

CORNERSTONE THERAPEUTICS INC

Form 8-K

June 22, 2009

**Table of Contents**

**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): June 16, 2009**

**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.)

**1255 Crescent Green Drive, Suite 250, Cary, NC**

(Address of Principal Executive Offices)

**27518**

(Zip Code)

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

**Not applicable**

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- 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))
-

**TABLE OF CONTENTS**

Item 1.01. Entry into a Material Definitive Agreement

Item 9.01. Financial Statements and Exhibits

SIGNATURE

EXHIBIT INDEX

EX-10.1 Amendment No. 1, dated June 16, 2009, to Development and Manufacturing Agreement

---

**Table of Contents**

**Item 1.01. Entry into a Material Definitive Agreement.**

On June 16, 2009 Cornerstone Therapeutics Inc. (the Company ), Neos Therapeutics, L.P. ( Neos ) and Coating Place, Inc. ( Coating Place ) entered into an amendment (the Amendment ) to the development and manufacturing agreement by and among Neos, Coating Place and Cornerstone BioPharma, Inc. ( CBI ), a wholly owned subsidiary of the Company, entered into on February 27, 2008, and supplemented on June 19, 2008 (the Neos/Coating Place Development Agreement ).

Under the Neos/Coating Place Development Agreement, 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 ( Product ) to compete directly in the U.S. narcotic cough suppressant market, subject to obtaining necessary approvals from the FDA.

The Amendment modifies the Neos/Coating Place Development Agreement primarily to clarify (i) the amounts payable to Neos related to manufacturing and supplying Product, (ii) the amounts payable to Coating Place for supply of its drug resin complex used in manufacturing Product, (iii) the Company s allowable expenses for purposes of determining the net profits from sales of Product, (iv) the characteristics and specifications of Product, and (v) the technology licensed by Neos and Coating Place will include any of their respective new patent applications or divisions or continuations of existing patent applications with valid claims that cover the Product. Additionally, the Amendment provides that the Company may at any time expand the territory for the Neos and Coating Place technology licenses to include any other countries besides the U.S. The Amendment also amends the termination provisions to provide that any party may terminate the agreement if a Product is not commercially launched on or before February 27, 2015. Prior to the Amendment, this termination right was allowed if commercial launch did not occur by February 27, 2013. Finally, the Amendment also makes certain administrative adjustments to several other provisions of the Neos/Coating Place Development Agreement, including with respect to payment terms under the agreement. All terms of the Neos/Coating Place Development Agreement not modified by the Amendment remain in full force and effect.

In addition to the Neos/Coating Place Development Agreement, in March 2008, CBI and Neos entered into a development, license and service agreement pursuant to which CBI obtained an exclusive license under Neos s patent-pending Dynamic Variable Release® technology to develop, manufacture and commercialize an anticholinergic and antihistamine combination product in the United States, subject to obtaining necessary approvals from the FDA. In August 2008, CBI and Neos entered into a 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.

A copy of the Amendment is attached as Exhibit 10.1 to this Current Report on Form 8-K, and the Company refers you to such exhibit for the complete terms of the Amendment, which are incorporated herein by reference.

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

(d) Exhibits.

See the Exhibit Index attached hereto.

**Table of Contents**

**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: June 22, 2009

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

---

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description of Document</b>
Exhibit 10.1+	Amendment No. 1, dated June 16, 2009, to Development and Manufacturing Agreement among Neos Therapeutics, L.P., Coating Place, Inc. and Cornerstone BioPharma, Inc., dated February 27, 2008.
+ Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.	