

CORNERSTONE THERAPEUTICS INC

Form S-3/A

May 12, 2011

Table of Contents

As filed with the Securities and Exchange Commission on May 12, 2011

Registration No. 333-166770

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

**PRE-EFFECTIVE AMENDMENT NO. 1
TO
Form S-3**

**REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

CORNERSTONE THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware

*(State or other jurisdiction of
incorporation or organization)*

04-3523569

*(I.R.S. Employer
Identification No.)*

**1255 Crescent Green Drive, Suite 250
Cary, North Carolina 27518
(919) 678-6611**

*(Address, including zip code, and telephone number, including area code, of
registrant's principal executive offices)*

Craig A. Collard

President and Chief Executive Officer

Cornerstone Therapeutics Inc.

**1255 Crescent Green Drive, Suite 250
Cary, North Carolina 27518
(919) 678-6611**

*(Name, address, including zip code, and telephone number,
including area code, of agent for service)*

Copies to:

David B. Clement

**Smith, Anderson, Blount, Dorsett,
Mitchell & Jernigan, L.L.P.
2500 Wachovia Capitol Center
Raleigh, North Carolina 27601
(919) 821-1220**

Andrew K. W. Powell

**Executive Vice President,
General Counsel and Secretary
Cornerstone Therapeutics Inc.
1255 Crescent Green Drive, Suite 250
Cary, North Carolina 27518
(919) 678-6524**

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of the Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
 (Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price per Unit(1)	Proposed Maximum Aggregate Offering Price(2)(3)	Amount of Registration Fee(4)
Common Stock, \$0.001 par value per share				
Preferred Stock, \$0.001 par value per share				
Warrants				
Total			\$94,950,000	\$6,769.93

(1) An indeterminate number of shares of common stock and preferred stock and an indeterminate number of warrants to purchase common stock or preferred stock are being registered hereunder for possible issuance from time to time at indeterminate prices, but in no event will the aggregate offering price exceed \$94,950,000 or if any securities are issued in foreign currencies, composite currencies or currency units, the U.S. dollar equivalent of \$94,950,000. Any securities registered hereunder may be sold separately or with other securities registered hereunder. The securities registered also include such indeterminate amount and number of shares of common stock and preferred stock as may be issued upon conversion of or exchanged for preferred stock and upon exercise of warrants or pursuant to antidilution provisions of any such securities. Separate consideration may or may not be received for securities registered hereunder that are issued upon conversion of, or in exchange for, or upon exercise of, as the case may be, convertible or exchangeable securities. In accordance with Rule 416 under the Securities Act of 1933, as amended, this registration statement shall be deemed to cover any additional securities that may from time to time be offered or issued to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(2)

Estimated in accordance with Rule 457(o) under the Securities Act of 1933, as amended, solely for the purpose of determining the applicable registration fee.

- (3) At no time will the aggregate market value of securities offered or sold in any given 12-month period exceed the amount allowed for in General Instruction I.B.6. of Form S-3.
- (4) Previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED May 12, 2011

PROSPECTUS

**\$94,950,000
Common Stock
Preferred Stock
Warrants**

From time to time, we may offer and sell the following securities with an aggregate offering price of up to \$94,950,000 in amounts, at prices and on terms described in one or more supplements to this prospectus (i) shares of common stock; (ii) shares of preferred stock; and (iii) warrants to purchase shares of common stock or preferred stock.

This prospectus describes some of the general terms that may apply to an offering of the securities. The specific terms and any other information relating to a specific offering will be set forth in a post-effective amendment to the registration statement of which this prospectus is a part or in a supplement to this prospectus, or may be set forth in one or more documents incorporated by reference into this prospectus. We may also authorize one or more free writing prospectuses to be provided to you in connection with a specific offering. You should read carefully this prospectus, the applicable prospectus supplement and any related free writing prospectuses that we have authorized for use in connection with a specific offering, as well as any documents incorporated by reference in this prospectus and the applicable prospectus supplement, before you invest.

This prospectus may not be used to offer and sell securities without a prospectus supplement.

We may offer and sell securities to or through one or more underwriters, dealers and agents, or directly to purchasers, on a continuous or delayed basis. If any agents or underwriters are involved in the sale of any of the securities offered by this prospectus, their names, and any applicable purchase price, fee, commission or discount arrangement with, between or among them, will be set forth, or will be calculable from the information set forth, in the applicable prospectus supplement. The supplements to this prospectus will provide the specific terms of the plan of distribution. The net proceeds we expect to receive from sales by us will be set forth in the applicable prospectus supplement.

Our common stock is traded on the Nasdaq Capital Market and is quoted under the symbol CRTX. On May 6, 2011, the last reported sale price of our common stock was \$6.35 per share.

As of May 6, 2011, the aggregate market value of our outstanding common stock held by non-affiliates was approximately \$51,941,970, based on 25,950,804 shares of outstanding common stock, of which 8,179,822 shares were held by non-affiliates, and a per share price of \$6.35 based on the closing price of our common stock on that date. As of the date hereof, we have not offered or sold any securities pursuant to General Instruction I.B.6 of Form S-3 during the prior twelve-calendar-month period that ends on, and includes, the date of this prospectus.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading Risk Factors on page 4 and those contained in the applicable

prospectus supplement and in any related free writing prospectuses that we have authorized for use in connection with a specific offering and in our Securities and Exchange Commission filings that are incorporated by reference into this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Prospectus dated May 12, 2011

<u>ABOUT THIS PROSPECTUS</u>	2
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	2
<u>ABOUT CORNERSTONE THERAPEUTICS INC.</u>	3
<u>RISK FACTORS</u>	4
<u>USE OF PROCEEDS</u>	4
<u>DESCRIPTION OF CAPITAL STOCK</u>	4
<u>DESCRIPTION OF WARRANTS</u>	7
<u>PLAN OF DISTRIBUTION</u>	9
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	9
<u>INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE</u>	10
<u>LEGAL MATTERS</u>	10
<u>EXPERTS</u>	10
<u>EX-5.1</u>	
<u>EX-23.1</u>	
<u>EX-24.2</u>	

ABOUT THIS PROSPECTUS

This prospectus is part of a shelf registration statement that we filed with the U.S. Securities and Exchange Commission, or SEC, using a shelf registration process. By using a shelf registration statement, we may sell any combination of the securities referred to herein from time to time and in one or more offerings as described herein up to a maximum aggregate offering price of \$94,950,000. Each time that we sell securities under this shelf registration process, we will provide a prospectus supplement to this prospectus that contains specific information about the securities being offered and the specific terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. If there is any inconsistency between the information in this prospectus and any prospectus supplement, you should rely on the prospectus supplement. Before purchasing any securities, you should carefully read both this prospectus, any prospectus supplement and any related free-writing prospectuses that we have authorized in connection with a specific offering, together with the additional information described under the heading **Where You Can Find More Information**.

You should rely only on the information contained or incorporated by reference in this prospectus, in any prospectus supplement and in any related free-writing prospectuses that we have authorized in connection with a specific offering. We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus, the accompanying supplement to this prospectus and any related free-writing prospectuses that we have authorized in connection with a specific offering. We will not make an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus, the prospectus supplement to this prospectus and any related free-writing prospectuses that we have authorized in connection with a specific offering is accurate as of the date on its respective cover, and that any information incorporated by reference is accurate only as of the date of the document incorporated by reference, unless we indicate otherwise. Our business, financial condition, results of operations and prospects may have changed since those dates.

When we refer to **Cornerstone Therapeutics**, **we**, **our** and **us** in this prospectus, we mean **Cornerstone Therapeutics Inc.**, a Delaware corporation, unless otherwise specified. Our principal executive offices are located at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518, and our telephone number is (919) 678-6611.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, any prospectus supplement, any related free-writing prospectuses that we have authorized in connection with a specific offering and the documents we incorporate by reference in this prospectus may include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as

Table of Contents

amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For purposes of these statutes, any statement contained herein or therein, other than a statement of historical fact, may be a forward-looking statement. We may, in some cases, use words such as anticipate, believe, could, estimate, expect, intend, may, plan, project, should, target, will, would or other words that convey uncertainty or outcomes to identify these forward-looking statements. Examples of risks and uncertainties that could cause actual results to differ materially from historical performance and any forward-looking statements include, but are not limited to, the risks described in our most recent Annual Report on Form 10-K, as well as any amendments thereto reflected in subsequent filings with the SEC. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date such forward-looking statements are made. You should read carefully and completely this prospectus, any applicable prospectus supplement and any related free writing prospectuses that we have authorized for use in connection with a specific offering, together with the information incorporated herein or therein by reference as described under the headings *Where You Can Find More Information* and *Incorporation of Certain Documents by Reference*, and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify all of our forward-looking statements by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

ABOUT CORNERSTONE THERAPEUTICS INC.

Cornerstone Therapeutics Inc. is a specialty pharmaceutical company focused on acquiring, developing and commercializing products primarily for the respiratory and related markets.

Our strategy is to:

Leverage commercial capabilities by promoting respiratory and related products to high prescribing physicians through our respiratory sales force and to hospital-based healthcare professionals through our hospital sales force;

Acquire rights to existing patent- or trade secret-protected, branded products, which can be promoted through the same channels to generate on-going high-value earnings streams;

Advance our development projects and further build a robust pipeline; and

Generate revenues by marketing approved generic products through our wholly owned subsidiary, Aristos Pharmaceuticals, Inc.

We believe that if we implement this strategy successfully, we can deliver consistent long-term earnings growth.

Our management team has broad experience in the acquisition, commercialization and development of pharmaceutical products. Additionally, our commercial understanding has allowed us to build effective sales forces that continue to grow our products and build relationships with key physicians within the respiratory and hospital markets.

We do not devote resources to early stage pharmaceutical research or captive manufacturing.

We believe that our business model and the competencies we have developed position us to add additional products in the respiratory space and can also be easily transferred to other related specialty market areas.

We currently derive the majority of our revenue from four key product families:

CUROSURF®, an FDA-approved natural lung surfactant for the treatment of Respiratory Distress Syndrome in premature infants, for which we acquired rights in the United States in August 2009;

Table of Contents

ZYFLO® and ZYFLO CR®, the only FDA-approved leukotriene synthesis inhibitor drugs indicated for prophylaxis and chronic treatment of asthma, for which we acquired worldwide rights in December 2003 and March 2004;

FACTIVE®, an FDA-approved fluoroquinolone antibiotic for the treatment of acute bacterial exacerbation of chronic bronchitis and community-acquired pneumonia, of mild to moderate severity, caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Mycoplasma pneumoniae*, *Chlamydia pneumoniae*, or *Klebsiella pneumoniae*, for which we acquired rights in North America and certain European countries in September 2009; and

SPECTRACEF® (cefditoren pivoxil) tablets, a third-generation cephalosporin indicated for the treatment of certain respiratory and skin infections, for which we acquired rights in the United States in October 2006.

We were incorporated in Delaware on July 14, 2000. Our principal executive offices are located at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518, and our telephone number is (919) 678-6611. Our corporate website address is www.crtx.com. We do not incorporate the information on, or accessible through, our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus.

Prior to our October 31, 2008 merger with Cornerstone BioPharma Holdings, Inc., or Cornerstone BioPharma, we were known as Critical Therapeutics, Inc., or Critical Therapeutics. Following the closing of the merger, former Cornerstone BioPharma stockholders owned approximately 70%, and former Critical Therapeutics stockholders owned approximately 30%, of our common stock. In connection with the completion of the merger, on October 31, 2008 we changed our name to Cornerstone Therapeutics Inc.

RISK FACTORS

Investing in our securities involves certain risks. Potential investors are urged to read and consider the risk factors and other disclosures relating to an investment in our securities described in any applicable prospectus supplement or free writing prospectus and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, as updated by our subsequent filings under the Exchange Act, and other reports and documents we file with the SEC after the date of this prospectus and that are incorporated by reference herein. You should consider carefully those risks as well as other information contained in this prospectus, any applicable prospectus supplement, the documents incorporated by reference herein or therein and any free writing prospectuses that we have authorized for use in connection with a specific offering, before deciding whether to purchase any of our securities. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities, and you may lose all or part of your investment.

USE OF PROCEEDS

Except as described in the applicable prospectus supplement, we anticipate using the net proceeds from the sale of our securities for general corporate purposes, including capital expenditures, working capital, repayment of any indebtedness outstanding, product and other acquisitions and other business opportunities. Pending such uses of proceeds, the net proceeds may be temporarily invested in short-term securities.

DESCRIPTION OF CAPITAL STOCK

This section describes the general terms of our common stock. The following description is based upon our Amended and Restated Certificate of Incorporation, as amended, which we refer to as our Certificate of Incorporation; our Fourth Amended and Restated Bylaws, which we refer to as our Bylaws; and applicable provisions of law. We have summarized certain portions of the Certificate of Incorporation and Bylaws below. This summary is not complete. The Certificate of Incorporation and Bylaws are incorporated by reference as

Table of Contents

exhibits to the registration statement of which this prospectus forms a part. You should read the Certificate of Incorporation and Bylaws for the provisions that are important to you.

Authorized Capital Stock

Our authorized capital stock consists of 90,000,000 shares of common stock, \$0.001 par value per share, and 5,000,000 shares of preferred stock, \$0.001 par value per share. As of May 6, 2011, there were 25,950,804 shares of common stock outstanding and no shares of preferred stock outstanding.

Common Stock

Voting

For all matters submitted to a vote of stockholders, each holder of common stock is entitled to one vote for each share registered in the stockholder's name. Our common stock does not have cumulative voting rights, and stockholders may take action by written consent.

Stockholder Action; Special Meeting of Stockholders; Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our Certificate of Incorporation and Bylaws provide that any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders may be taken if it is properly brought before the meeting and may be taken by written action in lieu of a meeting. Our Bylaws also provides that, except as otherwise required by law, a special meeting of stockholders can be called by the chairman of our board of directors, or the Board, our chief executive officer, the Board or stockholders owning at least 50% of our outstanding capital stock. Our Bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of persons for election to the Board. However, nominations of directors pursuant to the governance agreement dated May 6, 2009 with Chiesi Farmaceutici S.p.A., or Chiesi, and, solely with respect to certain sections identified therein, certain of our stockholders, or the Governance Agreement, are excepted from the advance notice procedures generally applicable to director nominations.

Bylaw Amendments

Under Delaware law, a Delaware corporation's bylaws can be amended by its stockholders and, if the corporation's certificate of incorporation so provides, by its directors. Our Bylaws may be amended by the stockholders with the approval of a majority of the shares present in person or represented by proxy at a meeting of stockholders and entitled to vote on the matter. Also, our Certificate of Incorporation permits the Board to amend or repeal our bylaws without the consent of our stockholders (except as provided by applicable law).

Dividends

Our stockholders are entitled to share ratably in any dividends declared by our Board, subject to any preferential dividend rights of any outstanding preferred stock. Dividends consisting of shares of common stock may be paid to our stockholders.

Liquidation and Dissolution

If we are liquidated or dissolved, the holders of our common stock will be entitled to share ratably in all the assets that remain after we pay our liabilities, subject to the prior rights of any outstanding preferred stock.

Other Rights and Restrictions

Our stockholders do not have preemptive rights, and they have no right to convert their common stock into any other securities. Our common stock is not subject to redemption. Our Certificate of Incorporation and Bylaws do not restrict the ability of a stockholder to transfer the stockholder's shares of common stock.

Table of Contents

Listing

Our common stock is listed on the NASDAQ Capital Market under the symbol CRTX.

Transfer Agent and Registrar

Our transfer agent and registrar for our common stock is First Shareholder Services.

Preferred Stock

Our Board is authorized, subject to any limitations under our Certificate of Incorporation or prescribed by law, without further stockholder approval, to issue up to an aggregate of 5,000,000 shares of preferred stock. Our Board may establish the applicable and relative designations, number of authorized shares, dividend rates and terms, redemption or sinking fund provisions, conversion or exchange rates, anti-dilution provisions, voting rights, liquidation preferences and other terms, preferences and limitations of any series of preferred stock it determines to issue. The existence of the authorized but unissued shares of preferred stock enables our Board to render more difficult or to discourage an attempt to obtain control of our company by means of a merger, tender offer, proxy contest or otherwise.

Delaware Law and Certificate of Incorporation and Bylaw Provisions

Anti-takeover Provisions

Section 203 of the Delaware General Corporation Law, or Section 203, is an anti-takeover provision that applies to Delaware corporations. It generally provides that any person or entity who acquires 15% or more of a corporation's voting stock (thereby becoming an interested stockholder) may not engage in a wide range of business combinations with the corporation for a period of three years following the date the person became an interested stockholder, unless (i) the board of directors of the corporation has approved, prior to that acquisition date, either the business combination or the transaction that resulted in the person becoming an interested stockholder; (ii) upon consummation of the transaction that resulted in the person becoming an interested stockholder, that person owns at least 85% of the corporation's voting stock outstanding at the time the transaction commenced (excluding shares owned by persons who are directors and also officers and shares owned by employee stock plans in which participants do not have the right to determine confidentially whether shares will be tendered in a tender or exchange offer); or (iii) the business combination is approved by the board of directors and authorized by the affirmative vote (at an annual or special meeting and not by written consent) of at least 66 and 2/3% of the outstanding voting stock not owned by the interested stockholder. Under Delaware law, a corporation can elect not to be subject to Section 203 by inserting a provision to that effect in its certificate of incorporation. In our Certificate of Incorporation, we have elected not to be governed by Section 203.

Limitation of Liability and Indemnification of Officers and Directors

Our Certificate of Incorporation contains provisions permitted under the Delaware General Corporation Law relating to the liability of directors. The provisions eliminate a director's liability for monetary damages for a breach of fiduciary duty, except to the extent that the Delaware General Corporation Law prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty. In addition, our Certificate of Incorporation contains provisions to indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law.

The limitations of liability and indemnification provisions in our Certificate of Incorporation and Bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duty. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit our stockholders and us. In addition, your investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

There is currently no pending material litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought.

Table of Contents

Governance Agreement

The Governance Agreement sets forth certain rights and obligations of the Company, Chiesi and certain stockholders concerning, among other things, certain corporate governance matters, the voting of Chiesi's shares of common stock, certain limitations on future acquisitions and dispositions of shares of common stock by Chiesi and certain rights of first offer to distribute and market the other party's products. The Governance Agreement became effective on July 28, 2009.

Under the Governance Agreement, our Board is required to consist of our chief executive officer, three independent directors under the NASDAQ Marketplace Rules and four persons designated by Chiesi. The number of persons Chiesi is entitled to designate for consideration for election to the Board to our Nominating and Corporate Governance Committee, or the Nominating Committee, will thereafter depend on the percentage of beneficial ownership held by Chiesi and its affiliates on a fully diluted basis, with a maximum of four persons so designated at any time. The Nominating Committee will nominate our chief executive officer and three independent directors.

The Governance Agreement provides that from July 28, 2009 to July 28, 2011, which we refer to as the Blackout Period, Chiesi will not directly or indirectly acquire or offer to acquire any shares of common stock except (i) with the approval of our Board and a majority of its independent directors; (ii) effected solely to the extent necessary to maintain the beneficial ownership of Chiesi and its affiliates at an amount equal to 51% of the shares of common stock on a fully diluted basis; (iii) pursuant to open market purchases in the same number of shares as certain stockholders of the Company transfer during the same period; (iv) in order to effect the acquisition of all of our outstanding capital stock by Chiesi and/or any of its affiliates, in accordance with the provisions of the Governance Agreement; and (v) pursuant to a mandatory tender offer by Chiesi that Chiesi will be required to make if Chiesi and its affiliates beneficially own 85% or more of our capital stock on a fully diluted basis. Also, during the Blackout Period, Chiesi will be prohibited from selling or otherwise transferring any shares of common stock except pursuant to a bona fide acquisition by a third party through a merger, consolidation, stock exchange or tender offer that was not solicited by Chiesi or its affiliates and that was approved by our Board and a majority of its independent directors.

The Governance Agreement further imposes certain standstill obligations on Chiesi during the Blackout Period, pursuant to which Chiesi and certain related persons are prohibited from soliciting proxies from our stockholders, participating in a group of persons that would be required to file a statement with the SEC if the group beneficially owned 5% or more of any class of our voting stock, granting proxies or entering into voting agreements and seeking additional representation on our Board.

DESCRIPTION OF WARRANTS

This description summarizes only the terms of any warrants that we may offer under this prospectus and related warrant agreements and certificates. You should refer to the warrant agreement, including the form of warrant certificate representing the warrants, relating to the specific warrants being offered for complete terms, which will be described and included in an accompanying prospectus supplement. Such warrant agreement, together with the warrant certificate, will be filed with the SEC in connection with the offering of the specific warrants.

We may issue warrants for the purchase of common or preferred stock. Warrants may be issued independently or together with common or preferred stock, and may be attached to or separate from any other securities.

We will evidence each series of warrants by warrant certificates that we will issue under a separate warrant agreement. We may enter into the warrant agreement with a warrant agent and, if so, we will indicate the name and address of the warrant agent in the applicable prospectus supplement relating to the particular series of warrants.

Table of Contents

Terms of Warrants. The particular terms of any issue of warrants will be described in the prospectus supplement relating to the series. Those terms may include:

the title of such warrants;

the aggregate number of such warrants;

the price or prices at which such warrants will be issued;

the currency or currencies (including composite currencies) in which the price of such warrants may be payable;

the terms of the securities issuable upon exercise of such warrants and the procedures and conditions relating to the exercise of such warrants;

the price at which the securities issuable upon exercise of such warrants may be acquired;

the dates on which the right to exercise such warrants will commence and expire;

any provisions for adjustment of the number or amount of securities receivable upon exercise of the warrants or the exercise price of the warrants;

if applicable, the minimum or maximum amount of such warrants that may be exercised at any one time;

if applicable, the designation and terms of the securities with which such warrants are issued and the number of such warrants issued with each such security or principal amount of such security;

if applicable, the date on and after which such warrants and the related securities will be separately transferable;

information with respect to book-entry procedures, if any; and

any other terms of such warrants, including terms, procedures and limitations relating to the exchange or exercise of such warrants.

The prospectus supplement relating to any warrants to purchase equity securities may also include, if applicable, a discussion of certain U.S. federal income tax and ERISA considerations.

Exercise of Warrants. Each warrant will entitle the holder thereof to purchase such number of shares of common stock or preferred stock at the exercise price as will in each case be set forth in, or be determinable as set forth in, the applicable prospectus supplement. Warrants may be exercised at any time up to the close of business on the expiration date set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void. Warrants may be exercised as set forth in the applicable prospectus supplement relating to the warrants offered thereby. Upon receipt of payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will, as soon as practicable, forward the purchased securities. If less than all of the warrants represented by the warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants.

Enforceability of Rights of Holders of Warrants. Each warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, that holder's warrant(s).

Table of Contents

PLAN OF DISTRIBUTION

We may sell the securities offered by this prospectus from time to time:

through agents;

through underwriters or dealers;

directly to one or more purchasers;

through a combination of any of these methods of sale; or

through any other methods described in a prospectus supplement.

We will identify the specific plan of distribution, including any underwriters, dealers, agents or direct purchasers and their compensation, in the applicable prospectus supplement.

If we use underwriters in the sale, the securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including:

negotiated transactions;

at a fixed public offering price or prices, which may be changed;

at market prices prevailing at the time of sale; or

at prices related to prevailing market prices.

Unless otherwise stated in a prospectus supplement, the obligations of the underwriters to purchase any securities will be conditioned on customary closing conditions.

We may sell the securities through agents from time to time. The prospectus supplement will name any agent involved in the offer or sale of the securities and any commissions we pay to them. Generally, any agent will be acting on a best efforts basis for the period of its appointment.

In compliance with guidelines of the Financial Industry Regulatory Authority, or FINRA, the maximum consideration or discount to be received by any FINRA member or independent broker-dealer may not exceed 8% of the aggregate amount of the securities offered pursuant to this prospectus and any applicable prospectus supplement.

Underwriters and agents may be entitled under agreements entered into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments that the underwriters or agents may be required to make. Underwriters and agents may be customers of, engage in transactions with or perform services for us and our affiliates in the ordinary course of business.

WHERE YOU CAN FIND MORE INFORMATION

We are a public company and file annual, quarterly and current reports, proxy statements and information statements and other information with the SEC. You may read and copy materials that we have filed with the SEC at the SEC public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. Copies of reports and other information from us are available on the SEC's website at <http://www.sec.gov>. Such filings are also available at our website at <http://www.crtx.com>. Materials accessed at or through our website are not a part of this prospectus.

We have filed a registration statement, of which this prospectus is a part, covering the securities offered hereby. As allowed by SEC rules, this prospectus does not contain all of the information set forth in the registration statement and the exhibits, financial statements and schedules thereto. We refer you to the registration statement, the exhibits, financial statements and schedules thereto for further information. This prospectus is qualified in its entirety by such other information.

Table of Contents

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference in this prospectus the information we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The following documents filed with the SEC are hereby incorporated by reference in this prospectus:

- (a) Our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed with the SEC on March 3, 2011;
- (b) Our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2011, filed with the SEC on May 12, 2011;
- (c) Our Current Report on Form 8-K filed with the SEC on February 7, 2011; and
- (d) The description of our Common Stock contained in our Registration Statement on Form 8-A filed on May 19, 2004, as amended by our Registration Statement on Form 8-A/A filed with the SEC on September 2, 2009, and any amendments or reports filed for the purpose of updating such description.

In addition, all documents that we subsequently file pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, either (i) prior to the filing of a post-effective amendment which indicates that all securities offered have been sold or which deregisters all securities then remaining unsold or (ii) after the date of the initial registration statement of which this prospectus is a part and prior to the effectiveness of the registration statement, shall be deemed to be incorporated by reference in this prospectus and to be a part hereof from the date of filing of such documents. However, any documents or portions thereof, whether specifically listed above or filed in the future, that are not deemed filed with the SEC, including without limitation the certifications required by Rule 13a-14(b) or Rule 15d-14(b) under the Exchange Act, any information furnished pursuant to Item 2.02 or 7.01 of Form 8-K or certain exhibits furnished pursuant to Item 9.01 of Form 8-K, shall not be deemed to be incorporated by reference in this prospectus.

Any statement in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for the purposes of this prospectus to the extent that a statement contained herein or in any other subsequently filed document which also is incorporated or deemed to be incorporated by reference herein modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will furnish without charge to you, upon written or oral request, a copy of any or all of the documents incorporated by reference herein, other than exhibits to such documents that are not specifically incorporated by reference therein. All requests should be sent to the attention of Andrew K. W. Powell, Executive Vice President, General Counsel, and Secretary, Cornerstone Therapeutics Inc., 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518 or made via telephone at (888) 466-6505.

LEGAL MATTERS

The validity of our securities issuable hereunder will be passed upon for us by Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., Raleigh, North Carolina.

EXPERTS

The consolidated financial statements of Cornerstone Therapeutics Inc. appearing in Cornerstone Therapeutics Annual Report (Form 10-K) for the year ended December 31, 2010 incorporated by reference in this prospectus and elsewhere in the registration statement have been so incorporated by reference in reliance upon the report of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing in giving said report.

Table of Contents

\$94,950,000
Common Stock
Preferred Stock
Warrants

PROSPECTUS

Table of Contents**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. *Other expenses of issuance and distribution***

The fees and expenses to be paid in connection with the distribution of the securities being registered hereby are as follows (all amounts except the registration fee are estimates):

SEC registration fee	\$ 6,770
Accounting fees and expenses	*
Legal fees and expenses	*
Printing fees	*
Miscellaneous	*
 Total	 \$ *

* Cannot be estimated at this time.

Item 15. *Indemnification of Directors and Officers*

Section 102 of the General Corporation Law of Delaware allows a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our Certificate of Incorporation provides that, except to the extent that the General Corporation Law of Delaware prohibits the elimination or limitation of liability of directors for breach of fiduciary duty, none of our directors shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director.

Section 145 of the General Corporation Law of Delaware provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against amounts paid and expenses incurred in connection with an action or proceeding to which such person is or is threatened to be made a party by reason of such position, if such person shall have acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal proceeding, if such person had no reasonable cause to believe his or her conduct was unlawful; provided that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the adjudicating court determines that such indemnification is proper under the circumstances.

Our Certificate of Incorporation provides that we must (i) indemnify our directors and officers to the fullest extent permitted by Delaware law and (ii) advance expenses, as incurred, to our directors and officers in connection with a legal proceeding to the fullest extent permitted by Delaware law. These provisions are not exclusive of any other rights to which a director or officer may be entitled by law, agreement, vote of stockholders or disinterested directors

or otherwise.

Cornerstone BioPharma Holdings, Inc., or CBHI, our wholly owned subsidiary, has entered into an indemnification agreement with Craig A. Collard, our President, Chief Executive Officer and Chairman. Among other things, the indemnification agreement requires CBHI to indemnify Mr. Collard for expenses incurred by Mr. Collard 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 agreement also provides for mandatory advancement of expenses to Mr. Collard.

In addition, we maintain insurance on behalf of our directors and officers insuring them against liability asserted against them in their capacities as directors or officers or arising out of such status.

II-1

Table of Contents

The above arrangements may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duty. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit our stockholders and us. In addition, your investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. We believe that these provisions are necessary to attract and retain talented and experienced directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

Item 16. Exhibits

The list of exhibits filed as a part of this registration statement on Form S-3 is set forth in the Exhibit Index immediately preceding the exhibits hereto and is incorporated herein by reference.

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

II-2

Table of Contents

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be

governed by the final adjudication of such issue.

II-3

Table of Contents**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing this Registration Statement on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the Town of Cary, State of North Carolina, on May 12, 2011.

CORNERSTONE THERAPEUTICS INC.

By: /s/ Craig A. Collard

Craig A. Collard
President, Chief Executive Officer and Chairman

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the date indicated.

Name	Title	Date
/s/ Craig A. Collard Craig A. Collard	President, Chief Executive Officer and Chairman (Principal Executive Officer)	May 12, 2011
/s/ Vincent T. Morgus Vincent T. Morgus	Executive Vice President, Finance and Chief Financial Officer (Principal Financial Officer)	May 12, 2011
/s/ Ira Duarte Ira Duarte	Director of Accounting (Principal Accounting Officer)	May 12, 2011
* Alessandro Chiesi	Director	May 12, 2011
* Christopher Codeanne	Director	May 12, 2011
* Michael Enright	Director	May 12, 2011
* Anton Giorgio Failla	Director	May 12, 2011
* 	Director	May 12, 2011

Michael Heffernan

*

Director

May 12, 2011

Robert Stephan

*

Director

May 12, 2011

Marco Vecchia

*By: /s/ Andrew K.W. Powell

Andrew K.W. Powell
Attorney-in-fact

II-4

Table of Contents

EXHIBIT INDEX

Exhibit No.	Description
1.1	Form of Underwriting Agreement.(1)
1.2	Form of Placement Agent Agreement.(1)
4.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004).
4.2	Amendment to the Registrant's Certificate of Incorporation, effecting a 10-to-1 reverse stock split of the Registrant's common stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K dated October 30, 2008).
4.3	Amendment to the Registrant's Certificate of Incorporation, changing the name of the corporation from Critical Therapeutics, Inc. to Cornerstone Therapeutics Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K dated October 30, 2008).
4.4	Amendment to the Registrant's Certificate of Incorporation, effecting certain changes pursuant to the Governance Agreement among Chiesi Farmaceutici S.p.A., the Registrant and certain other stockholders of the Registrant dated May 6, 2009 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K dated August 27, 2009).
4.5	Fourth Amended and Restated Bylaws of the Registrant dated July 28, 2009 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K dated July 27, 2009).
4.6	Form of Certificate of Designation for Preferred Stock(1)
4.7	Form of Preferred Stock Certificate(1)
4.8	Form of Warrant Agreement (including form of warrant certificate)(1)
5.1	Opinion of Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P.
23.1	Consent Grant Thornton LLP, Independent Registered Public Accounting Firm.
23.2	Consent of Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P. (contained in Exhibit 5.1).
24.1	Power of Attorney (included on signature page of the original filing of this Registration Statement on Form S-3).
24.2	Power of Attorney of Vincent T. Morgus and Marco Vecchia

(1) To be filed by amendment or as an exhibit to a current report on Form 8-K and incorporated herein by reference, if applicable.