

CORNERSTONE THERAPEUTICS INC
Form SC 13D/A
August 06, 2009

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

SCHEDULE 13D

**Under the Securities Exchange Act of 1934
(Amendment No. 1)***

Cornerstone Therapeutics Inc.
(Name of Issuer)

Common Stock, par value \$0.001 per share
(Title of Class of Securities)

21924P103
(CUSIP Number)

with a copy to:

**Chiesi Farmaceutici SpA
Via Palermo 26/A
43122 Parma, Italy
Attention: Marco Vecchia
Facsimile: +39 0521 774468**

**Morgan, Lewis & Bockius LLP
502 Carnegie Center
Princeton, New Jersey 08540-6241
Attention: Emilio Ragosa
Facsimile: (609) 919-6701**

(Name, Address and Telephone Number of Person Authorized to
Receive Notices and Communications)

July 28, 2009

(Date of Event Which Requires Filing of this Statement)

If the filing person has previously filed a statement on Schedule 13G to report the acquisition which is the subject of this Schedule 13D, and is filing this schedule because of Rule 13d-1(e), 13d-1(f) or 13d-1(g), check the following box.

Note: Schedules filed in paper format shall include a signed original and five copies of the schedule, including all exhibits. See §240.13d-7 for other parties to whom copies are to be sent.

* The remainder of this cover page shall be filled out for a reporting person's initial filing on this form with respect to the subject class of securities, and for any subsequent amendment containing information which would alter disclosures provided in a prior cover page.

The information required on the remainder of this cover page shall not be deemed to be filed for the purpose of Section 18 of the Securities Exchange Act of 1934 (Act) or otherwise subject to the liabilities of that section of the Act but shall be subject to all other provisions of the Act (however, see the Notes).

CUSIP No. 21924P103

13D/A

1 NAME OF REPORTING PERSONS
I.R.S. IDENTIFICATION NOS. OF ABOVE PERSONS (ENTITIES ONLY)

Chiesi Farmaceutici SpA EIN:

2 CHECK THE APPROPRIATE BOX IF A MEMBER OF A GROUP

- (a)
- (b)

3 SEC USE ONLY

4 SOURCE OF FUNDS

WC

5 CHECK BOX IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED PURSUANT TO
ITEM 2(d) OR 2(e)

6 CITIZENSHIP OR PLACE OF ORGANIZATION

Italy

7 SOLE VOTING POWER

NUMBER OF 18,923,134 (1)

8 SHARES BENEFICIALLY OWNED BY

SHARED VOTING POWER

0

9 EACH SOLE DISPOSITIVE POWER

REPORTING

PERSON 18,923,134 (1)

WITH SHARED DISPOSITIVE POWER

10
0

AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON

11
18,923,134 (1)

CHECK BOX IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES

12
o

PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)

13
72.7%(2)

TYPE OF REPORTING PERSON

14
CO

(1) Includes (i) 11,902,741 newly issued shares of common stock, par value \$0.001 per share (Common Stock) of Cornerstone Therapeutics Inc. (the Company) acquired by Chiesi Farmaceutici SpA (Chiesi); (ii) 1,600,000 shares of outstanding Common Stock acquired by Chiesi from two stockholders that are entities controlled by Craig A. Collard, the President and Chief Executive Officer of the Company, and Steven M. Lutz, the Executive Vice President, Manufacturing and Trade of the Company; (iii) 4,183,619 shares of outstanding Common Stock and options to acquire 967,090 shares of Common Stock held by Mr. Collard, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals Ltd., Steven M. Lutz, the Lutz Family Limited Partnership, Dr. Dickson, Mr. Price, Mr. Franklin and Mr. Roberts, which Chiesi may be deemed to beneficially own as a result of the voting commitments of those persons described above pursuant to which each has granted Chiesi an irrevocable proxy and agreed to vote all shares beneficially owned by him or it in favor of a series of proposed amendments to the Company s certificate of incorporation; and (iv) 269,684 shares of Common Stock that the Company believes it will be required to issue under the Stock Purchase Agreement if requested by Chiesi within 90 days of the closing of the Company Stock Sale. Chiesi may request the Company to issue additional shares so that Chiesi will beneficially own 51% of the Company s outstanding Common Stock on a fully diluted basis as of the closing of the Company Stock Sale, after giving effect to the Company Stock Sale and Chiesi s purchases of Common Stock from Cornerstone Biopharma Holdings, Ltd. and Lutz Family Limited Partnership. Chiesi disclaims beneficial ownership of the shares and options held by Mr. Collard, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals, Steven M. Lutz, the Lutz Family Limited Partnership, Dr. Dickson, Mr. Price, Mr. Franklin and Mr. Roberts, except to the extent of its pecuniary interest therein.

(2) Calculated based on 24,800,316 shares of Common Stock outstanding as of July 30, 2009 (as reported in the Company s definitive proxy statement on Schedule 14A dated August 5, 2009).

Item 1. Security and Issuer

This Amendment No. 1 to Schedule 13D (as amended, the Schedule 13D) amends and restates the Schedule 13D dated May 6, 2009 (the Initial Statement) and relates to the common stock, par value \$0.001 per share (Common Stock), of Cornerstone Therapeutics Inc., a corporation organized under the laws of the State of Delaware (the Company). The principal executive office of the Company is located at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518. Information given in response to each item below shall be deemed incorporated by reference in all other items below. Capitalized terms not defined in this Schedule 13D have the meanings ascribed to them in the Initial Statement.

Item 2. Identity and Background

(a) This Schedule 13D is being filed by Chiesi Farmaceutici SpA (Chiesi).

(b) The principal business address and principal office address of Chiesi is Via Palermo 26/A, 43100 Parma, Italy. Chiesi is a pharmaceutical company headquartered in Parma, Italy.

(c) Attached as Schedule A is the name, principal occupation, business address and citizenship of each executive officer and/or director of Chiesi. Schedule A is incorporated into and made a part of this Schedule 13D.

(d) During the last five years, neither Chiesi nor any person listed on Schedule A has been convicted in a criminal proceeding (excluding traffic violations or similar misdemeanors).

(e) During the last five years, neither Chiesi nor any person listed on Schedule A has been a party to a civil proceeding of a judicial or administrative body of competent jurisdiction and as a result of such proceeding was or is subject to a judgment, decree or final order enjoining future violations of, or prohibiting or mandating activities subject to, federal or state securities laws or finding any violation with respect to such laws.

(f) Chiesi is organized under the laws of Italy. Schedule A sets forth the citizenship of each executive officer and/or director of Chiesi.

Item 3. Source and Amount of Funds or Other Consideration

Pursuant to the Stock Purchase Agreement, dated May 6, 2009, between the Company and Chiesi, on July 28, 2009, Chiesi purchased 11,902,741 shares of the Company's Common Stock (the Company Stock Sale). As provided in the Stock Purchase Agreement, in exchange for the shares issued to Chiesi, Chiesi (i) granted the Company an exclusive ten-year license to distribute and market Chiesi's Curosurf® product in the United States and (ii) paid the Company \$15,465,075 in cash. Based on a price per share of \$5.50, the aggregate consideration for the shares of Common Stock issued in the Company Stock Sale is approximately \$65,465,075. Concurrently with the closing of the Company Stock Sale on July 28, 2009, Chiesi purchased an aggregate of 1.6 million shares of Common Stock owned by two stockholders that are entities controlled by Craig A. Collard, the President and Chief Executive Officer of the Company, and Steven M. Lutz, the Executive Vice President, Manufacturing and Trade of the Company, pursuant to the Stockholders Stock Purchase Agreement, for \$5.50 per share in cash.

The source of the consideration provided by Chiesi for the purchase of an aggregate of 13,502,741 shares of Common Stock was working capital. No borrowed funds were used to purchase the 13,502,741 shares of Common Stock, other than any borrowed funds used for working capital purposes in the ordinary course of business.

Item 4. Purposes of Transactions

(a) (b) As stated above in Item 3, on May 6, 2009, the Company, Chiesi and certain related parties entered into a number of agreements, including the Stock Purchase Agreement, pursuant to which the Company agreed to issue and sell shares of Common Stock to Chiesi in exchange for (i) the exclusive rights to distribute Chiesi's Curosu^{ff} treatment in the U.S. for a 10-year term; and (ii) a cash payment of \$15,465,075. In connection with the transaction contemplated by the Stock Purchase Agreement, the Company and certain of its stockholders entered into a series of related agreements with Chiesi pursuant to which, among other things, two entities controlled by Craig A. Collard, the Company's President and Chief Executive Officer, and Steven M. Lutz, the Company's Executive Vice President, Manufacturing and Trade, agreed to sell an aggregate of 1.6 million shares of Common Stock to Chiesi for \$5.50 per share in cash.

The purpose of the proposed sales of Common Stock by the Company and by the entities controlled by Mr. Collard and Mr. Lutz and the entry into the other agreements entered into in connection with the proposed issuance and sale of shares of Common Stock to Chiesi is to form a strategic alliance between the Company and Chiesi through the transactions contemplated by the Stock Purchase Agreement and the other agreements described below.

Stock Purchase Agreement

On May 6, 2009, the Company and Chiesi entered into a Stock Purchase Agreement (the "Stock Purchase Agreement"), pursuant to which the Company agreed, subject to the terms and conditions set forth in the Stock Purchase Agreement, to issue and sell 11,902,741 shares of the Company's Common Stock to Chiesi. The Stock Purchase Agreement provides that, in exchange for the shares to be issued to Chiesi, Chiesi will (i) grant the Company an exclusive ten-year license to distribute and market Chiesi's Curosu^{ff} product in the United States and (ii) pay the Company \$15,465,075 in cash. Based on a price per share of \$5.50, the aggregate consideration for the shares of Common Stock to be issued in the Company Stock Sale would be approximately \$65,465,075.

The Stock Purchase Agreement contains customary representations, warranties and covenants by each of the Company and Chiesi, including, among others, covenants by the Company (i) to conduct its business in the ordinary course during the period between the execution of the Stock Purchase Agreement and the closing of the Company Stock Sale (the "Closing"); (ii) not to engage in certain specified transactions during such period, including declaring or paying any dividends or making any other distributions in respect of its capital stock; and (iii) following the Closing, if necessary, to issue additional shares to Chiesi so that Chiesi's ownership as of the Closing equals 51% of the Common Stock on a Fully Diluted Basis (as defined in the Stock Purchase Agreement). The Company has also agreed (i) not to (x) solicit proposals relating to alternative business combination transactions or (y) subject to certain exceptions, enter into discussions or negotiations or provide confidential information in connection with any proposals for alternative business combination transactions and (ii) after the Closing, to hold a second meeting of its stockholders to approve certain amendments to the Company's charter, including amendments necessary to effect the corporate governance provisions of the Governance Agreement described below.

The board of directors of the Company had determined the Company Stock Sale to be fair to and in the best interest of the Company and its stockholders and adopted resolutions approving the Company Stock Sale and recommending the Company's stockholders approve the Company Stock Sale.

The Closing was subject to various customary closing conditions, including, among others, (i)

approval by the Company's stockholders of the Company Stock Sale, (ii) expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and (iii) concurrent consummation of the Initial Stock Sale described below.

Concurrently with the execution and delivery of the Stock Purchase Agreement, Chiesi and two stockholders of the Company entered into a separate stock purchase agreement (the "Stockholders Stock Purchase Agreement"), pursuant to which two stockholders that are entities controlled by Craig A. Collard, the President and Chief Executive Officer of the Company, and Steven M. Lutz, the Executive Vice President, Manufacturing and Trade of the Company, agreed, among other things, to sell to Chiesi 1.6 million shares of Common Stock owned by such stockholders (the "Initial Stock Sale"). The Closing of the Company Stock Sale and the Initial Stock Sale occurred on July 28, 2009.

License and Distribution Agreement

In connection with and concurrently with the execution and delivery of the Stock Purchase Agreement, the Company and Chiesi entered into a License and Distribution Agreement (the "Distribution Agreement"), pursuant to which Chiesi will license and grant to the Company the exclusive distribution rights to Chiesi's Curosurf® treatment in the United States for a ten-year term beginning, at Chiesi's election, on one of three dates during the third or fourth quarters of 2009 (whether or not the Closing under the Stock Purchase Agreement has occurred by then), which will automatically renew for successive one-year periods unless specified prior written notice is given. Under the Distribution Agreement, the supply price for Curosurf® will equal the greater of a specified percentage of the net sales price for such product or the applicable floor price set forth in the Distribution Agreement.

Governance Agreement

In connection with and concurrently with the execution and delivery of the Stock Purchase Agreement, the Company, Chiesi and, solely with respect to certain sections identified therein, certain stockholders of the Company entered into a Governance Agreement (the "Governance Agreement"), which sets forth certain rights and obligations of the Company, Chiesi and such 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 upon the Closing on July 28, 2009.

On July 28, 2009, the date that the Governance Agreement became effective, the Company's board of directors was reconstituted to consist of its chief executive officer, three independent directors under the NASDAQ Marketplace Rules and four persons designated by Chiesi. The four directors designated by Chiesi are Alessandro Chiesi, Maria Paola Chiesi, Anton Giorgio Failla and Robert Stephan. The number of persons Chiesi is entitled to designate for consideration for election to the Company's board of directors to the Company's nominating committee will thereafter depend on the percentage of beneficial ownership of the Company held by Chiesi and its affiliates on a Fully Diluted Basis (as defined in the Governance Agreement), with a maximum of four persons so designated at any time. The Company's nominating committee will nominate the Company's chief executive officer and three independent directors.

The Governance Agreement also provides that during the period beginning on the date of Closing and ending 24 months thereafter (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 the Company's 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 (as defined in the Governance Agreement), (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 the outstanding capital stock of the Company 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 the Company's capital stock on a Fully Diluted Basis (as defined in the Governance Agreement). 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 of the Company 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 the Company's 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 the Company's stockholders, participating in a group of persons that would be required to file a statement with the Securities and Exchange Commission (the SEC) if the group beneficially owned 5% or more of any class of the Company's voting stock, granting proxies or entering into voting agreements and seeking additional representation on the Company's board. The Governance Agreement also provides that (i) the Company has a right of first offer with respect to the distribution and marketing in the United States of any pharmaceutical products owned or controlled by Chiesi or any of its affiliates that Chiesi makes available for distribution in the United States and (ii) Chiesi has a right of first offer with respect to the distribution and marketing outside the United States of any pharmaceutical products owned or controlled by the Company that the Company makes available for the distribution in any territory outside the United States.

The Governance Agreement, including each party's right of first offer on the other party's products, will terminate (i) if the Stock Purchase Agreement is terminated prior to Closing; (ii) on the second anniversary of the effective date of the Governance Agreement; or (iii) at the earliest of (A) such time as Chiesi and its affiliates beneficially own Common Stock constituting 100% of all of the outstanding Common Stock on a Fully Diluted Basis (as defined in the Governance Agreement), (B) such time as Chiesi and its affiliates beneficially own Common Stock constituting less than 10% of all of the Common Stock on a Fully Diluted Basis (as defined in the Governance Agreement) or (C) the effective time of a Change in Control (as defined in the Governance Agreement) of the Company. In addition, the Governance Agreement will terminate with respect to any stockholder party thereto at such time as the stockholder is no longer employed by the Company.

Stockholders Agreement

In connection with and concurrently with the execution and delivery of the Stock Purchase Agreement, the Company, Chiesi and certain stockholders of the Company (Craig A. Collard, the Company's President and Chief Executive Officer, and Steven M. Lutz, the Company's Executive Vice President, Manufacturing and Trade, and certain related entities) entered into a Stockholders Agreement (the Stockholders Agreement) pursuant to which the stockholders agreed not to sell or otherwise transfer a number of shares equal to approximately 80% of the shares of Common Stock held by them as of May 6, 2009 (the Covered Shares), subject to certain exceptions described in the Stockholders Agreement. In addition, the stockholders agreed they would not, directly or indirectly, acquire or offer to acquire any shares of Common Stock, subject to certain exceptions described in the Stockholders Agreement. The Stockholders Agreement also provides that beginning on the date on which the restrictions on transfers by the stockholders of the Covered Shares lapse and for a 30 day period thereafter, Chiesi will have the option, exercisable in whole but not in part on a single occasion, to acquire all the stockholders' Covered Shares, at a price per share of \$12.00 (subject to adjustment for any stock split, stock dividend, reverse stock split or similar adjustment). Each stockholder also agreed, subject to certain conditions, that at any meeting of the stockholders of the Company called to consider a transaction

in which Chiesi or its affiliate will acquire all the outstanding capital stock of the Company, the stockholder will vote all shares of Common Stock owned by such stockholder at the applicable record date set for such meeting in the same proportions that the shares of Common Stock owned by the other stockholders of the Company (other than Chiesi and its affiliates) are voted on such matter.

On June 26, 2009, the Company, Chiesi, Craig A. Collard, the Company's President and Chief Executive Officer, Steven M. Lutz, the Company's Executive Vice President, Manufacturing and Trade, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership executed an Amendment to the Stockholders Agreement (the "Amendment to Stockholders Agreement"). The Amendment to Stockholders Agreement provides that Annex A to the Stockholders Agreement is replaced by Annex A of the Amendment to Stockholders Agreement. The Stockholders Agreement, as amended, became effective upon the Closing on July 28, 2009.

Registration Rights Agreements

In connection with and concurrently with the execution and delivery of the Stock Purchase Agreement, the Company and Chiesi entered into a Registration Rights Agreement (the "Chiesi Registration Rights Agreement"), pursuant to which the Company agreed to provide registration rights to Chiesi with respect to the shares of Common Stock to be acquired in the Company Stock Sale. Under such agreement, following the Blackout Period, Chiesi will be entitled to require the Company to file with the SEC certain registration statements under the Securities Act of 1933, as amended, (each a "Demand Registration") with respect to the resale of the shares of Common Stock acquired pursuant to the Initial Stock Purchase Agreement and the Stock Purchase Agreement up to four times, and to include its shares of Common Stock in any registration the Company proposes for its own account or for the account of one or more of its stockholders.

In connection with and concurrently with the execution and delivery of the Stock Purchase Agreement, the Company and the stockholders of the Company who entered into the Stockholders Agreement also entered into a Registration Rights Agreement (the "Stockholders Registration Rights Agreement") substantially similar to the Chiesi Registration Rights Agreement. Under such agreement, such stockholders will be entitled to two Demand Registrations during the Blackout Period and three Demand Registrations thereafter. The stockholders will also have the right to include their shares of Common Stock in any registration the Company proposes for its own account or for the account of one or more of its stockholders.

Voting Agreements

In connection with the Stock Purchase Agreement and concurrent with the execution thereof, Chiesi, the Company (solely with respect to Section 2(b) thereof) and the Stockholders, who collectively held approximately 49.18% (including 982,090 shares of Common Stock issuable upon exercise of stock options within 60 days of May 6, 2009 (assuming such stock options are fully vested upon the Closing)) of the outstanding shares of Common Stock as of the close of business on May 6, 2009, entered into a voting agreement (the "Stockholders Voting Agreement"), pursuant to which the Stockholders granted to Chiesi irrevocable proxies over the shares of Common Stock owned by them and agreed to vote the shares of Common Stock owned by them in favor of the Company Stock Sale and approval and adoption of the proposed amendment to the Company's certificate of incorporation, subject to the terms and conditions of the Stockholders Voting Agreement.

The Stockholders agreed to not transfer any shares of Common Stock owned unless the person to which such shares are being transferred shall have executed and delivered a counterpart of the Stockholders Voting Agreement and agreed pursuant thereto, for the benefit of Chiesi, to hold such shares

subject to all terms and conditions of the Stockholders Voting Agreement, subject any Common Stock owned to any pledges, liens or other encumbrances or arrangements or grant any proxies or powers of attorney with respect to any Common Stock in contravention of the obligations under the Stockholders Voting Agreement. The Stockholders Voting Agreement will terminate upon the earlier of the approval of the adoption of the proposed amendment to the Company's certificate of incorporation by the affirmative vote of the holders of not less than 75% of the issued and outstanding shares of Common Stock or the termination of the Stock Purchase Agreement.

The Company agreed pursuant to Section 2(b) of the Stockholders Voting Agreement to not, and is unconditionally instructed not to, permit on its books and records transfers by, issue new certificates to or record any vote of such stockholders, unless such stockholder has complied with the terms of the Stockholders Voting Agreement.

The Company and Chiesi also, on May 6, 2009, entered into a voting agreement (the Chiesi Voting Agreement), pursuant to which Chiesi agreed to vote all of its shares of Common Stock in favor of the approval and adoption of the proposed amendment to the Company's certificate of incorporation.

The foregoing summary of the transactions contemplated by the Stock Purchase Agreement, Distribution Agreement, Governance Agreement, Stockholders Agreement, Amendment to Stockholders Agreement, Registration Rights Agreements and Voting Agreements is qualified in its entirety by reference to the copies of the Stock Purchase Agreement, Distribution Agreement, Governance Agreement, Stockholders Agreement, Amendment to Stockholders Agreement, Registration Rights Agreements and Voting Agreements included in Exhibits 1, 2, 3, 4, 5, 6, 7, 8 and 9 to this Schedule 13D and incorporated herein in their entirety by reference.

(c) Not applicable.

(d) On July 28, 2009, pursuant to the Governance Agreement, the Company's board of directors was reconstituted to consist of its chief executive officer, three persons previously selected by the Company's board who qualify as independent directors under the NASDAQ Marketplace Rules and four persons designated by Chiesi. The four directors designated by Chiesi are Alessandro Chiesi, Maria Paola Chiesi, Anton Giorgio Failla and Robert Stephan. The number of persons Chiesi is entitled to designate for consideration for election to the Company's board of directors to the Company's nominating committee will thereafter depend on the percentage of beneficial ownership of the Company held by Chiesi and its affiliates on a fully diluted basis, with a maximum of four persons so designated at any time. The Company's nominating committee will nominate the Company's chief executive officer and three independent directors.

(e) Other than as a result of the Company Stock Sale and Initial Stock Sale described above, not applicable.

(f) Not applicable.

(g) The Stock Purchase Agreement contemplates that an amendment to the Company's certificate of incorporation will be adopted, filed, and become effective following the Closing in accordance with applicable law, and amended and restated bylaws of the Company were adopted concurrently with the approval of the transactions contemplated by the Stock Purchase Agreement and became effective immediately prior to the Closing.

(h) (i) Not applicable.

(j) Other than as described above, neither Chiesi, nor to Chiesi's knowledge, any of the individuals or entities named in Schedule A to this Schedule 13D, currently has any plan or proposal which relates to, or may result in, any of the matters listed in Items 4(a) - (i) of Schedule 13D (although they reserve the right to develop such plans).

Item 5. Interest in Securities of the Issuer

(a) - (b) As of the close of business on July 28, 2009, Chiesi beneficially owns 18,923,134 shares of Common Stock, representing 72.7% of the Company's issued and outstanding shares of Common Stock. The 18,923,134 shares of Common Stock includes (i) 11,902,741 newly issued shares of Common Stock acquired by Chiesi; (ii) 1,600,000 shares of outstanding Common Stock acquired by Chiesi from two stockholders that are entities controlled by Craig A. Collard, the President and Chief Executive Officer of the Company, and Steven M. Lutz, the Executive Vice President, Manufacturing and Trade of the Company; (iii) 4,183,619 shares of outstanding Common Stock and options to acquire 967,090 shares of Common Stock held by Mr. Collard, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals Ltd., Steven M. Lutz, the Lutz Family Limited Partnership, Dr. Dickson, Mr. Price, Mr. Franklin and Mr. Roberts, which Chiesi may be deemed to beneficially own as a result of the voting commitments of those persons described above pursuant to which each has granted Chiesi an irrevocable proxy and agreed to vote all shares beneficially owned by him or it in favor of a series of proposed amendments to the Company's certificate of incorporation; and (iv) 269,684 shares of Common Stock that the Company believes it will be required to issue under the Stock Purchase Agreement if requested by Chiesi within 90 days of the closing of the Company Stock Sale. Chiesi may request the Company to issue additional shares so that Chiesi will beneficially own 51% of the Company's outstanding Common Stock on a fully diluted basis as of the closing of the Company Stock Sale, after giving effect to the Company Stock Sale and Chiesi's purchases of Common Stock from Cornerstone Biopharma Holdings, Ltd. and Lutz Family Limited Partnership. Chiesi disclaims beneficial ownership of the shares and options held by Mr. Collard, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals, Steven M. Lutz, the Lutz Family Limited Partnership, Dr. Dickson, Mr. Price, Mr. Franklin and Mr. Roberts, except to the extent of its pecuniary interest therein. All calculations made herein are made in accordance with Rule 13d-3(d) of the Securities Exchange Act of 1934, as amended, and are calculated based on 24,800,316 shares of Common Stock outstanding as of July 30, 2009 (as reported in the Company's definitive proxy statement on Schedule 14A dated August 5, 2009).

To the knowledge of Chiesi, no shares of Common Stock are beneficially owned by any of the individuals or entities named in Schedule A to this Schedule 13D.

(c) Neither Chiesi, nor, to the knowledge of Chiesi, any of the individuals or entities named in Schedule A to this Schedule 13D, has effected any transaction in Common Stock during the past 60 days, except as disclosed herein.

(d) - (e) Not applicable.

Item 6. Contracts, Arrangements, Understandings or Relationships with Respect to Securities of Issuer

Other than the Stock Purchase Agreement, Stockholders Stock Purchase Agreement, Distribution Agreement, Governance Agreement, Stockholders Agreement, Amendment to Stockholders Agreement, Registration Rights Agreements and Voting Agreements, to the best knowledge of Chiesi, there are no contracts, arrangements, understandings or relationships (legal or otherwise) among Chiesi and the persons or entities identified in Item 2 and between such person or entity and any person or entity with respect to any securities of the Company, including but not limited to transfer or voting of any of the

securities, finder's fees, joint ventures, loan or option arrangements, puts or calls, guarantees of profits, division of profits or loss, or the giving or withholding of proxies.

Item 7. Material to Be Filed as Exhibits

Exhibit No. Description of Document

- Exhibit 1 Stock Purchase Agreement, dated as of May 6, 2009, by and among Chiesi Farmaceutici SpA and the Company (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 7, 2009 (File No. 000-50767)).
- Exhibit 2 License and Distribution Agreement, dated as of May 6, 2009, between Chiesi Farmaceutici SpA and the Company (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 7, 2009 (File No. 000-50767)).
- Exhibit 3 Governance Agreement, dated as of May 6, 2009, by and among the Company, Chiesi Farmaceutici SpA, and solely with respect to the sections identified therein, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 7, 2009 (File No. 000-50767)).
- Exhibit 4 Stockholders Agreement, dated as of May 6, 2009, by and among the Company, Chiesi Farmaceutici SpA, Craig A. Collard, Steven M. Lutz, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 7, 2009 (File No. 000-50767)).
- Exhibit 5 Amendment to Stockholders Agreement, dated as of June 26, 2009, by and among the Company, Chiesi Farmaceutici SpA, Craig A. Collard, Steven M. Lutz, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 29, 2009 (File No. 000-50767)).
- Exhibit 6 Registration Rights Agreement, dated as of May 6, 2009, by and between the Company and Chiesi Farmaceutici SpA (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 7, 2009 (File No. 000-50767)).
- Exhibit 7 Registration Rights Agreement, dated as of May 6, 2009, by and among the Company, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 7, 2009 (File No. 000-50767)).
- Exhibit 8 Voting Agreement, dated as of May 6, 2009, by and between the Company and Chiesi Farmaceutici SpA (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 7, 2009 (File No. 000-50767)).
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Exhibit No. Description of Document

Exhibit 9 Voting Agreement, dated as of May 6, 2009, by and among Chiesi, Cornerstone Biopharma Holdings, Ltd., Carolina Pharmaceuticals Ltd. and Lutz Family Limited Partnership, Brian Dickson, Josh Franklin, David Price and Alan Roberts (incorporated by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 7, 2009 (File No. 000-50767)).

SIGNATURE

After reasonable inquiry and to the best of the knowledge and belief of the undersigned, the undersigned certifies that the information set forth in this statement is true, complete and correct.

Dated: August 6, 2009

Chiesi Farmaceutici SpA

By: /s/ Paolo Chiesi

Name: Paolo Chiesi

Title: Vice President

SCHEDULE A**Chiesi Farmaceutici SpA****Directors**

Name	Position	Principal Occupation	Business Address	Citizenship
Alberto Chiesi	President & CEO	President & CEO	Via Palermo 26/A 43100 Parma Italy	Italian
Paolo Chiesi	Vice-President & Director of R&D	Vice-President & Managing Director	Via Palermo 26/A 43100 Parma Italy	Italian
Alessandro Chiesi	Director	Affiliates Coordinator International Division	Via Palermo 26/A 43100 Parma Italy	Italian
Andrea Chiesi	Director	R&D Planning and Control Director	Via Palermo 26/A 43100 Parma Italy	Italian
Maria Paola Chiesi	Director	Corporate Marketing Director	Via Palermo 26/A 43100 Parma Italy	Italian
Anita Chiesi	Director	Pharmacist	Via Palermo 26/A 43100 Parma Italy	Italian
Gianandrea E. De Bernardis	Director	Managing Director, Team System Lince Group	Via Palermo 26/A 43100 Parma Italy	Italian
Carlo Sante Antonio Salvatori	Director	Managing Director, Unipol Gruppo Finanziario SpA (Listed in Italy)	Via Palermo 26/A 43100 Parma Italy	Italian

Executive Officers (1)

Name	Position	Business Address	Citizenship
Alberto Chiesi	President & CEO	Via Palermo 26/A 43100 Parma Italy	Italian
Paolo Chiesi	Vice-President and Director of R&D	Via Palermo 26/A 43100 Parma Italy	Italian
Marco Vecchia			Italian

Legal & Corporate
Affairs Director

Via Palermo 26/A
43100 Parma
Italy

Ugo Bettini

Human Resources
Director

Via Palermo 26/A
43100 Parma
Italy

Italian

- 1 The listing of these individuals for purposes of this Schedule 13D shall not be deemed an omission that such individuals are officers under Italian law.
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Name	Position	Business Address	Citizenship
Danilo Piroli	Finance & Control Director	Via Palermo 26/A 43100 Parma Italy	Italian
Anton Giorgio Failla	Corporate Development Director	Via Palermo 26/A 43100 Parma Italy	Italian
Maria Paola Chiesi	Corporate Marketing Director	Via Palermo 26/A 43100 Parma Italy	Italian
Paolo De Angeli	International Division Director	Via Palermo 26/A 43100 Parma Italy	Italian
Vanda De Cian	Corporate Drug Development Director	Via Palermo 26/A 43100 Parma Italy	Italian
Alessandro Chiesi	Affiliates Coordinator International Division	Via Palermo 26/A 43100 Parma Italy	Italian
Andrea Chiesi	R&D Planning and Control Director	Via Palermo 26/A 43100 Parma Italy	Italian
Giovanni La Grasta	Industrial Operations Director	Via Palermo 26/A 43100 Parma Italy	Italian