 2.01 of this Current Report on Form 8-K, which is incorporated into this Item 5.01 by reference.

Immediately following the closing of the Merger on October 31, 2008, former CBHI stockholders beneficially owned, directly or indirectly, approximately 67% of Cornerstone's voting securities.

In connection with the Merger, Trevor Phillips, Ph.D., Critical Therapeutics' President and Chief Executive Officer and Thomas P. Kelly, Critical Therapeutics' Chief Financial Officer and Senior Vice President of Finance and Corporate Development, were terminated without cause effective as of October 31, 2008. In addition, Jeffrey E. Young, Vice President of Finance, Chief Accounting Officer and Treasurer, will be terminated without cause effective as of November 14, 2008. Scott B. Townsend, Esq., Critical Therapeutics' General Counsel, Senior Vice President of Legal Affairs and Secretary continues to serve as Cornerstone's General Counsel, Executive Vice President of Legal Affairs and Secretary.

On October 30, 2008, the board of directors of Critical Therapeutics appointed each of the following executive officers of CBHI to serve, as of the effective time of the Merger, as executive officers of Cornerstone:

Name	Position with Cornerstone Following the Merger	Position with CBHI Prior to the Merger
Craig A. Collard	President and Chief Executive Officer	President and Chief Executive Officer
Chenyqua Baldwin	Vice President, Finance, Chief Accounting Officer, Controller, Assistant Treasurer and Assistant Secretary	Vice President, Finance

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Name	Position with Cornerstone Following the Merger	Position with CBHI Prior to the Merger
Brian Dickson, M.D.	Chief Medical Officer	Chief Medical Officer
George Esgro	Vice President, Sales	Vice President, Sales
Steven M. Lutz	Executive Vice President, Manufacturing and Trade	Executive Vice President, Commercial Operations
David Price	Executive Vice President, Finance, Chief Financial Officer, Treasurer and Assistant Secretary	Executive Vice President, Finance, and Chief Financial Officer

Effective as of the effective time of the Merger, Trevor Phillips, Ph.D., Richard W. Dugan, Jean George and Christopher Mirabelli, Ph.D., resigned from Critical Therapeutics' board of directors and Christopher Codeanne, Craig A. Collard, Michael Enright, Michael Heffernan and Alastair McEwan were elected to Cornerstone's board of directors by Critical Therapeutics' board of directors. Messrs. Collard and McEwan served as directors of CBHI prior to the closing of the Merger. The press release dated November 5, 2008 announcing the election of Cornerstone's new directors is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

The information regarding the resignations of Critical Therapeutics' board of directors, the terminations without cause of Messrs. Phillips, Kelly and Young and the election and appointment of Cornerstone's new directors and executive officers included in Item 5.01 above is incorporated herein by reference. Biographical information regarding each of Cornerstone's executive officers is included in the section entitled Executive Officers and Directors Executive Officers beginning on page 294 of Amendment No. 3 to Critical Therapeutics' Registration Statement on Form S-4 (the Form S-4), which was filed with the SEC on September 29, 2008, and is incorporated herein by reference. Descriptions of the material terms of the agreements with each executive officer are included in the section entitled Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table beginning of page 312 of the Form S-4 and are incorporated herein by reference. Effective October 31, 2008, Mr. Price's Restricted Stock Agreement was amended and restated to provide that he would receive 1,365,629 shares of restricted stock of CBHI immediately prior to the consummation of the Merger. The descriptions of the agreements with Cornerstone's executive officers are not complete and are qualified in their entirety by reference to the documents attached hereto as Exhibits 10.27, 10.28, 10.29, 10.30, 10.31, 10.32, 10.33, 10.34 and 10.35, which are incorporated herein by reference. On April 12, 2005 and October 1, 2005, CBHI entered into indemnification agreements with its sole directors, Mr. Collard and Mr. McEwan, respectively. Among other things, the indemnification agreements require CBHI to indemnify Messrs. Collard and McEwan for expenses incurred by Mr. Collard or Mr. McEwan in connection with actions or proceedings in connection with his service as a director, officer, employee, agent or fiduciary of CBHI or of any other enterprise that he is or was serving at CBHI's express written request. The indemnification agreements also provide for mandatory advancement of expenses to Messrs. Collard and McEwan. The foregoing description of the indemnification agreements is not complete and is qualified in its entirety by reference to the form of indemnification agreement attached hereto as Exhibit 10.36, which is incorporated herein by reference.

Effective as of the effective time of the Merger, each of Messrs. Codeanne, Enright and Heffernan were appointed to the audit committee of the board of directors, each of Messrs. Heffernan and Enright were appointed to the compensation committee, and each of Messrs. Enright and Codeanne were appointed to the nominating and corporate governance committee. Mr. Codeanne was appointed the chairman of the audit committee, Mr. Heffernan was appointed the chairman of the compensation committee, and Mr. Enright was appointed the chairman of the nominating and corporate governance committee. Each of Messrs. Codeanne, Heffernan and Enright were determined to be independent of management.

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The terms of office of the directors are divided into three classes: Class I, whose term will expire at the 2011 annual meeting of stockholders; Class II, whose term will expire at the 2009 annual meeting of stockholders; and Class III, whose term will expire at the 2010 annual meeting of stockholders. Class I consists of Mr. Collard, Class II consists of Mr. Codeanne and Mr. Enright, and Class III consists of Mr. McEwan and Mr. Heffernan.

Descriptions of transactions between the executive officers and directors and Cornerstone are included in the section entitled "Certain Relationships and Related Transactions, and Director Independence" beginning on page 298 of the Form S-4 and are incorporated herein by reference.

The policy of the Cornerstone with respect to the compensation of directors is expected to be determined at the first meeting of the board of directors following the effective date of the Merger.

On December 23, 2005, CBHI's board of directors adopted the Cornerstone BioPharma Holdings, Inc. 2005 Stock Incentive Plan (the "2005 Stock Incentive Plan"), pursuant to which awards may be made under the plan for up to 10,000,000 shares of CBHI's common stock. A description of the material terms of the 2005 Stock Incentive Plan is included in the section entitled "Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table" beginning on page 312 of the Form S-4 and is incorporated herein by reference. Effective October 31, 2008, the 2005 Stock Incentive Plan was amended and restated to provide that awards that expire, are terminated, are surrendered or are canceled without having been fully exercised or are forfeited in whole or in part are immediately cancelled and are no longer available for the grant of additional awards under the 2005 Stock Incentive Plan.

In May 2005, CBHI's board of directors adopted the Cornerstone BioPharma Holdings, Inc. 2005 Stock Option Plan (the "2005 Stock Option Plan"), pursuant to which stock options to purchase up to 10,000,000 shares of CBHI's common stock could be awarded to employees, directors and consultants. Effective October 31, 2008, the 2005 Stock Option Plan was amended and restated to reduce the number of shares reserved for issuance under the plan to 373,650, the total number of stock options previously granted under and not returned to the 2005 Stock Option Plan. The 2005 Stock Option Plan permits CBHI's board of directors to grant both incentive stock options and nonqualified stock options under the plan. CBHI's board establishes the exercise price for options granted under the plan and determines the fair market value of the common stock. The board also establishes the term and vesting requirements for any option award; provided, however, that no option may expire more than ten years after the date of grant. CBHI's board of directors may amend or terminate the 2005 Stock Option Plan at any time.

Stock option grants awarded under the 2005 Stock Option Plan are subject to adjustments in the event of a change in CBHI's capitalization, liquidation, dissolution, reorganization or change in control.

In the event of a change in CBHI's capitalization, such as a stock split, reverse stock split, combination or reclassification of shares, spin-off, recapitalization, the payment of a stock dividend (but only on the common stock) or any other increase or decrease in the number of issued shares effected without receipt of consideration by CBHI or other similar change in capitalization or event, the board of directors may adjust the terms of option grants, including the number of securities and exercise price per share of each outstanding option.

In the event of a "Corporate Change" effected by a transaction in which the consideration consists only of stock of another issuer, the 2005 Stock Option Plan generally requires that all outstanding options and option agreements in force at the time of the "Corporate Change" be assumed and continue to remain in full force and effect following the transaction. In the event of a "Corporate Change" effected by a transaction in which the consideration does not consist solely of the stock of another issuer (e.g., an all cash or part cash and part

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stock transaction), all options that are not vested and exercisable at the time of the Corporate Change will terminate immediately.

For purposes of the 2005 Stock Option Plan, the term Corporate Change means one of the following events: (i) the merger, consolidation or other reorganization of CBHI in which the outstanding common stock is converted into or exchanged for a different class of securities of CBHI, a class of securities of any other issuer (except a parent or subsidiary of CBHI), cash or other property; (ii) the sale, lease or exchange of all or substantially all of the assets of CBHI to any other corporation or entity (except a parent or subsidiary of CBHI); or (iii) the adoption by shareholders of CBHI of a plan of liquidation or dissolution. The following events are expressly excluded from the definition of a

Corporate Change for purposes of the 2005 Stock Option Plan: (i) a merger, consolidation or reorganization of CBHI which would result in the voting stock of CBHI outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity), in combination with the ownership of any trustee or other fiduciary holding securities under an employee benefit plan of CBHI, at least 60% of the combined voting power of the voting stock of CBHI or such surviving entity outstanding immediately after such merger, consolidation or reorganization of CBHI, or (ii) merger, consolidation or reorganization of CBHI effected to implement a recapitalization of CBHI (or similar transaction) in which no person acquires more than 49% of the combined voting power of CBHI's then outstanding stock.

The descriptions of the 2005 Stock Incentive Plan (as Amended and Restated Effective October 31, 2008) and the 2005 Stock Option Plan (as Amended and Restated Effective October 31, 2008) are not complete and are qualified in their entirety by reference to the documents attached hereto as Exhibits 10.37 and 10.38, respectively, which are incorporated herein by reference.

Item 5.03. Amendments to Charter and Bylaws

On October 30, 2008, the board of directors of Critical Therapeutics approved an amendment to Critical Therapeutics certificate of incorporation effecting a 10-to-1 reverse stock split of the issued shares of Critical Therapeutics common stock (the Reverse Stock Split Amendment). Upon the effectiveness of the Reverse Stock Split Amendment (the Split Effective Time), the issued shares of Critical Therapeutics common stock immediately prior to the Split Effective Time were reclassified into a smaller number of shares, such that a Critical Therapeutics stockholder now owns one new share of Cornerstone's common stock for each 10 shares of issued common stock held by that stockholder immediately prior to the Split Effective Time. The Reverse Stock Split Amendment was approved at the Special Meeting of Critical Therapeutics stockholders held on October 31, 2008 and became effective immediately prior to the effective time of the Merger.

On May 1, 2008, the board of directors of Critical Therapeutics approved an amendment to Critical Therapeutics certificate of incorporation to change the name of the corporation from Critical Therapeutics, Inc. to Cornerstone Therapeutics Inc. upon the consummation of the Merger (the Name Change Amendment). The Name Change Amendment was approved at the Special Meeting of Critical Therapeutics stockholders held on October 31, 2008 and became effective on October 31, 2008 following the consummation of the Merger.

The foregoing description of the Reverse Stock Split Amendment and the Name Change Amendment is not complete and is qualified in its entirety by reference to the documents attached hereto as Exhibits 3.1 and 3.2, respectively, which are incorporated herein by reference.

Item 8.01. Other Events.

Cornerstone is filing herewith as Exhibit 99.3 certain risk factors that are relevant to Cornerstone after giving effect to the consummation of the Merger.

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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.

Date: November 5, 2008

CORNERSTONE THERAPEUTICS INC.

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

Exhibit No.	Description of Document
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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Exhibit No.	Description of Document
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.
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.

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Exhibit No.	Description of Document
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.
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.

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Exhibit No.	Description of Document
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.
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	

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Security Agreement by Aristos Pharmaceuticals, Inc. and Cornerstone BioPharma Holdings, Inc. in favor of Paragon Commercial Bank dated June 25, 2008.

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Exhibit No.	Description of Document
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 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.
+ Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.	